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CASE SERIES

Out of the Clinic, into the Home: The in-Home Use of Phantom Motor Execution Aided by Machine Learning and Augmented Reality for the Treatment of Phantom Limb Pain

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Purpose: Phantom motor execution (PME) facilitated by augmented/virtual reality (AR/VR) and serious gaming (SG) has been proposed as a treatment for phantom limb pain (PLP). Evidence of the efficacy of this approach was obtained through a clinical trial involving individuals with chronic intractable PLP affecting the upper limb, and further evidence is currently being sought with a multi-sited, international, double blind, randomized, controlled clinical trial in upper and lower limb amputees. All experiments have been conducted in a clinical setting supervised by a therapist. Here, we present a series of case studies (two upper and two lower limb amputees) on the use of PME as a self-treatment. We explore the benefits and the challenges encountered in translation from clinic to home use with a holistic, mixed-methods approach, employing both quantitative and qualitative methods from engineering, medical anthropology, and user interface design.

Patients and Methods: All patients were provided with and trained to use a myoelectric pattern recognition and AR/VR device for PME. Patients took these devices home and used them independently over 12 months.

Results: We found that patients were capable of conducting PME as a self-treatment and incorporated the device into their daily life routines. Use patterns and adherence to PME practice were not only driven by the presence of PLP but also influenced by patients' perceived need and social context. The main barriers to therapy adherence were time and availability of single-use electrodes, both of which could be resolved, or attenuated, by informed design considerations.

Conclusion: Our findings suggest that adherence to treatment, and thus related outcomes, could be further improved by considering disparate user types and their utilization patterns. Our study highlights the importance of understanding, from multiple disciplinary angles, the tight coupling and interplay between pain, perceived need, and use of medical devices in patient-initiated therapy.

Keywords: phantom limb pain, neuropathic pain, augmented reality, phantom motor execution, ethnography, user interaction design

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Introduction

Phantom limb pain (PLP) has been defined by the International Association for the Study of Pain (IASP) based on its perceived location; the phantom limb (IASP global year against neuropathic pain (2014–2015)). However, phantom limb pain (hereafter referred to as PLP) has a complex etiology and thus can be elicited by different sources, such as nociceptive (neuromas) and/or neuropathic.[1] Promising results have recently been

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published using surgical innervations to address nociceptive sources (neuroma pain),[2,3] but neuropathic causes remain unresolved,[4] even by pharmacological interventions.[5] This work is focused on neuropathic PLP and a non-invasive, non-pharmacological method to treat it.

PLP has been hypothesized as arising from the stochastic entanglement of the pain neurosignature with impaired sensorimotor circuitry.[1] In accordance with the implications of this hypothesis, a myoelectric pattern recognition (MPR) device was developed to promote Phantom Motor Execution (PME) as a treatment for PLP. PME engages motor neural circuitry in the central and peripheral nervous systems, ultimately resulting in the activation of the musculature at the residual limb while attempting phantom movements. By extracting motor intention from the stump's muscular activity, one can provide patients with real-time feedback utilizing Augmented and Virtual Reality (AR/VR), as well as serious gaming (SG).[6]

Preliminary evidence of the efficacy of this approach was obtained through a clinical trial involving individuals with intractable PLP affecting the upper limb,[7] and further evidence is currently being sought with a multi-sited, international, double blind, randomized, controlled clinical trial with upper and lower limb amputees.[8] All these experiments have been conducted in a clinical setting supervised by a therapist. However, when considering how the reduction of PLP relates to acquisition and maintenance of motor skills of the phantom limb, the question naturally emerges as to whether this treatment approach could be self-administered at home. The learning of phantom motor skills requires practice and occasional rehearsal is likely necessary to maintain said skills. With this in mind, we deemed it sensible to explore the feasibility of embedding PME in patients' home environments and daily life.

Studies of prescribed home use therapies have suggested that approximately 65 percent of patients will be non-adherent to some degree, due to factors such as lifestyle changes, complexity of the prescribed regime, lack of ability to fit the regime into normal routines, and the patient's internal level of motivation to do the treatment.[9] We were interested in understanding how these extrinsic lifestyle and personal factors interact with the patient's perceived need for the treatment as governed by pain levels, producing particular patterns of use and adherence.

In this manuscript, we present a series of four case studies on the use of Phantom Motor Execution as a self-treatment strategy for PLP. These case reports, involving two transhumeral and two transfemoral amputees, describe these patient's experiences using the therapy in their homes. We aimed to explore the benefits and the translational challenges encountered in the transition from clinic to home use. We hypothesized that home therapy yields efficacious results in pain reduction comparable to findings observed in the clinic, with the advantages of independent, customizable, personalized use outside of the hospital, as patients adapt the therapy to their individual preferences and lifestyles. In developing a more holistic understanding of how patients use the device at home and motivate themselves to perform the therapy, design recommendations can be drawn for future development of at home-based therapy systems.

In this study, we employ a multidisciplinary approach, enlisting the methodical and analytical tools of a biomedical engineer, medical anthropologist, and user interface designer. We chose this approach to elucidate not only the technical and quantitative data surrounding patients' in-home use of the therapy, but also to understand qualitatively the patient's relationship with their device and therapy program and develop design requirements for future in-home device development. Medical anthropology is the study of how social, cultural, biological, and structural factors intersect and interact with people's experiences of health, illness, medical treatments, and differentially distributed access to well-being. The primary methodological tool of anthropology is ethnography – sustained, immersive, long-term exposure of the anthropologist to individual's lives and worlds – in the endeavor to get as close as possible to understanding their firsthand experiences, practices, and values. Medical anthropology thus has the potential to complement, deepen, and even sometimes challenge the study of medical interventions through a more holistic lens.

Our study engages ethnographic insights into the lives of patients, involvement of family members, and behavioral patterns surrounding therapy to contextualize the clinical and quantitative perspectives. This multidisciplinary approach allows us to identify patterns otherwise overlooked using one method alone, offering an expanded appreciation of the many interrelated variables (physical, social, and structural) that drive patient home therapy regimes. Our study thus offers a methodological example of how engineers can work alongside interaction designers and anthropologists to produce a more deeply situated understanding of medical device development, use and efficacy, with the final aim of bringing such a device into the hands of the patient.

Materials and Methods

Design

All patients were provided with and trained to use a MPR and AR/VR device in a laboratory and/or clinical setting. Patients then took these devices home and used them freely and independently over the course of 12 months. At the end of the treatment period, the research group interviewed the subjects in an in-home setting and gathered the training data stored by the training software. The study was approved by the Regional Ethical Review Board in Gothenburg and was carried out in accordance with the relevant guidelines and regulations. All subjects provided their written informed consent to take part in the study and its publication.

Participants

Four limb loss patients (2 upper and 2 lower limb amputees) participated in this study. In the following we describe their backgrounds and their introductions to PME treatment.

Subject 1

Subject 1 (S1) is a 77-year-old man (born in 1941) who underwent an acute transhumeral amputation over 50 years ago (1964) in a motor vehicle accident, at age 24. S1 suffered from incapacitating phantom limb pain soon after the amputation, which severely impacted his sleep, mood, and ability to work. S1 experienced limited but unsustained PLP relief from hypnosis and mirror therapy. S1 was the first patient to undergo the PME treatment in 2013, resulting in the relief of nearly 50 years of PLP.[6] S1 was also the first person to use the device in-home, outside the clinic or laboratory.

Subject 2

Subject 2 (S2) is a 56-year-old man who lost his arm in 2011 in a tractor accident. He developed phantom limb pain directly after the accident, which he described manifesting as his hand clenched tightly in a fist. In 2014, he commenced PME therapy joining the first clinical trial on PME.[7] S2 had consistently taken morphine since the accident to help manage his PLP. Before joining the clinical trial, he used to take morphine pills in combination with morphine plasters, however by the end of his participation in the clinical trial he abandoned the plasters. He noticed that the valence of his pain changes with the seasons, getting markedly worse during winter, and he is currently using oxynorm (5mg/daily) to supplement his pain management.

Subject 3

Subject 3 (S3) is a 72-year old man who lost his leg in 1985 in a tractor accident. For the first 19 years after his accident, he did not experience debilitating phantom limb pain. Yet in 2014 S3 started to experience "unbearable" pain. The patient subsequently took part in a study using PME in lower extremities, which resulted in a significant decrease in PLP.[10] Following sustained PME treatment, the patient reported that his pain has returned to the level it was 20 years ago, "a manageable place." S3's pain was reported as worst in the middle of the night, when nothing else can distract him. As his son described, "my father is incredibly active. When he is always moving his body, he can't feel the pain. He once told me he wished he could just keep busy working for 24 hrs straight."

Subject 4

Subject 4 (S4), at 28 years old, is the youngest and in-home PME and AR/VR device user, and the only female in this study. She is a transfemoral amputee who lost her leg in a motor vehicle accident in 2009, when she was 18 years old. S4's phantom limb pain began almost immediately after her amputation and was, as she describes, "excruciating". S4 was prescribed a heavy dosage of oxycodone to manage her pain. For nine years, she continued taking oxycodone pills consistently. The pill was the only thing that allowed her to sleep, to escape what she called a "gnawing, annoying, relentless" sensation. She did not pursue any other pain management treatments during this time but was troubled by the strength of the medication and its numbing effects. In 2017, S4 was trained in PME and the AR/VR device in lab settings, upon which she took the device home with her. She continued the treatment at home, allowing periods of complete cessation of oxycodone.

Intervention: Home Use System

The PME treatment facilitated by MPR, VR/AR, and SG has been extensively described previously for the upper limb[6,7] and for the lower limb.[10,11] The same treatment methods were employed in this study. Briefly, motion intent is inferred via MPR using myoelectric activity from the stump musculature. First, the MPR algorithm is trained by recording the myoelectric signals associated with the phantom motions to be exercised. Once the aimed motions are trained and thus recognized by the decoder, these can be used to command the following virtual environments:

1. A VR environment featuring a virtual limb that is freely controlled by the subject.
2. An AR environment to allow the subject to visualize themselves (in real-time) with a virtual arm/leg superimposed on their stump. The AR environment uses a conventional webcam which inputs a video feed that is analysed to track a fiducial marker, thus allowing the virtual limb to remain in the anatomically correct position while the subject moves.
3. A racing game (Trackmania Nations Forever, free version) controlled by the subject's limb movements.
4. Target Achievement Control (TAC) test initially introduced by Simon and colleagues[12] and used in this study as implemented in BioPatRec.[13] The test requires the subject to match target postures presented in random order on the screen. The subject attempts to match the posture by moving the virtual limb with accuracy (i.e. the target posture can be overshot) and within a 10-second interval.

A user-friendly system (software and hardware) was developed for independent use at home. The software included a pain survey to monitor the level of PLP based on the Short Form of the McGill Pain Questionnaire (SF-MPQ) since prior clinical evidence gathered from patients using our system indicated this metric as the most sensitive measure of changes in pain.[7] Although subjects in this study were free to use the system according to their needs and to best suit their lifestyles and schedules, the recommended regimen was two sessions per week for at least 90 mins of training (this regimen has demonstrated efficacious in our previous clinical experience). Patients were also asked to occasionally fill in the pain survey in order to monitor the long-term profile of their PLP.

Data Collection and Outcome Measures

Data concerning the use of the system was stored in the software and collected at the end of the one-year study period. We monitored the frequency of the sessions, number of recording session per session and number and type of motions per recording session. Data regarding pain was collected through the self-administered questionnaire included in the software, which reports dates and times. The subjects were instructed to fill in the questionnaire at the end of every training session. The outcome measures considered were:

- Treatment adherence: Monitored as the number of sessions carried out monthly.
- Session duration: Inferred from the timestamps of the recording sessions as the time elapsed between the first and last recording of the day. This time interval was then increased by the average time between two consecutive recording sessions in order to account for the time spent in virtual environments by training with the last recording session.
- Pain Rating Index: Computed as the sum of the scores for all descriptors of the Short Form of the McGill Pain Questionnaire (SF-MPQ).[14] The SF-MPQ consists of 15 pain descriptors rated on a 4-point scale from 0 to 3. The range of the PRI is therefore 0 to 45.

Due to the small sample size and variations in patients' home situations, lifestyles and personal preferences, this study was not conducted as a clinical trial, nor does it draw conclusions of statistical significance. Rather, it is a series of case studies following patient progress through the therapeutic regimen.

Ethnographic Methods

In-depth, unstructured and non-directive interviews[15] lasting from 60–90 mins were conducted with each patient in their home environments. The interviews were aimed at elucidating patient narratives,[16,17] medical history, prior experience with phantom limb pain and treatment therapies, and the broader holistic context of the person's life, family, hobbies, motivations, and personality. Yet acknowledging that people do not always readily articulate their behaviors and practices when asked about them, these interviews were complemented by participant observation[18] during rehabilitation. Employing a patient-centred approach to ethnography,[19] which emphasizes intimate attention to an individual's subjective and emic "experience-near," the anthropologist followed subjects in their homes, chronicling their strategies for navigating everyday life with their devices. These engagements reach beyond what subjects say in self-report into the realm of embodied practice.

Survey of Use Preference

A self-report questionnaire was administered to identify how long the subjects used each training exercise as well as whether they preferred a certain type over the other. In addition, the subjects were asked in an open-ended question for feedback about possible improvements of the system for home use. The results from the self-report survey were incorporated with the ethnographic data using the KJ Method to

develop insight into the themes and relationships among the qualitative data[20]. The basic steps of the KJ Method are as follows. First, quotes are extracted from a qualitative data source, such as interviews or surveys, and written down on separate cards. The quotes are then scanned to identify common themes, and subsequently grouped together under the headings of these themes. These classifications are inherently subjective and decided upon by the researcher(s)' interpretation of the data. Further naming and subclassification of the assorted groups is then performed as needed. This classified data from the KJ Method was used to identify user types and suggest future requirements from the therapy regime.

Results

Usage data for the four participants were gathered over one year of study and are summarized in bar graphs showing adherence to the treatment, and in histograms showing the distribution of session durations. Self-reported pain levels over time are illustrated as trends of Pain Rating Index (PRI) over time. All the data are summarized per subject and illustrated in Figure 1–4 (one figure per subject), which consists of three panels (A–C). The results of the survey about use preferences are reported in Table 1.

Panel (A) of Figure 1–4 reports the trend of the self-reported level of pain as estimated by the PRI (range 0–45), presented as monthly average. The typical pain descriptors chosen by each subject are reported in the respective captions: as it can be noted from all figures, the level of pain remained relatively constant and low over time. Consequently, the pain descriptors also held stable, showing mild variations only within the individual ratings.

Each of the adherence bar plots (panel (B) in Figure 1–4) condense information about therapy adherence as percentage of the suggested monthly sessions carried out by each participant. Biweekly training (eight sessions per month) was considered the optimal treatment frequency. For example, the first bar of Figure 1B shows a treatment adherence of 137.5%, meaning that Subject 1 carried out 11 training sessions during the first month. Note that the subjects started the home treatment in different months; it ensues that "month 1" in the x-axis does not correspond to a specific month but rather the start of the treatment for that specific subject. The number on top of each bar represents the average number of movements per recording session month by month. The training software theoretically allows the user to train up to 18 movements simultaneously. However, patients can rarely achieve above six movements due partly to the limitations posed by MPR with surface EMG and a limited number of recording channels (up to eight, in the device used). Reporting the monthly average of movements performed per recording session is taken to

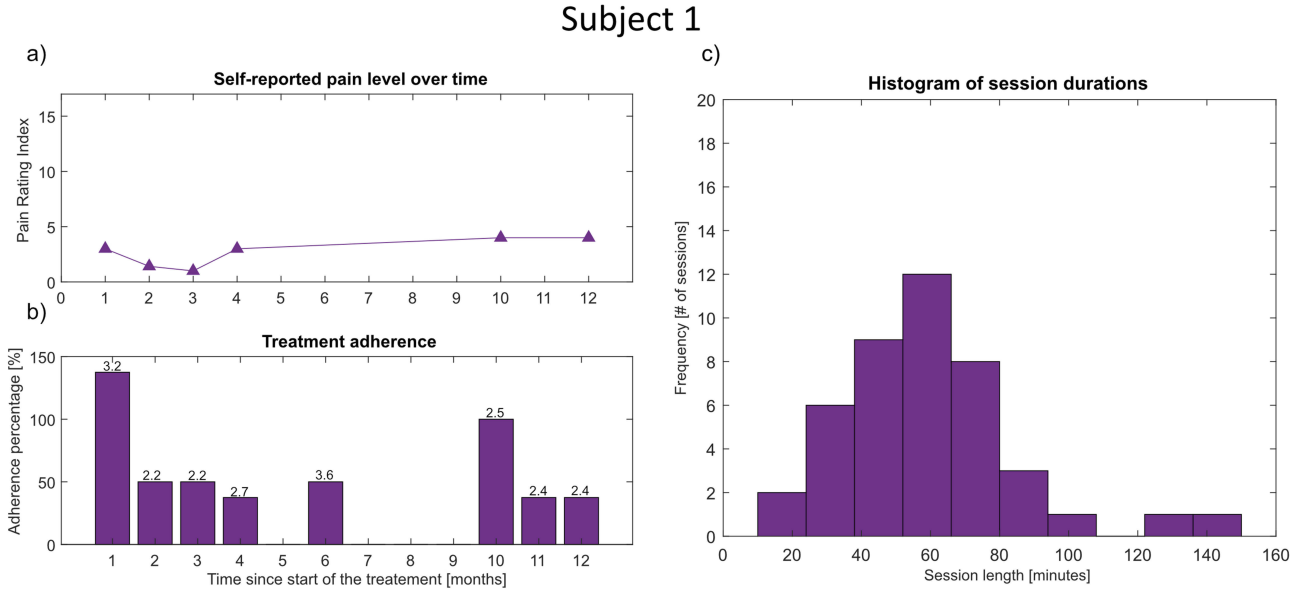

Figure 1 Panel (**A**) presents the self-reported level of pain as expressed by the Pain Rating Index (the sum of the scores give to the chosen McGill pain descriptors) over time (x-axis). The range of the PRI is between 0 and 45 however the range of y-axis of this graph has been reduced to 0–15 to improve the quality of the data visualization, since this is the interval containing the PRI for all participants. The value presented in the graph is the monthly average (y-axis). Pain level was not reported in those months where no data points are shown. (**B**) Treatment adherence data expressed as percentage of the suggested treatment frequency (eight sessions a month). The number presented on top of each bar represents the average number of movements trained in a given month. (**C**) Histogram of the session duration, each bar represents the number of session (value on the y-axis) of a given length (value on the x-axis). Figure 1 presents data relative to Subject 1. The only pain descriptor reported by Subject 1 is hot-burning.

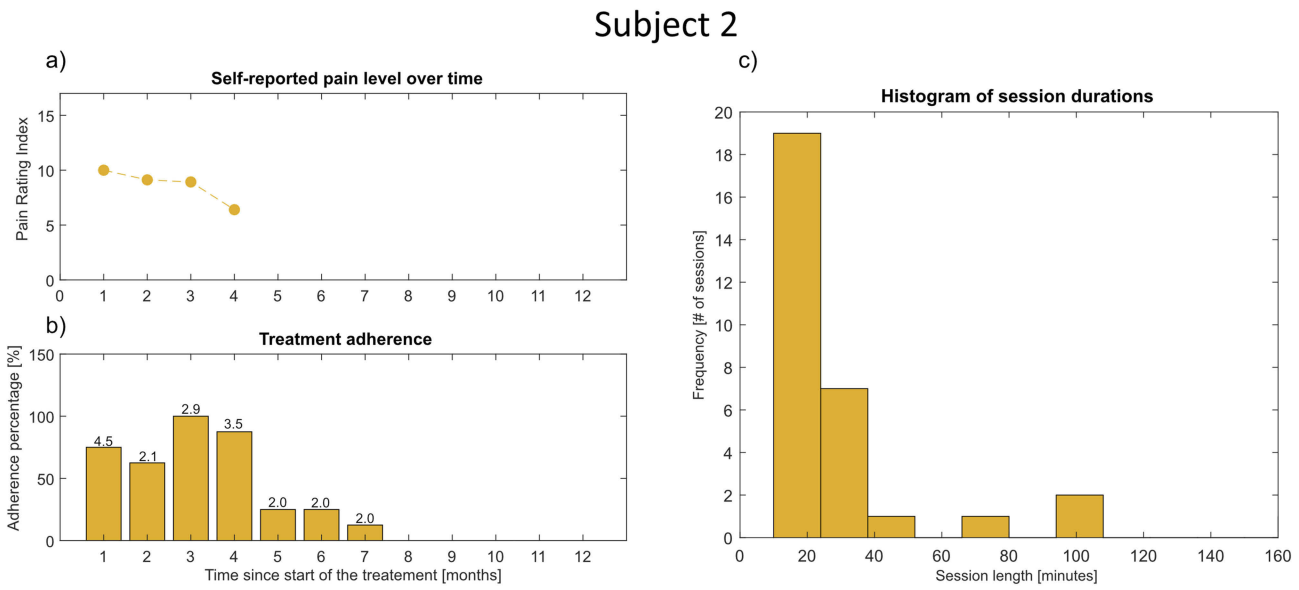

Figure 2 Data relative to Subject 2 presented in an analogous way to Figure 1. Panel (**A**) presents the self-reported level of pain; (**B**) treatment adherence; (**C**) histogram of the session duration. Typical pain descriptors reported by Subject 2 were: throbbing, shooting, stabbing and aching.

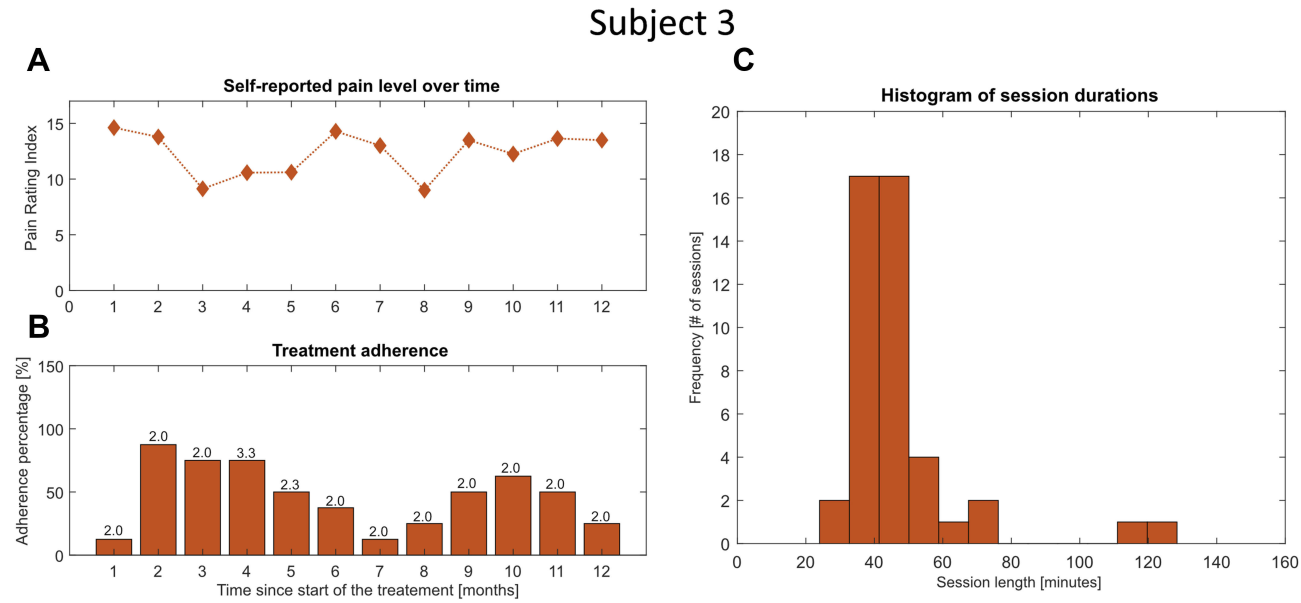

Figure 3 Data relative to Subject 3 presented in an analogous way to Figure 1. Panel (**A**) presents the self-reported level of pain; (**B**) treatment adherence; (**C**) histogram of the session duration. Typical pain descriptors reported by Subject 3 were: throbbing, stabbing, sharp, gnawing, hot-burning, aching and splitting.

indicate the complexity of the exercises carried out: the more movements trained within the same recording session, the higher the complexity of the classification task for the MPR algorithm. An increasing number of movements requires superior motor skills of the stump musculature in order to maintain quality performance with the VR/AR and SG environments.

From this way of presenting adherence data, it becomes clear that over the course of the first seven months the usage frequency generally decreases among all subjects. Subject 1 starts in January and interrupts the treatment between July and September, resuming the therapy with 100% adherence in October. S2 starts in August but phases out completely by March. S3 starts in December and trains throughout the

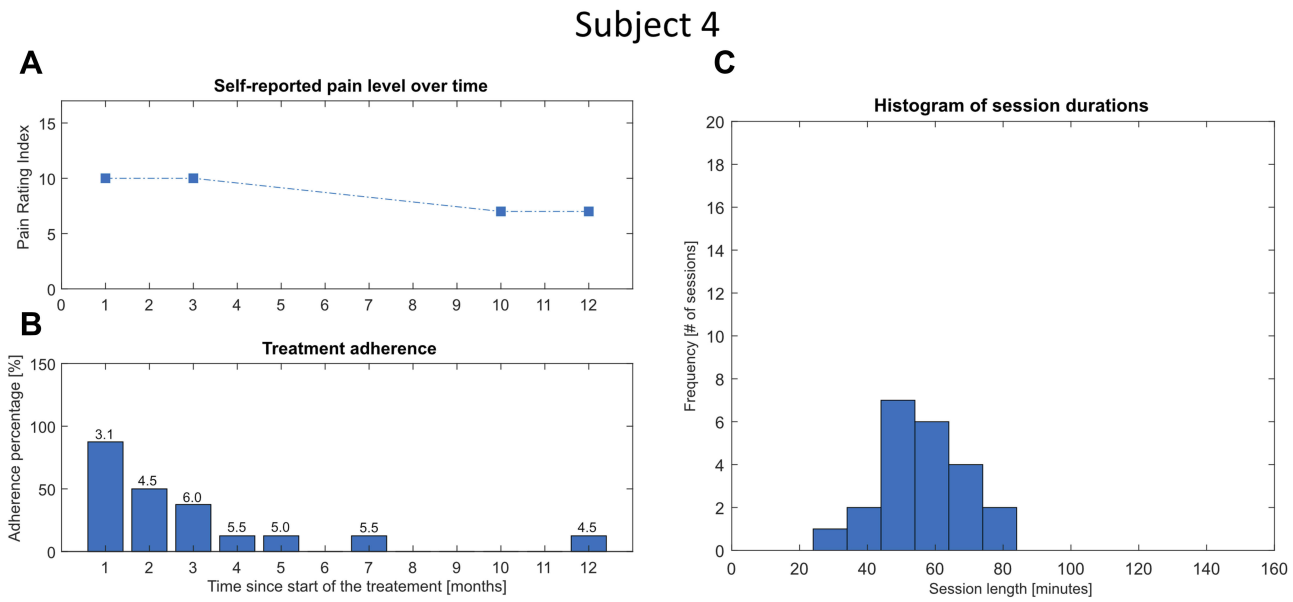

Figure 4 Data relative to Subject 4 presented in an analogous way to Figure 1. Panel (**A**) presents the self-reported level of pain; (**B**) treatment adherence; (**C**) histogram of the session duration. Typical pain descriptors reported by Subject 4 were: cramping, gnawing, heavy, tender, tiring-exhausting, punishing-cruel.

whole year: the frequency of training decreases in over summer months only to increase again during the following winter. S4 starts in October and trains with decreasing frequency over the following 7 months; after a long interruption of four months, she returns to therapy at the end of the monitoring year.

The complexity of the movements appears idiosyncratic; for each subject such idiosyncracy remains relatively constant over time. Session duration, in panel C, is presented in the form of histograms and indicates that all subjects spent less time training than the advised 90 mins, but also shows a large within-subject variation of session length.

Table 1 Self-Reported Use Preferences Using PME Device

Self-Reported Use Preferences	S1	S3	S4
Therapy Duration	1.5 hrs-2 hrs	1 hr-1.5 hrs	1.5 hrs-2 hrs
Average TAC Time	0–10 mins	More than 20 mins	15–20 mins
Average AR Time	More than 20 mins	More than 20 mins	0–10 mins
Average VR Time	I do not use the VR Limb	More than 20 mins	0–10 mins
Average Game Time	0–10 mins	I do not use the race car game	I do not use the race car game
Preferred Exercise	AR Limb	TAC Test	TAC Test
Factors that Prevent you from doing therapy	Time Shortage	Number of Electrodes	Time Shortage
What additional assistance do you need to carry out the session	None	Not needed, practiced many times and learned by doing	Someone who feels where to place the electrodes on the muscles
Progress Marker	Increase in Sleep, decrease in daily pain levels	Pain decreases by 30–50%	-
Open Recommendations	-	Reusable Electrode interface, shorter treatment times more often	More exercises with a goal to reach, and reduce timing

Abbreviations: PLP, phantom limb pain; MPR, myoelectric pattern recognition; PME, phantom motor execution; AR/VR, Augmented and Virtual Reality; SG, serious gaming; TAC, Target Achievement Control; SF-MPQ, Short Form of the McGill Pain Questionnaire; PRI, pain rating index; PMI, Phantom Motor Imagery.

Table 1 displays the results of the user preference survey. It was not possible to survey S2 because he terminated the use of the device several months preceding the interview time. From these results a discrepancy emerges in the estimate of time spent training as inferred from the data stored in the software (panel C of Figure 1–4) versus the data reported by the users themselves (Table 1), with the latter always exceeding the former.

Ethnographic Results

Ethnographic results are first presented for each subject, followed by ethnographic analysis of cross-cutting themes among all subjects, elucidating four key findings. All descriptors regarding the therapy and pain experiences that are contained in quotations are subjects' own words from interviews with the anthropologist. These descriptors were chosen by the subjects themselves, elicited through their own free-associations, rather than offered as prompts in the interview. Descriptors regarding therapy and pain experience that are not contained in quotations are the anthropologists' observations and interpretations drawn from participant observation as well as themes present in the interviews.

S1 reported a shift in frequency and consistency of his at-home treatment, largely depending on his level of present pain and corresponding motivation. For the first few years using PME at-home, S1 practiced the therapy regularly:

> It was much simpler for me to use the system at home. I started with ambition. If I did it every day, what would happen? For a time I used it every other day, just to see if the pain were to disappear even more, but there actually wasn't too much of a difference.

After a few months of frequent sessions at home, S1 was able to stabilize his pain levels with less regular intervals of the therapy. When pain was manageable, S1 deprioritized the therapy. "I wish I did it a bit more often," S1 admitted. "I'm not hindering you!" S1's wife chimed in. S1 acknowledged that his wife often reminds him to practice the therapy, citing that she can "sense a difference" when he has been more regular with the treatment. Still, "life gets in the way," as he explained, and sometimes weeks pass between his treatment sessions:

> It's easy to say 'no, I have to do this first.' So that is the problem when one is responsible at home for their own treatment. One must prioritize the treatment. When I start to feel that the pain is becoming a problem again, then I prioritize it. When the pain isn't so bad, I think 'not just now, I can do it tomorrow.

Here, S1 highlighted the challenge of in-home treatment maintenance when pain is not so present or acute and that the use of the therapy is often driven by current pain level. S1 reported that he typically performs a treatment session for two hours. Despite years of using the AR/VR device, S1 continued to find enjoyment and novelty in the treatment. "It doesn't feel like (two hours) because it takes so much concentration, it's so fun even after all these years … it's not very easy, it requires concentration, it isn't the same every time," he reflected. S1 progressed through all four activities but tends to prefer the AR configuration and the TAC test. A former professional race car driver, S1 enjoyed playing the game, especially delighting when he can steer the car with movements from his little finger, motivated by reaching a "best time." Despite his familiarity with the device, some elements, including electrode placement on the skin of the residual limb to record clear myoelectric signals, remained "challenging" throughout the course of the study. From time to time signal quality still varies. One time I got such good signals that I took a permanent pen and marked on my skin where they were. But it washed away after a few showers. This one is easy, he points to one electrode that lay just above a scar, "I just follow the scar slightly up." As S1's description demonstrates, in-home use of the AR/VR device requires learning and knowing the locations on one's body in relation to signal quality. During one treatment session, the anthropologist noticed S1 whispering under his breath, intently focused on the virtual on-screen hand, coaxing the little finger as if he were addressing a young child. This moment evinced the degree to which patients like S1 envision the virtual arm as intimately connected to the user's own body – if not a virtual representation of one's own phantom hand, then at least something which they can guide and control with effort and positive self-talk. "The best part is when I can control these little fingers here," he points to the fourth and fifth fingers. "That happens just a few days a year. It happened just three nights ago!" This challenge—seeing if he can control the two little fingers—seemed to drive each and every treatment session, his barometer of success. "The brain realizes that one can move the little fingers; it realizes they (still) exist there," he explained. His invocation of the brain speaks, uncannily, to the underlying theory of PME.

S2 is a unique patient in that he adapted PME therapy to not require the use of the AR/VR device, a regimen he

calls "in-head exercises." S2 ceased the use of the device because he felt only a few minutes of training was necessary to achieve pain relief, and this was not worth the time required to place the electrodes. When the research team visited S2 at his home, they were most interested in better understanding how he practices PME without the AR/VR device. It was crucial to ensure S2 was not merely envisioning or imagining the movements in his mind (which would purportedly only engage Phantom Motor Imagery [PMI]) but rather that he was actively engaging the muscle groups around the stump to execute movement in the phantom arm and hand (purportedly engaging the sensorimotor system). S2 described his method as such: He sits or lays on the sofa and tries to relax, directing his attention to the phantom pain (which he otherwise tries to avoid it through distraction). He first thinks about the movement, then performs the movement, feeling the muscles in his residual limb contract. In this description, S2 made a clear distinction between passively thinking and actively performing the movement, signaling to the research team that he was in fact engaging the muscles in the way PME intends. Like the other three subjects, S2 developed his own routine for practicing PME, yet his was more frequent with a much shorter duration: he trained roughly four times a day, for just one to two minutes at a time. The exercise he most often performed was opening and closing his phantom hand. It took only one minute before he started to feel the pain diminish. Still, S2 continued to take oxycodone to manage his pain every day. However, he has greatly decreased his intake of pain medications, halting his earlier use of morphine plasters and using low-dose tablets instead. Still, it appeared that PME exercises served as a supplement, while morphine remained his first-line treatment. Interestingly, even though they did not currently have an AR/VR device at home, S2 and his wife took meticulous care of its operating instructions, which they kept in a binder with pages laminated. In this binder, they had pictures of S2's stump with the electrodes placed in their optimal position for producing the clearest signals (his physiotherapist's idea). Even despite his current non-use of AR/VR device, S2 acknowledged its importance in initiating his own treatment practice. "Without the device, I would have never come up with this method," S2 said, referring to his "in-head exercises." S2's case testifies to the possible efficacy of PME independent of the therapeutic technology developed and traditionally used to facilitate it.

S3 was the subject who most enlists his family's help in the therapy's practice. His wife participated actively in each session, helping him set up the device, place the electrodes on his stump, and navigate the program's various activities on the laptop. His son was often involved as well, troubleshooting when the program has any technical difficulties, and was also the main point of contact between S3 and the researchers. S3 also created the most strictly regimented schedule for his PME treatments, built into his family's weekly routine: every Monday and Thursday, around 5 or 6pm, before dinner. Each training session, S3 began with a different leg movement. After completing the recording session, he skipped the Virtual Reality portion of the treatment, often preferring the Augmented Reality version. In fact, he spent a majority his time with AR/VR device using the Augmented Reality; he disliked the car racing game as he found it tedious and difficult to control ("I just kept crashing the car"). S3's son, who was actively involved in the treatment, encouraged his father to use the TAC test, reasoning that "it's better because there's something to follow . . . so you know what you're doing," but S3 seemed to prefer using the Augmented Reality for its videocam representation of himself, the room, and his virtual leg. The anthropologist visited S3 twice – first with the research team and then alone – and found that the patient responded positively to the research team's suggestions and advice with regards to adherence and motivation. On the first visit, the patient seemed to be struggling with the treatment and unabated pain. A researcher identified S3 failed to follow the treatment instructions. S3 had not been increasing the level of challenge by performing new movements. The researcher then stressed the importance of this progression for the efficacy of the therapy. On the follow-up visit, the anthropologist observed a marked behavioral, even emotional shift in the patient's interaction with the technology. S3's stamina and tolerance appeared much higher, he grew less frustrated with the system, and the overall sense of motivation, enjoyment, even "belief" (his own descriptor) in the therapy, seemed much higher by the end of the study. Concomitantly, the patient reported a "reduction" in his phantom pain in the weeks following the implementation of a refocused approach, as per the research team's advice. Of all in-home patients, it seemed that S3 and his family had folded the AR/VR device into their home environment in the most intimate way, with specific household arrangements that facilitated the technology's use. Unlike the other patients, who used their laptop screen for the

treatment, S3 broadcasted the AR/VR exercises from his laptop onto a large TV screen in the living room. His wife and he purchased the laptop specifically for using the PME software. They stored the laptop and device on a roller-cart, which they covered with a towel, the same towel that S3 later placed on top of a chair to sit on when he performs the treatment. S3 and his wife have appropriated other everyday home objects into helpful tools that enabled the use of the AR/VR device. Since the reference electrode placed on S3's wrist often slipped due to sweat, they regularly placed a rubber band around it. S3 and his wife pasted the AR-reference, a barcode-looking piece of paper used to track the virtual arm onto the webcam of the patient's body, onto the cover of an old hardcover book, which they placed at the foot of S3's chair when not in use. S3's wife also recorded S3's activity scores in a handwritten notebook, actively participating in her husband's treatment. This manual progress-tracking constituted a form of care and sociality formed around the therapy.

S4 began her in-home PME treatment on the suggestion of a friend who was familiar with the treatment. She began to notice that it was "working" (her term) when one night, two months after she started the treatment and for the first time in nine years, she forgot to take her oxycodone pill. To her surprise, she slept an entire night without pain. She then continued ceasing her pills for one month but kept practicing PME. Several weeks later, she also stopped her PME treatment, thinking "it had worked" and was no longer necessary. But one month later, the PLP and disrupted sleep returned. This initiated a period of titrating between oxycodone and PME. S4 took the pill on and off, and began training with AR/VR device again, just twice a month. Five months after initiating the in-home treatment, she had continued this titration process, moving between sporadic oxycodone use and sporadic PME training to regulate her pain. S4 found that when she is not taking oxycodone, she was "more awake, energetic, less groggy," and had more responsive reflexes. At the beginning of her treatment, S4's at-home PME sessions would last 1.5–2 hrs. After several treatments, she reduced their duration to 1–1.5 hrs. While at the outset she utilized all of the AR/VR device activities (VR, AR, TAC Test, and gaming), she preferred to use the TAC Test, finding it "most helpful and effective" and began focusing her time and energy solely on that activity. At the time of the interview, her PME regimen consisted of a recording session for multiple simultaneous movements and two to three rounds of the TAC Test, which takes her roughly 1 to 1.5 hrs. For S4, a decrease (or cessation) of oxycodone signified the efficacy of PME as a stand-in treatment. Her assessment of whether the treatment was "working" changed over the course of the study in proportion to her use of it (more consistent use correlated to greater perceived efficacy). Her approach to focusing on the TAC Test also evinced an optimization of the treatment to fit her needs, a personalization of the therapy. S4's affinity with the TAC Test spoke to her broader identity as a professional athlete, motivated by the pursuit of scoring points and reaching goals. As S4 explained, "The TAC Test is an exercise where you have to reach the goal." She described this goal-reaching aspect as motivating; a higher score yields greater satisfaction. After several months of using the AR/VR device, she expressed that she had identified how to reach a higher score: she must optimize the electrode placement positioning on her stump. S4's goal score for each treatment session was 100%; she repeated the test until she reached as close as possible and attempted to repeat this two or three times. As such, her treatment session was guided less by a specific set time length, or by the progression through the PME exercises, but by the achievement of her self-identified "goal" (100% on the TAC Test). S4 found the AR/VR device itself a bit cumbersome; the software was not compatible with her Mac laptop, so she had to borrow her grandmother's PC laptop. S4 learned to place the electrodes on her stump herself but enlisted the help of friends in their placement, as well as over Skype with the research team in Gothenburg.

The analysis of ethnographic research elucidated the following four key findings:

1. Subjects developed their own PME routines surrounding frequency of practice and which activities they prioritize (and deprioritize). These routines varied from several-minute micro-sessions practiced four times daily (S2), to regularly scheduled bi-weekly evening sessions (S3), to more sporadic ad-hoc use based on severity of pain and perceived "need" for the treatment (S1 and S4). Subjects worked the treatment into the contexts of their everyday lives and saw the value of being able to practice the therapy on their own time without having to travel to the clinic. At the same time, sometimes life "gets in the way" (S1) and postponing or skipping treatment sessions became easier when competing with the demands of everyday life.

When this disruption occured, returning or increasing pain signaled to those without a regular PME schedule the need to re-prioritize their treatment.

2. Subjects customized and personalized PME to fit their bodies, pain levels, personalities, interests, and lifestyles. In doing so, they cultivated ways to stay motivated and engaged in the therapy. Patients personalized by prioritizing the AR/VR device activities that best align with their needs. S1 performed all activities sequentially, emphasizing the AR configuration and gaming, gauging his performance by his ability to move the fourth and little fingers of his phantom hand independently. S2 performed PME independent of the AR/VR device, thus proving the potential viability of the therapy absent of the device and its activities. S3 focused almost exclusively on the AR configuration, which he enjoyed most for its real-world reflection of his home environment, but also performed the TAC Test on the encouragement of his son, who believed it was more goal-oriented and thus motivating. S4 prioritized the TAC Test for its feedback of a percentage-based score; the pursuit of 100% tapped into her athletic goal-oriented motivation.
3. For most subjects, PME fit within the wider context of a pain management regimen. For three out of the four subjects, it was a supplemental treatment used in the context of continued low-dose pain medications, abating the need for higher dosage. While S1 had completely ceased use of pain medication since using PME, S2 and S3 still took low-dose pain meds daily. For these subjects, PME was a supplemental treatment that allowed them to manage their pain on a lower dose. S4 vacillated between taking pain meds and using PME, but unlike S2 and S3, she alternated these treatments rather than using them concomitantly.
4. In-home, the device became "domesticated" materially, contextually, and socially. Subjects like S3 recruited and adapted everyday home objects (books, roller carts, rubber bands etc.) into supplemental objects in the use of the AR/VR device, folding in the device into the material context of the home. In this way, it can be said that the device took up residence in subjects' households. Family members (in the case of S1 and S3) participated in the treatment – actively, in the case of S3, whose wife navigated the software interface and placed the electrodes on her husband's limb, and passively, in the case of S1, whose wife reminded and encouraged him to practice the therapy regularly. Thus, it was not only the subject, but also family members who engaged with the device both directly and indirectly.

Identification of User Types

The information regarding the use of the system was extracted from the ethnographic unstructured interviews and analyzed using the KJ methodology: Figure 5 summarizes the resulting workflow.

Proceeding subject by subject, the anthropologist read aloud relevant sections of the unstructured interview referring to the use of the system. The user researcher wrote down quotes and paraphrased information on separate cards. After reviewing each subject interview, the user researcher then organized the cards according to the themes that emerged: Personalized Dosing, Assistance/Support System, Definition of Progress, Motivation, Faith in Therapy, Storage of Device, Patient Improvisation, Electrode Placement and Tracking Progress. After studying these nine themes, the user researcher and anthropologist searched for discrepancies in themes within the groups to create further subgroups. The categories with notable discrepancies in themes included subjects' approaches to personal dosing, their definition of progress, their faith in therapy and their motivations for performing the therapy. The data under these categories was then subdivided into the two user types: the goal-oriented user and the experiential user. For the remaining five categories, no subcategorization was needed.

These user types are archetypes, informed by but not directly reflecting any one individual patient, used solely to contextualize the functional requirements for the design of the user interface. In some cases, patients straddled the two user types. The survey results support these two user types and also demonstrate differences in the time patients spend on each AR/VR activity.

User Type I: Goal Oriented User

These users mark their progress with PME based on completion of a goal, rather than cumulative time passed, and prefer goal-oriented activities such as the TAC test over time-based activities like AR or VR. These users could be more interested in feedback from the therapy in terms of markers for completion of certain goals. S3 and S4 both

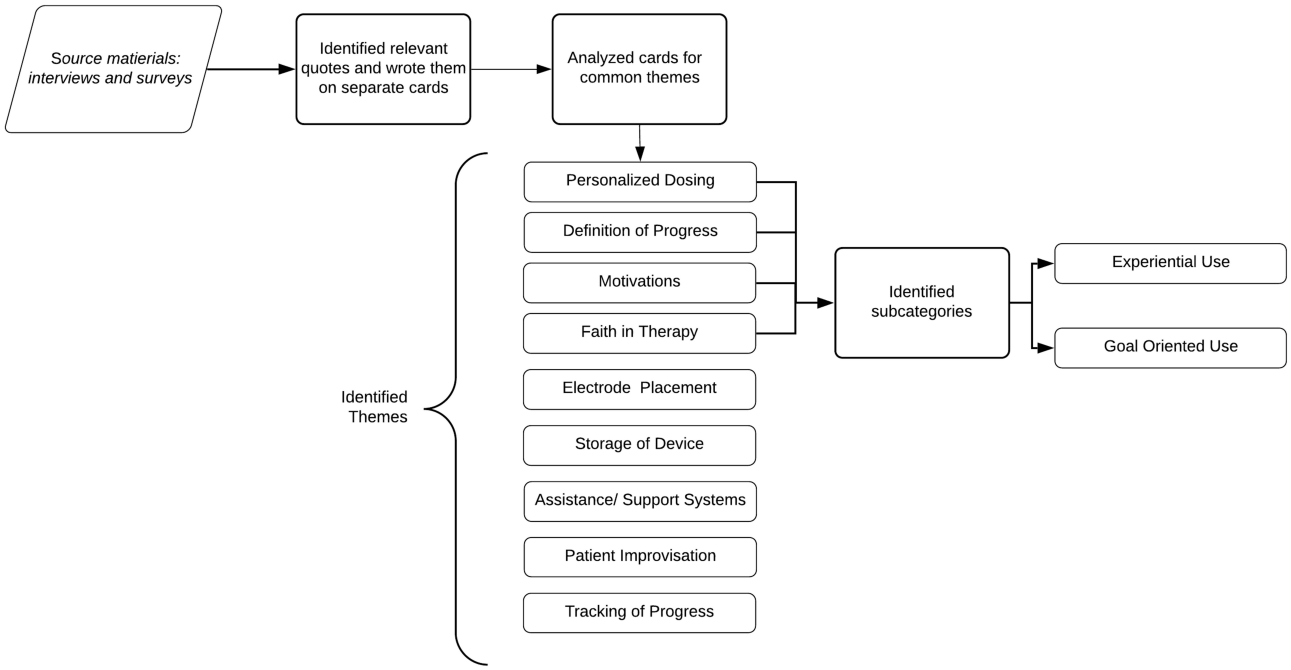

Figure 5 Flowchart presenting the steps and the results of the KJ analysis.

exhibit patterns of a goal-oriented user in that they both exhibit a preference to the TAC Test (see Table 1), in which the user strives to achieve a goal movement. While S3 identifies the TAC test as a preference, he also practices often with the AR limb, which also corresponds to User Type II patterns, indicating that user preferences are not always clear-cut between the two types.

User Type II: Experiential User

These users see the therapy regime through the scope of the AR experience, which renders the user's physical body and the virtual limb in the same screen using a webcam, also reflecting their actual environment. The Experiential User may place more importance on the realistic qualities of the AR limb in terms of sizing, colour and shape as well as how responsive and realistic the virtual limb is with regards to the user's perception of their phantom limb. This user will often base their practice more on a time marker than achieving a specific movement goal. This pattern of use was ascertained in observation of S3's preference for experiential practice through motor execution and S1s self- preference (see Table 1). It must be noted that patients may enter PME with previous experience from other forms of pain management therapies, including mirror therapy,[21–23] where visual feedback is considered the main conducive of pain relief: In these cases, the verisimilitude of the anthropomorphic feedback is of paramount importance. This introduces a potential discrepancy between the goal of PME therapy, which is based on the improvement of the motor execution, and the user's expectations and goals. This may translate into a preference for the anthropomorphic components of the PME therapy, such as the AR, disfavoring those components that do not involve a virtual limb, i.e. the racing game. Furthermore, mirror therapy sessions may be based off of practicing for a set amount of time rather than reaching a motor execution goal. In order to address this potential user bias and translate it into the new underlying theory of PME, a time-aware software interface should be developed in order to deliver feedback on the time spent at each level of movement difficulty (single degree of freedom movements, multiple degree of freedom movements, simultaneous movements) and motivate the patient to attempt more complex movements or to test their skills after the experiential practice.

Discussion

This study demonstrates the adaptability of a technological therapy (PME) to treat PLP in the home, where patients drive its usage. Hypotheses on the working mechanism of PME as a treatment of PLP, as well as for the genesis of the condition itself, have been discussed at length by Ortiz-Catalan along with clinical results and potential confounding factors.[1] The purpose of this study was not to

assess therapeutic efficacy but rather to interpret how a previously clinical therapy can be translated into home contexts, at the user's discretion. Subjects were instructed to use the AR/VR device at will, adapting it to their needs. The adherence data indicates that patients use the system more intensively in the first weeks of receiving the device, and then diminish their usage as pain decreases, as evidenced by lapses in use. Use is taken up again in an ad-hoc fashion, at need, often driven by the recurrence of pain. As a consequence, the pain graph might not necessarily depict how the treatment affects patients' pain, but rather how their pain level drives the use of the therapy. Treatment adherence, then, changes depending on patients' needs.

This tight coupling and interplay between pain, perceived need, and use requires a multidisciplinary approach. Alone, the pain rating does not reflect everything about the intricacies and motivations driving (or deterring) a patient's in-home device use. Therefore, we involved an anthropologist and user interface designer, along with their qualitative methodologies, to better understand use behaviors, patterns, and barriers. Their analysis indicates that users' profiles differ depending not only upon their needs, but also upon their motivations and daily life contexts. Patient adherence is especially important in this form of therapy because of the underlying mechanisms of PME.[1] This makes understanding and designing for different user groups and understanding user expectations a critical task to improving the adherence and outcome of the therapy regime at home.

The self-reported use preferences indicate two key barriers to adherence. The first is time. The therapy demands significant time (one to two hours per session), requiring the patient to incorporate the regimen into their everyday life. The second barrier is the need for reusable electrodes. The cost and availability of single-use electrodes can make the therapy prohibitively expensive or inaccessible and therefore could decrease adherence to therapy regime.

In order to design a device compatible with multiple user types, the following functions are recommended. For the Experiential User, a time display recording both duration and frequency will allow for tracking and recording within the interface. AR should be further developed to meet variations in skin color, nail color and size of limb, to expand relevance to wider, more diverse user populations and enhance their engagement. For the Goal Oriented User, feedback on results (i.e. movement accuracy measured by the TAC test, level of complexity of limb movement combinations) should be displayed to drive motivation. Additional goal-oriented activities and markers could recognize accuracy on different combination of movements. Indeed, the average number of limb movements shown in panel B of Figure 1–4 does not evidence any significant increase over time, indicating a need for the software to prompt the patients to increase difficulty.

Users should be enabled to set personal goals for the therapy using different measures of success (i.e. Increase Movement Accuracy, Decrease Pain, Improve Sleep Quality). User data (adherence, TAC scores, time) should be comprehensively presented as a form of feedback and self-monitoring. This underscores the need for ways to track long-term progress, considering breaks in therapy and consequent need to refresh PME skills. Finally, feedback on progression and level of complexity of movements needed in therapy will make treatment sessions more efficient.

The main limitations of this study include a small sample size (n=4). The inherent variability of patients' home situations makes generalizability difficult, but also serves to demonstrate the versatility and flexibility of both the device and its therapeutic applications. Patients have adapted the regimen to their home lives and developed personalized routines. This paper is a proof of concept. Future research should focus on a more systematic and robust investigation on the home use of the device, including compliance over a longer period of time.

Conclusion

This study holds methodological relevance for a broader research context beyond that of phantom limb pain. Healthcare services and therapeutic technologies are increasingly moving outside of the clinic into the home, a global trend growing with the digitization and development of artificial intelligence and user-friendly design. This domestication of health technology raises both new possibilities and challenges, as well as creates unprecedented encounters between humans and technologies in their own domain, demanding a new approach to studying these relations. This paper offers an example of how to study and monitor the use of such health technologies in the home. By including the social expertise of a medical anthropologist and the human-machine interface expertise of a user interface designer, we approach this phenomenon holistically adding a social perspective to a question that would normally be answered in terms of clinical and quantitative data. What emerges is a more nuanced picture of the motivations, barriers, and desires driving patient-led

in-home care, which in turns is used to design interventions that increase the technology's capacity and relevance.

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References

1. Ortiz-Catalan M. The stochastic entanglement and phantom motor execution hypotheses: a theoretical framework for the origin and treatment of phantom limb pain. *Front Neurol*. 2018;9:748. doi:10.3389/fneur.2018.00748
2. Valerio IL, Dumanian GA, Jordan SW, et al. Preemptive treatment of phantom and residual limb pain with targeted muscle reinnervation at the time of major limb amputation. *J Am Coll Surg*. 2019;228(3):217–226. doi:10.1016/j.jamcollsurg.2018.12.015
3. Woo SL, Kung TA, Brown DL, Leonard JA, Kelly BM, Cederna PS. Regenerative peripheral nerve interfaces for the treatment of postamputation neuroma pain. *Plast Reconstr Surg - Glob Open*. 2016;4(12):e1038. doi:10.1097/GOX.0000000000001038
4. Ives GC, Kung TA, Nghiem BT, et al. Current state of the surgical treatment of terminal neuromas. *Neurosurgery*. 2018;83(3):354–364. doi:10.1093/neuros/nyx500
5. Alviar MJM, Hale T, Lim-Dungca M. Pharmacologic interventions for treating phantom limb pain. *Cochrane Database Syst Rev*. 2016;10:CD006380. doi:10.1002/14651858.CD006380.pub3
6. Ortiz-Catalan M, Sander N, Kristoffersen MB, Håkansson B, Brånemark R. Treatment of phantom limb pain (PLP) based on augmented reality and gaming controlled by myoelectric pattern recognition: a case study of a chronic PLP patient. *Front Neurosci*. 2014. doi:10.3389/fnins.2014.00024388
7. Ortiz-Catalan M, Guðmundsdóttir RA, Kristoffersen MB, et al. Phantom motor execution facilitated by machine learning and augmented reality as treatment for phantom limb pain: a single group, clinical trial in patients with chronic intractable phantom limb pain. *Lancet*. 2016:2885–2894. doi:10.1016/S0140-6736(16)31598-7.
8. Lendaro E, Hermansson L, Burger H, et al. Phantom motor execution as a treatment for phantom limb pain: protocol of an international, double-blind, randomised controlled clinical trial. *BMJ Open*. 2018;8:7. doi:10.1136/bmjopen-2017-021039
9. Bassett SF. The assessment of patient adherence to physiotherapy rehabilitation. *NZ J Physiother*. 2003;31(2):60–66.
10. Lendaro E, Mastinu E, Håkansson B, Ortiz-Catalan M. Real-time classification of non-weight bearing lower limb movements using EMG to facilitate phantom motor execution: engineering and case study application on phantom limb pain. *Front Neurol*. 2017;8(September):1–12. doi:10.3389/fneur.2017.00470
11. Lendaro E, Ortiz Catalan M, Ortiz-Catalan M. Classification of non-weight bearing lower limb movements: towards a potential treatment for phantom limb pain based on myoelectric pattern recognition. *2016 38th Annu Int Conf IEEE Eng Med Biol Soc*. 2016;5457–5460. doi:10.1109/EMBC.2016.7591961
12. Simon AM, Hargrove LJ, Lock BA, Kuiken TA. Target achievement control test: evaluating real-time myoelectric pattern-recognition control of multifunctional upper-limb prostheses. *J Rehabil Res Dev*. 2011;48(6):619–627. doi:10.1682/JRRD.2010.08.0149
13. Ortiz-Catalan M, Brånemark R, Håkansson B. BioPatRec: a modular research platform for the control of artificial limbs based on pattern recognition algorithms. *Source Code Biol Med*. 2013;8(1):11. doi:10.1186/1751-0473-8-11
14. Melzack R. The short-form McGill pain questionnaire. *Pain*. 1987;30(2):191–197. doi:10.1016/0304-3959(87)91074-8
15. Firmin MW. Unstructured Interview. In: Given, LM (ed.) *THE Sage Encyclopedia of Qualitative Research Methods*. SAGE Publications, Inc; 2008;2:907 doi:10.4135/9781412963909.n475
16. Kleinman A. The illness narratives: suffering, healing, and the human condition. *Acad Med*. 2017;92(10): 1406. doi:10.1097/ACM.0000000000001864
17. Mattingly C, Garro LC. *Narrative and the Cultural Construction of Illness and Healing*. University of California Press; 2000.
18. Bernard HR. *Research Methods in Anthropology. 2nd* ed. AltaMira Press; 2011.
19. Hollan D. The relevance of person-centered ethnography to cross-cultural psychiatry. *Transcult Psychiatry*. 1997;34(2):219–234. doi:10.1177/136346159703400203
20. Scupin R. The KJ method: a technique for analyzing data derived from Japanese ethnology. *Hum Organ*. 1997;56(2):233–237. doi:10.17730/humo.56.2.x335923511444655
21. Ramachandran VS, Rogers-Ramachandran D. Synaesthesia in phantom limbs induced with mirrors. *Proc Biol Sci*. 1996;263(1369):377–386. doi:10.1098/rspb.1996.0058
22. Chan BL, Witt R, Charrow AP, et al. Mirror therapy for phantom limb pain. *N Engl J Med*. 2007;357(21):2206–2207. doi:10.1056/NEJMc071927
23. Finn SB, Perry BN, Clasing JE, et al. A randomized, controlled trial of mirror therapy for upper extremity phantom limb pain in male amputees. *Front Neurol*. 2017;8(JUL):1–7. doi:10.3389/fneur.2017.00267