RESULTS OF TARGETED MUSCLE REINNERVATION IN INDIVIDUALS WITH A TRANSRADIAL AMPUTATION

Kristi L. Turner, DHS, OTR/L [1], Ann Simon, PhD [1,2], Laura Miller, PhD, CP [1,2], Levi Hargrove, PhD [1,2], Todd Kuiken, MD, PhD [1,2]

[1] Shirley Ryan AbilityLab, Chicago, IL, USA [2] Northwestern University, Chicago, IL, USA

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.

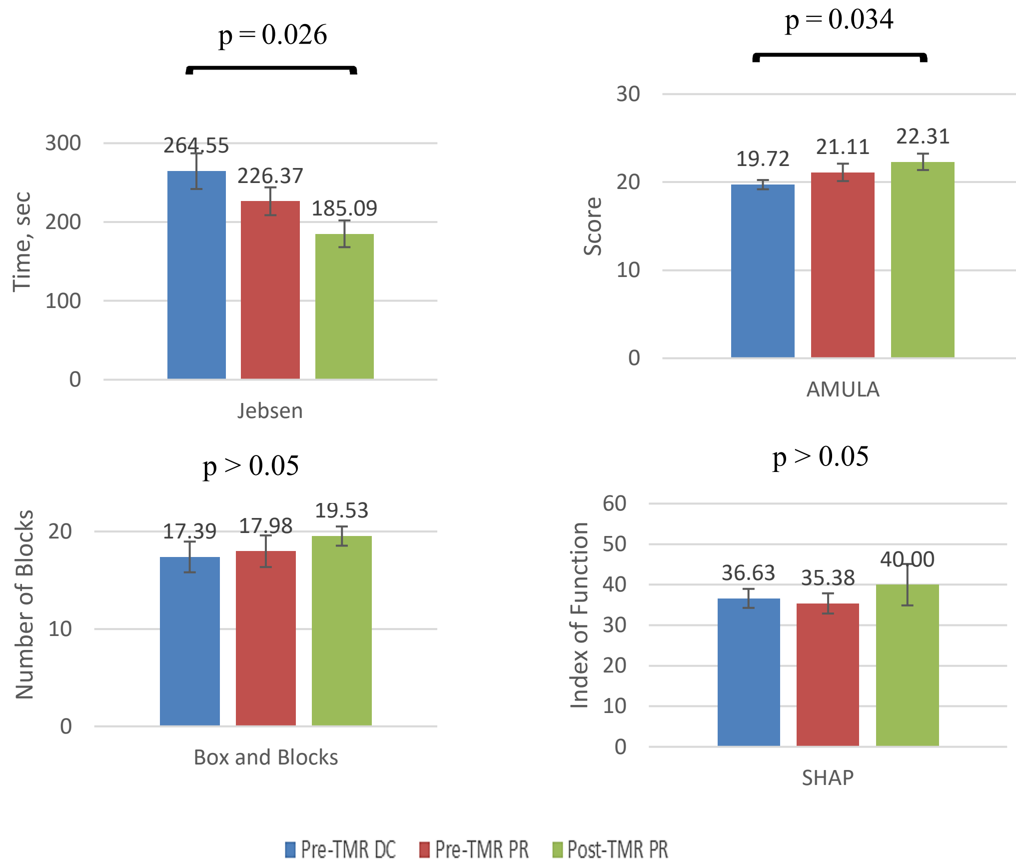

Figure 3: *Top Row*: Jebsen Hand Function Test and AM-ULA: statistically significant improvement in performance was found between DC Pre-TMR & PR Post-TMR conditions. *Bottom Row:* Box and Blocks Test and SHAP Test: no statistical difference in performance was found between conditions.*Data from participant 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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