PRELIMINARY RESULTS OF A PORTABLE TAKE HOME PHANTOM LIMB PAIN MANAGEMENT SYSTEM

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ABSTRACT

Phantom limb pain (PLP) is a common complaint in individuals with limb absence. PLP can persist chronically, necessitating effective management strategies beyond temporary pharmacological relief and invasive surgeries. Phantom motor execution, implemented through virtual reality (VR)-based therapy, has emerged as an effective alternative option to help manage PLP. This paper presents preliminary findings of an ongoing large-scale clinical study including individuals with upper or lower limb absence evaluating the effectiveness of a portable device for at-home PLP management as an accessible solution for VR-based therapy.

INTRODUCTION

Individuals with upper or lower limb absence often suffer from pain [1] that can severely impact their daily activities. This includes not only residual limb pain (RLP) but also phantom limb pain (PLP), which is prevalent following amputation [2]. PLP symptoms can start immediately post-amputation and frequently persist as a chronic problem throughout recovery. Classified as neuropathic pain, PLP typically leads to treatments that are pharmacological in nature, offering only temporary relief. While invasive methods or surgeries can provide some relief, they are generally considered only after less invasive options have failed [3]. There's a growing need for alternative PLP management strategies for individuals with limb loss.

Non-invasive treatments like motor imagery and mirror therapy, which are thought to leverage the brain's ability for neuroplasticity, have been developed to reduce pain. Motor imagery involves performing movements with the intact limb while visualising the same movements with the phantom limb. Mirror therapy involves performing movements with the intact limb while attempting to execute the same movements with the phantom limb as visual feedback is provided through a mirror. Interestingly, activities that engage the muscles in the residual limb, such as those used in mirror therapy, tend to be more effective, possibly due to the activation of muscle groups [4].

Therapy is advised for those with limb loss to improve muscle strength, educate on proper muscle contractions for prosthetic control, and educate different ways to carry out activities of daily living. The extent and quality of such training and therapy significantly impact rehabilitation success. Regularly wearing and using a prosthesis has been linked to better management of PLP, although RLP and PLP can influence the duration a prosthesis is worn [5],[6]. In addition, not all individuals with limb loss choose to regularly wear a prosthesis to help engage and strengthen residual limb muscles.

Virtual reality (VR) systems using muscle signals measured from the residual limb have emerged as promising tools for PLP management. Such systems promote muscle involvement by providing real-time task and game control practice, gaining acceptance as a practical clinical therapy option [7],[8]. Despite its potential benefits, VR-based therapy has lacked widespread at-home implementation and has not been evaluated extensively on the lower limb loss population which experience a higher prevalence of PLP [9]. Here, we present preliminary findings of an ongoing clinical study evaluating the effectiveness of a portable Phantom Limb Pain Management System (PLP-MS) developed for home use by individuals with upper or lower limb loss who suffer from PLP.

METHODS

Device: The Phantom Limb Pain Management System (PLP-MS) is a device that includes (1) an adjustable cuff with electrode sensors that attach to the arm/leg and measure EMG signals from the remaining limb muscles (Figure 1a), (2) a built-in hardware module that converts the user's EMG signal patterns into game commands using pattern recognition, (3) a custom mobile software application with a range of virtual training games (Figure 1b), and (4) a secure, HIPAA-compliant cloud-based storage system that allows study personnel to access user data remotely and monitor device activity and participant compliance with the study protocol. The device can be set up according to the side (right/left) and level (below- or above-elbow and below- or above-knee) of limb loss and can choose between 4-6 motions to control during virtual gameplay. These motions include hand open/close, wrist supination/pronation and elbow flexion/extension for the upper limb and ankle inversion/eversion, ankle dorsiflexion/plantar flexion and knee flexion/extension for the lower limb. The pattern recognition controller is trained by entering EMG data for each chosen motion during a calibration that the user initiates.

Participants: Individuals with limb loss/difference of upper, lower, or multiple limbs, who self-report PLP of 4 or greater on a 0-10 scale at least twice a month are enrolled. Although the trial is ongoing, we expect to enroll up to 48 individuals to participate in the clinical trial (ClinicalTrials.gov Identifier: NCT05915065). Informed consent is obtained under the guidelines and approval of the Northwestern University IRB prior to data collection.

Protocol: The study consists of: clinician-led instruction on how to use the PLP-MS, baseline outcome measurements, an 8-week home trial with the PLP-MS, post-home trial outcome measurements (week 8), and follow up outcome measurements at weeks 16, 24, and 32. The main outcome measure is the difference in the pain rating index (PRI), which is the total of the pain items on the Short Form McGill Pain Questionnaire (SF-MPQ) between baseline and post-treatment assessments. Other outcome measures include: a Visual Analogue Scale (VAS) for pain, the Patient-Reported Outcomes Measurement Information Systems (PROMIS) tools: a numerical rating scale (NRS) for pain (Pain Intensity 1a), Pain Interference 4a, and Sleep Disturbance 4a, PEG Scale (measuring pain intensity, interference with enjoyment of life, and interference with general activity), and Patient Health Questionnaire-2 (PHQ-2). Participants work with either a registered occupational therapist or a certified prosthetist for all parts of the study including training with the PLP-MS, outcome measurements, and all subsequent follow-up sessions.

Participants are sent the PLP-MS and receive up to four training sessions remotely via a secure Zoom link or in person (if local). Participants are provided with detailed instructions on setting up the system and navigating through the mobile software application which is downloaded onto their personal or provided mobile device. Training involves providing clinical guidance on how to perform muscular contractions to train the EMG-pattern recognition algorithms for controlling a virtual limb and instruction on how to play games within the mobile app. The number of training sessions for each participant is adjusted depending on their speed of learning how to independently use the PLP-MS.

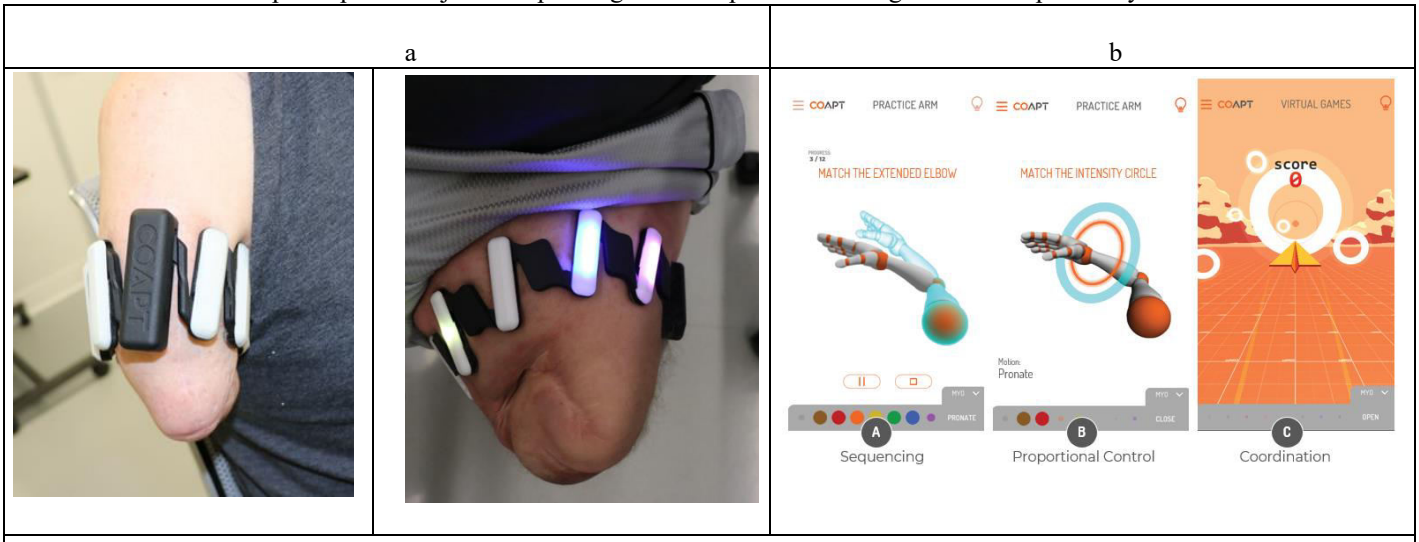


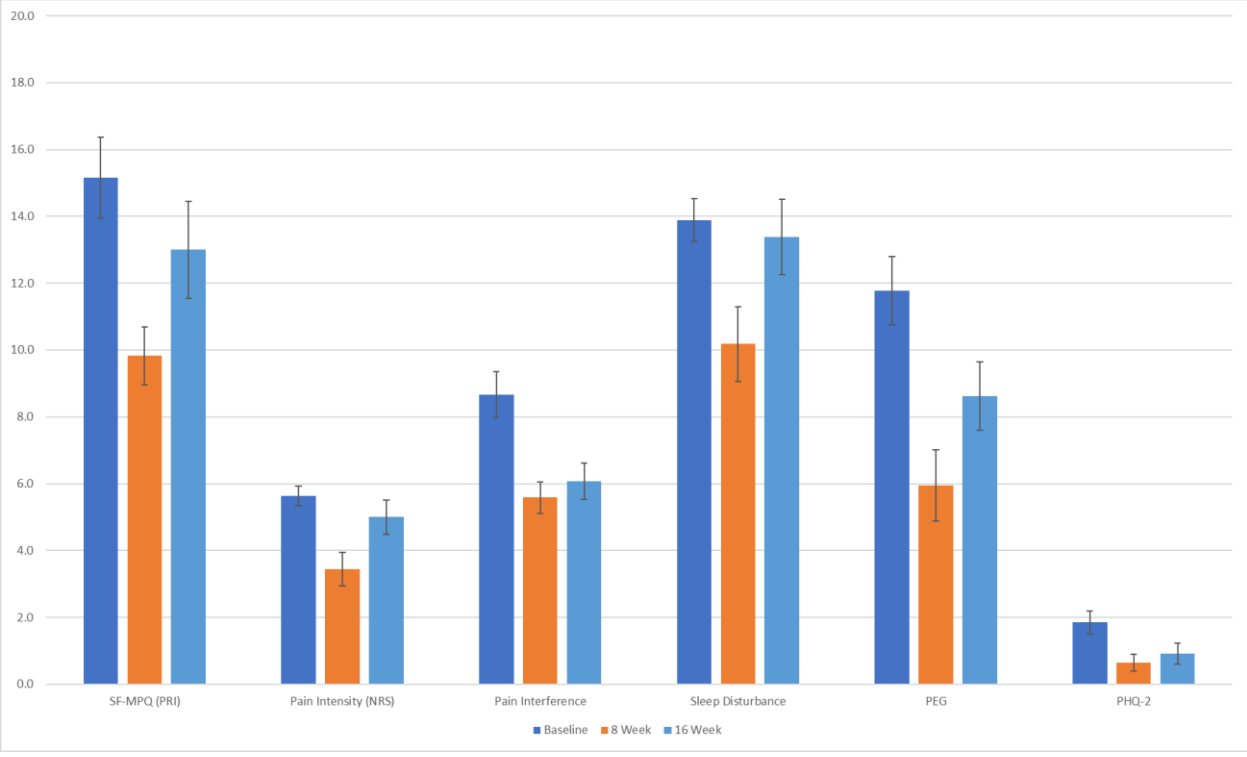
Figure 1: Phantom Limb Pain Management System a) EMG cuff that is donned on users' residual limb and includes 16 electrode sensors to record EMG (8 EMG pods – white, main pod – black) b) Screenshots of various virtual training games included in the mobile application.

After completing training and baseline outcome measurements, participants begin an eight-week home trial with the PLP-MS system, which requires a minimum total usage requirement of 1.5 hours per week and a recommended usage of 4-5 days per week for 20-40 minutes. Study personnel remotely monitor usage and device performance and contact participants as needed. Participants are also encouraged to contact study personnel for any concerns or troubleshooting throughout the home trial. Outcome measurements are collected after participants complete the home trial, and again at 16, 24, and 32 weeks to determine if changes in PLP persist.

RESULTS

To-date, thirty-one individuals with limb loss/difference of upper (below-elbow =5, above elbow = 5), lower (below-knee = 11, above-knee = 10) have been enrolled in the study. Seventeen participants have completed the 8-week home trial, post-home trial outcome measurements (week 8) and 13 participants have completed 16-week follow-up. Initial results of the primary outcome PRI indicate a decrease between Baseline (mean ± standard error; 15.2 ± 1.2) and post-home trial (week 8) (9.8 ± 0.9), indicating a potentially clinically meaningful change in PLP (suggested to be a change in PRI of at least 5 points) [10], [11] . The PRI increases towards baseline in 16-week follow-up (13.0 ± 1.5).

Secondary outcomes indicate a similar trend of improvement from Baseline to post-home trial (week 8) with two of the outcomes remaining lower than baseline at 16-week follow-up. Pain Intensity (NRS) scores show a decrease from Baseline (mean ± standard error; 5.7 ± 0.3) andpost-home trial (3.4 ± 0.5) with an increase towards baseline at week 16 (5 ± 0.5). Sleep Disturbance scores show a decrease from Baseline (mean ± standard error; 13.8 ± 0.6) and post home trial (10.2 ± 1.1) and increase almost to Baseline at week 16 post treatment (13.4 ± 1.1). PEG scores indicate a decrease from Baseline (mean ± standard error; 11.8 ± 1.0) and post home trial (5.9 ± 1.1) and increase in week 16 (8.6 ± 1.0). Pain Interference scores indicate a decrease between Baseline (mean ± standard error; 8.7 ± 0.5) and post home trial (5.6 ± 0.5) and remained lower than Baseline in week 16 (6.1 ± 0.5). This is also seen in PHQ-2 scores with a decrease between Baseline (mean ± standard error; 15.2 ± 0.3) and post home trial (0.6 ± 0.2) and in week 16 post treatment (0.9 ± 0.3). As this is an ongoing clinical trial, a statistical analysis will not be performed until the completion of the study.



DISCUSSION

The initial findings suggest that the PLP-MS therapy may effectively lower PLP across participants with either upper or lower limb absence. It seems symptoms may recur after stopping the treatment, in line with previous studies [11]. Participants reported feeling less pain in terms of both intensity and frequency while using the PLP-MS, and many wanted to continue their treatment past the first 8 weeks. This clinical trial is still in progress and a thorough statistical analysis will be performed after it is completed. Further analyses will also examine how the outcomes may be influenced by different factors, such as the level of limb-difference and the frequency of device use. However, we are encouraged by the preliminary trends observed in the pain-related outcome measures and the initial feedback about the overall usability and functionality of the PLP-MS as a method of at-home PLP treatment that we've received from study participants.

A key and distinctive feature of this work is that it can be delivered remotely using telerehabilitation methods and adherence to device use can be tracked using the connected health platform. Clinicians can also monitor whether participants are using the device as instructed, and through quick inspection of their EMG signals recorded during user calibrations and virtual gameplay, they can confirm that they are trying to perform, rather than imagine, the specified movements. This study successfully demonstrates the accessibility of VR-based therapy for PLP management through the use of a portable system with cloud connectivity, allowing individuals to independently perform their own treatment, in their daily life. Additionally, the VR approach offers a safe alternative without drug-related side-effects, which could provide lasting relief for those who suffer from PLP.

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