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Clinical Practice

CONSENSUS CLINICAL STANDARDS FOR THE PROSTHETIC MANAGEMENT OF UNILATERAL TRANSRADIAL AMPUTATION

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ABSTRACT

Consensus clinical standards of care were recently developed through three rounds of Delphi consensus surveys. The 40 statements that reached consensus standards for inclusion encompassed indications for general prosthetic consideration, as well as indications and considerations for body powered, externally powered and oppositional silicone restoration prostheses, terminal device selection, the selection of body powered control strategies, considerations for moisture, debris or heavy duty use, activity specific prostheses and indications for multiple terminal devices. These standards may serve to guide clinical decision making and inform medical policy.

INTRODUCTION

While substantially less common than major lower limb amputation, major upper limb amputation accounts for approximately 16% of the major limb loss affecting an estimated 2.2 million Americans.[1] While clinical practice guidelines have been developed for the broad holistic care of the individual with upper limb amputation or limb deficiency,[2-3] there has been an absence of detailed clinical guidance with respect to prosthetic management. A relatively recent multi-disciplinary State of the Science Conference, held by the American Academy of Orthotists and Prosthetists addressed design options for upper limb prostheses. The Conference concluded that those rehabilitation professionals that have amassed considerable experience in working with upper limb amputation and limb deficiency should be recognized as the most informed source of currently available evidence.[4]

Recent years have seen the emergence of a number of clinical practice guidelines based on the published evidence and addressing prosthetic patient populations. These have included post-operative care, prosthetic foot selection, transtibial socket design and prosthetic knee selection.[5-11] When the published evidence for a given episode of care is limited, the highest level of available evidence is collaborative consensus from subject matter experts, with the Delphi process being commonly employed.[12] Several such guidelines have been performed and disseminated within the field of prosthetic rehabilitation.[13-15] The use of Delphi consensus techniques in prosthetic and orthotic rehabilitation has been summarized via systematic review with a number of best practice recommendations.[12] The purpose of this abstract is to summarize the methods and findings of a recently published Delphi consensus exercise to establish clinical care standards in the prosthetic management of individuals with unilateral transradial amputation or limb deficiency.[16]

METHODS

The full details of the methodology associated with these consensus guidelines has been published elsewhere[16] and can be summarized as follows. Project directors from a national provider of upper limb prosthetic rehabilitation met with a focus group of experienced upper limb clinicians to review available systematic reviews in the area of upper limb prosthetic rehabilitation and identify postulates related to the indications, contraindications, and considerations associated with prosthesis type (e.g., body powered vs externally powered) and terminal device type (e.g., hand vs hook) with regard to unilateral transradial prosthetic management. These initial postulates (n=40) were then entered into a secured, web-based survey platform. A panel of 20 certified prosthetists, each of whom oversaw the care of at least 85 new upper limb prosthetic cases per year, and two occupational therapists, both of whom treated at least 75 upper limb prosthetic patients annually, anonymously considered each postulate, rating their degree of

agreement or disagreement with each and providing clarifying or qualifying statements to explain their position. The panel was geographically diverse with an average of 21 years of clinical experience.

Consensus standards for the acceptance of a clinical postulate was predefined at 80%. Those postulates that exceeded this threshold were retained within the clinical consensus standards. Those that did not were assessed by the project directors and amended to reflect the comments from the Delphi survey panel. Amended postulates where returned to the panel for subsequent review and potential acceptance. A total of 3 rounds of anonymous surveys were administered. In the first round of surveys 31 postulates were accepted by the panel with 9 postulates failing to reach the consensus threshold. Eleven of fourteen amended postulates were accepted in the second round. A final postulate was presented and accepted in the 3rd survey round.

RESULTS

Once the survey rounds were concluded and consensus postulates were determined, they were aggregated by the following topic areas for ease of integration into clinical practice

Prosthetic Candidacy

Candidacy for a prosthesis may be based upon functional need, psychosocial considerations or preservation of the contralateral extremity. A prosthesis should be considered for an individual with unilateral transradial amputation or limb deficiency when any of the following is identified: An individual is unable to accomplish self-care activities or ADLs independently; an individual has functional, vocational, or avocational needs that cannot be met without a prosthesis; the person's psychosocial acceptance of their amputation/limb deficiency would be improved by the use of a prosthesis; or an individual is at risk of overuse syndromes on their sound side.

Body Powered Prosthesis Candidacy

There are a number of considerations that should be assessed prior to the recommendation and provision of a body powered prosthesis. These include patient education and awareness as well as certain physical attributes. Patients should fully understand the restriction, associated pressures and donning and doffing requirements associated with a control harness and be able to physically tolerate those elements. In addition, they should accept and understand that activities requiring dynamic prehension will be predominantly performed with a hook, rather than a hand. With regard to physical presentation, a patient's residual limb must possess adequate soft tissue coverage and integrity to allow cyclical loading of the limb within the prosthesis as experienced during cable activation of the terminal device. This tolerance may be facilitated with appropriate interface materials or socket design. Similarly, patients must possess adequate soft tissue coverage and integrity over those body segments underlying the control harness of the prosthesis. Finally, candidates for a body powered prosthesis must possess adequate strength and range of motion to generate the necessary cable force and excursion to actuate their terminal device.

Externally Powered Prosthesis Candidacy

Prior to the recommendation and provision of an externally powered prosthesis the following elements should be evaluated and considered. The candidate should possess adequate control input to control an externally powered prosthesis through EMG, FSR, electronic switch or linear transducer and understand and accept the noise, weight and charging requirements associated with an externally powered device. An externally powered prosthesis should be considered when one or more of the following is identified: A candidate lacks the strength or range of motion required to generate the necessary cable force or excursion for a body powered prosthesis; A candidate lacks the necessary soft tissue coverage and integrity to allow cyclical loading of the limb within the prosthesis, even with appropriate interface materials and socket design; a candidate anticipates the need for sustained, high grip strength through movement; a candidate's functional work envelope cannot be confined primarily to the area immediately in front of them; there is a compromise to gross body movements of the shoulders or back and/or an existing neurological compromise to the sound side upper limb (such as pain, numbness, or tingling); or a candidate has been previously fit with either an oppositional or body powered prosthesis and could not integrate it fully into their desired ADLs or vocational responsibilities, either because of mechanical constraints or psychosocial rejection.

Oppositional Silicone Restoration Prosthesis Candidacy

An oppositional silicone restoration prosthesis (sometimes termed "passive" or "aesthetic" prosthesis) should be considered when the user's primary priority is an aesthetic restoration of their forearm and hand, the user fully

understands and accepts the absence of active prehension, and the user fully appreciates the cosmetic limitations of an oppositional prosthesis.

Terminal Device Selection

Non-anthropomorphic hook-type terminal devices should be considered when enhanced visibility and find motor dexterity during object manipulation are desired and the user of a body powered prosthesis required a durable terminal device. Alternately, hand-type terminal devices should be considered when the associated psychosocial acceptance of an anthropomorphic terminal device is indicated for the patient, and the cosmetic and fine motor dexterity limitations of such terminal devices are fully understood by the patient.

Body Powered Control Strategies

Users of body powered prostheses will need to actuate their devices using either the more common voluntary opening strategy or the less frequently utilized voluntary closing strategy. The former should only be considered when the user presents with adequate strength to overcome the mechanical resistance mandated by the necessary grip strength of the terminal device and fully understand and accepts the relationship between available grip strength and the strain experienced through the harness during operation of the terminal device. Similarly, the voluntary closing control strategy should only be considered when the user understands and accepts the potential energy expenditure and cognitive load associated with sustaining grip strength through range of motion.

Moisture, Debris and Heavy Duty Use

With the recent improvements in certain externally powered components, appropriately designed body powered and externally powered prostheses can be considered when exposure to moisture, debris or heavy duty use is anticipated.

Activity Specific Prostheses

Activity Specific Prostheses should be considered when the user's needs during a give activity exceed the capabilities of alternate prosthetic designs and/or terminal devices.

Multiple Prostheses

Multiple prostheses or terminal devices may be indicated when the user's needs exceed the capabilities of a single prosthesis type or terminal device.

DISCUSSION

The aim of this effort was to establish treatment guidelines for the prosthetic management of unilateral transradial amputation and limb deficiency. While a degree of subjectivity is innate to Delphi consensus methodology our protocols were consistent with those used in prior Delphi consensus efforts in the field and recommended best practices.[12] This included initial postulate generation based on available evidence, the selection of a highly knowledgeable and experienced expert panel of an appropriate size, attainment of a high response rate, *apriori* establishment of a high standard of consensus and the use of multiple rounds of surveys to refine postulates towards consensus acceptance.

The Delphi processes facilitated the establishment of clinical practice standards for the prosthetic management of individuals with unilateral transradial amputation in the absence of strong, detailed evidence from existing clinical research and systematic literature reviews. Many clinicians lack the necessary expertise in the area of upper limb prosthetic management to allow a high degree of confidence in treating this population towards optimal clinical outcomes. These clinical care standards may help inform clinical decision-making processes to ensure that essential elements are taken into clinical consideration. However, they are not so prescriptive as to preclude the individual judgment of the clinician or the values and preferences of the patient. These consensus standards have also been welcomed by medical directors and policy makers in addressing the void that would otherwise be present in the prosthetic management of this relatively small patient population.

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PPP-ARM: A QUALITY IMPROVEMENT BY INCORPORATING PATIENT INVOLVEMENT AND BY ADDING A DECISION AID FOR TERMINAL DEVICES

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ABSTRACT

Introduction: The Prosthesis Prescription Protocol of the upper limb (PPP-Arm), is a digital tool to structure, underpin and evaluate the prescription of upper limb prostheses (ULPs) in rehabilitation centres in the Netherlands that prescribe ULPs. The results of evaluating five years of PPP-Arm use, the recently developed Dutch Quality Standard for Prosthetic Care (D-QSPC) and the wish for facilitating shared decision-making led to this study. We aimed to develop and implement quality improvements and a patient decision aid (PDA) to the national digital protocol PPP-Arm.

Methods: Improvements for PPP-Arm were identified by an evaluation with clinicians after five years of PPP-Arm-usage and based on the recommendations described in the D-QSPC, focussing on new elements that should be incorporated in PPP-Arm. The PDA about Terminal devices for people with Upper Limb Absence (PDA-TULA) was developed in a systematic co-creation process following the steps described by the International Patient Decision Aid Standards. The improved PPP-Arm and the newly developed PDA-TULA were pilot-tested in the real-life national rehabilitation setting.

Results: The following improvements were made to PPP-Arm: the option to add images to the prosthesis application for the health care insurer, access for patients to PPP-Arm in order to complete surveys, digitally signing prosthesis applications, view educational material, and more structure was integrated in the description of the stepped care process. Furthermore, the PDA-TULA was added to PPP-Arm, which informs patients about available Terminal Devices (TDs), then stimulates the patient to consider their own preferences regarding the TD options, and lastly provides an overview of the patients' preferences in relation to the available TD options. Implementation of the pilot-test regarding the improvements of PPP-Arm is ongoing, we expect it will lead to better usability, modernization, and increased patient involvement in the treatment process. Pilot-testing of the PDA-TULA showed that patients and clinicians experienced benefits from the PDA-TULA regarding the prosthesis selection process.

Conclusion: PPP-Arm has been improved, adjusted to the renewed D-QSPC, and supplemented with the PDA-TULA. Results emphasize the importance to cooperate with all stakeholders and pilot-test changes and new products in the real-life setting to develop and improve products that suits the needs of all stakeholders.

INTRODUCTION

The Prosthesis Prescription Protocol of the upper limb (PPP-Arm) is a national tool to structure, underpin and evaluate the prescription of upper limb prostheses (ULPs). The protocol creates a uniform and structured, nationally applicable, prescription policy and is based on the World Health Organization's criteria of the International Classification of Functioning (ICF; Figure 1). PPP-arm was initiated in 2009, digitalized in 2012, and implemented into all ten rehabilitation centres that prescribe ULPs in the Netherlands in 2016. PPP-Arm has been co-created by patients, rehabilitation teams, orthopaedic workshops, and health insurance companies, collaborating in the working group PPP-Arm [1]. After five years of nationwide use, the users expressed a need to evaluate and improve PPP-Arm.

Additionally, the publication of the new Dutch Quality Standard for Prosthetic Care (D-QSPC) [2], which should be implemented into the Dutch health care process, affirmed the need to update PPP-Arm. Furthermore, shared decision making is becoming increasingly important in clinical practice, especially regarding preference-based decisions such as ULPs [3]. A patient decision aid (PDA) could support the shared decision-making process between patient and clinicians by informing the patient about available options and helping them to clarify their values related to those options [4]. Therefore, this study aimed to develop and implement quality improvements and a PDA to the national digital protocol PPP-Arm.

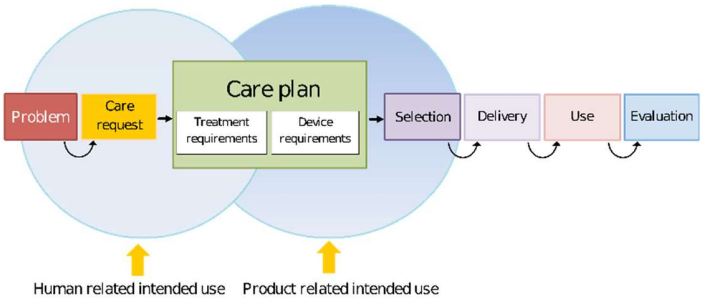

Figure 1: Structure of PPP-Arm

METHOD

Adjustments to PPP-Arm

Adjustments to PPP-Arm were based on 1) an evaluation among clinicians and 2) recommendations provided by the recently published D-QSPC.

1) The evaluation consisted of collected feedback and suggestions from clinicians of ten rehabilitation teams during the last five years and discussion during several meetings of the national working group amputation and prosthetics of the upper limb (WAPA).
2) The recommendations of the renewed D-QSPC were analysed focussing on elements that should be incorporated in PPP-Arm, for example: PPP-Arm should be more patient oriented, more structured in the application of the stepped care process and should use the same terminology as the D-QSPC.

A proposal for adjustments was presented to and approved by the WAPA members. After incorporation of the improvements to PPP-Arm, the protocol was implemented and tested in clinical practice by ten rehabilitation teams. In each team a knowledge broker (KB; a member of the prosthetic team, mostly a therapist) was responsible for the implementation of the new version of PPP-Arm within his own centre. A national project coordinator was appointed, who maintained contact with all parties involved, collected questions and problems regarding the improved PPP-Arm, and organized meetings to further implement the PPP-Arm.

Development and pilot-test of PDA-TULA

The local Medical Ethics Review Board of the University Medical Centre Groningen waived formal study approval regarding the PDA-TULA (METc 2018/582). Participants of focus groups, surveys and interviews provided written informed consent. The documentation template of the International Patient Decision Aid Standards was used to develop the PDA about Terminal devices for people with Upper Limb Absence (PDA-TULA) [5]. First, the scope was determined. A focus group among clinicians was organized and the target audience for the PDA-TULA was determined: people with major unilateral upper limb absence. Second, a steering group with patients, clinicians, a prosthetist, researchers, an ICT expert, and implementation experts was assembled. Third, the contents and design of the PDA-TULA were elaborated. The contents were based on a qualitative meta-synthesis [6], a focus group with patients [6], a survey among patients [7] and prosthetists, a nationwide digital meeting with clinicians, information from manufacturers, and discussions with the research team and steering group. To determine the design, drafts of the PDA-TULA were made, improved based on the feedback of the steering group, and the PDA was integrated into the software. Fourth, the PDA-TULA was alpha tested by patients, clinicians, health care insurers, researchers, and an implementation expert. All feedback was processed, resulting in the beta-version of the PDA-TULA, which was implemented and pilot-tested for five months in nine rehabilitation centres. To support the implementation process, the following actions were taken: co-creation of the PDA-TULA, usage of the network of KBs of PPP-Arm, option

for financial support for KBs, organization of meetings with the KBs, assignment of a project coordinator for technical support and questions during the pilot, provide updates about the PDA-TULA on national meetings and in newsletters for stakeholders. Telephone interviews with patients, KBs and clinicians were conducted to evaluate the PDA-TULA.

RESULTS

Implementation of adjustments to PPP-Arm

Based on the feedback derived from PPP-Arm users (ten rehabilitation teams) and analyses of the D-QSPC, the following improvements were made to PPP-Arm:

- Creation of a patient hub, a digital environment that can be accessed by the patient in order to exchange questionnaires and entry the PDA-TULA.
- Addition of the option to provide a digital signature for patients and professionals in order to digitally approve the prosthesis application.
- Integration of the Dutch version of the Quebec User Evaluation of Satisfaction with assistive technology (D-QUEST). Via the patient hub, D-QUEST can be sent digitally, completed and stored in PPP-Arm.
- Creation of easier access and management of the prosthesis information folder in the protocol: Administration page for content managers to add/remove educational materials for patients.
- Addition of the option to add photos to the prosthesis application report.
- Addition of the option to define the function of all separate users (i.e., doctor, occupational therapist, physiotherapist, hand therapist, prosthetist) to guarantee safety and transparency.
- Application of the terminology of the D-QSPC in PPP-Arm.
- Structuring and improvement of choices in the stepped care process.
- Development and integration of the PDA-TULA (see below).

Currently, pilot-testing is ongoing. We expect the adjustments will lead to a quality improvement of PPP-Arm: better usability, more structure, modernization, better access to educational material and increased patient involvement in the prosthesis selection process. Pilot-test results will be revealed at the conference.

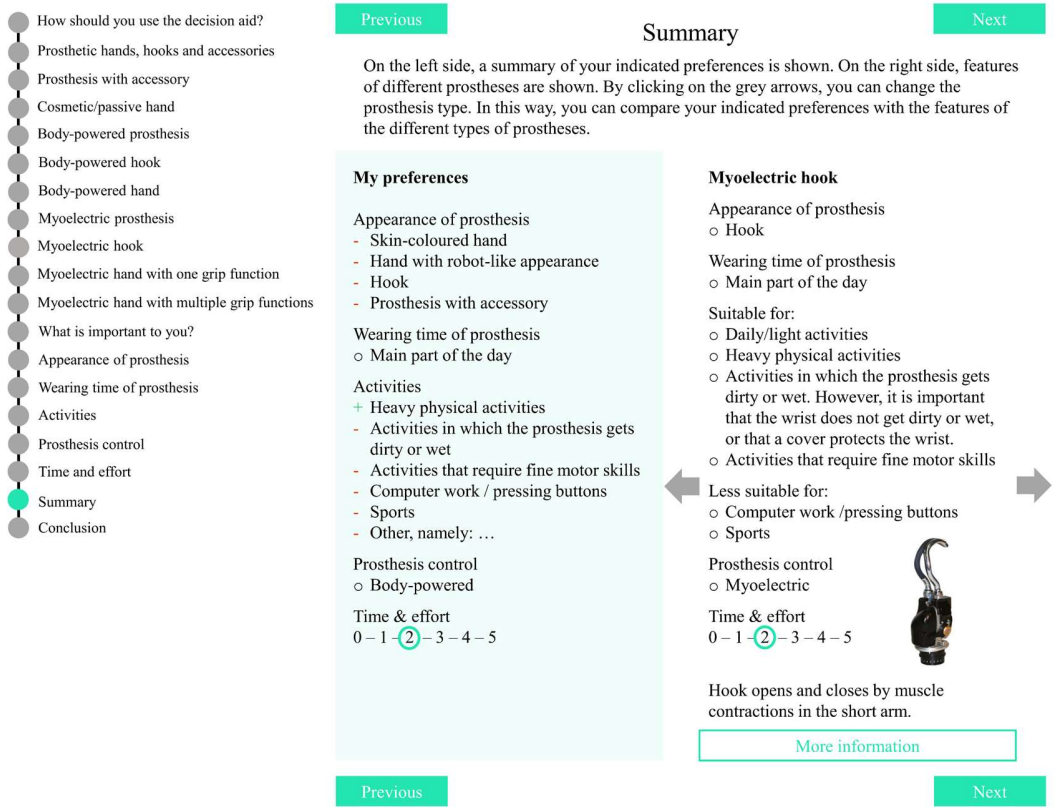

Figure 2: Example of the summary page of the last part of the digital PDA-TULA.

Development and pilot-test of PDA-TULA

The PDA-TULA consists of four parts. In the first part, patients are asked to enter personal information, which can be imported into the patient's file by the clinician. In the second part, general information about seven Terminal Device (TD) categories is provided: prosthesis with a tool/accessory, cosmetic/passive hands, body-powered hooks, body-powered hands, myoelectric hooks, myoelectric hands with one grip, and myoelectric hands with multiple grips. To fulfil the need of experienced ULP users, more detailed information can optionally be consulted by accessing underlying pages within the PDA-TULA. In the third part, patients are stimulated to consider what is important for them regarding their ULP. Information about five prosthetic aspects is provided (appearance, wearing time, activities, prosthesis control, time and effort), each followed by a question about the patient's preferences regarding that aspect. In the last part, a patient profile is created based on the patient's preferences. This profile can be compared with the profiles of the TD options (Figure 2). A PDF with a summary of the results and the patient's questions for the next consultation is available for the patient and clinician.

Patients were enthusiastic about the PDA-TULA, they stated that the PDA helped them to get an overview of the available TD options and go through the information at their own pace. Additionally, KBs and clinicians indicated that the PDA-TULA was of added value and could be used as educational material in the prosthesis selection process. However, some patients needed help to go through the PDA (e.g., non-Dutch speakers, insufficient digital skills). Provided feedback from the telephone interviews were discussed with the steering group and subsequently final refinements were made to the beta-version of the PDA-TULA (e.g., addition/change of some pictures, textual clarifications).

CONCLUSION

PPP-Arm was modernized, improved, adjusted to the new D-QSPC, and supplemented with the PDA-TULA. Clinicians, KBs, and patients were involved in the development of the PDA-TULA and update of PPP-Arm. Pilot-testing of the PPP-Arm improvements is still ongoing. However, the pilot test in the real-life rehabilitation setting enabled further improvements of PDA-TULA based on the experiences of the different stakeholders, which resulted in many positive responses from the involved stakeholders. This study, therefore, emphasizes the importance to cooperate with all stakeholders and pilot-test changes and new products in the real-life setting to make a product that suits the needs of all stakeholders.

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The authors thank all people who helped with the quality improvement of PPP-Arm and/or with the development of the PDA-TULA.

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Upper Extremity Prosthetic Rehabilitation: A 20 day plan of therapy, education and coaching.

By Josef Butkus, MS OTR/L, Occupational Therapy Supervisor, Walter Reed National Military Medical Center, Bethesda, MD, USA.

Rates of prosthesis rejection continue to remain around 50% despite technological advances in the field [1]. There are a number of factors involved in the whether someone chooses to wear a prosthesis or not [2]. There are also life circumstances that may contribute to not wearing a prosthesis [2]. One of the challenges to successful acceptance of an Upper Extremity prosthesis may be a delay in fitting, inefficiencies in care, and lack of consistent treatment [2,3]. Frequently patients suffering limb loss are seen by providers who have limited experience with this type of injury and are only able to offer patients limited insight into the use of their prosthesis. This presentation proposes a protocol of prosthetic training to ensure consistency and quality of care.

Walter Reed National Military Medical Center (WRNMMC) has received many military members who suffered upper extremity limb loss over the past 20 years. Patients at Walter Reed have had the benefit of exceptionally experienced staff, peer support, funding for new developing limbs, recreation therapy, robust adaptive sports/reconditioning and housing for patients and their families while undergoing rehabilitation. Rates of prosthetic acceptance have been anecdotally better than studies of the civilian populations, but because the programs are so different it requires more study to determine why. Some differences of care are that patients enjoy much more therapy time, insurance support, funding for newly developed devices and a commitment to return patients to a full, active lifestyle involving fitness and adaptive sports. This presentation will serve as an opportunity to look at a

treatment protocol, concepts, education and training that have been hallmarks of the UE prosthesis training program in Occupational Therapy at Walter Reed NMMC.

With a limited opportunity for prosthetic training and acceptance, therapy should focus on facilitating the patient to learn how the device can best assist them in daily life. Attaching anything to a physical body is awkward, and much more so if it is suspended off an extremity. Whether a person chooses to use a prosthesis is entirely up to the individual. What medical professionals can control is helping the patient achieve a high level of proficiency and knowledge of the device. If proficiency is achieved, theoretically the patient will have more autonomy and have a good understanding of how the device may best assist the patient. Medical staff should encourage the patient to take ownership of the device and progress towards some level of embodiment of the device. Patients often have gone through recent physical and emotional traumatic events which need to be counteracted with as much positive and enjoyable circumstances surrounding the prosthesis as possible. Knowledge of activities and how best to adapt them for success with a prosthesis is a vital part in this process.

This proposed treatment plan includes the key components of prosthesis skills, knowledge of the device and how to adapt a task to perform efficiently. Ideally a patient would attend more than 20 sessions but more may not be possible due to insurance or time limitations of the patient. The treatments focus on building a patient's confidence in analyzing efficient performance. Coaching and offering feedback in actual tasks assist the prosthesis user in developing more efficient motor plans. This document will serve as a resource for new therapists to the population and assist them to make sure they have covered all aspects of prosthesis training. This plan will focus on 20 therapy sessions to present a method to progress skills and knowledge across a continuum to achieve acceptance and proficiency with the prosthesis.

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Clinical Research

ADAPTIVE EMG PATTERN RECOGNITION REDUCES FREQUENCY AND IMPROVES QUALITY OF AT-HOME PROSTHESIS TRAINING FOR UPPER LIMB MYOELECTRIC PROSTHESIS WEARERS

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ABSTRACT

Upper limb myoelectric pattern recognition-controlled prostheses use machine learning algorithms to identify a wearer's intended movement from their muscle activity patterns. However, many factors can contribute to changes in the characteristics of the EMG input signals (electrode shift, muscle fatigue, limb position etc.) during everyday prosthesis use which can diminish controller performance. Multiple in-lab studies have demonstrated promising results towards improving controller performance by employing advanced algorithms, none of which have been tested clinically, that can adapt to these changes. This paper presents the implementation of a supervised-adaptation algorithm on a commercially available pattern recognition control system that makes use of historical EMG data collected during previous user-initiated calibration routines to update the existing classification model. In an at-home clinical study, we evaluated whether real-world use of adaptive classification reduces how often upper limb prosthesis wearers need to recalibrate their pattern recognition system.

INTRODUCTION

Pattern recognition style of myoelectric prosthesis control has benefitted many individuals since commercialization in 2013. Using machine learning techniques to decode complex muscle activity patterns recorded from electromyographic (EMG) sensors, a pattern recognition controller can provide wearers natural and intuitive control of their powered prosthesis [1]. A key feature of pattern recognition is that is needs to learn the wearer's unique EMG patterns corresponding to each type of prosthesis motion they want to control. This is achieved by inputting representative data during system training (i.e., calibration). The inability of a control system to classify the user's EMG inputs significantly affects user control of their prosthesis device. This often leads to frequent recalibration which can be quite time-consuming and burdensome for many pattern recognition wearers.

Effective EMG pattern recognition requires wearers to make repeatable, consistent muscle contractions [2]. Studies have shown that it is possible for control algorithms to achieve accuracies greater than 90% under ideal laboratory conditions [3], [4]. However, classification accuracies deteriorate significantly under more realistic usage scenarios such as when electrodes shift positions [5], when the user changes the posture/position of their residual limb [6], or when modulating the force of their contraction. To address these deteriorations, the most effective method might be to collect additional algorithm training data that is representative of these conditions. After representative data is collected, the control system may be adapted to incorporate this new data.

The default behaviour of many existing pattern recognition systems is to clear the existing classification model from memory each time the user initiates a calibration. Studies have shown that an alternative solution, which instead modifies the existing classifier using EMG input data recorded upon recalibration, has the potential to improve pattern recognition control. In lab-based studies, Vidovic et al. found that classification accuracy improved from 75% to above 92% [7] and Cummins et al. found that classification error rates significantly decrease across multiple days of training data [8] when utilizing such adaptive calibration strategy. These promising results point to the need for clinical implementation; yet, no studies have evaluated the effectiveness of using pattern recognition adaptation under realistic use conditions – i.e., while prosthesis wearers use their device at-home in their own environment. Here, we present preliminary results from an at-home study where upper limb myoelectric pattern recognition wearers used a supervised adaptation calibration paradigm. Our primary hypothesis is that using adaptation reduces the frequency at which recalibration is needed. In a randomized, cross-over study design, we compared everyday wearers' calibration frequency and the quality of their EMG input data between their prosthesis use with and without the adaptive classification algorithm.

METHODS

Participants:

Five individuals with upper limb difference/absence (three at the transradial level and two at the transhumeral level) have completed the at-home study. Two additional individuals are currently enrolled, and two others withdrew their study participation. All participants provided informed consent in accordance with the Institutional Review Board and Human Research Protection Office.

Apparatus:

Participants used their existing Coapt Complete Control Gen2® pattern recognition control system to control their motorized arm components. The number and type of prosthesis motions participants had enabled varied depending on the type of powered devices connected (hand, wrist or elbow combination). Gen2 system users are able to train their EMG pattern recognition controller by performing either a prosthesis-guided or software-guided motion calibration sequence using the Complete ControlRoom software application [9]. The classification algorithm of the control system is linear discriminant analysis (LDA) [10] which, when enabled, clears the existing classifier from memory upon a user-initiated motion calibration sequence. Effectively, new EMG input data recorded during a calibration replaces the existing data and only this data is used to create a new LDA classifier.

Changing the control system to the adaptive classification algorithm can be easily done by accessing the controller settings in the software. This classification model uses covariate shift adaptation to update the class means and pooled covariance matrices of an existing LDA model using the new EMG input data recorded during each subsequent user-initiated calibration. The control system retains memory of the existing LDA classifier which does not clear until the user manually performs a full system reset. A full derivation of the adaptive algorithm can be found in [7]. It is important to note that the default classification algorithm employed by the Complete Control Gen2 system for all new and existing wearers is the adaptive algorithm, thus study participants were not naïve.

Following each calibration, the EMG input and classifier data is analyzed by the Control Coach® [11]. The Control Coach® uses artificial intelligence to detect calibration issues and to evaluate the quality of the calibration data. In addition to providing feedback messages (up to two per motion) to users on how to improve calibration quality, the software tool provides a star rating for each enabled prosthesis motion relating to the potential severity of any calibration data quality issues detected (1 star = most severe, 5 stars = least severe). The overall calibration quality is determined by computing the average star rating across all motions. The Gen2 system hardware also has data logging capabilities to monitor at-home prosthesis use including prosthesis wear-time, calibration frequency, commanded motion frequency and device output speeds, electrode liftoff frequency and Control Coach® data.

Procedures:

Participants were asked to use their prosthesis at-home for a total of 16-weeks. Each participant was randomly assigned to one of two study groups. For the first 8-weeks, participants used their Gen2 system with the adaptive classification algorithm either ON or OFF, and for the second 8-weeks, the opposite classification algorithm was enabled. Only research personnel had access to the controller settings to enable or disable the adaptive algorithm at the beginning of each 8-week period so that participants were blind to the classification algorithm enabled on their system throughout the experiment. At the beginning of each 8-week period, research personnel manually performed a full control system reset to clear out any existing calibration data. Participants were then asked to complete an initial motion calibration sequence. At the end of the study, participants completed a questionnaire asking about their preferences towards the type of classification algorithm used in both 8-week periods in terms of their perceived prosthesis control efficiency and controller performance.

RESULTS

Our primary outcome measure was calibration frequency which we defined as the ratio between the number of times users initiate a calibration sequence and the number of times the user powers on their prosthesis. This calibration frequency metric accommodates for differences in user wear-time and number of calibration events. We compared calibration frequency during each 8-week period in which the adaptive algorithm was either ON or OFF for each user (Fig. 1, left). Preliminary results reveal a trend towards a reduction in calibration frequency among participants with the adaptive algorithm ON. Three out of the five participants reduced their calibration frequency on average by 43% while one participant showed a marginal increase and another participant nearly doubled calibration

frequency with the adaptive algorithm ON. Our preliminary analysis also shows a trend towards increased prosthesis wear-time per calibration (Fig. 1, middle) as four out of five participants demonstrated an increase in how many hours (on average, 2.7 more hours) they used their prosthesis with the same classifier before recalibrating. Four out of the five participants also showed improvements in the quality of their calibration data, as measured by the Control Coach® star ratings, with the adaptive algorithm ON (Fig. 1, right).

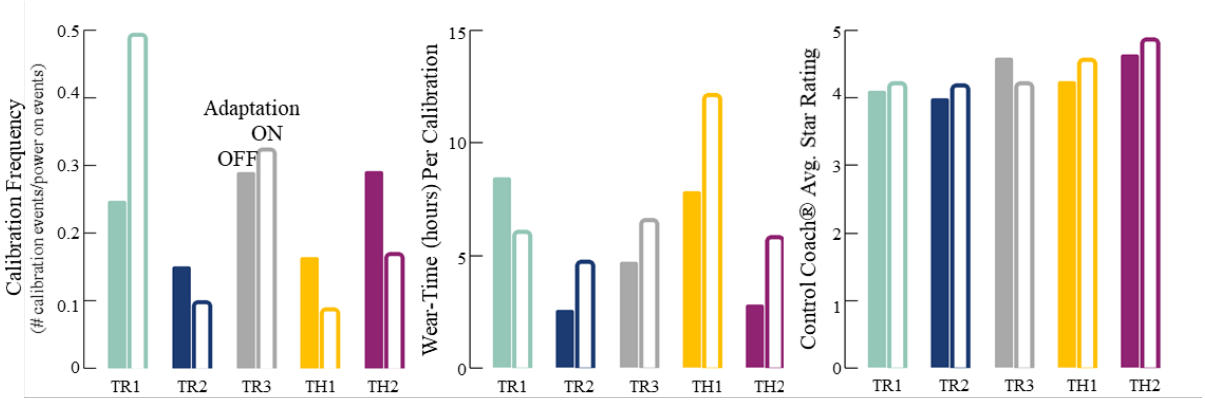

Figure 1: Differences in individual participant logged prosthesis use data including (left) calibration frequency (middle) wear-time per calibration (right) average calibration quality star-ratings when the adaptation classification algorithm was enabled or disabled on their pattern recognition control system.

DISCUSSION

We presented preliminary results of an at-home study to determine whether an adaptive classification algorithm for upper limb myoelectric prosthesis wearers reduces how often users choose to recalibrate their pattern recognition controller when using their prosthetic device within their home environment. By adding new data to the pattern recognition classifier rather than completely clearing the existing classifier, we implemented an adaptive algorithm that affords the controller the opportunity to generalize to more movements, prosthesis use conditions and a larger set of EMG input data. Our preliminary analysis reveals a trend towards a reduction in calibration frequency and an increase in how much time elapses before users choose to recalibrate their device when the adaptation algorithm was enabled. Interestingly, four of the five participants reported, in a Post-Study Questionnaire, that they felt they achieved better control performance during the 8-week period when the adaptive algorithm was enabled on their device. The implementation of supervised controller adaptation on a commercial pattern recognition system that decreases the need for recalibration, and even improves home-use performance can have a far-reaching clinical impact on prosthesis wearers.

An adaptive classification strategy may provide a means not only to reduce the frequency of user recalibration, but also to improve their functional prosthesis control. Another main finding of our preliminary results was that users improved their calibration quality when the adaptive algorithm was enabled. This result provides preliminary evidence that adding additional EMG input data can improve calibration quality which may translate to enhanced user control of their prosthetic device. Further analysis of participants' usage logs and virtual game data collected during each 8-week period is needed to determine the correlation between the quality of their calibrations and their control efficiency within both a virtual environment and their home environment.

While the adaptation algorithm implemented on the control system can generalize over a broader set of EMG calibration inputs, it is unable to account for EMG signal noise recorded during regular prosthesis use. EMG signal quality is a significant factor in users being able to consistently achieve adequate control of their device. While there are several physiological and engineering factors that can affect EMG signal quality (including external noise, muscle fatigue, electrode-skin impedance), myoelectric prostheses require that the electrodes maintain contact with the skin surface to ensure proper user function. The Complete Control System can detect such electrode liftoff events which can be used to monitor signal quality issues. Interestingly, the two users who had higher a calibration frequency when the adaptive algorithm was off also had a high frequency of electrode liftoff events. Currently, the

only way for users to counteract frequent electrode liftoff is by disabling the electrode channels with a noticeably high occurrence of liftoff events.

Participants in this study were required to perform a full motion calibration sequence to either replace or update their control system's classifier during both 8-week periods. However, one of the added features of the adaptative calibration algorithm is the ability to add EMG input data to a single motion rather than completing the entire motion sequence. This feature provides users a convenient way to update and improve their classifier for a single motion if they feel that their control efficiency for that motion has deteriorated or if there are prosthesis use conditions where they want to train with that specific motion. Since participants in this study were existing Complete Control system wearers and the adaptive classification algorithm is the default behaviour of the system, many who normally rely on the "Single Motion Add Data" feature to improve their prosthesis control did not have access to it. In fact, one of the participants who withdrew from the study reported that the inability to use the "Single Motion Add Data" feature as the primary reason for withdrawing from the study.

DISCLOSURES

This work was supported by the Department of Defense, through the Orthotics and Prosthetics Outcomes Research Program Prosthetics Outcomes Research Award under Award No. W81XHW-17-1-0645. Opinions, interpretations, conclusions and recommendations are those of the authors and are not necessarily endorsed by the Department of Defense.

Coapt, LLC is the manufacturer of the FDA-cleared Class II medical device, called the Complete Control System, used in this study. Wright, as Research Principal Investigator, is an employee of Coapt, LLC. Lock, as CEO, has financial interest in Coapt, LLC.

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CHALLENGES OF UPPER LIMB FITTING IN CANADA: A SURVEY OF UPPER LIMB PROSTHESIS USERS AND CLINICAL PROSTHETISTS IN CANADA

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ABSTRACT

Purpose: This study aimed to survey Canadian upper limb prosthesis users and clinical prosthetists (who fit the device) to examine physical and psychosocial factors that influence the acceptance and rejection of using an upper limb prosthesis. *Methods:* Two separate, custom-built questionnaires were developed and sent to Canadian clinical prosthetists to participate and distribute to their upper limb patients. *Results:* This survey received responses from 47 clinicians, 22 prosthesis users, and one non-prosthesis user from nine provinces. Due to the small data set, responses did not show any statistical significance; however, the results highlight several important factors and the importance of patient-prosthetist relationships and rehabilitation services. *Conclusion*: Upper limb fitting in Canada has its challenges, and similar to other research, there are several important factors to focus on when considering acceptance of upper limb prostheses.

INTRODUCTION

Individuals with upper-limb absence (ULA) account for 3 to 15% of all amputations and have relatively lower rates of acceptance/use than those with lower-limb absence (LLA) [1]. Studies show that acceptance rates for ULA individuals are 27 to 56%, whereas LLA individuals have a 49 to 95% acceptance rate [2]. Limb loss is considered “trauma”, as the correlation between mental-self and real-self disrupted, which can affect an individual’s interaction with the sense of belonging and the acceptance of a prosthetic limb. Acquired/traumatic limb loss accounts for 80 to 90% of all ULA, which can be correlated to the high and varying rates of prosthesis rejection, ranging from 24 to 70% [3]. Canadian research regarding upper limb prosthesis acceptance and rejection rates and reasons are limited and outdated since there are no official reporting requirements [4]. Furthermore, with the technological advancements in prosthetics, these rates have changed and should be updated [5]. The purpose of this study was to survey Canadian upper limb prosthesis users and clinical prosthetists (who fit the device) to examine physical and psychosocial factors which influence the acceptance and rejection of using an upper limb prosthesis. The results of this study will help address this void in Canadian upper limb research and improve our understanding of why acceptance and rejection of upper limb prostheses occurs.

METHODS

Questionnaire

Two separate, custom-built questionnaires were developed from a literature review of existing surveys and relevant research to focus on the most prevalent factors impacting prosthesis acceptance. The prosthesis user/non-user questionnaire collected participant demographics, limb loss specifics, prosthesis user background, and prosthesis acceptance and rejection related factors. The clinician questionnaire collected clinician and clinic demographics, prosthesis availability and rehabilitation, and prosthesis acceptance and rejection factors. The surveys were provided in English and French and administered through the online survey platform Google Forms and the post if needed. Certified clinical prosthetists across Canada were the primary recruitment source, as survey links were distributed via an invitation email. The clinicians were asked for their participation in the survey, as well as, to aid in dispersing the prosthesis user/non-user survey, to their patient list that met the inclusion criteria. The inclusion criteria for the clinician questionnaire were Canadian certified prosthetists (CP), certified prosthetists orthotists (CPO) and prosthetic residents, and that the clinic at which they worked fitted upper limb prostheses. The criteria for inclusion in the prosthesis user/non-user survey were upper limb amputees of any length, age 19 years or older, and who currently use a prosthesis or have chosen to reject using a prosthesis. A total of 47 clinicians (CL), 22 prosthesis users (PU) and one non-prosthesis user (NPU) participated in the survey. Questionnaires with a minimum of 75% completed answers were used, and for questions which were not answered by all participants the response rate was included in the results separately. Data was processed using t-tests with two-tailed distribution and two-sample unequal variance and two

sample proportion z-test, with an alpha level of 0.05. All statistical analysis was computed using Minitab 19.2020 (Minitab® LLC State College, Pennsylvania, USA), and a variance equality was not assumed for this. The Research Ethics Board at the University of New Brunswick (REB #2021-135) approved this study.

RESULTS

Clinician and clinic demographics

Clinician participation came from nine provinces, with 40.4% working in hospital-based clinics. The majority, 70.2%, of CL were CP, ranging from less than five to over ten years of experience. Most clinicians' ULA patients represented less than 10% of their clinic's population, with the average age of patients between 36 to 65 years. Clinician and clinic demographics are presented in Table 1.

Table 1: CL (p=46) and PU (p=20)

Complaint	Pooled sample proportion	Test statistic	P-value (p>0.05)
Fit	0.23	-4.0845	2.000
Maintenance/ repair	0.169	-2.592	1.990
Function	0.350	0.000	1.000
Glove issues	0.166	-1.203	1.771
Comfort	0.275	1.504	0.133
Cosmetics	0.228	0.356	0.722
Myo-hand/ device	0.135	0.547	0.585
Harness	0.120	1.150	0.250
Durability	0.106	0.971	0.331
Skin irritation	0.092	0.776	0.438
Technology	0.064	0.305	0.760

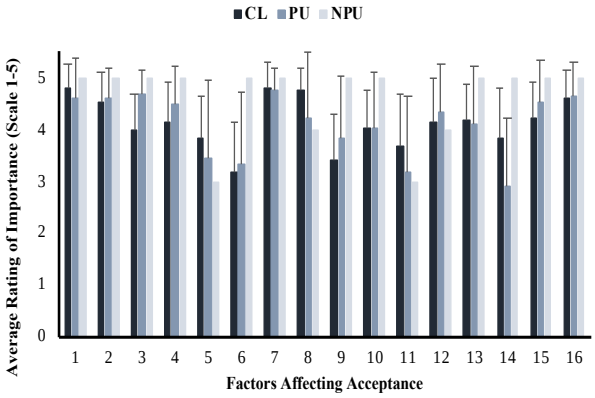

Figure 1: CL, PU and NPU ratings of importance for factors affecting acceptance. Likert scale of 1 to 5, with 1 being not at all important and 5 being very important. Standard error bars represent standard deviation. Factor Key: 1-Function of the prosthesis, 2-Ease of prosthetic device use, 3-Ease of putting on/taking off the prosthetic device, 4-Weight of the prosthetic device, 5-Cosmetic quality of prosthetic device, 6-Sufficient sensory feedback from the prosthetic device, 7-Socket and harness comfort, 8-Skin/body irritation from prosthetic device, 9- Heat produced while wearing the prosthetic device, 10-Satisfaction with prosthetic device technology, 11-Past prosthesis experience, 12-Lifestyle, 13-Availability of prosthetic services, 14-Access to therapy and training for prosthetic device use, 15-Confidence of prosthetist, 16-Quality of patient-prosthetist relationship.

Users and Non-Users demographics and limb loss specifics

Out of 23 individuals with ULA, 22 currently use a prosthetic device, and one did not. Participants identified as 43% female and 57% male and were primarily in the age range of 36 to 65 years and reported from five different provinces. 91% of the participants were unilateral amputees, mainly transradial (52%). Acquired amputation accounted for 65%, and of the acquired ULA individuals, 73% had their limb loss occur on their dominant arm. Prosthesis user and non-user demographics and limb loss specifics are documented in Table 2.

Table 2: Factors rated greater than or equal to 4.0 for the level of importance in influencing prosthesis acceptance.

	Factors																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17*	18*	19*	20*
CL	+	+	+	+	-	-	+	+	-	+	-	+	+	-	+	+	-	+	-	+
PU	+	+	+	+	-	-	+	+	-	+	-	+	+	-	+	+				
NPU	+	+	+	+	-	+	+	+	+	+	-	+	+	+	+	+				

+ = ≥4.0, - = < 4.0, *Factors only asked in clinical questionnaire. Factor Key: Same as Figure 1, with the addition 17-Patient gadget tolerance, 18-Amputation level, 19-Time to initial fit, 20-Funding availability.

Factors affecting “acceptance” of a prosthesis

CL, PU and NPU rated a list of 16 factors on the level of importance with regards to how it would affect the “acceptance” of a prosthesis. A statistical difference was not found between the CL and PU, as their ratings of importance were relatively similar. Except for their ratings for Access to therapy and training for prosthetic device use, there was a statistical significance ($p= 0.06$), with the CL rating a higher importance value, than the PU and NPU. The order of the highest-ranked factors, varied slightly between the two groups. PPU’s top 5 factors, in order of highest to lowest average rating, were: socket and harness comfort, ease of putting on/taking off the patient’s prosthetic device, quality of patient-prosthetist relationship, the function of the prosthesis, ease of prosthetic device use. Whereas the top 5 factors for CL, in order of highest to lowest average rating was: function of the prosthesis, socket and harness comfort, skin/body irritation from prosthetic device, quality of the patient-prosthetist relationship, ease of prosthetic device use.

Common complaints

In order of greatest occurrence, the following top 5 PU complaints were mentioned in clinicians’ responses (n=46): weight, function, comfort, cosmetics, cost, whereas the top 5 PU complaints mentioned in the PU responses were (n=20): fit, maintenance/repair, function, glove issues, cosmetics. Table 1 documents commonly mentioned complaints and their statistical analysis values.

Patient-prosthetist relationship

On average, PU rated their overall relationship with their prosthetist 4.55 on a scale of 1 to 5, and the NPU participants rated theirs as a 5. Furthermore, 73% of PU agreed that they believe their level of satisfaction with their prosthetist influenced their decision to use a prosthesis, whereas the NPU did not. Similarly, 89% of CL agreed that PU's satisfaction level with their prosthetist can influence their acceptance of a prosthesis. However, there was no statistical difference between the two proportions, ($p = 0.09$).

Rehabilitation services

82% of PU have worked with a rehabilitation specialist, whereas the NPU did not. 74% of CL answered yes to coordinating rehabilitation services for their patients after fitting, with 64% of the specialists being occupational therapists (OT), 26% physiotherapists (PT) and 10% covering other specialists, such as physiatrists and psychologists.

DISCUSSION

Although the sample size for this study is relatively small and thus restricts the ability to show statistical analysis, these findings still present a great deal of preliminary data for Canadian upper limb prosthetics.

Participant demographics

Since ULA makes up a small portion of the limb loss population, it is understandable for most CL to have a limited amount of experience fitting upper limb PU and the various levels of limb loss. In the final question of the clinician questionnaire, participants are asked to provide their final thoughts on the current challenges in Canada regarding prosthesis acceptance and rejection. Prosthetist knowledge and having access to an experienced upper limb fitting prosthetist, had the third-highest occurrence rate (17%, n=47). It is recognized that the number of NPU does not allow for statistical analysis to occur; however, the answers provided are still considered to be a finite view of a NNPU’s reasons for rejection.

Factors affecting "acceptance” of a prosthesis

Similar to previous research, CL and PU identify factors such as function of the prosthesis, socket and harness comfort, ease of putting on/taking off prosthetic device, ease of prosthetic device use, skin/body irritation from prosthetic device and quality of patient-prosthetist relationship [5]. Table 2 shows all ratings given greater than or equal to 4.0, which represents important to very important on the provided Likert scale.

Common complaints

Comparing the common complaints listed by the PU and CL allows for an analysis of how the CL are possibly interrupting user complaints and, what complaints are important to the users. When comparing the top five occurring complaints, it is interesting to note that two of the clinician’s listed complaints are not in the top five for PU. When given the opportunity to report on their most common complaints, PU do not focus on weight or cost, unlike the CL. CL may be more focused on these two factors since they have an important influence on the PPU’s use of and ability to use a prosthesis. 72% (n=16) of the PU participants (n=22), use body-powered or myo-electric hook/hands, which is when weight implications can become more

prominent. However, the survey results show that the PU is more concerned about the fit, maintenance, and function, which is understandable. If the prosthesis does not function properly, then the weight of the device is null and void.

Patient-prosthetist relationship

All three groups scored the quality of patient-prosthetist relationship ≥4.0 and both CL and PU groups rated this factor in the top five highest for its importance. There is no statistically significant difference between the group's ratings. An additional comment in a clinician's survey said, "*well-fitting/comfortable device can be accepted by any patient regardless of their feelings towards the prosthetist. It is often easier to get to the well-fitting/comfortable device is both parties have a healthy working respect for each other*." This statement aligns with the current study's data and past research where the strength of each factor affects acceptance placed the quality of this relationship in the top five highest rankings [6]. Especially for younger patients, who may be clinic clients for a longer amount of time, the relationship with their clinician could hold an even greater influence factor in their decision to accept and continually use a prosthetic device.

Rehabilitation services

Rehabilitation and training can be influential on the prosthesis user. For acquired amputation, a good rehabilitation program is often divided into four phases: acute postsurgical, subacute pre-prosthesis training, basic prosthesis training, and advanced long-term rehabilitation [7]. The sooner training can start, the greater the period of "high acceptance" is, which influences the prosthesis user's willingness to use a prosthesis [8]. A common complaint reported in the current study was the lack of functionality or having too high of expectations for how well the prosthesis would function. Research shows that quality prosthesis training can positively impact the function and use of the prosthesis, for the rest of the user's life [8]. CL, who reported not coordinating rehabilitation services after fitting, provided reasoning, such as: "*Therapists with expertise/experience with upper limb amputees are not available in our area (i.e., northern regions especially)," "Depends on access to publicly funded rehab therapists. No private therapists specialize in UE training"* and *"Depends on the level of confidence/experience (i.e., Often for people with new amputations we do coordinate rehabilitation with an OT and PT. However, for experienced PU we do not as they are already confident users.*)." Improving the rehabilitation coordination and quality of training, is important for the overall prosthesis fitting process, especially as prosthetic device technology becomes more advanced. As user gadget tolerance becomes more difficult, experienced rehabilitation services will become more influential in the acceptance, and long-term use, of a prosthetic device [7]. In addition, to optimize rehabilitation, previous studies report the importance of sharing experiences between rehab centres, to spread knowledge of upper limb prosthetics [9].

CONCLUSION

The results suggest that Canada's upper limb prosthesis fitting has areas in need of improvement. Many factors can influence prosthesis acceptance, mainly focusing on function, ease of use and comfort of various components. Therefore, it is important for multidisciplinary teams of CL to focus their attention on improving these factors. Additionally, elements such as quality of patient-prosthetist relationship and rehabilitation services are shown to greatly impact a PPU's willingness to try a prosthesis and then consistently use it. Future research should focus on developing validated clinical research surveys to increase Canadian data, and track improvements, as prosthesis technology continues to change, and upper limb fitting improves through awareness and education. Awareness and qualification could also impact the number of survey participants, as CL and upper limb amputees may become easier to contact and more interested in helping with data collection. This research can help initiate the surge for Canadian upper limb fitting data collection and in turn better the quality of life of Canadian's living with ULA.

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EFFECT OF MULTI-GRIP MYOELECTRIC HANDS ON DAILY ACTIVITIES, PAIN-RELATED DISABILITY AND PROSTHESIS USE COMPARED WITH SINGLE-GRIP PROSTHESES

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ABSTRACT

Objective: To evaluate the effect of multi-grip hands on performance of daily activities, pain-related disability and prosthesis use, in comparison to single-grip hands. Design: Single-case AB design. Patients: Nine adults with upper-limb loss participated. All had previous experience of single-grip myoelectric prostheses and were prescribed a prosthesis with multi-grip functions. Methods: To assess the changes in daily activities, pain-related disability and prosthesis use between single-grip and multi-grip prosthetic hands, the Canadian Occupational Performance Measure, Pain Disability Index, and prosthesis wearing time were measured at multiple occasions. Visual assessment of graphs and multi-level linear regression were used to assess changes in the outcome measures, adjusting for xx, yy, and zz. Results: At 6 months' follow-up self-perceived performance and satisfaction scores increased, prosthesis wearing time increased, and pain-related disability reduced in participants with musculoskeletal pain at baseline. On average, 8 of the 11 available grip types were used. Most useful were the power grip, tripod pinch and lateral pinch. Conclusion: The multi-grip hand appears to be associated with higher performance and satisfaction of individually chosen activities, increased prostheses use and lower pain-related disability. A durable single-grip hand may still be needed for heavier physical activities. With structured training a standard two-site electrode control system can be used to operate a multi-grip hand.

INTRODUCTION

It is well known that myoelectric prostheses are being used in varying degrees [1]. To improve the usability of prosthesis, myoelectric prosthetic hands have been developed with multiple grip functions. The multi-grip prostheses have the potential to facilitate fine motor skills and enable a natural movement pattern [2], which, over time, may reduce pain due to a reduction in compensatory movements, and avoidance of overuse of the contralateral limb. However, the impact of these hands on the users' daily life has been sparsely studied, and the results have been inconsistent. Both users and clinicians reported that many of the multi-grip functions are rarely used [3]. There are several possible reasons for this; notably that all functions in the multi-grip hand need to be mastered, which may take time, training and, inevitably, require higher cognitive load [4]. Another reason for not using the full potential of the multi-grip hand may be incomplete training [5,6]. With inadequate training the patients may use their multi-grip hand in the same way as they have used a single-grip prosthesis [7,8]. Questions arise as to whether extensive training in control skills and use of multi-grip functions will facilitate actual use of the prosthesis, and whether this will have an effect on prosthesis users' activity performance and pain-related disability.

AIM

The overall aim of this study was to evaluate the effect of multi-grip myoelectric prosthetic hands on the performance of daily activities, pain-related disability and prosthesis use, in comparison with single-grip myoelectric prosthetic hands. A secondary aim was to study the users' ability to learn and use the multi-grip hand functions with a standard 2-site control system.

METHOD

A single case AB-design was used.

Participants and procedure

Inclusion criteria were: age 18 years or older, upper limb loss due to amputation or reduction deficiency present at birth, being a previous user of a conventional myoelectric prosthesis (single-grip) and having had training in using it, and having currently being prescribed a multi-grip prosthetic hand. Nine patients (5 males/4 females) mean age 31,8 (range: 18-59) years with various causes of limb loss and various prosthesis wearing time (range: <1-15 hours /day) were prescribed a multi-grip hand during September 2017- September 2020 and included in the study. They were all fitted with a bebionic multi-grip hand from Ottobock, Vienna, Austria, and using 2-site direct control.

In the prescription procedure the patients identified activities that were hard to perform with their present conventional myoelectric hand. The activities required fine motor skills which the participants thought maybe could be easier to perform with a multi-grip prosthetic hand. Examples of activities were to hold a book, shake hands, use cell phone, carry shopping bags, dress children, cook, and use a keyboard.

The participants were assessed 3 times before fitting with their single-grip prosthesis for a base-line (Phase A). Thereafter, the intervention followed, including fitting a multi-grip hand and a period of training and follow-up (Phase B). They had 2 days of intensive training at the time of fitting the bionic hand, and further training at the follow ups after 2 weeks, 1, 2, 3 and 6 months after fitting. A total of 6 assessments were made with the multi-grip hand (bebionic).

Outcome measures

To assess the changes in daily activities, pain-related disability and prosthesis use between single-grip and multi-grip myoelectric prosthetic hands, the Canadian Occupational Performance Measure (COPM), Pain Disability Index (PDI), and prosthesis wearing time were measured at multiple time-points. A study specific questionnaire was also used at the 6 months follow up to investigate the usefulness and actual use of the available grip types.

The COPM is an interviewer administered assessment of individually selected problems in daily life activities. Patients define the 5 most important activities and score the quality and satisfaction with performance on a 1-10 scale where higher score indicates higher quality of performance or satisfaction with performance. The COPM scores were calculated according to the manual, with the sum of scores divided by the number of activities.

The effect on pain-related disability was measured with the PDI. This generic instrument measures the impact of prolonged pain on a person's ability to participate in essential life activities. The PDI is able to detect from low to high levels of pain-related disability on a 0–10 scale in 7 dimensions. The scores on all the dimensions are summed on a scale of 0–70, where a higher score indicates more obstacles in essential life activities due to pain.

The secondary aim, to study the users' ability to use the multi-grip hand functions, was assessed with a modified Southampton Hand Assessment Procedure (SHAP) and Assessment of Capacity for Myoelectric Control (ACMC). A modified SHAP was used to measure ability to switch between grips. The participants performed all tasks in the test in a sequence, and switched grip between each task. Time taken to complete all tasks was registered. The ACMC was used to see how well the participants learned to control and use the new prosthetic hand in daily activities. The ACMC is an observational based assessment with 22 items scored on a 0-4 scale of capacity for control of the prosthesis. Higher scores indicate higher ability. The ACMC raw scores were processed through the website resulting in an overall score ranging from 0-100.

Analyses

The changes in COPM, PDI, ACMC, and modified SHAP scores were assessed using both visual assessment of graphs [9] and multilevel linear regression models [10]. In the multilevel models, level 2 represented the individual and level 1 represented multiple measurement occasions from baseline to 6 months that were nested within level 2. Follow-up time was used as a categorical variable, with Phase A (baseline) as the reference. The coefficients indicate

differences in scores between baseline and each follow-up occasion in Phase B, with adjustment for xx, yy and zz. Confidence intervals (CIs) not overlapping zero were considered to indicate a statistically significant difference.

RESULT

Performance of daily activities

The graphs present crude scores for occupational performance and satisfaction scores in COPM, both of which increased in all individuals after using the multi-grip hand (see Figure 1). Adjusted multilevel regression models showed that, after 3 months, quality of performance scores increased, by a mean of 3.9 points (95% CI=3.2–4.6) and satisfaction with performance scores increased by 4.9 points (CI=4.0–5.7) (see Table 1).

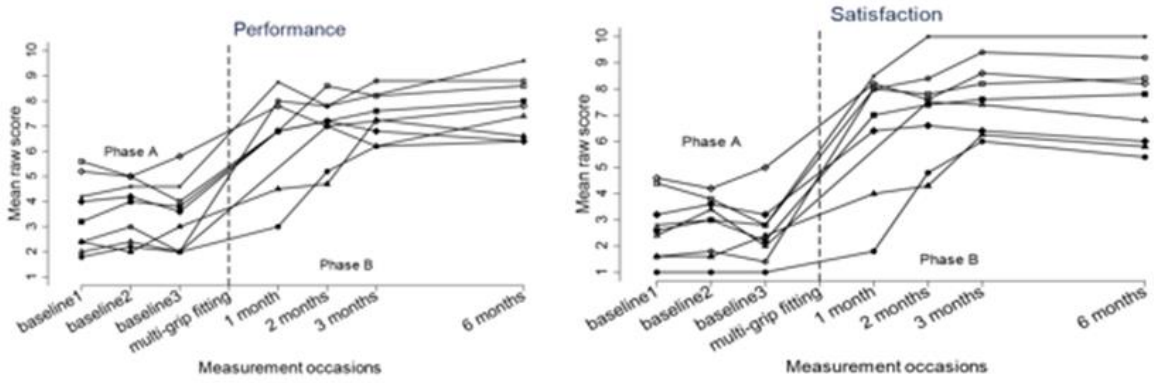

Figure 1: Visual assessment of graphs of quality of and satisfaction with performance, as measured with the Canadian Occupational Performance Measure (COPM). Performance= Quality of performance; Satisfaction= Satisfaction with performance. Raw scores range from 1 to 10, with 10 representing the best possible score. (Phase A=baseline with the single-grip hand, Phase B=follow-up after fitting the multi-grip hand.

Table 1. Coefficients, 95% confidence intervals and p-values using multilevel linear regression models for COPM, PDI, ACMC and modified SHAP scores, with adjustment for xx, yy and zz.

	Data collection time point	**COPM** Performance	**COPM** Satisfaction	**PDI**	**PDI (n=5)***	**ACMC**	**Modified SHAP** Light objects, seconds	**Modified SHAP** Heavy objects, seconds
		Coefficient (95% CI)	Coefficient (95% CI)	Coefficient (95% CI)	Coefficient (95% CI)	Coefficient (95% CI)	Coefficient (95% CI)	Coefficient (95% CI)
Phase A	Baseline	Reference	Reference	Reference	Reference	Reference	Reference	Reference
Phase B	2 days	No data collected	No data collected	No data collected	No data collected	-18.5 (-24.5 to 12.4) p<0.001	26.3 (8.1 to 44.4) p=0.005	28.3 (12.2 to 44.3) p=0.001
	2 weeks	No data collected	No data collected	No data collected	No data collected	-12.4 (-18.4 to -6.5) p<0.001	7.7 (2.8 to 12.7) p=0.002	8.9 (-1.2 to 19.0) p=0.085
	1 month	3.0 (2.1, 3.8) p<0.001	3.8 (2.7, 4.9) p<0.001	-2.0 (-9.9 to 5.9) p=0.620	-4.6 (-18.1 to 8.9) p=0.504	-4.2 (-8.6 to 0.3) p=0.068	9.3 (2.9 to 15.8) p=0.004	12.1 (-3.1 to 27.4) p=0.119
	2 months	3.5 (2.9, 4.0) p<0.001	4.5 (3.6, 5.4) p<0.001	-4.0 (-10.8 to 2.8) p=0.249	-7.2 (-18.4 to 4.0) p=0.209	-4.8 (-9.5 to -0.2) p=0.042	5.0 (0.4 to 9.6) p=0.033	1.2 (-8.4 to 10.9) p=0.801
	3 months	3.9 (3.2, 4.6) p<0.001	4.9 (4.0, 5.7) p<0.001	-9.0 (-16.3 to -1.7) p=0.015	-14.4 (-23.0 to -5.8) p=0.001	-1.4 (-6.1 to 3.2) p=0.545	2.3 (-2.3 to 6.9) p=0.330	3.4 (-6.3 to 13.1) p=0.494
	6 months	4.3 (3.6, 4.9) p<0.001	4.8 (3.9, 5.7) p<0.001	-7.7 (-14.0 to -1.3) p=0.018	-13.8 (-21.8 to -5.8) p=0.001	-2.5 (-7.8 to 2.8) p=0.359	6.5 (-5.2 to 18.1) p=0.275	-3.7 (-13.4 to 6.0) p=0.454

*Includes only the 5 participants who reported pain-related disability in the Pain Disability Index at the baseline measurements.

Pain-related disability

Five participants reported that musculoskeletal pain was limiting their participation in essential life activities at baseline. This activity limitation generally declined after fitting a multi-grip hand. At the 6-month follow-up the number of participants reporting any pain-related disability had decreased from 5 to 2. In the adjusted multilevel analyses, focussing on the 5 participants who reported pain-related disability at baseline, it was found that, compared with baseline, their PDI mean score decreased significantly, by a mean of –14.4 (CI=–23.0 to –5.8) at the 3-month follow-up, and by –13.8 (CI=–21.8 to –5.8) at the 6-month follow-up (see Table 1)

Prosthesis use and perceived usefulness of multi-grip features

Participants increased their self-reported prosthesis wearing time after switching to a multi-grip hand, from a mean of 6.9 hours a day with single-grip hand to 8.8 h a day with the multi-grip hand at the 6-month follow-up. The median number of grip types used was 8 out of 11 (range 7–10). Grip types that were considered most useful and were used most were the power grip, tripod pinch and lateral pinch.

Prosthetic skill

Initially, when the participants were fitted a multi-grip hand, their skill in prosthesis control (ACMC scores) decreased compared with their baseline performance with the single-grip hand. After 3 months, the score of most of the participants increased to a level similar as with the single-grip hand. The time to perform the modified SHAP test became longer 2 days after fitting the multi-grip hand, compared with baseline with the single-grip hand. However, by the measurement after 2 weeks, it decreased to a similar level as with the single-grip hand. (Table 1)

CONCLUSION

The multi-grip myoelectric prosthetic hand has favourable effects on performance of, and satisfaction with, individually chosen activities, prostheses use and pain-related disability. A durable single-grip myoelectric prosthetic hand may still be needed for heavier physical activities. With structured training, a standard 2-site electrode control system can be used to operate a multi-grip myoelectric prosthetic hand, and many of the prosthetic functions are actually used.

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IMPACT OF UNILATERAL TRANSRADIAL PROSTHESIS IN UPPER LIMB UTILIZATION RELATIVE TO ABLE-BODIED CONTROLS: INSIGHTS FROM WIRELESS ACCELEROMETER DATA

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ABSTRACT

Hand loss profoundly impacts daily functioning. The use of an upper limb prosthesis can restore a measure of both unimanual and bimanual upper limb function for this population. We asked unilateral, transradial amputees (N=22) and healthy controls (N=20) to wear wireless accelerometers on their forearms and distal prostheses, as well as on their upper arms bilaterally to capture data over 3 days while the subjects were in their natural environments. Prosthesis users wore their devices an average of 11 hours/day. They exhibited heavier reliance on their sound side upper limb than on their affected limb. However, they were observed to engage in unimanual activity with their prostheses an average of 20 minutes/day compared to the 60 minutes of mean unimanual activity observed in the non-dominant extremity of control subjects. Bimanual activity among prosthesis users was recorded for an average of 4 hours/day compared to an average of 5 hours/day in the control population. While participants generally exhibited 70% reliance on their lower arm segment relative to their upper arm segment, on the affected extremity of the amputee participants, this reliance dropped to 50%, suggesting a need for greater upper arm activity to preposition the prosthesis in space. Upper arm accelerometers confirmed that engagement of the upper arm segment in upper limb amputees diminish when the prosthesis is removed. Collectively, this data begins to demonstrate the ability of transradial prostheses to preserve both unimanual and bimanual functionality. (This abstract focuses on a subset of previously published data from Frey S, Motawar B, Buchanan K, et al. Greater and more natural use of upper limbs during everyday life by former amputees versus prosthesis users. *Neurorehabil Neur Rep.* 2022;36(3):227-38).

INTRODUCTION

Upper limb amputation has a profound impact on both function and quality of life.[1-4] Prostheses can improve outcomes, but disuse occurs among a minority of patients[5] and those that use a prosthesis often rely heavily on their intact limbs during everyday life.[6] This tendency towards one-handedness has been associated with greater disability and overuse injury.[7]

Recent literature has attempted to quantify the engagement of upper limb prostheses through wrist-worn accelerometers.[6] These efforts have observed that prosthesis users demonstrate a preference towards their intact side, a lack of correlation between prosthesis wear and prosthesis use and a lack of correlation between prosthetic skill and prosthetic engagement.[6]

We implemented a wireless accelerometry protocol to record upper extremity movements during 3 days of normal activity in transradial amputees and healthy age-matched controls. Prior studies only implemented the forearms and prostheses at the distal wrist levels to capture hand and terminal device movements.[6] In contrast, in addition to bilateral distal sensors we placed sensors proximally above the elbows. This allowed us to evaluate between-group differences in both upper arm and residual limb movements and the use of the upper arm by amputees when not wearing their prosthesis. We sought to better define the extent to which transradial prostheses were able to enable the unimanual and bimanual upper limb engagement observed in able-bodied controls. This effort was part of a larger trial that additionally enlisted both hand transplant and hand replant patients which has been published elsewhere.[8]

METHODS

Ethics

The protocols was approved by the University of Missouri Office of Human Protections and the Human Research Protection Office at the Department of Defense and was performed in accordance with the Declaration of Helskinki. All participants provided informed consent.

Participants

With respect to the data reported in this abstract, we used wireless accelerometers to capture data on limb use across 3 consecutive days in 2 groups of interest. Group 1) users of unilateral transradial prostheses (N=22, aged 56.4 ± 17.1 years, 1 female, 30.2 ± 21.6 years after traumatic amputation). Half of the limb loss group had dominant hand affected; and Group 2) healthy age-matched controls (N=20, aged 53.4 ± 15.8 years, 3 females, 18 right handed. Current amputees used a variety of prostheses: exclusively body-powered (n=8), exclusively myoelectric (n=7), both body-powered and myoelectric (n=5), passive (n=1) and unknown (n=1). On average, the amputee group had used a prosthesis for 26.09 ± 20.93 years, with their current prosthesis being in use for an average of 7.11 ± 14.46 years. Prosthesis users were recruited through Hanger Clinic and local and national advertising, resulting in a convienence sample of individuals who responded to recruitment materials.

Data Collection

Data collection on this trial has been reported in detail elsewhere[8] but is described briefly as follows. Four accelerometer sensors (GT9X Link, ActiGraph Corp, Pensacola, FL) were shipped to subjects. Subjects wore these accelerometers for 3 consecutive days. The data collection included 2 weekdays and 1 weekend-day to sample both occupational and leisure activities. Two accelerometers were worn on the anatomical or prosthetic forearm to capture hand or prosthesis movements, and two accelerometers were placed above the elbows to capture upper arm movements.

Data Analysis

Data Analysis on this trial has been reported in detail elsewhere,[8] but is described briefly as follows. Activity counts were counted in 1-second epochs and downloaded from the accelerometer. Variables of interest were computed during awake time. For prosthesis users, we also identified prosthesis non-wear time.

Table 1: Variables of interest including measured unilateral and bilateral forearm activity and median reliance on the upper arm. (In general, the metrics of the affected limb of prosthesis users are compared against the nondominant limb of the control group, while the metrics of the unaffected or sound limb of prosthesis users are compared against the dominant limb of the control group).

	Amputees		Control Dominant		Control Nondominant	
	Mean	SD	Mean	SD	Mean	SD
Unilateral forearm activity (hours/day)	4.8	1.6	2.72	.89	N/A	N/A
Unilateral affected forearm activity (hours/day)	.33	.19	N/A	N/A	1.06	.46
Unilateral unaffected forearm activity (hours/day)	4.47	1.61	1.65	.54	N/A	N/A
Bilateral forearm activity (hours/day)	4.02	1.35	5.04	1.33	N/A	N/A
Median reliance on forearm, affected limb (%)	49.41	3.37	N/A	N/A	70.33	7.66
Median reliance on forearm, unaffected limb (%)	69.98	3.61	68.56	7.46	N/A	N/A
Median reliance on affected upper arm, prosthesis off (%)	25.37	12.44	53.58	5.35	46.42	5.35
Median reliance on affected upper arm, prosthesis on (%)	30.62	7.07	N/A	N/A	N/A	N/A

RESULTS

Our data found that prostheses were used an average of 79% of waking hours with a mean recorded utilization of 11.1 ± 1.8 hours/day. Additional variables of interest are shown in Table 1. Unilateral engagement of the prosthesis was recorded an average of 20 minutes per day. Unilateral engagement of the sound side extremity was recorded for an average of 4.5 hours per day. By contrast, unilateral activity in the dominant and non-dominant extremity of the control subjects were reported an average of 100 minutes and 60 minutes respectively per day. Among prosthesis users, an average of 4 hours of bimanual activity was recorded. By comparison, control subjects recorded an average of 5 hours of bimanual activity per day.

Reliance upon the forearm relative to the upper arm was recorded in four conditions; that of the dominant limb in controls, the non-dominant limb of controls, the sound side limb of the prosthesis users and the affected extremity of the prosthesis users. That mean forearm reliance ratios were reported at 69%, 70% and 70% respectively among the first three scenarios. In the last scenario a forearm ration of 50% was recorded.

Upper limb reliance among the non-dominant limbs of control subjects was observed at 46%. When the prosthesis was not worn, this ratio decreased to 25%. When the prosthesis was worn this variable increased to 31%.

DISCUSSION

While a minority of those with upper limb amputation eventually choose to abandon the use of a prosthesis, the subjects enrolled in our trial were found to wear their devices for more than 11 hours per day. During this period, prosthesis users engaged in both unimanual and bimanual tasks. Viewed collectively, prosthesis users engage in an average of 8.82 hours of upper limb activity. This is roughly one more hour of upper limb activity than that recorded on average for healthy controls (7.76 hours). This relative parity may reflect the similarities associated with activities of daily living (ADLs) in both groups, with upper limb amputees requiring additional time to complete upper limb tasks.

As observed by Chadwell et al,[6] the disparity between unimanual engagement of the prosthesis and unimanual engagement of the sound side limb is stark, observed at 20 minutes and nearly 4.5 hours respectively. However, the disparity between unimanual engagement of the prosthesis and unimanual engagement of the non-dominant extremity of the controls was much less pronounced at 20 and 60 minutes respectively. Our data suggest that transradial prostheses are able to preserve roughly 1/3rd of the unimanual activity duration typically associated with a non-dominant extremity.

Ostlie et al[9] observed a tendency for upper limb prostheses users to report preferentially engaging the use of their devices in bimanual tasks. Our data support this tendency, with engagement of transradial prostheses during bimanual tasks occurring an average of 4 hours daily. This value begins to approximate the 5 hours of bimanual tasks recorded among health controls, suggesting that transradial prostheses are able to facilitate approximately 80% of the bimanual activity duration observed in able-bodied controls.

The relative reliance upon the forearm relative to the upper arm was assessed in four conditions. Specifically, the ratio of forearm movement to upper arm movement was recorded in the dominant control limbs, the non-dominant control limbs, the sound side extremities of the unilateral amputees and the amputee's affected extremities. The mean values in the first three conditions were comparable at approximately 70%, suggesting that upper limb activity was predominantly executed distal to the elbow. By contrast, this ratio was observed to be much lower for the affected group at 50%. This may suggest a greater need for proximal joint motions to effectively preposition the terminal device in space for task execution. Pilot efforts to understand such proximal joint compensations have been reported.[10]

Interlimb reliance among the upper arms of the non-dominant limbs of control subjects averaged 46%. When prostheses were not being used, our amputee subjects demonstrated an even greater reliance on the upper arm segment of the unaffected limb, suggesting decreased engagement of the affected extremity (upper arm reliance of the affected extremity = 25%). When the prostheses were worn, the engagement of the affected extremity increased (upper arm reliance of the affected extremity=30%). This shift suggests increased engagement of the affected extremity with the prostheses on, better approximating the valued observed in the non-dominant extremities of control subjects.

This initial analysis was confined to users of unilateral transradial prostheses. Additional insights may be gathered when this data is compared against that collected from users of bilateral prostheses or among prosthesis users with more proximal amputation levels.

CONCLUSION

Upper limb prostheses are characterized by several limitations. These include their weight, limited dexterity and lack of sensory restoration. Yet, for all of these limitations, our findings suggest that transradial prostheses are able to facilitate roughly 1/3rd of the unimanual activity duration recorded upon the non-dominant extremities of able bodied controls. Similarly, transradial prostheses facilitate the performance of approximately 80% duration of the bimanual activity recorded among able bodied controls. Limitations in prosthetic dexterity is such that the proximal joint segments of the affected extremity appear to experience greater compensatory motion to facilitate upper limb function. Amputees appear to engage their residual limbs more frequently while wearing their prostheses than when prostheses are not being worn.

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MUSCULOSKELETAL COMPLAINTS AND HUMAN ASSUMED CENTRAL SENSITISATION IN INDIVIDUALS WITH BRACHIAL PLEXUS INJURY AND UPPER LIMB ABSENCE

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ABSTRACT

Background: Musculoskeletal complaints (MSCs) are a highly prevalent problem in subjects with upper limb absence (ULA) and Brachial Plexus Injury (BPI). Single-handed individuals often experience pain in multiple locations. Human Assumed Central Sensitisation (HACS) can be present in single-handed individuals. This study aims to determine the presence of HACS in single-handed individuals with MSCs compared to individuals without MSCs as well as two-handed controls.

Methods: This study aims to include 20 individuals with ULA, 20 with BPI, and matched two-handed controls. All participants filled in the Central Sensitisation Inventory (CSI) questionnaire (range 0-100, cut off value for CS ≥ 40). Furthermore, they underwent a Quantitative Sensory Testing (QST) protocol. Seven sensory tests were executed to quantify the function of the sensory nervous system: dynamical mechanical allodynia (DMA, range 0-100), mechanical detection threshold (MDT, range 0.125-1024mN), mechanical pain threshold & sensitivity (MPT, range 8-1024mN & MPS, range 0-100), wind-up ratio (WUR, ratio), and pressure pain threshold & sensitivity (PPS in N & PPT, range 0-100).

Results: Data collection is ongoing. At present, data of seven individuals with BPI are collected. CSI mean is 24 (SD 11.0). QST: DMA [1.0], MDT [1.3-1024.0mN], MPT [19.2-1024mN], MPS [0.6-25], WUR [1.33-4.5], PPS [27.5-138.0N], and PPT [1-50].

Conclusion: Preliminary results indicate that CS may be present in a subgroup of single-handed individuals with MSCs. This study sheds light on the role of CS in single-handed individuals and could give more insight in the frequently occurring MSCs in such individuals.

INTRODUCTION

Many individuals with one functional hand, such as individuals with upper limb absence (ULA) and brachial plexus injury (BPI), complain about musculoskeletal complaints (MSCs). The prevalence of MSCs in individuals with ULA is nearly twice as high as compared to two-handed controls (35% vs. 65%) [1]. A higher prevalence is also shown in a sample with BPI (49%) compared to a non-impaired control group (35%) [2]. They experience pain more often, but also in more bodily locations [1,2].

Pain can be described by three mechanistic descriptors according to the International Association for the Study of Pain (IASP): a) nociceptive pain, pain that arises from actual or threatened tissue damage to non-neural tissue and is due to the activation of peripheral nociceptors; b) neuropathic pain, pain caused by a lesion or disease of the somatosensory nervous system; and c) nociplastic pain [3]. Nociplastic pain is pain that arises from altered nociception despite that there is no clear evidence of actual or threatened tissue damage causing the activation of peripheral nociceptors or evidence for disease or lesion of the somatosensory system causing the pain [3]. However, in individuals with pain, multiple simultaneous mechanisms can play a role, described as mixed pain [4]. Central sensitisation (CS) is related to all three pain descriptors. CS is defined by the IASP as “the increased responsiveness of nociceptive neurons in the central nervous system to their normal or sub-threshold afferent input” [3]. Although CS has some overlap with nociplastic pain, it differs in the fact that CS refers to a neural mechanism and nociplastic pain to a pain

mechanism [5]. CS has been proven in animal studies, but not yet in humans, therefore CS should be regarded as a concept and therefore we used the term Human Assumed CS (HACS) [6]. Currently, no golden standard for HACS is available, and investigating HACS can be done by identifying reference clinical symptoms and signs [6]. Instruments like the Central Sensitisation Inventory (CSI) and the Quantitative Sensory Testing (QST) protocol are often used to assess the indicators of HACS [6]. An indicator for HACS is allodynia, a hypersensitivity to normally subthreshold innocuous stimuli [3,7]. Another indicator is hyperalgesia, an increased responsiveness to noxious stimuli [3,7]. Furthermore, temporal summation is another indicator, which is described as an increased response to repetitive noxious stimuli over time [7].

HACS has been researched in persons with other diagnoses, such as fibromyalgia and chronic low back pain [8], but not in single-handed individuals, despite the fact that it is known that many single-handed individuals suffer from musculoskeletal pain [1,2]. Knowledge about the presence of HACS could give additional insight into the development and persistence of MSCs, and could help clinicians in the treatment and prevention of those complaints [9]. This study aims to examine the presence of HACS in individuals with ULA and BPI with and without MSCs and healthy two-handed individuals, by performing the QST protocol [10] and evaluating results of the CSI [11]. We hypothesized that individuals with MSCs showed some indicators for HACS compared to individuals without MSCs. Within participants, we expected to see differences between a painful area and a non-painful area, showing more indicators in the painful area.

METHODS

The Medical Ethics Review Board of the University Medical Center Groningen (METc UMCG) approved the study (METc 2019/425). All participants signed an informed consent before the start of the study.

Three samples were included: individuals with ULA, either due to congenital transversal reduction deficiency or an acquired amputation, individuals with BPI, and matched controls. Participants were recruited via a list of adult eligible patients composed by clinicians of the UMCG, Center for Rehabilitation. Individuals with ULA were also recruited via the Dutch patient organization for persons with ULA. Controls were recruited via the network of the researchers through advertisements.

At the start of the measurements, participants filled in a survey with demographic and clinical characteristics (i.e. age, gender, handedness, cause of injury, affected side, level of injury, aid use). All participants also filled in the CSI questionnaire [11]. This is a self-reported questionnaire consisting of two sections (A and B) to assess the presence of HACS-related symptoms. In section A, 25 questions about how often a symptom occurred were rated on a 5-point Likert scale (range 0-100). A score higher than 40 could indicate HACS. Section B asked participants about previously diagnosed CS syndromes (CSS) and/or conditions related to HACS, such as restless legs syndrome or fibromyalgia.

Furthermore, all participants underwent the QST protocol. This protocol is composed of several sensory tests to quantify the function of the sensory nervous system [10]. Five sensory tests were executed resulting in seven outcomes. These were all performed on four body locations: thigh on the non-dominant/affected side as a control site, thigh on the dominant/unaffected side as a reference site, the most painful location of the upper extremity, and the location contralateral to this most painful location. The following tests were executed: 1) Dynamic Mechanical Allodynia (DMA): pain rating of a brush stroke (range 0-100); 2) Mechanical Detection Threshold (MDT): stimulus intensity of a Von Frey filament when touch was no longer perceived (range 0.125-1024mN); 3) Mechanical Pain Threshold (MPT): stimulus intensity of a pinprick when it becomes sharp (range 8-1024mN); 4) Mechanical Pain Sensitivity (MPS): the pain rating of the MPT (range 0-100), 5) Wind-Up Ratio (WUR): the ratio between pain rating of repeated stimuli and a single stimulus; 6) Pressure Pain Threshold (PPT): intensity in Newtons of pressure algometer; and 7) Pressure Pain Sensitivity (PPS): pain rating of the PPT (range 0-100).

Data records from the different tests and questionnaires were collected and imported into the database RedCap. The records were then exported that SPSS, where the analyses were performed. Before analysis, the ratio of the DMA and the WUR was calculated. A mean of the five repetitions of the MDT, MPT, and MPS was calculated, given that there were at least three valuable data points. Descriptive statistics of the sample characteristics and the main test results were calculated as median and range. Because data collection is ongoing, no statistical tests were performed.

RESULTS

Participants

Seven participants (six males) with BPI were included so far, since due to the COVID-19 regulations measurements were delayed. The median age of the participants was 65.3 years (range 36.3–74 years). The side of the BPI was right in four cases. The participants were diagnosed with BPI between 7 and 45 years ago (median 30 years). All seven had an accident that caused the BPI. Four individuals experienced MSCs in the previous year, while three did not. Of these four participants, three experienced MSCs during the last four weeks. The median duration of MSCs was 13 years (range 1.5–30 years). The location of the pain varied, in three of the participants with MSCs the most painful area was the affected shoulder/neck region. One participant experienced pain in the unaffected hand and fingers.

CSI outcomes

The mean (SD) of the CSI was 24 (11.00). Previously diagnosed CSS were jaw complaints (n=1), migraine (n=1) and neck injuries (n=2).

QST outcomes

The results for the QST are presented in Table 1. The DMA, an assessment for allodynia, was missing in almost all participants, indicating no pain from a single brush stroke. In the MDT, on the most painful site the intensities of the Von Frey hairs were higher compared to the contralateral site, indicating that the stimuli with lower intensities (i.e. thinner Von Frey hairs) were not felt and thus a decreased responsiveness. This was also seen in the MPT; a higher value meant that the pinprick was considered painful with a higher intensity (i.e. thicker pinprick), so less sensitive to the stimulus. Additionally, the stimuli were rated as less painful with the MPS. The WUR remained relatively similar between the test sites. All participants experienced more pain after the stimulus series in comparison with the single stimulus.

Table 1: QST test results for each test site.

QST Test (n=7)	Reference test site	Most painful test site	Contralateral test site (to most painful test test)[b]
1) DMA[a]	1.0 [1.0] (n=2)	1.0 [1.0] (n=1)	1.0 [1.0] (n=1)
2) MDT in mN	6 [3.2–11.2] (n=7)	9.6 [1.3–1024.0] (n=7)	3.1 [1.0–16.0] (n=6)
3) MPT in mN	115.2 [19.2–115.2] (n=7)	108.8 [16.0–1024.0] (n=7)	64.8 [19.2–454.2] (n=6)
4) MPS	3.4 [0.8–25.0] (n=7)	1.5 [0.6–7.5] (n=6)	3.5 [0.8–20.0] (n=6)
5) WUR[a]	2.5 [1.33–4.0] (n=7)	2.8 [2.0–4.0] (n=5)	2.67 [1.4–4.5] (n=5)
6) PPT in N	81 [45.0–138.0] (n=7)	46.5 [33.0–73.0] (n=6)	61.5 [27.5–93.0] (n=6)
7) PPS	4 [1.0–40.0] (n=7)	9.5 [2.0–50.0] (n=6)	16 [2.0–45.0] (n=6)

Legend: All results were reported as median [range] (n=). [a] The DMA/WUR cannot be calculated if the pain rating of the single stimulus was zero, those were registered as missing value. [b] One participant was not tested on the CTS. Abbreviations: QST, Quantitative Sensory Testing; DMA, dynamic mechanical allodynia; MDT, mechanical detection threshold; MPT, mechanical pain threshold; MPS, mechanical pain sensitivity; WUR, wind-up ratio; PPT, pressure pain threshold; PPS, pressure pain sensitivity;

DISCUSSION

Several individuals with ULA or BPI experience MSCs [1,2], which may indicate the presence of HACS in these people. Until now, knowledge on HACS in these populations remained underreported and this research aims to bridge that gap by using the CSI and QST protocol to assess indicators for HACS. In this study, seven individuals with BPI have participated. None of the participants reported a score above>39 points on CSI, which represents an often used cut-off point for the presence of HACS [11]. However, while often used, the validity of this cut-off is debated, and recently a clinically relevant cut-off of 30 points was suggested (males 25, females 33; [12]). Based on the newest cut-off, the presence of HACS is feasible in a subgroup in this study.

Regarding the QST results, differences were seen between the test sites, this could be explained by the fact that different body locations have different sensitivity to stimuli [10]. We did not find more indicators in the most painful site in comparison with the contralateral site. Almost all participants showed no values on the DMA, suggesting that allodynia is not present in these participants. Results on hyperalgesia, assessed with the MDT, MPT, and MPS, showed that the most painful site was less responsive and less painful than the contralateral side. Temporal summation is considered positive when the pain intensity increases with repeated stimuli, so this might be present [6]. However, there were no differences seen between the test areas. These surprising results might be explained because these QST tests consist of cutaneous stimuli and might not be very adequate for musculoskeletal conditions [13]. Another explanation could be that HACS was not present, but that the pain could be described as nociceptive, neuropathic, and/or nociplastic pain. These pain descriptors have to be examined with other tests and physical examinations. Furthermore, due to the lack of cut-off values for the QST, it is difficult to interpret the data [6].

This is to our knowledge the first study to examine the presence of HACS in single-handed individuals. The CSI and the QST are quite easily adapted into clinical practice and could give additional insight into individuals with ULA or BPI experiencing MSCs. However, individuals with ULA and BPI may also suffer from phantom pain and neuropathic pain. As we did not examine these pain conditions, this may have influenced the results. Currently, there is no golden standard for HACS and due to the lack of cut-off values for the QST, the presence of HACS is difficult to determine. Other QST measures, such as conditioned pain modulation (CPM) and thermal stimuli were not included in this study due to practical reasons. Adding these tests could give a broader insight into HACS in this population. As this is an ongoing study, only preliminary results were reported. More participants (also with ULA) will be included and we expect to be able to present more results at the congress. Hopefully, this will show explanations for the findings. Analysing the group with ULA and the controls could also show similarities and differences between the three samples.

In conclusion, this preliminary data showed possible HACS in a subgroup of BPI participants, depending on the applied cut-off score of the CSI questionnaire. Variability between subjects was considerable. This suggests that an individual approach could be more efficient. With more results, this study could shed light on the role of the pain mechanisms and CS in single-handed individuals. This could give more insight into MSCs in individuals with ULA and BPI, and could aid in the treatment and prevention of these complaints.

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THE EFFECT OF SENSORY FEEDBACK ON THE TEMPORAL ALLOCATION OF GAZE USING A SENSORIZED MYOELECTRIC PROSTHESIS

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ABSTRACT

Myoelectric prosthesis users have altered spatial and temporal allocations of gaze, likely influenced by both control proficiency and sensory feedback. Providing task-relevant and movement feedback can improve spatial visual allocation, but temporal patterns of gaze shift have not been reported for prosthesis users with sensory feedback systems. We present data from two prosthesis users with integrated touch and kinesthetic feedback in a myoelectric prosthesis performing a functional cup movement task while tracking eye and hand movements. Despite different skill levels and task performance, both participants showed improved ability to disengage eye fixation from the object and transition to the next movement plan when provided kinesthesia and touch feedback together. Temporal allocation of gaze, specifically, the ability for the eye to disengage after interacting with objects, seemed impervious to skill level and maybe a valuable measure of the ability to trust the sensory feedback, disengage vision, and motor plan forward in a sensorized prosthesis. Eye latency measures could be a valuable marker of control skill and feedback efficacy in prosthesis users.

INTRODUCTION

Myoelectric prosthesis users have disruptions to normal hand-eye coordination when interacting with objects. Generally, prosthesis users will fixate their gaze on the prosthetic hand and cannot look forward to the next target location of action [1], [2]. This behaviour is quite different from normal eye-hand coordination, where the eyes lead the hand and fixate on task-relevant areas to efficiently motor plan the next movement [3], [4] and may contribute to less use of the prosthesis for functional activities.

We have shown in a prior study that providing relevant touch and kinesthetic feedback in a sensory integrated myoelectric prosthesis can reduce the spatial allocation of vision, with reduced fixation to the hand and increased fixation to the next target in an object interaction task [5]. However, sensation is only one aspect of prosthetic performance that may influence visual behaviour; accurate control may also provide the confidence to look away from the hand once the object is firmly grasped and look ahead to the next target [6]. The transition of the gaze fixation may therefore be affected by both movement control and the type of sensory feedback provided.

Using a simulated transradial myoelectric prosthesis with non-disabled participants [7], we explored eye latency measures [3] for further insight into eye fixation and hand movements. The ability of the eye to precede the grasp of an object significantly correlated with hand trajectory variability and grasp time. Similarly, the ability to disengage the eye after pickup of the object to transition the gaze to the next dropoff location significantly correlated to hand trajectory variability, distance travelled, and transport time. Lastly, the ability of the eye to disengage after dropping off the object was related to release time. Similar to the findings of [8], control issues with opening and closing the prosthetic hand and controlling movement through space influenced the ability to temporally and spatially allocate visual fixation. Therefore, the temporal allocation of vision may be of value to explore in prosthesis users with sensory feedback, as presumably providing channels of real-time feedback should release vision to be more effectively used for motor planning.

This paper explores the changes to eye gaze transitions when picking up and dropping off objects in two participants with sensory integrated prostheses providing matched touch feedback (to the digits) and kinesthesia (sensation of hand grasp movement). Whereas touch sensation provides task-specific feedback on object contact during grasp, kinesthesia should improve the ability to reallocate vision for motor planning of the next movement. We also hypothesized that measures of hand function, used as a proxy of control skill [9], may affect the eye gaze adaptations seen with sensory feedback. If eye gaze metrics are responsive to changes with sensory feedback, this could be a valuable method of assessing both sensory feedback and control strategies from the perspective of movement planning.

METHODS

As described in [5], two participants that had undergone targeted motor and sensory reinnervation at shoulder disarticulation level (participant SD) and transhumeral level (participant TH) were fit with a bidirectional myoelectric prosthesis with touch feedback related to the prosthetic digits, and kinesthetic sensation of hand close. They performed trials in 3 conditions: *motor* (no feedback), *touch* (touch tactors activated), and *kinesthesia* (both touch and kinesthetic tactors activated). SD had control of 3 prosthetic movements (hand open/close, elbow flexion/extension, pronation/supination). TH only had control of hand open/close, due to technical difficulties with the prosthetic elbow. Both participants gave written informed consent for the study, which was approved by the ethics review board.

Participants performed the Cup Transfer Task of the Gaze and Movement Assessment protocol [10] which records eye gaze and hand movements as they pick up and transfer 2 compliant cups full of beads over a barrier on a table in front of them and then back to the starting location, for a total of 4 cup movements. SD performed 13 trials for motor and touch conditions and 9 trials for the kinesthesia condition. TH performed 20 trials for motor and 19 trials for touch and kinesthesia conditions. Data processing steps to attain metrics of interest for this analysis (eye latencies and hand function metrics) are described in [11].

As detailed in [3], eye arrival latency (EAL) was defined as the time the eye first fixates to the target location relative to the end of grasp for "pickup", and to the end of transport for "dropoff" of the object. Eye leaving latency (ELL) was defined as the time the eye first leaves the pickup location relative to the start of transport; and leaves the dropoff location relative to the end of transport. A shorter ELL is a more positive number, whereas a longer ELL is more negative (see: [3]). Target locking strategy (TLS) [8] was calculated as the ratio of percent (%) fixation to current minus % fixation to hand for the phases of reach and transport initially for each movement based on the average % fixation values, and then across movements as a summary metric of spatial gaze fixation. For EAL and ELL metrics, all trial values across the 4 movements were averaged per condition. Values are reported as mean (standard error of the mean).

RESULTS

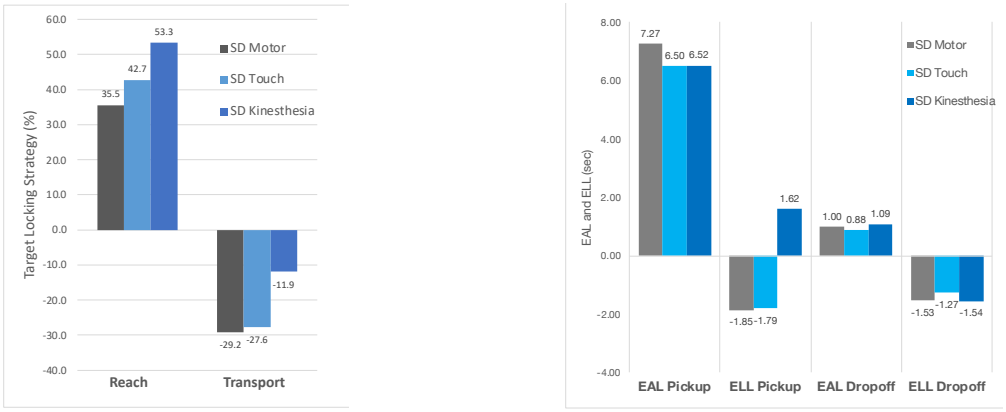
The two participants were different in skill level and control (Table 1). SD had longer task durations and spent more relative time in prolonged grasp phases (grasp SD 31.1(2.0)%; TH 23.4(2.2)%), compared to TH who had more prolonged transport phases (transport SD 24.0(0.6)%; TH 35.5(2.2)%). SD also showed longer hand distance travelled and greater hand trajectory variability in both reach and transport compared to TH, indicating a less efficient movement path. The hand movement metrics were substantially unchanged across conditions, except for slightly lower hand trajectory variability in reach for SD in the kinesthesia condition. SD showed an improved TLS for the kinesthesia condition in both reach and transport (Figure 1a), reflecting less fixation to hand and greater fixation to the next target. For reach, the value improved closer to normative, and for transport, the TLS became less negative (indicating greater target fixations, but still not greater than fixations to hand).

Regarding eye latencies of SD (Figure 1b), when transitioning from picking up the cup to transporting, in the motor and touch conditions the eyes lingered on the cup well into the transport phase (ELL pickup motor -1.85(0.13) sec; touch -1.79(0.15) sec). However, for the kinesthesia condition, the ELL became positive at +1.62(0.19) sec, indicating the eyes disengaged from the cup and shifted to the next target location while still in grasp phase. The other latency measures were not notably different between conditions for SD; in general, the EAL pickup values were very high (6.50-7.27 sec), reflecting the long reach and grasp times.

Table 1: Hand movement values across conditions

Metric average values across all movements	**Normative Reference**	**Participant SD**			**Participant TH**		
		Motor	***Touch***	***Kinesthesia***	***Motor***	***Touch***	***Kinesthesia***
Total task duration (sec)*	8.9 (0.1)	58.6 (3.4)	55.3 (1.9)	51.9 (1.5)	18.7 (0.2)	20.3 (0.3)	18 (0.2)
Hand distance travelled (mm)	4864 (47)	6497 (237)	6896 (153)	6998 (176)	5574 (24)	5497 (25)	5523 (18)
Hand trajectory variability Reach; Transport (mm)	18 (4); 19 (4)	71 (8.0); 50 (3.3)	75(9.2); 38(2.2)	58 (6.3); 52(5.7)	32(2.2); 25(0.7)	52(6.9); 30(2.1)	32(3.2); 21 (1.1)

*Calculated as sum of all phase durations



a b

Figure 1: Participant SD a) Target Locking Strategy (% fixation to current - % fixation to hand) averaged across movements for Reach and Transport phases. Normative value 79% for Reach and 67% Transport. b) EAL and ELL values at pickup and dropoff averaged for all trials per condition.

For TH, the movement profile was quite different. He moved faster, with less variability, as expected given the intact shoulder and only having to control one degree of freedom. He also had positive TLS values for all conditions in reach and transport, reflecting that he did not have high hand fixations (reported in: [5]), and TLS did not improve with kinesthesia. However, ELL at pickup had similar improvements as with SD; in motor and touch conditions ELL pickup was negative (ELL pickup motor -0.26(0.04) sec; touch -0.29(0.05) sec) and improved to positive for the kinesthesia condition at +0.22(0.09) sec (Figure 2), indicating he could disengage his eye fixation away from the object just before the end of grasp. The other latency measures also showed a trend to be closer to zero for the kinesthesia condition, specifically ELL at dropoff also showing earlier disengagement from the cup during release.

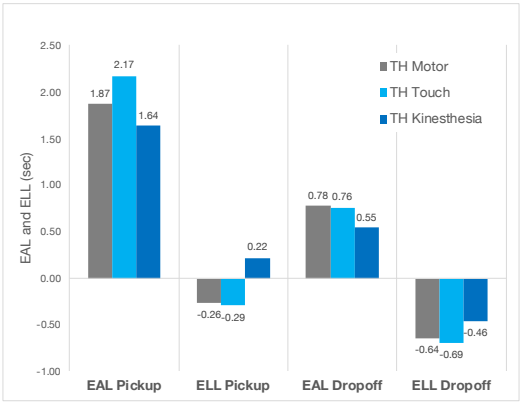


Figure 2: Participant TH EAL and ELL values at pickup and dropoff averaged for all trials per condition.

DISCUSSION

Touch and kinesthetic sensory feedback within a prosthesis system has been shown to improve spatial allocation of gaze fixation behaviour [5]. Spatial and temporal gaze transitions have also been shown to reflect control stability and performance and influence the interpretation of visual allocation [8]. Specifically, the impact of sensory feedback on eye behaviour might be determinant on control proficiency. In this analysis, both kinematic hand function measures and eye behaviours reflected the individual differences in skill and control performance. SD, at a shoulder disarticulation level using 3 degrees of freedom, had lower baseline motor function as reflected in slower movements, longer hand trajectory and higher variability. Providing positional awareness (kinesthesia) related to grasp function in addition to touch feedback had an impressive impact on spatial visual allocation, with improved target locking strategy. At pickup of the object, with kinesthesia and touch, SD was also remarkably able to temporally reallocate the gaze fixation forward when *still in the grasp phase*, thereby impacting both spatial and temporal gaze allocation behaviour.

TH, with an intact shoulder and controlling hand open/close, had a more confident reach and overall performance at baseline than SD. The addition of kinesthetic grasp and touch feedback did not change movement function or target locking, although he did show reduced fixations to hand [5]. TH's spatial allocation of vision was likely already positively influenced by his proficient motor control. However, the addition of kinesthetic feedback to touch improved the ability to transition the gaze more normally at the end of grasp and when releasing the object. The improvement in eye latency measures suggests kinesthesia increased confidence in disengaging vision from the object for motor planning of the following action.

Limitations of this study include only 2 participants representing different amputation levels and skill proficiency. With higher participant numbers, we could more thoroughly investigate the consistency of these trends and the statistical generalizability. There was no "only kinesthesia" condition due to the intense testing schedule and need to limit conditions, so the results do not directly tease out the differences between touch and kinesthesia, other than to note that touch alone did not provide the same improvements. We believe this underscores the importance of proprioception and kinaesthesia in releasing vision for motor planning in prosthesis users.

CONCLUSION

Temporal allocation of gaze, specifically, the ability for the eye to disengage after interacting with objects, seemed impervious to skill level and maybe a valuable measure of the ability to trust the sensory feedback, disengage vision, and motor plan forward in a sensorized prosthesis. Eye latency measures could be a valuable marker of both control skill and feedback efficacy in prosthesis users and should be further investigated.

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THE EFFECT OF SERIOUS GAME TRAINING ON UPPER LIMB PROSTHESIS CONTROL IN THE HOME ENVIRONMENT

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ABSTRACT

Background: The focus of the field of upper limb prosthesis has primarily been on lab-based studies, while user-complaints do hardly change. Focus should shift to home use training and assessment. The current paper establishes whether training with serious games in the home setting affect upper limb prosthesis activation signals in Pattern Recognition controlled prostheses.

Method: Ten upper limb prosthesis users were measured for a period of two weeks and were instructed to play serious games for at least 45 minutes per week. The activation signals before and after a serious game was played during daily life were measured. The activation signals were classified in involuntary and voluntary activations.

Results**:** More involuntary activation signals than voluntary activation signals were recorded. Second, no effects of serious game training on activation signals in daily life were found.

Conclusion: Even though no effect of serious game training was found, our findings show that recording and analyzing data derived from prosthesis users' daily life is feasible. However, much has still to be learned about the storage, applicability and meaning of this data. Our research underlines the importance of transitioning from lab-based research to research in daily life.

INTRODUCTION

Upper limb prostheses have undergone substantial technological improvements in the last two decades. For instance, the number of degrees of freedom of the prosthetic hand has increased by creating multi-grip hands and control has advanced to Pattern Recognition (PR) control, where multiple electrodes measure patterns of muscle activation that are matched to a grip pattern, cf. [1]. However, user complaints about the control of the prosthesis in daily life situations have hardly changed in the last two decades, despite these technical advancements [2]–[4]. This might be partly due to the fact that technological improvements have mainly been assessed in lab-based studies with a limited number of users [5]. In lab-based studies, mostly tasks were used that only partly cover the tasks that users perform in activities of daily living. To improve the quality of lab-based training, serious games (games that are designed to develop a certain skill while playing) have been used as a training tool to enhance prosthesis control [6]–[8]. However, effectiveness of serious game training on prosthesis use has not been evaluated in home use. Hence, the current study aims to determine the effect of training serious games in the home setting on upper limb prosthesis activation signals in PR controlled prostheses.

METHOD

The data collection of the Coapt Complete Control System for this study was conducted by Coapt LLC. Each participant provided informed consent in accordance with the WCG-IRB.

Design

The activation signals of the participants' upper-limb prosthesis were measured in their home setting when the device was turned on during a period of 2 weeks. Participants were instructed to use their prosthesis as they would in their normal day-to-day life with the only additional requirement to train with serious games provided by the Coapt system for at least 45 minutes per week. Participants were free to choose when they would train with the games, however they were urged to train multiple days.

Serious games

The Coapt system provided users with two serious games, Simon Says and In The Zone. Simon Says is a Fitts'-Laws style serious game in which participants control a virtual arm in an attempt to match a target posture (Figure 1). The virtual arm is controlled by the same activation signals as the real prosthesis.

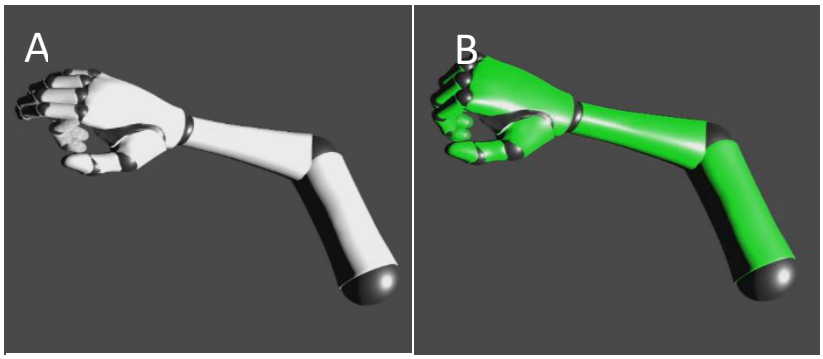

Figure 1. A) The user has to match the position of the 'shadow arm' (closed hand position) with the representation of their own prosthesis (solid arm, hand open position). B) When the user correctly matches their prosthesis position to the target position, the prosthesis turns green.

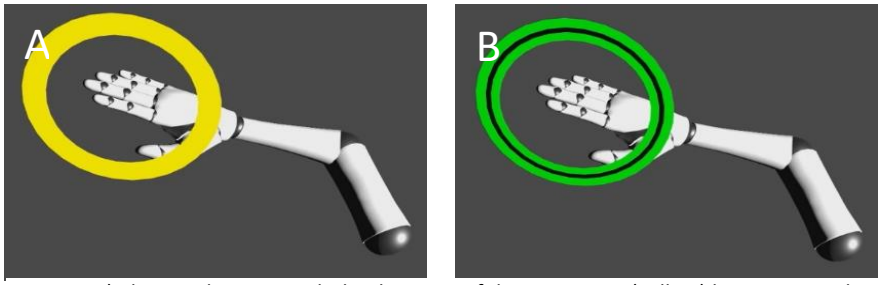

Figure 2. A) The user has to match the diameter of the target ring (yellow) by activating the joint with the correct amount of activation. B) When the user correctly matches the amount of activation (the black ring) with the target ring, the ring will turn green.

In The Zone is a serious game in which participants had to match a target intensity of muscle contraction levels. A virtual arm with a target ring around a specific joint and a ring which matched their actual contraction level (see Figure 2) was presented. By increasing the amount of muscle activation around that joint, participants were able to match the sizes of both rings.

Data storage and outcome measures

Data storage within the Coapt system was done in three steps. First, the system computed the number of consecutive time frames of 50 ms in which the user produced the same activation signal. Second, the system stored the data of each individual activation signal in one of two groups based on the number of consecutive time frames: involuntary activations (1-6 frames) and voluntary activations (<7 frames). Third, the system counted the frequency of each group of activation signals per individual motion of the system. As outcome measure we divided the number of activation signals per group by the total activations for all participants separate for each motion of the system. It was hypothesized that serious games would improve a user's prosthesis control, arguably resulting in more voluntary activation. When a user had more voluntary activation than involuntary activation after the serious games were played than before, it could be assumed that playing serious games improved that user's prosthesis control.

Statistical analysis

Due to the limited number of participants, a non-parametric Wilcoxon Signed Rank test was used to determine if there were differences in the ratio of the involuntary and voluntary activations of the Hand Open, Hand Close, Wrist Supination and Wrist Pronation modes before and after serious games were played.

RESULTS

Participant characteristics are presented in Table 1. The data show that there are more involuntary activation signals than voluntary activation signals for each prosthesis activation mode, see Figure 3. No significant differences were found between the ratio of involuntary and voluntary activations before and after the serious games were played (Figure 3) for both the Hand Open, Hand Close, Wrist Supination and Wrist Pronation modes.

Table 1. Characteristics of participants with transradial (TR) or transumeral (TH) defects

Participants	Sex	Age	Number of months of prosthesis use	Wear time (hours/2 weeks)	Number of games played/2 weeks (1 game = 5 minutes)
TR 1	Female	57	33	6.8	18 (90 min)
TR 2	Male	38	25	25.9	19 (95 min)
TR 3	Female	42	18	64.9	14 (70 min)
TR 4	Male	28	8	125.0	19 (95 min)
TR 5	Female	53	74	243.7	18 (90 min)
TR 6	Female	31	54	4.1	53 (265 min)
TR 7	Female	36	4	13.2	14 (70 min)
TH 1	Male	57	16	66.4	28 (140 min)
TH 2	Male	47	72	9.6	21 (105 min)
TH 3	Male	43	84	45.0	20 (100 min)

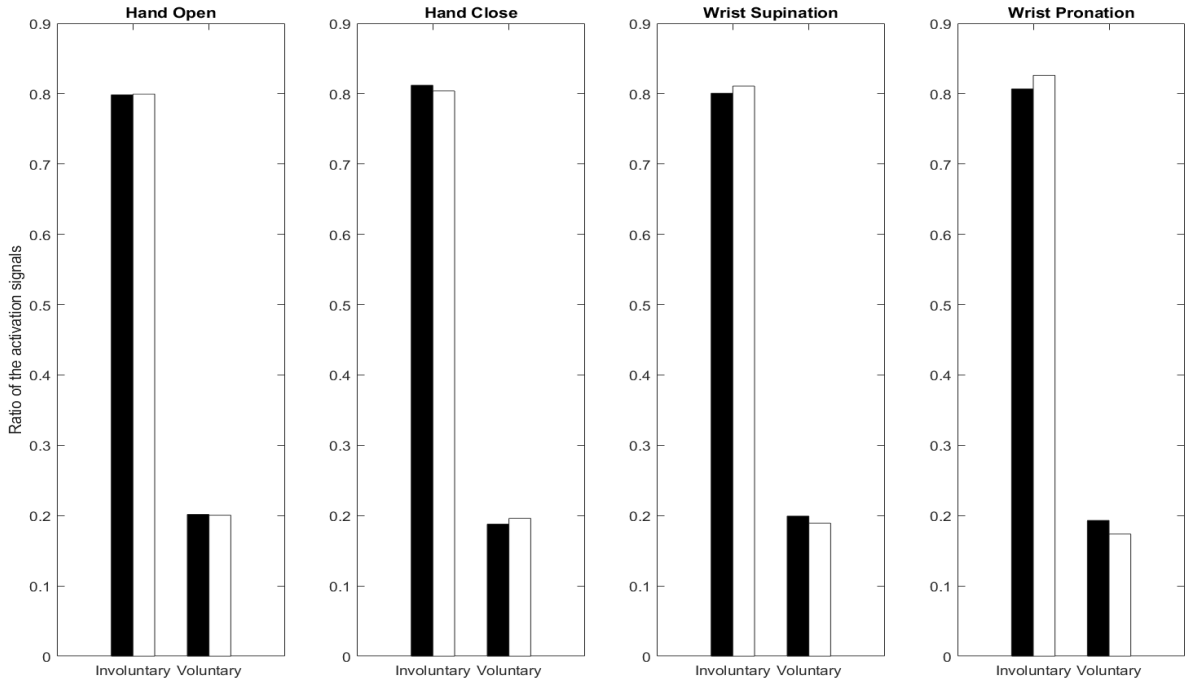

Figure 1. The average distribution of the activation signals for the Hand Open motion (first), Hand Close (second), Wrist Supination (third) and Wrist Pronation (fourth) are shown. The ratio of the activation signals (y-axis) was calculated (activation signals per group (x-axis) divided by the total) for all participants before a serious game was played (black bars) and after a serious game was played (white bars).

DISCUSSION AND CONCLUSION

Our main analysis of the effectiveness of serious games on activation signals in PR controlled upper limb prostheses showed no difference in the ratio of voluntary and involuntary activation signals when comparing before and after training. This null-finding may have different reasons that deserve further study. For instance, it might be that a

training period of two weeks is too short to find an effect of the training with serious games (see for instance Tabor et al 2018), or that the training time of minimal 45 minutes was not long enough. Moreover, it might be that the users included in this study were already quite experienced in the use of PR controlled prosthesis.

Another issue that deserves further study is the choice of the games. In this study we used the games that were available in the Coapt system. However, other studies have shown effectiveness of serious games that were task-specific [7], [9]. It might be that the serious games currently used were not specific enough to improve use of the prosthesis in the home setting due to training and focused too much on the control of the myo-signal.

An unexpected result of the current study is that we found more involuntary activations that voluntary activations. The origin of this result is not clear. It might be that the short activation commands do not result in activation of the prosthesis and therefore these signals are not controlled by the users, which might explain their high occurrence. This finding underlines the importance of longer lasting studies in the home setting of the prosthesis users instead of short lab-based research.

To conclude, in a first study to examine the effectiveness of serious games in home usage of PR controlled upper limb prostheses we did not find an effect of the serious games. We argued that the step to measuring in the home situation is an important one to further improve the field. Our current findings show that a type of training (i.e., serious gaming) that had shown to be effective in the lab, was not effective in the home situation. Therefore, our findings, although a null finding, show the importance to shifting focus to studies in home settings to improve PR controlled upper limb control.

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WELL-BEING AMONG INDIVIDUALS WITH UPPER LIMB AMPUTATION IS STRONGLY CORRELATED WITH BIMANUAL UPPER LIMB FUNCTION, ACTIVITY AND PARTICIPATION LEVELS, PROSTHETIC SATISFACTION AND LOWER RATES OF PAIN INTERFERENCE

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ABSTRACT

A retrospective analysis of 250 individuals with upper limb amputation or limb deficiency was performed to better understand the relationships being well-being and upper extremity function, activity and participation, prosthesis satisfaction and wear times and pain interference. Well-being, as a cumulative construct of quality of life and satisfaction was found to strongly correlate with self-reported physical function in bimanual tasks, self-reported activity and participation levels, self-reported satisfaction with prostheses and reduced pain interference. By contrast, neither age, gender, time since amputation nor reported prosthesis wear times were found to correlate with well-being in this population. While causality between these closely related and overlapping constructs may prove difficult to establish, their close relationships suggest that well-being in this population may be pursued through the thoughtful provision of an appropriate prosthesis and training to enable the performance of bimanual tasks tailored to the unique activity and participation needs of the individual.

INTRODUCTION

Upper limb amputation and congenital upper limb deficiencies are associated with a number of disabling characteristics. In addition to the obvious functional deficits attendant with the absence of the affected extremity, these individuals contend with a spectrum of pain experiences and social stigma, and in the case of acquired amputation, a dramatic alteration in self-image and vocation.

Well-Being has been described as a blended construct combining the elements of quality of life and satisfaction.[1] The restoration of well-being among individual with acquired upper limb amputation can be reasonably considered a primary objective of rehabilitation. Importantly, it may be influenced by a number of interconnected variables including an individual's functional upper limb capacity, their activity and participation amongst family, friends and society, and their daily pain levels and experiences.

Individuals who have undergone upper limb amputation have reported reduced scores with respect to the physical elements of their quality of life relative to both population norms[2] and individuals with lower limb amputation.[3] Similar findings have been observed with respect to the related construct of satisfaction with life even when controlling for a range of potentially confounding variables such as age, gender, marital status and educational level.[4]

With respect to limitations imposed upon activity, Gallagher et al identified frequently encountered broad activity limitations for this population. These included getting dressed (52.9%), taking care of household responsibilities (52.9%), and day-to-day work/school activities (40.0%).[5] Additionally, in consideration of restrictions to participation, the most frequently identified restrictions have been suggested in employment or job seeking (91.7%), family life (41.2%), leisure/cultural activities (41.2%), sports or physical recreation (38.5%), shopping (35.3%), living with dignity (35.3%) and socializing (23.5%).[5]

With respect to upper limb function, following upper limb amputation MacFarland et al found greater difficulty associated with bimanual activities such as washing and drying dishes, and food preparation and lesser difficulty

associated with tasks that lend themselves to one-handed performance such as driving, brushing ones teeth, and opening and closing doors.[6]

Beyond the described constraints to function, activity and participation, this population frequently contends with a number of often overlapping pain experiences. These include phantom limb pain, residual limb pain and overuse pains experienced in the sound side extremity or torso. One or more of these pain experiences has been reported by as much as 90% of those with upper limb deficiency, with most reporting multiple, overlapping pain experiences.[2,7] While phantom limb pain and residual limb pain appear to be more prevalent, overuse pains have been reported as both more severe and disruptive.[7]

The provision of an appropriate upper limb prosthesis may influence well-being in this population by restoring a measure of upper limb function and enabling improved activity and participation levels. While individuals with unilateral upper limb deficiency tend to rely heavily on their sound side limb for upper limb function, bimanual function is indicated for many daily tasks and may be enhanced with an appropriate prosthesis.[8]

Satisfaction with a prosthesis appears to be very user dependent, taking into consideration such elements as appearance, weight and reliability. Available evidence suggests that different upper limb prosthesis types (eg, body-powered, myoelectric and cosmetic) appear to address different areas of satisfaction with no consistently preferred device type.[8-9] Rather, prosthesis satisfaction appears most influenced by amputation level, with great satisfaction associated with more distal amputation levels.[9] Within the constraints imposed by amputation level, optimizing prosthetic satisfaction may be a product of matching device characteristics with user priorities.

The purpose of this retrospective analysis was to better understand the relationships observed between well-being and upper limb function during bimanual tasks, activity and participation levels, satisfaction with a prosthesis, and pain interference amongst a convenience sample of individuals with unilateral limb deficiency distal to the shoulder and proximal to the wrist who utilize and upper limb prosthesis

METHODS

Using the Prosthesis Evaluation Questionnaire-Well Being,[1] patients rated their satisfaction with life (SAT) and quality of life (QOL) over the prior 4 weeks. Scores range from 1 to 10, with higher scores indicating higher levels of well-being.

To evaluate upper limb physical function, a previously assessed custom 9-item short form derived from the PROMIS®-UE v2.0 item bank was administered (PROMIS-9 UE).[10] Patients were asked to report the level of difficulty associated with each item using a discrete, ordinal scale ranging from 1 (unable to do) to 5 (without any difficulty). Items included such tasks as opening and closing a zipper, cutting food using utensils and lifting or passing heavy items. All items within the PROMIS-9 UE are bimanual activities. Bimanual activities were intentionally chosen to attempt to isolate those activities where prostheses would be more likely to influence upper limb function. Raw scores were converted to t-scores using the healthmeasures.net scoring service such that a score of 50 corresponds to the average scores of the United States population.

Additional patient reported outcomes included the 4-item short form of the PROMIS-Ability to Participate in Social Roles and Activities (APSRA). This construct aligns well with the considerations of activity limitation and participation restriction proposed by the International Classification of Function, Disability and Health (ICF). Patients were additionally asked to report prosthesis satisfaction using the Trinity Amputation and Prosthesis Experience Scales- Revised (TAPES-R), a single item of pain interference (PROMIS-Pain Interference), number of months since amputation, hours of daily wear time per, age, and gender.

To analyse the data, a multivariate linear regression model was run (forward enter method) with patient well-being as the predicted variable. Secondarily, in addition to the multivariate model, each variable was separately analysed through a univariate linear regression to assess individual effects. This retrospective database review was approved by Western Investigational Review Board (Protocol #20170059).

RESULTS

There were 250 individuals with upper limb amputation that had an outcome of record for analysis. The majority had a transradial or wrist disarticulation amputation (73.2%), and reported amputation due to trauma (38.8%, or 66.4% of those with reported etiology). Slightly less than half reported having an electronic arm (46.0%).

The overall regression model was statistically significant ($R = 0.675$, $F_{(8,241)} = 25.162$, $p < 0.001$; Table 1).

Table 1: Correlates to Well-Being among Upper Limb Amputees

R=0.675	B	Standard Error	β	t	*P*
(Constant)	2.280	0.980		2.33	0.02*
Activity/Participation (APSRA)	0.077	0.019	0.335	4.03	<0.01*
Prosthesis Satisfaction (TAPES)	0.200	0.051	0.240	3.90	<0.01*
Pain Interference (PROMIS)	-0.328	0.114	-0.190	-2.88	<0.01*
Physical Function (PROMIS-9 UE)	0.028	0.014	0.152	1.94	0.05*
Daily wear time (hours)	-0.023	0.024	-0.059	-0.97	0.34
Time since amputation (months)	0.000	0.001	-0.009	-0.15	0.88
Gender (male)	-0.040	0.301	-0.008	-0.13	0.90
Age (years)	-0.001	0.008	-0.004	-0.08	0.94

DISCUSSION

This retrospective analysis provides some insight into those factors that appear to correlate most strongly with improved satisfaction and quality of life among individuals with major upper limb amputation or deficiency. While causality cannot be determined, the relationships between these various constructs provide a foundation for how the rehabilitation of this population may be best approached.

We assessed physical function through a custom short form of the PROMIS measure of physical function that has been validated within upper limb prosthesis users (PROMIS-9 UE).[10] Because of the tendency for prosthesis users to default to their sound side extremity to perform many unimanual activities, the items included in the custom PROMIS scale are bimanual tasks. A limitation of this measure is that it does not inquire as to whether an individual task is performed with or without the use of the prosthesis. It is possible that some users may employ alternate strategies to complete some of the items on the short form. However, the bimanual nature of these tasks suggests that the engagement of a prosthesis would have been more likely for many if not all of our respondents, especially given the overlapping correlations with higher reported rates of prosthesis satisfaction.

We observed a strong relationship between self-reported bimanual physical capacity and well-being. By contrast, the correlations between well-being and daily prosthetic wear times were only modest. This is consistent with prior published observation. Ostlie et al observed that despite good demonstrated prosthetic skills and high levels of prosthetic satisfaction and perceived usefulness, individuals with upper limb amputation reported engaging their prostheses to complete only about half of their ADLs with a stronger tendency towards prosthetic use observed in bimanual activities.[8] Chadwell et al also reported no correlation between prosthetic proficiency and daily prosthesis use.[11] Thus, it appears to be the user's ability to perform bimanual upper limb tasks when necessary, rather than their actual prosthesis wear times, that is more closely related to the overarching constructs of well-being and quality of life.

The relationship between well-being, upper limb function, activity and participation scores and prosthesis satisfaction warrant further study and consideration. It may be that those individuals with higher levels of physical function were more able to participate in their social roles and activities and, as a result, reported higher satisfaction and quality of life. Alternately, it may be that those individuals who were managed with prostheses more closely tailored to their activities and various roles reported both greater prosthesis satisfaction and higher levels of activity and participation, collectively culminating in higher satisfaction and quality of life scores. Causality between these

interrelated factors may be difficult to ultimately assign. Rather, their close associations should be seen as a strong rationale to pursue bimanual function with a prosthesis tailored to individual activity and participation requirements.

The correlation between reduced pain interference and increase well-being aligns with clinical observation. Individuals with upper limb amputation and deficiency often report a range of pain types and intensities.[2,7] These can include residual limb pain, phantom pain and pain related to over-use in the sound side extremity and through the upper back, neck and torso. Any of these pain types can ultimately have profound impacts upon well-being that would be difficult to overcome.

CONCLUSIONS

The constructs of QOL and SAT have been represented in the broader construct of Well-Being. Our data suggest that greater levels of Well-Being are correlated with higher levels of functional capacity with bimanual activity as measured with the PROMIS-9 UE, higher levels of activity and participation as measures with the PROMIS-APSRA, higher levels of satisfaction with prostheses as measured by the TAPES-R, and reduced levels of pain interference. By contrast, daily reported wear times, times since amputation, age and gender failed to correlate strongly with Well-Being. Prosthetic capacity in bilateral function, facilitation of activity and participation, satisfaction with prostheses and managing the complex pain experiences that can occur within this population appear to be key considerations in enhancing their overall well-being.

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Myoelectric Controls Algorithms

A WEARABLE SONOMYOGRAPHY SYSTEM FOR PROSTHESIS CONTROL

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ABSTRACT

Sonomyography (SMG) is a promising alternative to electromyography (EMG) for extracting control signals from functional muscle activity in real time. SMG uses ultrasound imaging to non-invasively record superficial and deep muscle activity, making it possible to differentiate the independent contributions of individual muscles during functional movements. Previous challenges surrounding the miniaturization of ultrasound instrumentation have prevented exploration of SMG as a feasible modality for prosthesis control. In this paper, we describe our work developing a 4-channel wearable ultrasound system capable of tracking in vivo muscle interfaces using frequency-modulated continuous wave imaging.

CLASSIFYING GRASPS USING SONOMYOGRAPHY

Surface EMG remains the primary method for sensing muscle activity to actuate a prosthetic hand. However, EMG suffers from poor amplitude resolution, a low signal-to-noise ratio, and is subject to crosstalk from adjacent muscles [1], [2]. These barriers can make it difficult to derive a rich set of control signals for intuitively controlling multiple degrees-of-freedom within a multiarticulate prosthetic hand. SMG is an alternative sensing modality that uses ultrasound imaging of muscle contractions to spatially resolve individual muscle activities with sub-millimeter precision. Because SMG enables spatiotemporal characterization of both superficial and deep muscle activity and is not subject to intermuscular crosstalk, SMG makes it possible to differentiate the independent contributions of individual muscles during voluntary movement. Control signals for driving a prosthetic hand can thus be extracted from the ultrasound signals using machine learning models (Fig. 1).

Similar to EMG control, SMG control employs a supervised learning framework that uses classification algorithms to compare features of ultrasound signals to training data. Ultrasound images of forearm muscle tissue have enough unique spatiotemporal information for classification algorithms to differentiate between various hand grasps. Our benchtop testing has revealed that SMG can identify five individual digit movements in able-bodied individuals with 97% cross-validation accuracy [3] and fifteen complex hand grasps with 91% cross-validation accuracy (Fig. 2) [4]. We also found that, with minimal training required, SMG can identify five grasps for individuals with upper limb loss with 96% cross-validation accuracy [5], [6]. These results indicate that SMG is a feasible means to classify hand grasps from muscle tissue for prosthesis control.

We investigated grasp classification using a sparse set of ultrasound scanlines to understand the minimum hardware requirements for a wearable ultrasound system [7]. We recorded ultrasound images from the forearms of five able-bodied subjects performing five grasps (power grasp, pinch, index point, key grasp, wrist pronation) using a 128-element linear array transducer. We then selected different subsets of scanlines to quantify the extent to which classification accuracy was affected. Even with a subset of only four scanlines, classification accuracy was virtually unchanged (94 ± 6% for 128 scanlines, 94 ± 5% for 4 scanlines). This demonstrates the feasibility of using a small number of single-element transducers rather than a full array, which simplifies the instrumentation that would need to be incorporated into a prosthesis socket. We thus chose to implement a wearable SMG system using only 4 individual transducers.

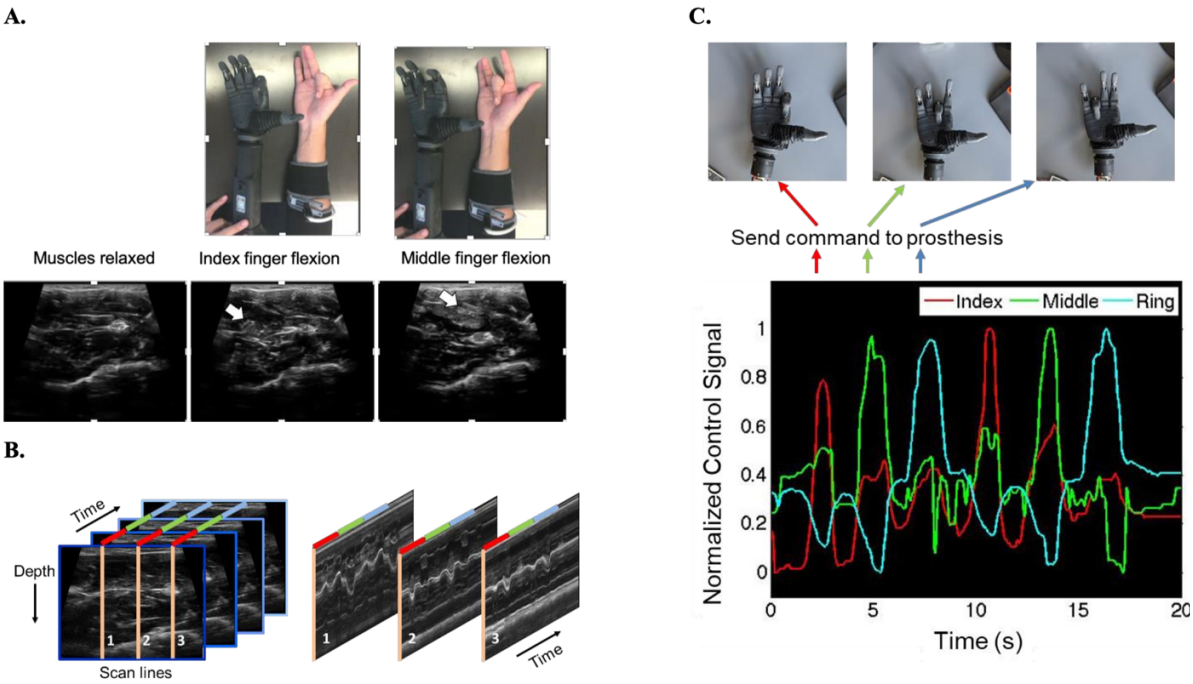

Figure 1. Schematic showing our approach to prosthesis control with SMG. (A) Muscle deformation over time is tracked with an ultrasound transducer placed on the forearm. The figure shows an able-bodied subject performing index finger flexion and middle finger flexion. The corresponding ultrasound images show different muscle compartments deforming for each movement. (B) M-mode ultrasound images (depth over time) show deformation of different muscle compartments over time corresponding to individual finger movements (red, green, blue segments). (C) Control signals are extracted based on the muscle deformation associated with individual finger movements (red, green, blue traces) and are then mapped to movement of a prosthetic hand.

DEVELOPMENT OF A WEARABLE ULTRASOUND SYSTEM

We have developed a 4-channel wearable SMG system for controlling a prosthetic hand (Fig. 2). Our implementation employs frequency-modulated continuous wave imaging instead of traditional pulse-echo approaches, which enables miniaturization of ultrasound parts using low-voltage commodity hardware and allows low-frequency processing speeds. A key feature of frequency-modulated continuous wave imaging is the use of a linear chirp signal to encode the depth of ultrasound reflections as a range of frequencies, which bypasses the need to transmit short-duration high amplitude pulses to create a depth-resolved map of the received reflections. We anticipate that our implementation of low-power ultrasound imaging will serve as the foundation for future prosthesis controlled by SMG.

Our ultrasound system consists of an AD5930 chirp generator, four single element ultrasound transducers, a power regulation subsystem, hardware for four-channel signal processing, and an external NI-6210 DAQ. The transducers are formed as single element PZT crystals with a 4.25 MHz center frequency and sized to be 7 mm in diameter and 0.5 mm thick. The PZT crystals are dampened with a silicone backing layer and mounted in a 3D-printed bracket that can be secured to a forearm with an elastic strap. The power subsystem is designed to take a 7.4 V battery input and provide ±5 V for the signal processing hardware. The signal processing hardware for each channel consists of a radio frequency (RF) amplifier, a demodulator, an audio frequency (AF) amplifier, and a low-pass filter. Because the depth is encoded as frequency, we low-pass filter the signal at 100 KHz to limit the imaging depth to 15 cm. The DAQ samples the output of the AF amplifier at 250 kS/s, and controlled with Matlab for the classification algorithms.

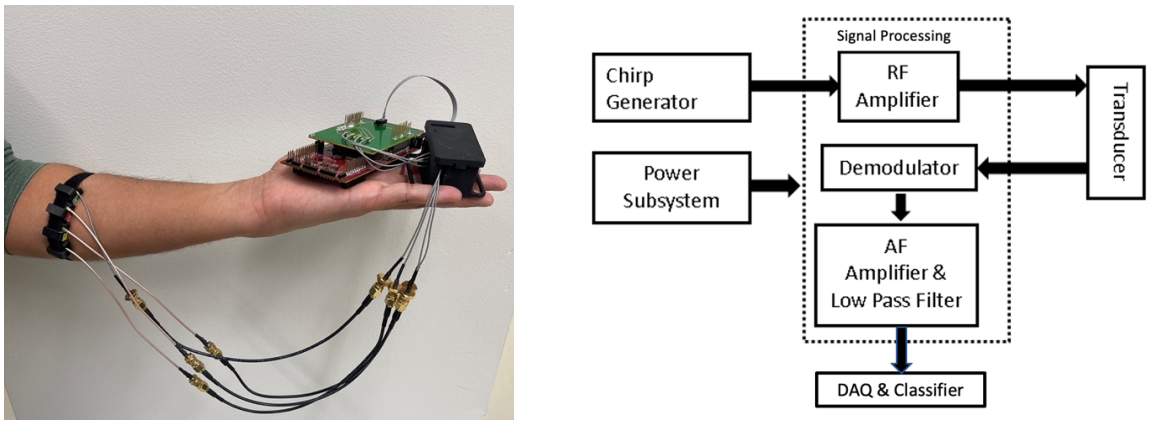

Figure 2. *Left:* The prototype of our 4-channel wearable ultrasound system. *Right:* System diagram of the hardware components.

We have also made some progress extending our wearable system to include an embedded processor capable of executing machine learning classification algorithms in real-time. We recently implemented a Linear Discriminant Analysis algorithm on the embedded processor and found it could predict a user's hand grasp with > 90% accuracy during benchtop testing, which is comparable to the classification accuracy obtained when analyzing the ultrasound signals using MATLAB (Fig. 3).

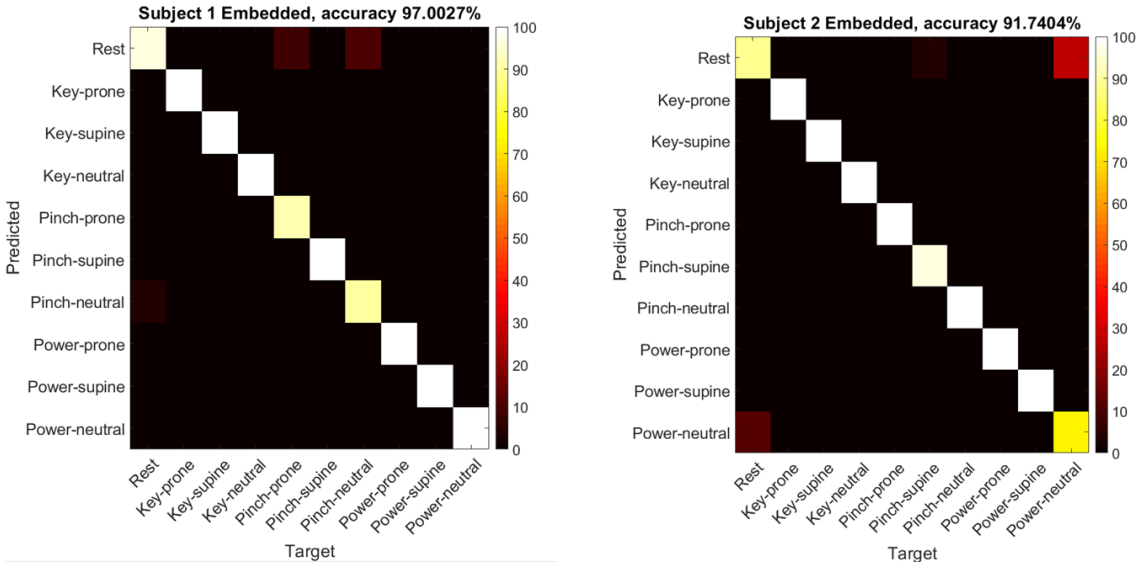

Figure 3. Offline grasp classification accuracy obtained using an embedded processor when testing two able-bodied subjects.

DISCUSSION

We believe SMG demonstrates numerous advantages over EMG, making it a promising modality for restoring dexterous movement to individuals using upper limb prostheses. One of the primary benefits of SMG is that muscle activity can be sensed with high spatial specificity, even in deep-seated muscle compartments. As a result, crosstalk

from muscles that are not associated with the intended movement is effectively suppressed. It is also noteworthy that full-resolution ultrasound imaging is not required to achieve robust classification. Classification accuracies are not affected even when a subset of only four ultrasound scanlines are used. Single-element transducers may be used instead of a full array, reducing the instrumentation required for implementing SMG control in standalone prostheses. Our testing has found that learning to use SMG requires minimal training. In fact, transradial amputees were able to achieve 96% classification accuracy for 5 grasps after only a few minutes of training time [5].

Our wearable SMG system can reliably record m-mode ultrasound imaging signals which can be used to classify hand grasps. Our future work focuses on implementing a wearable SMG system into an upper limb prosthesis to perform hand grasp classification in real-time. We have made considerable progress towards miniaturizing the front-end signal processing components, as well as implementing the grasp classification algorithms within an embedded system so that classification and control can be performed untethered to a computer. We are also working on packaging all the hardware components to fit within a socket alongside the hardware to drive a multiarticulate prosthetic hand. Our goal is to develop a complete SMG prosthesis control system for users to test within their own homes [8].

ACKNOWLEDGEMENTS

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ALTERNATIVE MYOELECTRIC CONTROL THROUGH NEURAL SYNERGISTIC INFORMATION

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ABSTRACT

This work combines for the first time structural and computational synergies defined by neuronal information. The main idea is to investigate the existence of motor neuron synergies and their potential as sources for myoelectric control. First, we developed a new version of the soft hand with 2 degrees of actuation (DoA) for prosthetic applications. Then, we used HD-sEMG to study the behaviour of motor units in different manipulation tasks and to identify motor modules or neural synergies. Based on this dimensionality reduction in both the mechanical prosthetic design and the neural control, we propose a method to map the neural information into prosthesis control. With this approach, we first show that neural synergies have greater dimensionality than classic muscle synergies. This property and a greater degree of independence determine the possibility of a natural, robust and simultaneous control of several DoA by neural synergies. The proposed method can be implemented into an available framework of online decomposition (i.e. online extraction of motor units) in order to create a platform to study different myoelectric control methods and compare their performance in a virtual environment, and in the real-time control of the SoftHand Pro-2. The creation of this platform permits further developments on the existence of modules in upper-limb motor control, the relation between different synergistic levels and its use for assistive and rehabilitative robotics with different type of patients.

INTRODUCTION

Modularity is present in both structural and computational components of a control architecture, and it has a functional purpose. It is commonly assumed that the remarkable versatility and adaptability in motor control is the result of employing modularity as the key organizational principle of the central nervous system [1]. Research on synergistic control has focused on developing analytical techniques to reveal the existence and the origin of the reduction in the dimensionality of the hand control space. The framework proposed in [2] suggests that the spinal circuits could explain many experimental observations about synergies revealed by studies of hand kinematics, kinetics, and EMG signals. Compared to animals and humans, state-of-the-art robotic hands still show limited and inflexible motor skills. Nonetheless, advances in robot technology allow researchers to explore and develop into how the motor, sensory, and cognitive functions might be integrated into meaningful architectures. The creation of artificial systems embedding synergies represents a benchmark to explore different concepts of modularity and to experimentally investigate possible interactions between motor and cognitive processes, which are fundamental for human understanding.

Postural synergies are considered to guide and simplify the design of hands, while allowing a high level of dexterity in the coordination of multiple joints. We developed a prosthetic version of a multi-synergistic hand (i.e. the SoftHand Pro-2) that presents two synergies, capable of reproducing continuous movement of all fingers in opposite directions. Improving upon the traditional advanced robotic hands, multi-synergistic permit the continuous mapping of different grasp patterns and their transitions. Moreover, multi-synergistic robotic hands could theoretically yield in-hand manipulation of objects. Note that to implement in-hand manipulation in fully actuated robotic hands, sophisticated algorithms and sensing strategies are generally required. The SoftHand Pro-2 could manipulate objects of different shapes with just two synergistic behaviors and requires a simpler control strategy. However, because of its synergistic nature, the control modality must match this concept and be also synergistic in order to create a proper mapping. Individual fingers movements, which are needed for simultaneous and proportional control during in-hand manipulation, are extremely hard to decode from sEMG sensors on extrinsic muscles (the common condition for

transradial amputee subjects). To overcome peripheral coupling when a task requires independent finger actions [3] or for several coordinated multi-digit actions [4], finer modulation of neuromuscular activity might be necessary. This work proposes an alternative myoelectric control strategy based on the functional organization of motor units (MU) and neuronal synergistic information. We hypothesize that this methodology presents higher dimensionality and better specificity than other alternatives, such as muscle synergies. Moreover, this control method may not only be adequate to command a synergistic prosthetic hand, but the integration of both structural and computational synergies contributes to the creation of a framework to further develop on the existence of modules in upper-limb motion control and its application for assistive and rehabilitative robotics.

This work represents a unique opportunity that combines the expertise in neural interfacing (ICL, London) and in soft-synergistic robotics and prosthetic hands (IIT, Italy). Although this investigation presents several applications, its major potential applies to the field of prosthetics, where robotic devices become part of subject's missing body parts. We hypothesize that the lack of modularity as a principal direction in the design of artificial arm mechanics and control algorithms burdens the acceptance of prostheses and a natural bionic integration. This study attempts for the first time to match neural synergistic information with kinematic synergies. We decoded the activity of motor neurons innervating the hand while 9 participants exerted isometric forces during different wrist and hand movements related to the corresponding kinematics of the prosthetic arm. We then identified components explaining the variance of the motor neuron outputs, named motor neuron synergies (MNS, firstly introduced in [5]). For a better understanding of the functional role of MNS, and observe their applicability in myoelectric control, we compared them with synergies extracted from EMG amplitudes, i.e., muscle synergies. This work provides insights into the organization of neural inputs to spinal motor neurons from an offline analysis and proposes the first myoelectric control that uses neural synergistic information to control robotic hands which, to date, has been inferred through analysis of muscle synergies. We plan to apply this myoelectric control to the physical prosthetic hand, designed with postural synergies, and test its feasibility in online experiments.

This work stems from a collaboration within the ERC Synergy Project Natural BionicS, which is an international and multidisciplinary collaboration of European researchers to create fully integrated, symbiotic replacements for human limbs. The consideration of computational synergies introduces a completely fresh perspective for myoelectric control and appear especially interesting for multi-synergistic robotic devices. Furthermore, this collaboration aims at providing a foundation for merging neuroscientific and robotic principles. Promoting the combination of both concepts (motor neuron and kinematic synergies), we expect to provide prosthesis users with dexterous robotic systems with more intuitive and natural control.

DEVELOPMENT OF MULTI-SYNERGISTIC HANDS

The selection of appropriate prescriptive synergies in robotic devices is a difficult task as the observed behavior in humans (descriptive synergies) does not necessarily reveal the required control used by the nervous system (prescriptive neural synergies). Defining task-relevant prescriptive synergies is further complicated as their performance depends on the specific parameters and context of the task. The earlier developed SoftHand Pro is able to realize a vast range of grasps, and provides improved adaptability due to ts physical compliance and its synergistic actuation (i.e. by an designed tendon-driven differential mechanism) for improved adaptability. Despite its effectiveness in many practical conditions, this artificial hand presented some limitations in terms of dexterity when compared to a natural hand. The use of a single degree-of-actuation (DoA)prevents the execution of more complex tasks, like fine pre-shaping of fingers and in-hand manipulation. As a consequence, the SoftHand Pro-2 has been developed for prosthetic applications and for taking advantage of recent advances in the concept of neural synergies.. This is an under-actuated soft prosthetic hand with two synergistic behaviours. The combination of multiple soft kinematic synergies provides a continuous workspace that, in theory, is able to reproduce several hand postures and in-hand manipulation with a natural approach. The aim is to generate additional motions with minimal changes in the original mechanics of the SoftHand Pro, which has been already tested in clinical environments and real conditions with positive outcomes [6]. This framework turns transmission friction from a disturbance into a design feature, as suggested in [7], doubling the DoAs with little additional complexity. The vision of associating this mechatronic design to specific neural structures is different from any other current approach to prosthesis design.

Mechanical design

The SoftHand Pro-2 exhibits a total of 15 joints mostly embedding the flexion/extension of its fingers (see Figure 1). One revolute joint is present at the thumb, accounting for its abduction for a better opposition. The remaining 14 joints embedded in fingers are compliant rolling-contact element (CORE) joints. Elasticity is introduced in each joint. A single tendon moves from the palm base, connecting all the fingers, and two motors actuate the tendon, pulling it from its two sides. If the motors move in the opposite direction, the tendon length is shortened, and the SoftHand Pro-2 closes exhibiting a power grasp. If instead, only one motors moves, the tendon pulls from the corresponding side, partly closing the hand and generating a non-power grasp, but a rotation of the fingers from side to side, which can generate pinch to index point postures.

Figure 1: Final design of the novel prosthetic hand, the SoftHand Pro-2.

Hand capabilities

This hand is able to perform both precision (i.e. pinch or tripod) and power grasps, as well as to manipulate objects while maintaining a stable grasp through the embedded intelligence in its autonomous finger contact forces. The hand demonstrates that a larger variety of grasping and manipulation tasks can be theoretically performed by combining only two DoAs with softness and synergistic behaviors. The capability of in-hand manipulation, such as for the pouring of a liquid may be also executed by exploring the two synergies at different intensity levels without any compensation at the wrist level (usually related to wrist abduction/adduction). Because of the exploration of friction, sequential control inputs, may result also in different hand configurations, which is considered a feature to be explored, especially if a patient uses proportional velocity control (PVC). Even though the problem of manipulation modelling is solved for fully actuated hands (i.e. when the hand kinematics are injective), this is more complex for synergy-based hands. However, prosthesis users would most of the time have visual feedback of the manipulated object. Therefore, with a more natural control of the prescriptive synergies of the artificial hand, the additional feature of in-hand manipulation may become a feasible capacity. This feature is explored in this work through the use of motor neuron synergies.

MOTOR NEURON SYNERGIES

One motor neuron can receive inputs from several corticospinal inputs, mediated by premotor interneurons. A motor neuron synergy (MNS, termed in [5]) corresponds to a stable pattern of muscle activation (dynamic system), observable already at the premotor neurons level. Contrarily, the extraction of muscle synergies considers the spatiotemporal organization only from individual muscles. The concept of MNS is compatible with the existence of motor primitives, which could correspond to a set of synergies that are simultaneously activated for the coordinated control of a more complex system. In practice, to extract neural synergistic organization, we factorized the output spike trains of motor neurons innervating the extrinsic hand muscles found at the upper forearm level (common area to place EMG sensors in transradial amputated subjects). In addition, it has been suggested that the descending motor commands may control the dynamics of a system by modulating the shape of its synergies. The theoretical framework in [8] incorporates the notion of variable time shifts for individual synergies, that could permit the quantification of the degree of flexibility of a synergy related to the width of its valley when activated. The inclusion of fixed and flexible synergies in the control loop are of interest for the precise control of prostheses and perturbation avoidance. Here, we recorded data from different able-bodied subjects while performing isometric contractions during different manipulation tasks. Then, we concatenate all EMG signals recorded through HD-sEMG sensors to extract common features among hand positions. The methodology proposed combines EMG signal decomposition for the extraction of MU, and the application of non-negative matrix factorization (NMF) to observe neural synergistic information. Then, we propose a mathematical relation among upper-limb movements included (which are feasible to replicate with the hardware) and the extracted MNS. Doing so, we define the motor inputs or control commands necessary for the use of the prosthesis and an appropriate mapping of the subject intentions into robotic postures. Figure 2 shows an example of the recorded data from a pilot subject and the offline analysis of their MNS. The matrix W is the time-invariant weights of the synergies observed in 63 MU. The matrix H shows the time-variant activation of the defined synergies and their morphology according to the recorded tasks, visible at the bottom of Figure 2. Results show the

repetitive use of MU in different hand postures, and accordingly, how this is translated into common neural synergies for different hand configurations.

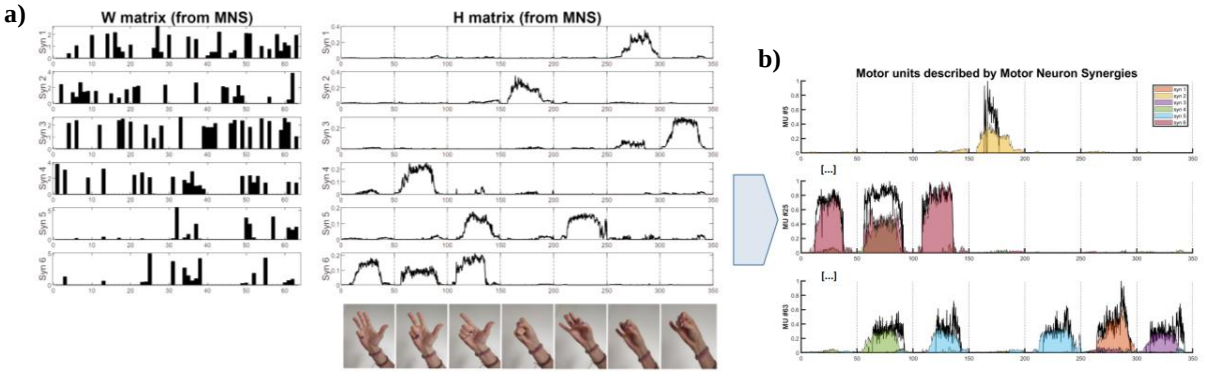

Figure 2: Example of motor neuron synergies from a pilot study. **a)** show the resulting matrices from NMF applied to motor units (MU), **b)** the reconstructed MU from the defined MNS. The vertical dashed lines in a) H matrix and b) represent the concatenation of the different manipulation tasks recorded and combined.

CONCLUSIONS

Preliminary results validate the potential of the proposed vision and the use of neural synergies for the control of postural synergies embedded in a prosthetic hand as an alternative myoelectric control that could permit more advanced manipulative skills with a natural approach. The methodology proposed can be implemented in a computationally efficient real-time interface based on the decoding of the activity of spinal motor neurons from wearable HD-sEMG sensors [9], which would permit the real-time testing of the control method while actively controlling the prosthesis with different subjects. Future work aims at the use of the resulting platform in the Medical University of Vienna with different types of patients (e.g. congenital, amputated subjects or patients with certain surgical conditions such as TMR), that will allow the investigation of how neuronal information varies across users. This framework permits future studies on the effect of modularity in the reduction of cognitive load in patients.

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ASSESSING THE FEASIBILITY OF USING SONOMYOGRAPHY FOR UPPER LIMB PROSTHESIS CONTROL

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ABSTRACT

Sonomyography (SMG), or ultrasound-based sensing of muscle deformation, is an emerging modality for upper limb prosthesis control with potential to significantly improve functionality. SMG enables spatiotemporal characterization of both superficial and deep muscle activity, making it possible to distinguish the independent contributions of individual muscles during functional movements. Early offline studies have shown that SMG is capable of accurately classifying motor intent among able-bodied individuals, but it has not yet been shown whether individuals with upper limb absence can successfully use this modality for prosthesis control. This paper describes our ongoing work towards implementing SMG control for individuals with upper limb absence in offline and real-time settings. We provide strong evidence supporting the feasibility of using SMG to control upper limb prostheses.

INTRODUCTION

Although designs of electromechanical prosthetic hands have improved over time, surface electromyography (EMG) remains the most common modality for sensing and decoding user intent. Unfortunately, using EMG to control a prosthetic hand with multiple degrees of freedom can be challenging for individuals due to the poor amplitude resolution and low signal-to-noise ratio inherent in EMG signals [1]. Sonomyography (SMG) is an alternative approach that uses ultrasound imaging of muscle deformation to spatiotemporally resolve both surface and deep musculature in the residual limb. Using SMG, it is therefore possible to derive a rich set of prosthesis control signals that may better account for the independent contributions of individual muscles. For example, we previously used SMG to identify five individual digit movements in able-bodied individuals with 97% offline cross-validation accuracy [2] and fifteen complex hand grasps with 91% offline cross-validation accuracy [3]. More recently, we have extended this work to better understand whether SMG is a clinically viable control modality for individuals with upper limb absence. This paper will discuss our ongoing work in this area and highlight opportunities for future study.

DEVELOPING PROFICIENCY WITH SONOMYOGRAPHY

One factor that may affect the feasibility of using SMG for prosthesis control is the length of pre-prosthetic training time required for individual with upper limb absence to learn to use it. Prior to receiving a prosthesis, patients must develop an ability to produce control signals that are sufficiently consistent and separable for accurate grasp classification. The pre-prosthetic training process can be lengthy and difficult in the context of EMG control [4], which presents a barrier to adoption of a prosthesis. However, our testing with SMG suggests that patients can rapidly complete pre-prosthetic training.

In a sample of eight individuals with transradial limb absence, we characterized grasp classification performance during their initial and subsequent exposures to SMG in order to understand how proficiency develops over time. Participants were asked to repeatedly perform a set of 4-7 grasps while ultrasound images of their residual limb musculature were recorded using a commercial ultrasound transducer. Grasps were self-selected based on what each participant felt was intuitive to perform. The images were saved to a database and subjected to leave-one-out cross-validation with a modified 1-nearest-neighbor classifier [5]. This process was completed once while the participants were naïve to SMG control to establish baseline performance. To assess whether performance could improve with further instruction, it was then repeated three times while participants received verbal and visual biofeedback about their performance. Lastly, participants returned for a second session on a different day to assess between-day repeatability. Despite being naïve, the participants achieved high classification accuracy during their initial exposure to SMG (96.2 ± 5.9%; Figure 1). Moreover, the accuracy did not systematically change with the provision of biofeedback or between days. Our findings suggest that individuals who are naïve to SMG can quickly and consistently achieve reliable grasp classification [5].

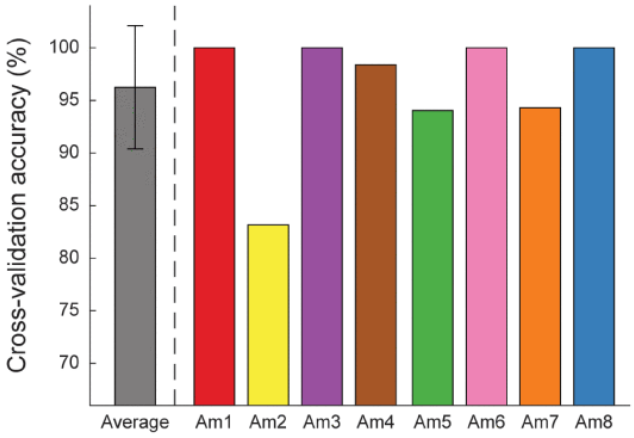

Figure 1: Average and individual classification accuracies during participants' first exposure to sonomyography.

USING SONOMYOGRAPHY WITH PROXIMAL LIMB ABSENCE

Our initial offline investigations of SMG focused on able-bodied individuals and individuals with transradial limb absence. However, we also investigated whether SMG may be a suitable control modality for individuals with limb absence at more proximal levels. Absence of the forearm may create challenges for using SMG because the muscles associated with wrist, hand, and finger control are primarily located in the forearm. To explore this issue, we asked an individual with transhumeral amputation to perform 11 hand motions (including six grasps and flexion of each individual digit) interspersed by periods of rest. The participant achieved high classification accuracies during both

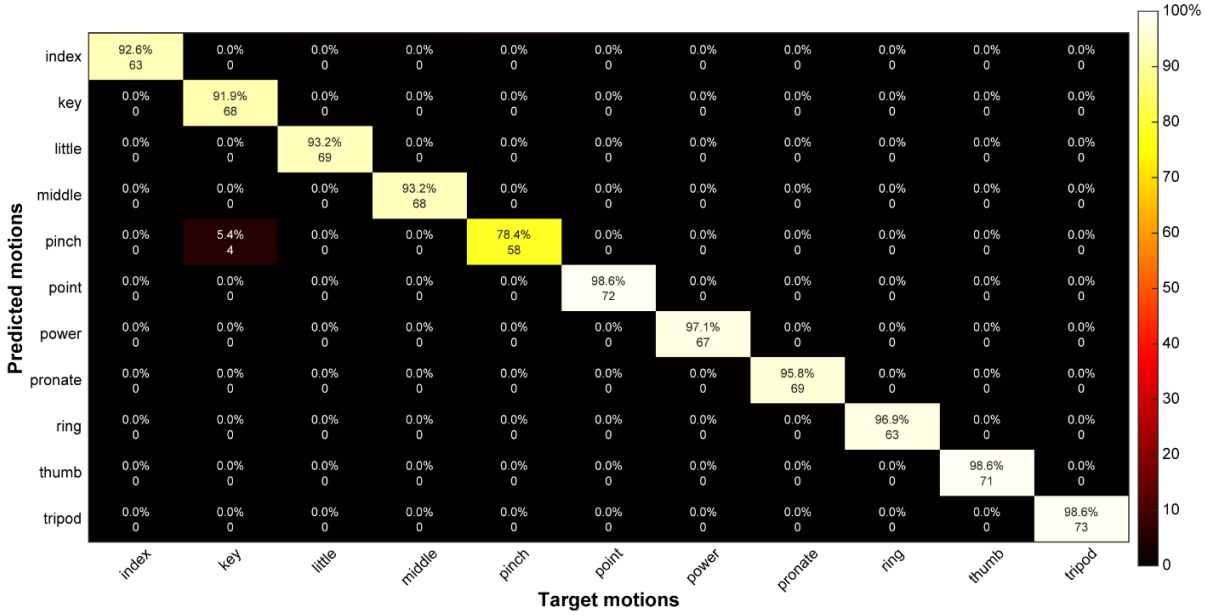

Figure 2: Confusion matrix for the motion end states achieved by an individual with transhumeral amputation. Integer values in each cell represent the total number of SMG image frames that were classified.

the motion end states (94.04%; Figure 2) and rest phases (98.34%) [6]. This promising result shows remarkable potential for using SMG to recognize individual finger movements and complex grasps in individuals with proximal limb absence. However, we acknowledge that our participant may have been uniquely able to achieve this outcome due to spontaneous muscle reinnervation, although his amputation surgery did not include targeted muscle reinnervation. More individuals must be assessed to understand how SMG can be best implemented in this population.

FUNCTIONAL TASK PERFORMANCE USING A SONOMYOGRAPHIC PROSTHESIS

Although we have shown that robust offline classification performance is possible with SMG, we also sought to understand the feasibility of using SMG to control a prosthesis in real-time functional settings. In contrast to the tightly-controlled settings in which offline classification performance is typically assessed, the use of a physical prosthesis involves many variabilities that can degrade classification performance. Notably, changes in the ultrasound imaging angle during arm movement could affect the acquired images, potentially causing misclassification. Thus, it must be confirmed whether classification is stable as users move their arm through their entire reachable workspace.

As a first step to understanding this issue, we asked an individual with bilateral limb absence at the wrist disarticulation level to perform a series of functional tasks using a prosthesis controlled by SMG. To collect data for training a linear discriminant analysis classifier, the participant moved her arms throughout her reachable workspace in a pre-defined pattern while maintaining a set of muscle contractions. Each contraction was mapped to a specific grasp within the prosthetic hand. Tripod grasp was initiated by wrist flexion, index finger point was initiated by wrist extension, and rest was initiated by a relaxed muscle state.

The participant then performed three functional tasks that involved grasping and moving one-inch wooden blocks. These tests were repeated every 30 minutes across three hours of continuous prosthesis wear without retraining the classifier. Box and Blocks Test (BBT) performance was measured by the number of blocks transferred over a barrier in one minute. Targeted Box and Blocks Test (tBBT) performance was measured by the time required to move 16 blocks over a barrier into predetermined positions. Rainbow Test performance was measured by the time required to move blocks located at various heights from a white board to a box at waist height. During each break between tests, the participant turned off the prosthesis and performed pre-defined tasks that were staggered to require increased arm movement over time. In addition to the test outcomes measures, we quantified the number of transient classification bouts to characterize the efficiency of grasp selection. A transient bout was defined as an instance when the classifier predicted a grasp for less than five consecutive frames. Fewer transient bouts indicate increased efficiency.

The participant successfully completed all tasks throughout the three-hour testing period [7]. The outcome measures remained generally stable over time (Figure 3), although we did observe a slight improvement in test scores during BBT with the left arm ($p = 0.038$) and during tBBT with the right arm ($p = 0.011$). There was only one negative effect of socket wear time on performance, as evidenced by a small increase in the number of transient bouts during the Rainbow test with the left arm ($p = 0.027$). Our results show that training a classifier to predict hand grasps while moving the arm throughout the reachable workspace is a practical strategy for reducing misclassification related to changing arm position. Additionally, this study supports the feasibility of using SMG to control upper limb prostheses in real-world applications.

CONTINUING WORK

As part of our continuing work towards demonstrating the utility of SMG control, we are working to develop wearable low-power ultrasound systems that can be integrated into a prosthetic socket. The functional tests reported in this paper were conducted with the participant tethered to a tablet-based commercial ultrasound system that could not easily be transported. We expect to see improved real-world performance when using a system optimized for SMG control that allows the user to move freely. We also anticipate that an optimized system would enable users to wear an SMG sensor for prolonged periods of time, permitting additional study on the stability of grasp classification during daily activities.

We envision a future with SMG as a viable option for upper limb prosthesis control, and we encourage research that examines the capacity of SMG to increase functional outcomes and satisfaction among prosthesis users. Future work will focus on systematically evaluating the functional benefits of SMG control, such as whether using SMG contributes to higher scores on standard clinical tests, improved quality of movement, greater patient-reported satisfaction, and reduced cognitive load. Although myoelectric control strategies continue to demonstrate remarkable clinical utility, we anticipate situations in which SMG control would be considerably advantageous. There is also

opportunity to examine hybrid approaches using both SMG and EMG to enable more intuitive control for users with upper limb loss.

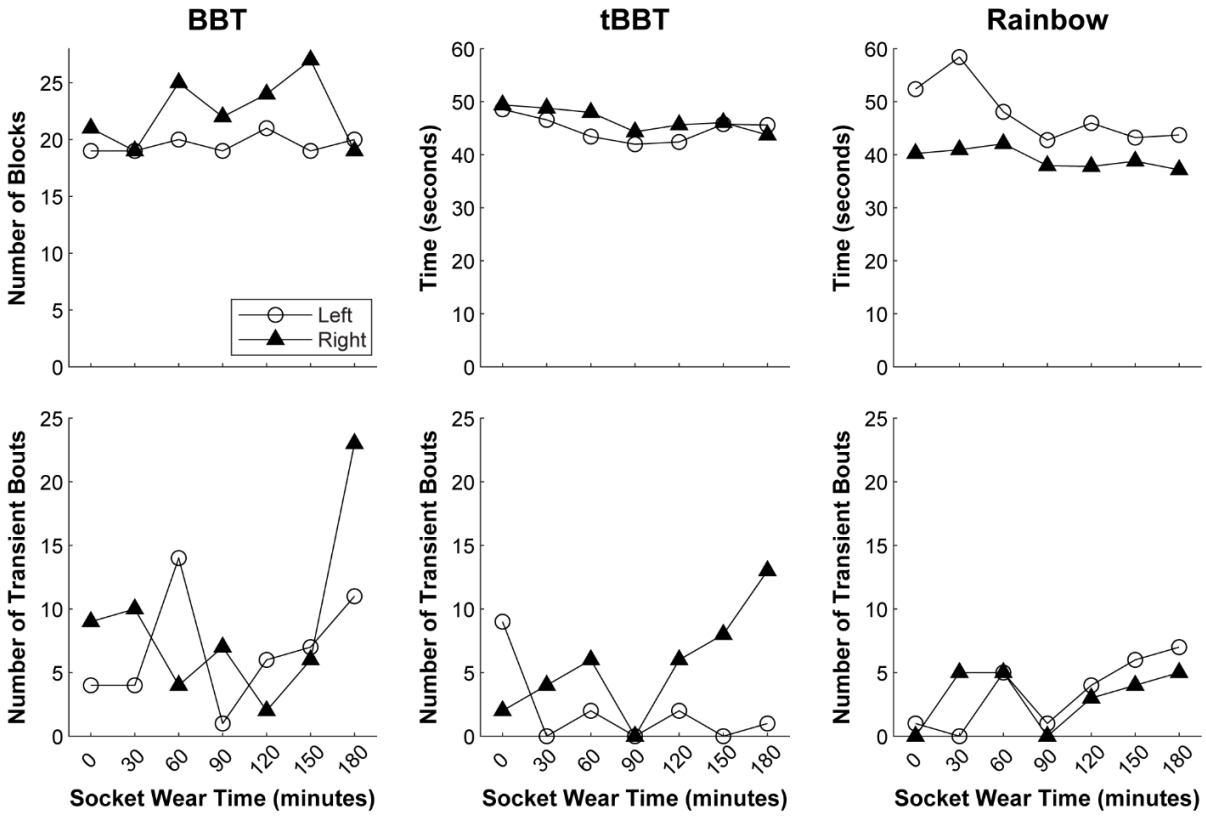

Figure 3: Functional outcome measures achieved during testing (BBT = Box and Blocks Test; tBBT = Targeted Box and Blocks Test)

ACKNOWLEDGEMENTS

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CHARACTERISATION OF MYOELECTRIC ARTEFACTS IN CLINICAL SOCKETS

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ABSTRACT

A significant disparity exists between the functionality promised by modern multi-grip myoelectric prostheses and the reality of myoelectric control using clinical-standard sockets and electrodes. Unpredictable prosthesis behaviour means users will often choose not to use their prosthesis for certain tasks. One source of unpredictability in upper-limb prostheses are unintended device activations, that is to say prostheses opening or closing when the user did not intend for the action to occur. Unintended device activations occur when the output of electromyography sensors reach a given threshold. During closed-loop control it is usually not possible to determine whether sensors reach threshold due to mechanical disturbances inducing motion artefacts or because of genuine, but unintended, muscle activity. We present preliminary data from experiments which use arrays of sensors to characterise how and why artefacts may occur in clinical-standard upper-limb prosthesis sockets. Current data show early trends in physical positions which lead to unintended activation and shows some artefacts are concurrent with intended muscle activity.

INTRODUCTION

Myoelectric upper-limb prostheses suffer from high rejection rates [1]. Lack of functionality, or commonly a lack of functional gain in wearing a device, remain key factors in upper-limb prosthesis rejection [1,2,3]. Modern multi-function devices offer a range of grasp patterns; however, users of myoelectric devices typically find them difficult to control [4]. This lack of control, or lack of ability to predict how a prosthesis will move, has been posited as a reason for passive use of active devices and for device rejection [4]. A source of unpredictability in modern myoelectric devices is the myoelectric interface with the skin [6]. While experimental electromyography (EMG) research typically uses EMG sensors adhered to the skin, upper-limb prosthesis users control their devices via sensors housed in custom built sockets. This leads to mechanical coupling of the sensors, which can produce artefactual EMG as sensors move relative to the skin [5]. These artefacts are likely to contribute to unintended device activation, a key factor limiting the degree to which users can be confident in device behaviour.

In this paper we present preliminary results from a set of closed-loop experiments which aim to characterise and label artefactual EMG obtained using clinical grade sensors. To achieve this, we fitted clinical bypass sockets or prosthesis simulators with a range of sensors and compared the data acquired to create ground truth labels for artefactual EMG.

METHODS

Participants

Three participants (1 male, 2 female) who are anatomically intact and free from neurological or motor disorders were recruited. The study was approved by the Local Ethics Committee at Newcastle University (ref: 20-DYS-050). All participants provided written informed consent prior to the start of the experiment.

Experimental setup

Limb-intact participants performed a simple closed-loop myoelectric control experiment while wearing an instrumented clinical bypass socket. The bypass socket of one participant was made using the traditional casting, rectification and lamination approach, and two were created using a hybrid approach combining digital scanning with traditional clinical techniques [5]. An example bypass socket is shown in Figure 1a; the sockets are designed to simulate a hybrid supracondylar design. Sockets were fitted with two clinical standard surface electrodes (RSL Steeper SEA200). A two axis soft flex sensor (Bendlabs) was mounted on the posterior part of the socket and connected to

participants' upper arm to capture elbow flexion and extension. The clinical standard electrodes and the soft flex sensor were connected to an Arduino Nano sampling at 500 Hz. Eight EMG sensors (Delsys Quattro) were positioned in a band around the forearm distal to the clinical electrodes and fixed in place with a bandage. The Delsys Quattro units were placed on the exposed part of the. Data from the Delsys sensors and the Arduino Nano were synchronised and sampled on a PC using the AxoPy experimental library for human-computer interfacing [6].

Experimental Calibration

Participants performed a flex sensor calibration routine which involved moving their elbow through five positions. Two arm orientations were assessed, referred to as vertical and horizontal. In the vertical condition, participants performed a calibration with the shoulder relaxed such that flexion and extension of the elbow moved the forearm in the vertical plane. In the horizontal condition, participants performed the same calibration with the arm abducted to 90° such that flexion and extension of the elbow moved the forearm in the horizontal plane. Within each condition, the five elbow positions attempted to capture participants' range of movement on one axis, with targets one and five capturing top and bottom in the vertical condition and left and right in the horizontal condition. The arm position for target three aimed to be perpendicular to the display providing visual feedback in both cases.

Electromyography data from the clinical electrodes were calibrated to provide normalized muscle activity for use in the closed-loop experiment. Participants performed a calibration during which they were asked to perform activity representative of rest, y_r, and comfortable contraction, y_c. Normalized muscle activity, $\hat{y}$, was calculated according to $\hat{y} = (y - yr) / (yc - yr)$ and used throughout the experiment.

Experimental protocol

Participants performed four experimental blocks comprised of 40 trials under two conditions. A visual depiction of the experimental protocol is shown in Figure 1b.

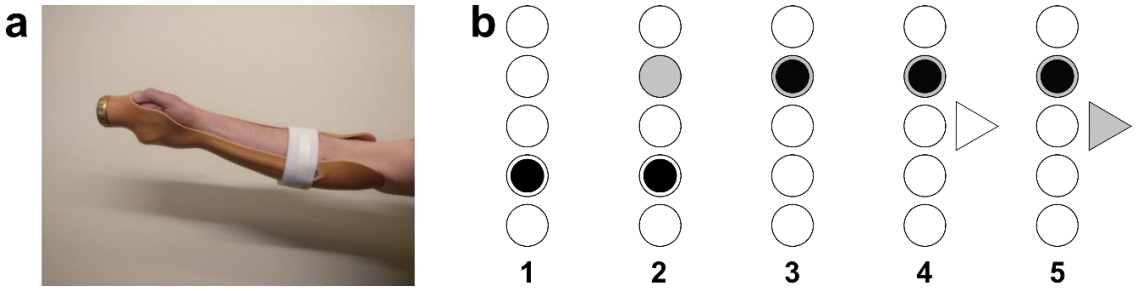

Figure 1: (a) Example bypass socket. (b) Visual prompts used in vertical arm position experimental protocol. 1: Participant views five vertical positions with current position highlighted. 2: Target position is presented. 3: Participant moves arm to target position. 4: Prompt indicates to activate the flexor (left arrow) or extensor (right arrow). 5: Feedback may be presented if muscle activity reaches threshold value.

At the start of a trial participants were presented with five circles. In the vertical condition, the five circles were aligned vertically (Figure 1b1). A target was presented (Figure 1b2) to prompt participants to move their arm to the correct position. Once in position (Figure 1b3), an arrow was presented to indicate which muscle group to activate (Figure 1b4). In the vertical condition a right arrow prompted activation of the extensors and a left arrow indicated activation of the flexors. In the horizontal condition an up arrow indicated activation of the extensor and a down arrow activation of the flexor. In the second block of each condition, participants received feedback if they reached normalised activation level $\hat{y} = 1$ (Figure 1b5). Participants used a single left-handed joystick (FragFX FragChuck, SplitFish Gameware) to pause the experiment to avoid fatigue. The first two blocks were performed in the vertical condition and the second two in the horizontal condition.

RESULTS

Two analyses are ongoing. The first is intended to probe the degree to which limb and socket position and orientation influence unintended myoelectric activations. The second is a manual data labelling exercise to

differentiate different forms of myoelectric artefacts. Due to the limited number of participants tested no statistical analyses were performed.

Arm position

Trial data were differentiated into correct and incorrect activations according to whether or not normalised activation level $\hat{y} \geq 1$ was reached on the prompted clinical electrode channel prior to any unintended activation of the other clinical electrode. Classification results for the five limb positions in the horizontal and vertical conditions are shown in Figure 2a and 2b respectively. In the horizontal condition, Figure 2a, results trend lower as the elbow is flexed and the forearm moves across the body. In the vertical condition, Figure 2b, lower classification results are observed as the arm is fully extended. Figures 2c and 2d show a breakdown of misclassification results for two participants. In both participants, misclassification distributions in the horizontal condition are distinct from those in the vertical condition.

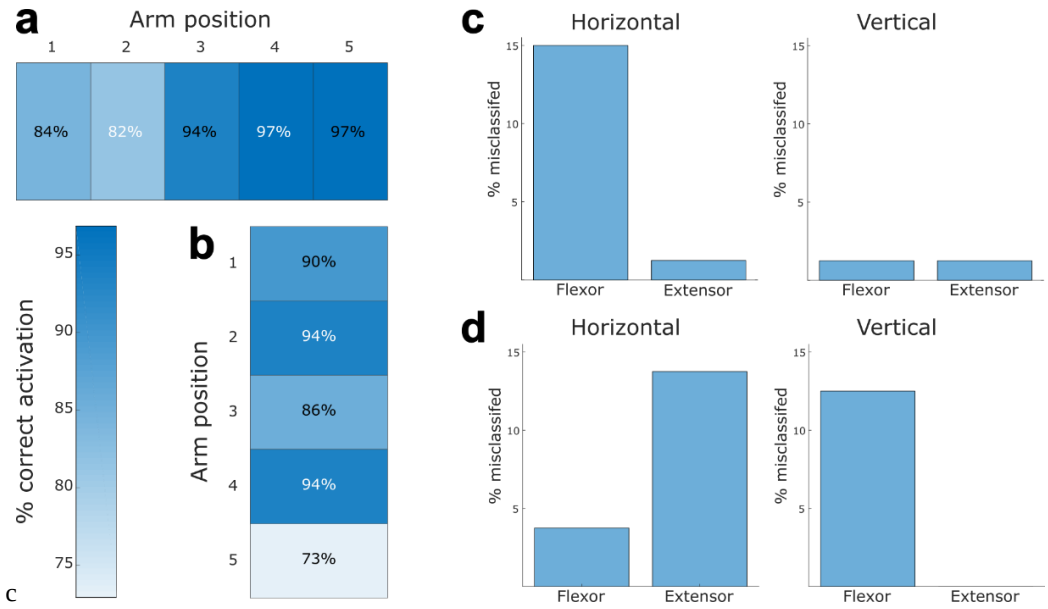

Figure 2: (a) Percent of correct activations in the horizontal condition. (b) Percent of correct activations in the vertical condition. (c) & (d) Misclassifications for two participants broken down into the horizontal and vertical experimental conditions.

Manual artefact analyses

Experimental data were manually analysed on a trial-by-trial basis. Electromyography sensor data obtained from clinical surface electrodes were compared to those obtained from the array of Delsys sensors. Trials in which the clinical data could not be explained by EMG activity observed in neighbouring Delsys electrodes were labelled as artefacts. Two common artefact types observed across participants are shown in Figure 3. Both Figure 3a and Figure 3b show artefactual EMG activity observed in the clinical electrode on the extensor side, during a flexor contraction. In both cases, artefacts occur concurrently with both the intended muscle activation and a degree of unintended co-activation. Our working hypothesis is that this activity represents unintended electrode shift caused by intentional muscle activation on the contralateral side of the bypass socket.

Figure 2b shows a change in baseline activity on the clinical electrode occurring at eight seconds, following an EMG artefact. During inspection it was observed that changes in baseline activity at the end of a trial period often led to the succeeding trial commencing with a similar shifted baseline.

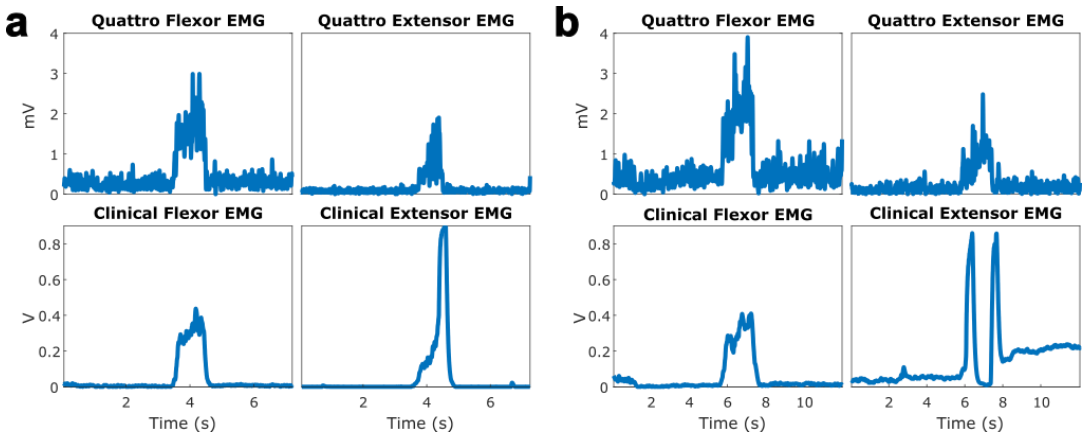

Figure 3: Sample artefactual EMG activity observed in clinical standard electrodes. Both figures show activity observed in the flexor and extensors via clinical standard electrodes on the bottom row. The upper row shows the nearest neighbour Delsys sensor. (a) Sample showing single peak artefact. (b) Sample showing double peak artefact.

CONCLUSION

We have demonstrated a proof of principle method whereby myoelectric artefacts can by observed and recorded in a clinical simulation socket. This work is being undertaken as part of a larger project which aims to develop a joint mechanical electrical method to ameliorate electrode artefacts in clinical standard upper-limb prosthesis sockets [7]. The primary goal of this phase is to characterise any consistency in arm positions contributing to the generation of artefactual EMG and create ground truth artefactual EMG data for analysis. Current results trend towards more EMG artefacts being generated at limb position extremities, and changes dependent on limb orientation. We aim to run complementary studies in participants with limb absence using a modified socket design and fewer probe electrodes.

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DEMONSTRATION OF AN OPTOGENETIC NEURONAL CONTROL INTERFACE

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ABSTRACT

Improved nerve interface approaches are sought for prosthesis control and sensory feedback as well as visceral organ study/modulation. Optical approaches that can read-in and read-out neural activity have advantages over electrode-based systems in terms of selectivity and non-invasiveness. To address limitations of existing nerve interface designs, we present an optical approach capable of reading activity from individual nerve fibers using activity-dependent calcium transients. Here we demonstrate the feasibility of using activity-dependent calcium transients to a control prosthetic hand. This work provides a proof-of-concept for an optogenetic nerve interface demonstrating as it does our ability to read-out signals at the axonal scale in real-time and apply it to a devices control.

INTRODUCTION

We are developing a Bidirectional Optogenetic Neural Interface to read-in and/or read-out action potentials from a nerve with the goal of creating a neural interface that is selective yet minimally invasive to the nerve. There are significant drawbacks to current nerve interface approaches. They either lack specificity - they use nerve cuff electrodes, such as the Flat Interface Nerve Electrode (FINE) Array**[1]** that must sit on the outside of the nerve and measure signals originating inside the nerve bundle, or they involve penetrating the nerve with needle electrodes - such as Longitudinal Intrafascicular Electrodes (LIFE)**[2]** or the Utah Slant Array**[3]**. Penetrating electrodes tend to be hard and rigid, resulting in a stiffness mismatch that causes irritation and necrosis, decreasing longevity. Instead of using electrical interfacing with the nerve, we will use light activated ion channels (opsins) and fluorescence protein Ca^{2+} or voltage indicators that allow stimulation and recording of action potentials of specific afferent or efferent neurons using viral vector transfection. Our Optogenetic Neuronal Interface is based on a fiber optic coupled miniature two-photon microscope with electrowetting adaptive optics **[4-7].**

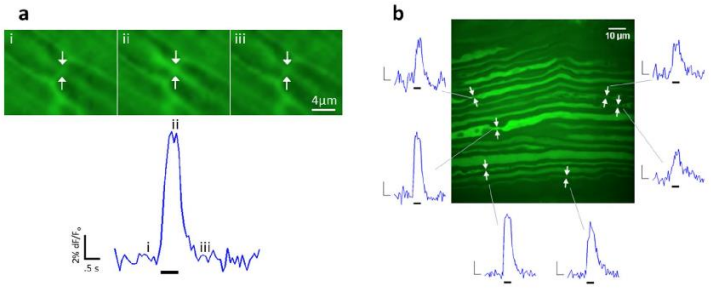

Figure 1: *Action potential elicited calcium signal detection in tibial nerve axon nodes of Ranvier [1].*

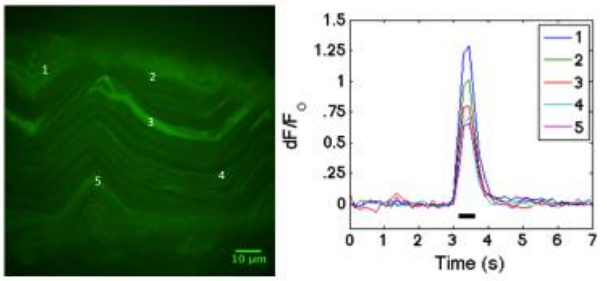

Figure 2: *Action potential elicited calcium signal detection in vagus nerve axons with GCaMP6f.*

The Bidirectional Optogenetic Neuronal Interface system is based on the principal of two-photon (TP) excitation**[8,9].** In TP excitation, a fluorophore is excited by short pulses of laser light. TP excitation offers intrinsic axial cross sectioning because the process only occurs at the focus of the objective lens. The technique offers resolutions of 175 nm lateral and 451 nm axial for 900 nm light focused with a 1.2 NA objective. This approach, when combined with a lateral scanning head, provides axon scale resolution that can be used to selectively interrogate an axon while excluding signals from the remaining tissue.

Peripheral nerve *read-out* of activity using calcium-sensitive fluorescent reporters: We have demonstrated read-out of genetically expressed activity-dependent calcium indicators, such as GCaMP6f, has been demonstrated in other work in vitro**[10]** [**Figure 1** & **Figure 2**]. We have also shown how a viral vector might be used as a mechanism for delivery of long-term optical protein expression in mouse neurons for optical read-out **[11]. Selective photo-stimulation (*read-in*) in nerve:** We have also demonstrated the ability to selectively read-in (or stimulate) to nerves optically [**Figure 3**].

Here we further demonstrate the feasibility of using optical approaches for prosthesis control by imaging the axonal fluorescence produced by action potentials travelling in an in vitro mouse nerve and using the change in image intensity to drive a prosthetic hand in real-time. This work provides a proof-of-concept for an optogenetic nerve interface demonstrating as it does our ability to read-out signals at the axonal scale in real-time and apply it to a devices control.

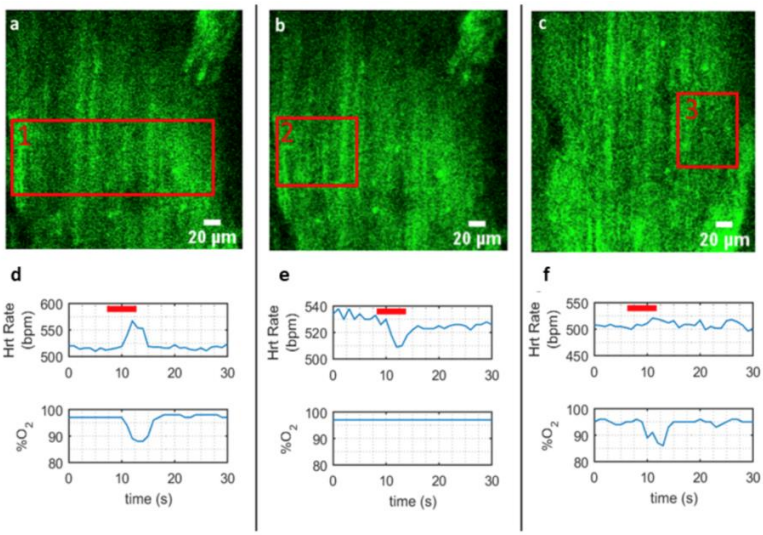

Figure 3: *Spatially selective photo-stimulation elicits differential vitals responses. (a-c) Regions (1-3) of 1040nm photo-stimulation within the cervical vagus nerve of an anesthetized ChAT-GCaMP6s mouse. (d-f) Corresponding vitals responses to photo-stimulation; region 1 elicits an increase in heart rate and a decrease in oxygen saturation; region 2 elicits a decrease in heart rate and no change in oxygen saturation; region 3 elicits a decrease in oxygen saturation. 1040nm stimulus was applied for 4 seconds with 20 ms pulses at 20 Hz.*

METHODS

Nerve Preparation: The sciatic nerve and its tibial nerve branch are excised from adult wild type mice and loaded from the tibial end with a synthetic calcium indicator (2 mM Calcium Green-1 Dextran, ex/em = 506/531 nm) dissolved in a buffer containing 130 mM KCl and 30 mM MOPS, pH 7.2 in *accordance with Supplementary Figure 1, Fontaine et al, 2017* ***[11]*** **(Figure 4) .** The tibial end is freshly cut in a zero-calcium buffer to ensure open axon cylinders before being suctioned into a tight-fit electrode with the dye buffer to facilitate longitudinal axonal dye-loading via diffusion and/or axoplasmic transport. The suction electrode on the tibial nerve also serves to record electrical activity within the nerve. The sciatic end of the nerve is drawn into a suction electrode for electrical stimulation of compound action potentials (CAPs). All experiments were performed in accordance with our Institutional Animal Care and Use Committee (IACUC) regulations and approved protocol.

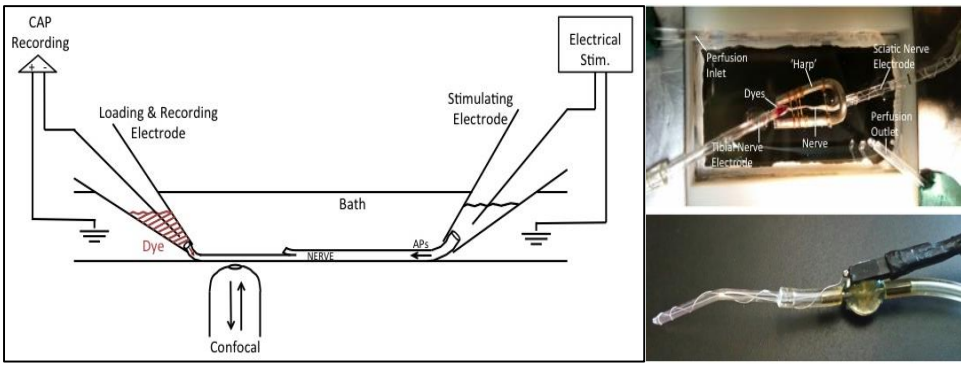

Figure 4: *Nerve dye-loading, electrophysiology & imaging configuration*

Electrophysiology: CAPs are generated and recorded throughout the experiment using 50 µs square pulses to confirm and monitor nerve viability. The stimulation voltage threshold for maximum CAP amplitude is determined. CAP amplitudes were monitored throughout the duration of the incubation period, to confirm stable nerve health.

Optical Imaging/Recording: Dye labeled axons were imaged in a region of nerve near the tibial recording electrode. The nerve was gently pressed to the optical glass of the chamber with low-tension silk strings attached to a small weight for imaging on an inverted microscope. Placement of the small 'harp-like' device did not affect the CAP. Fluorescence imaging was performed on a spinning disk confocal microscope (Intelligent Imaging Innovations, Marianas). A 515nm laser line was used to excite the Calcium Green-1. Pixels were binned (2x2) to improve the frame read-out time for fast imaging. To record calcium transients, time-lapse images were acquired at 12-20Hz (motor update rate), during which the nerve was stimulated by an electrical stimulator triggered via TTL pulses from the microscope. Fluorescence was imaged onto an EMCCD camera (Photometrics Evolve) through a 525/50nm emission filter. Images were collected with a 63X, 1.4NA oil-immersion objective lens. Photobleaching of the signal was kept minimal by the reduction of laser power and exposure, and any mild decay due to photobleaching was not removed.

***Prosthetic Hand Modification*:** The electronics in the original Bebionic v2 hand (RSL Steeper, UK) **(Figure 5)** were replaced with a custom motor controller system (Sigenics Inc., Chicago, IL) and included a central Arduino controller board and six

satellite boards referred to as 'penny boards' (as they were the size of a penny). Each penny board was connected by a four-wire I2C bus with each board associated with an individual finger for finger flexion/extension with two for the thumb to drive flexion/ extension and abduction/ adduction. For velocity control motor commands indicating the speed and direction of motion for the driven finger were sent from a Matlab script to the Arduino (SparkFun Electronics, Boulder, CO) which converted the serial commands into I2C commands. Position encoder values from the prosthetic finger motor were recorded simultaneously and converted to joint angle measurements post hoc. For the Bebionic the fingers can flex from 0-95° and run at a max speed of about 2 rads/sec. For position control, desired finger position is sent over the I2C bus to the motor controller and a local on-board PID loop handles positioning of the finger.

Control Interface and Method: A standard laptop computer running SlideBook 6.0 software (Intelligent Imaging Innovations) took the raw time-lapse images from the microscope and sent them to a custom Matlab program (Mathworks, MA) which calculated the intensity of the region-of-interest

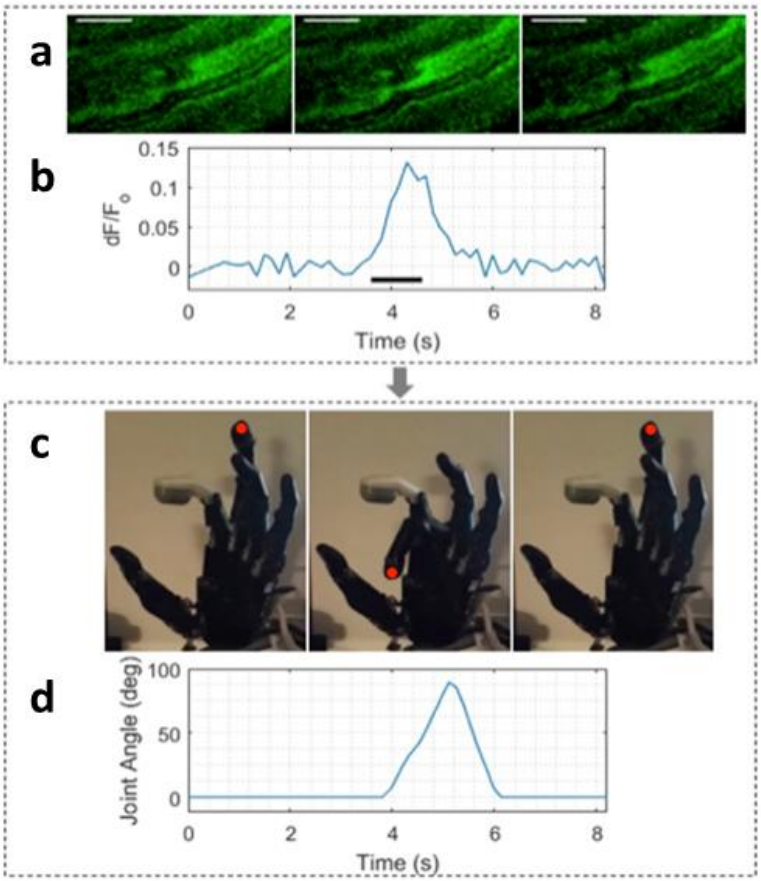

Figure 6*: Real-time prosthetic digit actuation by action potential evoked calcium fluorescence signal in a peripheral nerve axon. (a) Confocal images of a CalciumGreen-1-Dextran-loaded axon node-of-Ranvier used to control finger actuation, shown before, during and after the activity-induced fluorescent signal (scale bar 10μm). (b) Quantitative trace of the calcium-fluorescence signal in response to the 1s, 100Hz train of action potentials (black bar). (c) Prosthetic hand's middle finger flexes and extends under control of the optical signal from panel b. Virtual red dot denotes the tip of the middle finger driven in the experiment. (d) Corresponding finger joint angle illustrates digit flexion occurring during supra-threshold optical control signal.*

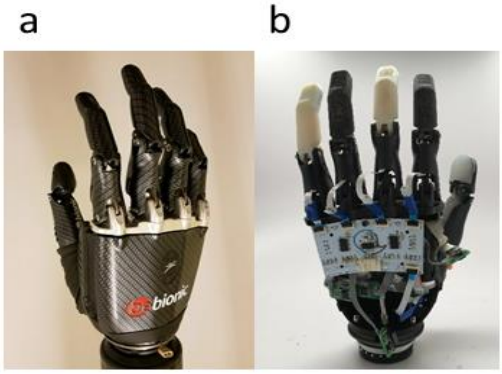

Figure 5*: (a) Commercially available Bebionic v2 hand (b) Modified Bebionic hand used for finger actuation experiments. Custom electronics were installed in order to control individual motors within the prosthesis. The Bebioinc has motor encoders that can measure finger position and be used in closed -loop control..*

(ROI) on the selected axon and based on the computed value sent commands to the motor controllers of the prosthetic hand via a serial link. A setup function in the Matlab script established the serial communication between the computer and the prosthetic hand. A second function received the time-lapse captures from SlideBook and translated the image data into an optical signal by averaging nodal ROI pixel intensities in each frame. The change-in-intensity is the control signal-of-interest. We see a baseline intensity for zero firing rate and a 15-18% for a firing rate of 125Hz. Since baseline is not constant, we set a threshold of 2%. This gives us our command signal range: for 0-125hz we expect a 2-18% dF/F which should map to 0-100% of our command signal for the motor. Initially we mapped the optical signal to the prosthetic finger velocity in an open-loop velocity control paradigm that is standard-of-care [**12**]. The hand was set up in a "cookie-crusher" configuration so single-site control could be used. In this case when the amplitude of the signal rises above the optical signal threshold the finger was driven in flexion at a speed proportional to the change-in-intensity. Velocity gains were adjusted to achieve a full range of motion.

RESULTS

An axon which fluoresced in response to the simulated motor command was selected. The calcium response originated at the center of the selected node-of-Ranvier and propagated bi-directionally into the internodal region of the axon. The nodal region, which was used for the motor command signal, showed approximately

12% change (dF/F) in fluorescence intensity. This signal amplitude was comparable to that achieved in prior work for an action potential pulse train frequency of 100 Hz [12]. Since an open-loop velocity control paradigm was employed, the digit was driven in flexion for the duration of the supra-threshold optical signal at a rate proportional to the signal intensity (about 1.5 rads/sec). Upon cessation of the command signal the finger is driven in extension at max speed (2 rads/sec) until the hand is fully open, per the cookie-crusher paradigm (**Figure 6).**

Proportional Control was demonstrated using previously recorded signals collected for a range of action potential pulse trains frequencies which were then used post-hoc to drive fingers in a position-control paradigm. As characterized in earlier work **[10]** average fluorescence amplitudes of sustained stimulus are linearly modulated by the action potential pulse train frequency. Such graded signals therefore encode intensity of the motor command. The fingers flexed to a position proportional to the intensity change produced by action potential pulse train frequency which was modulated between 25-125Hz (**Figure 7).**

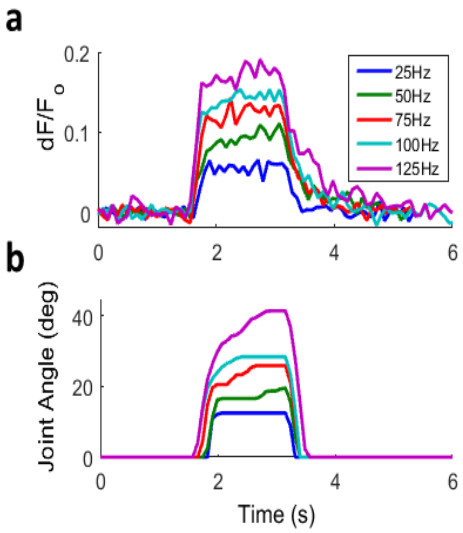

Figure 7: *Motor flexion of the prosthetic digit is graded by the action potential pulse train frequency of the optical calcium signal. (a) Graded calcium-fluorescence transients in an axon node-of-Ranvier in response to a range of action potential frequencies. (b) Resulting finger joint angles of the prosthetic finger as driven with control signals from panel a.*

While previous studies have optically stimulated peripheral nerve axons for functional modulation of motor units [13-15] using the light-activated ChannelRhodopsin2 (ChR2) there is an absence of literature describing the use of optically obtained signals from peripheral axon activity for device control. However, the range of action potential frequencies used to drive the prosthesis in this study is within a physiologically relevant range since action potential pulse train frequency typically varies between 15-500Hz (in the non-refractory range). The control signal was derived from a 1 second, 100 Hz action potential burst would likely correspond to a low-side motor command. The present experiments demonstrate the potential for read-out and control using an *ex vivo* model. In other work [11] we have demonstrated that similar signals (dF/F) can be obtained using a genetically encoded calcium indicator, GCaMP, with a retro-viral (rAAV) delivery.

CONCLUSIONS

Proof-of-concept for an optogenetic nerve interface is demonstrated by showing our ability to read-out signals at the axonal scale in real-time and apply it to the control of a prosthetic hand. Optical signals generated by frequency modulated action potentials in an axon were transduced to provide proportional prosthetic finger actuation.

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MOTOR UNIT SUBSET SELECTION FOR SCALABLE REAL-TIME INTERFACING

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ABSTRACT

Current methods for motor unit (MU) based human-machine interfacing do not scale well with the expansion of output functionality. This is due to the high computational demands of the initial MU parameter extraction via decomposition of high-density surface electromyography recordings. We propose an alternative approach that relies on task-specific batch decomposition processes along with a MU subset selection step to address feature redundancy. Offline analyses were conducted using EMG and kinematics pertaining to 18 wrist/forearm motor tasks recorded from 11 able-bodied subjects. The mutual information-based minimal Redundancy Maximal Relevancy (mRMR) feature selection framework was tested and compared to Maximal Relevancy (MR) and two arbitrary selection methods. Subset MUs were then used for joint kinematics estimation corresponding to those 18 motor tasks by three different regressors. The mRMR selection scheme was found to retain MUs with the highest predictive power. When the portion of tracked MUs was reduced to 25%, regression accuracy decreased by only 3.5%.

INTRODUCTION

The firing times of motor neurons are the most basic unit of neural drive responsible for instigating muscle force generation. Such information could be leveraged to facilitate more intuitive and dextrous human-machine interfacing (HMI). The application of blind source separation techniques on high-density surface electromyography (EMG) recordings has been previously used to estimate the motor unit (MU) firing times embedded within the surface signal [1], [2]. Such methods have been extended to online applications which permit real-time interfacing driven by the direct firing activity of MUs. So far, this has been demonstrated in control of up to 2 Degrees of Freedom (DoFs) [3], [4].

Current methods for MU-based interfacing do not scale efficiently with the expansion of supported functionality due to the high computational demands of the initial decomposition phase. In particular, the gradient-based and fixed-point iteration methods used to optimize separation vectors scale poorly with the significant increase in data that accompanies each supported function. We propose conducting this initial extraction of MUs in a task-wise manner with separate batch processes to leverage distributed computing resources and to reduce the overall initialization time of the interface. To address the resultant redundancy in extracted sources, a MU subset selection step is implemented using feature selection techniques.

The feasibility of the proposed interfacing pipeline was analysed in cross-validation format using EMG from 18 motor tasks pertaining to the single and pair-wise combined activations of three wrist/forearm DoFs. From the train data set, MUs were identified via task-wise batch decomposition and MU subset selection was performed. The minimal Redundancy Maximal Relevancy (mRMR) feature selection scheme proposed in [5] was tested along with Maximal Relevancy (MR) and two arbitrary schemes based on randomness and MU activity. From the test data set, the activities of subset MUs were extracted with an online decomposition algorithm and used for kinematics estimation. Results using three regression algorithms: linear regression (LR), multilayer perceptron (MLP) and kernel ridge regression (KRR) were obtained. Assessment of the selection criteria was made based on the changes to open-loop estimation accuracy as subset sizes were reduced.

METHODS

Subjects

Eleven healthy subjects, seven male and four female, all right-handed, aged 26-34, participated in the experiment. The study was approved by the local ethical board of Aalto University and all participants gave their written informed consent in accordance with the Declaration of Helsinki.

Experimental Protocol

High density EMG was recorded from each subject's dominant side with three 8x8 electrode matrices spaced evenly around the bulk of the forearm. The channels were sampled at 2048 Hz by a benchtop bioamplifier (OT Bioelettronica, IT). Wrist joint angles and rotation were recorded at a rate of 80 Hz with three wireless Inertial Measurement Units (IMUs) (Xsens Technologies B.V, NL) attached to the posterior sides of the upper-arm, mid-forearm and hand. Subjects were seated upright with their recorded limb relaxed by their side. Three repetitions of single and pair-wise combinations of motions pertaining to wrist flexion/extension (FL/EX), radial/ulnar deviation (RD/UD) and forearm pronation/supination (PR/SU) were recorded with trapezoidal activation profiles of 2 s ramp time and 10 s plateau time resulting in a dataset of 18 motor tasks. Recordings and analyses were carried out using an in-house developed Matlab (MathWorks Inc, MA, USA) framework. Offline analyses were conducted in cross-validation format where the training set comprised of two repetitions of each motor task while the test data was formed from the remaining repetitions. Initial MU extraction, subset selection, and estimator training were conducted with the train set while the pseudo-online decomposition algorithm was applied to the test set to simulate the real-time interfacing.

Batch and Online Decomposition

The batch decomposition methodology employed in this work follows that of [1] while the online decomposition algorithm is based on the methods proposed in [3], [6]. In brief, the batch algorithm sequentially estimates a set of separation vectors, **B,** that compensates for the action potentials of their respective MUs and de-mixes the source activities, **S,** from an extended EMG, $\tilde{\mathbf{Z}}$, that has been centered and then whitened with **W**:

$$\mathbf{S}_c = \mathbf{B}_c'\mathbf{W}_c\left(\tilde{\mathbf{Z}}_c - \mathrm{E}[\tilde{\mathbf{z}}_c(k)]\mathbf{1}\right) \tag{1}$$

where $\mathbf{1}$ is a vector of ones of appropriate size, subscript $c \in \{1, \dots, C\}$ denotes the enumerated coding of a motor task and $C = 18$ in this work. Peak detection on each source signal, then k-means++ binary clustering of the peaks gives a set of spike cluster limits, $\Psi = \{(hi_n, lo_n), n = 1, .., N\}$. Following a refinement step, sources are vetted by their silhouette (SIL) score which is analogous to a pulse-to-noise ratio and lagged versions of extracted sources are discarded. The pseudo-online decomposition algorithm thus applies the pre-conditioning and separation vectors to unseen data for source extraction while stored clusters inform the estimation of spike times. The schematic for this process is given in Fig 1B which also shows the computation of the *decomposed spike count* feature vector, $\mathbf{x}(t)$, from windowed EMG, $\mathbf{Z}(t)$.

MU Subset Selection

A full feature matrix is first constructed by extracting the activities of all identified MUs over the full training data set. This is achieved by applying the online decomposition algorithm to extract the activities of MUs initially identified from individual motor tasks over the entire repertoire of training movements (Fig. 1A). To formulate the selection methods, it is convenient to define the activity of each MU as a random variable within set $F = \{x_n, n = 1, .., N\}$. The subset selection step now identifies a subset, S, based on some optimality criterion and future deployment of the online decomposition algorithm would only need to extract the activities of MUs within S.

Under the MR selection scheme, the MUs whose activities share the highest mutual information with the motor task annotation, ℓ, are prioritized:

$$\max_{S \subseteq F} \sum_{x_n \in S} \mathrm{I}(x_n; \ell). \tag{2}$$

where I(;) returns the mutual information between its argument variables.

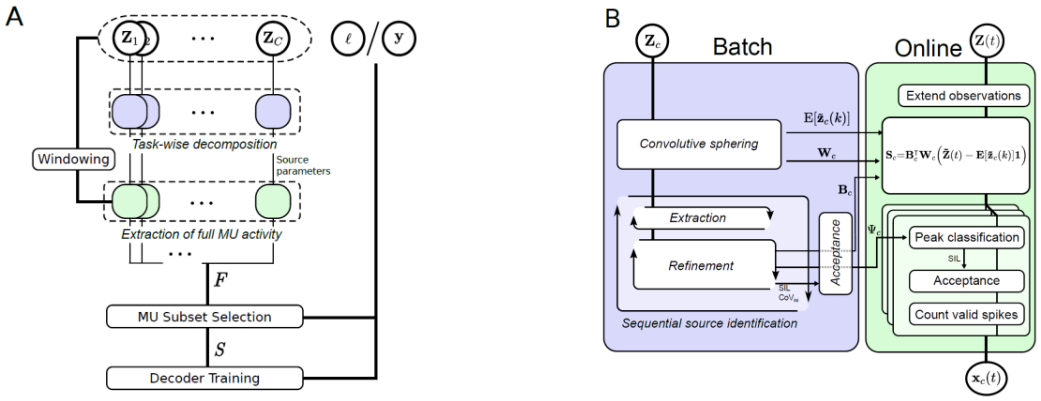

Figure 1: (A) Initialization process of the proposed MU-based interfacing. (B) Schematic for batch and online decomposition techniques showing the parameters that are transferred.

The mRMR scheme sequentially compiles S where, in each step, candidate MUs are also penalized by the mutual information they share with MUs that have already been selected. The criterion to satisfy at each step now writes as

$$\max_{x_n \in F-S} \frac{\mathrm{I}(x_n; \ell)}{\frac{1}{|S|}\sum_{s \in S} \mathrm{I}(x_n; s)}. \tag{3}$$

For comparative purposes, two naive selection schemes were also tested. The first is to select MUs by random while the second method prioritized MUs that were most active during the training movements.

Regression Algorithms

In LR, a linear mapping between S and kinematic labels ($\mathbf{y}$) is established by the Penrose-Moore pseudoinverse method. For MLP-based estimation, single hidden-layer feedforward networks using the tanh activation function are trained via the Levenberg-Marquardt backpropagation algorithm with each DoF estimated by a dedicated network while the optimal hidden-layer node counts are obtained via grid search. With KRR, a mapping is formed by the inner products between samples projected to a higher dimensional kernel feature space. The radial basis function is employed. Two hyperparameters, the ridge regularization scale and the kernel spread, are optimized via grid search.

Statistical Analysis

Decoding accuracy was gauged by the coefficient of determination (R^2) between estimated kinematics and ground truth. Repeated-measures ANOVA followed by Bonferroni-corrected pairwise comparisons were used to detect statistically significant differences between the different selection scheme and subset size combinations tested for each regressor.

RESULTS

On average, 20.3 ± 8.8 viable MUs were extracted via batch decomposition from the two training repetitions of each motor task.

Decoding performances from the different subset selection scheme and subset size combinations are shown in Fig. 2. Statistically significant differences were detected amongst the subset selection-size combinations for all decoding algorithms. Apart from the LR results, mutual information-based selection schemes (MR/mRMR) prevented significant performance drops when the number of MUs extracted for estimation were reduced by 50%.

Table I shows the average R^2 values yielded with subset sizes reduced to 25%. Overall, mRMR-selected MUs retained the highest predictive power and resulted in the lowest performance drops (-3.5%) while randomized selection performed the worst (-14.8%).

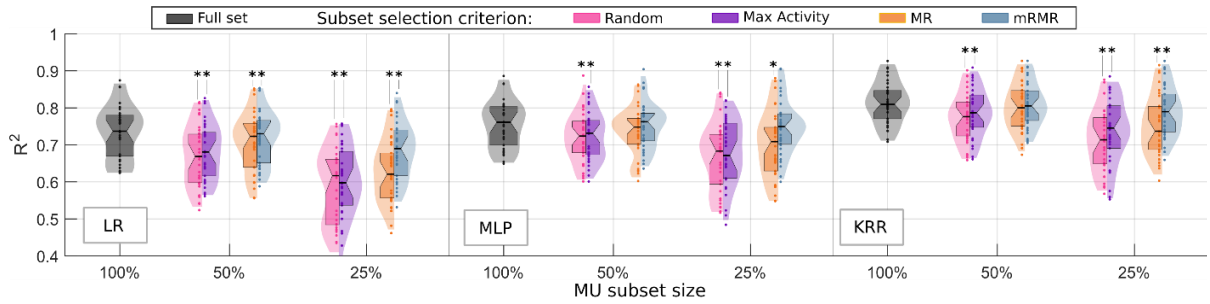

Figure 2: Violin plots of estimation performance of different regressors, MU subset selection methods, and MU subset sizes. Light shaded areas represent probability density functions estimated by kernel density estimation, while darker shaded blocks show the 1st-3rd quartile range. Corresponding medians are indicated by black notches. Statistically significant differences with corresponding full MU set are indicated by asterisks.

Table 1: Regression-based decoding performance (R^2) at MU subset size = 25%

	LR	MLP	KRR	Average
Full set	0.73±0.07	0.76±0.06	0.82±0.06	0.77±0.07
Random	0.58±0.11	0.67±0.09	0.71±0.08	0.65±0.11
	-20.6%	-11.7%	-12.6%	-14.8%
Max Activity	0.6±0.10	0.68±0.09	0.74±0.08	0.67±0.11
	-18.5%	-10.1%	-9.7%	-12.6%
MR	0.63±0.09	0.70±0.09	0.75±0.08	0.69±0.10
	-14.6%	-7.1%	-7.8%	-9.7%
mRMR	0.69±0.08	0.75±0.08	0.79±0.07	0.74±0.09
	-6.8%	-0.08%	-3.0%	-3.5%

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PROPORTIONAL ELECTROMYOGRAPHIC CONTROL OF A BIONIC ARM IN A PARTICIPANT WITH CHRONIC HEMIPARESIS, MUSCLE SPASTICITY, AND IMPAIRED RANGE OF MOTION: A CASE STUDY

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ABSTRACT

The long-term goal of this research is to restore intuitive and proportional motor control to stroke patients with an assistive exoskeleton. Stroke is the leading cause of disability in the United States, with 80% of stroke-related disability coming in the form of hemiparesis, presented as weakness or paresis on half of the body. Current electromyographic-(EMG)-controlled assistive exoskeletons do not allow for fine force regulation. That is, current control strategies provide only binary, all-or-nothing, control based on a linear threshold of EMG activity. In this case study with one hemiparetic stroke patient, we show that state-of-the-art EMG control algorithms can provide proportional control of a bionic arm despite weak and spastic muscle activity. The participant completed a virtual target-touching exercise with an EMG-controlled bionic arm by attempting to grasp (close) or extend (open) their hand. The participant completed the task under two conditions, with EMG from their paretic arm and with EMG from their healthy, contralateral arm. For grasping, there was no statistical difference in task performance for the paretic and healthy arms, but there was a significant decrease in the EMG signal-to-noise ratio for the paretic arm. For extension, there was a significant decrease in both task performance and EMG signal-to-noise ratio for the paretic arm. Despite these differences, the participant was still able to complete the target-touching task with the paretic arm. These preliminary results show it is possible, for at least some patients, to provide proportional control of assistive devices using weak and spastic EMG. Importantly, information regulating fine force output is still present in EMG despite a visually immobile arm due to hemiparesis. Future work will validate these findings with additional stroke patients with varying presentations of hemiparesis and move into controlling upper-limb exoskeletons.

INTRODUCTION

Stroke is the leading cause of disability in the United States, with more than 795,000 people suffering from a stroke each year. Eighty percent of stroke-related motor deficits are in the form of upper-limb hemiparesis [1]. Hemiparesis makes it difficult to complete activities of daily living and thereby reduces quality of life and autonomy. Upper-limb exoskeletons controlled by electromyography (EMG) have been shown to assist patients with hemiparesis in activities of daily living [2]. However clinical upper-limb exoskeletons typically use a binary, “all-or-nothing” control algorithm that makes it difficult to perform fine motor activities such as manipulating fragile objects. Previous studies investigating proportional EMG control from stroke patients have focused on force (torque) control of an elbow exoskeleton [3] and robot-assisted wrist movement [4]. However few studies have investigated the feasibility of proportional EMG control of the position of the hand for stroke patients.

Proportional control of myoelectric prostheses has been achieved through a variety of different algorithms, including k-nearest neighbors [5], support vector machines [6], Kalman filters [7], convolutional neural networks (CNNs) [8], [9], long-short term memory networks [10], and recurrent CNNs [11]. In this case study, we explored if a Kalman filter could also provide proportional control of a myoelectric prosthesis for a single patient with hemiparesis. We show that proportional control can be readily achieved using this widely-used algorithm despite significantly lower EMG signal-to-noise ratio and a visually immobile arm. We also show that, for at least some movements, the quality of the proportional control can be similar to that from healthy EMG.

METHODS

Human Subjects

This case study involved a single human subject. Informed consent and experimental protocols were carried out in accordance with the University of Utah Institutional Review Board. The participant was male, 44 years of age, and experienced a stroke four years prior to the study. At the time of the study, the participant had severe spastic hemiparesis on the left side of his body. The participant scored a 1 on the Manual Muscle Test, indicating no visible movement of the arm but a palpable tendon prominence and flicker contraction. The participant scored a 3 on the Modified Ashworth Scale, indicating a considerable increase in muscle tone that made passive movement of the hand difficult.

Signal Acquisition

Surface EMG (sEMG) from the participant was collected using a symmetric bilateral pair of custom EMG sleeves [8], such that each electrode roughly targeted the same muscle group across sleeves. EMG was sampled at 1 kHz and filtered using the Summit Neural Interface processor (Ripple Neuro Med LLC) as described in [7]. EMG features used for estimating motor intent consisted of the 300-ms smoothed mean absolute value on 528 channels (32 single-ended channels and 496 calculated differential pairs) calculated at 30 Hz, as described in [7].

EMG signal-to-noise ratio (SNR) was calculated by taking the mean absolute value of the EMG signal during movement and dividing it by the mean absolute value of the EMG signal during rest. EMG SNR was calculated for the 32 single-ended channels (i.e., one SNR value per each electrode for the sleeves on the right and left arms). EMG SNR was calculated separately for grasping (closing the hand) and extension (opening the hand).

Experimental Setup

The participant was instructed to mimic preprogramed movements of a virtual prosthetic arm (MSMS, John Hopkins Applied Physics Lab) with either their healthy or paretic arm. sEMG was recorded while the participant mimicked those movements (Fig. 1). Preprogramed movements included hand grasping (simultaneous flexion of D1-D5) and hand extension (simultaneous extension of D1-D5). Each movement consisted of a 0.7-s rise time, 3-s hold time, and a 0.7-s return to baseline, as described in [7], [9]. The participant completed ten trials of each movement. This exercise was completed separately for the healthy arm and the paretic arm.

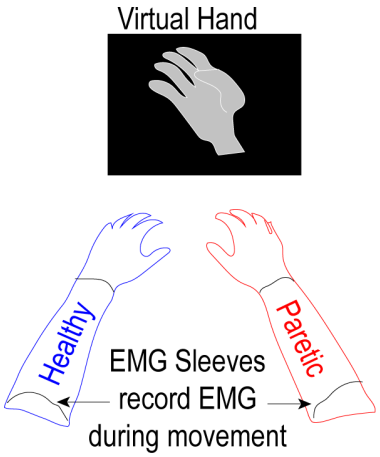

Figure 1: Experimental Setup. Participants were instructed to mimic the preprogramed movements of the virtual arm with their healthy arm or paretic arm. EMG activity was recorded using a symmetric bilateral pair of custom 32-electrode EMG sleeves.

EMG Control Algorithm

The EMG control algorithm used in this study was a modified Kalman Filter (MKF) [7]. The MKF provides an efficient recursive algorithm to optimally estimate the probability of hand movement when the likelihood model (i.e., the probability of the EMG activity given current hand position) and prior models (i.e., the state model of how position changes over time) are linear and Gaussian. In the implementation presented here, the MKF predicts the instantaneous position of the hand based on EMG activity of the arm at the current time point. The main difference between this study and [7] is that no threshold was applied to the output of the MKF.

Virtual Target-Touching Task

To evaluate proportional control of both arms, the participant completed a target-touching task controlling the virtual arm and attempting to move it into a target window. In this task the targets were placed at 50% of the maximum flexion and extension. Importantly, training data for the MKF was collected at 100% of the maximum flexion and extension, and thus, the task provides a measure of how well control extrapolates to novel intermediate positions. For each trial, the participant was instructed to stay within the target window for 5 seconds. The participant was instructed to relax between trials for 2 seconds for the healthy arm and 10 seconds for the paretic arm. The targets had a ±10% error tolerance, such that the participant received visual feedback indicating when they were within the target window.

The participant completed 20 trials of hand grasping and 20 trials of hand extension for both the healthy and paretic arms.

The root mean square error (RMSE) was calculated between the target window and the participant's kinematic output, such that values within the target window resulted in an RMSE of 0. The percent time within the target window (PTT) was calculated as the total time that the participant's kinematic output was within the target window out of the total duration of the task (five seconds).

Statistical Analysis

SNR, RMSE and PTT data were tested for normality using the Anderson-Darling test of normality. Paired t-tests were then performed between the healthy and paretic for each performance metric.

RESULTS

Paretic EMG had Lower SNR for Both Hand Grasping and Hand Extension

EMG activity during instructed hand grasping was visually similar between the paretic and healthy arms (Fig. 2A). In contrast, EMG activity during instructed hand extension was substantially less for paretic arm compared to the healthy arm (Fig. 2B). For both hand grasping and hand extension, SNR was significantly less for the paretic arm compared to the healthy arm (Fig. 2C).

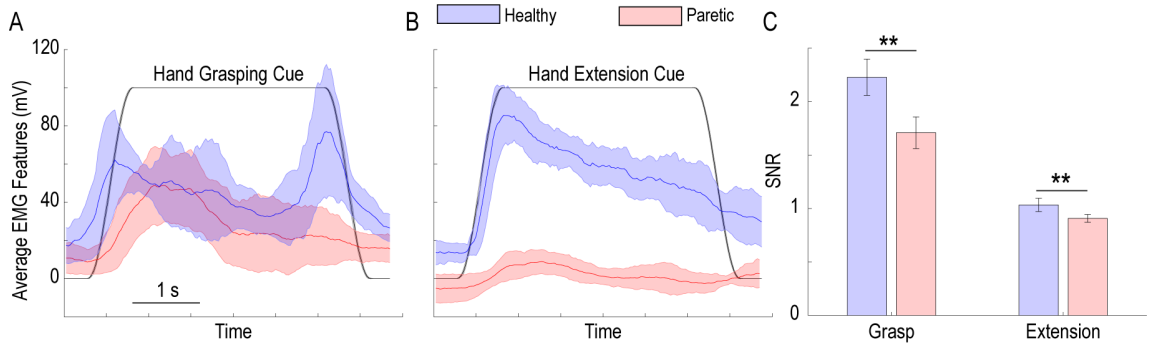

Figure 2. EMG activity from paretic and healthy arms during instructed hand grasping and hand extension. A) The average EMG feature (mean absolute value) of the healthy arm (blue) and the paretic arm (red) during instructed hand grasping (black line). Data show mean and standard deviation. B) The average EMG feature of the arm during instructed hand extension. C) SNR of the paretic EMG was lower than that of the healthy EMG for both movements. Data show SNR from the 32 electrodes for both the EMG sleeves on the paretic and healthy arms. Data show mean and standard error of the mean. ** $p<0.01$, paired t-test, n=32 electrodes.

Proportional Control Possible for Both Arms, but Worse for Paretic Hand Extension

The participant was able to complete the virtual target-touching task with EMG control from both their healthy and paretic arms. Kinematic output was similar between the paretic and healthy arms during instructed hand grasping (Fig. 3A). The average kinematic output was also similar between the paretic and healthy arms during instructed hand extension, however, kinematic output was less precise for the paretic hand, as evidenced by a larger standard deviation (Fig. 3B). For hand grasping, the participant had no significant differences between their paretic and healthy arms for RMSE (paretic arm 12.2% worse; Fig. 3C) and PTT (paretic arm 2.6% better; Fig. 3D). For hand extension, the participant's performance was significantly worse for their paretic arm compared to their healthy arm; RMSE was 128% worse (** p<0.01, paired t-test) and PTT was 52.4% worse (** p<0.01, paired t-test).

Importantly, despite significantly worse performance with the paretic arm for hand extension, the participant was still able to control the hand proportionally and complete the virtual target-touching task. The RMSE and PTT values reported here are similar to those found with amputees (RMSE means ~0.1; PTT means ~0.5 (Citterman et al., MEC 2022)) and healthy participants (RMSE mean ~0.15, PTT between 0.14 and 0.43) [12]. Thus, even the worst control the participant experienced was equivalent to that of other healthy participants. The participant was particularly excited about their ability to finely control the virtual bionic arm, despite the fact that his hand did not visually move. In a spontaneous moment of joy, the participant took out his phone to record a video of the virtual hand gently opening and closing.

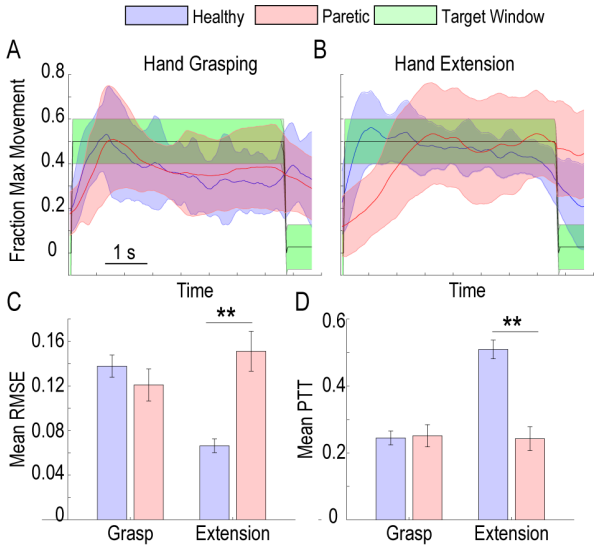

Figure 3. Performance of the virtual target-touching task for the healthy arm (blue) and paretic arm (red). A) Participant's kinematic output when attempting to perform a partial hand grasp (50% output). Data show the mean and standard deviation of the kinematic output across the 20 trials of the task. The green area represents the target window that the participant was attempting to remain within. B) Participant's kinematic output when attempting to perform partial hand extension (50% output). C) The RMSE between the participant's kinematic output and the target window was significantly greater for the paretic arm for hand extension (i.e., the paretic arm had significantly worse performance). No significant difference was found for hand grasping. Data show the mean and standard error of the mean across the 20 trials of the task. D) Similarly, the PTT was significantly less for the paretic arm for hand extension (i.e., the paretic arm had significantly worse performance). No significant difference was found for hand grasping.

CONCLUSSION

This case study with one participant shows promise in advancing and improving control for upper-limb exoskeletons for use after stroke. We specifically show that even though there are significant differences between the EMG signal between the healthy and paretic arms, widely-used myoelectric control algorithms can still extract useful information related to fine force regulation and provide proportional control in real-time. We also show that for at least some movements, performance can be equivalent to that of healthy EMG. Future work will extend this study to more participants and validate real-time proportional control with an exoskeleton manipulating fragile objects.

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ROBUSTNESS OF FREQUENCY DIVISION TECHNIQUE IN A SIMULTANEOUS AND PROPORTIONAL MYOELECTRIC CONTROL SCHEME

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ABSTRACT

It is important for myoelectric control schemes to be robust to various non-stationarities in electromyography (EMG) signal such as unintended activations and contraction level variations. In order to address this limitation, the present study compared performance measures of two EMG processing pipelines with two filtering techniques: frequency division technique (FDT) and standard bandpass processing (Bandpass) in a simultaneous and proportional myoelectric control (SPEC) scheme for two contraction levels (medium and high). Twenty able-bodied participants (14 males and 6 females, age 23.4 ± 3.0) performed wrist movements (flexion/extension, rotations and combined movements) in two degrees-of freedom (DOF) virtual tasks. FDT had a mean completion rate (CR) of 95.33%, which was significantly higher than the SPB technique with a CR of 64.08% ($p<0.001$). FDT method performed significantly better in all other performance indices in at least one movement type. Furthermore, there was no significant difference in the performance of FDT between medium and high contraction levels, while there were such differences for bandpass filtering. This study showed that FDT is advantageous in regression based online myoelectric control as it generates a more accurate, robust and contraction level invariant scheme for performing prosthetic hand movements. This study is the first to use frequency-based features with a SPEC scheme and shows promise for more intuitive prosthetic devices.

INTRODUCTION

Myoelectric prostheses use EMG signals for performing prosthetic functions. Conventional control of a myoelectric prosthesis involves mapping the amplitude of EMG signals to the desired prosthetic function. Challenges with the direct control scheme such as EMG crosstalk have led to the use of pattern recognition (PR), a machine learning approach that classifies EMG features to activate different prosthetic functions [1]. Currently, the state-of-the-art PR technique uses linear discriminant analysis (LDA) classifiers applied to a set of time domain (TD) features [2]. However, PR techniques only allow control of one DOF at a given time (sequential control) which is contrary to the natural control flow of the neuromuscular system. In order to achieve a more natural hand movement, simultaneous rather than sequential control is more desirable. Recently researchers have explored regression techniques, which allow for simultaneous and proportional control of the prosthesis [3, 4]. It has been found that linear regression (LR) performed superior to PR in an online closed loop setup [4]. The promising results of regression techniques has warranted further research to improve control of current prosthesis.

However, regression and PR techniques demonstrate relatively poor performance in real-world conditions due to the non-stationarities in EMG patterns and the noise introduced from different sources [5]. These variations or the non-stationaries in EMG may be caused by several factors including variations in training muscle contraction levels [6] and activation of an undesired degree of freedom [7, 8] are critical. One filtering approach using a frequency division technique (FDT) was proposed to increase varying contraction levels in PR-based myoelectric control [9], and this approach was demonstrated in a closed-loop online PR experiment [10], where. the control scheme with the FDT filter was found to be robust against varying levels of training contraction and it performed significantly better than the traditional band-pass technique. Further research with the FDT filtering on simultaneous and proportional myoelectric control (SPEC) scheme paired with FDT is warranted to corroborate findings in the PR-based myoelectric control scheme. Therefore, the purpose of this study was to compare the performance of the FDT and the traditional bandpass processing on a linear regression (LR) based online myoelectric control scheme while intact subjects completing virtual tasks. This study also examined the effects of varying training contraction level on the performance of the FDT based myoelectric control scheme to determine its robustness against force variation.

METHODS

Frequency Division Technique (FDT)

The FDT directly calculates the spectral power of various frequency bands of sEMG using discrete Fourier transform (DFT) by dividing the full bandwidth of sEMG signals into L segments. For the ith segment, let $f_{i,1}$ and $f_{i,ni}$ denote the frequency values of the two endpoints. The feature is defined as

$$DFT_i = F\left[\sum_{j=1}^{n_i}\left|X\left(f_{i,j}\right)\right|\right], \text{i=1,2,...}L \qquad (1)$$

where, $X(\cdot)$ denotes the magnitude of the FFT spectrum, F denotes a non-linear smoothing function. In the current study, F is the root operator is used with a value of 2/3. The whole frequency band of EMG (20-450 Hz) is subdivided into six (L=6) equi-width frequency bands (20-92, 92-163,163-235,235-307,307-378, and 378-450 Hz) [10].

Protocol

Twenty intact-limbed participants (6 females and 14 males) with a mean age of 23.4±3.0 years participated in the study. The study was approved by the University Research Ethics Board (REB 2018-079). The participants were asked to sit on a chair in an upright position with both of their upper limbs in a resting position. They faced a computer screen, at an approximate distance of 75 cm. Eight equally spaced (19 mm inter electrode distance) bipolar electrodes (Duotrodes, Myontronics, Inc) were placed at approximately 1/3 distal measured from the olecranon process to the styloid process of the ulna to cover the circumference of the forearm. A commercial wireless biosignal amplifier (Trentadue, OT Bioelettronica, Italy), sampled at 1000 Hz, was used to transmit the signals. The dominant forearm was used for the electrode placement.

Feature Extraction and Testing

The surface EMG signals were processed initially using the common averaging method [10]. This was followed by two filtering techniques for two separate analyses, the band-pass filtering and FDT. The Bandpass filtering involved applying a bandpass filter (second order, Butterworth) from 20 Hz to 450 Hz followed the TD feature set extraction [10]. For FDT, the signals from each channel were divided into specific frequency sub-bands. LR was used for the simultaneous and proportional scheme. The outcomes of the regression model were mapped to the virtual task.

The experimental testing session consisted of two phases: 1) calibration phase and 2) control phase. The window size for processing was set to150 ms and the regression models provided an output every 50 ms. The calibration phase involved training a regression model using EMG signals with position labels of the cursor during wrist flexion/extension (DOF1) and hand pronation/supination (DOF2). In the calibration phase, the participants were instructed to follow the position of a cursor on a screen. In the training phase, the subjects performed two contraction levels: the wrist movements at the normal contraction level, *i.e.* 'train-medium', and wrist movements at a strenuous contraction level, *i.e.* 'train-high'.

From the data acquired in the training phase, a LR model were generated for each of the combination of the two contraction levels, *i.e. train-high* and *train-medium* and two filtering techniques: Bandpass, and FDT, resulting in four experimental sets in the control phase: medium-Bandpass, medium-FDT, high-Bandpass and high-FDT. In the subsequent control phase, the participants performed goal-directed tasks using the four LR models in a random order [10]. In each experimental session, 20 targets from each type of task group, termed type I, type II, and type III at

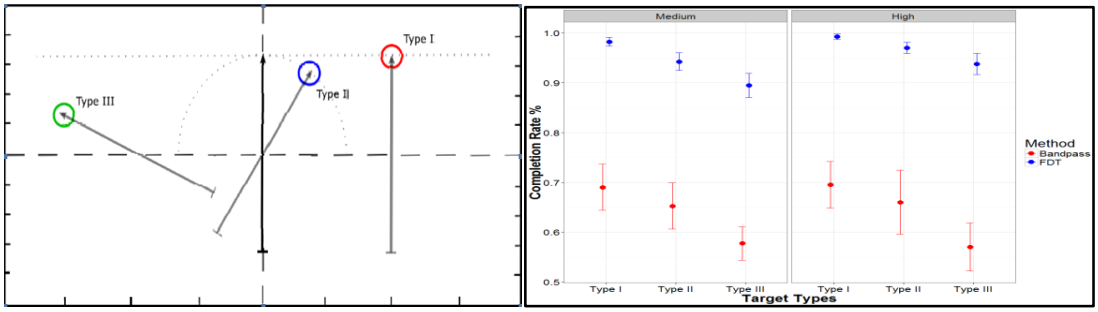

Fig. 1. Left: Goal oriented tasks: type I (flexion/extension DOF only), type II (pronation/supination DOF only) and type III (combination of flexion/extension DOF and pronation/supination DOF). The grey arrow represents the desired position for the completion of the tasks. Right: Mean CR for varying contraction levels (train-medium and train-high) and different processing methods (Bandpass and FDT) for the three types of targets (type I, type II and type III). The error bars represent the standard error.

different locations were provided on the screen (Fig. 2). The targets in type I only require the activation of wrist flexion/extension (DOF1), targets in type II require activation of wrist supination/pronation (DOF2), and targets in type III requires activation of both DOFs. The participants were instructed to place the tip of the arrow in the targets. Instead of sequential articulation of each DOF as in a PR-based control scheme, a simultaneous articulation of both DOFs was used. To measure the performance of these tasks, the performance indices used were: 1) completion rate (CR), the ratio of number of successfully completed task to the total number of tasks in percentage 2) time to reach (T2R), time taken to reach a target in seconds 3) throughput (TP) ratio of task difficulty and task completion time in bits/s and 4) near miss (NM), number of times the cursor enters the target but exits before the completion of 300 ms.

Kruskal Wallis (non-parametric test) was used to determine if the CR of the two filtering techniques were significantly different. Also, for the control participants repeated measures analysis of variance (ANOVA) was used to test for significant differences in mean performance indices (T2R, TP, NM) between FDT and Bandpass from successful trials. With significance resulting from the interaction of main factors the Bonferroni post hoc comparisons were performed to test significant differences in performance measures between FDT and Bandpass. For all the tests, level of significance was $p<0.05$. All the statistical tests were performed using RStudio 1.0. 136 (RStudio, Boston, MA).

RESULTS AND DISCUSSIONS

The mean CR of FDT was 95.33%, which was significantly higher ($p<0.001$) than Bandpass which had a mean CR of 64.08%. This indicates that FDT clearly outperforms the Bandpass. This was supported by the lower variability in CR for FDT compared to Bandpass, indicating less inter-subject variation. In addition, all participants performed equally well with FDT. The same training data was used to train both the processing/feature extraction methods. It was observed for most of the participants that while performing the Bandpass technique, the task arrow was unresponsive in at least one of four LR models. There was also frequent unwanted activation of the non-target DOF. For example, when an individual attempted a wrist extension there was undesired activation of supination as well. On the contrary, the FDT (CR>95%) was robust to unwanted activations and provided a more efficient control scheme. These activations have been briefly discussed by previous regression studies [7, 8], but there has been no detailed analysis on unwanted activations and it is crucial for further studies to research these non-stationarities and mechanisms of addressing them.

The mean T2R was significantly lower ($p<0.001$) for two types of targets (I and III) with FDT than Bandpass (Fig. 3). The mean TP was significantly higher ($p<0.001$) for two types (I and III) with FDT than Bandpass (Fig. 3). The mean NM of only type I target was significantly lower ($p<0.001$) for FDT. The Bandpass performed significantly better ($p<0.001$) than FDT for type II targets. A lower NM implies a more accurate position control. For FDT, the T2R and TP values suggested that the participants performed type I (horizontal only) and III (horizontal and rotation) tasks more easily and at a faster rate. Also, for both techniques, the variability was observed to be consistent for T2R, TP and NM (Fig. 3) suggesting that the participants had equal performance for all target types and across contraction levels. The overall TP and T2R values found in this research were comparable to previous study [10], however the NM was found to be higher. A possible explanation for higher NM is for some participants, the task arrow was unstable at higher pronation and supination angles, thus the participant had to hold it for longer increasing the NM. The mean NM was still low enough to allow real time control and the participants were able to complete tasks.

It was found that there were no significant differences in the mean values of any of the performance measures (CR, TP, T2R, and NM) between the train-medium and the train-high runs for FDT. For CR, the variability was lower

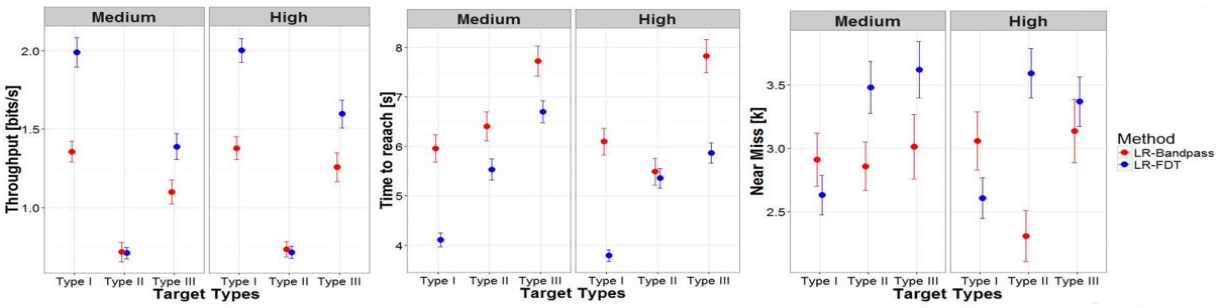

Fig. 3. (From left to right) Mean TP, T2R and NM values for varying contraction levels (train-medium and train-high) and different processing methods (Bandpass and FDT) for the three types of targets (type I, II and III). The error bars represent the standard error.

for FDT than for Bandpass (Fig. 2). For T2R, TP and NM, the variability was found to be consistent across contraction levels for both FDT and Bandpass (Fig. 3). This demonstrates that the performance of FDT is robust to contraction level variations while training. This observation agreed with the findings in [10], which used PR-based methods with FDT and found no difference between performance measures of medium and high contraction level variations [10]. Previously it has also been found out that the power spectrum of some frequency bands are not affected by varying contraction levels [9]. For the testing phase, the participants could perform tasks with any contraction level (medium or high). This finding is very important as the participant's control is independent of the contraction level performed during the training. A freedom of performing movements at a desired contraction level without any performance degradation would be beneficial for the prosthesis users to complete daily living tasks with limited errors.

CONCLUSION

The results from this study suggest that the proposed FDT performs significantly better than the Bandpass method in a LR-based control scheme. Also, the FDT technique is less variant to changing contraction levels. The two processing methods compared in the study used time domain (TD) features and frequency domain (FD) features. Most research studies to date have used the TD feature set. Results found in this study are promising and suggest a need for further research using FD features. The findings of this study directly relate to the robustness of FDT as a myoelectric control scheme which is critical for clinically viable advanced prosthetic control. In another research work (currently under review), the FDT technique demonstrated higher completion rates for individuals with trans-radial amputations compared to the Bandpass. Robustness against these non-stationaries allows users the freedom to operate a prosthesis at their desired contraction levels and prevents erroneous prosthetic functions. Thus, FDT in SPEC control scheme promises greater accuracy, robustness to varying contraction levels, and is more intuitive.

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SHARED-CONTROL DECREASES THE PHYSICAL AND COGNITIVE DEMANDS OF MAINTAINING A SECURE GRIP

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ABSTRACT

Upper-limb amputees commonly cite difficulty of control as one of the main reasons why they abandon their prostheses. Combining myoelectric control with autonomous sensor-based control could improve prosthesis control. However, the cognitive and physical impact of shared control and semi-autonomous systems on users has yet to be fully explored. In this study we introduce a novel shared-control algorithm that blends proportional position control predicted from electromyography (EMG) with proportional position control predicted from an autonomous machine using infrared sensors embedded in the prosthetic hand's fingers to detect the distance to objects. The user's EMG control is damped in proportion to the machine's prediction of an object's position in relation to a given finger. The shared-control algorithm was validated using three intact individuals completing a holding task where they attempted to hold an object for as long as possible without dropping it. Shared control resulted in fewer object drops, 32% less cognitive demand, and 49% less physical effort (measured by EMG) relative to the participant's EMG control alone. These results indicate that shared control can reduce the physiological burdens on the user as well as increase prosthetic control.

INTRODUCTION

Upper-limb amputees abandon prostheses at a high rate [1], [2], in part due to unintuitive and poor control [3]. One solution to improving prosthetic control is to automate the prosthesis using embedded sensors to aid in conforming the grasp to an object [4]–[7]. However, to date, autonomous prostheses have been designed to accomplish a specific task and are not necessarily adaptable to general use. Semiautonomous hands have been demonstrated to outperform human control when handling fragile objects [4] and can increase prosthesis contact area to a given object [6]. Although the benefits of shared control have been evaluated with respect to task performance, the impact of shared control on a user's physiological state (i.e., cognitive and physical effort) has not yet been evaluated.

In this study, we introduce a novel autonomous controller that predicts an object's distance from the fingers using embedded proximity and pressure sensors in the fingertips. We also introduce a novel shared-control algorithm that attenuates a user's EMG output based on the prediction of the autonomous controller. We validate the shared-control algorithm using a holding task, in which participants attempt to continuously hold an object while completing a secondary detection response task (DRT). We show that shared control improves grasp security and decreases the physical and cognitive burden on a user compared to that of EMG control alone. Making a hand more dexterous, while increasing its ease of use, may ultimately decrease prosthetic hand abandonment and increase patient quality of life.

DESIGN

Autonomous Controller

A left-handed TASKA hand (TASKA, Christchurch, New Zealand) was retrofitted with fingers containing pressure and infrared proximity sensors (Point Designs LLC, Lafayette, CO, USA) [4], [8]. A multilayer perceptron (MLP) was designed

with 10 hidden layers to predict object distance from the infrared and pressure sensors. Training data was collected by oscillating the thumb towards and away from white 3D-printed objects in the shape of a cylinder, cube, and cone. The ground-truth distance from the object for the training data was computed by measuring the kinematic position of the finger upon initial contact with the object (i.e., when pressure was first recorded), and then retroactively using the difference between that kinematic position and the current position to determine the current distance to the object. Example training data can be seen in Fig. 1. For training the MLP, 70% of the total data was randomly selected as the training data, 15% was selected for validation data, and the remaining 15% was used for testing. During run-time, the kinematic prediction from the autonomous controller was computed as the sum of the current position of the thumb and the predicted distance to the object.

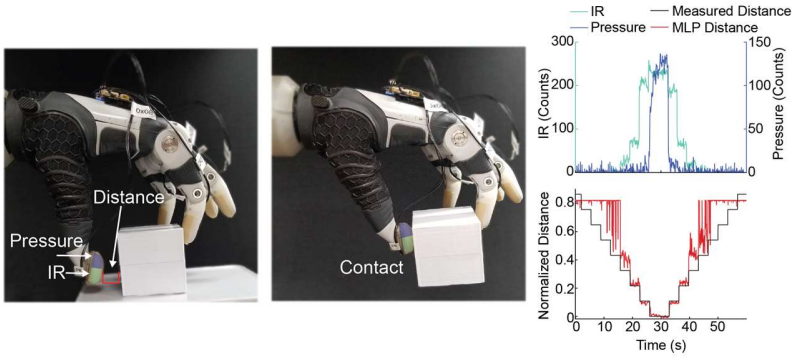

Figure 1: Labelled image of sensorized prosthetic hand (Left) and a subset of the training data used to create the autonomous controller (Right). Training data was collected using a cube, cylinder, and cone. The thumb was programmed to approach each object 20 times. Each approach consisted of incrementally moving the thumb forward, then waiting approximately 3 s before moving the thumb forward again. After contact, the thumb retracted from the object in a similar fashion. The autonomous controller is more accurate when the object is closer. That is, the predicted distance (red) more closely aligns with the ground-truth measured distance (black) as the distance becomes smaller.

METHODS

Human Testing

Three healthy intact participants (21.67±0.58 years old; 33% female) were recruited for this study. All the participants were right-hand dominant. None of the participants had prior experience with myoelectric prostheses. Informed consent and experiment protocols were carried out in accordance with the University of Utah Institutional Review Board.

Signal Acquisition

Surface EMG from the participants was collected using a custom EMG sleeve [9]. EMG was sampled at 1 kHz and filtered using the Summit Neural Interface Processor (Ripple Neuro Med LLC) as described in [10]. EMG features used for estimating motor intent consisted of the 300-ms smoothed mean absolute value (MAV) on 528 channels (32 single-ended channels and 496 calculated differential pairs) calculated at 30 Hz, as described in [10]. The embedded fingertip sensor readings were sampled at 30 Hz and passed through a median filter with a time window of 10 samples. Sensor drift was removed from the pressure sensors using a high-pass filter that was toggled on and off by the sensor crossing a threshold.

Shared Control

The human position goal, u_h, was computed using a modified Kalman filter (MKF) [11]. The MKF was fit to surface EMG (sEMG) data collected during five preprogrammed trials of full-flexion pinch between the thumb and index fingers and five trials of full extension of the same digits. Both control techniques only affected one degree of freedom in the form of a pinch grip between the thumb and index finger. To form the pinch grip, the index finger was set to a constant position while the thumb was flexed from 0 (felly extended) to 1 (fully flexed). Control of the hand was shared between the human position goal from the MKF, denoted u_h, and the machine position goal as computed by the MLP, u_m. Both human and machine control are normalized to a range of zero to one. The shared goal, u_s, was then computed as the following:

$$u_s = u_m + u_h(1 - |u_m|) \quad (1)$$

This effectively attenuates the human's control of the hand in proportion to the remaining range of the digit. A minimum threshold was set such that the thumb would only move if the infrared sensor rose above a given value. Once contact was detected, the machine predictions were frozen until the pinch was released by the human controller. An sEMG toggle was used to trigger the shared-control algorithm [4]. The sEMG toggle switched the user between shared control and human control based on the output of the MKF. For example, if the MKF predicted that the human was attempting to extend to a position

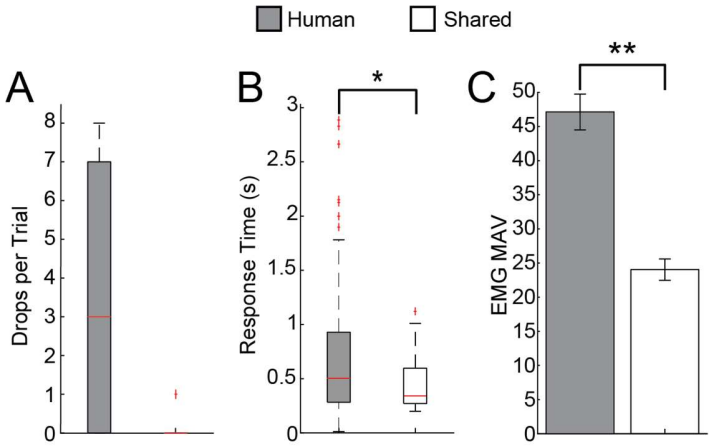

Figure 2: Task performance, cognitive effort, and physical effort required for the human control and shared control. A) Shared control improved grasp security as indicated by less total drops. B) Shared control also reduced cognitive demand, as evidenced by a significantly lower response time for the DRT ($p < 0.001$, Wilcoxon rank-sum test). C) Shared control also reduced physical effort, as shown by a significant decrease in the EMG MAV ($p < 0.001$, paired t-test). Bar plots show mean ± standard deviation. Box plots show median, inter-quartile range, and most extreme non-outlier value. Red pluses denote outliers.

greater than 50% of the extension range, the output would be switched to the human-only control scheme. To return to the machine-control state the user had to flex 1% of the flexion range. This aided the participant in releasing the object without altering the evaluation of the shared controller's performance during object grasping.

Task & Performance Metrics

The participants donned the prosthesis using a custom bypass socket [11]. The participants then completed a holding task in which they were instructed to use the prosthesis to pick up a white 3D-printed cube and hold it for two minutes without dropping it. If the object was dropped the participant was instructed to pick it up as quickly as possible and continue the task. The number of times the cube was dropped during a trial was recorded as a measure of grip security. The participant completed the holding task for four trials using human control and shared control in a pseudo-randomized counter-balanced format. While completing the holding task, the participant also simultaneously completed a tactile detection-response task (DRT) to measure their cognitive load [12]. The DRT requires the participant to push a button in response to a small vibrating motor on their collar bone. Both the response rate (i.e., how often they respond to the vibratory stimuli) and response time (i.e., how long it takes to press the button after a vibratory stimuli) are used as direct measures of cognitive load. The EMG MAV on the 32 electrodes was also recorded during the hold task as an indicator of the physical effort (muscle activity) needed to complete the task. Data was aggregated across all participants and screened for normality. Pairwise comparisons between the human control and shared control were then performed using a paired t-test for parametric data or Wilcoxon rank-sum test for non-parametric data. All values are reported and shown as mean ± standard deviation.

RESULTS

Shared control decreases cognitive and physical demands while increasing grip security

Combining human and machine control allowed the participants to hold the object more reliably than when only human control was used. Only one drop was recorded under shared control, whereas up to eight drops were recorded under human control, with a median of three drops per trial for human control (Fig. 2A). Shared control resulted in no significant difference in the response rate of the DRT compared to human control (63.19 ± 13.87% vs 63.58 ± 11.43%, respectively). However, participants had significantly faster response times to the DRT when using shared control, indicating less cognitive demand (0.719 ± 0.056 s vs 0.444 ± 0.022 s, respectively; $p < 0.001$, Wilcoxon rank-sum test; Fig. 2B). Furthermore, participants had significantly lower EMG activity with shared control than with human control (24.10 ± 10.48 vs 47.13 ± 17.53; $p < 0.001$, paired t-test; Fig. 2C).

Error in human-control is dampened in shared-control

Using the shared-control algorithm, the participants were able to hold an object more reliably while using less physical and cognitive effort. Example traces of the human control, machine control, shared control, and contact position from a single participant are shown in Fig. 3. The thumb

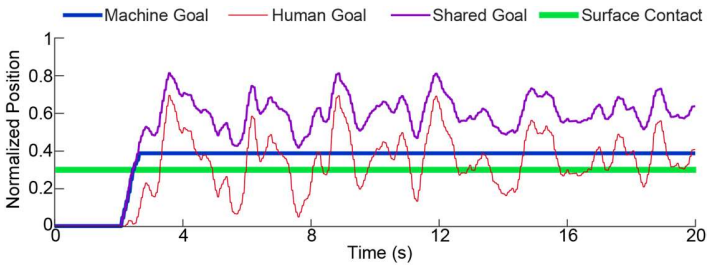

Figure 3: Example traces of the machine control (blue), human control (red), and shared control (purple) from the first 20 seconds of a shared-control trial. The shared-control signal is the result of calculating the goal using Eq. 1 using the human and machine control signals. The position at which the hand made contact with the object (i.e., pressure was detected) is shown by the green line, so any position goal above the green line increases the grip force while positions less than the green line indicate the grip releasing the object. Times when the human goal is below the green line represent times in which the participant would have dropped the object without the shared control.

made contact with the cube at a position of 0.3, and, although the machine did not give a perfect prediction, the thumb moves to a position near this goal. By starting closer to the object, and adding the two control techniques together, the shared algorithm is able to decrease the physical effort of the user. The human control also has a high degree of variability, and variations in the human goal below the point of object contact, would have resulted in multiple drops of the object. By scaling the human control based on the machine prediction, we effectively decreased the variability in the kinematic position. This in turn results in greater performance and less physical effort, which then allow the user to focus on other tasks.

DISCUSSION

In this study we demonstrated that sharing control between a human EMG decoder and an autonomous controller can benefit the user by decreasing their physical and mental effort while increasing their grip security on a given object. Decreasing the complexity and effort of use of upper-limb prostheses may ultimately lead to a reduction in prosthesis abandonment. Being able to hold an object securely without considerable mental or physical strain comes naturally to someone with an intact hand, but is still a challenge for users of upper-limb prostheses.

In future iterations of this design, we intend to scale the human control logarithmically rather than linearly. Scaling the EMG decoder output in a logarithmic fashion follows a biomimetic paradigm and would grant users finer levels of control with smaller objects. We will also train the MLP predictions of object distance using continuous data as opposed to the discrete steps used for this work. The MLP estimates were found to overestimate the object distance when the digit was in motion. Providing a more accurate machine estimate would lead to a shared-control algorithm capable of handling fragile objects. We also intend to expand the shared-control approach presented here to multiple DOFs. We anticipate that shared control implemented across all the digits will further increase the benefits seen here when working with complex objects by reducing the variation in grasping force between digits.

ACKNOWLEDGEMENTS

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TAKE-HOME TRIAL OF THE GLIDE HAND AND WRIST MYOELECTRIC CONTROL ALGORITHM: A CASE STUDY

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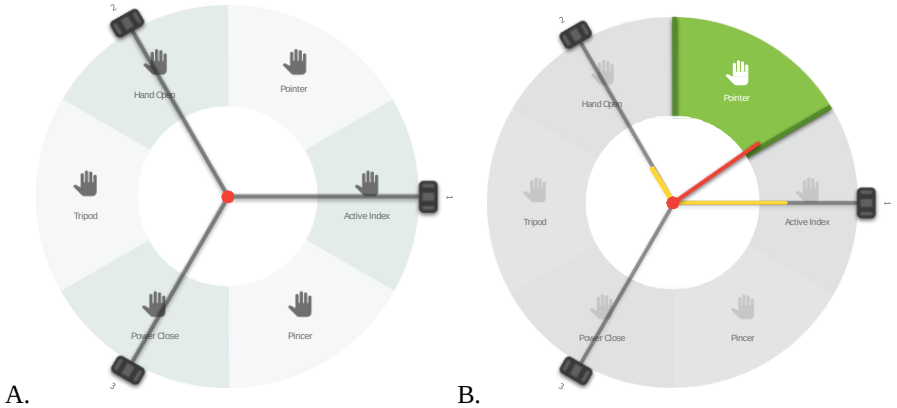
ABSTRACT

One of the most exciting developments in the field relates to the mechatronic advances which have enabled the creation of dexterous terminal devices, wrist rotators and powered elbows. However, their clinical impact has been limited by a lack of effective myoelectric control strategies. To address this challenge, we have developed a novel control strategy based on the Postural Control algorithm, which we call the Glide Controller. In this paper, we describe the first clinical fitting of the Glide system and present qualitative results on the fitting outcomes. We also discuss the implications of this control strategy from a patient and clinician perspective.

INTRODUCTION

The disparate progression of myoelectric control algorithms and their associated multi-functional prosthetic hands has caused mismatched technologies to become available to people with upper limb amputation. Several multi-functional myoelectric prosthetic hands are available today; however users are only able to access a small subset of the total number of grip patterns which are possible [1]. The prosthetic hands typically come with several methods for accessing different grip patterns including 1) myoelectric triggers, 2) buttons on the hand, or 3) gesture control [2], [3], [4]. These switching mechanism can require up to three different steps to switch between the current grip and the desired grip. Not surprisingly, many amputees find this process cumbersome and non-intuitive [5], [6], [7]. Moreover, using muscle triggers such as a co-contraction to control multiple grip patterns or movements is considered slow, cognitively demanding and unintuitive [5], [6], [7].

An intuitive control method, called pattern recognition, is emerging, however, several hurdles remain. Many researchers (including ourselves) have turned to pattern recognition of multichannel myoelectric signals in order to develop more intuitive control of advanced prostheses including the control of grasp patterns of multi-functional hands [8]. Pattern recognition algorithms seek to correlate patterns of surface EMG activity with a given intended movement command [9], [10]. Correlation is determined by calibrating a machine learning algorithm with labelled training examples in the form muscle activity recorded while the user holds a static posture. Because these patterns are representative of natural behaviors prior to amputation, control of the prosthesis via pattern recognition is intuitive and potentially increases the number of controllable DOFs. The most significant challenge for pattern recognition algorithms is that they require highly consistent and noise-free EMG signals [6]. This is



A. B.

Figure 1: A. Exemplary Glide domain where the EMG electrodes (1-3) are mapped in a radially fashion. Various hand grips are placed into wedges around the domain with a null state surrounding the origin (white). B. The real-time EMG activity is present with the yellow vectors and the resultant vector (red) determines the hand or wrist function that is selected.

particularly true as the number of degrees of freedom (DOF) in prosthetic hands increase. Thus, it would be highly preferable to develop a solution that can work without any calibration or extensive subject training.

Here we present an alternative control strategy, the *Glide* myoelectric control algorithm, which maps the electromyographic (EMG) signals to a radial mapping of prosthetic hand grips or wrist functions (Figure 1). The Glide algorithm is based upon our previous work on the Postural Control algorithm in the Biomechatronics Development Laboratory [11]–[13]. The basis of Glide algorithm is the vector summation of EMG signals from 2-8 EMG electrodes which is manifested as a "Glide vector" which is projected onto the Glide domain. The domain can be partitioned into "wedges," which are correlated to single hand grips or wrist functions. A given wedge's inner radius determines the onset threshold for a movement. Once the Glide vector exceeds the onset threshold, the amplitude of the Glide vector is proportionally mapped to the velocity of the wedge's associated movement until the vector reaches the outer radius of the wedge, which corresponds to the maximum velocity of the movement. The mapping of the Glide domain is adjustable so that wedges can be placed anywhere in the domain, the inner and outer radius of the wedge can be independently changed, and the arc-length of each wedge can be made larger or smaller. These customizations allow for strong independent EMG signals to command certain functions and co-activity of other EMG signals to control other functions. The customizability ensures that the system can be fit to myoelectric prosthetic users with a broad range of abilities. Here we present a case study of a subject with trans-radial amputation who utilized the *Glide* algorithm with both hand and wrist function in a take-home trial.

METHODS

A single subject was recruited by clinicians at Handspring Clinical Service office in Salt Lake City, UT. The subject presented as a recent trans-radial amputee with a long residual limb length (8.5"). This subject was a novice myoelectric prosthetic user and had no prior experience with a myoelectric device outside of clinical sessions. The subject was originally amputated at a wrist disarticulation level but underwent a surgical revision for shortening to remove a neuroma and to improve the shape of the residual limb for prosthetic fitting. In addition, the surgeon salvaged and relocated the flexor pollicis longus muscle closer to the surface in order to provide an additional myosite for surface EMG control. The subject was fitted with a three-site *Glide* system where the electrodes were placed over the following muscles: 1) flexors digitorum, 2) extensors digitorum, and 3) flexor pollicis longus. The *Element* electrodes (Infinite Biomedical Technologies LLC, Baltimore MA) were integrated into the custom self-suspending HTV silicone prosthetic socket, the *FlexCell* battery and the *Glide* control system was integrated into the outer prosthetic socket. The TASKA prosthetic hand (TASKA Prosthetics, Christchurch, New Zealand) and wrist rotator (Motion Control, Salt Lake City, Utah) were utilized to provide the user with multiple hand grasps as well as wrist pronation and supination.

The *Glide* algorithm was configured to include the following hand grips and wrist motions: 1) hand open, 2) hand close, 3) wrist pronation, and 4) wrist supination. The gains for each of the electrodes were adjusted independently. EMG smoothing was enabled. A feature called walls was also enabled which prevents activation of a different hand/wrist function until the signal drops below the on threshold of the active Glide domain wedge.

After the subject enrolled in the study, the prosthetic system was fitted to the subject and tuned for best performance by the prosthetist. Training on use of the system was conducted by the prosthetist. The subject completed a battery of outcomes measures including 1) The McGann Feedback Form, 2) The OPUS: Satisfaction With Device and Services, 3) OPUS Upper Extremity Functional Status, and 4) OPUS: Health Quality of Life Index. The subject went home with the *Glide* system for a total of 4 weeks. Outcome measures were collected at initial fitting, two weeks post-delivery, and four weeks post-delivery. The outcome measure results and qualitative comments from the subject and prosthetist are provided here.

RESULTS

Experimental Results: The outcome measures were collected during the initial fitting, two-week session, and four-week session. Table 1 depicts the outcome measures over those sessions. The McGann Client Feedback Form results indicate an increase in prosthetic satisfaction across the four-week trial from 53% during the initial fitting to 97% satisfaction during the four-week session. The OPUS results provided a mixed description of the patient's satisfaction, functional status, and health quality in that not all outcome measures improved across the four-week session. Nonetheless, the single-subject quantitative results for the first-time use of a new technology is an encouraging step

forward and suggests that the Glide algorithm can be an affective tool for the control of multi-functional prosthetic hands.

Table 1. – Outcome measure results across the initial fitting, 2-week session, and 4-week session

Experimental Session	McGann Client Feedback Form	OPUS–Satisfaction with Device	OPUS-Functional Status	OPUS–Health Quality of Life
Initial fitting	53%	39	46	74
2-week session	88%	36	30	78
4-week session	97%	38	43	73

Qualitative Results: The subject owns an excavation company and has a history of operating heavy machinery. This type of equipment utilizes joysticks with multiple switching mechanisms to manipulate the implements of the equipment. This experience was very useful for translating into prosthetic control. He was quoted as saying, "In the beginning I thought it was pretty easy. And the more and more as I go with this I recognize it is capable combining functions to do something different. So I'm getting better at it." His responses to the McGann Feedback forms indicated that as he became more familiar with the system his satisfaction increased. During the take home trial period the subject was fit with a Glide system with three electrodes. During one of the follow-up appointments he commented that he wanted to try adding a fourth electrode into the system as he stated, "I have the signals" referring to his ulnar deviators. This fourth electrode will be added in the future and further data will be collected.

DISCUSSION

Technological Progress: The Glide system is the next logical iteration of a traditional two site myoelectric control system. It has clinical implications for individuals who have had a conventional amputation surgery, but also has significant added benefits when combined with more contemporary amputation surgical methods such as TMR. From a clinical perspective it bridges the gap between a two-site myoelectric system and a full pattern recognition system. Selecting among multiple movements can be simpler than using EMG triggers such as co-contraction, double and triple impulses. While "joystick" control of the wrist is the most straightforward method to access different wedges within the Glide domain, it is also possible to use intuitive motions for control. It also bridges this gap from a cost standpoint as well. Fabrication is no more difficult or complex than a traditional two site system. The space requirements for the system are also minimal within the socket. Processing power consumption is low with no appreciable reductions in battery life as compared to a two-site system.

Clinical Perspective: There were some initial challenges in the clinical fitting as this was the first clinical application of the Glide algorithm. Part of the challenge was in learning how to refine and fine tune the arc lengths of the wedges, adjusting the gains and thresholds, enabling and disabling the walling features, and then proper queueing and instruction for the user. However, the technology proved to be quite adaptable and flexible. Initially the subject was sent home with only hand functions on the primary axis and the wrist functions as secondary fast rise actions like what a four-channel control system would be. This was challenging for him. Given his lack of myoelectric control experience he would inadvertently activate the wrist functions quite often, which proved to be frustrating to the participant. In particular when the wrist would start rotating unexpectedly and get into a unnatural anatomical posture, his whole ability to control the prosthesis would degrade. He expressed that this was because once the prosthesis was in an unnatural posture his sense of embodiment of the prosthesis completely disconnected. Fortunately, with an update to the control algorithm, wrist functionality was added as a primary function instead of as only a fast rise secondary function. Doing so allowed for defining additional Glide domain wedges for wrist control which the subject was able to activate with a high level of accuracy.

Initially when training the subject, he was queued to try and visualize moving his phantom limb as would be done in pattern recognition training and calibration. This worked to some degree, however it was never really consistent. The resultant vector would end up moving around quite a lot and not stay in one clearly defined area. It took some time to recognize that this queueing would not work and that another strategy needed to be developed. It was determined that we need to help the users conceptualize that the electrodes function somewhat like a joystick. It is best to put the primary functions right on the axis of the electrodes on the Glide domain. Once the subject has good control of each independent axis, then they can be queued to start trying to make combinations of contractions between adjacent electrodes on the Glide domain. The goal being to help the subject generate a resultant signal that is exactly

in the middle of the pair of electrodes on the Glide domain. In doing so, with three electrodes six separate functions can be controlled. With four electrodes, eight separate functions could be controlled. By also allowing for fast and slow rise the potential exists to control double the amount of functions. The Glide system is not limited to the number of regions that could be created. Therefore, as an individual gains improved control in combining the signals, additional wedges can be added to the Glide domain to add additional functions. This will allow the individual to be able to access specific grip patterns of multi-articulated terminal devices as well as additional wrist functions such as flexion and extension.

Unlike in pattern recognition systems where the process of classification is somewhat obscured from the user and the prosthetists, the Glide system allows the prosthetists and the user of the technology to visually see on the Glide domain what the function will be without any ambiguity or uncertainty. It also allows the prosthetist to easily adjust the Glide domain mapping and ensure easier selection of each function. By increasing the arc of the wedge on the Glide domain and adjusting the on and maximum thresholds, the prosthetist can effectively accommodate for accuracy and fatigue of signals. Clinically, it was found to be very helpful to be able to adjust this tolerance. Past clinical experience with pattern recognition systems has shown that sometimes throughout the day as a user's muscles fatigue their classification accuracy may diminish resulting in unwanted behavior. The Glide domain interface allowed for the clinicians to adjust the wedge size and shape in order to avoid this pitfall.

Clinical Implications: A system built on the Glide algorithm provides a novel advance to traditional myoelectric control. When set up with only two electrodes it functions in the same way that a conventional two site system would. However, it provides a significant clinical advantage for controlling an increased number of functions and motions of a prosthesis when additional electrodes are added into the system. This is accomplished without time consuming additional fabrication and minimal additional hardware and processing power. Increasingly, the possible controllable motions of a prosthesis outnumber the inputs that a user has available thereby requiring complex switching strategies or signal processing algorithms in order to activate them. The limitation on a user's ability to benefit from these additional motions is correlated to the number of inputs available to them. Future applications could see connecting non-EMG inputs into the Glide system in combination with EMG signals. This could help individuals with limited surface EMG sites, such as higher level amputees, also benefit from this technology.

Because the Glide system allows for more granular control, the amount of time programming was longer than for a conventional two site system or for a pattern recognition system. There is a learning curve to the system, but over time with further fittings and documentation of outcomes a guideline of best practices will be able to be developed. This will be critical for widespread adoption by clinicians.

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TRAINING PROSTHESIS CONTROL IN THE LAB AND THE HOME

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ABSTRACT

Historically, experiments involving motor learning-based control schemes use real-time feedback. It is unclear, to what extent previous results are attributable to transient performance effects caused by closed loop adaptive processes, rather than motor learning. To investigate, we performed two long-term experiments. Experiment 1: a lab-based study compared use of continuous and delayed visual feedback to assess long-term stability of skill retention; we trained ten participants using either continuous or delayed visual feedback over four consecutive days with a follow-up probe on week three. Experiment 2: a home-based study validated that the training protocols introduced in experiment one can train forward models outside of the laboratory in an appropriate period. Three participants trained over five days with a goal of maximising proficiency via bespoke training structures.

INTRODUCTION

Motor learning theory claims that the feedback provided to the outcome of an action can have a large influence on learning [1]. While providing real-time feedback can yield rapid performance gains, this effect is often short-lived, and ultimately disappears with time or when feedback is withdrawn [2,3].

Previous learning-based control schemes have typically provided concurrent visual feedback of the participant's control signals real time [4-6]. However, users do not generally have access to real-time closed loop feedback of the state of their control signals [7]. Typically, users only receive terminal feedback as their prosthetic device moves [8], which is relatively slow [9]. Therefore, it is crucial that users can consistently reproduce the correct muscle activity for control in the absence of concurrent feedback. This necessitates that control tasks be learned, internalised, and retained. In this context, online concurrent feedback may contribute to closed loop control [10] allowing participants to develop dependencies on continuous visual cues to generate muscle activations [3]. Feedback dependencies may inhibit retention of the forward models necessary for motor-learning based methods of prosthesis control [2].

Abstract decoding is a learning-based control scheme that exploits the human nervous system's plasticity to resolve the mapping of muscle activity to prosthesis output [4]. Abstract decoding places learning requirements on the user, in return offering reduced overall algorithmic complexity in sensor requirements; the overall promise being the restoration of multiple hand grasps using two electrodes without cumbersome sequential switching [5].

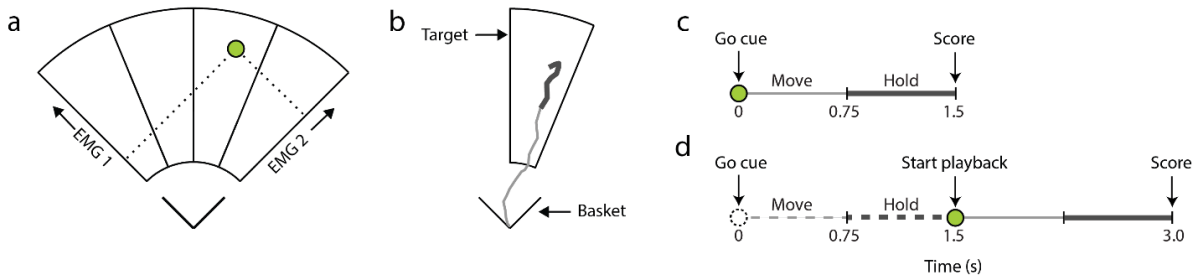

Figure 1: The MCI task. (a) The 2D myoelectric interface space. Cursor position shown in green. (b) A representative cursor trajectory from basket to target. Thick cursor mark denotes the hold period. (c-d) Task timing structure for the Concurrent and Delayed conditions, respectively, denoting cues and the move, hold and playback periods. Dashed traces correspond to the 'blind' control input window. Solid traces indicate when the cursor's motion was visible during a trial.

METHODS

Ethics

All participants gave informed written consent. Ethical approval was granted by the local committee at Newcastle University (Ref: 20-DYS-050).

Myoelectric Task

The myoelectric task involved moving a cursor within a 2-dimensional MCI outlined in Figure 1. Normalized muscle activity recorded from two control sensors determined cursor position on the interface [5]. The amplitude of activity in each muscle determines the cursor position along a single axis. Trials were ~1.5 s long and comprised two periods of equal length, referred to as move and hold. On target presentation, the aim was to keep the cursor within the target bounds. Figure 1b shows a representative trial from a proficient user. At the end of a typical trial, a score was presented.

Feedback Conditions

The availability and timing of feedback during a trial was manipulated depending on the trial condition. Each group either experienced concurrent or delayed feedback of their control input. In the concurrent condition, the cursor position always reflected the normalized muscle activation levels of the EMG channels used for control at that time frame. In the delayed condition, all feedback was withheld until active control input had ceased. At the end of the trial, the cursor activity was played back to the participant at the same rate as it occurred.

The trial block structure contained two distinct trial structures, acquisition blocks and retention blocks. Acquisition blocks refer to the learning conditions, either Concurrent or Delayed. Retention of ability was assessed using zero feedback trial blocks, where no cursor or score feedback was presented over 40 consecutive trials. Retention was assessed at the start and end of each day.

Experiment 1

Ten participants did four days of training in the laboratory plus a follow-up after an 18-day hiatus. Retention tests were carried out at the start and end of each training session. Each acquisition block consisted of 80 trials.

Experiment 2

Three participants did five days of delayed feedback training with a bespoke structure. Each training session lasted approximately an hour, including setup and breaks. Each training block consisted of 60 trials.

Measures

A ‘decoder score’ metric was used post-hoc to compare MCI task score to classification accuracy of machine learning based systems. The predicted target was calculated offline as the first target the cursor dwelled within consecutively for 240 ms [12]. If the predicted and presented targets agreed a decoder score of one was obtained, otherwise a score of zero was received.

RESULTS

Experiment 1

A comparison of average retention scores in the Concurrent and Delayed groups is shown in Figure 3a. Average acquisition scores in the Concurrent and Delayed groups are shown in Figure 3b. In the Concurrent group, acquisition scores increase but no equivalent trend is observed during retention tests over the four days of training. In contrast, the Delayed group retention scores follow a similar trend of improvement with acquisition.

Significant differences in performance were found in the retention tests performed on day four, first test (Concurrent: 0.32 ±0.12; Delayed: 0.55 ±0.15; $p < 0.05$), final test (Concurrent: 0.28 ±0.13; Delayed: 0.62 ±0.15; $p < 0.05$). There was no significant difference in initial retention performance during the follow-up session (Concurrent: 0.27 ±0.12; Delayed: 0.48 ±0.15; $p = 0.1$). However, after two refresher acquisition blocks the Delayed group retention

was significantly higher than the Concurrent group on the final block (Concurrent: 0.34 ±0.13; Delayed: 0.63 ±0.12; $p < 0.05$).

Experiment 2

Data tracking the participants' average score over the five days of training are shown in Figure 3. Confusion matrices of each participant's first and best block decoder score are shown in Figure 3b and c, respectively.

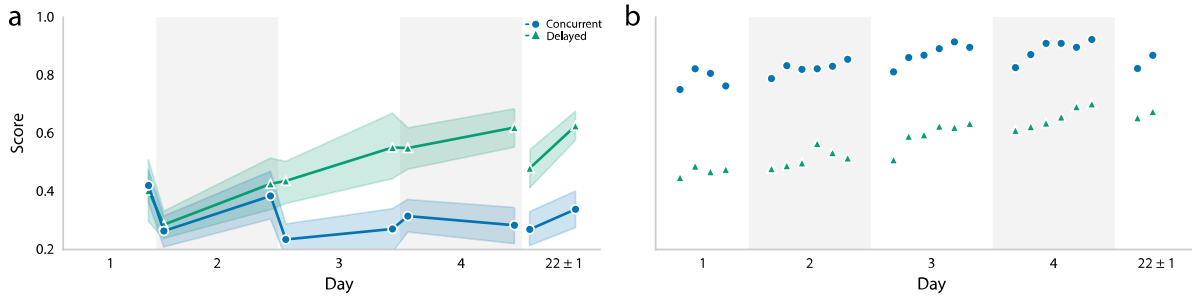

Figure 2: The effect of the feedback conditions on retention and acquisition. Days are separated by alternating gray and white backgrounds. Points show the block mean average. Horizontal axes are temporally aligned such that points are plotted chronologically. (a) Group retention scores over the initial four days of training and the follow-up session. (b) Group acquisition scores over the initial four days of training and the follow-up session.

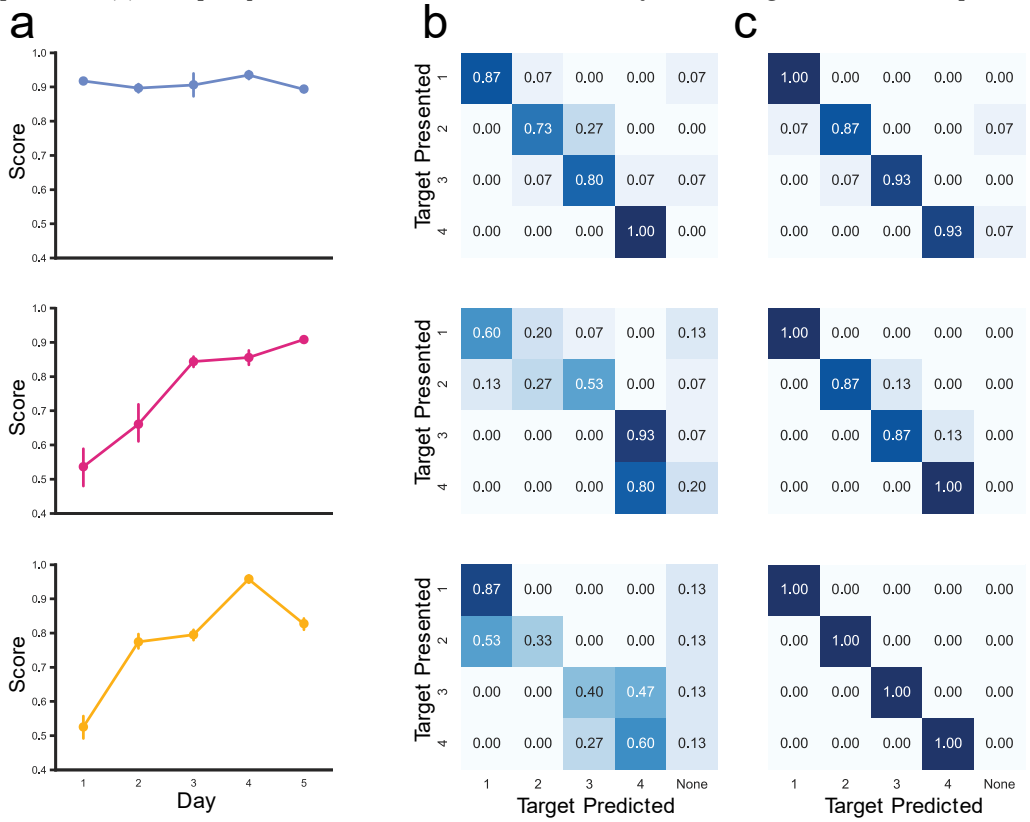

Figure 3: Overview of home-based training performance. (a-c) Refer to a column of plots, each row relates to the performance of a single participant. (a) Participant mean scores and cumulative blocks experienced over the five days of training. Error bars correspond to the standard error of the mean. (b-c) Decoder score heatmaps of the first and best delayed feedback blocks, respectively.

CONCLUSION

Myoelectric control schemes based on motor learning have historically provided concurrent feedback during training and assessment of participant control acuity. While impressive performance can be achieved with the assistance of such feedback mechanisms, this has little meaning unless the user has access to a similar feedback loop during real control. This is problematic when considering that, in the real-world users typically do not have access to concurrent feedback of their control input. Our results show that with appropriate training it is possible to learn and consistently reproduce distinct abstract muscle contractions in the absence of concurrent feedback. This suggests no algorithmic assistance or additional hardware is necessary to restore four grasp classes to existing dual-site control devices.

Retention of skill can only be measured in the absence of the augmented feedback that was provided during training. To show that retention can be achieved with appropriate training, we collected on the largest closed-loop myoelectric control datasets that we are aware of i.e. 32,000 trials. Figure 1a-b shows that although lower scores are initially obtained with delayed feedback, the skills learned are retained over days. Conversely, the higher performance gains observed with concurrent feedback dissipates during retention tests. Figure 3c shows the equivalent of 4-class confusion matrices which reflect the upper bounds of what is possible with this abstract decoding interface. Preliminary experiments are showing similar control rates in prosthesis control.

ACKNOWLEDGEMENTS

This work was supported by the UK Engineering and Physical Sciences Research Council (EPSRC), (grant number: EP/R004242/1) and by the National Institute for Health Research (NIHR) Devices 4 Dignity (D4D) Starworks (project: STWK-006).

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TRANSFER OF ABSTRACT CONTROL SKILLS TO PROSTHESIS USE

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ABSTRACT

Computer interface tasks have shown that motor learning based control schemes enable multi-grip myoelectric control with only two electrodes. However, it is unclear if this control transfers to prosthesis use. Here, we test if training abstract control with delayed feedback transfers to prosthetic control in a 7-session experiment. Two participants completed five 1-hour training sessions in between a pre- and post-test. The abstract decoding scheme ensured participants had access to five grips (power, tripod, point, lateral, and hand open), and the prosthetic tests included a grip matching task, the modified box and blocks task, and a pick and place test. Both participants increased their grip matching score, reaching a classification accuracy of 93.33% and 98.33%. They also increased the amount of blocks they relocated in the modified box and blocks test, completed the pick and place test faster, lowered the amount of objects they dropped, and increased the accuracy of the grips they selected during the pick and place test. These results show that a motor-based training strategy of abstract control transfers to prosthetic use, enabling five grips with only two electrodes.

INTRODUCTION

Myoelectric prosthesis are commonly controlled with a standard agonist/antagonist direct control, while some devices with additional electrodes use pattern recognition (PR) [1]. Studying the use of these devices in a home environment shows that most prosthesis users only use 3 or 4 grips, with the most common grip accounting for around 50% to 80% of use [2], [3]. Simon and colleagues found that users had slightly more configured grips for direct control (4.8) than PR (3.8) when using their prosthesis at home [3], providing more functionality with less hardware requirements. However, accessing all grips in direct control requires users to cycle through the grips with mode switching, making the control cumbersome.

Abstract control, a motor learning based control scheme, allows myoelectric users to access multiple grips without mode switching, using only two electrodes [4]. We have previously shown that people with a limb difference can learn abstract control [4], and that training with delayed feedback allows people to retain this skill [5], [6]. Here, we test if the skill gained during a home-based computer interface task transfers to prosthetic control. Participants took part in lab-based pre- and post-tests, and completed five 1-hour training sessions in their home environment.

METHODS

Participants

Two participants (2 female) who are able bodied and free from neurological or motor disorders were recruited. The study was approved by the local ethics committee at Newcastle University (ref: 20-DYS-050), and participants provided written informed consent prior to the start of the experiment.

Experimental setup

Participants performed a range of myoelectric control tasks, all based on two-channel abstract control. Two EMG electrodes were placed on the extensor carpi radialis and flexor carpi radialis. Signals were acquired using a custom network-enabled myoelectric platform [7]. The platform enables streaming of EMG data over Bluetooth Low Energy to a PC running the AxoPy Python library, allowing real time myoelectric control. Muscle signals were smoothed

using the mean absolute value (MAV), with a window length of 750ms. Muscle estimations were updated at a rate of 50Hz.

Abstract control allows participants 5-class myoelectric control (4 movement classes + hand open) with the use of only 2 electrodes. Shortly, EMG channels are calibrated for each participant, where normalized activity for each channel is:

$$\hat{y} = (y - y_r) / (y_c - y_r)$$

where $\hat{y}$ is the normalized muscle activity, y the MAV, y_r the activity when the participant is at rest, and y_c represents a comfortable contraction. The normalized activity of both muscles determines the position of a cursor within a 2D V-shaped interface [4]. For this experiment, the V-shaped interface was divided in 4 targets, each representing a specific grasp. From left to right, the targets represented the following grips: 'power', 'tripod', 'pointer', and 'lateral'. Once the prosthesis was closed, hitting any of the targets resulted in the prosthesis returning to the 'hand open' state.

Experimental design

The experiment consisted of 3 main stages: a pre-test, training phase, and post-test. The pre- and post-test consisted of the same tasks.

Pre- and post-test: Participants wore a transradial bypass socket [8], fitted with the Touch Bionics robo-limb prosthetic hand, throughout the experiment. At the start of the test, both EMG channels were normalized as described above. Subsequently, participants completed 2 blocks of 60 trials to familiarize themselves with the abstract myoelectric control interface. In these blocks, a target was presented at the start of each trial, and the participants could see the cursor moving based on their muscle activity. Once the cursor was in contact with or inside a target for 750ms, the trial was completed. If the participant reached the intended target, this was considered a 'hit'.

The main prosthesis control experiment consisted of three parts:

- Grip matching task: participants were presented with a target on the screen, similar to the familiarisation phase. However, during the target matching task, no feedback was presented to the participant, thereby testing the retention of skill [6]. Each participant completed 2 blocks of 60 trials.
- Modified box and blocks test (MBB): participants completed 5 trials of the MBB test [9]. When participants grabbed more than 1 block in a single movement, the additional blocks were removed from the results.
- Pick and place test: four objects, each associated with a specific prosthesis grip, were placed on a 2x4 grid on a table in front of the participant, with a 15cm distance between grid point. Participants were instructed to move all objects forward from right to left, after which they placed them back on the grid points closest to them from left to right. Participants repeated the trial 4 times. When participants selected the wrong grip, participants were told to open the hand and try again. If they selected the wrong grasp 3 times, participants were told to move on to the next object. Next to the time it took to complete the trials, the amount of repetitions to a grasp, and the amount of objects that were dropped were recorded.

Training: In between the pre- and post-test, participant completed five 1-hour training sessions, spread over 1 week. During these sessions, participants completed an abstract control task in their own home, without wearing a prosthesis. At the start of the first training session, the EMG channels were normalized as described above. This calibration was used throughout the rest of the training. During the training, participants performed a delayed abstract control task, as described in [5]. Participants performed blocks of 60 trials, and were told to complete as many blocks as felt comfortable during their training time.

Due to the limited amount of participants, no statistical tests were performed at this time.

RESULTS

Training

Participant 1 (P1) completed 36 training blocks, while participant 2 (P2) completed 35 blocks. P1 reached a maximum hold score of 97.07%, while P2 reached 95.05%.

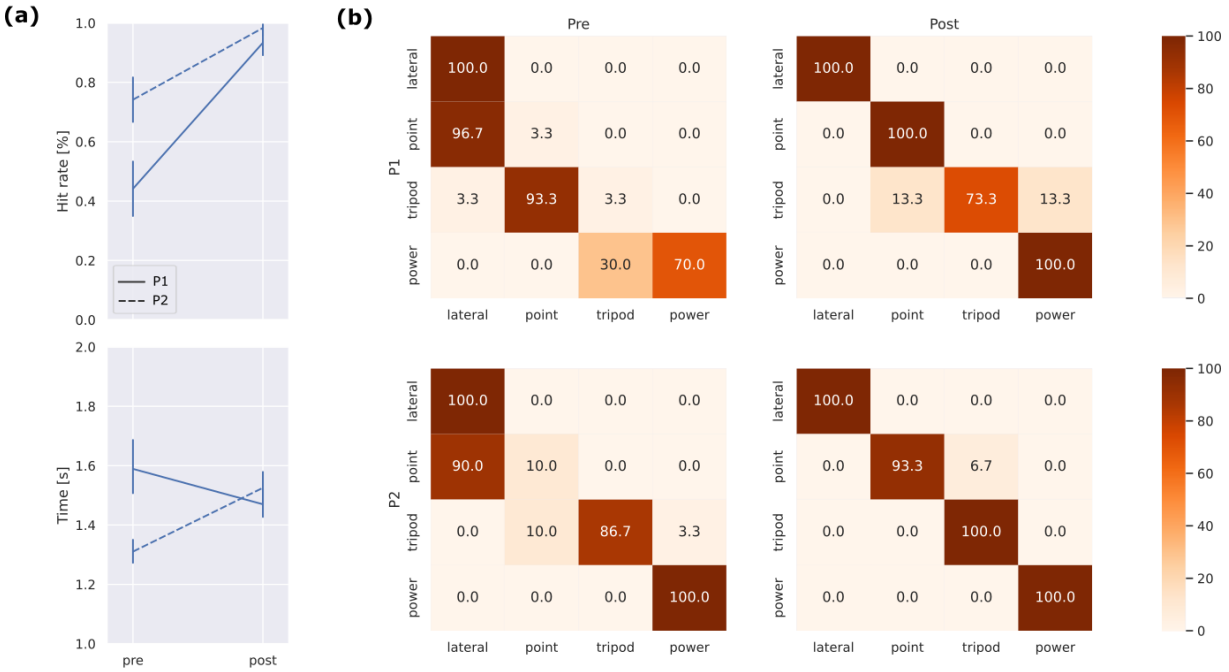

Figure 1: Results of the grip matching task. (a) Hit rate and completion time for pre- and post test, split up by participant. (b) Confusion matrices of pre- and post-test for both participants.

Pre- and post-test

The results of the grip matching task are presented in Figure 1. Training allowed P1 to increase her performance from 44.16 ± 49.66% to 93.33 ± 24.94%, while the score of P2 increased from 74.17 ± 43.77% to 98.33 ± 12.80%. These scores represent the performance without any visual feedback. Subsequently, each trial lasted until the participants selected a grip, and the chosen grip was recorded. Figure 1b shows the confusion matrices for this task. In the pre-test, participants were able to select the lateral and power grip, the grips associated with the corner targets of the abstract interface, but they had difficulties selecting the grips associated with the two middle targets. Training allowed them to select these targets as well.

Both participants increased the amount of blocks they picked up during the MBB post-test, from 5.2 ± 1.47 to 8.2 ± 0.75 and from 8.2 ± 1.67 to 8.8 ± 0.98 for P1 and P2 respectively. They also increased all measures during the pick and place post-test: they completed the trials faster (P1: 109.69 ± 2.92s to 68.71 ± 8.58s; P2: 69.99 ± 8.64 to 55.50 ± 7.05s), had to repeat less grips per trial (P1: 4.5 ± 3.20 to 2.00 ± 1.00; P2: 2.25 ± 0.83 to 1.00 ± 0.71), and managed to not drop any objects during the post test (pre-test: 0.5 ± 0.5 for P1, and 0.25 ± 0.43 for P2).

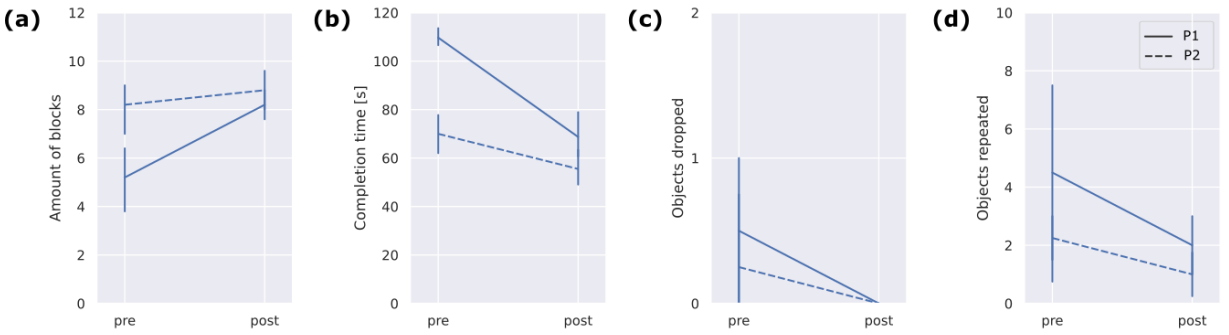

Figure 2: (a) Results of modified box and blocks test. Completion time of trials (b), the amount of objects participants dropped per trial (c), and the amount of times participants had to repeat a grip per trial due to initially selecting the wrong grip (d).

CONCLUSION

This paper shows that abstract myoelectric control, trained by performing a computer interface task, translates to prosthetic control. We designed a training protocol based on delayed feedback, allowing participants to retain their skills when no feedback is available, or when using a prosthesis. As a result, participants were able to reliable control five grips (hand open + four closed grips) with 2 electrodes, suggesting prosthesis users could have access to the same amount of grips without the need for additional hardware or mode switching. Currently, we only have data for two participants. However, due to the improvement in all functional tasks for both participants, we expect our full dataset to show the same pattern.

ACKNOWLEDGEMENTS

This work was supported by the UK Engineering and Physical Sciences Research Council (EPSRC), (grant number: EP/R004242/2 and EP/R511584/1) and by the National Institute for Health Research (NIHR) Devices for Dignity (D4D) Starworks (project: STWK-006).

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USER-SPECIFIC MIRROR TRAINING CAN IMPROVE MYOELECTRIC PROSTHESIS CONTROL

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ABSTRACT

State-of-the-art transradial prostheses can provide intuitive and proportional myoelectric control by training an algorithm to correlate surface electromyographic signals from the residual forearm muscles to intended movements of the amputated hand. One training paradigm, "mimicked training," relies on amputees mimicking a prosthetic hand with their missing hand such that the corresponding muscle activations are correlated to the preprogrammed kinematics of the prosthetic hand. A second training paradigm, "mirrored training," relies on unilateral amputees mirroring their contralateral hand with their missing hand such that the muscle activations are correlated to the kinematics of the contralateral hand (determined via a motion capture). Prior work with intact participants demonstrated that the kinematics of a given hand are more closely related to that of an individual's contralateral hand as opposed to the preprogrammed kinematics of a prosthesis. This abstract continues our investigation into the training data for myoelectric prostheses by exploring the impact of these training paradigms on real-time prosthetic control with amputees completing a functional task. For one out of three participants, mirrored training significantly improved task performance. These preliminary results demonstrate that mirrored training may provide more dexterous control through task-specific, user-chosen training data. These results can guide myoelectric training for proportional and dexterous control.

INTRODUCTION

The current standard of care for upper-limb amputees is unsatisfactory and, as a result, up to 50% of upper-limb amputees abandon their prostheses, citing poor and unreliable control as a primary reason. One approach to providing more intuitive and reliable control is to leverage supervised machine-learning algorithms that correlate residual muscle activity to motor intent. These supervised machine-learning algorithms require a training session in which a patient-specific training dataset is collected. The training dataset consists of synchronized muscle activity and the intended kinematic positions of the prosthesis.

To date, most research has focused on improving the machine-learning algorithm [1]–[8]. However, the quality of the training data is also a critical component of the run-time performance of machine-learning algorithms [1], [2], [9]. There are two widely used approaches (i.e., training paradigms) to collecting training data for prostheses. One training paradigm, herein referred to as "mimicked training", relies on amputees mimicking preprogrammed movements of a prosthesis with their missing hand such that the corresponding muscle activations are correlated to preprogrammed kinematics of the prosthesis. A second training paradigm, herein referred to as "mirrored training", relies on unilateral amputees mirroring their contralateral hand with their missing hand such that the muscle activations of the missing hand are correlated to the kinematics of their intact contralateral hand (determined via motion capture). Our prior work with intact participants demonstrated that the kinematics of a given hand are more closely related to that of an individual's contralateral hand as opposed to the preprogrammed kinematics of a prosthesis [9]. This suggests that mirrored training provides more accurate training data and therefore should provide better prosthesis control than mimicked training.

Here, for the first time, we specifically tested whether or not mimicked or mirrored training would lead to improvements in real-time prosthetic control. Using two widely used algorithms, a linear Kalman filter and a non-linear convolutional neural network, we compared the performance of mimicked and mirrored training with amputees performing the Clothespin Relocation Task (CRT) [10]. We show that there is minimal difference in the subjective workload of each training approach and that user preference varies. However, we also show that the training paradigm may have significant impact on task performance for some participants. These results imply amputees should be given a choice between both paradigms or that a combination of the two may yield best control.

METHODS

Human Subjects

A total of three transradial amputees with prior myoelectric experience were recruited for this study. Two of three participants were male and all participants were between the ages of 55 and 65 years old. Informed consent and experimental protocols were carried out in accordance with the University of Utah Institutional Review Board.

Training Data Recording

Training data for the machine-learning algorithms, was collected across a total of four training sessions. Participants performed two sessions (1.5 minutes each) of mirrored and mimicked training respectively Fig 1. Prior to the training sessions, participants were instructed to perform the CRT with their intact hand to understand what movements would be necessary to complete the task. Participants were instructed to only perform two movements: open/close of the hand (simultaneous flexion/extension of D1-D5) and pronation/supination of the wrist. Participants then donned the prosthesis (LUKE Arm, DEKA), and performed a session of mirrored training at their own pace using self-selected movement patterns. Training data from this first mirror-training session was used to train an algorithm and participants were allowed to temporarily control the prostheses. The participant then performed a second self-directed mirror-training session. The same two stage training process was then repeated for mimicked training.

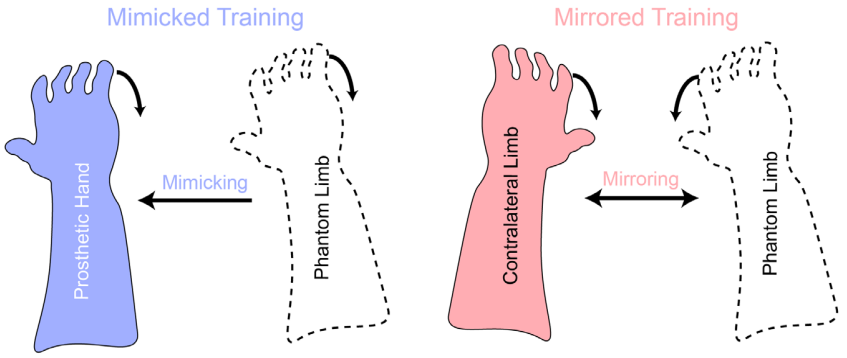

Figure 1: Overview of the mimicked training (left) and mirrored training (right) for collecting training data for myoelectric prostheses. During mimicked training, the user is watching a prosthesis move while simultaneously mimicking the movement of the prosthesis with their phantom limb. During mirrored training, the user performs bilaterally mirrored movements, such that the motion of their intact contralateral hand mirrors that of their phantom limb.

Signal Acquisition

Infrared hand images of the contralateral limb were converted to 3D hand coordinates using custom MATLAB software. Joint angles were calculated based on an orthogonal palm vector. A total of two joint angles were calculated for the contralateral hand: D2 flexion/extension and wrist pronation/supination. The joint angle of D2 was used to measure grasping (i.e., simultaneous flexion/extension of D1-D5). Joint angles in the training data were normalized from -1 (maximum extension) to 0 (rest), and from 0 to 1 (maximum flexion) for each mirror-training session. The rest position of each joint was determined by the average angle while the participant relaxed for 15 seconds prior to each training session.

Surface electromyography (sEMG) was recorded from the surface of the residual limb using a custom EMG sleeve [11]. Thirty-two monopolar sEMG electrodes were sampled at 1 kHz using Micro2+Stim Front-Ends and a Summit Interface Processor (Ripple Neuro LLC). The 300-ms smoothed Mean Absolute Value (MAV) was calculated at 30 Hz for the 32 monopolar electrodes, as well as for all possible differential pairs (i.e., 496 differential pairs) [5].

Machine-Learning Algorithms

A total of two machine-learning algorithms were used in this study. The first was an eight-layer convolutional neural network (CNN). The CNN predicts kinematic position based on a spatiotemporal “image” of sEMG activity over the last 10 samples in time, described in more detail in [1]. The CNN utilizes convolution to learn complex spatiotemporal relations within EMG activity that correlate to kinematic position. The second algorithm used in this study was a modified Kalman filter (MKF), as described in [5]. The MKF provides an efficient recursive algorithm to optimally estimate the position of the bionic hand when the likelihood model (i.e., the probability of EMG activity given the current kinematic position) and prior models (i.e., the state model of how kinematics change over time) are linear and Gaussian. The inclusion of prior information about the system state enables an efficient recursive

formulation of the machine-learning algorithm and effectively smooths noisy estimates in a mathematically principled way.

Modified Clothespin Relocation Task

The CRT provides a simple way to assess the ability of individuals to simultaneously grasp and rotate their wrist. The CRT involves moving a clothespin from a horizontal bar to a vertical bar. Clothespins are placed eight inches down the length of the horizontal bar and 8 inches up the vertical bar. If the participant drops the clothespin or takes longer than one minute the attempt is considered a failure.

Participants were instructed to complete the CRT with the prostheses under four different conditions: 1) using the CNN trained with data collected via mirrored training, 2) using the CNN trained with data collected via mimicked training, 3) using the MKF trained with data collected via mirrored training, 4) using the MKF trained with data collected via mimicked training. Participants performed the task six times for each of the four aforementioned conditions. The four conditions were tested in pseudo-randomized counter-balanced blocks to minimize order effects. During each block, participants were given eight attempts to move the clothespins. A block was finished after three successfully transfers or if all eight attempts were used. After the final block for a given condition, the participants completed the NASA Task Load Index (TLX) survey of subjective workload as well as a survey of embodiment adapted from [12]. At the end of the experiment, participants were asked to rate the four decodes from best to worse.

Data Analysis

Data were screened for normality. A two-way analysis of variance (factors: algorithm and training paradigm) was performed for each participant individually. No significance differences were observed for the algorithms, so a subsequent pooled analysis was performed to look at the effect of training paradigm. Because the number of completed clothespin transfers varied based on success rate, an unpaired t-test was used to compare between the mimicked-training and mirrored-training data.

RESULTS

Mirrored Training Can Improve Speed on the CRT

We saw no significant difference between mimicked training and mirrored training on the overall success rate of transfers for the CRT. However, in general, mirrored training decreased the transfer time on the CRT for two of the three participants, although this was only significant for one of the three participants. Participant one saw a 12% improvement in speed with mirrored training ($p = 0.19$, unpaired t-test), participant two saw a 57% improvement in speed with mirrored training ($p < 0.05$, unpaired t-test), and participant three saw a 5% decrease in speed with mirrored training ($p = 0.68$, unpaired t-test; Fig 2).

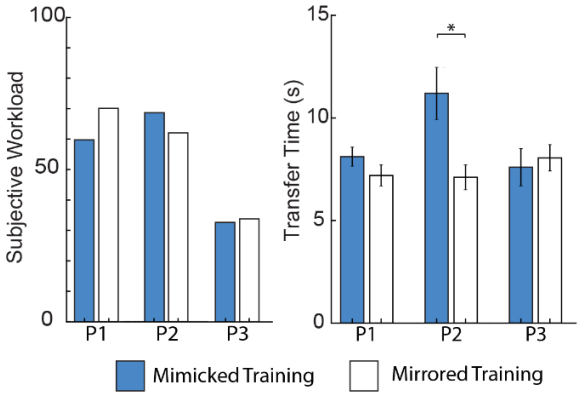

Figure 2: Differences between mimicked training and mirrored training during the CRT. Subjective workload varied among participants, but no differences were greater than the minimum detectable change. Transfer time decreased with mirrored training for participants one and two, but this trend was only significant for participant two.

No Detectable Difference in Subjective Workload or Embodiment between Mimicked Training and Mirrored Training

Subjective workload during the training sessions was comparable between mimicked training and mirrored training (Fig 2). Mimicked training has a slightly lower subject workload score for participants one and three, but none of the differences in subjective workload were greater than the minimum detectable change of 15 points [13]. Similarly, there were no significant differences or meaningful trends in the embodiment scores between the training paradigms. User preference between the training paradigms also varied. Participant one favored mimicked training, participant two favored mirrored training, and participant three had no preference.

DISCUSSION

Task-specific and accurately labeled training data is critically important for algorithm performance. Here, we compare the impact of two different training paradigms on the run-time performance of two commonly used machine-learning algorithms for use on a real-world functional task. Overall, we that subjective workload was similar between

the training paradigms and that user preference varied. Mirrored training is capable of providing significantly better prosthetic control algorithm, but this improvement is unique to individuals.

Prior work showed that mirrored training provides more accurately labeled kinematics than the mimic approach [9]. The results presented here suggest that the more accurately labeled kinematics can also translate to improved run-time prosthetic control. We hypothesize that the benefits of more accurately labeled kinematics from mirrored training will become more pronounced with more complex machine-learning algorithms and more complex task.

The results presented here suggest that users should be given a preference in the training paradigm. However, there are several other important factors to consider when selecting a training paradigm. For example, mirrored training is only available to unilateral amputees and requires additional motion capture equipment and calibration to ensure accurate kinematics. That said, the work presented utilized a Leap Motion (Ultrahaptics) that cost less than $100 USD, requires low computational power and no extensive technical knowledge to use. The ability to allow users to collect their own self-selected training data could prove useful when training on complex activities of daily living. Task-specific training has been shown to improve performance on activities of daily living [2]. Furthermore, this approach empowers amputees to be control of their personal data and the type of movements they can perform with their bionic limb.

The ability of mirrored training to significantly improve run-time performance for some participants warrants further investigation. Future work should replicate these findings with additional participants, multiple training sessions and more complex tasks to more precisely quantify the impact of training paradigm on run-time prosthetic control.

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Myoelectric Controls Implementations

DEEP AND SURFACE SENSOR MODALITIES FOR MYO-INTENT DETECTION

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ABSTRACT

Electromyography is the gold-standard among sensors for prosthetic control. However, stable and reliable myocontrol remains an unsolved problem in the community. Amid improvements currently under investigation, one focuses on alternative or complementary sensors. In this study, we compare different techniques, recording surface and deep muscle activity. Ten subjects were involved in an experiment in which three different modalities were attached on their forearm: force myography, electro-impedance tomography and ultrasound. They were asked to perform wrist and grasp movements. For the first time, we evaluate and compare in an offline analysis these three different modalities while recording several hand gestures.

INTRODUCTION

Although surface electromyography (sEMG) has been used for decades in myoelectric control, it is subject to several drawbacks, such as sweat, electrode shift, muscular fatigue, or cross-talk among others [1]. Possible alternatives are being investigated in order to potentially replace or complement sEMG. For instance, in [2], it was shown that force myography (FMG), which is based on the deformation of the forearm due to muscular contractions, provides a more stable signal compared to electromyography. Although there are of course still some steps to go before integration, FMG showed a higher separateness of clusters and a higher accuracy when compared to sEMG. However, both sEMG and FMG are *surface* techniques, meaning that they record information mostly from surface muscles. Indeed, even though FMG indirectly contains some information about deeper muscle activity, these two techniques are still considered surface modalities. Deeper acquisition sources could therefore potentially provide important missing information. For example, ultrasound (US) imaging has already been evaluated for myocontrol with positive results for single finger movements [3]. Another deep sensing modality has also gained interest in recent years due to the search for alternatives to sEMG: Electrical Impedance Tomography (EIT). In medical EIT, particularly for myocontrol of the hand, a certain number of electrodes are placed around the forearm and a micro non-invasive alternating current is applied to one of them while the others measure bioimpedance. This process is repeated by applying the current in each electrode, in turn, until completion of the circle. The collected measurements can be reconstructed into a tomographic image using a back-projection algorithm [4]. The technique has already shown that it can be used to discriminate different hand movements offline with good classification accuracy using a support vector machine algorithm [5] EIT has also been integrated in an armband together with sEMG [6].

In this paper, we describe an experiment comparing FMG, US and EIT and discuss their potential for myocontrol applications. Ten subjects were fitted with the three modalities simultaneously and asked to perform wrist and grasp movements. To the best of our knowledge, this is the first time these three modalities have been compared in an experiment. The results show that US is always within the first two best performing algorithms for each hand/wrist gesture.

MATERIALS AND METHODS

Experimental setup

The EIT system used in this experiment was developed by the University of Siegen [7]. It consists of 16 electrodes placed around the forearm and provides 256 raw values. Its output frequency was approximately 2.7Hz. Post-filtering and processing to reconstruct the tomographic image were performed using the EIDORS library [4].

FMG data were collected using a custom-made armband with a Velcro strap and 10 force sensitive resistors developed at DLR [2]. The data were filtered with a second-order Butterworth low-pass filter with a cut-off frequency of 1Hz and saved at 94.2Hz. FMG was preferred over EMG due to the potential interference with the EIT system, which would have injected microcurrents into the same area where the EMG sensors would have recorded electrical muscle activity.

The newly developed portable US system was developed by the Fraunhofer IBMT [8] and is one of the smallest systems available for ultrasound imaging, as the probe is flat and circular, unlike the normally bulky probes of medical systems. The 1161px by 162px B-mode displayed image was streamed into our software and stored at a frequency of approximately 5.1Hz. A bird's eye view of the experiment can be seen in Figure 1(A).

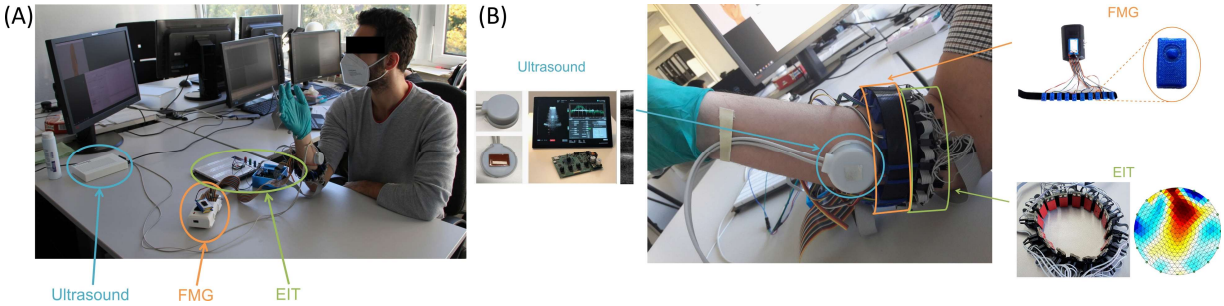

Figure 1: (A) Bird's eye view of the experiment. (B) Zoom on the modalities.

The three devices were placed in the following order from proximal to distal: EIT, FMG and US, as shown in Figure 1(B). Both the EIT and FMG systems were sending the data to our Interactive Myocontrol software via Bluetooth while the US device sent its data via USB.

Subjects and experimental protocol

Ten people (8 men, 2 women, 32.5 +/- 6.3 years old) took part in this experiment. Half of the subjects wore the sensors on their left arm, and the other half on their right arm. A sequence consisted of eight actions: rest, power, point, precision (tridigital), wrist flexion, wrist extension, wrist supination and wrist pronation. After a familiarisation phase, three repetitions of the sequence followed. All subjects signed an inform consent form and the experiment was previously approved by the DLR Work Ethical Committee.

The subjects sat in front of a table and placed their elbow on the table so that the arm was in line with the shoulder and the forearm formed an angle of about 90° to the upper arm, with the palm facing the side of the body. A 3D hand model on a screen indicated which hand movement had to be performed. For each action 2 seconds of data were recorded, with up and down phases lasting 1 second each and a further 2 seconds of non-captured rest between each action. For each subject and each repetition, the order of the actions was randomized.

Data analysis

The machine learning used for the analysis was Ridge Regression (RR), as it has the advantage with high-dimensional (HD) data that combined movements are possible without having to be trained, as was the case with HD-FMG [9]. The hyperparameters were evaluated for each subject using cross-validation.

For each modality, different feature selection methods were chosen for comparison. Each modality was rescaled between 0 and 1. The 255-feature vector of EIT data was compared with restored images from different reconstruction algorithms of the EIDORS library. The first two methods use a basic solver using unfiltered back-projection. This is one of the simplest algorithms for reconstructing an EIT image. The second method uses additional artificially

generated data compared to the first one. The third method is the Gauss-Newton approach with one-step iteration: it is the most commonly used for back projection in clinical and experimental publications. US data cannot be processed directly in the RR algorithm due to its size and must be reduced by feature selection algorithms. The first feature selection algorithm for US is Region of Interest Gradient (ROI-G) [10]. It has already been used successfully in experiments on US [11] and HD-FMG [9]. After some preliminary tests, a square of 40px with a step size of 30px was chosen as ROI. The other feature selection algorithms consisted of rescaling the matrices to a smaller size by selecting one row in n with n in $\{14, 20, 25, 30\}$ as the different step sizes. For all methods, the features were amplified by a factor of 10 and filtered through a second-order Butterworth low-pass filter with a cut-off frequency of 1Hz.

In order to compare the accuracy of the individual feature selection method, the normalized root mean square error (nRMSE) was calculated. This was averaged across all subjects, using the first two repetitions as the training samples and the last repetition as the test set. We also performed a comparative analysis of cluster separability for each modality. For each subject and each cluster pair (C_i, C_j), we evaluated a numerical index called the Safety Index [11], which indicates how separated two clusters are in a given input space. The Safety Separateness Index of the clusters was calculated as follows: it is the ratio between the maximum standard deviation of cluster C_i (evaluated over all dimensions) and the Euclidean distance between cluster C_i and C_j, $s_{ij} = \frac{max(\sigma_i)}{||\overline{C_i} - \overline{C_j}||}$ where σ_i is the standard deviation of cluster C_i and $\overline{C}$ is the mean of cluster C. In addition, the average number of principal components to reach 99% of the variance of the input space was calculated across all subjects.

RESULTS

The nRMSE of RR for each modality was calculated action-wise as shown in Figure 2. The results were evaluated statistically across all actions using Friedman test for non-parametric data, showing that the nRMSE was statistically significantly different across the different modalities $X2(9) = 40.8$, $p < 0.0001$, with a moderate effect size $W=0.453$. The post-hoc Wilcoxon paired test could not conclude between which methods after the Holm correction for multiple comparisons.

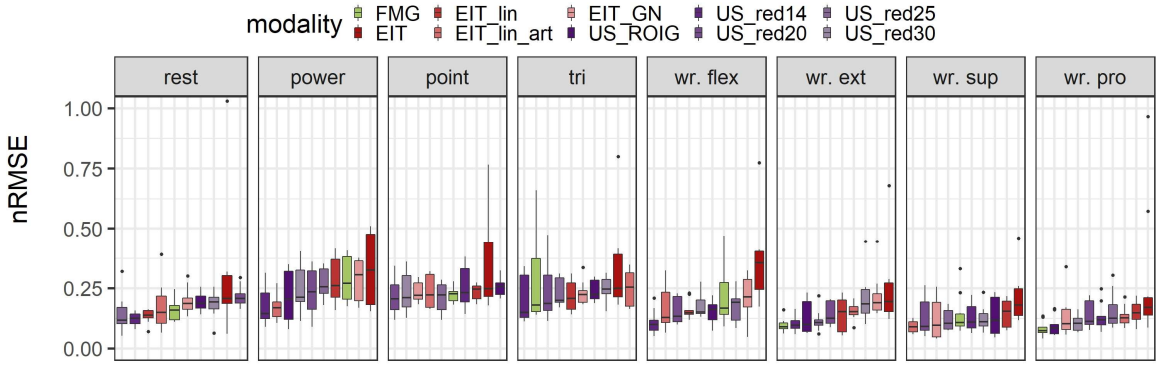

Figure 2: nRMSE on the three modalities and their respective feature selections: FMG in green, EIT in red, US in purple. The modalities are sorted in an increasing order of the median of nRMSE (best performing first) for each action.

The number of principal components (PCs) for reaching 99% of the variance of the input space was calculated for each subject and averaged for each modality in Table 1. This needs to be compared with the actual input space, i.e. the number of features, of each modality, which is also reported in the table.

Table 1: Number of features for each method. Average and standard deviation (SD) of the number of principal components in order to reach 99% of the variance. Separateness index (mean and SD) indicating the separateness of the clusters (the lower the better).

Modality	**EIT**	**EIT_GN**	**EIT_lin**	**EIT_lin_art**	**FMG**	**US_red14**	**US_red20**	**US_red25**	**US_red30**	**US_ROIG**
Number of features	256	740	740	740	10	348	996	531	329	234
Number of PCs (mean)	14.3	3.6	4.1	3.6	6.3	25.7	27.2	24.6	23	51.7
Number of PCs (SD)	2.9	0.7	1	0.7	0.8	6.4	6.5	5.8	5.5	7.4
Separateness index (mean)	0.495	0.098	0.089	0.093	0.181	0.067	0.1	0.111	0.126	0.143
Separateness index (SD)	0.341	0.034	0.025	0.03	0.05	0.015	0.039	0.025	0.029	0.023

The safety index to estimate the separateness of the clusters was evaluated and averaged across all subjects for each modality. Non-reconstructed EIT shows the lowest separability, while US rescaled every 14 rows shows the highest one.

DISCUSSION

Figure 2 shows that, despite no clear method standing out from the others, at least one feature selection algorithm from US is always in the top two according to nRMSE. FMG, with its 10 features, surprisingly performs better than the other algorithms for wrist extension and wrist pronation. The basic solver EIT_lin_art is the best performing for wrist supination. Comparing the number of principal components necessary to reach 99% of the input space, the US-related number of components are the highest ones, but generally exhibits a good cluster separateness index, especially the US_red14, which has the best separateness. Non-reconstructed EIT has the worst overall Safety Index. However, this could be explained by electrodes with high impedance that would negatively affect other measurements and that are filtered in the reconstruction algorithms. The EIT reconstruction algorithms have surprisingly a low number of PCs and better cluster separability than most of US methods. However, the fact that the number of PCs is lower than the number of gestures to be controlled could explain the generally lower nRMSE results compared to US and possibly indicate that important data is lost during reconstruction. This could also be due to the lower sampling rate of EIT.

Several feature selection algorithms were tested here on the different modalities. Unfortunately, none of them has yet been able to clearly outperform the others, with some modalities performing better than others for some movements. This might indicate that sensor fusion could be the ultimate solution. However, US was among the best performing methods according to nRMSE and to some extent cluster separateness index. Further feature selection algorithms should be evaluated to confirm this indication. In addition, the three modalities should be evaluated online and on amputees. However, due to the limited length of the stumps, it might be necessary to reduce the number of modalities to the two best performing ones.

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ESTABLISHING BIONIC PROSTHETIC CONTROL IN INDIVIDUALS RECEIVING TARGETED MUSCLE REINNERVATION FOR PAIN PREVENTION

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ABSTRACT

Targeted muscle reinnervation for the prevention of neuromas and phantom pain (N-TMR) is rapidly emerging as standard surgical intervention. The efficacy of N-TMR for pain treatment and the low complexity of the nerve redirection procedure at the time of amputation have been a key aspect of its widespread adoption. However, N-TMR was not developed for prosthetic control. Unlike the original prosthetic-focused targeted muscle reinnervation surgeries, N-TMR often redirected nerves to less accessible muscles. Therefore, using surface electromyography to measure the activity of the deeper reinnervated muscles for prosthetic control is very difficult especially since muscle orientation, signal separation, and electrical crosstalk are also not considered during N-TMR surgery. To address these limitations, we investigated the feasibility of applying sonomyography, a prosthesis control technique that is capable of measuring reinnervated muscle activity across the depths of the residuum. We applied ultrasound imaging techniques paired with image processing and machine learning algorithms to classify patterns of muscle activity according to the motor intentions of participants' missing limbs. In two participants with transhumeral amputation and N-TMR surgery we demonstrated that 4-6 functionally relevant missing hand and wrist movements could be classified with 82% to nearly 100% accuracy. We suggest that like the original prosthetic-focused targeted muscle reinnervation surgeries, N-TMR provides opportunities to establish bionic interfaces with advanced prostheses. We see a significant opportunity to improve prosthetic motor outcomes for the growing number of individuals with high-level amputations that are receiving this procedure for pain prevention.

INTRODUCTION

Mechatronic upper limb prostheses have become exceptionally sophisticated. Control of these advanced systems has evolved to leverage surgical, engineering, and neuroscientific approaches that detect users' intentions directly from their motor nervous systems [1], [2]. Here, Targeted Muscle Reinnervation (TMR) has demonstrated significant potential as a long-term, real-world nerve machine interface for individuals with high level upper limb amputations [3], [4]. By redirecting severed nerves, the patient's intentions to move their missing limb are amplified by the residual muscles and can be used to establish a bionic link to control their prosthesis. However, like almost all bionic control interfaces, to ensure the best functional outcomes, TMR requires a large interdisciplinary team to plan and execute the surgical procedure prior to therapy and prosthesis fitting. TMR is most often performed as a secondary surgery and relevant factors related to prosthetic control inform surgical decisions. For example, the muscles to be reinnervated are carefully chosen and may be first denervated from native nerves, surgically modified, and/or moved to ensure that electromyographic (EMG) signals will be robust and that crosstalk is minimized when operating prostheses [5], [6]. As the degree of surgical planning and technical complexity is high, most individuals with high-level amputations do not have access to this procedure and the functional benefits it may provide.

A variant of TMR surgery is rapidly gaining widespread clinical acceptance. Unlike prosthesis-focused TMR, targeted muscle reinnervation for the prevention of nerve-related amputation pain (N-TMR) is a less complex intervention to manage the disorganized nerve growth after amputation. N-TMR helps prevent phantom and nerve-related pain by redirecting severed nerves to the closest appropriate muscle nerve branches [7]–[9]. N-TMR does not typically require large interdisciplinary teams and at some institutes it is being offered as standard-of-care at the time of primary amputation surgery. Although only recently emerging, the effectiveness in pain prevention and low surgical complexity have resulted in the number of individuals with N-TMR vastly expanding. However, N-TMR was not designed for bionic control of prostheses and current EMG control interfaces can be challenged to effectively measure the activity of reinnervated muscles. This is because surgical consideration is not given to muscle orientation, separation, or the prevention of EMG signal crosstalk; and importantly, EMG sensors remain on the skin's surface while the reinnervated muscles are often located deeper in the residuum.

Sonomyography is an emerging prosthetic control technique that derives control signals from muscle activity across the depths of the residuum [10]–[12]. Although this robust control technique was established in non-TMR amputee populations, it has tremendous potential in unlocking bionic control for the growing population of individuals receiving N-TMR surgeries. Sonomyography uses a small ultrasound transducer positioned on the residual limb to image the muscle deformations that occur below the surface of the skin. Image processing and machine learning algorithms are applied in real-time to capture patterns of muscle deformation, classify them according to the user's motor intentions, and actuate the corresponding prosthetic movements. Sonomyography holds multiple potential benefits including the accurate detection of minuet muscle deformations throughout the residuum, capturing continuously variable activity to proportionally command prosthetic movements, and improved signal to noise ratios when compared to traditional EMG approaches [12], [13].

The objective of this case series was to investigate the degree and accuracy to which sonomyography techniques could be applied to detect missing hand and wrist motor-intentions from the reinnervated muscles of two individuals with transhumeral amputation and N-TMR surgery. We hypothesized that attempting missing limb movements would generate distinct patterns of muscle deformations in the reinnervated musculature, and the combination of ultrasound imaging and machine learning could accurately predict the user's motor intentions from this muscle activity.

METHODS

Two participants with transhumeral amputations and N-TMR surgery were recruited. Protocols were approved by UC Davis' Intuitional Review Board and subjects provided written informed consent prior to participation.

Par-1 was a 52-year-old female with left transhumeral amputation and N-TMR surgery. She did not regularly wear a prosthesis, and it had been 6 months since her N-TMR surgery at the time of testing. Her median, ulnar, and radial nerves were all transferred to her left pectoralis major muscle branch. She reported experiencing a phantom hand that was telescoped at the end of her residual limb and described very minor phantom pains. She also reported being able to visualize moving her missing fingers.

Par-2 was a 40-year-old male with left transhumeral amputation and N-TMR surgery. He did not regularly wear a prosthesis and it had been almost 18 months since his N-TMR surgery at the time of testing. His median and ulnar nerves were transferred to his pectoralis minor muscle branch, and his radial and musculocutaneous nerves to the serratus anterior muscle branch. He reported feeling a phantom limb with minor to moderate phantom pain experienced as tingling, shocks, tightness, or itching.

Data Collection

Participants were seated with their residual limb at their side. A Terason 3200T uSmart Ultrasound system with a 16HL7 linear array transducer (Teratech Corp) was used to capture muscle deformations with an imaging depth set to 4 cm [12]. The transducer was affixed to the reinnervated pectoral areas of each participant using a custom bracket and medical bandages at the location of maximum tissue displacement; determined by motoring the ultrasound screen and asking participants to freely attempt moving their missing hands. Once affixed, participants were asked to attempt a series of functionally relevant missing-hand and -wrist movements which included power grasp, pinch grasp, key grip, digit 2 extension (pointing), wrist rotation, and wrist flexion or extension [14]. Each movement was repeated 10 times. Patients were encouraged to mirror their intended motion with their unaffected limb and were able to view a live feed of the ultrasound images to assist with motor visualizations. Ultrasound video data was sampled at 30Hz, labelled, and stored for post hoc classification analysis.

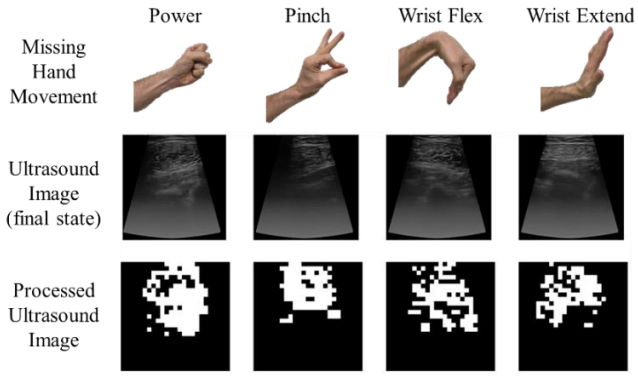

Figure 1: Ultrasound image processing procedure

Data Analysis

Raw ultrasound video data were captured at a 1920x1080 pixel resolution. Video frames were post-processed which included cropping and down sampling to a 128x128 image by averaging

neighbouring pixels. Thresholding was performed such that pixels became black or white creating a binary image resembling a QR code (Figure 1) [10]. To classify missing hand movements, we first identified the frames depicting the final movement position for each repetition of each missing hand and wrist movement. As ultrasound recordings ended with the patient at their final movement state, the Pearson correlation distance from the first frame to all following frames was used to estimate when the final state was first achieved. These identified frames were then used as feature vectors for a K nearest neighbour (KNN) machine learning algorithm to determine which grasps produced distinct and separable tissue deformation states. To quantify the accuracy to which hand and wrist movements could be predicted using the KNN classifier, a leave-one-out cross validation of the dataset was performed [15].

RESULTS

Par-1 completed all 6 hand and wrist movements. They did not report any difficulties in visualizing these missing limb movement and there was no apparent muscle spasms or fatigue effects observed during data collection. Classification accuracies for each movement ranged from 89.5% through 96.8% (Figure 2).

Although Par-2 was able to visualize and attempt moving their missing hand into a variety of positions, they reported this task physically and mentally challenging. As a result, each time they attempted to move their missing limb, they required time to concentrate and often intensely contracted their residual muscles. They were able to complete data collection for 4 hand and wrist movements (pinch, power, wrist flexion, and wrist extension) prior to muscle fatigue, spasms, and testing duration forcing the termination of the experiment. Three movements were classified with greater than 99.9% accuracy and pinch grip was able to be classified with 82.0% accuracy (Figure 2).

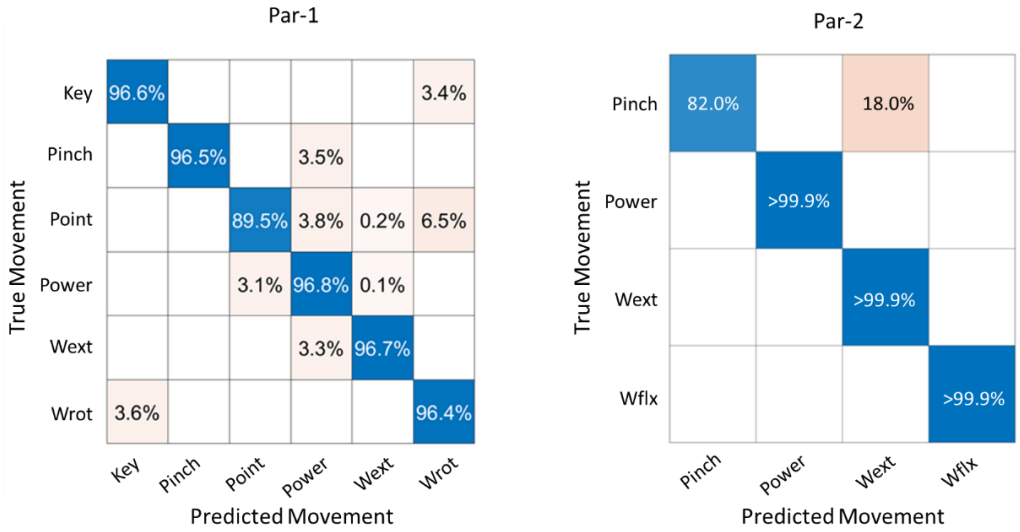

Figure 2: Classification accuracy. Diagonal elements show the accuracy of our algorithms in predicting a missing limb movement from muscle deformation patterns, and the off-diagonal elements represent the likelihood of misclassification. Wext- wrist extension, Wflx- wrist flexion, Wrot- wrist rotation.

DISCUSSION

This work supports that individuals who have received N-TMR have untapped potential to establish bionic links with their prostheses. We found that detectable patterns of reinnervated muscle activity existed with attempts to move the missing limb and this activity could be used to reliably infer missing-limb motor intentions. This was true even for Par-2 who has not used his reinnervated muscles to control a prosthesis, nor his once-intact limb for nearly 18 months. Although he was challenged by the experimental tasks, and muscle fatigue impacted his ability to complete testing, he still produced data that was consistent and accurately classifiable across 4 missing limb movements. We suggest that the effects of fatigue and the ability to visualize and perform missing had movements may improve with training. Further investigation is warranted to better understand how learning and therapeutic approaches may be applied to maximize the accuracy and dexterity that sonomyography may offer individuals with N-TMR.

These data are also compelling given the nature of the nerve reassignments. Par-2 had his median and ulnar nerves transferred to the pectoralis minor muscle branch. The pectorals minor is a deeper muscle covered by the more superficial pectoralis major. It was this region of his chest where the ultrasound transducer was located. The fact that our approaches captured and classified reinnervated muscle activity in this area demonstrates the utility of sonomyography and its ability to measure contraction patterns throughout the depths of the residuum. Further, Par-1 had 3 individual nerves (median, ulnar, radial) all transferred to a single muscle branch (pectorals major). Attempts to move the missing hand/wrist into functionally relevant configurations still generated unique patterns of muscle activity despite the reinnervation of only a single motor branch. An advantage of Sonomyography is the ability of a single sensor and machine learning algorithms to detect even minuet differences across contraction patterns which is emphasized by these findings.

As N-TMR continues to grow as an adopted standard for the prevention of neuromas and phantom pain, so too will the opportunity for patients to reap the benefits of advanced prosthesis control strategies. This work provides evidence that like those who received prosthetic-focused TMR, patients with N-TMR can establish bionic control over their prostheses, they just need to provide the appropriate muscle measurement interfaces. Ultrasound technology continues to be miniaturized, and now battery-powered handheld systems are commercially available making them feasible to incorporate in prostheses. Further, wearable prosthesis-focused sonomyography systems are currently undergoing commercial development. Taken together, this may allow the expansion of N-TMR beyond an effective intervention for pain prevention to include the benefits associated with neural-control of advanced prostheses.

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EXPLORING THE POTENTIATION OF SENSE OF OWNERSHIP THROUGH PROPRIOCEPTION FOR A SENSORY INTERFERENCE TASK

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ABSTRACT

A strongly perceived sense of ownership (SoO) of an amputees' device paired with agency leads to aspects of embodiment for that device. The purpose of this research was to explore the potentiation of SoO through proprioception while using a tactile feedback modality. In a sensory interference task, participants responded to vibrotactile stimulation presented to their index finger and thumb while experiencing incongruent and congruent visual feedback, with and without proprioceptive feedback. We found that participants' crossmodal congruency effect (CCE) scores for the vibrotactile feedback were higher when experiencing proprioceptive feedback that aligned with the movement of the virtual hand on the screen. Providing prosthesis users with more intuitive and useful sensory feedback may increase their perceived SoO of their device. When paired with agency, this can lead to improving their control performance and device acceptance.

INTRODUCTION

Improving prosthesis control performance can contribute to better user experience while using a device. Effective embodiment, defined as a prosthesis being 'part of' the user and having a psychological investment into the self, has been found to promote better control performance and help restore the perceived integrity of a body that has been altered by amputation [1]–[3]. Research suggests that embodiment arises from the interplay of sense of agency (SoA) and sense of ownership (SoO) [4]. SoA is elicited by the experience of initiating and controlling your actions, and it distinguishes our own self-generated actions from actions generated by others [5]. SoO is defined as the user's perception of their device identifying with and belonging to their body, occurring as the result of the integration and interpretation of visual, tactile and proprioceptive signals [3]–[7]. It is well known that linking augmented feedback to improvements in performance is challenging and researchers need to be strategic and intentional on the purpose and delivery of the sensory feedback [8]–[12]. Exploring sensory feedback for upper-limb prosthesis users that enables SoO and SoA and thus embodiment is accordingly a meaningful area of study.

In recent work, we explored the fusion of tactile and kinesthetic feedback on performance and ownership for two participants with sensory-motor targeted reinnervation [10]. In a similar sensory interference task to what is described in this paper, we found that both participants showed levels of limb ownership that were aligned with able-bodied responses to skin deformation; however one participant had reduced CCE scores when kinesthesia was added to their tactile feedback modality. This result was unexpected and was possibly influenced by technical inconsistencies in the participant's kinesthetic feedback system. The sample size of this work was limited due to international travel requirements and the intensive experimental time required. In order to explore this further with a larger sample size, we re-designed the experiment to accommodate able-bodied participants, as described in this paper.

The goal of this study was to determine the influence of proprioceptive feedback on perceived SoO for a sensory interference tactile feedback task. Existing literature has demonstrated that the crossmodal congruency effect (CCE) score can be used as an objective measure for perceived SoO [13]. To explore the potentiation of SoO through proprioceptive feedback, we calculated CCE scores during a sensory interference task. Participants were subjected to vibrotactile feedback to either their finger or thumb and were instructed to respond where they felt the stimulation via foot pedals. Simultaneous to the vibrotactile feedback, visual feedback was provided on a virtual hand on a screen either congruent or incongruently. Participants completed two sessions of the experiment: with and without proprioceptive feedback.

EXPERIMENTAL DESIGN

Recruitment

Written informed consent was obtained under the guidelines and approval of University of New Brunswick's Research Ethics Board prior to conducting the experiment. Fourteen able-bodied participants completed the study [mean age = 27.7yrs, range = 19–51yrs, 5 female, 1 left-handed]. Participants were randomly assigned feedback modality order to account for learning effects. Participants completed their second session one week after their first at the same time of day in an attempt to ensure similar levels of alertness between the two sessions.

Experimental Setup

Participants placed their dominant hand behind a monitor displaying an image of a hand in the same anatomical position as the participant (Fig. 1 a). Vibro-tactile motors (Precision Microdrives 10mm Linear Resonant Actuators – 4mm type) affixed to the participants index finger and thumb with medical tape (3M, Micropore) provided vibrotactile feedback (2.5G, 175Hz) corresponding to when the virtual hand had grasped the object on-screen (Fig. 1 b). The participants index finger and thumb were also secured to a slide potentiometer (Bourns Inc. 10KΩ 45mm travel range) in order to ensure that the position of their hand matched the position of the image on the screen. When participants pressed a key on a keyboard with their non-dominant hand, the virtual hand on the screen began to close at a fixed speed of 52deg/s. A PC running Processing (Release 3.5.4) displayed the GUI while also controlling the inputs and outputs through an Arduino Uno R3 microcontroller. A motor controller (Adafruit Industries LLC, model 2305) was controlled by the Arduino to actuate the vibrotactile motors.

Simultaneous to the vibrotactile feedback provided to either the participants' index finger or thumb, visual feedback on screen representing an LED was provided to either the index finger or thumb of the virtual hand upon object contact. This visual feedback was either incongruent or congruent to the tactile stimulation (Fig. 2 a). A green circle representing a fixation LED remained in the middle of the virtual object being grasped on-screen, half-way between the index and thumb (Fig. 2 b). Participants were instructed to respond where they felt the tactile feedback via foot pedals (Ammoon Sustain Damper Pedal), indicating with the toe pedal if they felt the vibrotactile stimulation on their index and with the heel pedal if they felt the stimulation on their thumb.

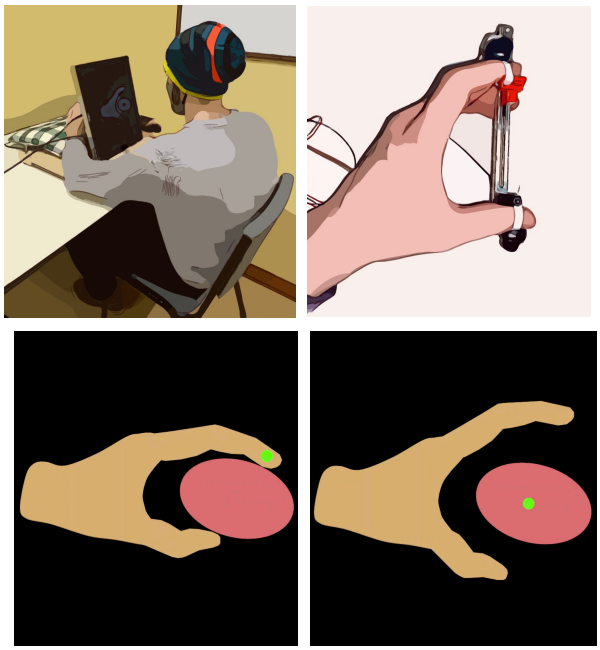

Figure 1: Experimental Setup. a) An able-bodied participant looking at an image of a hand on a monitor with their dominant hand behind the screen in the same anatomical position. Note that the lights were off for all testing conditions. b) The dominant hand of the participant affixed with vibrotactile motors and a linear potentiometer. c) Virtual hand-close indicating the end of a trial with the distractor LED illuminating on the index finger, either congruent or incongruent to the tactile feedback provided to the participants' dominant hand. d) The point of focus for participants, a fixation LED in the middle of the object on-screen.

Participants wore noise-cancelling headphones playing Brownian noise to mask background noise. Participants completed two sessions of this experiment; each session was assigned a different feedback modality. In one session, participants were instructed to keep their hand in a static open position during all trials. In the other, the participant mimicked the hand closing on the screen. Hand position was verified by the linear potentiometer and the trial was rejected if the participant's hand position did not match the position of the hand on the screen at the start and end of the trial, with a tolerance of ±1cm. Participants completed 10 practice trials with the lights in the room on and the Brownian noise off, followed by 10 practice trials with the lights off and Brownian noise on. They then completed four testing blocks of 64 trials each, with the lights off and Brownian noise on. Participants rested for 2 minutes between blocks.

Outcome Measures

The crossmodal congruency effect score (CCE_{Score}) objectively quantifies incorporation without being susceptible to experimenter biases and is calculated as the difference in the mean response time between congruent and incongruent trials [14].

$$CCE_{Score} = \bar{t}_{incongruent} - \bar{t}_{congruent} \quad (1)$$

Statistical Analysis

Statistical analysis was performed using RStudio IDE software. A Shapiro-Wilk test was used to investigate homogeneity in the variances of the data. As the CCE score data variances were found to be nonhomogeneous, a Wilcoxon signed-rank test was conducted with CCE score as the dependent variable and feedback modality as the independent variable. The confidence interval was calculated using the standard deviation (95% CI = mean ± 1.96 × SD). All numbers in the text refer to mean ± SD.

IV. RESULTS

To explore the potentiation of SoO through proprioceptive feedback for a vibrotactile feedback modality, we assessed participants incorporation for each condition by calculating their CCE scores when completing the sensory interference task. We found that adding proprioception did indeed allow the potentiation of SoO, achieving significantly higher CCE scores (122.17 ± 61.45) than when only tactile feedback was used (88.61 ± 60.61) (p-value = 0.009), see details in Fig 2.

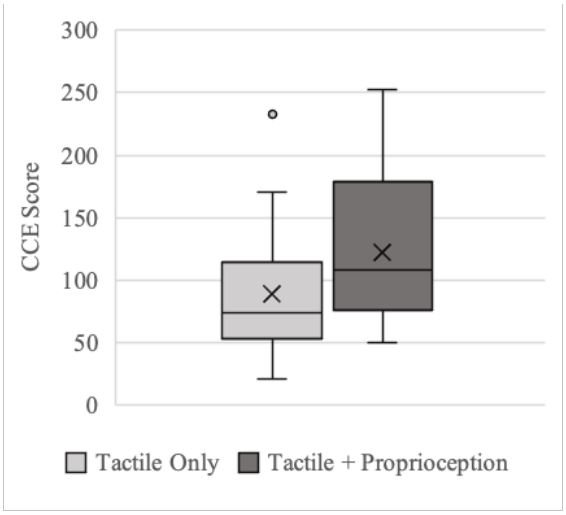

Figure 2: Box-plots showing the CCE scores for the tactile only and tactile + proprioception conditions. CCE Scores increase with the addition of proprioceptive feedback to the feedback modality. The mean of the data is represented as the x within the boxes while the median is represented as the line. The bottom and top of the box represent the lower and upper quartile, containing 50% of the data. The lines outside of the box represent the minimum and maximum values. The circle represents the outlier.

DISCUSSION

The goal of this study was to determine the influence of proprioceptive feedback on perceived SoO for a sensory interference tactile feedback task. To explore the potentiation of SoO through proprioceptive feedback, we calculated CCE scores for a sensory interference task which included two sessions, one with their hand in a static position (tactile only condition) and one with their hand mimicking the hand close on-screen (tactile + proprioceptive condition). We found that participants achieved higher CCE scores in the tactile + proprioceptive feedback condition than in the tactile-only feedback condition, indicating they had a higher level of ownership for the tactile + proprioception feedback modality. This study suggests that SoO can be potentiated through the addition of proprioceptive feedback to a tactile feedback modality. Providing prosthesis users with more intuitive and useful sensory feedback may increase their perceived SoO of their device. When paired with agency, this can lead to improving their control performance and device acceptance.

Although the results found in this study suggest that SoO can be potentiated through the addition of proprioceptive feedback to a tactile feedback modality, this work did not decouple proprioception and kinesthesia. A follow-up study worth considering is to replace the key-press hand close actuation with an isotonic and isometric actuation in order to allow for this decoupling. From there, these results must still be confirmed in the target population. Future studies may access more sensory-motor targeted reinnervation participants as it becomes the standard of care for prosthesis control, neuroma and pain management [10].

During data collection, two participants reported feeling simultaneous vibrations in their index and thumb throughout the experiment. After further investigation, this was determined to be phantom vibration. This is likely due to participants gaining an illusory SoO over the virtual hand on screen due to proprioceptive drift [4]. Two different participants reported that the vibrotactile stimulation was always congruent with the visual feedback. After completing trials with their eyes closed to eliminate visual feedback, it was determined that the stimulation was both incongruent and congruent, however the participants were perceiving the visual stimulation to always be correct. In one case, the subject was not able to correctly respond to incongruent trials rendering their data unusable due to high error percentage (53.1%). One subject was excluded for failure to reliably coordinate their hand close with the hand close on-screen.

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RESULTS OF TARGETED MUSCLE REINNERVATION IN INDIVIDUALS WITH A TRANSRADIAL AMPUTATION

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ABSTRACT

Targeted Muscle Reinnervation (TMR) surgery has been performed for over a decade in individuals with high levels of limb loss (transhumeral and above) to improve their ability to operate a myoelectric prosthesis [1]. However, it is unknown if TMR can improve the ability to operate a multi-articulating hand in individuals with limb loss at the transradial level. The objective of this study was to evaluate whether TMR improves control of a multi-articulating hand using pattern recognition control. A secondary objective was to look at control of a multiarticulating hand with direct control and pattern recognition before TMR surgery (Pre-TMR). Eight individuals with transradial limb loss who had previously used myoelectric control were recruited. Participants were fit with a passive wrist and multiarticulating hand with eight available grips. Home trials were completed Pre-TMR using pattern recognition and direct control, and after TMR (Post-TMR) using pattern recognition control. Occupational therapy was given prior to each home trial for each control type: direct control Pre-TMR, pattern recognition Pre-TMR, and pattern recognition Post-TMR. Outcome measurements were performed at the end of each home trial. A statistically significant improvement was found for both the Jebsen-Taylor Hand Function Test and the Activities Measure for Upper Limb Amputees (AM-ULA), between direct control Pre-TMR and pattern recognition control Post-TMR.

INTRODUCTION

Transradial amputation is the most common type of major upper limb loss and greatly impacts the functional tasks performed in daily life [2]. As more multi-articulating hands come onto the market, the ability to operate all the available functions of these devices more intuitively is required. However, this has remained a challenging task. One myoelectric option for control is direct control, in which the user isolates agonist and antagonist muscles of the forearm to open and close the hand. Users must then toggle between grips either by performing different actions such as hold open, double impulse, etc. Many devices are also able to utilize other non-EMG methods as well, such as positon triggers, button on hand, grip chips or apps ona smartphone in order to select the appropriate grip for their chosen task. Although this allows users to utilize multiple grips, these strategies may be more inconvenient, especially if frequently changing grips is required to complete one task.

Another myoelectric control option is pattern recognition (PR) which can allow myoelectric prosthesis users to operate more complex systems [4] without the need for EMG or non-EMG triggers. With PR, the user performs the intended prosthesis movement with their residual limb musculature.These muscle patterns are recorded by the prosthesis controller and are then associated with the grip. For an example with a multiarticulating hand, if power grip is wanted, the user performs power grip with their residual limb and the prosthesis goes into power grip. In addition to PR technology, Targeted Muscle Reinnervation (TMR) surgery has been effective at improvingneural control of a myoelectric prosthesis in individuals with higher levels of limb loss [3].This surgery involves taking residual nerves from the amputated limb and transferring them to other muscles to allow for increased EMG locations and more intuitive control. PR technology can be used by individuals with various levels of limb loss and has been shown to improve prosthesiscontrol, compared to direct control, when combined with TMR [5]. However, it is unknown if TMR improves control of a multi-articulating hand in individuals with limb loss at the transradial level.

METHODS

Eight participants with transradial level limb loss from the Shirley Ryan AbilityLab in Chicago, IL and Walter Reed National Military Medical Center in Bethesda, MD participated in the study (Table 1). Participants were fit by a certified prosthetist with a custom socket with eight bipolar electromyography (EMG) channels, a passive wrist, a modified Ossur i-limb Ultra hand [6]. A clinically available pattern recognition myoelectric controller, Coapt COMPLETE CONTROL Gen1 system [7], that was used and modified for this study to allow for direct control and data logging. A registered and licensed occupational therapist providedtraining for direct control (DC) and PR control, determined grips chosen, and how to use the various grips during functional tasks (Figure 1). All participants received a minimum of 4 sessions of training (each session was approximately 3 hours over

two visits to the center) for each style of control. The number of grips was chosen based on the therapist and user feedback to ensure reliability and functional use of each grip. For this study, eight grips were available that targeted variations of the commonly used and most functional grips (Fine pinch, 3 jaw chuck, power, key, and index point). Two eight-week home trials were completed using DC and PR control, in random order, Pre-TMR surgery: DC Pre-TMR and PR Pre-TMR.

For DC, only two of the eight EMG channels were used for control including the channels positioned over the wrist extensors and flexors for opening and closing the hand. To switch grips, participants performed one of four triggers (hold open, double impulse, triple impulse, and co-contraction). This allowed participants to toggle from a default grip to up to 4 additional grips for a total of up to 5 configured grips. The prosthetist and occupational therapist worked with the participants to determine which triggers were easiest for them to perform and assigned the most functional chosen grips to those triggers. For example, if power grip was identified as the most functional grip for that participant's daily activities and co-contraction was the easiest trigger to achieve, that grip was assigned to co-contraction. Once the participant was at home, changes to these triggers could not be done without the participant coming back to the center. During all three home trials, participants were instructed to wear the prosthesis a minimum average of two hours a day. The therapist remained in regular contact with the participants to ensure use,further assist in how to incorporate the prosthesis in their daily tasks, and problem solve any control issues.

With PR, all eight EMG channels were used and the remaining channels were selected with TMR in mind to capture remaining forearm musculature. Participants calibrated the prosthesis by pushing a button on the prosthesis and following the prosthesis while it moved through the assigned grips performing the natural movements in their residual limb that corresponded with each grasp pattern. This allowed participants the ability to re-calibrate their prosthesis at any time and at any location. Inboth DC and PR control, grips could only be switched once the hand was fully open which moved the hand to a neutral or natural hand position, then they could perform the desired trigger (if in DC) or muscle movement (if PR) to achieve the desiredgrip.

Following the two Pre-TMR 8-week home trials, all subjects underwent TMR surgery. During TMR surgery, the ulnar nerve was transferred to the flexor carpi ulnaris muscle and the median nerve was transferred to either the flexor digitorum superficialis or brachioradialis muscle. At least six months post-TMR users returned to ensure a well-fitting socket and prosthesis functionality. Additional OT training was provided including reassessing the chosen grips and number of grips prior to users completing an additional 8-week home trial with pattern recognition control: PR post-TMR.

The outcome measures completed at the end of each home trial included the Box and Blocks Test, Jebsen-Taylor Hand Function Test, AM-ULA, and the Southampton Hand Assessment Procedure (Figure 2) (Note: participant number 8's post-TMR outcome measures were excluded from analysis. His 8-week home trial began just prior to the start of the Covid-19 pandemic and he was unable to return to the laboratory for outcome measures testing until an additional 5 weeks following his home trial. During this time gap he was only wearing his prescribed prosthesis as confirmed by no usage logged on the study arm.). Means and standard deviations were used to compare outcome measurement scores and number of grips selected between DC Pre-TMR, PR Pre-TMR, and PR Post- TMR.

Table 1: Participant Demographics

Subject	**Gender**	**Age**	**Years Post Amputation**	**Etiology**	**Home Prosthesis**		**Pre-TMR Testing Order**
					Myoelectric Control	***Terminal Device***	
1	Male	29	1.5	Trauma	Coapt Pattern Recognition	Bebionic Hand	DC, PR
2	Male	39	3	Trauma	Direct Control	Bebionic Hand, Motion Control ETD	DC, PR
3	Female	48	12	Trauma	Coapt Pattern Recognition	Bebionic Hand, Motion Control ETD	PR, DC
4	Male	31	1	Trauma	Direct Control	Ottobock Michelangelo Hand	PR, DC
5	Male	42	1	Trauma	Direct Control	Ottobock Sensorspeed Hand, Motion Control ETD	DC, PR
6	Male	53	12	Trauma	Direct Control	i-limb, Ottobock Sensorspeed Hand	DC, PR
7	Male	58	1	Trauma	Direct Control	Motion Control ETD	PR, DC
*8	Male	29	1.5	Trauma	Direct Control	Bebionic Hand, Motion Control ETD2	DC, PR

PR: pattern recognition; DC: direct control, * PR Post-TMR home trial and outcome measures not included as indicated above.

a b c d

Figure 1:*a:* examples of functional training task. *b:* Performing a task from the AM-ULA *c*: Performing a task from the Jebsen TaylorHand Function Test. *d*: Performing a task from SHAP.

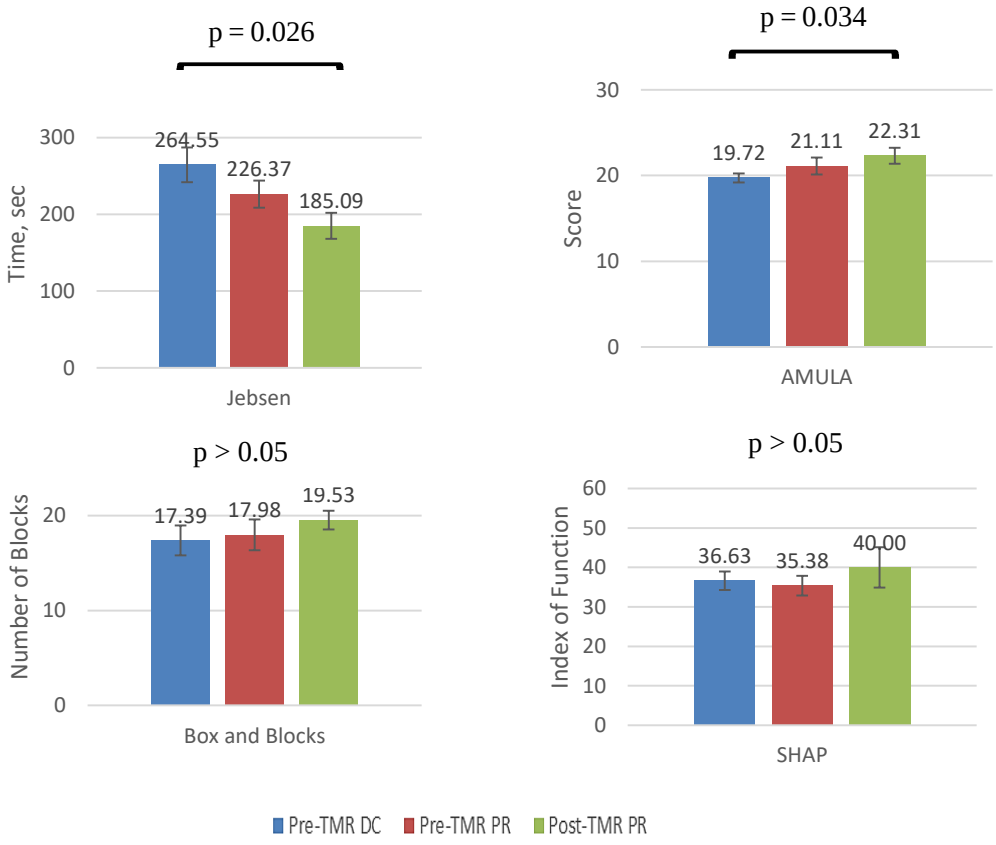

Figure 3: *Top Row*: Jebsen Hand Function Test and AM-ULA: statistically significant improvement in performance was found between DC Pre-TMR & PR Post-TMR conditions. *Bottom Row:* Box and Blocks Test and SHAP Test: no statistical difference in performance was found between conditions.*Data from participant 8 was not included in Post-TMR PR analysis.

RESULTS

For the number of grips selected, participants were able to access an average of 4.75 (SD = .46) grips in DC Pre-TMR, and 3.63 (SD = .52) grips for PR Pre-TMR. For PR Post-TMR participants had an average of 4.14 grips (SD = .69). There was a statistically significant improvement in Jebsen-Taylor Hand Function test scores (Figure 3) (P = .026) and the AM-ULA scores (Figure 3) (P = .034) between DC and PR post-TMR but not the between PR pre-TMR and PR Post-TMR scores. Therewas no statistical difference in the Box and Blocks Test scores (p > .05) (Figure 3) or the SHAP scores (p > .05) (Figure 3) between DC, PR pre-TMR or PR Post-TMR. Although this study found no statistical differences between all pairwise comparisons, there was a trend showing DC with lower performance, followed by PR pre-TMR, with the highest performancewith PR post-TMR.

DISCUSSION

Both the Jebsen Taylor Hand Function Test and the AM-ULA showed a statistically significant improvement between DC Pre-TMR and PR Post-TMR. The AM-ULA is not a timed test so participants likely took their time to select better grips for each task. This reduced issues of difficulty to achieve certain grips. However, this assessment does score on speed of completing each task, skillfulness with the prosthesis, and quality of movement (including compensatory movements). This may indicate that individuals had improved overall skill with grip selection and using their prosthesis during functional tasks post-TMR.

The SHAP test has a variety of tasks to encourage a variety of grips to be used. However, if a participant had a challenging time achieving some of the desired grasps, likely they ended up utilizing a non-optimal grip for some of the tasks. This may have forced compensatory movements to complete the task, take longer to complete the task, or possibly not be able to do the task [8]. For example, if they were using fine pinch for a task that required power grip such as holding a jar. Because the Box and Blocks test requires only open and close of the hand and no changing of grips is needed we did not expect to see a statistical difference between control conditions or before or after TMR surgery.

Although participants had access to the number of grips they were able to control while in the clinic with the occupational therapist, during outcomes testing some participants stayed in the same grasp no matter what task they were performing due to difficulty switching or not wanting to bother switching to another grip. For example, in DC, if the user had difficulty doing a trigger reliably (such as triple impulse), they might not use the grip assigned to that trigger often, though they might use an easier trigger (such as hold open). While subjects were provided training prior to and (as necessary) during the home trial during outcomes testing, additional training or reassessment of control of grips may have improved outcome scores.

A limitation of the current results is that it is difficult to distinguish whether participants improved with PR post-TMR due to having more experience with the hand or whether TMR did improve their control. It is clear that control was not impacted negatively with TMR and anecdotally most participants reported decreased pain similar to a recent study [9]. This study also had a low number of participants. Given the year-long commitment, requirement to undergo TMR surgery, and participate in three 8-week home trials, recruitment for this study was difficult. Another limitation is that all the participants received the same amount of training on the device and the control strategy, however some could have benefited from additional therapy.

ACKNOWLEDGEMENTS

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AUTHOR DISCLOSURE

Coapt LLC, which manufactures the devices being tested in this research, has a technology transfer and license agreement with the Shirley Ryan AbilityLab. Drs. Kuiken and Hargrove are responsible for the design, conduct, and reporting of this research and also have ownership interests in Coapt LLC. These interests have been fully disclosed to Shirley Ryan AbilityLab and Northwestern University and a conflict management plan is in place.

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SKILL ACQUISITION IN PROSTHESIS FORCE CONTROL WITH SUPPLEMENTARY EMG FEEDBACK

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ABSTRACT

Supplementary feedback interfaces for myoelectric prostheses enable users to learn, plan and execute the movements for controlling their prostheses. The ability to execute these movements reliably and accurately – 'skill,' can be studied by assessing speed-accuracy trade-offs (SAF). Here we used the SAF framework to empirically investigate skill acquisition with a closed-loop interface that uses EMG feedback, during a functional prosthesis force-control task. Preliminary results suggest that over 3 days the SAF shifts vertically upwards, while its shape remains consistent. Faster grasping remained less accurate compared to when participants used the supplementary feedback to carefully guide their behavior. We believe that studying the SAF not only enables us to quantify skill acquisition or learning effects, but also to more broadly understand the performance characteristics of closed-loop user-prosthesis interfaces.

INTRODUCTION

Force control is a fundamental problem in the field of myoelectric prostheses. Various control and feedback interfaces have been developed to improve the robustness of grasping with prostheses. Many of the control interfaces require users to learn novel ways of contracting their muscles to control the devices, and several (supplementary) feedback interfaces have been developed to promote learning and execution of these contractions [1 – 3]. However, how users acquire this skill, operationally defined as reliable and accurate movement execution [4], has not been thoroughly investigated in the literature.

Speed-accuracy trade-off (SAF) is a well-known behavioural phenomenon and provides a framework to study motor skill acquisition [4 – 6]. Assessing SAF across days enables better understanding of the changes in speed and accuracy that occur through learning, as opposed to just comparing performance improvements (such as success rates), since such performance could be improved simply by decreasing speed, but skill can be inferred only when both speed and accuracy change in the expected direction (faster speed, greater accuracy) [4, 5]. Here, we use this framework to understand how the learning of skilled prosthesis force control is promoted by using an established feedback interface – EMG feedback [3].

Specifically, in this study we investigated learning induced changes in the SAF in prosthesis force control using a functional box-and-blocks task. Participants used a closed-loop interface comprising of simple proportional control and EMG feedback [2] to perform a force matching task (apply a specified force on the blocks) at four different speeds, over 3 days. The four different speeds targets were imposed through time constraints, named Very Fast (0-2s), Fast (1-3s), Medium (2-4s) and Slow (4-8s). They were chosen to (1) sample the SAF appropriately and (2) emulate scenarios where users either rapidly or carefully and slowly modulate their muscle contractions to apply a desired force with their prostheses. Thereby, we assessed the SAF across days, to understand if/how participants' skill changed with practice and discussed the potential implications regarding (closed-loop) prosthesis interface design.

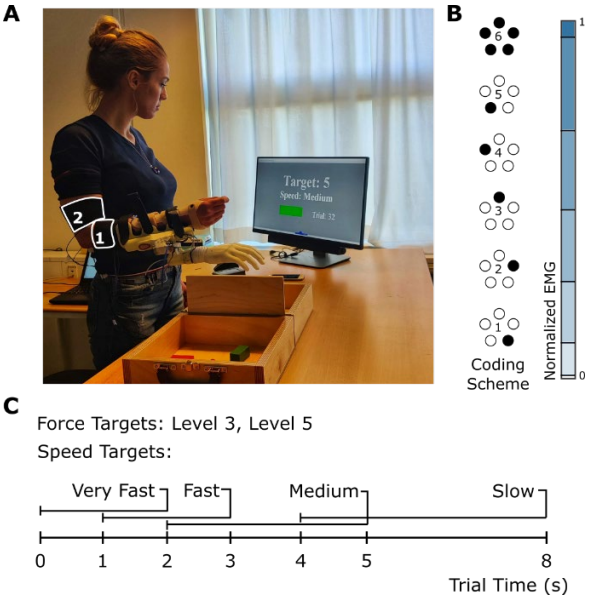

Figure 1: Experimental setup. (A) Experimental setup shows a participant using (1) 2-dry EMG electrodes and (2) 5 vibrotactors to perform a modified box-and-blocks task over 3 days. (B) Spatial coding scheme to convey EMG biofeedback through vibrotactors. (C) Force and speed targets (restrictions) for the task, used to derive a speed-accuracy trade-off.

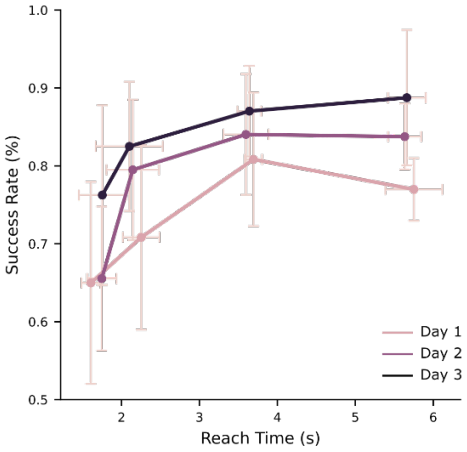

Figure 2: Learning induced changes in the Speed-Accuracy Trade-off. Success rates achieved across speed targets (very fast, fast, medium, and slow) are plotted against the measured reach time in the corresponding condition.

METHODS

Participants

Five healthy able-bodied participants (age: 24.8 ± 1.6) naïve to the task were recruited. All participants signed an informed consent form in accordance with the Research Ethics Committee of the Nordjylland Region (N-20190036).

Experimental Setup

The experimental setup is shown in Figure 1(A). Two dry-EMG electrodes (OttoBock 13E200) were positioned, one each on the wrist flexors and extensors, located by palpating. A small ink mark was made on both locations to ensure the placement remained similar on all days of the experiment. Five vibrotactors (C3, EAI Inc.) were placed equidistantly around a cross-section of the upper arm. Participants donned a wrist immobilization splint and a bypass socket holding the prosthesis (Michelangelo Hand Prosthesis, OttoBock GmBH). The electrodes output the linear envelope of EMG, sampled by the prosthesis controller at 100 Hz and transmitted to a laptop PC. Based on the received signal, the PC activated the vibration motors to implement EMG feedback to the user, and to transmit commands for the closing and opening of the prosthesis.

Participants used isometric wrist flexion to proportionally control (through a piecewise linear mapping) the closing speed of the hand. The maximum closing velocity corresponded to 50% of maximum voluntary contraction of the flexor activation. Hand opening was triggered by reaching 20% MVC of the wrist extensor activation. The boundaries of the piecewise linear mapping containing 6 levels (Figure 1(B)) between EMG commands and prosthesis velocity were chosen such that (1) the width of discrete levels increased at higher contractions to compensate for the inherent variations in the EMG signal at higher contractions, and (2) there was a one-to-one mapping between the participants' EMG commands and the prosthesis force levels. Participants received discretized vibrotactile feedback of their EMG commands through a spatial coding scheme (Figure 1(B), [7]). In this setup, the EMG feedback enables predictive control of prosthesis grasping force. To achieve the desired force level (from 1 to 6), the participants needed to modulate their muscle contraction to reach the desired EMG level as indicated by the feedback. Due to the one-to-

one mapping, the force level attainted after the closing would correspond to the EMG level maintained by the participant.

Experimental Protocol

The experiment was conducted over three consecutive days. On each day, we first measured the participants' MVC to calibrate the proportional control interface, followed by a familiarization phase for both control and feedback interfaces (see [7]). Then, a brief visually guided coaching phase was performed in which the participants were instructed how to modulate their muscle contractions at different speeds relevant to the task.

The participants performed a force-matching task, where they picked up blocks by applying a target force (level 3 or 5) and transported it into an adjacently placed box (Figure 1(A, C)). Additionally, they had to perform the task at specified speeds: Very Fast (0-2s), Fast (1-3s), Medium (2-4s) and Slow (4-8s), with the help of a timer (shown as a bar to them, Figure 1(A)). Participants performed 6 blocks of 32 trials each ([4 repetitions x 2 target levels] x 4 speed conditions), with a self-chosen period of rest between the blocks. The targets were presented in a block-randomized fashion, where the speed target remained constant for 8 trials, within which the force targets were randomized. Each trial started with a beep notification, followed by displaying the target force and target speed for the trial. The participants then used the closed-loop interface to generate appropriate EMG commands to reach the required target force. However, they needed to do this by respecting the timing constraint - if the target force was achieved before or after the indicated time window, the trial was considered failed. Upon reaching the target force, they were instructed to relax and trigger hand opening. After the end of each trial, they received visual feedback about their success/failure in both target force and speed. The same protocol was repeated on all three days.

Outcome Measures and Data Analysis

The EMG commands and the force generated by the prosthesis were recorded for each trial. We defined 'reach time' as the time elapsed between start of the trial and the time at which the maximum force was reached during the trial. Thereby, a successful trial was one in which the maximum force was within the target level and the reach time satisfied the target speed. Thereby, success rates – calculated as % successful trials – were computed to evaluate differences in learning across days. Mean and standard deviation of the success rates are reported.

RESULTS

Preliminary results indicate a clear speed-accuracy trade-off in prosthesis force control with a closed-loop interface, and a significant improvement across days for all speed conditions. Participants started with a performance ranging from 65 ± 13% (Very Fast) to 77 ± 4% (Slow) on Day 1 and improved by Day 3 to 76 ± 11% (Very Fast) and 89 ± 8% (Slow). Surprisingly, participants improved almost identically across all speeds, except in the Medium condition (Very Fast to Slow: 11 ± 20%, 11 ± 10%, 6 ± 6% and 11 ± 9%). Improvements from Day 1 to Day 2 (0.4 ± 7%, 8 ± 13%, 3 ± 7% and 7 ± 5%) were also larger than the improvements from Day 2 to Day 3, except in the Very Fast condition (10 ± 14%, 3 ± 13%, 3 ± 8% and 5 ± 7%).

DISCUSSION

Here we quantified skill acquisition in prosthesis force control using supplementary EMG feedback through changes in the SAF. Building on our previous work [7], we established in the present study that the same (closed-loop) interface, used at different speeds (relating to feedforward vs feedback control policies) yielded very different performance outcomes (here, success rate). The improvement of success rate, observed consistently at all specified speeds (a shift in the SAF itself) is a strong indicator for the improvement in the skill. Such an inference would not have been possible if the performance were sampled only at a single point on the SAF at two separate times (before and after practise, for example). In this case, if the accuracy and speed did not change in expected direction, it would be hard to say if the skill improved, or if the difference in performance was due to sampling the same SAF curve in two different points. Therefore, deriving the SAF enables a more holistic understanding of the range of performance afforded by a particular interface. Moreover, we observed that despite training, the trade-off exists between speed and

accuracy, and that the shape of the SAF did not appreciably change, further indicating that SAF is a practically useful framework to quantify how closed-loop interfaces enable users to develop flexible control policies.

While speed-accuracy framework has been used by the prosthesis community, in terms of the Fitts' Law task, here we use a more general formulation applicable to tasks other than pointing or its derivates. The next step in the present research is to increase the subject pool in order to conduct more systematic analysis. Future work can utilize the framework of SAF to evaluate the effect of different (feedback) interfaces on learning, and to understand how different interfaces might enable users not just to have different performance, but different trade-offs.

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TOWARD SEMI-AUTONOMOUS PROSTHETIC HAND CONTROL: APPLYING EMBEDDED NEURAL NETWORKS TO IMPROVE SENSOR FUSION IN PROSTHETIC FINGERTIP SENSORS

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ABSTRACT

We present an application of embedded, real-time neural network predictions to produce reliable sensing and enable semi-autonomous control of a prosthetic hand with embedded tactile sensors at the fingertips. We simultaneously predict the force magnitude and the position of contact, requiring on average 32.8ms, thereby enabling real-time measurements. We demonstrate 97.2% offline classification accuracy on the contact position, and a root mean squared error of 1.38 N (mean absolute error of 0.68 N) in predicting the force magnitude. Neural networking training is performed off-line on a Desktop computer using Keras and compiled into efficient C-code for a nrf52840 microcontroller using the open-source tool "nn4mc." The training model, as well as the nn4mc compiler, are available online, allowing prosthetic engineers to incorporate real-time, sensor-based inference into their prosthetic design.

INTRODUCTION

Approximately 60,000 people live with major upper-limb amputations in the United States [1]. Many individuals opt to use a prosthetic device to restore some level of functionality. A variety of myoelectric prosthetic hands are now available, including multi-functional devices that can achieve different grasp patterns [2]. However, without sensory feedback, these advanced devices are lacking compared to intact limbs. This is why older technologies like body-powered devices, which do provide some sensory feedback, continue to be commonly used [3].

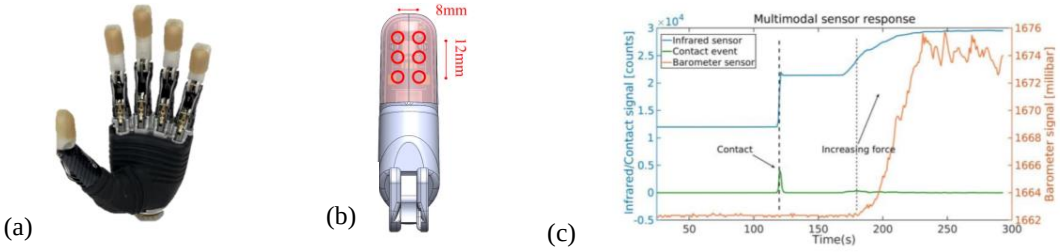
Adding sensory feedback to myoelectric devices can allow for semi-autonomous control, where the control is shared between the human and the device [4]–[6]. Prior methods relied on data that occurred after contact with an object [7]–[9] or extrinsic camera systems [6]. The Point Touch fingertip sensors enable three-phased control which depends on where the prosthetic device is relative to a nearby object. Myoelectric control systems are used for direct volitional control of the hand. Then, autonomous functions pre-contact and post-contact are enabled using proximity and force detection within the fingertip sensors. This future effort will be built upon the developments presented here.

Amputees can benefit from receiving haptic feedback on the localization of contact in order to obtain finer contextual information on the grasping task being performed [10]. Here, we present current developments on onboard neural network predictions with the help of the *nn4mc* compiler[1][11]. We simultaneously predict force magnitude and region of contact at the fingertip based on barometric and infrared sensor signals. The model used for prediction is embedded into the microcontroller that collects sensor data. This eliminates overhead in communication, increases the safety and security of the user's raw sensor data, and enables prosthetic engineers and designers to embed advanced predictions that can be computed at lower latencies.

BACKGROUND

The Point Touch is a novel multimodal tactile sensor that consists of an infrared proximity sensor and a barometric pressure sensor embedded in an elastomer layer [12]. Signals from both sensors measure proximity (0-10 mm), contact (0 N), and force (0-50N) which can be utilized in a variety of ways. The barometer provides a reliable force measurement for neural interfaces when restoring the sense of touch [12]. The proximity sensor presents a new possibility of using prosthetic fingers to "see" the world around them.

[1] https://nn4mc.com



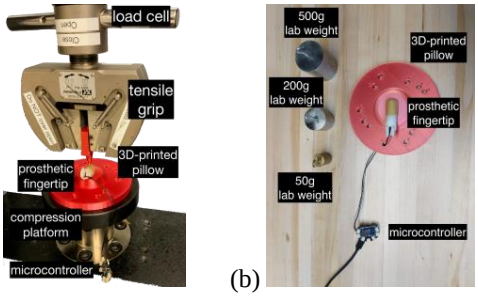
(a) (b) (c)

Figure 1: (a) The Point Touch integrated into the Bebionic hand. (b) High-level sensor architecture (c) Sensor response when a small piece of cotton is dropped onto the sensor and pressed.

MATERIALS AND METHODS

Experimental Procedure

Our approach consists of three steps: data collection, neural network training, and deployment of the neural network model on a microcontroller that collects sensor signals from the fingertip.



(a) (b)

Figure 2: (a) Data collection setup using a universal test machine and a custom-made pillow for the fingertip sensor. (b) Experimental setup to collect real-time prediction results from the fingertip.

We collect force data and sensor signal data from a universal testing machine (UTM) (Universal Testing Machine, MTS Systems). A custom compression test up to 50N is conducted via positional control of the UTM (see Figure 2a). We zero the position of the tip of the UTM when mild contact occurs with the surface of the fingertip elastomeric material. The material is met with a 5mm externally threaded surgical steel ball (Steel Balls, Prjndjw Jewelry). Then, the force is recorded at the PC (Instron TW Elite on Windows) that controls the UTM machine and the barometric and infrared sensor data is collected directly from the fingertip board. Figure 2b displays the experimental setup to collect real-time results. A set of three dead weights where each mass is placed in a direction normal to the fingertip sensor area. Figures 4a–4e are extracted using the experimental setup in Figure 2b.

Algorithm Design and Implementation

We keep a window of 30 data samples at a time. This window behaves like a double-ended queue (deque): when each of the fingertip samples is collected for both barometric and infrared sensor data, the front of the deque is pushed with the most recent sensor data samples, whereas the last sample in the window is deleted.

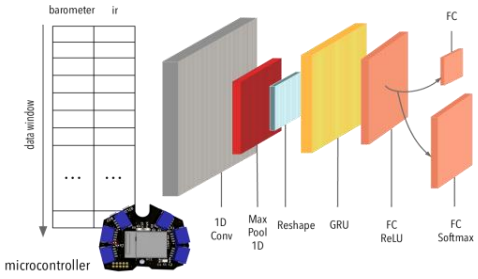


Figure 3: Neural network model; the architecture is interpreted from left to right.

The neural network model begins with a 1-dimensional convolutional layer with 16 filters and a kernel of size 2. We add a 1-dimensional max-pooling layer with a pool size of 3 and 3 strides. The output is then reshaped into a row vector. A gated recurrent unit (GRU) of 20 units of output takes the row vector and feeds its output to a fully-connected

(FC) layer with a rectified linear unit (ReLU) that outputs 10 units. The output of this layer is copied into two other FC layers: a one-neuron-wide FC hyperbolic tangent layer that outputs the normalized values for force and a 6-unit-wide FC layer with a softmax activation function that outputs the probability density function of the region of touch. The neural architecture is shown in Figure 3. The GRU is needed to trace temporal information through the recurrent layer's internal memory [13]. The output of this neural network is a 7-element vector $\boldsymbol{v} = \{v_0, v_1, \ldots, v_6\}$, where each value is between -1 and 1. This is then mapped back into force in Newtons and elements $\{v_1, \ldots, v_6\}$ indicate values between 0 and 1. Here, $v_i = 0$ indicates a value of l of the region i having any external contact and $v_i = 1$ means a high likelihood of the region i having any force applied to it.

For training, a 5-fold time series is split and each split trains using a batch size of 50 samples and for 20 epochs. The offline testing set results for location of contact are displayed in Figure 4a. We use a mean-squared-error loss for the part of the neural network that is learning normalized force magnitude and a categorical cross-entropy loss for the part of the neural network that is predicting the localization of contact.

The deployment of the neural network into the microcontroller is done through *nn4mc* [11], an open-source compiler that generates C code to be flashed to the low-power microcontroller that controls the fingertip sensors. This compiler allows for a lightweight and easy-to-integrate set of code. When profiled, the *nn4mc*-generated code achieves an average of 32.8 ms to perform each forward pass, which fits properly with the overall 16 Hz sampling frequency of the rest of the firmware at the embedded platform.

RESULTS

Figures 4a shows the raw barometric response of the sensor to an applied load. Figure 4b shows real-time results for force prediction in Newtons. From this data, we compute a root mean squared error of 1.38 N and mean absolute error of 0.68 N. Figure 4c shows the offline testing set region detection error. Regions 4 and 6 yield the maximum error with a failure rate of 6% and Region 3 yields the minimum error with a failure rate of 0%. For the probability of the location of contact, we truncate values above 50% as a positive contact prediction and values below 50% as a negative contact prediction.

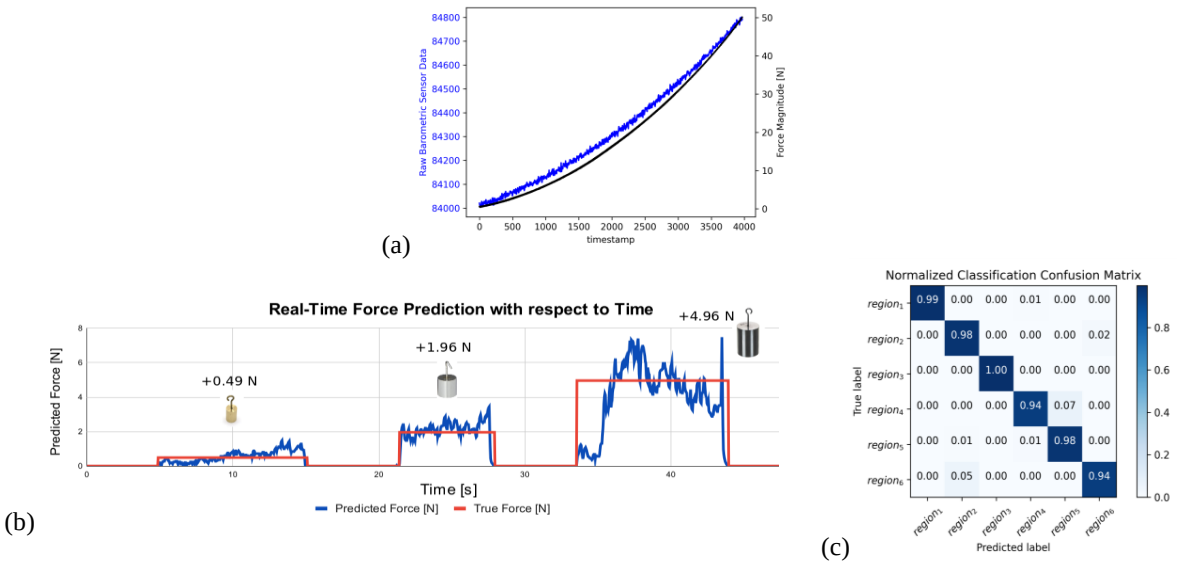


Figure 4: (a) Raw barometric signal after applied load. (b) Real-time onboard force prediction results using three dead weights. (c) Confusion matrix representing offline classification performance.

DISCUSSION

Figure 4a shows the raw barometric sensor responding to changes in the applied pressure prior to the predictions made by the neural network. Figure 4b shows the predictions for force to have an average absolute error of 0.68 Newtons, which comes mostly from the transient response to the finger being exposed to a 500-gram weight and human error when placing this weight. If we scale this error to the maximum force tested in the experiment illustrated

in this figure, we obtain an approximate of 13.6%, which exceeds the allowable tolerance of less than 5% of error in the force prediction. These results can be improved by refining the data collection experiment.

For the contact localization, we observe that the regions located at the distal half of the fingertip yield the highest performing predictions. This corresponds to the actual location of the sensors on the PCB, as shown in Figure 1b. In the future, we wish to test whether this data is sufficient for a semi-autonomous control paradigm for prosthetic hands, which will inform how to further improve the proposed design and machine learning architecture.

CONCLUSION

We demonstrated measuring force and proximity measurements within a commercially available prosthetic finger. We used an embedded, real-time neural network to predict force values and classify where the forces are imparted on the fingertip sensor. The combination of force, proximity, and spatial location data in an onboard embedded processor provide an opportunity for real-time control of prosthetic devices in a new fashion, in particular sharing control of a myoelectric prosthetic hand between the prosthetic user and the robotic device. Future work will implement a three-phased myoelectric control system followed by testing with able-bodied subjects and amputees.

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VOICE RECOGNITION CONTROL OF A MULTI-ARTICULATING HAND FOR IMPROVED GRASP SELECTION

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ABSTRACT

About half of upper-limb (UL) amputees do not wear a prosthesis. This is, in part, related to an inability to take full functional advantage of the prosthesis. To help address this issue, we have developed the Voice Activated Prosthesis Interface (VAPI) to allow individuals to supplement their conventional control with voice commands. Specifically, this study targeted accessing multiple grip patterns in multi-articulating hands. Data from amputee test subjects is reported showing an improvement in the time to complete tasks, more accurate grip selection, and reduced frustration with the prosthesis when using the voice recognition technology compared to standard myoelectric control.

INTRODUCTION

It is generally agreed that only about half of upper-limb (UL) amputees wear a prosthesis [1,2]. This is often because the prosthesis does not return enough function for the burdens of weight, discomfort, non-cosmetic appearance, lack of durability, etc. [3]. One primary reason for the lack of prosthesis acceptance is the inability to control the device effectively. Difficulties with control result because multiple prosthetic joints are being controlled with a limited number of inputs from the user. The issue becomes even greater with more proximal amputation as there are even more joints to control with even fewer inputs available.

Current input options for UL amputees are limited and include switches, electromyographic (EMG) inputs from residual musculature, force sensitive resistors, linear transducers, etc. In addition, many amputees don't have the ability to use these inputs effectively (e.g., muscle atrophy can lead to unusable EMG signals). Also, conditions such as traumatic brain injury or other cognitive deficits can make it difficult to understand and produce reliable input signals. Even for proficient users, most current control strategies often require sequential control of the various system joints.

The lack of independent and intuitive control inputs also leads to existing complex prosthetic mechanisms being underutilized. For example, in recent years there have been substantial advancements in prosthetic mechanisms such as multi-articulating hands (Figure 1). These hands have the ability to produce dozens of different grip patterns that can be selected based upon the task being performed. However, grasp pattern selection can be complex and difficult to understand. Therefore, most users only utilize a maximum of four hand grasps due to the difficulty in reliably switching between grip patterns.

VOICE ACTIVATED PROSTHESIS INTERFACE

Upper limb amputees are looking for solutions that allow them to regain the function they lost after their amputation. To address this need, Liberating Technologies, Inc. (LTI) has developed the Voice Activated Prosthesis Interface (VAPI) controller which incorporates the ability for the amputee to use their voice to generate control signals for their prosthesis.

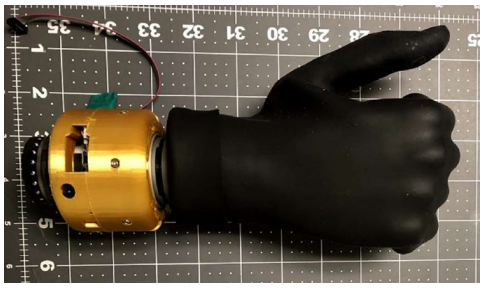

Figure 1: *Prototype VAPI with iLimb Hand*

Speech is the most natural and highest bandwidth mode of communication for humans [4]. Therefore, we aim to augment users current control schemes with the addition of their voice as a new input modality. Using this approach, VAPI has the ability to access larger numbers of grip patterns within multi-articulating hands as well as fluidly perform tasks that require coordinated sequential movements of multiple prosthetic joints, such as opening a door.

LTI has prototyped a fully embedded and stand-alone VAPI controller (Figure 1) to demonstrate feasibility of the concept. The current phase of research has been focused on developing three major components of the VAPI system: (1) the 'command interpreter' which interprets the commands through the voice recognition engine; (2) the 'command sequencer' which determines what control signals to generate based on the voice command; and (3) at the output controller to drive the terminal device (Figure 2).

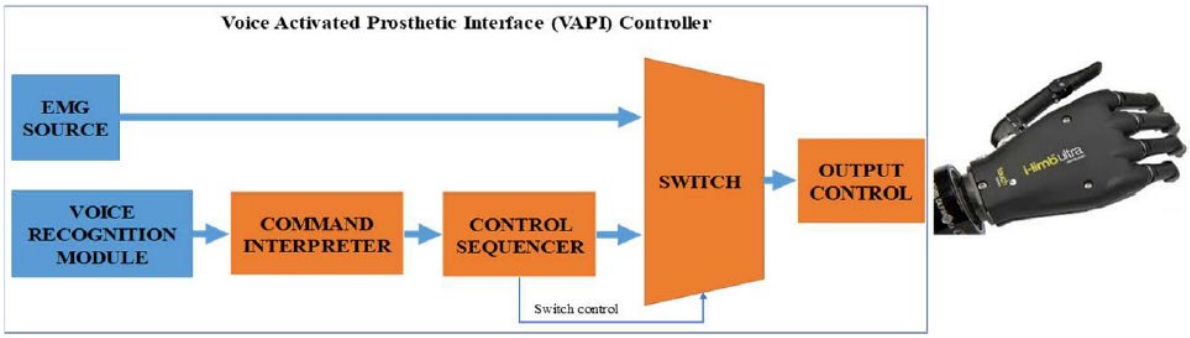

Figure 2: *Voice Activated Prosthesis Interface (VAPI) quick disconnect controller architecture.*

As demonstrated in Figure 2 the VAPI is used in addition to the user's standard EMG signals, with the control sequencer determining if the EMG or voice inputs will control the terminal device. The VAPI system uses a trigger word to 'wake up' the voice recognition module (e.g., 'Alexa…') which then listens for the command word. This helps to reduce accidental activation of the prosthesis. After receiving the voice command, the VAPI produces the necessary command signal to elicit a grip change in the hand. Control is then relinquished back to the EMG sensors for the user to open or close the hand after the correct grasp pattern has been achieved.

VOICE COMMANDS AND RECOGNITION ACCURACY

With our partners at eSoftThings and Sensory, Inc., we developed a series of phonetically distinct command sets to test to determine which would produce the highest classification accuracy. Preliminary tests had six subjects perform five trials of each word in eleven different command sets. Figure 3 demonstrates that we were able to elicit up to 98% recognition accuracy for two of the command sets (#2&#8). The command set that was selected for future testing included the command words: "finger pinch," "power grip," "tripod," "key grip," "hand," and "wrist," with the latter two being used to toggle between hand and wrist control.

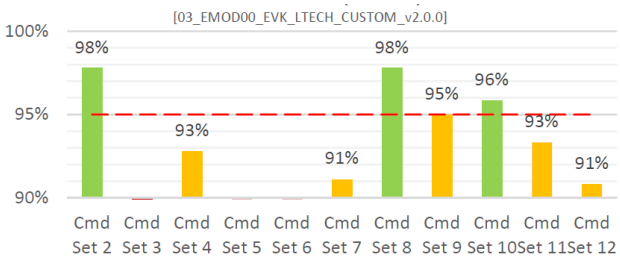

Figure 3: *Recognition accuracy results over 30 trials for each command set. Our goal was 95% (red dotted line).*

FUNCTIONAL OUTCOMES TESTING

Methods: We performed a set of standardized functional outcomes measures including the University of New Brunswick (UNB) Test of Prosthesis Function. While this test was originally intended for children, there has been shown to have acceptable reliability and preliminary evidence of validity for adults [5]. In addition to the UNB, we worked with our study Occupation Therapist (OT), Dr. Debra Latour, to develop a set of custom tasks that represent activities of daily living (ADL) where multiple grasp patterns may be useful. These included pouring and drinking, dressing tasks (put on sock, tie shoelaces, zip vest), turn doorknob, wrap a package and add written address label, etc.

Ultimately the user needs to generate the appropriate control signals to make the desired grip change. However, users will not always be able to switch into the desired grip pattern at the desired time. This could be due to imprecise muscle coordination (e.g., producing a double impulse when a triple impulse is required, not holding 'hold open' long enough, etc.), fatigue, misinterpreted voice commands, etc. Therefore, in addition to scoring the tests described above, we also tracked how often the subjects were not able to switch into the desired grip (i.e., 'Missed Grips').

Each subject completes the battery of tests either using EMG-only control or EMG with Voice Recognition (VR) control. Each subject was provided with an iLimb Ultra hand and VAPI for testing. In EMG-only mode, the hand was programmed to have four different mode switching commands used to access four different grip patterns within the iLimb (i.e., lateral, 3 jaw chuck closed, cylindrical, and precision pinch closed) via standard EMG switching commands including hold open, double pulse, triple pulse, and co-contraction. To ensure the length and weight of the prostheses were the same in both test conditions, the VAPI was installed, but disabled, during EMG-only control.

The subjects were trained on the VAPI and EMG switching and allowed to practice with each until they indicated they were comfortable with the control. Each subject then completed three trials of each task including both the UNB and custom tasks to simulate activities of daily living (ADLs).

Results: We have tested two subjects with limb loss thus far and testing is currently ongoing. We will have more subjects (both amputee and able-bodied) completed by the conclusion of the research funding in June of 2020. One subject with limb loss was an experienced two-site EMG user with a Touch Bionics iLimb multi-articulating hand. The other was a novice two-site EMG user with a Steeper beBionic multi-articulating hand. The experienced user was able to complete the full set of tasks three times. Due to fatigue, the novice user was unable to complete the full set of tasks. The novice user fatigued, in part, because the hand used for testing was significantly larger than their usual hand and the subject was unaccustomed to the additional weight.

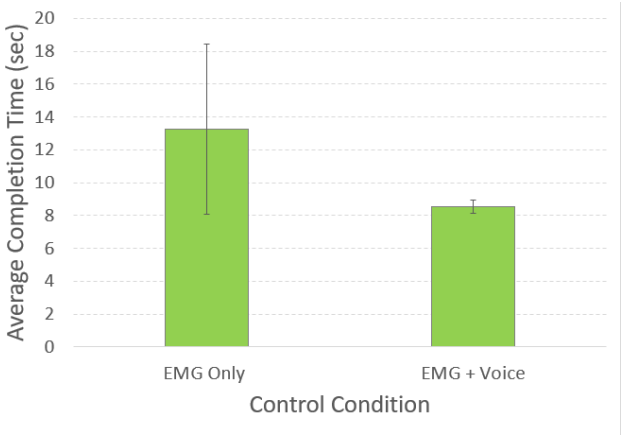

Figure 4: *Average task completion time with 95% confidence intervals with EMG Only grasp selection or EMG with voice control grasp switching.*

UNB: Traditionally the UNB focuses on scoring spontaneity and skill. The measure of spontaneity defines a person's tendency and impulse to use their prosthesis effectively when attempting a two-handed task. In determining a person's level of skill, it may be evident that the person is able to perform the requested task but demonstrates the need for additional training or motivation to refine their abilities when using their prosthesis [6]. Scoring results from the UNB did not show a substantial improvement in spontaneity or skill for VR.

Timing: One of our original hypotheses was that voice recognition control would allow the user to complete their tasks faster. Our experienced user demonstrated that they were able to complete the tasks ***35% faster*** (13.3 seconds to 8.6 seconds) when using voice recognition (Figure 4).

Missed Grips: The experienced two-site myoelectric user that completed the full three rounds of testing was observed to have made 2.8 times more grip switching mistakes when using EMG-only control than when they used voice control (Table 1). These results were consistent across both the UNB and custom tasks. In addition, with EMG-only control, each missed grip would require an additional muscle exertion to achieve the desired grip.

Table 1: Number of Missed Grips per control condition

	Control Method		**Ratio (EMG only/ EMG+Voice)**
	EMG-only Control	***EMG + Voice Control***	
Missed Grips	51	18	2.8

Anecdotal Feedback: Missed grip changes were a substantial source of frustration for both control methods. Survey results demonstrated that both subjects preferred the voice control and had lower frustration levels with VR due to fewer grip transition mistakes. One user reported reduced exertion when using the voice control. Both subjects also reported frustration with the length and weight of the prototype system.

DISCUSSION / CONCLUSION

Preliminary data indicates that voice recognition control of an upper limb prosthesis demonstrated more accurate multi-articulating hand grip selection than standard EMG-control methods. These data also indicated that it is possible to complete tasks more rapidly with voice control.

We believe that as individuals are able to easily and reliably access a greater number of grip patterns, they will be more likely to select the grip pattern that is ideal for the task at hand. With proper grip selection, it is likely that individuals will be able to reduce compensatory movements, which have been shown to lead to long term overuse injuries and joint damage [7].

It should be noted that there are other methods that can be used for selecting grip patterns that were not investigated in this study. These include the use of pattern recognition systems as well as the gesture control built into the iLimb Quantum. While these alternative methods are promising, there is a ceiling to the number of grasps that

can be accessed through these methods. It has been reported anecdotally that pattern recognition can reliably access three to four grip patterns and the gesture control adds four patterns. We plan to compare voice recognition control to these methods in future trials.

FUTURE WORK

Testing of the VAPI system is currently ongoing with three additional amputee subjects and several able-bodied subjects to be completed by June 2020.

In addition to testing the current system, we are continuing to make further technical enhancements to the VAPI system with our current funding. One enhancement is to implement remote microphones, such as lapel or in-ear microphones, to detect and wirelessly transmit the voice commands to the VAPI for processing. This will move the microphone from its current location in the wrist, which has the potential to be interfered with if the individual were to choose to wear clothing such as a heavy, long-sleeved jacket. We will also investigate communicating directly with a multi-articulating hand itself over Bluetooth to be able to access an even larger number of grip patterns.

Finally, we are in the process of developing a new outcome measure specifically designed to assess the ability of individuals to access different grip patterns. We refer to this test at the Grip Switch Assessment (GSA). The GSA was inspired by the Box and Block Test, a commonly used measure to assess unilateral gross manual dexterity. The GSA was designed to measure a user's ability to efficiently switch between multi-articulating hand grips while manipulating simple objects. The assessment involves measuring the time it takes for a user to switch into the proper grip and carry a set of objects over a short obstacle (Figure 5). If the patient takes longer than 30 seconds to achieve the proper grip the test administrator will have the patient move onto the next item. This cut-off reduces the continued frustration of the patient and keeps the GSA trial time to under two minutes. The order of the objects is randomized with each trial.

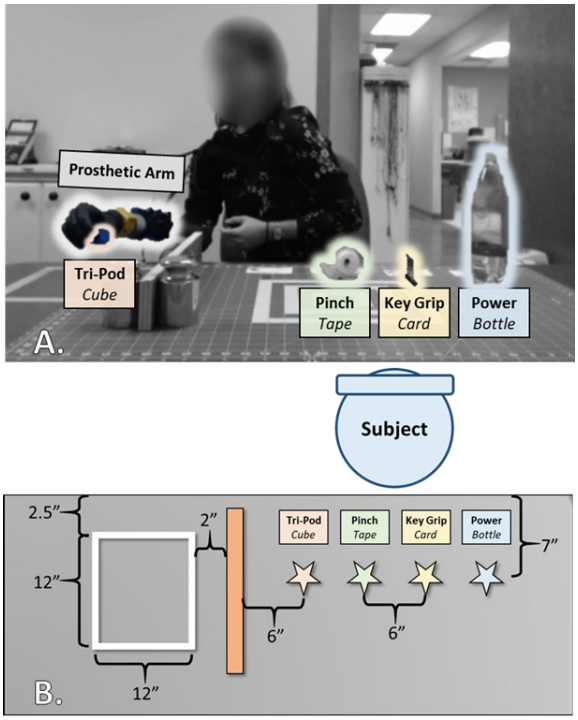

Figure 5: *A - An able-bodied participant manipulating the first object during a GSA trial. B - A diagram of the table arrangement to administer the GSA for a patient affected in the right arm.*

ACKNOWLEDGEMENTS

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Prosthetic Devices/Materials

A PILOT EVALUATION OF KINEMATIC CHANGES WITH POWERED WRIST FLEXION FOR TRANSRADIAL PROSTHETIC USERS USING THE GAZE AND MOVEMENT ASSESSMENT (GAMA) METRIC

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ABSTRACT

Wrist function is essential for correct positioning of the hand; however, few available prosthetic wrists provide powered flexion/extension. Users must compensate for this lack of function by performing compensatory body movements that may cause injuries and lead to device abandonment. Using the Gaze and Movement Assessment (GaMA) metric, we evaluated task timing, endpoint trajectories and 3D angular joint kinematics when using a 1-DOF wrist compared to a 2-DOF wrist in combination with a 1-DOF hand. We hypothesized that with the 2-DOF wrist, kinematics would be more similar to normative data and that users would perform fewer compensatory movements than when using the 1-DOF wrist.

INTRODUCTION

During the past decade, terminal devices available to upper limb prosthesis users have improved significantly, to the point where several powered multi-degree-of-freedom (DOF) hands that provide individually articulating fingers are commercially available. Such devices have the potential to significantly improve functionality; however, movement of the wrist to correctly position the hand in space is necessary for optimal functional use of the arm and hand [1]. Work by Montagnani et al. highlighted the importance of wrist dexterity [2]. In this work, individuals with intact limbs performed several functional tasks while wearing braces to block use of certain wrist and hand DOFs. Subjects performed poorest using a 1-DOF wrist + 1-DOF hand and best using an intact, unconstrained hand and wrist. Interestingly, performance with a 2-DOF wrist + 1-DOF hand and a 1-DOF wrist + multi-DOF hand were equivalent, indicating the importance of wrist movement in compensating for limited hand function.

Evaluating the benefit of new components and control mechanisms can be challenging, as most validated outcome measures assess the time required to complete various tasks without assessing the quality of the movement or the specific DOF(s) activated to accomplish the task. The Gaze and Movement Assessment (GaMA) metric, developed

Figure 1: a) Device used for the study. b) Participant wearing the device, in “home” position, ready to begin the Cup Transfer Task.

and validated at the University of Alberta under the DARPA's Hand Proprioception and Touch Interfaces (HAPTIX) program, quantifies motion (three-dimensional angular kinematics and hand movements) and gaze behaviour during simulated real-world tasks [3-6]. The two tasks utilized for the GaMA, the Cup Transfer Task and the Pasta Box Task, require movements representing day-to-day functional requirements, while challenging typical prosthetic limitations such as reaching and transporting objects at varying heights and across the body, with elements of risk and collision avoidance (Fig. 1b). Each task can be subdivided into specific phases of reaching, grasping, transporting and releasing objects. A performance aspect encourages the participant to work efficiently, and tasks are short to allow multiple repetitions within a reasonable testing time frame to assess performance consistency.

A powerful aspect of GaMA data analysis is the ability to assess differences across various phases of each movement and each task. These results provide valuable information not only on proximal joint and body compensatory movements, but on control of the terminal device and motor variability. We hypothesized that the time to complete the task would be slower when the additional wrist flexion/extension degree of freedom was utilized but the compensatory movements, specifically the trunk and shoulder, would be decreased.

METHODS

One individual, a 73-year-old male individual with a transradial level amputation, was fit with a 2DOF wrist and OttoBock Transcarpal hand (Figure 1a). The wrist allows for 351 degrees of rotation and 100.5 total degrees of flexion (58 degrees) and extension (42.5 degrees). The prosthetic components were connected to a test socket, which was fit with an Ossur upper limb silicone liner and a lanyard suspension (Figure 1b).

Marker plates were placed on the upper arm, forearm, dorsal hand, trunk, and pelvis and individual markers were placed on the index finger and thumb. The participant wore Pupil Labs Core eye-tracking system, with 4 additional markers connected to the frame for tracking of head movements. Markers were placed on the wrist, epicondyles and torso for calibration. After calibration, the participant was instructed how to perform the task and was able to practice, with guidance from an Occupational Therapist, prior to data collection. The task, performed standing, was the Cup Transfer Task of the Gaze and Movement Assessment (GaMA) [3]. During the Cup Transfer Task, a cup close to the participant was first picked up from the top and moved across a divider (M1). Then a second cup, further from the participant, was picked up from the side and moved across the divider (M2). The two cups were then returned to the original position, in the reverse order (M3 and M4). In between moving the cups from one side of the divider to the other, the hand returned to a "home" position on the side of the table. During the practice and data collection session, the device was controlled by an engineer connected to the system via a bluetooth connection. As the user practiced and performed the task, he verbally indicated to the engineer his desired movements. This strategy reduced the impact of inadvertent movements and fatigue, while allowing the evaluation of the impact of the wrist movement on the timing and joint kinematics. Each cup movement was divided into 4 phases: Reach, Grasp, Transport and Release.

Two sets of data were recorded. For the first set, the participant was able to request hand open and close and wrist rotation movements; the wrist flexion was kept in a neutral position. For the second set, the participant was also able to request wrist flexion and extension movements. Data were collected until six trials were completed without errors for each configuration set. The data compared between the two configurations included the timing for the reach, grasp, transport and release phases of each movement, the endpoint trajectory, and the joint kinematics. The study was approved by the Northwestern University IRB.

RESULTS

As expected, trials in which the participant utilized the wrist flexion and extension (FE On) took longer than those when only the wrist rotator was used (41.69s$\pm$4.75 vs 28.43s$\pm$4.57). The additional time was primarily in the "Reach" phase of the movements, as the individual was prepositioning the device. (Figure 2).

Though the mean distance travelled of the hand endpoint for the various movements was not notably different between conditions, except for M2, the path travelled was visually different, especially for M2 and M3, with wider trajectories for the movement of the cup further away from the participant back to the original position with FE off.

Joint kinematics were calculated for the 2 conditions and compared to normative data (n=14). Though the prosthetic user did include wrist flexion and extension movements during the task with FE on, the average range of motion used was less than that of the normative population (34 degrees vs 92 degrees).

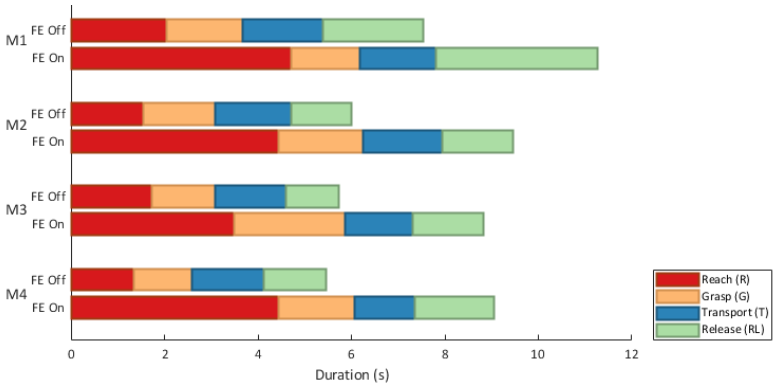

Figure 2: Breakdown of the timing of the 4 different cup movements, M1-M4.

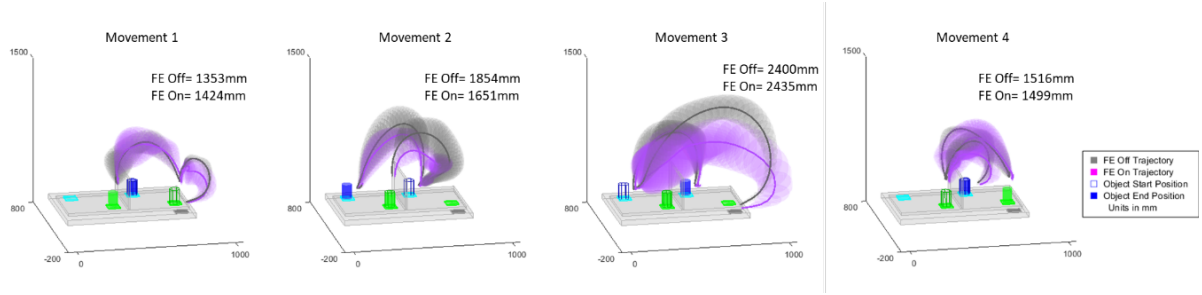

Figure 3: Trajectory of the prosthetic hand during the 4 movements: average with ± 1 standard deviation (SD) shaded. The mean overall distance of each curve (in mm) is shown for both conditions.

Table 1: Total range of motion (in degrees) at each DOF. Prosthesis user data indicates mean across trials [between-trial SD]. Normative data indicates mean of participant means [between-participant SD].

	Wrist FE OFF	***Wrist FE ON***	***Normative***
Trunk Flexion/Extension	21.1 [1.6]	17.3 [0.8]	18.7 [5.9]
Trunk Lateral Bend	24.5 [3.0]	18.1 [2.2]	11.6 [2.8]
Trunk Axial Rotation	25.3 [1.0]	21.9 [2.3]	17.5 [4.3]
Shoulder Flexion/Extension	59.3 [5.4]	60.5 [3.4]	73.3 [8.6]
Shoulder Abduction/Adduction	42.3 [5.1]	44.1 [7.2]	35.9 [5.4]
Shoulder Internal/External Rotation	60.0 [6.4]	55.2 [8.8]	59.9 [8.4]
Elbow Flexion/Extension	64.3 [5.4]	68.5 [7.5]	96.4 [7.9]
Pronation/Supination	20.3 [1.6] *	20.9 [2.9] *	78.5 [9.0]
Wrist Rotation	6.6 [2.4]	65.1 [30.2]	
Wrist Flexion/Extension	10.1 [2.1] *	33.8 [6.7]	91.8 [10.4]
Wrist Ulnar/Radial Deviation	8.8 [1.4] *	10.0[1.6] *	32.1[7.1]

* Participant did not have access to these DOFs. Non-zero values are the result of error in the system, or inadvertent marker movement/socket movement

Lateral trunk bend and axial rotation showed an increased total range of motion when comparing normative values to Flexion On and Flexion Off conditions (Table 1). The prosthetic user also used less shoulder flexion/extension and elbow flexion/extension compared to normative. The prosthetic user held his arm in a more adducted position early in the task in both conditions compared to normative data with a slight increase in total ROM for shoulder abduction/adduction for both conditions.

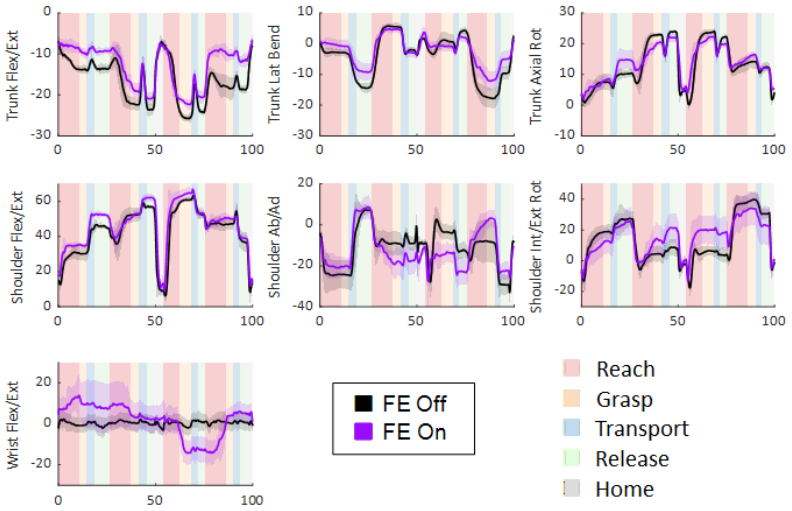

Figure 4: Time Normalized Joint Kinematics. Top row (L-R) Trunk: Flexion/Extension, Lateral Bend, Axial Rotation. 2nd Row (L-R) Shoulder: Flexion/Extension, Ab/Adduction, Internal/External Rotation; Bottom Row: Wrist Flexion/Extension. Vertical shading behind the plots represents the phases of the task.

DISCUSSION

As hypothesized, utilization of the additional degree-of-freedom (wrist flexion and extension) did increase the time required to do the task. The range of motion utilized at the wrist was much less than normative data. However, there were changes in the hand trajectory as well as the joint kinematics. In both conditions, the prosthesis user employed more trunk lateral bending and axial rotation compared to the normative population. However, the addition of wrist flexion and extension did appear to reduce the overall peak-to-peak to values closer to the normative values. The shoulder motion was different from normative, with less flexion and more abduction/adduction range utilized in both conditions.

There are limitations to this pilot study. In order to ensure that the device was moving as desired without any inadvertent movements from poor control or fatigue, the user orally indicated his desired movements. An engineer then drove the device as instructed. Though the participant had used a multifunction wrist system in the past as part of other research studies, the individual evaluated did not have the opportunity to control the prosthesis in a home environment. It is expected that additional training and usage will allow future users to more naturally include the additional degrees of freedom into various tasks. This may continue to improve how the users coordinate trunk and shoulder movements to perform the task. Based on this initial study, with the addition of wrist flexion and extension, we continue to expect improvements in trunk and shoulder compensatory movements.

ACKNOWLEDGEMENTS

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A TRANSRADIAL MODULAR ADAPTABLE PLATFORM FOR EVALUATING PROSTHETIC FEEDBACK AND CONTROL STRATEGIES

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ABSTRACT

Novel multi-modal and closed-loop myoelectric control strategies may yield more robust, capable prostheses which improve quality of life for those affected by upper-limb loss. However, the translation of such systems from an experimental setting towards daily use by persons with limb loss is limited by the cost and complexity of assessing all the possible sensor and feedback configurations. The comparison of different control strategies is further complicated by the use of disparate prosthetic socket and simulated prosthesis designs across experiments. This study aims to address these issues through the development and preliminary assessment of a Modular-Adaptable Prosthetic Platform (MAPP) system for use in experimental control strategy evaluation. The MAPP system is compatible with a variety of commercially available control and feedback devices and can be used in experiments involving participants with either intact or amputated limbs. The modular design enables compatibility with novel devices and quick reconfiguration of components. We compared EMG and FMG data acquired with the MAPP system to a previously characterized transradial simulated prosthesis, using able-bodied subjects. The MAPP was shown to match or exceed the control accuracy achieved using a rigid simulated prosthesis, while providing the added benefits of modularity. This device shows promise as a research tool which can catalyze the deployment of advanced control strategies by enabling comprehensive and standardized assessment of control and feedback strategies.

INTRODUCTION

Recent developments in robotic prostheses have yielded many advancements including multi-articulated hands [1], [2], machine learning based controllers [3]–[5] and sensory feedback systems [6]–[8]. However, translating these improvements to wearable prosthetic devices remains challenging. Before translating these advancements to clinical use, thorough assessment and validation of the potential benefits are required. A significant bottleneck for assessment arises due to the tradeoff between experiment scale, representativeness of real-world conditions, and time/resource costs [9]. Numerous factors besides the control strategy itself, including end-effector loading, sweat, limb-position, and acceleration can affect the performance of a prosthetic system, and these conditions must be recreated during the experimental assessment to provide accurate insights into real-world performance [8], [10]. Simulating a realistic physical limb-socket interface within a participant- and control strategy-specific prosthesis requires a custom-designed and manufactured socket [10], [11], which is not easily adapted for various control and feedback systems.

An alternate strategy to custom-designing prosthetic sockets for testing persons with amputation is often pursued by having able-bodied persons wear a simulated prosthesis with or without an end-effector attached. Researchers have used various versions of simulated prostheses to investigate performance of commercial prosthetic hands [12], performance of novel control strategies [13], [14], kinematic movement trajectories when using prosthetic hands [15], and the effect of providing sensory feedback to users on performance in functional tasks [7]. There is, however, an incomplete understanding of how well results collected from these studies translate to daily use in a prosthesis by a person with limb loss. Furthermore, comparisons across studies are limited due to the disparate versions of the prostheses utilized. There is thus a need for a modular platform that accommodates multiple sensors and feedback systems and can be worn by both able-bodied persons and persons with amputations to facilitate these crucial comparisons. This study aims to address this gap through the design and assessment of an inexpensive and easy-to-use 3D-printed transradial Modular-Adaptable Prosthetic Platform (MAPP).

Figure 1: *Overview of the 3D-printable MAPP with a HANDI-hand attached to it* [2].

Table 1: *Design specifications for MAPP system*

Item	Design Specification	Achieved Specification
Length adjustability	10 – 40 cm	Achievable with multiple exterior panels
Fit intact limbs	Achieve Target	Target met
Prosthesis interface	Compatibility with iLimb, BeBionic, and HANDi Hand	Target met; expand modularity with new components
User input sensor integration	6 sites; compatible with commercially-available electrodes	10 sites; compatible with FSRs, MyoBock (Ottobock Inc.), and Bagnoli (Delsys, Inc.) electrodes
Context detection & sensory feedback	Accommodate 2 sensory-feedback modalities & IMU	Compatible with mechanotactile & vibrotactile feedback and IMU
Cost	$500	< $200
Fitting time	< 15 minutes	10 min initial fitting; 2-4 min re-donning
Socket weight	500 g	450 g
Shear/ axial load	2 kg	5 kg
Comfort	Comfortable over the course of an experiment (3 hrs)	Comfortable for 3 hrs (user-reported)
Sanitation	Non-porous, cleanable interface surface with limb	All contact surfaces lined with closed-cell neoprene

MATERIALS AND METHODS

Socket Design Requirements

Critical features were identified through consultation with prosthetists from the Glenrose Rehabilitation Hospital. Table 1 summarizes the design requirements and specifications for the developed socket. Unless otherwise stated, all components were 3D-printed using Ultimaker 2+ (Ultimaker BV) and Makerbot Replicator 2 (MakerBot Industries, LLC). Rigid components were printed using PLA and flexible components using Ninjaflex Cheetah filament (Ninjatek, Inc.). Figure 1 shows the design of the MAPP platform as a prosthetic socket for a person with transradial amputation. The developed socket consists of rigid panels supported by stainless steel M4 threaded rods with flexible cushions attached via Velcro® (Velcro BVBA). All panels are connected to a ring at the distal end of the socket.

Suspension

Suspension is achieved through radial compression generated by tightening the circumferential straps threaded through each rigid panel. Alternating regions of soft tissue compression and release are created by the cushions and spaces between them, distributed both radially and axially along the limb. This design choice improves translation of motion between bone and socket as described in [16].

Adaptability

To accommodate different limb lengths, the spacing between each 3D-printed panel can be adjusted and fixed by adjusting the position of the nuts embedded in each panel along the rods attached to the adjacent panel. A panel can also be removed entirely by unscrewing the rods which anchor it to the adjacent panel. This combination of modularity and adjustability enables the socket to accommodate residual limbs extending beyond 5 cm (the length of one panel) from the cubital fossa and up to 5 cm proximal to the wrist. Different limb thicknesses are accommodated by interchangeable inner rings with different diameters. As forearms are not cylindrical in nature, the channels in each panel through which the rod substructure passes are purposely made loose-fitting such that the slope between each panel can be adjusted. Furthermore, the interfacing cushions are made slightly compliant and convex such that they can match the profile of the limb surface without causing pinch points. When the circumferential straps are tightened, the socket profile is maintained due to opposing pressure exerted between each of the straps, cushion infill material, and limb surface (Figure 1). Able-bodied participants can be accommodated by replacing the connecting ring and distal support cushion with a hollow connecting ring. An optional hand mount can be screwed to that ring, thereby restraining the hand and fingers if isometric contractions are necessary. The hand mount, offset in the radial direction, directly fits with the Quick-Connect Wrist (Otto Bock, Inc.) to connect commercial end effectors. Custom 3D-printed adapters enable compatibility with other end-effectors.

Modularity and Socket Structure

The MAPP enables user input and sensory feedback devices to interface directly with a user's limb across a range of positions. Such devices can be embedded in each interior panel (Figure 2), providing a direct interface with the user's limb through which suspension loads are transferred. Rigid inserts provide a stable base for various actuators, which can be interchanged to accommodate other devices. Sensors can also be mounted in the spaces between regions with panels via the Velcro-backed circumferential straps. Velcro-backed modules prevent slip relative to the circumferential straps, and radial compression from the straps provides a stable interface with the user's limb. The interchangeable outer-panels add to the stability of this mounting method by securing the position of the circumferential straps relative to the rest of the socket structure with a Velcro-backed surface. Further, these outer panels provide an interchangeable platform for mounting devices (see Figure 1) on the socket's surface. A final method of modular device mounting is provided by the rails connecting the main panels. 3D-printed

Figure 2: *Exploded view of a) FSR and b) surface EMG electrode into panel system via removable inserts.*

mounts can be threaded onto these rods providing a rigid platform which provides direct access to the user's limb via the spaces between exterior panels.

The interchangeable in-cushion sensor modules were designed to fit FSRs as described in [17]. Myobock 13E200 Electrodes (Ottobock Inc.) and Bagnoli Electrodes (Delsys, Inc.) were also made compatible with the initial prototype, enabling a mixed method of user-input detection. C2 and C3 vibrotactors (Engineering Acoustics Inc.) were similarly embedded into the interior cushion via interchangeable inserts, providing vibrotactile feedback in any cushion. 3D-printed mechanotactile tactor modules, the design of which is described in [8], were integrated into both the removable panels and substructure. The modularity of this socket system enables the integration of Inertial Measurement Units (IMU) (BNO055, Adafruit Industries) that could be used to detect forearm orientation and acceleration with respect to an inertial reference frame.

The structural rod segments were selected to support a 2 kg end effector load in both the transverse (ie. weight of 2 kg end load with residual limb parallel to ground) and axial (ie. 2 kg end load with residual limb perpendicular to ground). Using ASME Elliptic Failure Criteria and a life of at least 10,000 cycles of fully reversed loading, M4 rods were selected, leading to a minimum factor of safety of 2.5. The 3D-printed exterior panels were tested using both SolidWorks FEA (Dassault Systems, Inc.) and mechanical loading in the aforementioned configurations. These tests demonstrated that the overall minimum factor of safety was still limited by fatigue or bending of the rods; therefore, the socket system was capable of safely supporting up to a 2 kg end-effector or payload.

Figure 3: *A participant wearing a) the Modular-Adaptable Prosthetic Platform as a simulated prosthesis and b) the orthotic splint.*

Socket Interface Validation Study

Participants: Eight able-bodied, right-handed, male participants (mean and standard deviation of age: 28.8 ± 8.2 years) volunteered to participate in this study. Written informed consent according to the University of Alberta Research Ethics Board (Pro00077893) and the German Aerospace Center's internal committee for personal data protection (DLR authorization 3.7.2017) was obtained.

Experimental setup: Participants conducted the experiment while wearing the developed MAPP (Figure 3a) and while using a version of an orthotic splint commonly used to simulate a prosthesis (Figure 3b). Participants were randomly assigned to start with one condition or the other. For each simulated prosthesis, a band of five evenly-spaced Myobock electrodes and a concentric band of five FSRs as described in [17] were placed on the participant's right forearm [18]. Signals from both bands were processed using the same hardware as [17], with a 3rd-order low-pass Butterworth filter and cut-off frequency of 1 Hz to remove high-frequency disturbances. Mean absolute value for each channel was extracted and used to train a linear-discriminant analysis (LDA) classifier, representative of commercially available classifier-based controllers [3]. An i-LIMB Ultra prosthetic hand was attached to simulate the effects of normal prosthesis loading on each socket (Figure 3). Participants were asked to match seven gestures (rest, index point, power grip, wrist flexion, wrist extension, forearm pronation, forearm supination) shown on a computer screen for two-second intervals, three times each.

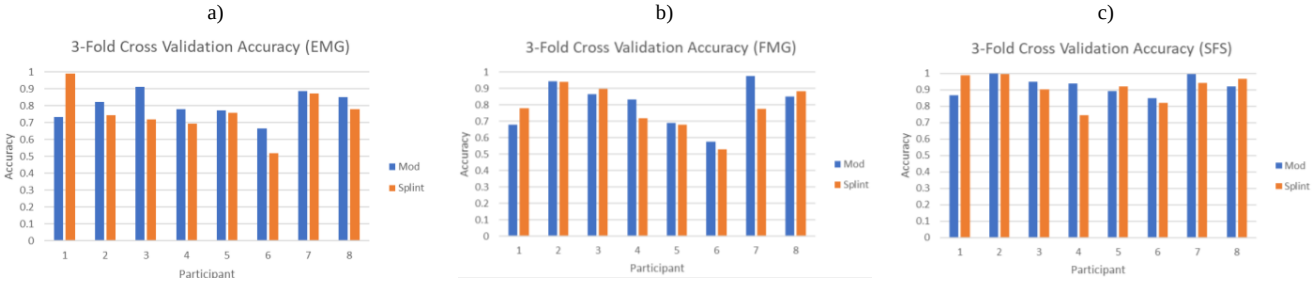

Figure 4. *Offline performance was assessed for each participant using a three-fold cross validation using a) EMG only, b) FMG only, and c) mixed-modality based on a sequential forward search (SFS)*

Data Acquisition: Offline performance was assessed for each participant using a three-fold cross validation (one for each repetition of a gesture). Assessment was performed using data from a) EMG only, b) FMG only, and c) mixed-modality based on a sequential forward search (SFS) to select the best-performance from 5 channels for each participant.

Results: Figure 4 shows that collecting data when using the MAPP enabled similar accuracy results as when using the orthotic splint across all sensor modalities.

DISCUSSION AND FUTURE WORK

Here, we developed a low-cost modular transradial socket system, which can accommodate multiple geometries of the forearm, along with multiple configurations of user-input, context detection, and sensory feedback devices. We tested the developed system with sEMG and FMG and a pattern recognition control strategy for seven gestures. Offline performance of participants using MAPP was similar to their performance when using the orthotic splint.

Future work will include comparison of online performance between the MAPP, orthotic splint, and socket systems. Using machine learning strategies to map input to action may reveal whether functional performance using a splint, or the MAPP provides a better prediction of clinical performance when deployed within a prosthetic socket. The effects of variables like end-effector loading, limb position, and acceleration are not well-characterized in control strategies. Therefore, paired assessment of the MAPP with a suction socket incorporating identical control strategies in different contexts may demonstrate the extent to which each platform captures these contextual changes. In conclusion, the cost time- and resource-savings, and flexibility to test a variety of novel prosthetic control strategies in a common platform, such as the one developed here, may accelerate the throughput of prosthetic control strategy validation.

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AN INEXPENSIVE AND ADAPTABLE PROSTHETIC WRIST IMPROVES DEXTERITY AND REDUCES COMPENSATORY MOVEMENTS

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ABSTRACT

Many presently available prostheses lack a functional wrist. Here, we highlight the development of an inexpensive prosthetic wrist that can be adapted to work with various sockets and prostheses. Using this prosthetic wrist, we explore the functional and cognitive impact of using a prosthetic wrist to perform activities of daily living. We measured task performance, compensatory movements, and cognitive load while transradial amputees performed a Clothespin Relocation Task (CRT) using a prosthesis attached to the wrist controlled by surface electromyography (EMG). Three transradial amputees performed the task with and without EMG control of the wrist. In aggregate data, the success rate was significantly higher in the wrist condition (61% ± 9% mean, ± standard error) than in the no-wrist condition. Compensatory movements were also better; e.g., the maximum leftward bend at the hip was less in the wrist condition (18.9° ± 1.2°) than in the no-wrist condition (15.0° ± 1.4°). The addition of controlling a prosthetic wrist had no significant impact on cognitive load, as assessed by the NASA Task Load Index survey and the detection response time to a secondary task. This work suggests that using a prosthetic wrist may increase dexterity and reduce joint strain for amputees without requiring a significant increase in cognitive effort compared to that of EMG control of a hand alone. These results can guide future development and prescription of upper-limb prostheses.

INTRODUCTION

Transradial amputees have expressed a strong desire for powered wrist prostheses. Indeed, the top five priorities for transradial amputees, in order of importance, were reported as: wrist rotation, simultaneous movements of multiple degrees of freedom, wrist deviation, wrist flexion/extension, and reduced cognitive demand [1]. Other priorities included reduced weight, improved durability, and increased strength [1]. Without a wrist, amputees are forced to compensate with unnatural movements to complete routine activities of daily living (ADLs) [2], [3]. The continual use of these motions causes damage to the musculoskeletal system over time [4], [5].

Despite the end-user desire for functional wrist movements, very few prostheses incorporate a powered wrist module [6], [7], and those that do are often expensive or not widely available. Here we describe the development of a powered, 3D-printed, inexpensive and adaptable prosthetic wrist. We also validate the function of this wrist with three transradial amputees and show more natural upper-limb kinematics without a significant increase in cognitive load. This work constitutes an important step towards addressing amputees' self-reported needs and reducing compensatory movements that would otherwise cause musculoskeletal damage.

METHODS

Wrist Design

The Utah wrist was designed with two degrees of freedom (DOFs) to provide pronation/supination and flexion/extension of the wrist (Fig. 1). The second DOF can also be used for deviation depending on how the prosthesis is mounted to the wrist. To mimic the strength of a natural wrist, two high-power hobby servo motors (Hitec D980TW, Hitec RCD USA, Poway, CA) were used with a 7.5-V, 20-A power supply (967-CUS200LD7R5, TDK-Lambda Americas Inc., National City, CA) to provide 4.3 N-m of torque. The wrist was designed to adapt to different prosthetic hands (Fig. 1C) and sockets (Fig 1E). The wrist was 3D printed using polylactic acid (PLA) to minimize the weight and cost of materials. See Table 1 for the full design specifications.

Functional Assessment and Participants

The clothespin relocation task (CRT) is a commonly used upper-limb dexterity assessment that involves moving a clothespin from a horizontal bar to a vertical bar. The clothespin is placed 8 inches down the length of the horizontal

bar and 8 inches up the vertical bar (Fig. 2A) [8]. Participants were instructed to move as many clothespins in a 30 second window as possible. Dropped clothespins were recorded against successful attempts to measure success. The CRT was completed by three transradial amputee participants with and without the wrist enabled. The wrist was connected to a functional check socket (Citterman et al., MEC 2022) and a left-handed TASKA hand (Fig. 2B). All participants gave written informed consent before taking part in experiments, in accordance with the University of Utah Institutional Review Board and the Department of Navy Human Research Protection Program.

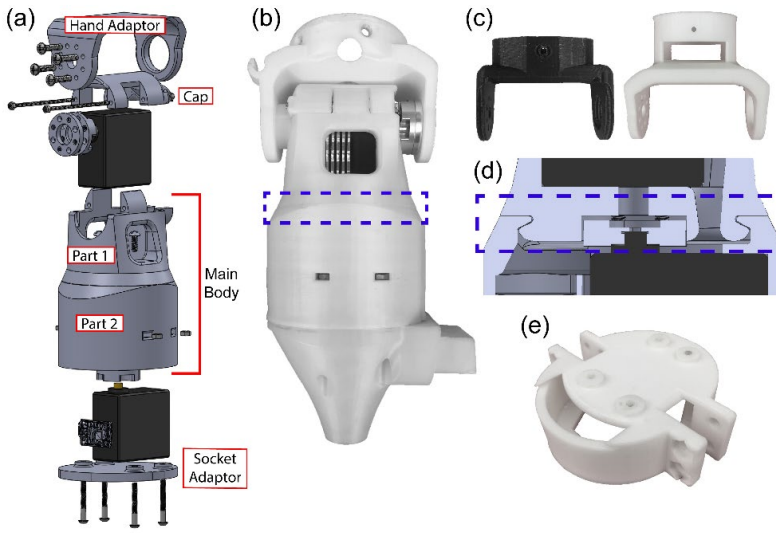

Figure 1: A) Exploded view of the Utah Wrist. **B)** A photo of the assembled wrist with the attachments to connect to a bypass socket. **C)** The wrist can adapt to a variety of different terminal devices by printing a new interface part such as the two shown here. **D)** Expanded view of the rotary joint mechanism, as highlighted in part B. **E)** The wrist can connect to different kinds of sockets by printing out a new interface such as the part shown here.

During the CRT, the participants had inertial measurement units (IMUs) attached to their chest and left bicep to measure any compensatory movements (Fig. 2C). While completing the holding task, the participant simultaneously completed a detection-response task (DRT) to measure their cognitive load [9]. The DRT requires the participant to push a button in response to a small vibrating motor on their collar bone. Both the response rate (i.e., how often they respond to the vibratory stimuli) and response time (i.e., how long it takes to press the button after vibratory stimuli) are used as direct measures of cognitive load. Participants completed the CRT as many times as possible within 30 seconds. Data were collected with and without the wrist in a pseudo-randomized counter-balanced blocks. The success rate was defined as the total number of successful transfers out of the total number of attempts within the 30-second time period. Participants completed the NASA Task Load after each block (i.e., with the wrist and without the wrist).

Table 1: Design Specifications

Degrees of Freedom	Pronation/Supination in series with Flexion/Extension or Radial/Ulnar Deviation
Length	11.8 cm
Weight	360 g
Range of Motion	Pronation/Supination – 180 Degrees Radial/Ulnar Deviation or Flexion/Extension – Up to 175 Degrees
Torque	4.3 N*m (both motors)
Cost	< $600

Signal Acquisition

Surface EMG from the participants was collected using a custom EMG sleeve [10]. EMG was sampled at 1 kHz and filtered using the Summit Neural Interface processor (Ripple Neuro Med LLC) as described in [11]. EMG features used for estimating motor intent consisted of the 300-ms smoothed mean absolute value (MAV) on 528 channels (32 single-ended channels and 496 calculated differential pairs) calculated at 30 Hz, as described in [11]. Joint angles were measured using two shimmer3 IMUs (Shimmer Sensing, Dublin, Ireland) attached to the participant's chest and bicep. A third IMU was placed on the table in a fixed orientation to provide a reference. The IMUs measured acceleration, rate gyration, and magnetic heading at 64 Hz, which were then used to calculate quaternions and generate rotation matrices for leftward bend at the hip.

EMG Control

A modified Kalman filter (MKF) was trained using individual and combination movements to control grasping/opening of the hand, pronation/supination of the wrist, and flexion/extension of the wrist. Training data consisted of participants mimicking pre-programmed movement of the individual DOFs in isolation, as well as combination movements involved simultaneous movement of two DOFs (e.g., grasping and rotating). Additional

details regarding the modified Kalman filter and training data can be found in [12]. A latching filter was applied to the kinematic output of the prosthetic hand to increase grasping stability. [13]

Data Analysis

Participants were given two blocks of 30 seconds to complete the CRT as many times as possible for a given condition. Thus, the number of attempted clothespin transfers was variable per condition and per participant, but the overall success rate was fixed to two per participant (i.e., one success rate for each of the two 30-second blocks). Data were aggregated across all participants and blocks and determined to be parametric by the Anderson-Darling test. The success rates with and without the wrist were compared using a paired t-test. Similarly, the detection response rate and NASA TLX scores were compared using a paired t-test. Because the total number of attempted transfers was not consistent between conditions, the maximum joint angles with the wrist and without the wrist were compared using an unpaired t-test. Similarly, the detection response time was compared using an unpaired t-test. Because the data were parametric, all data is reported as mean ± standard error.

RESULTS

Task Performance Improved with Use of Wrist

In the data aggregated across trials and blocks, the task success rate (Fig. 3A) was higher with use of the wrist (61% ± 10%) than without the wrist (33% ± 15%); ($p < 0.05$; paired t-test). Thus, task performance was 85% higher with use of the wrist.

Amputees Required Less Compensatory Movements with Use of Wrist

Moving the clothespin from the horizontal bar to the vertical bar without the wrist required the participant to compensate by bending leftward at the hip. When the wrist was enabled, participants naturally used the wrist to perform the task with movements more akin to an intact hand. Collectively, the three participants showed a significant difference in the maximum joint angle at the hip (Fig. 3B). Maximum hip joint angle was 18.9° ± 1.2 without the wrist compared with 15.0° ± 1.4 with the wrist ($p < 0.05$, unpaired t-test). Thus compensatory movements at the hip were 21% smaller when wrist control was enabled.

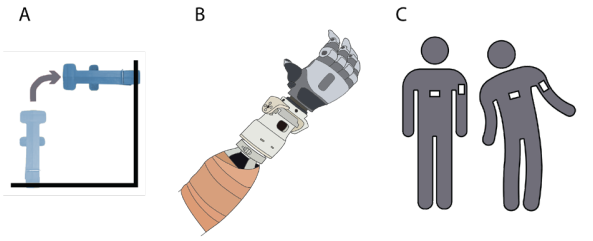

Figure 2: A) The Utah wrist was attached to the amputee participants using the transradial check socket. **B)** IMUs were attached to the amputee participant's chest and bicep to show the deflection angles as the amputee attempts to complete the task. **C)** The amputee was instructed to pick up a clothespin and move it from a horizontal beginning position to a vertical end position.

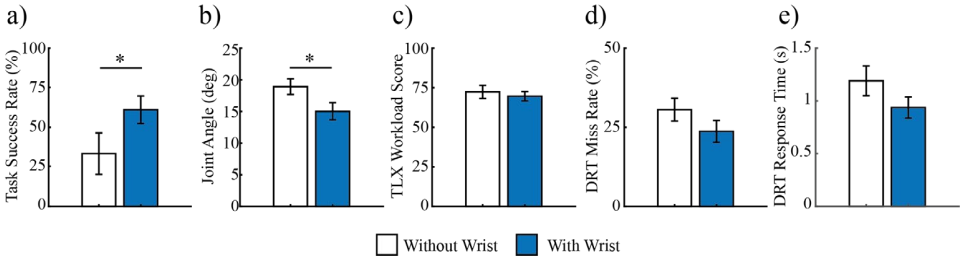

Figure 3: A) Success rate for the CLT was significantly greater with the wrist compared to without the wrist. **B)** Compensatory movement at the hip (i.e., the maximum angle deviation) was significantly reduced with the wrist compared to without the wrist. **C)** No significant differences were seen in the subjective workload with the wrist vs without. **D)** No significant differences were seen in the DRT miss rate with the wrist vs without. **E)** No significant differences were seen in the DRT response time with the wrist vs without. Data show mean ± standard error. * $p <$ 0.05. Paired t-tests were used for task success rate, subjective workload, and DRT response rate (N = 6). Unpaired t-test were used for the maximum angle deviation (N = 23 attempts vs N = 25 attempts) and the DRT response time (N = 39 responses vs N = 42 responses).

Use of the Wrist Did Not Significantly Increase Cognitive Load

Somewhat surprisingly, adding two additional controllable DOFs with the wrist did not significantly increase cognitive load. Collectively across participants, the subjective workload was reported as 72.4 ± 4.1 without the wrist and 69.6 ± 2.9 with the wrist ($p = 0.624$, paired t-test; Fig 3C). There were also no significant differences in the DRT response rate, 31% ± 3.6% without the wrist and 24% ± 3.5% with the wrist ($p = 0.33$, paired t-test; Fig 3D), or the DRT response time, 1.19s ± .14s without the wrist and .93s ± .1s with the wrist ($p = 0.1432$, unpaired t-test; Fig 3E).

CONCLUSION

We developed a low-cost 2-DOF prosthetic wrist that can adapt to various prosthetic terminal devices and sockets. We found that task performance was significantly better and compensatory movements significantly smaller when wrist control was enabled. We also found that the cognitive demand on the participants was not significantly different with the addition of two new EMG-controlled DOFs at the wrist. These results constitute an important step towards the widespread availability of functional prosthetic wrists for amputees and researchers alike.

ACKNOWLEDGEMENTS

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CASE STUDIES: FITTING PATIENTS WITH HEAVY DUTY BI-DIRECTIONAL RATCHETING THUMB RAIL PROSTHESIS FOR CARPOMETACARPAL AMPUTATIONS

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ABSTRACT

The loss of the thumb from the hand is a debilitating injury representing a 40% impairment to the hand. The replacement of the function of the thumb is a challenging engineering problem for prosthetic device designers due to the numerous degrees of freedom of the thumb. Most commercially available prosthetic devices for thumb amputations do not provide for adduction or rotation of the thumb. Here, we describe the design of a modular locking adduction rail for people with thumb loss proximal to the metacarpophalangeal joint. This device is compatible with the commercially available Point Thumb prosthetic thumb from Point Designs and allows users to move the prosthetic thumb from a flat hand position to an oppositional position. The design of the bi-directional adduction rail is briefly detailed. Then, two case studies are presented which detail the clinical implementation of the adduction rail into a partial hand prosthetic socket for two different patients. These are some of first trial fittings of the adduction rail system and demonstrate significant functional gains achieved with this novel device.

INTRODUCTION

Partial hand amputation is 10 times more common than all other categories of upper limb amputation combined [1]. These amputations can be a severe disability, especially if the amputation involves the thumb and/or multiple digits. Upper limb amputation can cause physical, psychosocial, and economic damage to an individual and can lead to depression, anxiety, loss of self-esteem, and social isolation [2], [3]. Fewer than half of partial hand amputees are able to return to the same job after amputation and most find that the prosthetic devices are insufficient to meet the demands of their work [4].

The loss of the thumb presents a particularly challenging type of partial hand amputation. The thumb is an essential digit in the formation of grasps and production of appropriate grip strengths for activities of daily living [5]. The loss of the thumb represents a 40% reduction in hand function [5]. The complexity of the thumb kinematics creates a challenge in the reproduction of the five degrees of freedom in a prosthetic device including three flexion, an adduction, and a rotation degree of freedom [6]. Flexion only makes up approximately 25% of the thumb's function [7]. Today, there are passive prosthetic thumbs (e.g. – TITAN Thumb, Partial Hand Solutions), body-powered thumbs (e.g. - ThumbDriver, Naked Prosthetic), and powered prosthetic thumbs (e.g. – iDigits, Ossur). In these cases, the prosthetic devices predominately recreate the flexion degrees of freedom of the thumb. In this work, we sought to design a bi-directional adduction rail which adds two additional degrees of freedom to the commercially available Point Thumb.

Table 1 compares the different prosthetic options available. Impairment values are calculated using the American Medical Association (AMA) guide for evaluating upper extremity impairment [7]. This comparison does not factor in issues like loss of sensation, device durability, and device ease of use, all of which have a significant role in device adoption and retention. Application of the Point Thumb and adduction rail system provides the largest range of motion and most functional benefit.

Table 1: Digit and hand impairment remaining after fitting of a thumb prosthesis.

Prosthesis	Examples	Impairment*	
		Digit	Hand
No Device	---	100%	40%
Static Opposition Post	livingskin™	55%	22%
MP Flexion	TITAN Thumb	37%	15%
MP and IP Flexion	Point Thumb	31%	12%

MP Flexion and Radial Abduction	VINCENTpartial passive	27%	11%
MP Flexion and Adduction	i-Digits Access[1] VINCENTpartial active[2]	17%	7%
MP Flexion, IP Flexion, and Adduction	Point Thumb with Adduction Rail[1] prototype	10%	4%

[1]Adduction is passive, [2]Adduction is active
**Does not include impairment due to lack of sensory information*

ADDUCTION RAIL DESIGN

The adduction rail presents a novel method to translate the thumb between a hand open position to an opposed adducted position. The adduction rail entails a curved, toothed track that serves as the interface between the prosthetic socket and the thumb carriage. The curve of the track enables the center of rotation of the adduction motion to be located virtually inside the residual limb thus reducing the total size of the prosthesis. The ratchet teeth on the track enable a similar locking mechanism as found in the Point Thumb and other mechanical digits offered by Point Designs. The carriage rides along the track and houses the pawls which engage the ratcheting teeth and thereby locks the carriage in an adducted position. Two levers enable the user to lock/unlock the pawls and translate the carriage along the track in a bi-directional manner. This dual pawl-lever system enables the ratchet to function in two directions unlike a traditional ratchet. A shell covers the carriage and provides a rotational degree of freedom between the thumb and carriage using a spring-loaded toothed mechanical interface. All features of the bi-directional adduction rail can be manipulated in a unilateral fashion. Finally, a variety of shell designs enables the fixturing of different prosthetic thumb options onto the adduction rail.

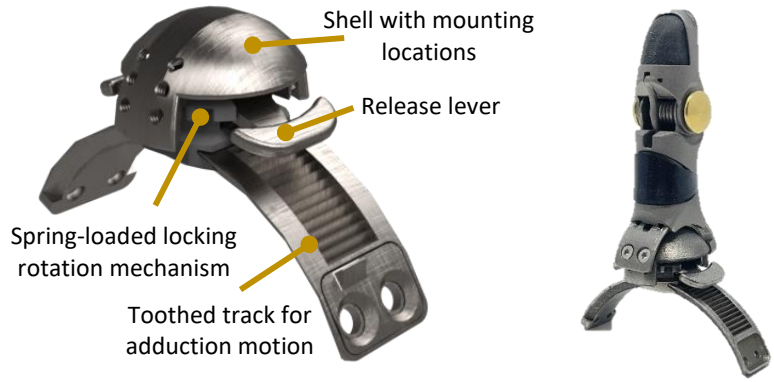

Figure 2: (Left) Rendering of adduction rail prototype with design features highlighted. (Right) Physical adduction rail prototype with Point Thumb attached.

Initial prototypes of the adduction rail were produced using metal laser sintering additive manufacturing techniques. The use of additive manufacturing methods enables the creation of internal mechanisms and unique toothed profiles which are used throughout the adduction rail. Hand tools were used to post-process the printed components which were then assembled into functional prototypes using other off-the-shelf springs and fasteners. Prototypes were provided to collaborating clinicians in order to conduct initial case studies of the Point Thumb and adduction rail.

CASE STUDY 1

Presentation - The subject is a 61-year-old right hand dominant male. He owns and works in an industrial metal shop. His left thumb was amputated at the carpometacarpal (CMC) joint due to trauma in 2002. He has not used a prosthesis before, due to limited device designs for his level of amputation and has adapted well to life without his left thumb. He reports only having issues with controlling two-handed tools and playing guitar. He desires a heavy-duty thumb component for his work environment and to reduce the over-use syndrome he has begun to experience in his right hand/arm.

Treatment – The patient was fit with a partial hand socket, a static Point Design thumb, and the adduction rail prototype (see Figure 3). He was immediately impressed with his ability to hold large objects (tube of cleaning wipes and a tissue box). Smaller objects were a bit more troublesome to grasp (screwdriver handle and a screw). The patient was able to use the device for at least three weeks both at work and at home.

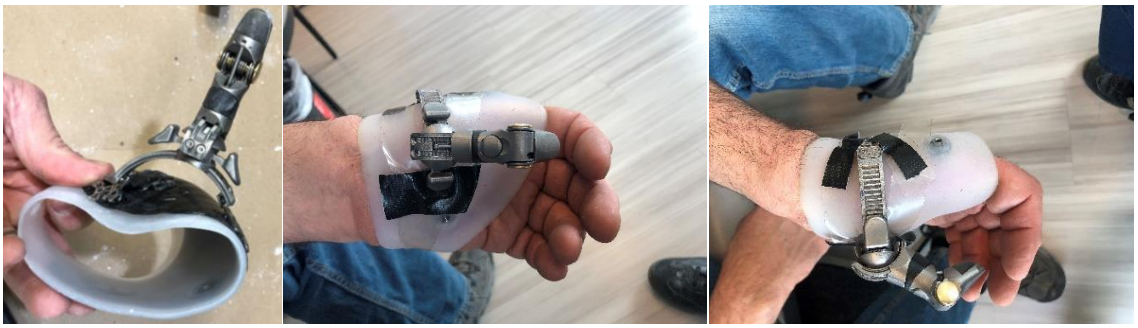

Figure 3: The adduction rail prototype and Point Thumb mounted to the partial hand socket.

Outcome – Patient reported, remotely, that he has liked the thumb but has not been able to get to the office for in-person follow-up due to illness in the family. Additional follow-up for this patient will be conducted in the coming months to collect more feedback and some outcome measures. As seen in Figure 3, one of the challenges with this fitting was the patient's presentation and the fitting of the adduction rail track close to the residuum. This issue was addressed in the next iteration of the device that was used in the case study in the following section and the fitting was significantly improved.

CASE STUDY 2

Presentation – The patient is a 45-year-old female who sustained a workplace injury in 2010 resulting in the amputation of her left thumb at the carpometacarpal (CMC) joint. The injury also resulted in a long transradial amputation of her right hand. At the time of the evaluation, the patient reported using various transradial prostheses but had not received a prosthesis for the left thumb. Prior to the accident she was right-handed but has since relied heavily on her left hand for activities of daily living. Her left hand became the dominant side, capable of hook and cylindrical grasp paired with extreme wrist flexion and fine motor grasp between index and middle digits via MCP adduction. She is the primary caretaker of her home, performing most of the upkeep, including: lawn care, gardening, caring for chickens and large dogs, cooking, sweeping, dusting, shopping, etc. She has resorted to compensatory strategies and modified tools to continue performing as many of her ADL's as possible, but reported significant overuse symptoms and a heavy reliance on others for assistance.

Treatment – Due to the variability of the patient's daily tasks, a passively positionable thumb and novel adduction rail were recommended to improve her grasp security with delicate objects, as well as heavy duty – outdoor activities. The adduction rail prototype would allow her to manually maneuver the thumb in various opposed and non-opposed positions. The patient was fit with a trial prosthesis that included a custom high temperature vulcanized (HTV) silicone socket with a vivak frame. The adduction rail prototype and Point Thumb were mounted on the frame and aligned in a manner that gave the patient access to as many grasp patterns as possible.

Figure 4: Patient demonstrating the ability to achieve a variety of oppositional grasps to hold various objects as well as a flat hand posture to maximize use of the intact digits.

Outcome – The patient immediately saw functional benefit of the prosthesis in the clinic. She demonstrated the ability to position the thumb and rail with both her right transradial prosthesis and distal end of her residual limb. The patient used the prosthesis for approximately 3 weeks. She reported using the prosthesis 3-5 hours at a time, with the longest duration being 8 hours. She found it to be most useful in carrying heavy items such as buckets of water, chicken feed, and dog bowls. Inside the home she found immediate benefit when holding anything with a handle, including brooms, vacuum cleaners, pots, pans, duster, paint brush, and a paint roller. She reported significant benefit in having the ability to modify the adduction angle to best position the thumb according to the object being grasped. Due to her being so well adapted to using her remaining digits for fine motor tasks, she appreciated the ability to move the thumb to a non-opposed position so it would not interfere, especially when typing and using a computer mouse. A definitive prosthesis will be provided and continued follow up including outcome measures are planned.

CONCLUSION

Thumb amputations, particularly at the CMC joint, present a variety of complicated functional, psychological, and occupational challenges. Restoration of the adduction and rotational degrees of freedom of the thumb is important for facilitating most grasps used in performing ADLs. The prototype adduction rail system presented here, in combination with the Point Thumb, allows for a robust thumb prosthesis that provides for flexion, extension, adduction, and rotation of the thumb. The two case studies presented here illustrate the need for such a device in that a traditional statically mounted thumb would limit the patient's ability to perform a number of key functional grasps. In both cases, use of the adduction rail and Point Thumb allowed patients to achieve their functional goals, ranging from metal work to caretaking activities. These positive early trial fittings indicate that the adduction rail system provides significant benefits to patients with CMC level amputations.

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CASE STUDIES: FITTING PATIENTS WITH HEAVY DUTY RATCHETING MECHANICAL THUMB PROSTHESES FOR METOCARPOPHALANGEAL LEVEL AMPUTATIONS

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ABSTRACT

Thumb amputation presents a significant challenge for people due to the thumb's importance in creating stable functional grasps. Most thumb amputations are a result of trauma and most people with these amputations work in heavy manual labor occupations. The lack of many durable and functional prosthetic devices has caused many of these people to change or lose their jobs. This can lead to significant psychological and quality of life issues.

Here we present three different case studies of patients with metacarpophalangeal (MP) joint level thumb amputations being fit with a heavy duty ratcheting mechanical thumb prosthesis, the Point Thumb. The Point Thumb features anatomical flexion at both the MP and interphalangeal (IP) joints, a virtual MP joint center for better anatomical joint alignment, heavy duty metal construction, 10 different lockable positions, and the two methods of unlocking to allow for unilateral use. The first case is a patient with multiple digit amputations who desired to return to a manual labor job. The second case is a patient with an amputation of his dominant thumb who desired to improve effectiveness performing activities of daily living (ADLs). The third case is a patient with a left thumb amputation who desired to lift heavy objects to continue his hobbies and work. This patient had previous prosthesis experience and found the Point Thumb to be more functional than a cosmetic restoration or the TITAN Thumb. In all cases, the Point Thumb allowed patients to achieve their functional goals. These cases highlight the unique challenges present with thumb amputation and demonstrate the potential of the Point Thumb to provide users with a robust prosthetic thumb capable of handling heavy manual labor occupations.

INTRODUCTION

Approximately 500,000 people in the United States are currently living with an upper limb amputation [1]. About 92% of upper limb amputations are of the hand, finger, or thumb [1] and an estimated 45,000 new hand and finger amputations occur every year [2]. About 83% of these amputations are a result of trauma [1], [3]. The majority of these amputations are of fingers, 73%, with thumb amputations making up only 16% [4]. However, the loss of a thumb is far more significant than the loss of a finger; an amputation of the thumb at the MP joint leads to 40% impairment of hand function and 22% whole body impairment [5]. Additionally, the thumb is required to perform all but one of the most common grasps used to perform activities of daily living (ADLs) (Figure 1) [6]. Not only does the loss of a thumb create tremendous functional challenges, it can also create psychological challenges including depression, anxiety, social isolation, and low self-esteem [7], [8]. Despite the obvious importance of the thumb, recent studies have shown that the replantation rate for thumb amputations is declining [9] and patients are rarely fit with a prosthetic device of any kind [10].

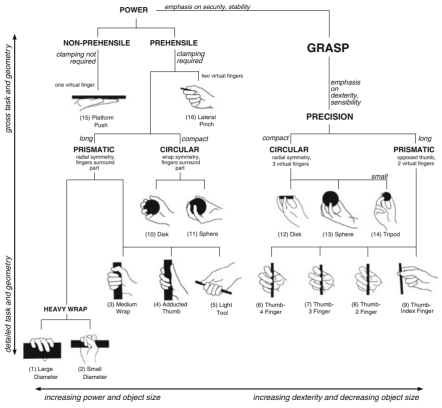

Figure 1: Most common grasps used to perform ADLs [6]

BACKGROUND

Clinical Significance

The thumb plays a critical role in hand function as it provides the primary source of opposition in nearly every functional grasp [6]. Thus, the nearly 74,000 people in the US

with thumb amputations face significant functional challenges [1], [4]. For the thumb, an amputation at the MP joint leads to 22% of whole body impairment [5]. This degree of functional impairment can lead to job displacement as many of these amputations occur in heavy manual labor occupations which can no longer be performed after the amputation (Figure 2).

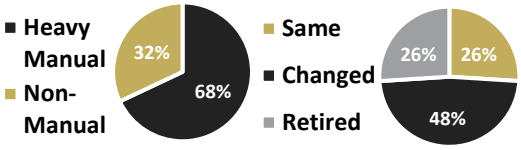

Figure 2: (Top) Work performed prior to partial hand amputation. (Bottom) Job status after receiving partial hand amputation [11]

Prosthetic Options

There are several prosthetic options currently available for people with thumb amputations. In general, they can be sorted into four categories: cosmetic, body-powered, passive/positional, and externally powered (Figure 3).

Figure 3: Overview of prosthetic solutions for thumb amputations. (a) custom silicone thumb (stamos and braun prothesenwerk) (b) livingskin™ (Ossur) (c) X-Thumb (Didrick Medical) (d) ThumbDriver (Naked Prosthetics) (e) VINCENTpartial passive (Vincent Systems) (f) TITAN Thumb (Partial Hand Solutions) (g) i-Digits Access (Ossur) (h) VINCENTpartial active (Vincent Systems)

Cosmetic devices, such as livingskin™ (Ossur), are mostly an aesthetic option and provide limited functionality. Body-powered devices, such as the X-Finger (Didrick Medical) and the ThumbDriver (Naked Prosthetics), are more functional by providing active flexion and opposition. These devices are limited, however, by their reliance on a custom fit and limited grip force. Passive/positional devices, such as the VINCENTpartial passive (Vincent Systems) and TITAN Thumb (Partial Hand Solutions), provide adjustable flexion and opposition so are generally more functional than cosmetic solutions. These devices, however, often require the use of the user's contralateral hand to position the device. Externally powered devices, such as the VINCENTpartial active (Vincent Systems) and i-Digits Access (Ossur), are controlled using myoelectric signals and provide active flexion, manual or active adduction, and active opposition. Durability and intuitive control systems are generally a challenge with these types of devices.

Table 1 provides a comparison of the different prosthetic options available in terms of their range of motion. The impairment values are calculated using the American Medical Association (AMA) guide for evaluating upper extremity impairment [5]. This comparison does not factor in issues like loss of sensation, device durability, and device ease of use, all of which have a significant role in device adoption and retention. Even so, this shows that large functional gains can be made by simply including flexion at one or two joints.

Table 1: Thumb prosthesis functional comparison from the perspective of digit and hand impairment remaining after fitting the prosthesis.

Prosthesis	Examples	Impairment*	
		Digit	Hand
No Device	---	100%	40%
Static Opposition Post	livingskin™	55%	22%
MP Flexion	TITAN Thumb	37%	15%
MP and IP Flexion	Point Thumb	31%	12%
MP Flexion and Radial Abduction	VINCENTpartial passive	27%	11%
MP Flexion and Adduction	i-Digits Access[1] VINCENTpartial active[2]	17%	7%

[1]*Adduction is passive,* [2]*Adduction is active*
**Does not include impairment due to lack of sensory information*

As durability is a key issue for people desiring to return to work in heavy manual labor jobs, body-powered and passive/positional devices are generally preferred. Despite this preference, there are still limited options for heavy-duty devices and thus new devices must be developed.

Point Thumb

The Point Thumb, by Point Designs, is a new heavy-duty passive/positional device with 10 different lockable positions in flexion and two degrees of freedom (DoFs) (Figure 4). It is the only device that features motion at the IP joint to achieve anatomical flexion as well as the only device to feature a virtual MP joint center to achieve anatomical joint alignment. With two methods of unlocking the ratchet mechanism, it is also able to be used unilaterally.

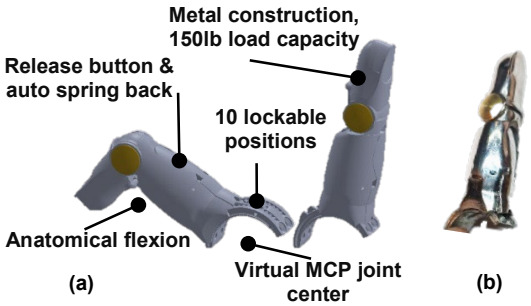

Figure 4: (a) Rendering of Point Thumb prototype with design features highlighted. (b) Physical Point Thumb prototype

CASE STUDY 1

Presentation

The first patient is a 49-year-old male who sustained a workplace injury resulting in a partial hand amputation of the left 1st-3rd digits at MP joint and 4th digit distal to IP joint. At the time of the initial clinical evaluation he and his wife were caring for 7 foster children including 2 infants. He has seasonal work as a firefighter which he aims to return to. He is also considering returning to his previous job as a laborer which requires handling tools, lumber and heavy bags of supplies.

Figure 5: (Left) Patient's presentation and prosthesis with Point Thumb, two Point Digits, and one Point Partial. (Right) Patient lifting a weight with prosthesis.

Treatment

Due to the ruggedness of his occupational goals, passively positionable digits were recommended to improve grasp security. The intended use of the prosthesis was for work and ADLs including his hobby of logging. Externally powered options were contraindicated for his reported goals. The Point Thumb was considered a good option due to its robustness and ability to flex at the IP joint, which in this case was critical for achieving opposition with digits 1 and 2.

The patient was fit with a partial hand custom high temperature vulcanized (HTV) silicone socket and carbon fiber frame. The Point Thumb was used for the 1st digit and two full length Point Digits (Point Designs) were used for the 2nd and 3rd digits. Additionally, a partial finger prosthesis, the Point Partial (Point Designs), was used for the 4th digit by creating a separate custom HTV thimble style socket.

Outcome

The patient was able to securely hold long handled tools and cylindrical items. Pinch grip was made possible by the attachment of the Point Thumb mounting bracket to the silicone socket rather than the carbon frame. This flexibility allowed for some adduction to improve opposition, particularly active opposition between the Point Thumb and the 4th and 5th digits.

The patient adapted to use of the prosthesis quickly. Within one month the patient reported using the device to assist in chainsaw operation as well as use of an axe. He reported wear of the prosthesis up to 12 hours per day without issue but with an average of 4 to 6 hours.

The Disabilities of the Arm, Shoulder, and Hand (DASH) standardized outcome measure was used to assess prosthesis effectiveness. The patient experienced a reduction in DASH score from 22 to 15, which while not meeting the minimum clinically important difference demonstrates important functional gains from the Point Thumb.

CASE STUDY 2

Presentation

The second patient is a 36-year-old male who sustained a right dominant thumb amputation secondary to a workplace accident. He previously worked in corrections and at the time of the initial clinical evaluation was considering alternate career options. He did, however, express a desire to return to his prior employer in some capacity and for some time.

While recovering from his injury, he is the primary caregiver for his children, while his wife works full time. He has difficulty with numerous ADLs given decreased ability to pinch and grasp with his previously dominant hand. Measurements taken during hand therapy indicated an 85% reduction in hand strength of his dominant hand compared to his non-dominant hand.

Figure 6: Patient's socket with Point Thumb prothesis

Treatment

The patient's goals dictated a digit for opposition that would be durable and very strong. His occupation necessitated a variety of thumb positions to provide pinch of flat lumber as well as grasp of round handles and tools. This requirement indicated he would benefit from the Point Thumb as it has motion at both the MP and IP joints.

Outcome

The patient was fit with a partial hand custom HTV silicone socket and carbon fiber frame. The Point Thumb was integrated rigidly into the carbon frame with alignment allowing for precision pinch, tripod pinch, as well as cylindrical and spherical grasps. More quantitative outcome measures will be reported after the patient has used the new device for an extended period.

CASE STUDY 3

Presentation

The third trial patient is a 57-year-old male who sustained a workplace injury resulting in the MP level amputation of the left thumb (Figure 7). At the time of the initial clinical evaluation he was working in a construction

environment, mainly in carpentry. His main functional goal was the ability to grasp objects such as tools and materials such as lumber to perform his daily tasks at work, continue working on cars as a hobby, and perform ADLs at home.

Figure 7: (Left) Patient's presentation. (Right) Patient using Point Thumb to hold a spray bottle

Treatment

The patient was initially fit with a custom silicone restoration and a passively positional thumb, the TITAN Thumb, attached to a dynamic muscle contoured interface. An externally powered thumb was contraindicated due to the patient's bulbus distal presentation as well as a dirty and possibly wet working environment.

The patient found that the cosmetic restoration did not allow him to grasp heavy objects. While the TITAN Thumb gave the patient increased ability to grasp heavy objects, the patient found the need to use his contralateral hand to unlock it unacceptable. The Point Thumb was then fit as a replacement to the TITAN Thumb and found to correct this issue by allowing unilateral use.

The patient was ultimately fit with a partial hand custom HTV silicone socket and carbon fiber frame. The Point Thumb was integrated into a carbon fiber thumb cap that was glued to the HTV silicone underneath and allowed for grasp of both large and small objects.

Outcome

The patient reported increased satisfaction with the Point Thumb due to the novel spring back mechanism. This trial fitting was very recent and thus the collection of standardized outcome measures data is ongoing. Further results will be reported after the patient has used the new device for an extended period.

CONCLUSION

Thumb amputations present a variety of complicated functional, psychological, and occupational challenges. Most people with thumb amputations work in heavy manual labor occupations and the lack of robust prosthetic options up to this point prevents many of them from returning to work. The Point Thumb is a new robust passively positionable ratcheting prosthetic thumb with flexion at the MP and IP joints designed for use in heavy-duty work environments. The three case studies presented here illustrate the complexity of thumb amputation cases and demonstrate the viability of the Point Thumb as a robust prosthetic thumb for heavy manual labor occupations. In all cases, use of the Point Thumb allowed patients to achieve their functional goals, ranging from using a chainsaw to carrying lumber. These positive early trial fittings indicate that the Point Thumb has strong potential and warrants further study.

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DEVELOPMENT AND CHARACTERIZATION OF A MULTIARTICULATE PEDIATRIC HAND AS A RESEARCH PLATFORM FOR FUNCTIONAL IMPROVEMENTS

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ABSTRACT

Multiarticulate upper limb prostheses for children remain sparse despite the continued advancement of mechatronic technologies that have benefited the adult population. Research in the field of upper limb prostheses is predominately adult focused, although rates of pediatric upper limb prosthesis abandonment are inflated when compared to adults. The function a prosthesis offers is a driving factor influencing whether a child will continue to wear their prosthesis. The current standard-of-care pediatric devices typically offer a single degree of freedom open/close grasping function, a stark departure from the multiple grasp configurations provided in advanced adult devices. However, as mechatronic technologies continue to advance and multiarticulate devices emerge on the clinical horizon, understanding how this technology translates effectively to the pediatric population is essential. This includes exploring grasping movements that may provide the most beneficial outcomes as well as effective ways to control the newly available dexterity. Currently, no available pediatric research platforms exist that are dexterous and boast open access to hardware and programming that allows for the investigation and provision of multi-grasp function. Here we present the development of a pediatric research platform. This dexterous pediatric-sized hand offers six degrees of freedom and programmable grasping configurations. We present our design metrics, discuss the mechanical and electrical design, and provide device performance results through benchmark testing.

INTRODUCTION

Upper limb (UL) prosthesis abandonment is a pervasive issue in pediatric populations. In fact, 35%-45% of children will abandon their device in comparison to adults where abandonment rates are 23%-26% [1]. Adoption of a prosthesis requires the device to provide sufficient function and facilitate healthy social interactions to the extent that these benefits outweigh the drawbacks of discomfort, device weight, inadequate performance, and unwanted attention in social environments [1]. Standard-of-care devices often fall short of meeting these demands. One avenue to addressing the shortcomings of current pediatric prostheses entails increasing the functionality of these devices which may seem a daunting task given that hands move with 27 degrees of freedom [2] allowing for complex manipulations. However, nearly all tasks we perform with our hands rely on a limited repertoire of movements, and 6-9 hand grasp configurations can account for nearly 80% of activities in home and professional environments [3].

Numerous advanced adult UL prostheses are available and capable of achieving multiple grasp configurations including 4-5 of the top frequently used hand grasps [4]. However, there are limited pediatric devices with the same dexterity. Most children's devices provide a single degree of freedom open/close prehensile motion with the exception of a very few such as the Vincent Young 3, which provides up to 13 individual grasps. Recently, there have been experimental or non-clinical pediatric devices developed and reported in literature [5]–[9]. However, a common motivating theme among these designs has been to minimize the device cost, citing the expensive nature of commercially available pediatric prostheses. Many of these devices are therefore limited in functionality with 1-3 actuators [5]–[7] and thus a limited inventory of grasping motions is provided.

Despite current limitations, it is evident that advanced muti-grasp hands are on the clinical horizon for children. However, before effectively implementing these devices in the clinic or prescribing them to patients, further research and analysis are required to address current gaps in knowledge. For example, it is unknown which grasping motions may be most effective to support age-specific childhood play and daily activities. Further, it is unknown how conventional adult muscle-based prosthesis control may be translated to this population given that many were born with their limb difference and their affected muscles have never actuated an intact limb. However, few to no dexterous pediatric upper limb research platforms are available with open access to hardware and software programming that enable researchers to begin addressing these current knowledge gaps.

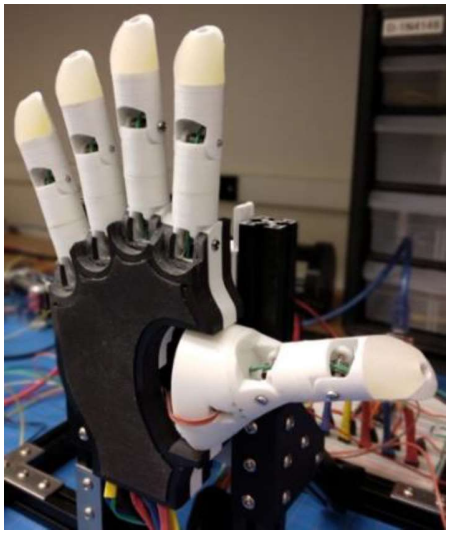

Figure 1. The BEAR PAW: a pediatric multiarticulate prosthetic hand with six degrees of freedom and programmable grasp configurations.

Our goal was to design an advanced child-size UL prosthesis with similar dexterity to those present in adult devices. We developed a UL pediatric prosthesis research platform that is openly programmable and capable of performing a multitude of grasp configurations. Here, we describe the design and fabrication of the Bionic Engineering and Assistive Robotics Laboratory's Pediatric Assistive Ware (BEAR PAW, Figure 1), as well as benchmark its mechanical and electrical performance.

DESIGN METRICS

Multiple design constraints were adopted to guide the development of the BEAR PAW. Firstly, the size of the prosthesis was important as a tradeoff exists between size and maximum digit actuation; as individual digit actuation increases, the size of the device also increases to effectively house the necessary components. To accommodate this metric, we referenced 50th percentile 8-year-old male and female anthropometric data to proportion our design [10], [11]. Our design can achieve 6 degrees of freedom which includes digit flexion/extension and thumb opposition. Weight is an important constraint, especially for children who do not yet have the strength of an adult [12]. The mass of an Ottobock Electrohand 2000 for children 8-13 years old was used as a baseline for comparison ($130\ g$). To achieve a lightweight dexterous design, we prioritized 3D-printing techniques for the advantages of the material's weight and produced a 177g device.

Electronics and the corresponding control were developed under two considerations: compact design and ease of use. An Arduino Pro Mini with a custom break out board mounted inside the wrist was developed to reduce the physical size of the electronics. Device communication was enabled via Bluetooth or USB to UART allowing for tethered or untethered control. A custom graphical user interface was developed in Processing 3 programming language to allow for ease of use through virtual buttons and potentiometers. Further, the device can accept serial inputs allowing it to communicate with common data acquisition systems. Together this allows for intuitive device control that can be agnostic to a variety of prosthetic control interfaces such as commercially available sEMG systems.

To define the physical capabilities of device actuation both closing time and force output were considered. Here, the time to close should be less than $1\ s$, reflecting values found among commercially available prosthetic systems [13]. The BEAR PAW was able to achieve an average of $0.67\ s$ for full hand articulation. Additionally, load considerations were selected to facilitate effective device performance across multiple grasping motions in a research setting. Target grasping force values of at least $500\ g$ ($4.9\ N$) were selected as most grasps are applied to objects less than this value [14]. Here the force output was achieved for multiple grasp configurations with corresponding loads ranging from $305\ g$ to $736\ g$.

Finally, a device cost of less than $1000 was selected to promote the accessibility of our system to other research laboratories. This was achieved by utilizing off-the-shelf componentry and open access software for a total raw materials cost of approximately $500 USD. The above design requirements, their corresponding metric/value, and the values achieved by our design are presented in Table 1. These metrics are an aggregate of values reported in literature describing adult research platforms [15] paired with values derived from clinical and engineering discussions.

Table 1. Design Metrics.

Design Requirement	Specification Metric:	Quantitative Value:	Achieved Value:
Size	Anatomical proportions:	8-year-old child	Metric met
Mass	Low mass:	< 130 g	177 g
Inexpensive	Low cost:	< $1000	$500
Degrees of Freedom	Digit actuation:	Flexion/Extension Thumb opposition	Metric met
Actuators	Servo control:	6 servos	6 servos
Electronics	Compact design:	Enclosed in hand	Metric met
Operation Time	Substantial power:	Mains power	Metric met
Control	Communication:	Bluetooth or USB to UART	Metric met
Ease of Use	High usability:	Graphical interface	Metric met
Grasp Speed	Time to close:	< 1 s	0.67 s
Force	Minimum force:	> 4.9 N	7.22 N

MECHANICAL & ELECTRICAL DESIGN

Mechanical: The BEAR PAW was developed in the computer automated design software SolidWorks 2020 and fabricated using a SigmaX R19 3D Printer with PLA material. The hand utilizes six KST-X08 series servo motors to actuate digit flexion/extension and thumb opposition; therefore, it is capable of a multitude of common grasping movements. Servo motors are mounted on the palmar and dorsal sides of the hand for digit flexion and thumb opposition along with one housed inside the thumb for flexion. To actuate the hand, the servo motors and synthetic cables follow a common tendon-driven actuation mechanism (with the exception of the geared thumb opposition). Here a pulley adheres to the servo motor shaft on which the synthetic cable is attached. The cable transverses the finger and is attached to the fingertip. When the servo rotates in one direction the cable is wrapped around the pulley causing digit flexion. Digit extension is achieved via torsion springs built into each joint to return digits to their extended positions.

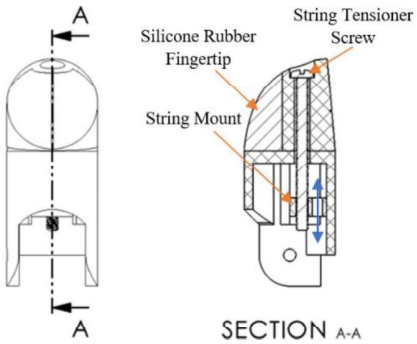

Figure 2. Cross-section of the distal and middle phalanx depicting the silicone rubber tip and the tendon tension mechanism. The string tensioner screw allows for the string mount to move up and down (motion given by the blue arrows) so that the string to be easily tensioned.

A novel cable tensioning mechanism is incorporated into each digit as depicted in Figure 2. The end of the synthetic cable is attached to a string mount that can be translated by tightening the string tensioner screw. Slack in the cable is inevitable and therefore the tensioning mechanism allows this to be mitigated. The BEAR PAW also includes silicone padded fingertips which aid in grabbing objects. These were made from Dragon Skin Silicone that were poured into 3D printed molds of the fingertips.

Electrical: The electronics enclosed in the hand consist of a 3.3V Arduino Pro Mini with an ATmega328 microcontroller, and a custom breakout board allowing for power connections and communication with external peripherals i.e., the six KST-X08 series servo motors and the HC-05 wireless Bluetooth module. The BEAR PAW can also be tethered to a computer by using a USB to UART breakout board and has six independently programmable degrees of freedom.

MECHANICAL & ELECTRICAL CHARACTERISTICS

The BEAR PAW was attached to a testing rig to obtain the mechanical and electrical characteristics of single-digit articulation along with 3 of the top 7 generalized hand grasps [14]. The force exerted by the hand, current under load, and power draw were captured. To obtain the mechanical force values, we developed a set of force-sensitive objects to be grasped by the BEAR PAW. Four custom manipulandum were fabricated to house calibrated SingleTact 8mm 10N miniature force sensors. An ACS723 current sensor was used to acquire the current load from the servo motors during actuation and the corresponding voltage was obtained to determine the power draw. These signals were passed into a National Instruments USB-6210 data acquisition system sampling at 4000 Hz and were stored using a MATLAB script. An Arduino program was written to actuate each motion over a 5 second period which was repeated 10 times to collect sufficient data [16]. Manipulanda were strategically placed in front of the BEAR PAW to capture the mechanical and electrical values during motion postures. BEAR PAW actuation for each manipulandum is displayed in Figure 3 a-d.

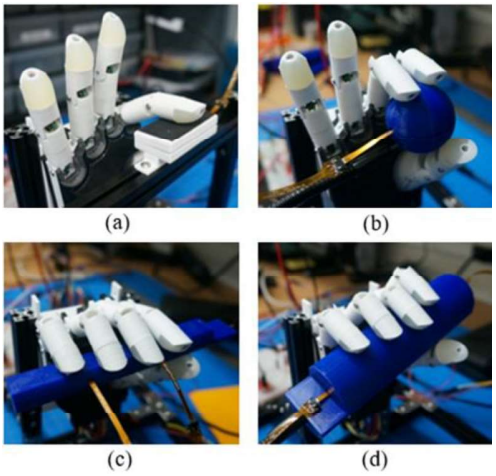

Figure 3. (a) Rectangular manipulandum used to test digit flexion and thumb opposition. (b) Sphere to test tripod (c) Flat edged small cylinder to test prismatic 4 finger grasp. (d) Large diameter cylinder to test power wrap.

A separate MATLAB script was written to read in the raw data for analysis. First, the force and current for each trial were converted from voltage via a linear transformation to newtons and amperes, respectively. Then each trial was cleaned to discard times when the hand was not active thereby collecting 2.5 seconds of force, current, and voltage data. The average force, current, and power values over the relevant time window were then calculated.

After obtaining the data for all ten trials across hand postures the averages and standard deviations for the force, current, and

power were calculated. It was found that among the motion postures, the forces, currents, and power ranged from $0.76\ N - 7.22\ N$, $0.68\ A - 1.79\ A$, and $3.39\ W - 8.72\ W$, respectively. This is tabulated in Table 2. The force was obtained to determine the capacity in which the hand can effectively manipulate objects in a research setting. Additionally, the current and power define specifications for future non-tethered implementation.

Table 2. Average Mechanical and Electrical Characteristics

Motion Posture	Mechanical and Electrical Characteristics		
	Force (Newtons)	*Current (Amps)*	*Power (Watts)*
Digits 2-5 Flexion	1.709 (±0.076)	0.675 (±0.069)	3.388 (±0.343)
Thumb Flexion	0.761 (±0.042)	0.751 (±0.002)	3.763 (±0.010)
Thumb Opposition	2.454 (±0.069)	0.729 (±0.003)	3.656 (±0.014)
Wrap	7.216 (±0.578)	1.789 (±0.052)	8.718 (±0.242)
Tripod	2.989 (±0.253)	1.433 (±0.035)	7.030 (±0.166)
Prismatic 4 Finger	5.714 (±0.190)	1.644 (±0.068)	8.011 (±0.316)

FUTURE WORK & CONCLUSIONS

This paper presents the development of the BEAR PAW, an advanced multiarticulate pediatric prosthetic hand with similar dexterity to that of adult devices. As such, it has the capability to provide children with more dexterity through multiple grasping configurations. We present mechanical and electrical characteristics to evaluate the device's effectiveness as a research platform. The long-term goal of this work is to refine and release the BEAR PAW as an open-source research platform to study pediatric prosthetic use with dexterous devices. In preparation, we plan for expanded analyses to capture performance characteristics across a multitude of grasping configurations. Further, an in-depth analysis of the BEAR PAW's grasping and maintaining capabilities will be evaluated and compared to other prostheses using the AHAP test [17]. Preparations are currently underway for an open-source release which includes developing fabrication and assembly guides, building a comprehensive bill of materials, and refining software.

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DEVELOPMENT OF A MODULAR SIMULATED PROSTHESIS AND EVALUATION OF A COMPLIANT GRIP FORCE SENSOR

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ABSTRACT

Grip force sensory feedback is commonly stated as a desirable feature for upper-limb myoelectric prosthetics. Many techniques for non-invasive grip force feedback are being investigated. However, the choice of force sensor, feedback location, and experimental apparatus typically vary between research studies, making it challenging to compare results. A standardized device where individual parameters can be adjusted would allow researchers to evaluate the impact of each variable on results. An example of such a device is a simulated prosthesis. Simulated prosthesis devices enable non-disabled individuals to participate in myoelectric prosthesis research experiments while ensuring consistency in experimental apparatus between participants. We developed a lightweight, modular, and inexpensive simulated myoelectric prosthesis capable of delivering sensory feedback to fingertips and proximal forearm. We integrated mechanotactile feedback devices to deliver modality matched feedback to the forearm and somatotopically matched feedback to the fingertips. We compared a commercial force sensor before and after being encapsulated within a compliant material under a variety of loading conditions. The encapsulated force sensor outperformed the standard sensor in all non-ideal loading conditions by a large margin. The use of this encapsulation technique dramatically increases accuracy in sensor readings when loading conditions differ from calibration conditions. This device will help facilitate myoelectric research by providing a consistent experimental apparatus between non-disabled participants for various control and feedback-oriented studies.

INTRODUCTION

Upper limb amputation results in loss of both motor and sensory function of the hand, harming an individual's economic, psychological, and social well-being [1]. Prosthetic technology attempts to mitigate these effects by restoring functionality to the lost limb. Current research in the upper limb prostheses field focuses on electrically powered devices controlled by the muscle signals in the residual limb, termed myoelectric prostheses [2]. Myoelectric devices utilize the existing neural pathways in an open-loop fashion, without specific feedback on the outcome of the action.

Upper limb myoelectric prostheses users commonly state sensory feedback as a desirable feature, with grip force ranking as the highest priority sensory input [3]. Many methods of non-invasive grip force feedback implementation are being investigated with promising results [4]. However, parameters such as feedback location, force sensors, and experimental apparatus are typically unique to each experiment, making comparisons between studies difficult. There is an ongoing need for devices capable of adjusting these parameters to allow researchers to evaluate each variable independently.

In previous studies, simulated prosthesis devices have been used to investigate myoelectric control [5] and sensory feedback techniques [6]. An evaluation of a simulated prosthesis device showed that it resulted in motion kinematics and performance metrics similar to those found in myoelectric users [7]. A Simulated Sensory Motor Prosthesis previously constructed within our lab allowed for somatotopically matched mechanotactile feedback during myoelectric control [8]. However, initial testing with the device showed various issues that justified a revision. The large size, non-modularity and weight of the device (1.3 kg) made it difficult to move naturally, causing discomfort over long periods.

The objective of this work was to optimize the size, weight, and comfort of the Simulated Sensory-Motor Prosthesis while maintaining the ability to provide sensory feedback to both the forearm and fingertips. This allows for both modality and somatotopically matched feedback to be used on the same experimental apparatus. An additional focus was placed on modularity to allow for interchangeable components for various user sizes or experimental conditions. The device was fit with inexpensive compliant

force sensors to measure the grip force of the end effector reliably. These sensors were evaluated and compared to standard sensors under various loading conditions to ensure accurate grip force measurement.

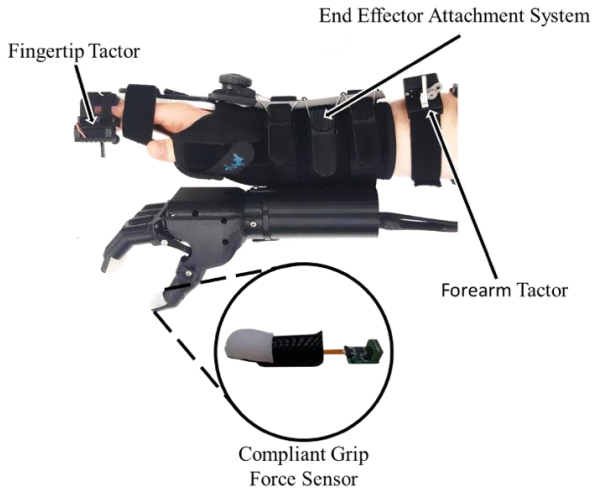

Figure 1: The MSP Overview

MECHANICAL DESIGN

Figure 1 shows an overview of the Modular Simulated Prosthesis (MSP) that was developed. A wrist and thumb support brace (MedSpec, USA) restrains the user's hand to ensure isometric contraction during electromyography (EMG) control. This commercially available product is designed to be comfortable, lightweight, adjustable, and leaves adequate space on the proximal forearm for EMG sensors and other devices. Additional finger flexion restraints were required to prevent the fingertips from colliding with the end effector. This was achieved by extending the existing metal supports within the brace with 3D printed PLA supports.

In previous simulated prosthesis devices, the prosthetic hand is typically mounted with a distal, radial, or ventral offset. Any combination of these offsets places the additional weight of the prosthetic hand off the axis of the user's arm, resulting in an undesired torque. Because the human hand width is much smaller than its length and breadth, this torque is minimized by offsetting in the ventral direction. An adjustable offset in the radial direction was also added to the MSP to resolve any line of sight issues that may arrive for specific tasks. An end effector attachment system was developed to attach the prosthetic hand to the brace while accommodating a variety of arm shapes and sizes. The system consists of a 3D printed bracket that rests midline on the ventral surface of the wrist brace and a cable tightening system (BOA, USA) that rests midline on the dorsal surface of the wrist brace. Attached to the bracket is a 3D printed wrist adapter for end effector mounting. The bracket is temporarily secured to the ventral side of the arm using a large Velcro strip. The cable tightening system is then wrapped around to the dorsal side, where 3D printed quick-connect clips are connected, completing the loop around the arm. The interlocking cable system is tightened to create a snug fit between the end effector and the participant's forearm to minimize the relative movement of the device.

A 3D printed, anthropometric, single-degree-of-freedom end effector was designed (Solidworks, 2018). The hand is driven by a Dynamixel MX-64AT servo motor (Robotis, Inc.). The fingers and thumb are actuated simultaneously using a linked bar mechanism, giving a gripping aperture of 100 mm. This end effector has a mass of 298 grams with a maximum continuous grip force of 11 N. The total mass of the MSP is 691 g with the end effector included, can be comfortably worn for 3 hours, and costs less than $1000 CAD. The end effector, feedback devices, and attachment system are all independent units creating a highly modular design that can be easily customized to fit specific needs.

SENSORY FEEDBACK DESIGN

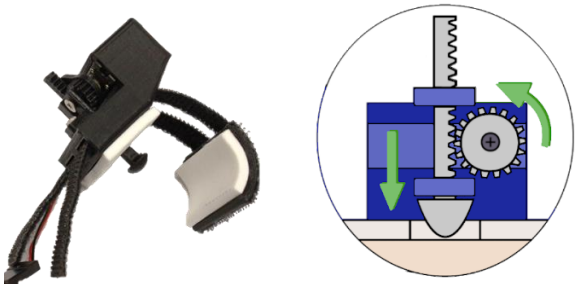

Figure 2: Mechanotactile Tactor Overview: (a) Fingertip Mounting System, (b) Motion Illustration

Sensory feedback is integrated into the MSP using small, inexpensive mechanotactile tactors modified from our earlier work [9]. The tactor devices use a lightweight Dymond D47 servo motor (Dymond, USA) with a 3D printed rack and pinion system to apply force to the user. We developed two mounting systems to apply somatotopically accurate feedback to the fingertips, or modality matched feedback to the forearm. The tactors are secured to the user with Velcro straps. Washable foam provides cushioning to prevent irritation to the user. The tactor with the fingertip mounting system is shown in Figure 2. The tactors can provide up to 12 N of force with a throw of 14 mm.

SENSORIZATION DESIGN AND EVALUATION

Measurement of grip force can be done through small force sensors placed on the fingertip of the prosthetic hand. Capacitive force sensors have previously been shown to perform better than commonly used force-sensitive resistors for this application [9]. These sensors are designed to be attached to a flat surface, with the force loading evenly distributed across its surface area. However, prosthetic hands undergo a variety of loading conditions that do not represent this ideal situation. Prosthetic fingertips with barometric pressure sensors embedded in elastomer [10] have previously been shown to provide pressure sensitivity in non-ideal loading conditions. It was hypothesized that encapsulating a capacitive force sensor in a compliant material would disperse the force evenly throughout the sensor, allowing for more robust measurement to various loading conditions.

Methods

A SingleTact S8-10 capacitive based force sensor (SingleTact, USA) was compared before and after being encased in Dragon Skin 10NV, a compliant silicone rubber based material (Smooth-On, USA). The two configurations are shown in Figure 2. A load cell (Omega LCM703 calibrated to a maximum error of 0.1N) was placed in line with an HS-35HD servo motor (Hitec RCD, USA) to apply force to the sensor through a PLA indenter. The load cell was read using Simulink Real-Time (Matlab 2014a) through a National Instruments data acquisition system (NI PCI6259). A force was applied between 0 and 10 N in a sinusoidal pattern for five total periods, similar to earlier work [9]. Loading periods of 0.5, 1, and 5 seconds were tested to account for dynamic loading effects. Each measurement was repeated three times to ensure repeatability between trials, for a total of 9 trials for each condition.

An indenter was made with a circular flat contact surface (10 mm diameter) and covered in a 2 mm thick foam to ensure even force distribution over the entire surface area of the sensor. Loading of this indenter directly aligned with the sensor acted as the ideal condition for both the baseline and the encapsulated configurations. All other conditions were compared to the ideal condition to evaluate the sensor's ability to adapt to various circumstances. An indenter with a 10 mm diameter curvature was tested to represent grasping a curved surface. The indenter position was moved by 4mm in both the proximal and distal directions to evaluate the effect of a non-central loading condition. For only the encapsulated configuration, a centred applied loading condition at a 15-degree angle was also evaluated.

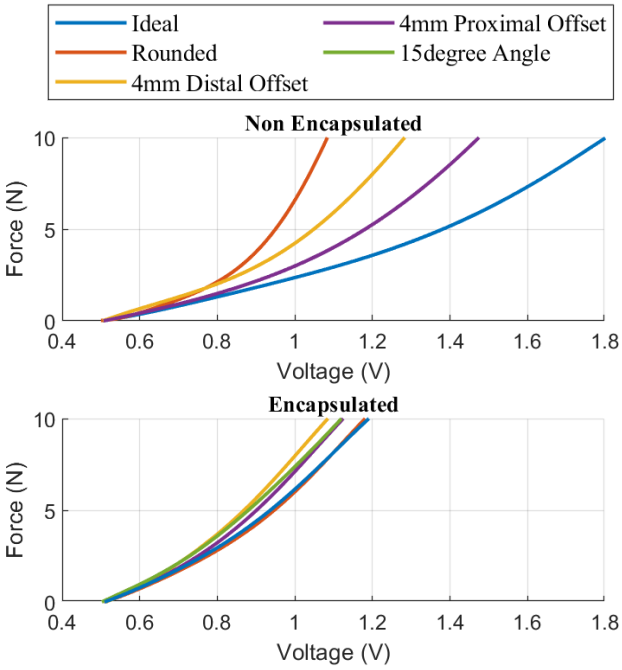

Figure 3: Loading Curve Comparison Between Various Conditions

The baseline and encapsulated sensors voltage to force relationship was calibrated using a 5th-degree polynomial curve fit to all trials under the ideal condition. This calibration curve was used to predict force outputs under all other conditions.

Results

The results for all conditions are summarized in Table 2. In the ideal condition, both sensors performed within the manufacturer's specifications at root mean square error (RMSE) of 2.2% and 2.5% of full-scale range (FS) for the baseline and encapsulated sensor. The RMSE of the baseline sensor was much more sensitive to changing conditions than the encapsulated sensor. The curved indenter condition produced a substantial decrease in performance for the baseline sensor, giving an RMSE of 36.4% FS. The encapsulated sensor was relatively unaffected with an RMSE of 2.9% of FS. Similarly, when the ideal indenter was shifted by 4mm, the RMSE for the baseline rose to 25.5% FS (distal offset) and 15.5% FS (proximal offset). The encapsulated sensor RMSE increased to 10.5% FS (proximal offset) and 7.2% FS (distal offset). Finally, the encapsulated sensor showed an RMSE error of 7.6% FS during the 15-degree angled loading scenario. Figure 3 shows each sensor's loading curve fit with a 5th-degree polynomial curve. The baseline sensor's loading curves are much more varied when

contrasted with the encapsulated sensor, illustrating the dependency on environmental conditions. For example, at a load of 10 N, the baseline sensor voltage output varies by 0.72 V (50.7% FS over 10 N) depending on the condition, while the encapsulated sensor only varies by 0.11 V (14.4% FS over 10 N).

Table 1: Summary of Experimental Results for Grip Force Sensor Comparison

Loading Condition	Baseline Sensor RMSE (N)	Encapsulated Sensor RMSE (N)
Ideal	0.22	0.25
Rounded	3.64	0.29
4 mm Distal Offset	2.55	1.05
4 mm Proximal Offset	1.55	0.72
15 Degree Angle	-	0.76

SOFTWARE DESIGN

BrachI/Oplexus, an open-source graphical user interface (GUI) designed for myoelectric prosthesis control [11], enables the EMG signal interpretation and end effector motion. A microcontroller (Arduino Uno, R3) controls the mechanotactile tactors and grip force sensors. Data logging capability is enabled at a frequency of 50 Hz. A custom GUI (Visual Studio, 2015) was created to communicate with the microcontroller for quick customization of tactor parameters.

CONCLUSIONS AND FUTURE WORK

A lightweight, modular simulated prosthesis was developed with integrated modality and somatotopically matched mechanotactile feedback. Grip force sensors were compared before and after being encapsulated in a compliant material under various loading conditions. In all non-standard loading conditions, the encapsulated sensors outperformed the baseline sensor. This device will help enable researchers to study feedback and control techniques in myoelectric prosthetics by providing a reliable test apparatus that easily allows for the manipulation of various parameters.

Future work includes evaluating the performance of the MSP to ensure that the device is an accurate representation of a myoelectric user and evaluate the effectiveness of various sensory feedback techniques. More modular components, such as alternative feedback devices of various modalities, could be designed to fit onto the device. The device is currently tethered to a one-meter long power cable, which may be restrictive for some studies. A wireless version of the MSP would make the device more flexible.

ACKNOWLEDGEMENTS

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FUNCTIONALLY VIABLE 3D PRINTED POLYMER TRANSRADIAL FRAME AND WRIST WITH VARIABLE COMPLIANCE DYNAMIC VOLUME SOFT SOCKET WITH INCREASED BREATHABILITY AND RANGE OF MOTION

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ABSTRACT

Nine of the top ten reasons that half of arm amputees reject prostheses are related to dissatisfaction with fit and comfort, primarily of sockets [1]. Traditional (particularly myoelectric) sockets severely limit range of motion (ROM), and create pressure, heat and moisture management, and tissue breakdown issues. Here we describe preliminary results from the testing of a new design of transradial frame and socket that combines advanced modern soft athletic shoe materials and construction with 3D printed frame counters to create a functionally viable 3D printed arm with integrated wrist and variable compliance socket weighing less than two pounds complete with harness and terminal device. The system has been used for cross country skiing and indoor rowing, sustaining hours of use in sweaty and friction-rich environments. The range of motion of the prosthesis was measured as compared to anatomical, showing a 59% improvement over a Veterans Affairs (VA) Hospital-provided self-suspending myoelectric socket. The arm and harness can bear tensile loads more than 50 pounds. Custom one-hand operable harness hardware can bear 65 pounds with a factor of safety of more than three.

BACKGROUND

Socket design has changed little in decades and is sorely in need of updating. Much research tends to focus on the symptoms, rather than the causes of socket shortcomings. Significant symptoms of the inappropriate use of unbreathable materials in socket design include sweat that collects in liners and sockets, and the damage that can occur to residual limbs as a result of its retention and continued use, as shown in Figure 1.

Figure 1: Sweat captured in a custom silicone liner during approximately ten minutes of mountain biking (left). With continued use, this can lead to tissue breakdown (right).

Recent research from the VA, for example, describes the use of a battery-powered device to remove sweat from a non-breathable hard socket [2]. While materials for upper limb sockets have tended to follow that of legs, the increased range of motion requirements of upper limb joints, coupled with tighter radii of curvature and lower soft tissue volumes of upper residual limbs remain critical differences. These differences make the traditional hard composite and non-

breathable liner construction of sockets perhaps even less suitable for upper limb sockets than for lower limb. While leather lacing sockets were replaced with composites in the 1940s, this can anecdotally be attributed primarily to factors such as efficiency in cost and time for providers, rather than in outcome or performance.

A number of manufacturers have released sockets that include deconstructed traditional frames and include flexible fabric components, allowing the adjustment of the shape and volume of the socket, including those produced by Lim Innovations and Martin Bionics [3, 4]. By virtue of the flexible components windowed in these sockets, which include polymer or fabric panels, and or gel or silicone liners within, these sockets can be adjusted throughout the day by the user for comfort. In general, these sockets continue to use non-breathable liners or inner sockets, are not available for the upper limb, or have upper limb versions that suffer from the standard limitations of self-suspended monolithic sockets (Figure [2]).

Figure 2: Adjustable volume transradial socket from Martin Bionics (left, similar to Chaz Holder's arm from CZ Biomed), RevoFit Transfemoral Socket from Revo Labs (right)

Because of the tapered nature of residual limbs of almost any level, standard suspensions for transradial amputees rely on components that extend above the elbow: either a harness including flexible hinges and a backplate, or some part of a rigid socket. Self-suspending sockets of monolithic composite material (High Fidelity, Northwestern, Meunster, TRAC, etc) all make different compromises about how to balance the security of the suspension with the inevitable loss of range of motion caused by the volume limitation on expansion in the cubital fold, the limits of elbow relief, and the capture of the humeral epicondyles [5]. Standard harnessed body-powered sockets usually slip to some degree to allow full flexion, as the residual limb is forced out of the socket by the expanding tissue at the cubital fold. These changes that occur at the elbow of any limb during flexion and extension, intact or residual, are at the root of this problem. Any socket at all, particularly one that is of a fixed volume during use (even if it is adjustable), must compromise about what happens to the bones as well as to the changing shape of the soft tissue that contains them as the bones move within the prosthesis and, indeed, within the skin of the residual limb itself. Figure [3] shows these dramatic changes, including in the length of the skin surfaces on the anterior and posterior sides of the elbow (left).

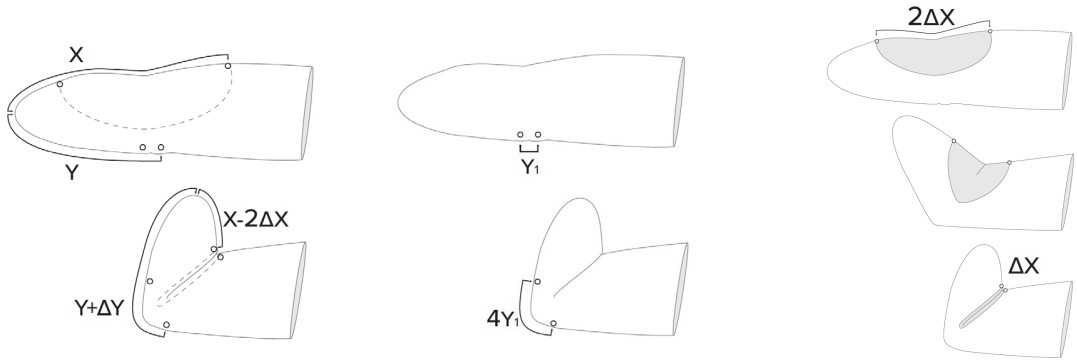

Figure 3: Challenges in securing a transradial limb across the elbow: From extension to flexion, there is a significant change in the length of exposed skin on the anterior and posterior, such that the exposed posterior length increases approximately fourfold from extension to flexion, while the anterior length is reduced by twice the depth of the cubital fold on flexion.

The posterior length is stretched approximately fourfold on flexion (center), most dramatically right at the olecranon. On the anterior side, the majority of the length disappears within the cubital fold (right). As anyone who has marked

the bony prominences of a residual limb for a prosthetic fitting is aware, the locations of all of them with respect to the skin surface, particularly the distal tip, depend significantly on the angle of flexion and are not static. The volume of the limb similarly varies, and circumferences around the elbow also increase significantly at full flexion. So far, no prosthesis for upper limb (or any level of amputation, for that matter), has sought to deal with these challenges by maintaining secure contact with the residual limb while adapting dynamically to the changes in skin surface length, limb volume, and the orientation of the bone within the limb.

METHODS

This research sought to address the deficiencies of current sockets by challenging both their materials and their design. We were inspired first by the modern athletic shoe industry, which has undergone dramatic changes since the 1940s. During this time, these products went from being simply constructed, of canvas and leather, to the complex assemblies that they are today. Second, we were inspired by the iconic Apollo EVA spacesuit, surprisingly designed by the Platex undergarment company, even as aerospace companies sought to replace their "temporary" soft-goods design ultimately consisting of 21 layers of functional fabrics with a science fiction-inspired articulated hard suit [6]. It was incredibly important, once we realised that we were essentially designing a form-fitting garment that needed to dynamically attach hard components to the body, to think of this process as both garment patternmaking as well as product development.

This proposed design returns the prosthetic arm to a shoe-inspired design, updating the leather construction common to both sockets and shoes of the 1940s with the materials and processes developed by the multi-billion dollar athletic footwear industry over the intervening 75 years. Modern athletic shoe uppers are now constructed by a variety of methods, including "sandwiches" of layers of overlapping cut patterns of materials with different degrees of stretch, breathability and wicking, which are combined to create a three-dimensional structure that itself has different properties in different places, and which integrates various hard structures, like shanks, arch supports, heel counters, and a lacing system.

This the fourth generation of hundreds of individual prototypes that we have made, representing everything that we have learned over the last four years. Significant challenges included finding materials strong, light and cheap enough for the hard goods components, the development of the lacing system and the incorporated flexible hinges, determining the necessary performance of the socket over different regions of the surface of the residual limb, and reconciling those requirements with those of obtainable materials and available performance.

DESIGN

The proposed design consists of three major groups of components, shown assembled in Figure [4]. The counters (1), like the heel counter of a shoe, "counter" motion in one or several particular directions. These include the forearm counters (1.1) which have pads to register the ulna and radius, and for purchase when applying pressure in flexion or extension at the distal tip. The elbow counter (1.2), can be thought of as a traditional backplate deconstructed and with pads that grab the olecranon fossa and humeral epicondyles. The textile socket (2) is composed of upper and lower pieces nested together and containing a collection of pads designed to interface with the counters, as well as the bones of the residual limb.

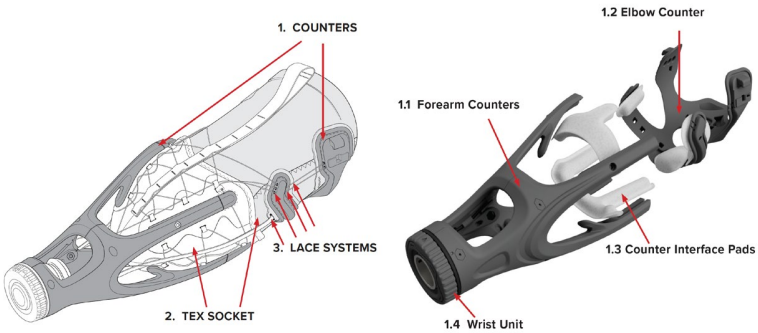

Figure 4: Arm components, including the textile socket, forearm and elbow counters, and the two dynamic lacing systems that secure the counters to the limb and socket throughout the range of motion.

The socket and pads are firmly secured through sewn connections to the counters. Finally, four separate lacing systems, making a total of 10 flexible hinges, are integrated with the textile socket and counters to ensure an intimate connection with the residual limb throughout the range of motion. Figure [5] shows how the two dynamic lacing systems, which we call the top lace and the hinge lace, adjust themselves throughout the range of motion in order to maintain a firm connection between the residual limb and the counters. The top lace does this through its routing over the cubital fold, tightening as the limb is extended, reducing volume at the elbow just as the arm does. The hinge lace, in contrast, only slightly tightens at flexion, but mainly helps maintain an intimate connection by exchanging the length between the anterior and posterior members of the pair on each side of the limb. This (along with the pad at the distal tip), ensures that the limb is not forced out of the socket at flexion as often occurs.

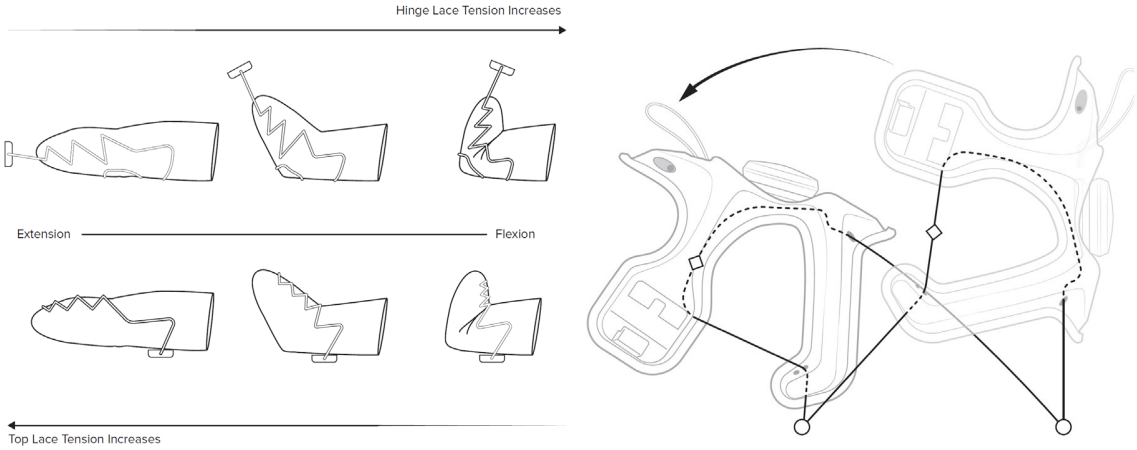

Figure 5: Diagram showing the changes in tension of the dynamic lace systems throughout (left), and of the four hinge crossings of the hinge lace loop, showing how the lace moves through the elbow counter (right).

RESULTS AND CONCLUSION

This version of the arm shows a 59% improvement in range of motion over a traditional myoelectric self-suspending socket (97 degrees), which is 94% of the patient (the author)'s anatomical 111 degrees. The complete system, including arm, harness, and Dorrance 5xTi hook, weighs 0.5 ounces less than a Bebionic hand and wrist, itself weighing just less than 2 pounds. The arm has been worn for hours of cross country skiing and indoor rowing, and can easily transport all of the heat and moisture from these high friction activities away from the limb to evaporate. While the design has yet to be tried on additional patients, we are now confident that it is both possible and worth doing, and have several efforts in place to do this. The arm could be used with any fabric sock with integrated electrodes for pattern recognition or direct EMG, and we have a concept, but no prototype for such a sock.

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PRELIMINARY ACTIVITIES TOWARDS A BATTERY CONSUME OPTIMIZATION ALGORITHM FOR PROSTHETIC HAND

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ABSTRACT

Optimization of the power consumption in Myoelectric hand prosthesis is a crucial issue that can affect the autonomy of the user and the weight of the device. This aspect seems to be barely addressed nowadays. Here we propose a high-level solution that can be implemented on a prosthetic hand, which combines a Current Sharing Algorithm and a Battery Management System with Optimal Output Current to: i) satisfy the daily requirements in terms of grasps and time, ii) enhance the battery life. This solution has been preliminarily implemented on the Mia Hand prosthesis (Prensilia SRL) showing promising results.

INTRODUCTION

In terms of consume, when used for biomedical applications, prosthetic hands can be classified as Portable Electronic Devices (PED). These are used during daily life for many consecutive hours without having the possibility to recharge the supplying power source, which usually consist of a battery pack. This aspect is often underestimated, and the result may lead to a poor design of a prosthetic hands which will require a bulky and heavy battery system. It is worth notice that "weight" represents one the most critical features for producing a successful and competitive prosthetic. In the design of robotic limbs, it is a common practice to take the weight at a minimum[1]. Due to the suspension system, and the external electronics, prosthetic devices are felt heavy by amputees even when the weight is similar to the sound limb.

The selection of the battery should also consider how the provided energy is distributed between the electronic components of the prosthetic hand. For the sake of clarity, all electronic components are going to be divided in two categories: a) **Fixed** - all components which power consumption is almost fixed during the operation (i.e. passive elements, microcontrollers, amplifier, etc.)[1]; b) **Variable** - all components which power consumption may drastically change during time (i.e. power converter, drivers, motors, etc.).

Concern must be address towards this second category in order to prevent unforeseen stress-full situations where huge amount of energy is demanded to the battery. A control strategy that does not take into account such dilemma may cause any prosthetic device to not be able to satisfy the daily operative time required by a patient or, in the worst-case scenario, may lead to battery failure. Since the described problems could ask for a re-design of the prosthetic hand, the objective of this paper is to present a high-level solution that can be implemented on any hand already available on the market. The presented solution will be divided in two parts: i) *Current Sharing Algorithm*, and ii) *Battery Management System with Optimal Output Current*.

METHOD

Case study

The case study we used is a research prosthetic hand (model Mia hand, Prensilia SRL) characterized by a transmission mechanism that implements a semi-independent actuation of the abduction/adduction of the thumb and of the flexion/extension of the index, by means of a single actuator. Thus, with only three BLDC motors the hand is capable to perform most of the grasps and gestures useful in activities of daily living [2].

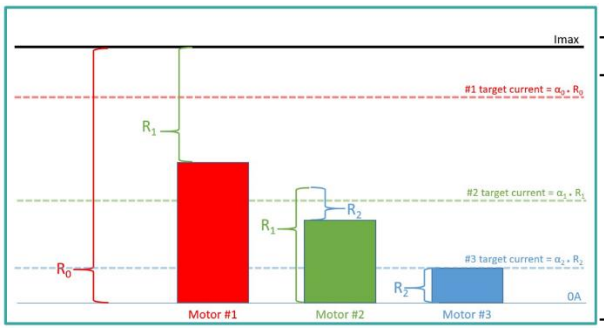
Current Sharing Algorithm

Current Sharing Algorithms (CSA) are a solution adopted in systems where a common resource, in this case the current, must be shared between multiple devices. Examples of current sharing algorithms can be found in many different applications: they have become very common in power electronics([3], [4]), where multiple loads require to be supplied with the same amount of current (sometimes also referred as *Load Sharing Algorithm),* in this cases the CSA tends to make disappear any

[1] The current consumed by all components changes during time since it depends on the battery voltage, but in this first category variations are so small that can be considered almost negligible.

unbalance between load currents, bringing the system to an equilibrium condition. Another application of the CSA can be found in the photo-voltaic field [Solar Array], where is used in order to provide energy in a sequential fashion to different points in a solar array, therefore optimizing the power efficiency. The algorithm presented in this paper can be seen as a generalization of the solutions presented above.

The Mia hand is a perfect example of why the solution adopted in the power systems described above cannot be exploited. In particular, in this hand the major contribute, in terms of grasping force, comes from the thumb, therefore providing the same amount of current to all fingers would not represents an efficient solution. It would be preferable to implement a sequential strategy similar to that adopted by the solar panel.



Algorithm 1: CSA - pseudo code

Result: I_{max} per motor
n = number of motors present in the hand;
$I_{residue}[0] = I_{battery,max}$;
for $(i = 1; i <= n; i++)$ **do**
  $I_{residue}[i] = I_{residue}[i-1] - I_{mot}[i]$;
  $I_{max}[i] = I_{residue}[i-1] \cdot \alpha[i]$;
end

Figure 1: Left) Motor currents shared among the motors of the Mia hand exploiting the CSA proposed. Right) Pseudo code of the CSA implemented.

The CSA developed for the Mia hand is presented in Figure 1 and can be described as follow:

1. An optimal current ($I_{battery,max}$) that the battery is able to provide is estimated. This parameter will be exploited by the *Battery Management System with Optimal Output Current* presented below;
2. Priorities are assigned to the motors according to the grasp selected by the patient/user (basically the order in which motor will move is defined);
3. The motor with the highest priority starts to move and thus starts to absorb current. The amount of current "left or available" ($I_{residue} = I_{battery,max} - I_{mot,1}$), will determine the limiting current for the second motor in order of priority[2].
4. the last item is repeated for all the remaining motors.

This process can be described as master-slave current sharing, were motor consumes current according to their priority with the commune purpose of sharing the source current without exceeding it.

Battery Management System with Optimal Output Current

The second part of the solution proposed in this paper aims to find the optimal current that the battery should provide to the CSA and that implements a *Battery Management System* (BMS). BMS are usually implemented in order to monitoring values descriptive of the pack's present operating condition. This is very useful, for example, to determine at priory the instantaneous available power that can be supplied[5]. Unfortunately, estimating the parameters needed to design a BMS could be time-consuming and expensive. For this reason, it was preferred to empirically measure the discharging characteristic of the battery adopted by the Mia hand. To this aim, a series of tests were conducted in which the hand had to perform different type of grasps while the battery voltage was recorded. The test results can be described as a series of linearized curves which shows the trend of the battery voltage: over repetitions of the same grasps and over different values of supplying current. In order to select the optimal current from a set of infinite possible choices, a constrain had to be defined. Thanks to Ian M. Bullock and his colleges [6], it was possible to evaluate the number of daily grasps performed by amputated patients. These are around 2500 grasps, divided between Cylindrical Grasps 40%, Precision 37.6% and Lateral 22.4%. In addition, from [7], [8], it was possible to determine the prosthetic daily wearing time, that is between 8 and 12 hours. This information set a target for the autonomy of the hand and thus are the target of our algorithm.

Taking into account such requirements, the optimal solution is the one satisfying the following optimization function:

[2] In order to execute this kind of algorithm, the current absorbed by each motor must be measured.

$$\textbf{objective function:} \quad \max_{I} \min (V_{end} - V_{limit})$$

This is a max-min problem, where V_{end} is the estimated battery voltage level that is "left" once daily requirements have been satisfied, while V_{limit} is the minimum voltage level guaranteed by the battery. This solution can be also described as follow:

1. The number of grasps left to fulfil daily requirement are measured;
2. A combination of the remaining grasps is selected;
3. For each combination, the voltage left once daily target has been satisfied is estimated;
4. Between all possible combinations, it is selected the one that permits to consume the highest current (best performance) without turning off the battery (battery failure).

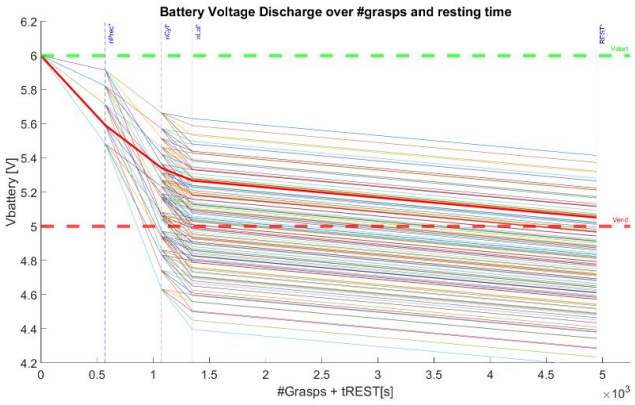


Figure 2: Example of application of the BMS with optimal output current[3].

In Figure 2 it is presented a possible scenario where a patient wants to perform a Precision grasp. The battery voltage is 6V and the minimum operative battery voltage is 5V. In this example, for each grasp, the consumed current could take one out of five different possible values. In Figure 2 it is possible to notice that not all the combinations of grasps could fulfil the daily target. The red broken line highlights the solution of the optimization problem described above. It is important to notice that grasps are ordered by the algorithm as follow: 1) The first grasp type selected is the one requested by the user; 2) The remaining grasps are order from the most consuming to the least consuming.

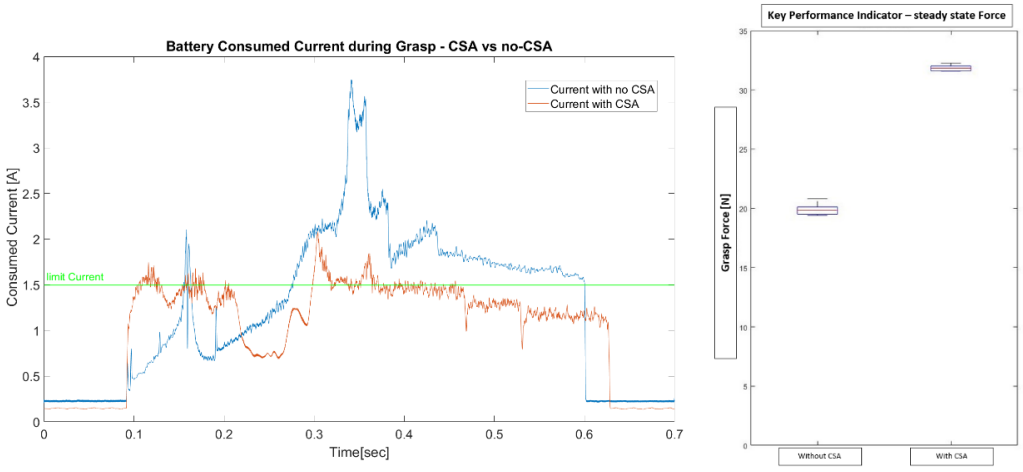


Figure 3 - Left) Battery Consumed Current - CSA vs no-CSA; Right) Grasping Force - CSA vs no-CSA

[3] The x-axis is homogeneous, first battery discharge characteristic is presented over the "left" number of grasps (#Grasps) then over the "left" resting time (tREST, period in which the hand is wore but not used).

RESULTS

The results of the discussed algorithm are shown in Figure *3*. It is possible to notice that the algorithm was able to drastically reduce the value of the maximum instantaneous power, measured in terms of maximum consumed current, required during grasp, while increasing the force exerted. The reason is that through sharing it was possible to supply the thumb motor, which is the major contributor in terms of grasping force, with an higher amount of current while preventing any degrading of the other motors performance.

CONCLUSIONS AND FUTURE WORKS

The presented work represents a preliminary study for the optimization of battery consume in the field of prosthetic hands. For the future it could be useful to: implement a model of the Mia hand battery as described in [5] and to integrate some kind of optimal control inside the CSA in order to have a more robust solution.

ACKNOWLEDGEMENTS

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TOUCH FEEDBACK AND CONTACT REFLEXES USING THE PSYONIC ABILITY HAND

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PSYONIC, Inc.

ABSTRACT

The PSYONIC Ability Hand is a commercially available multiarticulated prosthetic hand with six degrees of freedom and sensorized digits. Through using contact reflexes and vibration feedback, users can grasp delicate objects without damaging them. We show results that two subjects successfully grasp hollow eggshells and fragile cups statistically significantly more often when provided with contact reflexes and touch feedback.

INTRODUCTION

The Ability Hand

PSYONIC has developed the commercially available Ability Hand—a compliant, robust, sensorized prosthetic hand to be used by people with upper limb amputations. The Ability Hand is:

- Multiarticulated – all five digits flex/extend and the thumb rotates both electrically and manually
- Robust – compliant fingers allow the hand to withstand blunt force impacts to the fingers
- Lightweight – 460 g, carbon fiber palms make the hand light and strong
- Fast – using brushless motors with field-oriented control, the fingers can close 90 degrees in 200 ms
- Waterproof – IP64 waterproof rating, enabling washing the hand in water
- Sensorized – pressure from the fingertips, fingerpads, and lateral edges maps to a vibration motor

The Ability Hand uses a standard electronic quick disconnect and integrates with commercially available control systems (e.g. Coapt Pattern Recognition, OttoBock/RSL Steeper myoelectrodes, etc.). Apple and Android phone apps are available to configure the hand over Bluetooth as well as make firmware updates. USB-C charging allows the hand to be fully charged within one hour.

Fig. 1 The Ability Hand attached to a socket

Sensory Feedback

Poor manipulability due to the lack of sensory feedback is a leading cause of prosthesis abandonment [1-2]. While body-powered prostheses can give users some sensory feedback, these devices are limited in achievable grasps and can cause overuse injury in the shoulders of the user. There are several functional advantages to providing sensory feedback in a multiarticulated prosthesis, including contact detection and body self-identification [3]. An external study by Matulevich et al. [4] shows that users could grasp foam, crackers, and hollowed eggs statistically significantly faster (between 1.4x-3.3x) when using contact detection from pressure sensors on a prosthetic hand. Another external study by Berke et al. [5] showed users performing tasks more than 15 seconds faster on average when provided with contact detection.

In the Ability Hand, all five digits can be sensorized with four pressure sensors in each digit. The index and little fingers have pressure sensors on the distal fingertip, the fingerpad, and two on the outer lateral edges. The thumb, middle, and ring fingers typically have pressure sensors on the distal fingertip, the fingerpads, and one on each lateral side of the digit. These pressure sensor locations were chosen due to their increased likelihood of contacting objects. The sensor providing the highest pressure value is mapped to a vibration motor whose amplitude changes with the pressure applied.

To test the efficacy of the sensory feedback, we recruited two volunteer subjects. The first subject, S1, was a male, age 42, with a right proximal below-elbow amputation. The second subject, S2, was a male, age 78, with a left distal below-elbow amputation. S1 was fitted with a commercial muscle pattern recognition system developed by Coapt that we integrated to use with PSYONIC's hand. S2 used a custom linear transducer mechanism developed by PSYONIC that uses shoulder movements to control opening and closing the hand.

Subjects S1 and S2 were asked to use the hand at home for 1 week. Immediately prior to and after the home trial, both subjects participated in two experiments: 1) a cup grasping task, and 2) an eggshell cracking test. All methods were approved by IRB #13920 at the University of Illinois at Urbana-Champaign. Subjects also consented to images and videos to be taken during the experiments. Preliminary experiments were performed in Akhtar et al. [6].

In the cup grasping task the subjects were asked to grasp ten empty plastic cups. The distance between the outer tips of the index finger and thumb was measured to determine the amount of deformation of the cup. This process was repeated over 4 conditions: 1) with Touch Feedback and with Visual Feedback, 2) without Touch Feedback and with Visual Feedback, 3) with Touch Feedback and without Visual Feedback, and 4) without Touch Feedback and without Visual Feedback. The order of the conditions was randomized. These conditions were selected to observe differences in grasping performance when providing touch feedback, both with and without visual feedback.

For the eggshell cracking test participants were asked to grasp ten hollowed eggshells without cracking them. We recorded the number of eggshells cracked. Again, the process was repeated under the same four conditions as the cup grasping task. When providing touch feedback to subjects, a contact reflex was implemented in the hand that caused the hand to automatically stop when contact with the object was made. Fig. 2 shows a typical pressure sensor reading when grasping a hollowed eggshell.

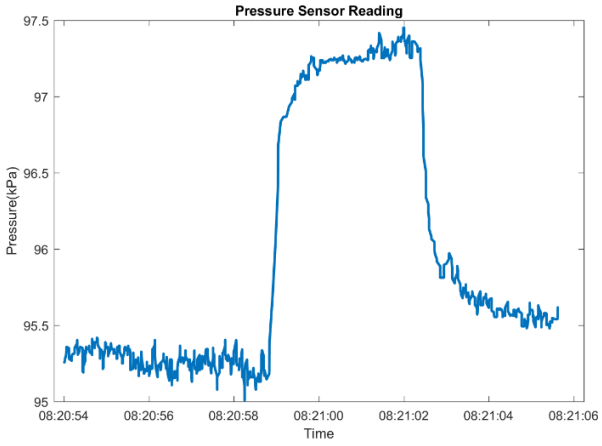

Fig. 2 Reading from pressure sensor on the finger pad of the distal index finger when Subject S1 grasped an eggshell.

Results from Subjects S1 and S2 across both sessions are given in Table I for the cup grasping task and Table II for the eggshell cracking test. For the cup grasping task, there was a statistically significant difference between feedback conditions as determined by a two-way repeated measures ANOVA ($F(3,3) = 567.7$, $p < 0.0005$). Post-hoc tests revealed that the touch feedback conditions (with or without visual feedback) statistically significantly outperformed both conditions without touch feedback ($p<0.05$). Consequently, we conclude that by providing touch feedback with contact reflexes users deform the plastic cup significantly less. There were no statistically significant differences between sessions, and the session had no significant effect on the condition.

Table I Results from cup grasping task

	Session	**Touch, Visual (mm)**	**Touch, No Visual (mm)**	**No Touch, Visual (mm)**	**No Touch, No Visual (mm)**
S1	1	80.3	79.5	37.4	39.4
	2	78.7	82.2	51.4	48.9
S2	1	77.3	80.2	38.6	38.9
	2	87.3	89.5	49.5	54.3
Grand Mean		**80.9**	**82.9**	**44.2**	**45.4**

For the eggshell cracking test, there was a statistically significant difference between feedback conditions as determined by a two-way repeated measures ANOVA ($F(3,3) = 21.63$, $p = .016$). There was no statistically significant differences between sessions, and the session had no significant effect on the condition. Again, touch feedback with contact reflexes resulted in better performance, with less eggshells cracked compared to when no touch feedback with contact reflexes was given (with or without visual feedback).

Table II Results from eggshell cracking test

	Session	**Touch, Visual (# cracked)**	**Touch, No Visual (# cracked)**	**No Touch, Visual (# cracked)**	**No Touch, No Visual (# cracked)**
S1	1	0	2	7	9
	2	0	3	6	6
S2	1	0	0	7	7
	2	2	1	8	6
Grand Mean		**0.5**	**1.5**	**7**	**7**

Fig. 3 shows images of the Subject S1 performing the eggshell cracking test. When touch feedback with contact reflexes was turned on, the subject could easily grasp the eggshell without cracking it, even while blindfolded. When touch feedback with contact reflexes was turned off, the subject usually cracked the eggshell, even when he could see it. Fig. 4 shows Subject S2 successfully grasping the eggshell while blindfolded when receiving touch feedback with contact reflexes.

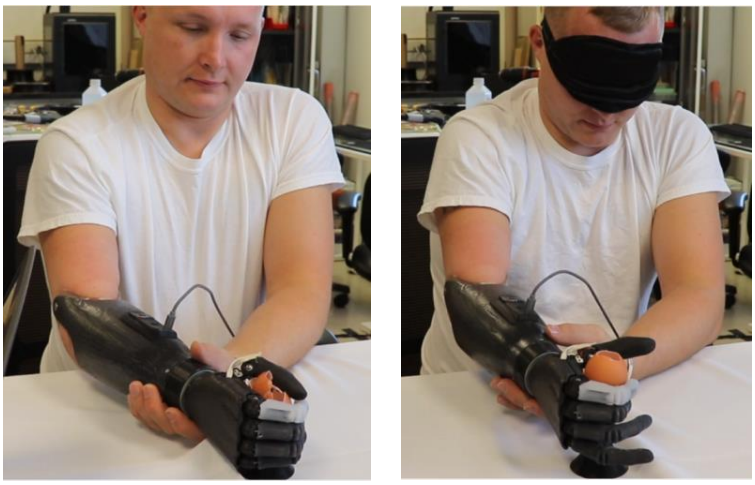

Fig. 3 Subject S1 cracking an eggshell when not receiving touch feedback while seeing the eggshell (left), but successfully grasping the eggshell when receiving touch feedback while blindfolded (right).

Fig. 4 Subject S2 successfully grasping the eggshell when receiving touch feedback while blindfolded.

Qualitative feedback from the subjects after the home trials was positive. Subject S1 reported he mostly wore the hand during work. Common tasks included holding drinks, driving, shaking hands, and sweeping. He liked the light weight of the prosthesis as well as the bionic look. Subject S2 liked the fact that our hand could work with both off-the-shelf myoelectric systems and a linear transducer system. He used a linear transducer system for the trial that he found to perform vastly better than a myoelectric system. He used this mainly to grasp glasses to drink from, for exercising on a stairmaster, and for assistance in typing (e.g. holding down the shift button on a keyboard). For improvements, he expressed that multiple settings for the pressure sensor contact reflexes would be helpful, as some objects require tight grips while others require delicate grips.

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UNIVERSAL, LOW-COST TRANSRADIAL CHECK SOCKET FOR RAPIDLY VALIDATING MYOELECTRIC CONTROL

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ABSTRACT

The validation of myoelectric prosthetic control strategies for individuals experiencing upper-limb loss is hindered by the time and cost affiliated with traditional custom-fabricated sockets. Consequently, researchers often rely on virtual reality or robotic arms to validate novel control strategies, limiting end-user involvement. Here we present a multi-user, low-cost, 3D-printed transradial socket for short-term use that can be custom-fit and donned rapidly, used in conjunction with various electromyography configurations, and adapted for use with various residual limbs and terminal devices. The check socket was fabricated prior to participants' arrival, fitted by the researchers within ten minutes, and donned in under one minute. It accommodated multiple individuals and terminal devices, and its total cost of materials was under $10 USD. Across all participants, the socket did not significantly impede functional task performance or reduce the electromyography signal-to-noise ratio. The socket was comfortable enough for at least two hours of use. The development of this universal transradial check socket constitutes an important step towards increased end-user participation in advanced myoelectric prosthetic research.

INTRODUCTION

Up to 50% of individuals with upper-limb loss abandon their myoelectric prostheses [1], often citing unreliable control as a critical factor [2]. More dexterous myoelectric control could improve prosthesis acceptance. However, validation of new control strategies with end users is limited by the time, cost, and expertise needed to fabricate a custom-fit socket with several embedded electrodes. Traditional transradial sockets include only two electrodes and require three to four visits with a prosthetist over three to six weeks for $800 to $3,000 before affiliated labor costs [3,4]. Due to these constraints, research is often limited to just one or a few individuals with upper-limb loss, often working in virtual reality environments or with a robotic arm mounted apart from the user. Other studies rely on intact participants or offline analyses with no active human involvement.

One approach to increasing end-user participation is to reduce cost by using an adjustable socket. Recent work in this area has focused on photogrammetry and expandable foams [5, 6]. Though these sockets reduce cost, they still require a lengthy fabrication process that must be repeated for each individual. While sockets that are both customizable and affordable have been explored, they have yet to be adapted for myoelectric prosthesis use.

To address these needs, we developed a multi-user, 3D-printed transradial check socket for functional validation of new myoelectric control strategies in research settings. The socket can be fabricated by the researchers prior to the participants' arrival, and rapidly fit, donned, and used. We explored its comfort and functionality with a high-count surface-electromyography (sEMG) control system. The development of this socket constitutes an important step towards expanding the involvement of individuals with upper-limb loss in myoelectric control research.

MATERIALS AND METHODS

Device Development

The multi-user check socket is designed to: i) optimize accessibility and cost; ii) accommodate a wide range of data acquisition (DAQ) methods, residual limbs, and prostheses; and iii) ensure durability, functionality, and comfort. The 3D-printed socket consists of four customizable struts that attach to a collet, which in turn connects to a custom terminal-device attachment that varies for each unique terminal device (Figure 1). A layer of self-adhesive wrap between the skin and the socket provides grip, and a second layer of self-adhesive wrap around the socket secures the fit. The socket design is available at https://github.com/utahneurorobotics/u-of-u-functional-test-socket.

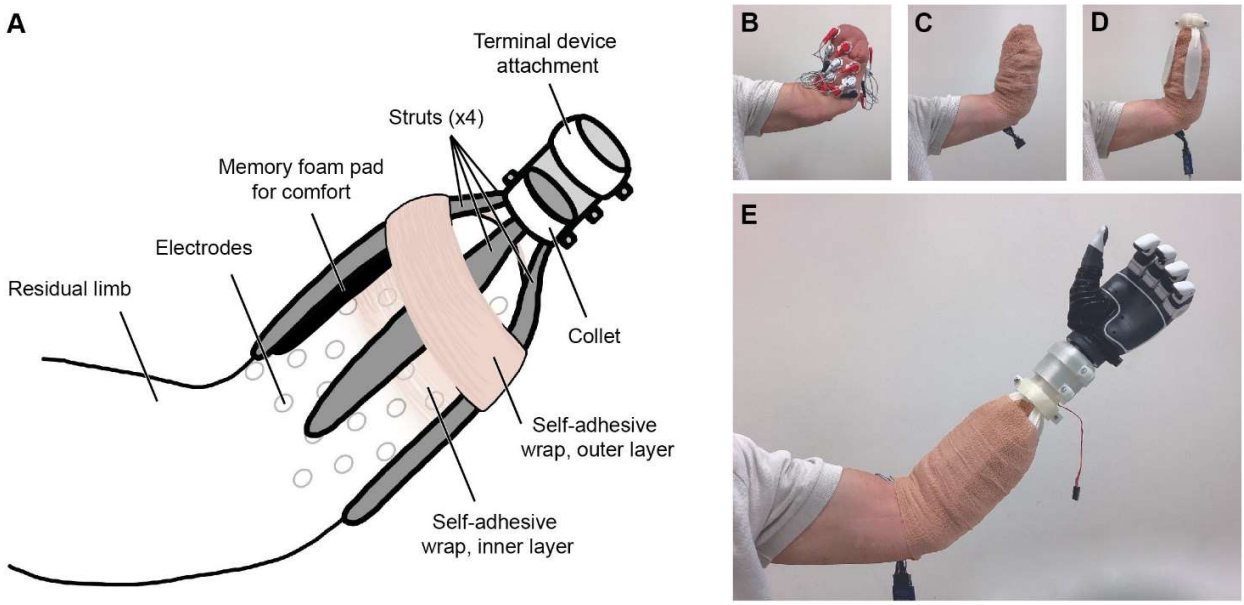

Figure 1: (**A**) Socket overview. (**B**) The residual limb is outfitted with sEMG electrodes and (**C**) wrapped securely in a disposable adhesive bandage. (**D**) After being heated, molded, and cut to the desired length, the custom-fit struts are attached to the collet, and the socket is donned. (**E**) A second layer of adhesive bandage is wrapped around the limb and socket system, and the socket is fit with a myoelectric prosthesis, pictured above with a TASKA hand. The 3D-printed components can be removed, reshaped, and reused with subsequent individuals without reprinting.

i) Accessibility

The 3D-printable design of the socket improves accessibility, enabling researchers without prosthetist expertise to complete both the fabrication and fitting processes. The socket is 3D-printed prior to the participant's arrival. Upon arrival, the custom-fitting process can be completed within ten minutes, and the socket can be donned in under one minute (Table 1), not including electrode placement, as this time will vary depending on the DAQ system. The total cost of materials of one socket is approximately $8.00 (Table 2), excluding other 3D-printer costs such as maintenance. This contrasts with recent low-cost sockets ranging from $100 to $200 [5, 6]. All components are widely available materials. The accessibility of this design is conducive to greater participant involvement, allowing those with transradial amputations to rapidly use and validate advanced myoelectric prostheses.

Table 1: Time Approximation, by Process

Fabrication (3D printing)	6 hours, 30 minutes
Fitting (molding struts)	10 minutes
Donning	< 1 minute
Doffing	< 1 minute

Table 2: Cost Analysis, in USD

3D-printed Components (i.e., filament)	$3.50
Hardware (i.e., nuts and bolts)	$1.00
Self-adhesive Wrap	$3.00
Memory Foam	$0.50
Total	**$8.00**

ii) Adaptability

Our socket is designed to be versatile and is compatible with a broad range of control methods, residual limbs, and terminal devices. The socket grants access to the skin for various means of control, and the 3D-printed struts can be molded around a range of DAQ methods (electromyography, magnetomyography, sonomyography, etc.) without affecting fit or comfort. The polylactic acid (PLA) filament allows the struts to be heated in a hot water bath or with a heat gun and quickly molded to the unique presentation of the participant's limb. The adaptability of the socket improves the overall participant experience by accommodating limb-volume fluctuations and avoiding any painful sites (e.g., bone protrusions, neuromas, wounds). The design is adaptable to other open-source connectors that can be printed along with the socket to accommodate a variety of commercially available prostheses. Such adaptability is also conducive to improved hand orientation, as the default position of the prosthesis can be adjusted by rotating the terminal device attachment within the collet (Figure 1A).

iii) Durability

The struts are printed flat to ensure structural stability [7] and take their contoured shape only in the custom fitting process. PLA offers greater toughness and higher break elongation, break load, and break strength when compared to other thermoplastic filaments [8]. The struts are designed to minimize deflection and slipping; a reinforcing layer along the top of each strut distributes weight and maintains structural integrity, and surface texture along the bottom creates grip. The surface area of the widened struts also helps distribute pressure evenly throughout the socket. Such weight distribution is key to supporting loads beyond that of the terminal devices. The weight of the socket is approximately 150 g, which is at the low end of the 100- to 420-g range for traditional sockets and low-cost alternatives [5, 9]. Incorporating memory foam beneath the greatest load-bearing strut further increases comfort. Altogether, these design considerations ensure comfort while promoting greater maximum load and durability.

Testing

Before participant recruitment, we tested the mechanical capabilities of the socket. Using a plaster limb replica, two modes of extreme-use load suspension were evaluated: vertical and horizontal. Vertical load suspension is most prone to slippage, so masses up to 8 kg (approximately twice that of a gallon of water [10]) were incrementally and statically hung. The amount, if any, by which the socket had slipped was recorded. The socket was also moved rapidly to simulate a dynamic load condition such as going down a flight of stairs. Horizontal load suspension is most likely to induce fracture; the same mass was added, and the degree, if any, of downward deflection was measured.

Three participants with transradial amputations were recruited for functional testing. The participants reported their perceived comfort at three time points in the experimental session using a 0-10 Likert scale [11, 12]. We utilized high-count sEMG (Ripple Neuro LLC, Salt Lake City, UT) and recorded data while participants mimicked movements of a virtual prostheses to train a modified Kalman filter [13] in order to provide myoelectric control. Signal-to-noise ratio (SNR) was measured with and without the socket during three movement sets [14]. Performance was evaluated via a target-touching task in a virtual environment [15] and the modified box and blocks test (BBT), in which participants were instructed to transfer 16 blocks arranged in a grid from one compartment of the box to the other [16].

Across all metrics, we tested within-participant performance and group-mean performance to interpret our results in the context of the larger patient population. All data were screened for normality prior to analyses. We performed paired t-tests to compare the socket- and no-socket cases and to compare with reported literature values.

RESULTS

Mechanical testing demonstrated socket reliability. Vertical load suspension up to 8 kg yielded no measurable slipping in static or dynamic conditions. In horizontal load suspension, less than 1º of vertical deflection was noted in the connection between the dorsal-most strut and the collet. This minimal deflection was elastic, as the socket quickly reverted to its original orientation once the load was removed. No perceptible fractures resulted from loading.

Three participants with transradial amputation were recruited for this study. Our socket encountered no difficulties accommodating the variance in arm length or circumference across these three individuals (residual limb length, 15 cm to 20 cm; circumference, 26 cm to 27 cm).

Comfort remained adequate throughout experimental sessions, but our socket was rated lower than participants' traditional clinically-prescribed socket. Immediately after donning, our socket scored 6.7 ± 1.2 on a 0-10 Likert scale (mean ± standard deviation). In comparison, traditional socket scores were reported to be 8.8 ± 1.3. There was an imperceptible degradation of comfort over time, with comfort scores of 6.5 ± 1.5 partway through and 5.7 ± 2.1 at the end of the experiment. The mean difference of 1.0 in comfort falls within the 2.7-point minimum detectable change [12]. Notably, the participant with the lowest reported comfort score remarked that it was still tolerable for multiple hours of use.

Functional testing demonstrated that the socket did not impede performance. SNR was comparable between socket- and no-socket cases across all three movements (Figure 2A). Similarly, target-touching performance was not hindered by the socket, as quantified by percentage times in target (PTT) (Figure 2B) and root-mean-squared error (RMSE) (Figure 2C). Lastly, modified BBT performance with our socket was comparable to literature values, with no reduction in the average number of blocks transferred with our socket as compared to values reported for myoelectric prosthesis users [17-19] (Figure 2D). Participants (N = 3) transferred 19 ± 3 blocks in 60 s compared to 13 ± 0 for modified BBT (N = 2) and 21 ± 6 for original BBT (N = 17).

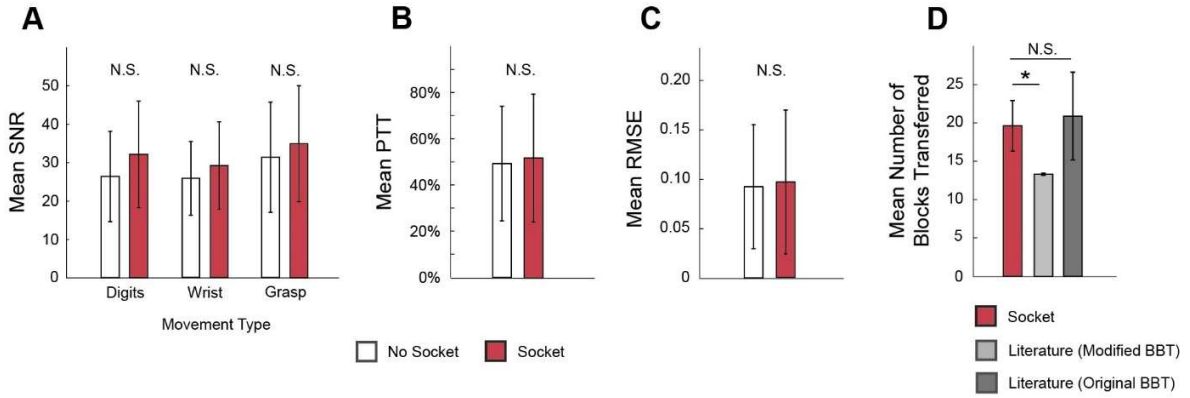

Figure 2: (**A**) Signal-to-noise ratio (SNR) was not affected by the socket for any movement type (N = 3). (**B**) For a virtual target-touching task, neither mean percent time in the target region (PTT) nor (**C**) mean root-mean-squared error (RMSE) were significantly different while using the socket (N = 3). (**D**) Modified box and blocks test (BBT) performance (N = 3) was comparable to literature values, with no statistical difference from reported values for the original BBT (N = 17). However, performance with the socket was significantly improved from reported values for the modified BBT (N = 2). *p< 0.025.

CONCLUSION

We developed a novel, multi-user check socket that can be used to quickly assess myoelectric control with individuals with transradial amputation. The socket makes custom myoelectric control more accessible; it can be printed in less than seven hours, custom fit within ten minutes, donned in under a minute, and the total cost is approximately $8.00. The socket also accommodates multiple individuals without requiring reprinting, adapts to volume fluctuations and painful sites, and works with a variety of terminal devices and DAQ methods. Importantly, the socket presented here is not intended to serve as a clinical diagnostic check socket, nor is it meant for long-term use as a definitive socket; rather, it is best utilized briefly in a research or clinical setting to explore myoelectric control with a physical prosthesis. Future work should validate this socket with additional participants and terminal devices.

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UPPER LIMB PROSTHESES – FUTURE PERSPECTIVES FOR BODY-POWERED PROSTHESES

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ABSTRACT

Body powered upper-limb prostheses (bpp) have many advantages over EMG-controlled, electrically actuated ones (myo's), including mass, reliability, and proprioceptive feedback. Despite these advantages, bpp are rejected as often as myo's. Reasons mentioned include mass (despite being lower than myo's), and comfort (especially of the harness). In addition, recent research has shown the operating forces of bpp being too high. As a result the main advantage of bpp – feedback – is overshadowed, and the high operating forces negatively influence the comfort.

Current research at the Delft Institute of Prosthetics and Orthotics aims at improving the performance of upper-limb prostheses. First results show a promising future for prostheses controlled and/or powered by body movements, while satisfying the basic requirements for upper limb prostheses.

INTRODUCTION

For centuries mankind has tried to provide people with an arm defect with some kind of a replacement for the limb parts missing [1]. One of the oldest examples known, dating back to 330 B.C, is a prosthetic hand found on an Egyptian mummy. This device is a cosmetic hand prosthesis, i.e. without moving parts, primarily aiming at the restoration of the wearer's outward appearance. Dating from mediaeval times and some later ages, several examples of passive hands remain. Some of them with a moveable thumb only, some with the four fingers moving together in one finger block, and others with passive, individually adaptable, fingers. In these hands the thumb and finger configuration can be locked in a chosen position by the activation of a knob. A few examples are the famous hands of Götz von Berlichingen [2, 3] and the hands made by Ambroise Paré [1].

The beginning of the 19th century brings about a tentative start with actively operated prostheses. Harnessing gross movements of other body segments operates these prostheses. Hence, this type of prostheses is called body-powered (bpp). Examples include prostheses designed by Ballif in 1818 [2], by Van Peetersen in 1844 [2], and by the Count de Beaufort in 1860 [1], Figure 1.

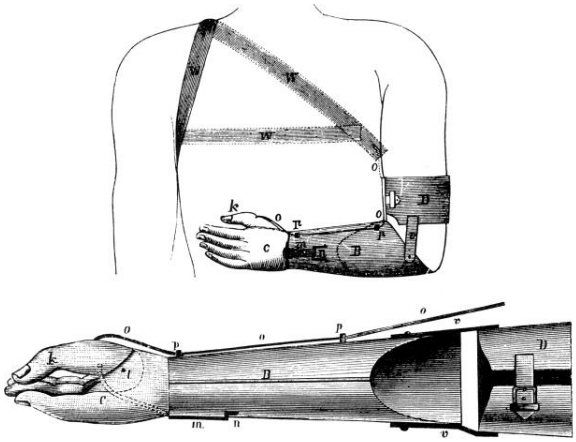

Figure 1 - Prosthetic forearm designed by Count De Beaufort in 1860. The hand is controlled by a cable, indicated by O, which is attached to a shoulder harness.

Around 1900 the first attempts to power prostheses from an external energy source, most likely to relieve the user from the relatively high operating forces in body powered prostheses, can be seen. Examples include electrically powered prostheses [2, 4], or pneumatically powered ones [2, 5].

During WWII the idea of using myo-electric signals for the control of prostheses was conceived [6]. After extensive research and development myo-control evolved into the present day EMG-controlled, electrically actuated prostheses (myo's) and is still the subject for many researches to try and improve this control method.

At the Delft Institute of Prosthetics and Orthotics [DIPO] three basic requirements for upper limb prostheses were established: cosmesis, comfort, and control [7]. Judging bpp and myo's against these requirements it can be seen that bpp have many advantages over myo's, including mass, reliability, and proprioceptive feedback. Despite these

advantages, bpp are rejected as often as myo's. Reasons mentioned include mass (despite being lower than myo's), and comfort (especially of the harness) [8]. Moreover, the functionality of myo's still lacks behind bpp (with the result of the Cybathlon 2016 and 2020 as an example).
Recent research has shed even more light into why bpp are rejected: the operating forces are too high [9-11]. As a result the main advantage of bpp – feedback – is secluded, and the high operating forces negatively influence the comfort.

At the Delft Institute of Prosthetics and Orthotics (DIPO) current research aims at improving the performance of upper-limb prostheses.

METHODS

Within several ongoing projects DIPO tries to improve different aspects of upper-limb prostheses. Four of these projects will be highlighted here:

• Natural grasping
Within this project a body-powered voluntary closing hand prosthesis with adaptive fingers, a high pinch force to operating force ratio, and a low mass will be designed.

• Self-grasping hand
The goal of this study is to design a next generation adjustable prosthetic hand. This prosthetic hand must be able to grasp objects without the help of the sound hand, and without the need of a harness or batteries.

• Haptic interface for prostheses control
This project aims to combine the advantages of externally powered prostheses (low operating effort, high pinch force) with the advantages of body-control (feedback). The idea is to measure movements of the body to control the aperture of the terminal device, and to measure pinch forces in the terminal device and feed them back to the body.

• Servo mechanisms
This project aims to enable prosthesis operation with low operating efforts. The envisioned servo mechanism uses pneumatic energy, as electro-mechanical servo mechanisms suffer from a high mass, and are sensitive for water and dirt.

RESULTS

The current status of the above mentioned project is discussed below.

• Natural grasping
A prototype hand was developed [12]. It has four adaptive, under-actuated fingers and a stationary thumb, Figure 2. The hand requires less energy (50-160%) of the user compared to current bpp-hands, while its mass is only 152 grams. Clinical test are ongoing.

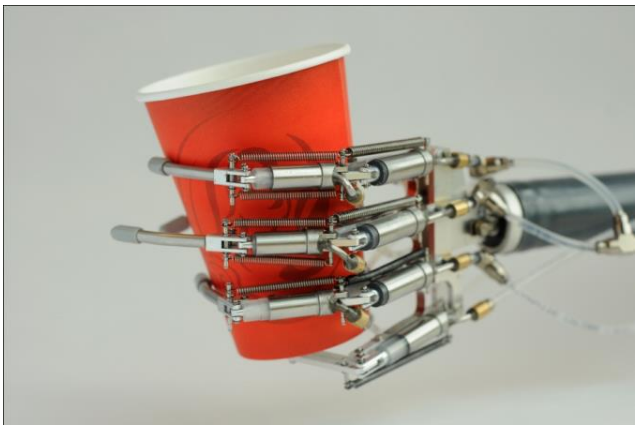

Figure 2 - The prototype of the Delft Cylinder Hand. It has four adaptive fingers actuated with two hydraulic cylinders in each finger, except for the little finger which has only one hydraulic actuator. The springs return the fingers to the open position at rest, and partly compensate for the counteracting forces of the cosmetic glove (not shown in the picture) as well. The cylinders in the hand receive the pressurized hydraulic fluid from a master cylinder incorporated in a shoulder harness.

• Self-grasping hand
Among the users of a hand prosthesis, about one-third uses a passive device. Nonetheless, little research is performed on improving passive hand prostheses [13]. At DIPO an innovative passive hand mechanism was designed. This hand has articulating fingers and can perform the hook grip, power grip and pinch grip. The gripping function is controlled indirectly by pushing an object to the hand, or directly by pushing the prosthetic thumb against a fixed object. The grip force is proportional to the applied push force. By releasing the push force, the grip force is locked and the object is being held. In order to release the object, a button has to be pushed after which the object can be released by pushing the object slightly into the hand. The hand, Figure 3, has a mass of 130 grams. A commercial version of this hand is almost ready for release.

Figure 3 – The Self-grasping hand, shown without the cosmetic glove. In the right picture, the button to unlock the hand is visible on the dorsal side of the hand [www.moveable.nl].

• Haptic interface for prostheses control
The designed interface utilizes skin anchors [14], Figure 4, connected by sensors and an actuator to record force/displacement and to provide feedback from sensors in the terminal device.

Figure 4 – The skin anchors placed on the body of a test subject. The cables are connected to the experimental set-up used verify the idea behind the haptic interface.

An experimental set-up, Figure 5, showed that the system indeed is able to provide input to the terminal device and gives proper feedback to the user [15]. Current activities include the design of a wearable actuator system.

Figure 5 – The experimental set-up. On the left the prosthetic simulator; in the middle and right part of the figure the master-slave unit is shown. Also visible are the cables and on the foreground, the skin anchors.

• Servo mechanisms
A hybrid system, Figure 6, was designed that closes a voluntary closing terminal device by a Bowden cable as usual, and automatically activates a pneumatic servo as soon as an object is grasped. The output of the servo is proportional to the cable force, with a three-fold amplification.

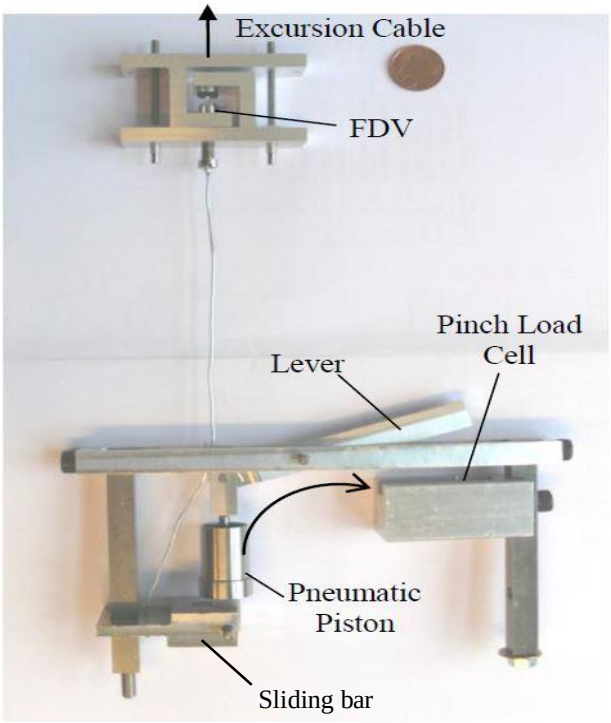

Figure 6 - An overview of the experimental setup. A cable (excursion cable) is connected to the force demand valve (FDV). The sliding bar will move when the excursion cable is pulled, this movement will cause the lever, which mimics a finger of the hand prosthesis, to rotate. Once the lever reaches the pinch load cell, representing the object to be grasped, the force in the excursion cable will rise. This increase in force will cause the FDV to start increasing its output pressure, which is connected to the pneumatic

piston. This will cause the pneumatic piston to start applying force on the lever. The same force locks the sliding bar.

DISCUSSION AND CONCLUSION

The current projects at DIPO all show the future promises for upper-limb prostheses. The Delft Cylinder Hand is the first hand prosthesis that fulfils most requirements of the user: low mass, low operating effort, and proprioceptive feedback. The haptic interface shows a promising way of avoiding the harness, while maintaining the proprioceptive feedback. In combination with the pneumatic servo mechanism a prosthesis that combines body-control with a low operating effort comes within reach.

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User Experience

A PLATFORM TO ASSESS BRAIN DYNAMICS REFLECTIVE OF COGNITIVE LOAD DURING PROSTHESIS USE

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ABSTRACT

Prosthetic hand operation often results in high levels of cognitive burden on the user which can lead to fatigue, frustration and device rejection. Previous work that quantified this cognitive load relied on subjective questionnaires or distraction tasks. We have adapted a protocol capable of real-time, objective, non-distracting assessment of cognitive load for use with individuals controlling a myoelectric prosthesis. Here we present this platform to assess cortical dynamics during prosthesis use. We describe a custom-built lightweight prosthesis simulator and an electroencephalography (EEG) assessment. We also present pilot work that shows how alpha inhibitory activity recorded with a wireless EEG system can be used to assess cognitive load.

INTRODUCTION

Efforts to improve upper-limb myoelectric prostheses often aim to provide a high degree of functionality to those living with limb-loss [1]. Despite technological advancement, these devices provide limited capabilities compared to intact limbs and impose a high cognitive load that results in fatigue and frustration [2], which can lead to device rejection [3]. Measurements to directly evaluate cognitive load are needed in order to further understand how efficient visuomotor behaviors develop during prosthesis learning and use. For this, electroencephalography (EEG) is ideally suited as it allows the measurement of ongoing neural activity with high temporal resolution. Active processing in engaged and task-relevant areas of the brain is reflected by a suppression in the magnitude (power) of oscillations in the alpha range (8-12 Hz) [4], [5]. The development of skilled motor performance is characterized by the efficient allocation of processing resources to task-relevant areas of the brain [6]. Recently, this approach was used to demonstrate a decrease in alpha power detected across the scalp during prosthesis use compared to an anatomical hand, reflecting more conscious control [7]. Based on this work, we present a platform to assess brain dynamics during prosthesis use. The first section describes a customizable, lightweight myoelectric prosthesis simulator created for the platform. The second section describes the wireless EEG equipment and the analysis used in the platform. We conclude by showing pilot data of the alpha distribution on the cortex reflecting functional inhibition which can be indicative of high cognitive load.

METHODS AND PILOT RESULTS

Prosthesis simulator

A novel, custom built, lightweight (approx. 900 g) 3D-printed myoelectric prosthesis simulator was built (Figure 1). This device allows for people with intact limbs to control a prosthesis. The University of Alberta's Handi Hand [8] was mounted to a wrist brace with a medial offset, a position chosen to minimize the effect on modulating arm kinematics [9] and to reduce visual occlusion of the prosthesis [10]. Two electrodes (Myoware, Advancer Technologies) placed on the dorsal and ventral surfaces of the forearm record electromyographic (EMG) activity from wrist extensors and flexors to be used for hand control. Force sensitive resistors (Interlink Electronics®, CA USA) (FSRs) embedded in the fingertips of the index and thumb of the prosthetic hand detect pressure changes normal to the sensor that drive vibrating resonant motors providing haptic feedback to the user.

Control

Signals from the two EMG channels are amplified, high pass filtered at 20 Hz and notch filtered at 60 Hz. Signals are then rectified and integrated to drive a proportional open-close controller. Proportional control of the closing and opening velocity of the hand is done by mapping the maximal and minimal velocities to the maximal and minimal EMG activity recorded. To normalize the controller for each participant, they are asked to perform wrist flexion and extension maximal voluntary contractions (MVCs) for 5 seconds at the beginning of the session to determine the maximal amplitude for each of the electrodes. Similarly, the minimal activity for flexors and extensors is experimentally determined by recording the baseline EMG activity of each sensor during a period of 5 seconds while the arm is resting in the prosthesis simulator. The minimal activity is set to a value three standard deviations above the mean recorded activity to reduce unintentional activation of the channels.

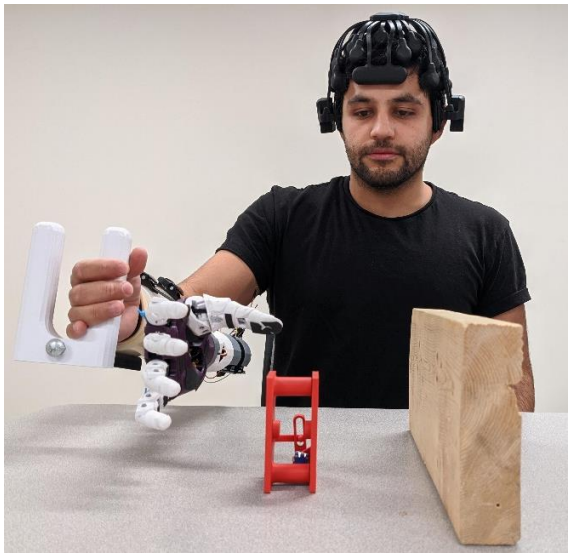

Figure 1. Experimental set-up displaying the custom prosthesis simulator and the dry-wireless EEG system. During experiments, the user's hand and arm are visually occluded.

Feedback

Changes in resistance captured by the FSRs at the fingertips control two haptic motor drivers (DRV265L, Adafruit Industries, New York, NY) that activate two corresponding linear resonant actuators (C10-100, Precision Microdrives, London, UK). These coin motors are in the inside lining of the forearm cuff and in direct contact with the skin of the forearm. The amplitude of the vibration of the haptic motors is mapped proportionally to the resistance change of the FSRs to represent the force detected at the fingertips. The magnitude of the minimally detectable vibration is determined individually for each participant and used as the lower edge of the mapping with the FSR signal.

EEG recordings

Cortical activity was recorded using EEG sampling at 1000 Hz. The electrodes are positioned on the head based on the standard 10/20 Channel system, with all referenced to the left and right earlobe. Data are transmitted wirelessly via Bluetooth from the cap directly to a PC and recorded using the software provided by the system manufacturer (Cognionics Data Acquisition, Version 3.6).

Blink and eye artifacts were removed using Principal Component Analysis and visual assessment [11]. EEG signals were then band-pass filtered from 0.1 to 100 Hz. Time-frequency decomposition of the signal was performed through short-time FFT on Hanning-tapered and zero-padded (up to 2000ms) overlapping segments (50% overlap) of 500 ms. These windows were recorded from 1000 ms before and after initial contact with the object to assess grasping force modulation (total time window of 2000 ms). Alpha power of EEG spectra has been previously used as a proxy to quantify functional inhibition of cortical areas [5], [7], [12], [13]. With this model, a greater level of alpha activity reflects a higher level of functional inhibition of a brain region [5]. After the FFT transformation, power (μV^2) in the alpha range (8-12 Hz) was averaged across overlapping FFT segments for each channel and trial. Channels on the scalp were divided in 7 functional regions of interest (RoI); left temporal (T7), left central (C3), frontal (Fz), right central (C4), right temporal (T8), parietal (Pz) and occipital (O1, O2). Power is then averaged across these channels to yield values for each region. Finally, the values are divided by the average baseline value obtained during the resting state to obtain an index of change in activity from the resting state [14].

Using this method, we were able to qualitatively identify high levels of alpha power reflective of functional inhibition of the occipital lobe during an eyes-closed recording. The occipital lobe is responsible for the processing of incoming visual information [15]. A sample recording from one participant is presented in Figure 2. This increase in alpha activity in posterior regions of the brain indicating low cortical activation has been well described since the late 1920's [15]. The wireless EEG setup presented here can identify alpha activity changes across the scalp.

DISCUSSION

A common goal in developing new myoelectric technology is to increase the clinical effectiveness of prostheses [3]. Despite advances in technology, most devices impose a high cognitive burden that can result in fatigue and frustration [2], and eventual prosthesis rejection [3], [16], [17]. Here, we present a platform to assess cognitive load during prosthesis use. The development of our prosthesis simulator facilitates experimentation with individuals not affected by limb-loss, allowing us to increase the statistical power of our studies. Furthermore, this system was manufactured using light-weight 3D printed parts, allowing for less constrained movements compared to previous simulators requiring suspension systems to offset the weight [10].

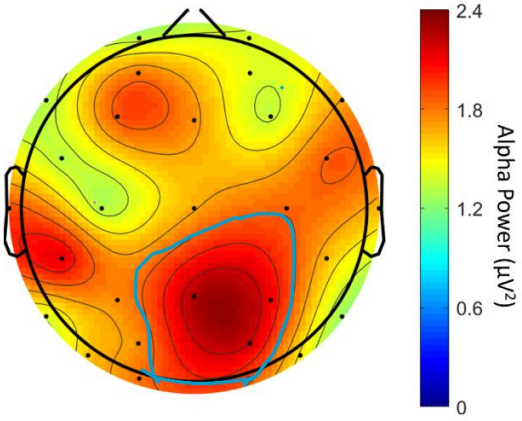

Figure 2. Sample alpha activity obtained during an eyes closed recording. Increased inhibitory alpha activity is present over the occipital lobe (outlined in blue), the area responsible for processing visual information [14].

Previous work has sought to assess cognitive load during prosthesis use using EEG [18], [19], however, only one previous study has displayed an overall reduction of alpha activity across the scalp in during prosthesis use compared to use of anatomical hand [7], indicating higher levels of cognitive load compared to the use of the anatomical hand. Based on this work, we present a platform aimed to help researchers and prosthesis developers investigate the effects of their prosthetic implementations on cognitive load. The advantage of our platform lies in the wireless EEG system utilized, as it does not restrict the movement of the user and avoids having large cable artifacts [20]. Furthermore, unlike the previous study using EEG to assess alpha activity [7], our protocol also includes a baseline normalization step, in which the relative differences in alpha activity between resting state and prosthesis use allows for the analysis of alpha changes exclusively due to prosthesis use, and allows for normalization across multiple assessment days [21].

From a practical perspective, it is important to understand how users develop efficient control of a prosthesis. Adaptive learning processes rely on the engagement of appropriate mental resources during practice and performance [14], [22], [23], and high levels of cognitive load have been shown to hinder them [22], [24]. As supposed to performance-based tests where users can increase their success rate with a higher level of attention and conscious engagement, we hope to combine this platform along with them to create a prosthesis-use testing battery evaluate not only performance but also user experience and cognitive strain while they learn and use the devices. Furthermore, EEG based assessments can provide insights about the cortical mechanisms responsible for the high levels of cognitive load, and drive evidence-based interventions on how to address them. Currently, we are conducting work using this EEG based approach to investigate the effects of adding augmented feedback on the cognitive load required to operate a myoelectric prosthesis, as augmented feedback could potentially reduce the visual attention and cognitive burden required to operate a prosthesis [18].

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A PSYCHOPHYSICAL APPROACH TO MEASURE THE SENSE OF AGENCY

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ABSTRACT

Increasing a prosthesis user's sense of agency over their device may lead to improved patient outcomes. Measuring agency, however, can be difficult. Widely used questionnaires may be prone to cognitive biases and an established proxy for agency, the intentional binding paradigm, can be attentionally demanding. In this study, we present and test a novel psychophysical time discrimination task to detect the intentional binding effect, i.e. the perceived compression of the time interval between a controlled action and its effect. The task uses a two-alternative forced choice time comparison task to avoid the attentional demands associated with temporal estimation using an auxiliary clock display (such as a standard Libet clock protocol). We show that the psychophysics protocol can detect the intentional binding effect during voluntary movements in a small pilot study (n=4). Participants also completed a standard Libet clock protocol that showed inconsistent results. We conclude with a discussion of protocol improvements. The psychophysical time discrimination assessment shows promise for use as an objective sense of agency metric suitable for prosthesis users.

INTRODUCTION

Users of myoelectric prostheses sometimes reject their devices, a choice that can attributed to a reduced sense of embodiment [1]–[3]. Embodiment involves several interrelated components such as the sense of localization, ownership, and agency [2]–[5]. In prosthesis users, the sense of ownership is elicited by coherent sensory feedback, whereas the sense of agency arises when there is consistent control of the device [1], [6]. Typical hand movements have intact sensation and control, generating a sense of ownership and agency, leading to a strong sense of embodiment [6]. However, in a prosthesis user, one or both of these contributing factors to embodiment may be deficient dependent on accessible sensory information or the fidelity of the control system.

Sense of agency (SoA), the focus of this work, is defined as the feeling of control over one's actions, which involves distinguishing self-generated actions from actions generated by others [3], [7]–[11]. When an action and its effect are temporally and spatially congruent, a stronger SoA is generated; however, when incongruent, the resulting error in sensory prediction reduces the likelihood that the SoA will arise [9], [10]. The SoA can still be modulated by other agency cues beyond sensorimotor integration such as sensation within the residual limb or the functionality and fit of the device [1], [2], [9], [12].

Existing approaches to measure the SoA are susceptible to various limitations and potential biases. Explicit measures of agency rely on conscious awareness as individuals directly report their agentic experience during movement trials on questionnaires [8], [10], [11], [13]. Subjective questionnaires are prone to both experimenter and cognitive biases through the influence of social desirability and impression management, and its heavy reliance on conceptual and evaluative self-awareness [7], [8], [14]. Frequently these questionnaires are paired with implicit measures in an attempt to avoid these associated demand effects, but implicit methods have not been well adapted to motor contexts.

The most widely used implicit measure of the sense of agency is the intentional binding paradigm [3], [8], [11], [13]–[17]. An intentional binding effect occurs between a voluntary action and its sensory consequence where an individual will perceive the time interval to be smaller than it actually was (Figure 1) [6], [8]. This warped time perception is attributed to delayed awareness of the active action and early awareness of the consequence, which temporally shifts these elements towards each other [11], [14]. Intentional binding is often measured using a clock reading paradigm, such as the Libet clock, in which participants report the end of an action-effect trial using the position of a rotating dot. A major limitation of the Libet clock approach, especially in motor contexts, is that the individual has to split their attention between the action and the position of the clock hand which can bias the estimation of event timing [10]. Attending to the dynamic clock display is visually and cognitively demanding, which could lead to reduced engagement in the motor task [14].

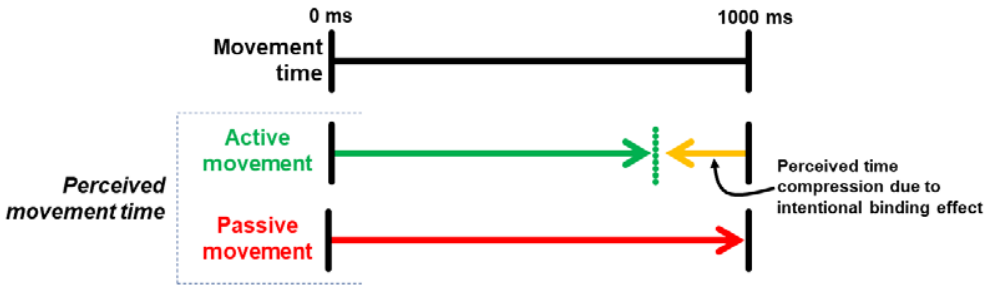

Figure 1: The intentional binding effect. Active movements are perceived to be temporally shorter than passive movements.

Here we propose and test a novel implicit measure of the SoA based on the intentional binding effect. We implement a two-alternative forced choice time discrimination task with an adaptive staircase to estimate the intentional binding-driven time compression observed during active movements. The temporal discrimination task between an active and a passive movement removes potential subjective bias seen with standard agency questionnaires and eliminates the need for Libet clock reporting, which may not be suited to prosthesis user experience assessment due to attentional demands. Here we tested this novel assessment and a traditional Libet clock protocol on four participants in a computer-based cursor movement task. This objective approach forms the basis for a potentially more reliable assessment of agency for prosthesis users as it provides a new measure that avoids limitations associated with previous methods.

METHODS

Four able-bodied Acadia University students were recruited for this study (two females, two males). Written informed consent according to Acadia University REB was obtained from participants before conducting the experiment. The experiment was run using a custom MATLAB program (ver. 2021, The MathWorks, Inc., Natick, Massachusetts, United States). All visual stimuli were presented on a 27-inch monitor with 1920 x 1080 resolution. Participants controlled on-screen movements with a wireless mouse (Logitech G703) set to 400 dots per inch sensitivity (the Windows mouse sensitivity setting was set as the third tick from the left on the linear adjustment slider). A barrier was placed over the participant's right forearm and hand to block visual movement cues of the arm throughout the experiment. Participants wore foam earplugs underneath over-ear noise-cancelling headphones playing Brownian noise to block any ambient audio cues.

Experimental Protocol

While seated, participants moved a small blue square cursor along a line from left to right to hit a red square target 22.4 cm away. The movement was initiated with a mouse click and concluded with a second mouse click. The experimental protocol consisted of the following 5 blocks:

Block 1 & 2: Familiarization trials of active and passive movements with no Libet clock present. Participants began with a training block of 25 cursor movement trials. In Block 2, participants watched 25 cursor movement trials (passive trials) recorded during Block 1 played back in a random order by the computer. Each participant's moving hand and arm were obscured from view while they focused on the screen.

Block 3: Psychophysics method testing. Participants completed an active cursor movement trial followed by a passive movement. The passive movement played back by the computer matched the trajectory of the preceding movement except its speed was modified. Participants were then asked to select the movement that was slower (i.e., longer duration) (Figure 2 - 1). The temporal stretch (or compression) of the passive movement was updated over subsequent trial pairs using an adaptive staircase [18]. Staircase parameters were set to determine the 50% discrimination threshold of the just noticeable difference (JND) of the magnitude of temporal adjustment between active and passive movements (Figure 2 – 2). The block continued until either the adaptive staircase hit 23 reversals, or the participant completed 200 total trials, whichever occurred first. The final temporal adjustment reached indicated the participant's perceived action-effect intervals for voluntary control with respect to their perceived action-effect intervals for involuntary control.

Block 4 & 5: Libet clock testing. Participants were asked to make the same action as before, but now a Libet clock (as in [16]) was positioned around the target. During the movement, a black dot rotated around the clock face. After a variable period of additional dot rotation following movement completion, participants were asked to estimate the position of the dot when the action ended. The difference between the actual movement end time and the clock-reported end time was recorded for each of 40 trials. In Block 5, participants were asked to watch 40 passive movements (recordings from Block 4 played back in a random order) and use the Libet clock to make the same estimation of movement end time.

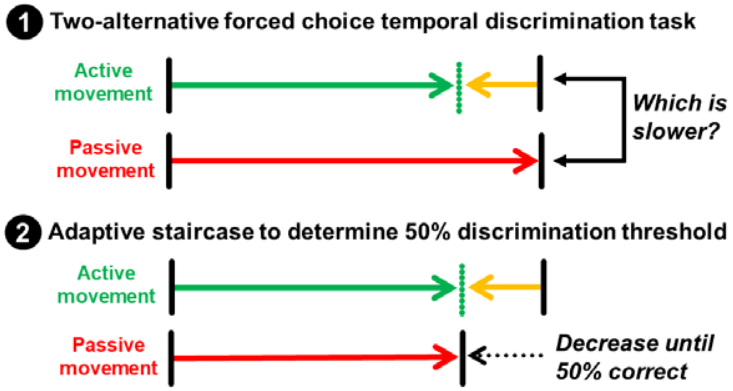

Figure 2. Psychophysical assessment to measure the intentional binding effect.

RESULTS

For three of the four participants, the psychophysics protocol detected an intentional binding effect during active movements. Pereived time compression of the active movement compared to the passive movement was more than 156 ms in these participants (Table 1). The adaptive staircase seemed to converge to the 50% discrimination threshold as evidenced by slopes of the best fit line over the final 8 reversals approaching zero (Figure 3). However, Participant 4's perceived time compression was vastly different (+374 ms). This participant made a mistake on the first JND trial pair selection and made comments about the initial difficulty of the task. The slope of the best fit line over the last 8 reversals was largest in this participant (Table 1), suggesting that the staircase may have still been converging at the end of their psychophysics block.

The traditional Libet clock assessment showed inconsistent detection of an intentional binding effect as active trials were perceived as similar to or longer in duration than passive trials (Table 1). A coding error resulted in an inaccurate data record for Participant 1.

Table 1: Summary of experimental results for Psychophysics and Libet clock assessments

	Psychophysics protocol		**Libet clock**
Participant #	*JND (ms)*	*Slope of last 8 reversals*	*Estimate-Actual (ms)*
1	-363	5.29	N/A
2	-164	-18.5	+2.9
3	-156	14.6	+105.85
4	+374	-29.4	+347.25

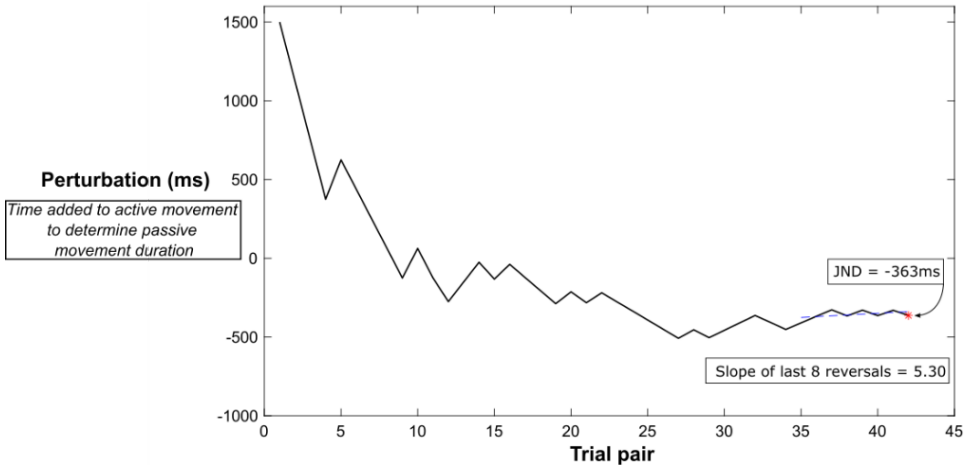

Figure 3. Representative adaptive staircase to determine temporal discrimination threshold for Participant 1.

DISCUSSION

Here we have demonstrated the feasibility and potential for a psychophysical approach to measure the sense of agency in people making movements. A robust intentional binding effect was observed in three of four participants. In the fourth participant, the initial task settings seemed to be too difficult for proper psychometric characterization. In an upcoming validation study of the protocol, we will add a JND familiarization block of 3 trial pairs and we will adjust the parameters of the adaptive staircase to ensure initial task success and increase the average staircase length to improve convergence.

The traditional Libet clock protocol produced unexpected results: active movements were perceived as longer than passive ones. Attentional demands of the task may explain this observation. In active movement trials, participants may focus their attention on the moving cursor resulting in delayed observation of the rotating clock. In passive movement trials, participants could focus more intently on the clock, reducing any response delays. Traditional Libet studies often involve key presses in response to auditory stimuli in which these attentional issues may be a nonfactor [16]. In future work we could test this attentional demand hypothesis by tracking gaze fixations during Libet motor trials. An interval estimation method where participants are required to verbally estimate the temporal interval between an action and its outcome may be more suitable to motor tasks [10], however, our earlier work suggests that similar approaches produce highly variable results [3].

Our novel psychophysical approach shows promise in objectively measuring intentional binding in a motor context. The assessment can be adapted for prosthesis users to provide detailed insight into the sense of agency in patient populations.

ACKNOWLEDGEMENTS

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Characterizing Self-Reported Prosthesis Use in Everyday Tasks

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ABSTRACT

A sample of 411 individuals with either unilateral or bilateral upper limb amputation (ULA) reported prostheses engagement when they performed a spectrum of common one- and two-handed tasks. We compared frequency of performing one- and two-handed activities by laterality (unilateral versus bilateral), by amputation level (for unilateral amputees), and by type of prosthesis used (for unilateral transradial amputees). A greater proportion of persons with bilateral amputations reported engaging their prosthesis in both one- and two-handed tasks. Those with more proximal amputation engaged their prostheses in fewer activities, and persons using myoelectric single degree of freedom devices engaged their prostheses in a greater proportion of activities as compared to those using other device types.

INTRODUCTION

Few studies have characterized upper limb prosthesis engagement in everyday tasks. Prior research suggests that persons with unilateral upper limb amputation rely on their non-amputated side and perform the majority of daily activities with their non-involved side. [1] Unilateral combat amputees reported using their prostheses during 21-25% of 23 activities, with those with more distal limb loss tending to perform more activities with their prostheses as compared to those with proximal (transhumeral (TH), shoulder level (SH)) limb loss. However, this study did not include persons with bilateral amputations. A separate study of unilateral and bilateral upper limb amputees reported that they engaged their prosthesis during 34-36% of activities included in the OPUS Upper Extremity Function Scale (UEFS). [2]

While we expect that persons with bilateral limb loss would engage their prosthesis in a greater proportion of activities, prior work did not stratify the sample by laterality, [1] or reported no differences [3]. It is likely that the type of prosthesis would impact the number and type of activities performed with a prosthesis. Myoelectric prostheses, for example, should not be exposed to water or harsh environments. Additional research is needed to describe prosthesis engagement during everyday activities. Such data would be useful for informing prosthetic training activities. Therefore, the purpose of this study was to characterize prosthesis engagement during everyday tasks, comparing performance for persons with unilateral and bilateral amputation. Further, we compared engagement of the prosthesis by unilateral amputation level, and by prosthesis type for persons with unilateral transradial (TR) amputation.

METHODS

The data for this report is a subset of cases collected in a large telephone survey. The sample consisted of U.S. military Veterans and civilians recruited through a variety of sources including VA databases, the Amputee Coalition of America, and a private prosthetics service company. Participants with major amputation (at wrist or more proximal) of at least one upper limb were included. Participants from the larger survey were included in this report if they were prosthesis users and reported information on prosthesis type and activity performance with the prosthesis.

Respondents shared demographic characteristics, amputation history, and current prosthetic device use and engagement in everyday tasks. Respondents reported whether they performed or attempted to perform each of 34 items with the assistance of their prosthesis in the past 2 weeks. The 34 items included 23 items from the UEFS, 5 additional items recommended by Jarl [4], and additional items identified by our research team as being challenging or relevant to women with upper limb amputation. We categorized 11 of these

activities as likely to be performed using one hand and 23 as two-handed activities.

We stratified the sample by laterality and calculated the proportion of each subgroup who completed each of the 34 tasks with their prosthesis. We compared the proportions using chi-square analyses. We compared proportions by amputation level for those with unilateral amputation using Kruskal-Wallis tests. We corrected for multiple comparisons using the Benjamini Hochberg procedure. [5]

We calculated the proportion of one and two-handed tasks completed by unilateral and bilateral amputees, and for unilateral amputees by amputation level, and compared the proportion of tasks completed using t-tests and ANOVA.

We classified the type of prosthesis used as body powered, myoelectric single degree of freedom (DOF) terminal device, and myoelectric multi-DOF terminal device, and compared the proportion of respondents who completed each activity with their prosthesis using Kruskal-Wallis tests. We also compared the proportions of tasks completed by prosthesis type using ANOVAs. These comparisons were limited to the sample with transradial/wrist disarticulation in order to provide robust estimates.

RESULTS

The sample for this report included 379 unilateral and 32 bilateral amputees. Characteristics of the sample are shown in Table 1. Participants were predominantly male (81%), white (83%), and not Hispanic (94%). TR amputation was most common (66%), followed by TH (20%) and SH (6%) levels.

Table 1: Characteristics of the Analytic Sample (N=411)

Gender	**N (%)**		**Mn (sd)**
Female	79 (19.2)	**Age**	61.8 (14.3)
Male	332 (80.8)	**Race**	**N (%)**
Laterality	**N (%)**	White	340 (82.7)
Unilateral	379 (92.2)	Black	32 (7.8)
Bilateral	32 (7.8)	Unknown	25 (6.1)
Amputation level (unilateral only)	**N (%)**	Mixed	14 (3.4)
Shoulder	25 (6.1)	**Ethnicity**	**N (%)**
Transhumeral	62 (20.0)	Hispanic	26 (6.5)
Transradial	272 (66.2)	Not Hispanic	373 (93.5)

Persons with unilateral amputation engaged their prosthesis in an average of 24% of unilateral tasks and 38% of bilateral tasks. While those with bilateral amputation engaged their prosthesis in 64% of unilateral and 46% of bilateral tasks (Figure 1).

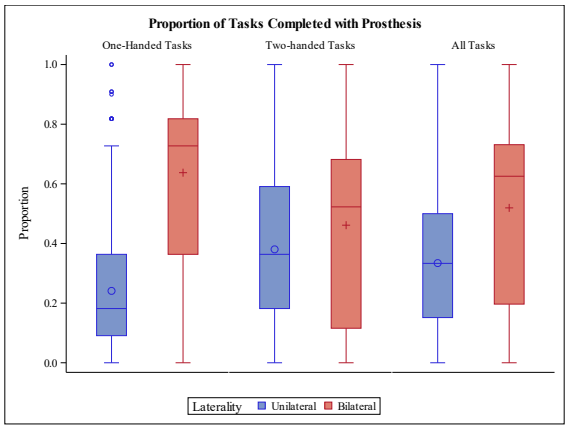
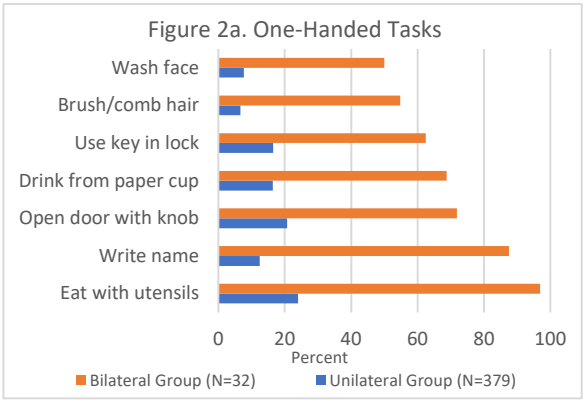


Figure 1. Box plots showing mean, median and distribution of proportion of tasks completed with prosthesis by laterality



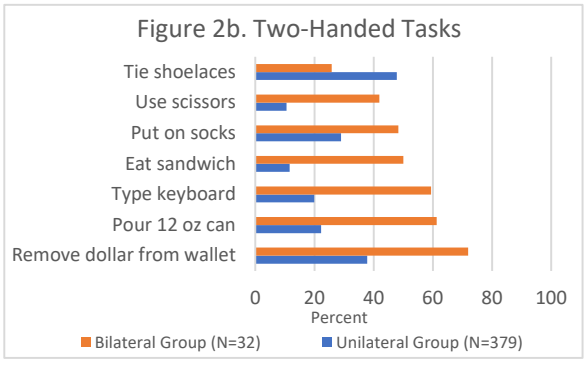
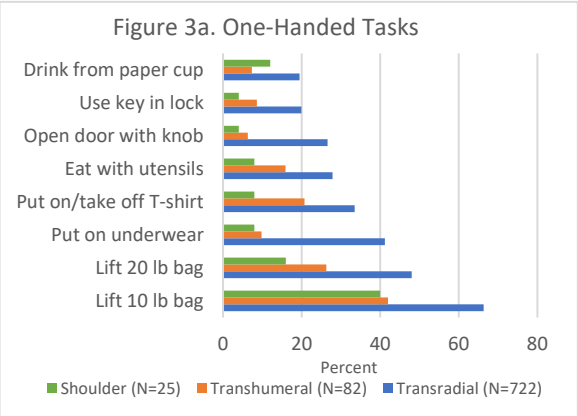


Figure 2a and 2b. Statistically significant differences in task performance by laterality

After adjusting for multiple comparisons, there were statistically significant differences in performance of 7 one-handed and 7 two-handed tasks by laterality (Figure 2). A higher percent of those with bilateral

amputation (compared to unilateral) completed these tasks, except tying shoelaces which had a higher completion rate for those with unilateral amputation. For persons with unilateral amputation, those with TR amputations engaged their prosthesis in an average of 28% of unilateral tasks and 43% of bilateral tasks as compared to those with TH (14% and 26%) and SH level amputation (10% and 22%), respectively.



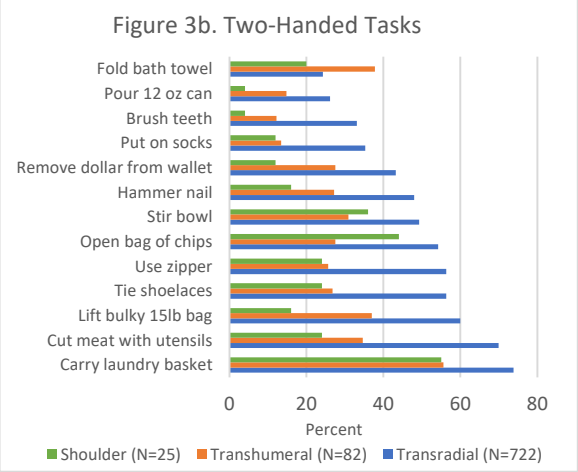
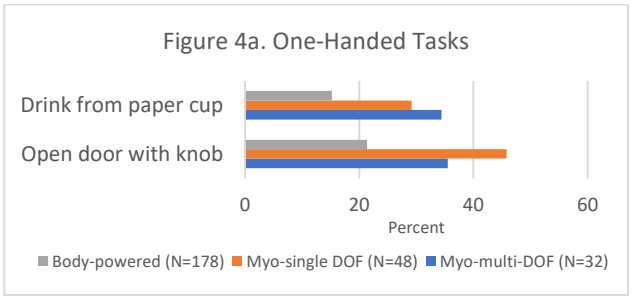


Figure 3a and 3b. Statistically significant differences in task performance by amputation level

Task completion rates varied significantly by amputation level for 8 one-handed tasks and 13 two-handed tasks (Figure 3). For these tasks, a higher percentage of the TR amputation group completed tasks with their prosthesis compared to those with more proximal levels.

A comparison of task performance by prosthesis type (for TR, unilateral amputees only) found that on average, body-powered prosthesis users engaged their prosthesis in 27% of unilateral tasks and 43% of bilateral tasks, compared to myoelectric single DOF users (35% and 50%), and myoelectric multi-DOF users (24% and 36%), respectively.

Two one-handed tasks and 6 two-handed tasks differed significantly by prosthesis type (Figure 4).



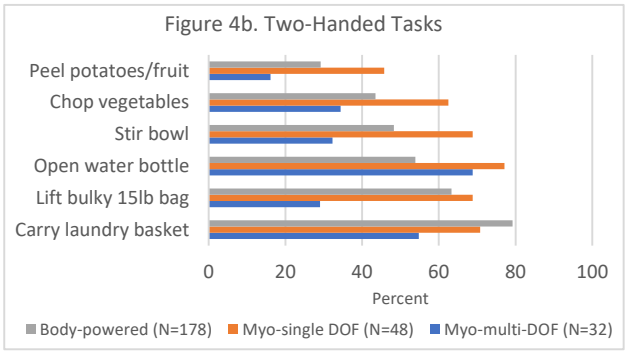


Figure 4a and 4b. Statistically significant differences in task performance by prosthesis type

DISCUSSION

This study compared frequency of self-reported engagement of the prosthesis when performing one- and two-handed activities of bilateral and unilateral amputees by amputation level and by type of prosthesis.

Persons with bilateral amputation engaged their prosthesis in more activities as compared to those with unilateral amputation. Specifically, persons with unilateral amputation engaged their prostheses in 24% of unilateral and 38% of bilateral tasks, while those with bilateral amputation engaged their prosthesis in 64% of unilateral and 46% of bilateral tasks. Our findings differ from that of Ostlie et al. who found that prosthesis users reported engaging their prostheses in approximately half of daily activities with a non-significant tendency for bilateral amputees to use their prosthesis in more tasks. [3]

Our study provides new information about the types of activities performed by prosthesis users, augmenting recent data obtained through accelerometer-based activity monitoring that found individuals with unilateral TR amputation engaged in bimanual activity

an average of 4 hours a day, but engaged in unilateral activities with their prosthesis for only 20 minutes [6].

Tying shoelaces emerged as a commonplace two-handed activity among those with unilateral amputation, along with removing paper currency from a wallet and donning socks. Among one-handed activities, eating with utensils, opening a doorknob, manipulating a key in a lock, and drinking from a paper cup were reported with the greatest frequency.

By comparison, bilateral amputees used their prostheses in 64% of unilateral and 46% of bilateral tasks. The most common one-handed tasks were eating with utensils and writing. Engagement of prostheses in two-handed tasks was less common than reported with one-handed tasks. Removing paper currency from a wallet, pouring a 12 oz. can and typing on a keyboard were the most commonly performed tasks.

While users of TR prostheses reported engaging their prostheses in one- and two-handed tasks more often than those with more proximal amputations, individual from this latter group reported engaging their prostheses across a spectrum of tasks (lifting and carrying tasks were performed the most). With respect to prosthesis type, engagement in both one- and two-handed tasks was highest for those using single degree of freedom myoelectric prostheses. This finding may reflect the enhanced grip strength associated with this prosthetic design.

Some persons with ULA may perform everyday tasks with only one extremity, or perform them by engaging their knees, teeth or other body parts or using assistive devices. We did not ask how respondents performed tasks, only whether they engaged the prosthesis during tasks. We did not ask about non-prehensile tasks and cannot make conclusions about differential engagement of the prostheses in these types of tasks. Spiers et al. observed a preponderance of non-prehensile prosthetic activities in daily activities [7]. Further research is needed to determine how prostheses are used, and whether there is active prehensile manipulation or non-prehensile use.

SUMMARY & CONCLUSIONS

Our findings demonstrate that individuals with bilateral ULA engage their prostheses in more tasks, especially more one-handed tasks as compared to those with unilateral ULA. Task performance with a prosthesis was reported less often for those with more proximal amputation levels than those with more distal amputation levels. Lifting and carrying tasks were the most common one-handed tasks performed by people with more proximal amputation levels. While similar patterns were observed across prosthesis type, engagement of single degree of freedom myoelectric devices was reported with greater frequency than engagement with body-powered or multi-articulating myoelectric hands.

ACKNOWLEDGEMENTS

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DATA LOGGING DURING PATTERN RECOGNITION CALIBRATION AS A REMOTE DIAGNOSTIC TOOL

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ABSTRACT

Pattern recognition control uses EMG from the entire residual limb to more intuitively control prosthetic devices. However, this requires a more intimate socket fit to maintain contact with these additional sensors. When users complain of issues with control, it can be difficult to diagnose if the issue is a need for additional practice and training or if there are issues related to the prosthetic fit that need to be addressed. Since pattern recognition allows the recalibration of the system by the user in any location, there is the opportunity to use this feature to assist in troubleshooting issues remotely. By analysing the data logging of calibration data in a pattern recognition system, it is possible to better identify the cause and potential solution in a remote setting.

INTRODUCTION

With pattern recognition (PR), multiple EMG channels can be used as input with all of the information used to calculate which "pattern" is being recreated. Since muscle signals do not need to be targeted and isolated, more information can be extracted from the user, potentially increasing the ability to control a multi-degree-of-freedom system [1]. The user needs to show the system each movement (calibrate the controller), which can be done by following prompts on a computer interface or following along with the prosthesis while it is moved through the different available movements. EMG is recorded by the controller and the classifier is then calculated.

For PR to be successful, the EMG channels must maintain good contact with the residual limb. When fitting a user in the office or a therapy environment, the EMG quality can be monitored as the user begins to perform functional tasks in different planes of movement and adjustment to fit made as needed. However, different environments temperatures and weight gain/loss can all affect signal quality.

When the user lives nearby it can be easy to have them come in for regular rechecks and adjustments; however, when a user lives far away, it can be difficult to troubleshoot the issue and identify if the issue with control is related to EMG quality or if the issue might be related to the need for additional training and/or a review of the patterns of movement associated with each degree-of-freedom.

As part of a study related to pattern recognition control of a transradial prosthetic system, users from across the country were recruited for home trials. During the home trial subjects were instructed to send home logs each week. However, there were instances of poor control noted and it was not logistically possible to bring in subjects for return rechecks. Since, during pattern recognition calibration EMG data are recorded and used to create the classifier, this property of the controller was used to collect data that could be used in a diagnostic manner for evaluation of fit and function. A protocol was developed to record information in various positions to allow repairs and adjustment to take place without an in person visit. This technique was also used to verify fit prior to beginning home trials.

METHODS

Eight individuals with a unilateral transradial amputation were fit with a Coapt pattern recognition system [2] passive wrist, and i-limb TMR revolution [3]. The study (including the ability to collect and record EMG data) was approved by the Northwestern University IRB. During the calibration process of pattern recognition control, data were recorded to be used to generate a classifier as the prosthesis moved through the various movements. The system would first collect EMG of the users' arm at rest (to align with "no movement" of the prosthesis). The prosthesis would then cycle through all of the enabled grasp patterns, opening and closing of each grasp 2 times. For this study, all calibration data was recorded and stored on the embedded controller for later post-processing.

Users were provided OT prior to participating in an 8-week home trial to evaluate their pattern recognition control of the multiarticulating hand. They were trained to calibrate their prosthesis whenever they felt their control had

degraded. They checked in weekly using a home log system. Logged issues or calls to the prosthetist/OT over this 8-week window often needed to be followed up and these issues were often difficult to diagnose. In a clinical setting, users would be brought in for a recheck to evaluate fit and function. Since this was not always possible due to distance, alternative options were explored.

Since EMG was recorded for later evaluation during the calibration, a fitting evaluation protocol was designed to use this recording for diagnostics. All subjects had a minimum of 3 grasp patterns enabled. During regular calibration, muscle contractions are recorded for 2 repetitions of hand open and hand close for each grasp (i.e., 4 cycles per grasp). For our users and at least 3 grasp patterns enabled, this allowed for the collection of 13 (no movement plus 4 cycles * 3 grasp patterns) 3-second data blocks. Users were prompted to perform specific movements in various positions during the data recording phases of calibration. The order of movements requested was recorded so that the data collected could be mapped to arm position/contraction type. Table 1 shows the protocol developed and used in most cases. For these diagnostic trials, when collecting movement and maximum voluntary contraction (MVC) data, subjects were instructed to move the arm around in space when the device was moving. When conducted remotely, this prompting occurred via phone call/skype to assist with timing. Six participants used the evaluation protocol developed to diagnose fit and training issues. Some subjects also performed the protocol in lab as a "check out" of fit prior to starting the home trials.

Table 1: List of prompted movements for each calibration for evaluation of EMG quality

***Arm supported**:* Regular calibration with the arm supported (resting on a table)
***Arm down at side**: R*egular calibration with the arm relaxed down at the side (hanging)
***Arm in front of body**:* Regular calibration with the arm in front (as if shaking hands)
***Arm sweeps and MVC** (Maximum Voluntary Contractions)* During the data collection blocks for this calibration, the subject was prompted as follows: 1. Arm down at side and contract all forearm muscles at MVC 2. Arm in front and contract all forearm muscles at MVC 3. Arm out to side and contract all forearm muscles at MVC 4. Forearm relaxed and sweep arm from down at side to up to cabinet level and back down, diagonally 5. Forearm relaxed and sweep arm side to side at cabinet level 6. Forearm relaxed and push in on socket and wiggle 7. Forearm relaxed and pull slightly on socket
Subject prompted to doff and re-don system and repeat the following:
Arm in front of body
Arm down at side

Data were downloaded from the embedded controller for further processing. In most cases this occurred when the arm was sent back by mail (cheaper than flying the user back for an in-person visit) or by downloading to a study computer sent to them. A custom Matlab script was written to import the files and create graphs of the 8 channels of EMG. Data were plotted with each movement plotted in sequential order (i.e., no movement followed by open/close/open/close of each configured grip) with the channels shown 1-8 from top to bottom. The date/timestamp of the data was included in the title for reference and custom titles could be applied. Some of the issues (mechanical and therapy related) that were possible to diagnose:

- No issues with EMG (i.e., clean) during normal use but intermittent EMG saturation either in different positions or during MVCs: Electrode lift off from contraction or position. Or an intermittent loose wire
- Constant EMG saturation or noise: Broken/loose wire or consistent lack of skin/electrode contact
- EMG saturation during muscle contractions: User contracting too hard
- No EMG noted at all (flatline): broken wire or electrode shorted
- High baseline noise on one or multiple channels: 60 Hz interference or potential skin/electrode contact issue with ground electrode
- Clean EMG collected but hand did not move properly during calibration: hand requires repairs
- EMG improperly timed contractions of regular training (contraction only in small part of each window): subject needs more training
- EMG barely detectible for all movements: EMG location not ideal or contractions too light

- Clean EMG but user has poor control after recalibration: user needs more training/alternative imaging for different grasp patterns
- EMG after redonning very different than first 2 trials: user needs more practice with repeating proper donning or recreating grasp patterns

RESULTS

The protocol was used throughout the study to confirm socket fit and EMG quality when subjects were in the lab for testing/fitting and also when subjects experienced control issues at home. Figure 1 shows an example of early fitting with the pattern recognition system. EMG muscle contractions are noticeable on every EMG channel but there is higher baseline noise on multiple channels. This signal noise can occur when electrodes pick up on 60 Hz interference or because of poor skin/electrode impedance matching, or intermittent electrode contact of one or more electrodes (either domes not fully contacting the skin or loose wired connection).

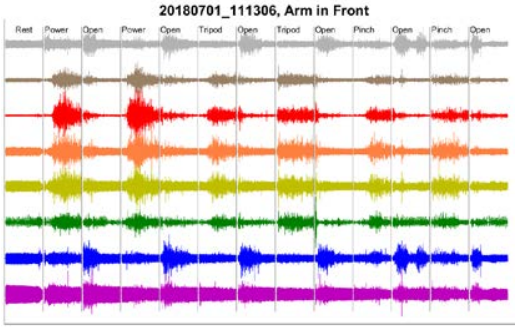

Figure 1: High baseline noise on multiple channels likely due to poor skin/electrode impedance matching or ground electrode not fully contacting the skin.

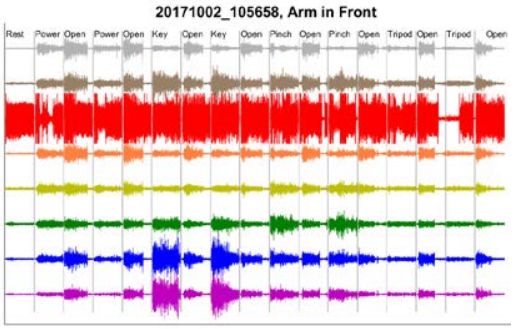

Figure 2: EMG analysis after arm sent in for adjustment. Noise seen on Channel 3 and loose wire located inside socket

Figure 2 shows a second example of the evaluation protocol used for remote troubleshooting. The subject had complained of poor control and was prompted through the diagnostic protocol prior to sending his arm in for review. Upon inspection of the data, channel 3 showed consistent noise across all movements and positions. This EMG contact was assessed and it was found that the wire connection inside the socket at the ring terminal to the EMG dome had broken during use. Though this failure would likely have been found with a thorough inspection of the device, the evaluation protocol made diagnosis and repair much quicker.

A more complex example can be found in Figure 3. This subject had previously undergone a revision surgery and was experiencing continued volume loss during the home trial. It was identified during planned follow up that he was having issues with control in some positions. The EMG from the evaluation protocol was compared to the locations of the electrode channels within the socket. The 4 images show the data collection for a) arm resting, b) arm at side, c) arm in front, and d) channel locations in the socket. When the arm was resting, it appeared that the soft-tissue was pulling away from the anterior channel (channel 4) and then pulling away from the posterior channels when the arm was extended (channels 3, 7, 8). Spacers were added to increase the depth of compression of the electrode domes on these 4 channels and the prosthesis was returned to the user. He reported improved control after return of the device and the EMG quality was verified at his next scheduled in person visit.

Other cases were noted where, upon completion of the evaluation protocol, the EMG quality was good. In these cases, the subjects would continue to work with the Occupational Therapist either in person or remotely to identify phantom movements that would create EMG unique to each grasp pattern.

DISCUSSION

Pattern recognition control has become more common in upper limb prosthetic fittings; however, the increase number of EMG channels associated with these systems can make troubleshooting fit and function difficult. It is

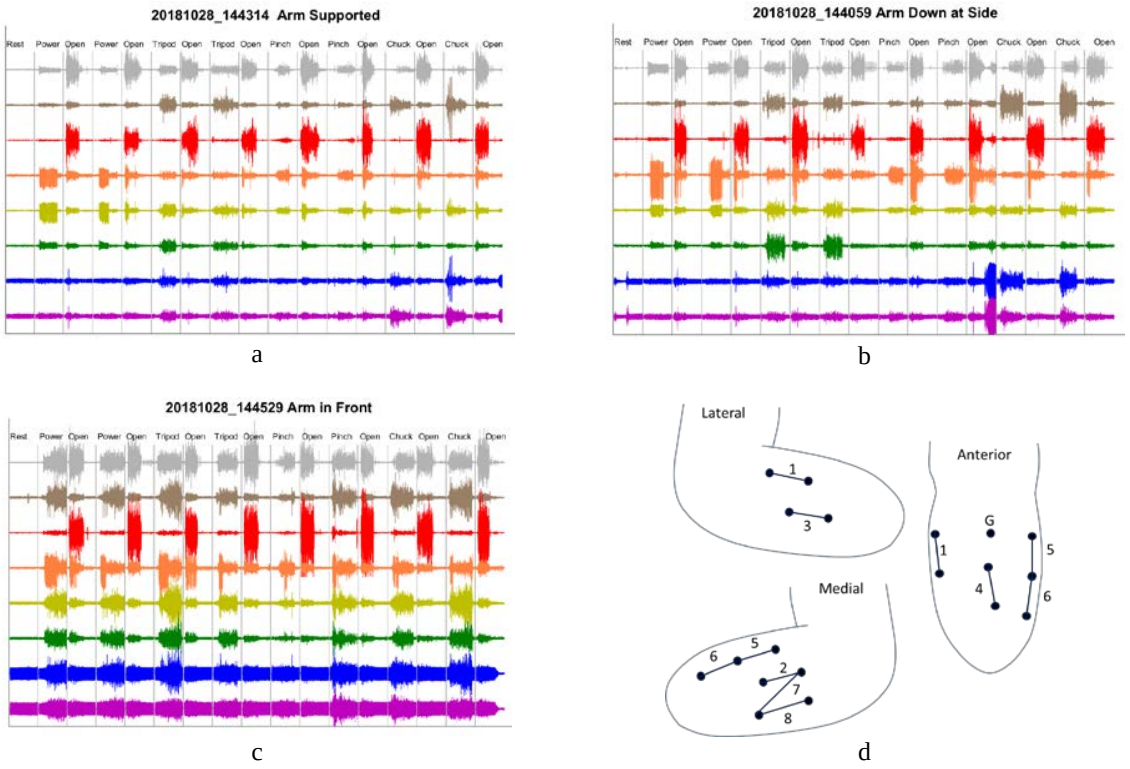

Figure 3: Remote troubleshooting with one subject. The 4 images show the data collection for a) arm resting, b) arm at side, c) arm in front, and d) channel locations in the socket. The 8 EMG channels are shown 1-8 from top to bottom in a-c. The thin vertical lines delineate where the EMG from the various movements (4 different hand grasp patterns) have been concatenated. Each vertical grey band represents 3seconds of data.

possible to visually review the EMG when the user is present but if issues arise a way of assessing the issue remotely is useful.

When EMG calibration data is recorded onto the prosthesis, this feature can be used to collect data to assess EMG and fit. This protocol was used on six individuals participating in home trials and was useful to diagnose loss of contact and broken wires, which were repairable without an in-person visit. In this study we needed to ship the prosthesis back to physically collect the data from the arm (or ship a laptop to the user), but if the data were downloaded remotely to a secure server it would be possible to identify problems with training or other issues that don't require repair to be completely resolved remotely. Additionally, the ability to remotely download the data would have allowed subjects to repeat the series of diagnostic training sessions to confirm that the repairs/socket modifications resolved the issue.

This evaluation protocol was also useful for confirming fit prior to the home trial by prompting the user to control the device in various planes of movement and as a baseline before home trial in case issues would arise later. This paper presents work done for a research study, but a similar evaluation protocol would be useful in the clinical environment to assist the prosthetist and occupational therapist to determine when it is necessary for a user to schedule follow up care.

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Key characteristics of upper limb prosthesis users influence Patient Experience Measure scores

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ABSTRACT

The Patient Experience Measure (PEM) was designed to assess psychosocial experiences of upper limb prosthesis users. While the PEM has been validated in a national study, differences in PEM scores based on participant characteristics have not been investigated yet. We present a secondary analysis of survey data demonstrating significant differences in PEM scores by amputation laterality (unilateral vs. bilateral), amputation level, and prosthesis type.

INTRODUCTION

The Patient Experience Measure (PEM) is a validated tool for assessing psychosocial experiences of upper limb prosthesis users consisting of six scales: social interaction, self-efficacy, embodiment, intuitiveness, wellbeing, and self-consciousness. The PEM was initially developed for use for studies of sensory enabled prostheses [1] and was subsequently refined in a large calibration study using contemporary measurement methods [2]. The prior calibration study examined structural validity, the ordering of items within scales, and the presence of differential item functioning by participant characteristics. However, we have not yet reported the summary scores of the PEM scales or analyses of the scores within subgroups of participants. The purpose of this analysis is to quantify and compare the PEM scores of key subgroups of interest. Specifically, we examined whether differences across the PEM subscales existed by prosthesis laterality, amputation level, and prosthesis type.

METHODS

This study presents a secondary analysis of data collected for the PEM calibration study. The sample consisted of U.S. military Veterans and civilians recruited through a variety of sources including VA databases, the Amputee Coalition of America, and a private prosthetics service company. Data was collected through telephone survey.

The PEM subscales query a variety of psychosocial experiences of upper limb prosthesis users (see [2] for full list of items within each subscale). The *social interaction* scale consists of 11 items addressing use of the prosthesis in physical interactions with others, such as shaking hands. The *self-efficacy* scale consists of 12 items addressing confidence in using the prosthesis to perform specific types of activities, such as handling fragile or small objects. The *embodiment* scale consists of 5 items related to self-attribution of the prosthesis and how it interacts with the body image. The 4-item *intuitiveness* scale includes items addressing the naturalness, clumsiness, speed, and concentration involved in using a prosthesis. The *wellbeing* scale consists of 6 items related to one's sense of wholeness, happiness, confidence, relaxation, freedom, and relief when not wearing a prosthesis. Finally, the 4-item *self-consciousness* addresses the user's sense of vulnerability, incompleteness, difference from others, and shyness when not wearing a prosthesis. Higher scores indicate better experience for all scales.

Scores of PEM scales were calculated for subgroups of participants across the following characteristics: amputation laterality (unilateral (UA) versus bilateral amputation (BA)), amputation level for UA only (transradial (TR), transhumeral (TH), shoulder (SH)) and prosthesis type (cosmetic (Cos), body powered (Bod), myoelectric single degree of freedom terminal device (MyoS), myoelectric multi-degree of freedom terminal device (MyoM)) Subgroup scores were compared using ANOVAs and t-tests. Prosthesis type comparisons were limited to the sample with unilateral TR/wrist disarticulation to provide robust estimates.

RESULTS

The sample for this analysis included 459 upper limb prosthesis users. The mean sample age was 61.9 (14.4) years old, 88 (20%) participants were women, and 378 (82%) were white. (Table 1). Of participants with unilateral TR amputation, there were 195 (65.4%), 53 (17.8%), 34 (11.4%) and 16 (5.4%) who used cosmetic, body powered, myoelectric single degree of freedom (DOF) and myoelectric multi-DOF prostheses respectively.

Table 1: Characteristics of Full Analytic Sample (N=459)

Gender	**N (%)**		**Mn (sd)**
Female	88 (19.2)	**Age**	61.9 (14.4)
Male	371 (80.8)	**Race**	**N (%)**
Laterality	**N (%)**	White	378 (82.4)
Unilateral	426 (92.8)	Black	40 (8.7)
Bilateral	33 (7.2)	Unknown	24 (5.2)
Amputation level (UA only)	**N (%)**	Mixed	17 (3.7)
Shoulder	26 (6.1)	**Ethnicity**	**N (%)**
Transhumeral	102 (23.9)	Hispanic	28 (6.1)
Transradial	298 (70.0)	Not Hispanic	421 (91.7)
		Unknown	10 (2.2)

Statistically significant differences were observed in PEM scores of persons with UA and BA (Figure 1). Mean and standard deviations of all measures are shown by subgroup in Table 2. Specifically, social interaction scores were higher among those with BA (p=0.0092), while wellbeing (p=0.04) and self-consciousness (p=0.01) scores were higher (i.e. better) among those with UA.

Distributions of PEM scores by amputation level are shown in Figure 2. There were significant differences in 4 PEM scales by amputation level: Social Interaction (p=0.002), Self-efficacy (p<0.0001), Embodiment (p<0.0001), and Intuitiveness (p=0.01). In all 4 scales, those with TR amputation had the highest scores while those with amputation at the SH level had the lowest scores. Participants with TH amputation tended to have intermediate scores.

Finally, distributions of PEM scores for those with TR unilateral amputation are shown by prosthesis type in Figure 3. Only social interaction (p=0.02) and self-efficacy (p<0.0001) scores differed significantly by prosthesis type. Those using cosmetic devices had the lowest scores on these two scales, myoelectric multi-DOF users had the highest social interaction scores, and body-powered users had the highest self-efficacy scores.

DISCUSSION

This study found statistically significant differences in PEM scores by amputation laterality, amputation level, and prosthesis type. Our analyses were bivariate only, and further multivariate analyses are needed to identify independent predictors of PEM scores to control for potential confounding.

Table 2 PEM scores by subgroups

		Social Interaction (N=390)	**Self-efficacy (N=405)**	**Embodiment (N=406)**	**Intuitiveness (N=406)**	**Wellbeing (N=454)**	**Self-consciousness (N=454)**
	N	**Mn (sd)**	**Mn (sd)**	**Mn (sd)**	**Mn (sd)**	**Mn (sd)**	**Mn (sd)**
Amputation Laterality							
Unilateral	426	49.6 (9.9)	50.0 (9.,9)	50.0 (9.9)	50.1 (10.2)	49.4 (9.7)	50.2 (10.0)
Bilateral	33	56.5 (8.3)	53.1 (9.9)	52.7 (10.2)	49.6 (7.7)	45.7(12.0)	45.6 (8.5)
Amputation level							
Shoulder	26	44.4 (11.5)	44.7 (12.8)	45.6 (11.6)	45.9 (9.6)	49.6 (11.8)	51.6 (10.2)
Transhumeral	102	47.6 (10.7)	46.9 (9.8)	46.7 (9.6)	48.4 (8.7)	49.9 (8.4)	50.0 (9.6)
Transradial	298	50.7 (9.3)	51.4 (9.3)	51.4 (9.5)	51.0 (10.6)	49.2 (9.9)	50.2 (10.1)
Prosthesis type							
Body-powered	195	50.3 (9.6)	52.4 (9.2)	51.0 (10.0)	51.3 (10.3)	49.1 (10.2)	50.5 (10.0)
Myoelectric single DOF	53	52.1 (8.7)	51.6 (9.6)	52.5 (8.5)	50.6 (11.1)	49.2 (9.5)	49.3 (10.7)
Myoelectric multi-DOF	34	53.6 (8.8)	51.0 (6.2)	50.8 (8.0)	48.1 (9.8)	49.2 (9.6)	52.0 (9.8)

Figure 1. Violin plots showing PEM scores by laterality

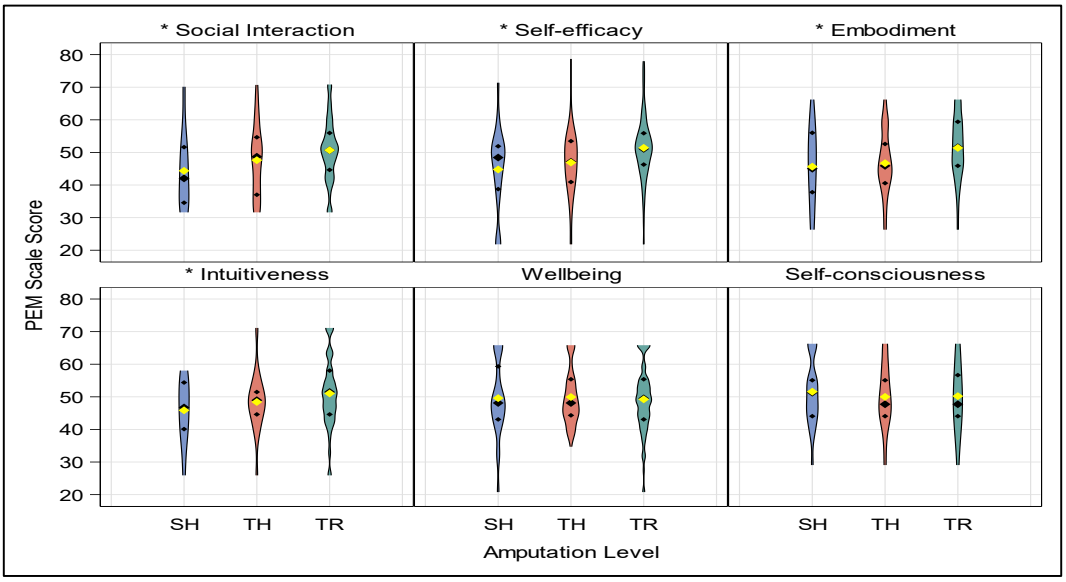

Figure 2. Violin plots showing PEM scores by unilateral amputation level.

Higher self-consciousness scores (i.e. less self-consciousness) in those with UA (as compared to BA) may be because persons with UA can perform tasks in public with their intact hand, limiting the attention drawn to their prosthesis. Similarly, higher scores in wellbeing may be because those with UA feel less impacted by their amputation. However, persons with BA had higher social interaction scores than those with UA, indicating that they feel more comfortable using their prosthesis in social greetings and to communicate emotion through touch. This may be explained by the increased experience and practice they have acquired with these tasks, given that they must perform them with their prosthesis, whereas persons with UA may predominantly perform them with their intact arm/hand, and thus do them infrequently.

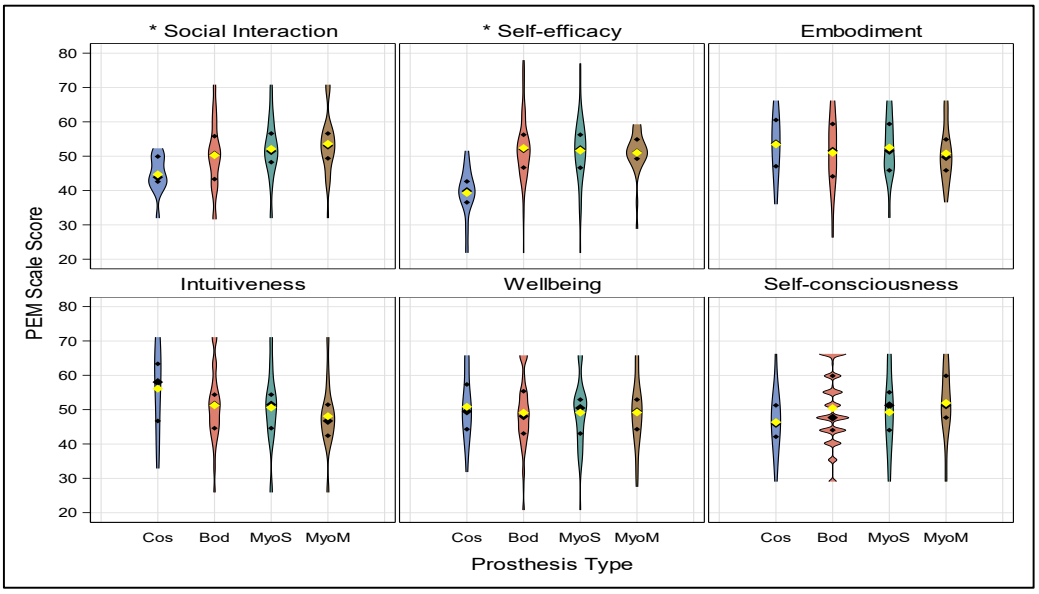

Figure 3. Violin plots showing PEM scores by prosthesis type.

The finding that persons with TR amputation had higher scores in self-efficacy, embodiment, social interaction, and intuitiveness is consistent with prior studies[3]. These scales reflect, to some degree, participants' experiences using the prosthesis and the ways in which they engage the prosthesis to accomplish tasks.

Persons with SH level amputation have limited means of control, which may contribute to lower overall perceived usefulness and functionality of the prosthesis. In contrast, scores on the wellbeing and self-consciousness scales, which address experiences when not wearing a prosthesis, did not differ by amputation level.

Comparisons by prosthesis type yielded significant differences in the social interaction and self-efficacy scales. These scales primarily ask about active prosthesis use in various tasks. Cosmetic prostheses are typically only used for supporting or stabilizing, which would explain their lower scores on these scales. There was no measurable difference in embodiment, intuitiveness, wellbeing, and self-consciousness subscales for people with unilateral TR amputation across prosthesis types, perhaps due to lack of sensitivity or potential confounding by user-relevant factors determining prosthesis choice. A variety of factors might explain why a person with TR amputation would be prescribed or choose to use a given prosthesis type, such as cost, durability, aesthetic factors, or reliability. Future analyses may identify other PEM score predictors or confounders.

SUMMARY & CONCLUSIONS

This study compared PEM by laterality, amputation level and prosthesis type. Findings suggest differences in psychosocial experiences that can be further explored in future research.

ACKNOWLEDGEMENTS

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Other

DISENTANGLING SENSORY AND MOTOR DEFICITS OF FINE HAND FUNCTION USING AN ELECTRONIC GRIP GAUGE (EGG) TO SIMULATE TRANSFERRING FRAGILE OBJECTS

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ABSTRACT

Evaluating hand dexterity is a critical aspect of assessing novel prosthetic technology and informing patient care. Current upper-limb dexterity assessments primarily target gross motor function and do not directly measure the ability of an individual to finely regulate their grip force. An increasingly popular test of fine motor function among researchers is a fragile-object test, in which participants are instructed to lift and transfer an object while minimizing their applied grip force. Here we present another instantiation of this fragile-object test, dubbed the electronic grip gauge (EGG). We use the EGG to quantify grip force and transfer rate for intact hands and myoelectric prostheses under three distinct conditions: 1) implicit grasping when transferring the object as fast as possible, 2) grasping when participants are instructed to minimize their grip force using endogenous tactile feedback and/or indirect sensory feedback, and 3) grasping when participants are instructed to minimize their grip force and have auditory feedback proportionate to their grip force. We show that a lack of tactile feedback is a significant reason for poor prosthetic control, as evidenced by significantly better prosthetic control with auditory feedback. We also show that even with supplemental auditory feedback, performance of the prosthetic hand was still substantially worse than the performance of the intact hand. These results suggest that artificial sensory feedback can improve prosthetic control, but that improvements in mechanical design and/or real-time control are also needed to replicate the dexterity of intact human hands.

INTRODUCTION

Up to 50% of amputees abandon their prostheses, often citing poor control and a lack of sensory feedback as primary reasons [1]–[3]. Clinical measures of upper-limb function typically focus primarily on gross manual dexterity. For example, the Box and Blocks test (BBT) is a widely used test of upper-limb prosthesis function in which participants transfer small wooden blocks over a vertical barrier from one side of a box to another as quickly as possible in one minute [4]. However, the BBT, like many other clinical measures of upper-limb function, does not directly measure the ability of an individual to finely regulate grip force, which is a vital aspect of hand control when manipulating fragile objects [5].

A common variant to the BBT to assess fine motor function involves introducing a “break” threshold to the wooden blocks to replicate transferring a fragile object such as an egg. This modification requires the user keeps their grip force above the force required to pick up the object and below the force required to “break” the object. Instantiations of this fragile-object task have involved metal plates separated by a weak magnetic field [5]–[7], paper blocks held together loosely with toothpicks [8], and 3D-printed blocks held together weakly with embedded magnets [9]–[11]. A more recent instantiation involves a 3D-printed block embedded with a strain gauge and accelerometer to precisely measure the grip force and load force exerted on the object [12], [13].

Here we build on these prior studies and introduce a similar instantiation as [12] involving a 3D-printed block embedded with a strain gauge and accelerometer, referred to as the electronic grip gauge (EGG). We first present an overview of the device design and different testing conditions. Then, we use the instrumented egg to quantify differences in the control of myoelectric prostheses and intact hands for healthy participants. We show that both grip force and object transfer time are substantially greater for myoelectric prostheses compared to intact hands. We also show that providing supplemental sensory feedback (auditory feedback) in proportion to the applied grip force significantly reduces prosthetic grip force and transfer time, further supporting the idea that a lack of tactile sensory feedback is a primary reason for poor control. This work also provides quantifiable benchmarks for intact hands and myoelectric prostheses for this increasingly popular fragile-object test.

METHODS

Device Design

The EGG consists of a 100-lb load cell (TE Connectivity Measurement Specialties), triple-axis accelerometer (Adafruit), and wireless microcontroller (Arduino MKR WiFi 1010) contained in a 3D-printed polylactic acid (PLA) shell (Fig. 1). The microcontroller amplifies and streams data from the load cell and accelerometer to the computer wirelessly at 100 Hz using the User Datagram Protocol. An LED on the microcontroller can be programmatically set to visually show the state of the EGG. The base of the EGG can be filled with small lead weights to vary the weight of the object between 132 g and 414 g. The assembled instrumented egg measures 60.5x42.7x80.5 mm and can be readily grasped by various prostheses. An embedded battery provides roughly 2 hours of battery life.

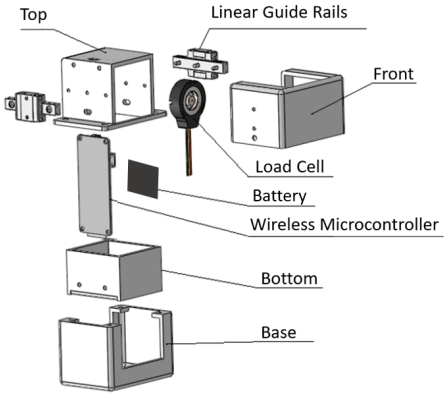

Figure 1: Exploded view of the EGG. The 3D-printed shell consists of top, bottom, front and base pieces connected with linear guide rails. The load cell and wireless microcontroller are housed between the top and bottom pieces.

Experimental Conditions

The EGG can be used under three different test conditions. In the first test condition, participants simply pick up and transfer the EGG as many times as possible within one minute while grip force is recorded. This test condition provides a measure of the transfer rate, similar to the BBT, and the users implicit grasping force, similar to the Grasping Relative Index of Performance [14].

In the second test condition, the experimenter sets an upper threshold on the grip force, such that the EGG will "break" and emit an audible sound if the participant's grip force exceeds the threshold. The participants are instructed to pick up and transfer the EGG as quickly as possible without breaking it. The difficulty of the task can be adjusted by lowering the break threshold or by increasing the weight of the EGG. In this study, the breakpoint was set to 11.2 N and the device weighed 414 g. The ratio of break force to weight in this study was 0.027 N/g; prior studies have used ratios of 0.032 N/g, 0.02 N/g, 0.015 N/g, and 1.34 N/g [7], [5], [9], [11], [8]. Because the EGG does not visually deform with increasing grip pressure, the only feedback the participants have regarding their applied grip force is endogenous (e.g., proprioception from forearm muscles or efference copy) or indirect (e.g., sounds of the prosthesis motor). Thus, this test condition provides a measure of the participant's innate sensorimotor grasping precision.

In the third test condition, the participant is again instructed to pick up and transfer the EGG as quickly as possible without breaking it. However, in this test condition, the participant is provided with auditory feedback regarding the grip force applied to the EGG. That is, a tone is played continuously and the pitch of the tone increases as the applied grip force approaches the break threshold. If the break threshold is exceeded, a second tone is played indicating the EGG has broken. This test condition also provides a measure of the participant's grasping precision. Using this test condition (continuous feedback) in conjunction with the previous test condition (discrete feedback) provides a way to systematically probe the impact of tactile sensory feedback on grasping precision. Significantly greater performance with continuous auditory feedback implies tactile feedback is impaired.

Participants and Experiment

Three neurologically healthy and physiologically intact participants volunteered in this study. Participants were between the ages of 18 and 21 (100% male). Informed consent and experimental protocols were carried out in accordance with the University of Utah Institutional Review Board. Participants were instructed to complete the three aforementioned test conditions (no feedback, discrete feedback, and continuous feedback), ten times each, with using both their intact hand and an EMG-controlled prosthesis. Participants moved the EGG over a 2-in vertical barrier.

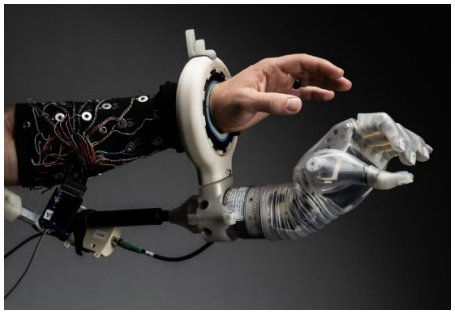

Figure 2: Prosthesis Setup. Participants wore an sEMG sleeve around their forearm and held a prosthesis via bypass socket fit around their wrist.

Prosthesis Control

Surface EMG from the participants was collected using a custom EMG sleeve [15]. EMG was sampled at 1 kHz and filtered using the Summit Neural Interface processor (Ripple Neuro Med LLC) as described in [16]. EMG features used for estimating motor intent consisted of the 300-ms smoothed mean absolute value on 528 channels (32 single-ended channels and 496 calculated differential pairs) calculated at 30 Hz, as described in [16].

A modified Kalman filter was trained to predict hand flexion and extension, as described in (Thomson et al., MEC 2022) and previous reported in [16], [17]. The participants donned a prosthetic hand (LUKE Arm; DEKA) using a custom bypass socket [18]. A latching filter was applied to the kinematic output of the prosthetic hand to increase grasping stability [7], [19].

Performance Metrics and Analysis

Data consisted of the transfer time and peak grip force for each test condition, each hand, and each participant. All data were screen for normality. Data were aggregated across participants and two-way analysis of variance (factors: hand and test condition) was performed. Subsequent pairwise comparisons (Wilcoxon rank-sum test) were performed using the Dunn-Sidak correction for multiple comparisons. Additionally, a grouped comparison with pooled data from the three test conditions was performed between the prosthesis and intact hand.

RESULTS

Overall, transfer time (Fig. 3) and grip force (Fig. 4) were significantly greater for the prosthetic hand compared to that of the intact hand (p's < 0.05; Wilcoxon rank-sum test). Across all three test conditions, average transfer time was 283.3% longer for the prosthesis and grip force was 92.6% stronger for the prosthesis.

When a break threshold was introduced (discrete feedback), we observed no significant difference in performance for the prosthetic hand or intact hand. For the prosthetic hand, this resulted in a substantial failure rate (i.e., roughly 50% of the peak forces exceed the blue line representing the break threshold in Fig. 3). For the intact hand, implicit grasping force (no feedback condition) was already below the break threshold and remained similar.

When continuous auditory feedback was introduced on top of the break threshold, prosthetic performance improved significantly (p < 0.05; Wilcoxon rank-sum test). That is, transfer time was reduced by 20.3% and grasping force was reduced by 23.7%. For the intact hand, continuous auditory feedback did not significantly improve the task performance relative to the discrete feedback condition. Overall, the median transfer time and grip force of the intact hand was similar across all three test conditions.

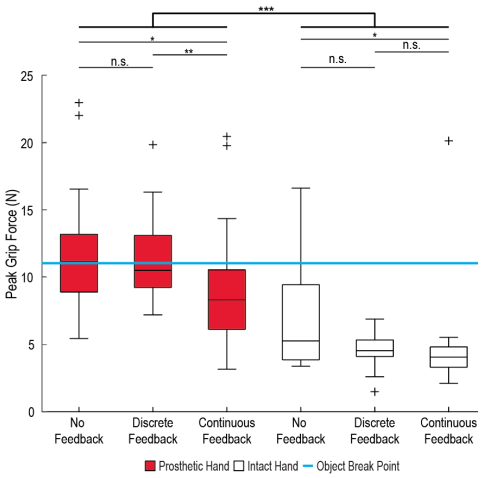

Figure 3: Grip force is significantly greater for the prosthetic hand compared to that of the intact hand. Data show peak grip force exerted on the EGG for ten trials for each of the three participants (N=30). Boxplots show median, inter-quartile range, and most-extreme, non-outlier values. Plus marks denote outliers. Blue line indicates the break threshold that participants attempted to keep their grip force below for the discrete-feedback and continuous-feedback conditions. Asterisks indicate different medians between conditions * (p<0.05), ** (p<0.01), *** (p<0.001); Wilcoxon rank-sum test; N=30 per group between test conditions and N=90 per group for the pooled comparison between the prosthetic and intact hands.

CONCLUSION

This study introduces another instantiation of a fragile-object test, based heavily on the design previous introduced in [12]. We expand upon the work in [12] by highlighting the embedded design and exploring different test conditions with both prosthetic and intact hands. The EGG introduced here quantifies grip force, load force, and object transfer time to enable more in-depth comparisons of fine motor function across people and technologies. Furthermore, the different test conditions provide an opportunity to systematically probe an individual's ability to finely regulate their grip force and quantify their innate tactile sensory feedback.

The results present here show that a lack of tactile sensory feedback is a significant reason for poor prosthetic control, as evidenced by improved dexterity when continuous auditory feedback is provided in proportion to exerted

grip force. Furthermore, we also show that even with supplemental auditory sensory feedback, performance of the prosthetic hand was still substantially worse than the performance of the intact hand. Thus, it is likely that a combination of diverse improvements in the areas of mechanical design, real-time control and sensory feedback are necessary to make prosthetic hands as dexterous as healthy intact hands.

ACKNOWLEDGEMENTS

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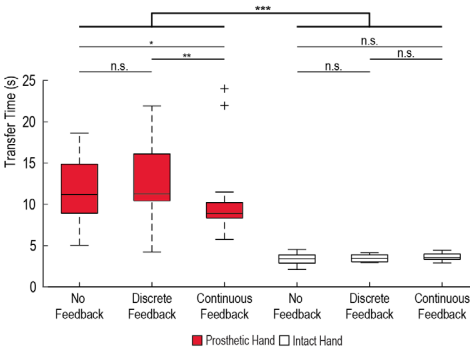

Figure 4: Transfer time is significantly greater for the prosthetic hand compared to the intact hand. Data show peak force exerted on the instrumented egg for ten trials for each of the three participants (N=30). Boxplots show median, inter-quartile range, and most-extreme, non-outlier values. Plus marks denote outliers. One outlier at a value of 32.04s is not shown for the prosthetic-hand no-feedback condition. One outlier at a value of 63.45s is not shown for the prosthetic-hand discrete-feedback condition. Blue line indicates the break threshold that participants attempted to keep their grip force below for the discrete-feedback and continuous-feedback conditions. Asterisks indicate different medians between conditions * ($p<0.05$), ** ($p<0.01$), *** ($p<0.001$); Wilcoxon Rank Sum Test (N=30 per group between test conditions and N=90 per group for the pooled comparison between the prosthetic and intact hands).

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THE ECONOMICS OF INNOVATION IN UPPER LIMB PROSTHETICS

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ABSTRACT

Upper limb external powered prosthetic technology in recent years has experienced advancements that have produced significant increases in costs to clinics, payers, and end-users. In the United States, for new technology to be considered, the technology must fit into a coding structure called the HCPCS L-Code system. If an established L-code has not been established or the l-code does not describe the new technology, an NOS (not otherwise specified) code might be utilized. Depending on the payer source, an NOS code might not be allowed and/or the desired reimbursement of the NOS code will be reduced significantly. Usefulness of these new technological advancements must also be provided to justify its use over more conventional technology. Both usefulness and cost of a specific technology are intimately tied to the overall economic value of the prosthesis. Because the way healthcare is provided and paid for in the United States, new technology and innovation is often first introduced in the United States. This paper intends to share the author's direct experience working within private clinics, federal institutions as well as manufacturers and payers. The goal is to provide insight on the challenges faced by payers, prosthetic providers, and end-users regarding the economics of innovation in the prosthetic and orthotics industry. Researcher, therapists and MD's and prosthetist should all benefit from this overview. Examples of the coding structure, increases in time for prosthetists to provide and maintain and justify new technology will be shared along with how payers handle innovation and payments.

INCREASES IN COST, TIME, AND SERVICE

Upper limb innovation and advancement has created an increase in costs to payers with the use of NOS codes which have resulted in doubling, tripling, and even quadrupling costs over traditional myoelectric systems. With this comes an increased co-pay to the end-user. Add to this the increased setup and servicing time by the treating provider along with the increased time commitment to the end-user. When comparing the delivery time required for an upper limb prosthetic system to that of a lower limb prosthesis, is not uncommon for the delivery time of an upper limb prosthesis to take up to two times longer for effectively deliver. Additionally, the time and expense required for proper occupational therapy to effectively train the user with the new technology must be considered. As technology advances, it is not uncommon for the technology to exceed the bandwidth of most clinicians providing and training this new technology. Because payment for a prosthetic device in the United States is all inclusive for the prosthetist providing the prosthesis, evaluation time, fitting time, and follow-up (for the first 90 days after delivery) are included in the payment of the prosthesis. Follow-up care after the initial 90 days is billable for a prosthetic office visit based on 15-minute increments. Payment will also be dependent upon whether the prosthetic provider has a contract with a particular payer.

OUTCOME MEASURES AND PROSTHETIC OPTIONS PROVIDED

While lower limb prosthetic evaluations have a variety of objective outcome measures to evaluate pre-prosthetic and post-prosthetic function which help to determine the current and anticipated functional level of the end-user, upper limb prosthetic outcome measure assessments are not as available or are less effective in predicting prosthetic effectiveness. Upper limb pre-prosthetic outcome measures rely primarily upon subjective reporting of the end-user. Post-prosthetic objective outcome measures are not as effective in predicting anticipated functional level of an upper limb end-user, and while they are available, they seem to be less effective in predicting when the end-user can progress to a more advanced technology. In addition, who conducts these upper limb outcome measures is critical. Often it is a tight collaboration between the occupational therapist and the prescribing MD as to when advancement to more complex technology is appropriate. Add to this, the challenge of an insurance company's upper limb prosthetic policy on the specific technology is allowed or not allowed, when it can be provided, and the timeframe a specific technology has to be utilized before another is considered. The chances of getting approval for advanced technology that does not

have an established L-code or has not been proven to be significantly effective over conventional technology can be very challenging.

ECONOMICS, PAYERS, AND L-CODES

In the United States, there are numerous insurance plans or payer sources available for the financial coverage of prosthetic devices. The Centers for Medicare & Medicaid Services (CMS) which developed the Healthcare Common Procedure Coding System (HCPCS) L-code system establishes specific codes and corresponding fee schedules for a combination of codes that make up an entire prosthesis. Specific to lower limb prosthetic codes, there are local coverage determinations (LCD's) which specify what codes can and cannot be utilized together along with set prices that determine final payment for a particular lower limb prosthesis. These LCD regulations alert the prosthetic provider to the proper and improper combination of established codes for a complete lower limb prosthesis. It is a method to manage the total costs of a lower limb prosthesis. Specific to upper limb prosthetics and the HCPCS L-code system, there are no LCD regulations that alert the prosthetic provider of proper and improper coding combinations for the delivery of a complete upper limb prosthesis. This is both a blessing and a curse. Not knowing what CMS will allow for payment can create delays for delivery of an upper limb prosthesis. CMS through the establishment of their Pricing Data Analysis and Coding (PDAC) system, has started to provide Correct Coding bulletins that have stipulated what codes can and cannot be utilized with upper limb multiarticulate hands and partial hands. While not a formal LCD, the Correct Coding bulletins have created challenges for upper limb innovation.

CMS is a federal insurance program that provides payment to individual 65 and older or to individual who qualify for a state funded Medicaid plan for low-income individuals. The Veteran Administration (VA) is the other Federal program established for military and veterans of the military. The VA has their own set of regulations that are based on the L-code system. Other insurance programs, known as 3rd party payers, provide prosthetic payment based on the type of prosthetic plan available from a particular insurance company. 3rd party payers also have specific upper limb prosthetic policies stipulating what is and is not allowed. Co-pays by the prosthetic end-user may or may not be a part of the insurance plan. Work related injuries are another category of insurance known as Workers Compensation which cover prosthetic needs of an injured worker. Because workers compensation often involves an attorney and there is liability for the injury, the process for prosthetic approval involves a legal proceeding. In these cases, advanced technology might be approved over that of any other type of insurance.

CONCLUSION

While advanced technologies and new innovation have benefits that may increase the usefulness of a particular upper limb prosthetic device to the end-user, not everyone who needs an upper limb prosthesis will benefit from new innovation. If there is a possibility an end-user could benefit from new innovation, obtaining it may be cost prohibitive. Access is dependent upon several factors including the type of insurance the end-user has, whether the loss of limb was the result of a work-related accident and how willing a provider is to try and obtain the technology. Continued research studies utilizing validated outcome measures must also show significant improvement to justify the total cost of the prosthetic limb being provided over more conventional technology. The uprising of Go-Fund-Me campaigns to raise thousands of dollars to offset the cost to the end-user of advanced upper limb technology is evidence of how the economics prosthetic innovation is at play. New policies and regulations from payers stipulating what codes and technology will or will not be allowed for upper limb technology is also evidence of the economics at play in upper limb prosthetics.

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