User Performance With a Transradial Multi-Articulating Hand Prosthesis During Pattern Recognition and Direct Control Home Use

Ann M. Simon[®], *Member, IEEE*, Kristi L. Turner, Laura A. Miller[®], *Senior Member, IEEE*, Benjamin K. Potter, Mark D. Beachler, Gregory A. Dumanian, Levi J. Hargrove[®], *Member, IEEE*, and Todd A. Kuiken

Abstract-With the increasing availability of more advanced prostheses individuals with a transradial amputation can now be fit with single to multi-degree of freedom hands. Reliable and accurate control of these multi-grip hands still remains challenging. This is the first multi-user study to investigate at-home control and use of a multi-grip hand prosthesis under pattern recognition and direct control. Individuals with a transradial amputation were fitted with and trained to use an OSSUR i-Limb Ultra Revolution with Coapt COMPLETE CONTROL system. They participated in two 8-week home trials using the hand under myoelectric direct and pattern recognition control in a randomized order. While at home, participants demonstrated broader usage of grips in pattern recognition compared to direct control. After the home trial, they showed significant improvements in the Assessment of Capacity for Myoelectric Control (ACMC) outcome measure while using pattern recognition control compared to direct control; other outcome measures showed no differences between control styles. Additionally, this study provided a unique oppor-

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Ann M. Simon, Laura A. Miller, and Todd A. Kuiken are with the Shirley Ryan AbilityLab, Center for Bionic Medicine, Chicago, IL 60611 USA, and also with the Department of Physical Medicine and Rehabilitation, Northwestern University, Chicago, IL 60611 USA (e-mail: asimon@ sralab.org).

Kristi L. Turner is with the Shirley Ryan AbilityLab, Center for Bionic Medicine, Chicago, IL 60611 USA.

Benjamin K. Potter is with the Department of Surgery, Walter Reed National Military Medical Center, Uniformed Services University, Bethesda, MD 20889 USA.

Mark D. Beachler is with the Orthotic and Prosthetic Service, Department of Rehabilitation, Walter Reed National Military Medical Center, Bethesda, MD 20889 USA.

Gregory A. Dumanian is with the Division of Plastic Surgery, Northwestern Feinberg School of Medicine, Chicago, IL 60611 USA.

Levi J. Hargrove is with the Shirley Ryan AbilityLab, Center for Bionic Medicine, Chicago, IL 60611 USA, also with the Department of Physical Medicine and Rehabilitation, Northwestern University, Chicago, IL 60611 USA, and also with the Department of Biomedical Engineering, Northwestern University, Evanston, IL 60208 USA.

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tunity to evaluate EMG signals during home use. Offline analysis of calibration data showed that users were 81.5% [7.1] accurate across a range of three to five grips. Although EMG signal noise was identified during some calibrations, overall EMG quality was sufficient to provide users with control performance at or better than direct control.

Index Terms—Below-elbow amputation, home use, myoelectric control, prosthesis function, machine learning.

I. INTRODUCTION

TRANSRADIAL amputation, the most common major upper limb amputation [1], greatly affects an individual's functional ability mainly due to the loss of the hand. Single degree of freedom body-powered or myoelectric hand prostheses can provide users with the basic capability of opening and closing to manipulate objects. A prosthesis with more than one grip may be desirable because the function of a single degree of freedom hand falls drastically short of the complex movements the human hand typically performs with relative ease [2], [3]. The clinical availability of prosthetic hands with more degrees of freedom have substantially increased [4], [5], [6].

Since the forearm contains multiple extrinsic hand muscles there is a growing number of studies investigating myoelectric hand control with multiple grips [7]. With myoelectric control, information from remaining muscles in the residual limb can be used to control prosthesis movements. The most common type of control has historically been two-site threshold-based direct control. A user can contract an agonist-antagonist pair of muscles of the forearm, often the wrist flexors and extensors, to proportionately close and open a prosthetic hand [8], [9]. To operate a prosthetic hand with multiple grips, often a myoelectric switching strategy (e.g., co-contraction, hold open), a smartphone app, and/or a button on the hand is configured to cycle between or select grips.

Multi-site myoelectric pattern recognition-based control has been proposed as an alternative to direct control. Lab-based evaluations of the system have been performed since at least the 1960s, including the demonstration of function by 10 above-elbow amputees using wearable prototypes [10]. Home-based evaluations of a pattern recognition controlled

This work is licensed under a Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 License. For more information, see https://creativecommons.org/licenses/by-nc-nd/4.0/ wrist and hand has also been performed in the late 1970s; five transradial users who had previous experienced with myoelectric direct control were able to learn to control six wrist and hand movements with pattern recognition [11]. This study reported that a major limitation was that the control system was not self-contained within the prosthesis. Improvements in electronics componentry have allowed these limitations to be overcome resulting in efficient and selfcontained pattern recognition systems to be created in the early 1990s [12], and extended to real-time multichannel systems over the subsequent decade [13]. Pattern recognition systems have been suggested as a more intuitive myoelectric control strategy [14], [15]. Individuals with a transradial amputation can perform physiologically appropriate muscle contractions for the grip or individual finger movement they want to control; studies have demonstrated 79% accuracy for five transradial users across seven different finger movements [16] and 90% accuracy for one transradial user across individual finger flexion and extension movements [17] Additionally, using pattern recognition to control various combinations of hand and wrist motions have been investigated showing real-time control of a virtual [18], [19] or physical transradial prosthesis [20]. Reliable and accurate control of all available degrees of freedom available remains a challenge.

Few studies have directly compared various myoelectric control strategies with end users. Two studies have demonstrated that individuals with a transhumeral or transradial amputation have tended to perform better with pattern recognition compared to direct control [21], [22] and a separate study showed nearly identical outcomes between these two control methods when transradial amputees controlled a two degree of freedom system [23]. Another study controlling the multi-degree of freedom DEKA arm with pattern recognition control reported mixed user views on the usability and desirability of the system compared to the control of their own prescribed prosthesis control [24].

While the majority of pattern recognition studies are still performed in-lab (as it has been since the 1960s), almost a decade has passed since the first commercial EMG pattern product became available in 2014 [25]. There is a strong need to push the field forward by evaluating multi-grip prostheses after individuals have had the opportunity to use them for some time in their home environment. Research in this important area is growing and there are now more studies that include longer accommodation periods of at-home use of a multi-grip hand (although not comparing control styles). Probsting et al. [26] evaluated use of Michelangelo hand (seven hand positions and movable wrist) and found that after at least four weeks use, individuals with a transradial amputation had a reduced perceived level of difficulty performing many activities of daily living compared to their prescribed single degree of freedom terminal device. Resnik et al. [27] reported a discrepancy between patterns of DEKA hand grip usage during in-lab tests and up to three months of home use. For example, power grip was used more often at home (median use of 52%) than during to in-lab testing (21%) while pinch and lateral grip were used less at home (4% and 14%, respectively) than during in-lab testing (11% and 25%, respectively). Widehammar et al. [28] investigated the effect of multi- vs single-grip myoelectric prosthetic hands using the Ottobock Bebionic hand (14 grip types). Individuals with a transcarpal amputation controlled the hand using direct control including myoelectric switching (in combination with using a button on the hand) for the multigrip option. Over six months of home use, performance and satisfaction with the multi-grip hand increased over time. While it was possible for individuals to control the multi-grip hand with standard 2-site direct control, they did not evaluate grip switching nor whether users selected the appropriate grip [28].

To date, there is only a case study comparing at-home pattern recognition control and direct control of a multiarticulating hand [29]. In this study, a user with unilateral dysmelia learned to control four grips of an OSSUR i-Limb hand prosthesis, In comparison to direct control with switching, after five days of home use with pattern recognition they reported more intuitive control while selecting the grips but also some uncertainty during proportional continuous movement. This uncertainty may have contributed to the outcome assessment (i.e., ACMC) showing better use with direct control compared to pattern recognition. The goal of this paper was to perform the first multi-subject multi-week study aimed at comparing home use and prosthesis control of two different myoelectric strategies for a multi-grip prosthesis. Users with a transradial amputation completed two 8-week home trials while operating the device with 1) conventional, myoelectric direct control with switching and 2) myoelectric pattern recognition. Following each home trial, users completed a suite of outcome measures. For pattern recognition, analyses of users' calibrations were performed to gain a deeper understanding of the EMG signals recorded during home use.

II. METHODS

Individuals were recruited across the US and all fittings and study testing were conducted at the Shirley Ryan AbilityLab in Chicago, IL and Walter Reed National Military Medical Center in Bethesda, MD to participate in this study (ClinicalTrials.gov Identifier: NCT02349035). Inclusion criteria were: age 18-95, history of a unilateral upper limb amputation below the elbow, and the ability to use a prosthesis under myoelectric control. Individuals were excluded if they were unable to use a prosthesis, had cognitive impairments that would interfere with their understanding of study requirements, or any significant co-morbidity that would preclude completion of the study. The study was approved by the Institutional Review Boards of Northwestern University (STU00101444) and Walter Reed National Military Medical Center (IRBNet#410731). All subjects provided written informed consent.

Eleven individuals with a unilateral transradial amputation were enrolled in the study. Table I outlines subject demographics including home prescribed prostheses and typical usage with their myoelectric prosthesis. Eight subjects successfully completed the study protocol. One subject, TR6, withdrew due to not being able to meet the daily usage requirement. Two subjects were withdrawn by study personnel due to noncompliance: TR8 was unreachable during his second home trial

Subject	Gender	Years Post Amputation	Age	Etiology	Prescribed Prostheses	Prescribed Myoelectric Prosthesis		
Subject					Components	Control	Usage	Tasks
TR1	Male	0.8	42	Left Trauma	Sensor speed hand, Motion Control ETD and ottobock electric wrist rotator	Direct	Full-time	Dressing and cooking
TR2	Male	1	31	Right Trauma	Michelangelo Hand and ottobock AxonRotation wrist rotator	Direct	Part-time^	Laundry and cooking
TR3	Male	1	58	Right Trauma	Motion Control ETD	Direct	Full-time	Household chores and welding
TR4	Male	1.5	29	Left Trauma	Bebionic Hand; Body-powered	Coapt Pattern Recognition	Occasional^	Fishing reel and lifting
TR5	Male	1.5	29	Left Trauma	Bebionic Hand; Body-powered	Direct	n/a ⁺	n/a ⁺
TR6*	Male	1.5	36	Left Trauma	OSSUR i-Limb	Coapt Pattern Recognition	Full-time	Flying plane
TR7	Male	2.9	39	Left Trauma	Bebionic Hand, Motion Control ETD	Direct	Occasional	Yardwork and small repairs
TR8*	Male	3.4	40	Left Trauma	Bebionic Hand, Motion Control ETD	Direct	Part-time	Dressing and household chores
TR9*	Male	11	36	Left Trauma	Bebionic Hand, Ottobock Greifer, Motion Control ETD, Sensor speed hand; Body-powered	Direct	Full-time	Working on cars and electronics
TR10	Female	12	48	Right Trauma	Bebionic Hand, Motion Control ETD and Motion Control electric wrist rotator	Coapt Pattern Recognition	Full-time	Morning ADLs and cooking
TR11	Male	12.8	53	Right Trauma	OSSUR i-Limb, Sensor speed hand; Body-powered	Direct	Part-time	Work related tasks (installing computers)

TABLE I SUBJECT DEMOGRAPHICS

Prosthetic usage: Full-time (8+ hrs/day, 7 days per week); Part-time (4-8 hrs/day, 5-7 days per week); Occasional (less than 4 hrs/day, 1-7 days per week); Sporadic (at least once a month)

ETD: electric terminal device

*Withdrawn subjects

^TR2 and TR4 reported at study enrollment their prescribed myoelectric prostheses were not fitting well. Tasks reported were for when it fit; neither participant chose to resolve fit issues of their prescribed prosthesis with their home clinician during study participation.

⁺TR5 had just received his 1st prescribed myoelectric prosthesis simultaneously with study enrollment and therefore did not have typical usage to report

and did not return for outcomes testing and TR9 completed the study but indicated he was not trying to control nor use his prosthesis in a useful way during the home trials or outcomes testing.

A. Study Protocol

1) Prosthetic System: A certified prosthetist fitted all users with a multi-articulating hand (OSSUR i-Limb Ultra Revolution [30]), a passive wrist rotator, and a myoelectric controller (COMPLETE CONTROL Gen1 system by Coapt, LLC [25]). The COMPLETE CONTROL system is a clinically available pattern recognition system that was modified for this study to also allow for direct control and data logging. Eight electromyography (EMG) electrode pairs were embedded into a flexible inner liner and socket. To use the same socket and electrode setup for both direct and pattern recognition control, care was taken when determining the location of electrodes. Two electrode pairs were placed over the wrist flexors and extensors for threshold-based direct control; direct control only accessed these two channels. The remaining six electrodes were placed over remaining residual limb forearm muscles; pattern recognition control accessed all eight channels

For direct control, channel gains and thresholds were configured in a dual-differential or a first-over strategy for proportional control [9]. To switch between a default grip and other grips, up to four triggers (hold hand open, double and triple hand open pulse, and co-contraction) were configured. Participants switched between grips when the hand was fully open. Clinical judgment and user feedback were used to determine the number of triggers and ultimately the number of grips each individual would use, as well as which grip would be assigned to each trigger. Direct control settings were modified as necessary during in-lab training or testing during pre- and post-home trial visits but not modified at home.

For pattern recognition control, participants auto-calibrated their control at any time by making natural muscle contractions that followed along with a series of pre-programmed grips [31], [32]. This auto-calibration process recorded and auto-labeled myoelectric data for each trained grip. A well-established classification system [12], [33] was trained which used 200 ms analysis windows with a 25 ms update increment, extracted time domain and auto regressive features, and classified data using a linear discriminant analysis classifier [15], [34], [35]. Hand speed control was proportional to the



Fig. 1. Participants using their multi-grip hand prosthesis under pattern recognition and direct control. Participants gave permission for the use of their identifiable images.

EMG activity [36]. To switch between grips users sustained a 'hand open' muscle contraction which moved the hand to a baseline/natural hand position before performing the muscle contraction for the new desired grip. This scheme balanced the potential desire to remain in a grip even if the hand was fully open (similar to direct control) and only switch to a new grip following a sustained hold open. Clinical judgment and user feedback were used to determine the maximum number of grips and which grips the individual would use. Users had the ability to auto-calibration in the lab or at home whenever they desired.

2) Pre-Home Trial Training: Participants were educated on and practiced with both direct and pattern recognition control strategies, regardless of the style of control of their prescribed device. Individuals participated in therapy (Fig. 1) with certified and licensed occupational therapist to learn how to properly control the multi-articulating hand under both myoelectric direct control (DC) and pattern recognition control (PR) and how to best incorporate their prosthesis into their activities of daily living. To avoid training biases (e.g., some therapists may be more highly trained with direct control compared to pattern recognition control), the same occupational therapist who has extensive experience in training both control styles trained and tested all participants. They received a minimum of four training sessions for a total training time of 8-12 hours prior to each 8-week home trial. During training users performed a variety of functional tasks to ensure proficiency of each control type. Training was considered complete and the user ready to start the home trial once he or she was able to reliably operate all the functions of the prosthesis and perform functional tasks with the prosthesis. Additionally with pattern recognition control users also needed to demonstrate understanding of the calibration process (e.g., when calibration may be needed, how to calibrate, etc). Completion of training was at the discretion of the occupational therapist with input from the user on comfort of use.

The order of control type was randomized. A reduced set of 8 of the 24 available i-Limb grips [30] were available including lateral, power, thumb precision pinch opened and closed, thumb 3 jaw chuck opened and closed, standard 3 jaw chuck closed, and index point. Of note, all users had up to five triggers that could be assigned in direct control; this was the total that was possible without other aids (app, button, grip chips, etc). For pattern recognition, the system was capable of having all 8 grips configured if users were able to control them, however the maximum configured and reliably controlled by any participant was four. For each user, grips assigned during direct control did not always match grips assigned during pattern recognition control. To more clearly define any differences between myoelectric control strategies, no alternative methods of changing grips (e.g., grip chips, IMU based gesture control, smartphone application, etc.) were used.

3) Home Trial: During each 8-week home trial, participants were required to check-in regularly with an occupational therapist, maintain an average daily usage of at least two hours per day, and log the activities they were performing with their prosthesis. Users were also asked to denote any grip(s) that were difficult to control and to rate their overall prosthesis function on a scale of 1-10 where 1 corresponded to poor function and 10 corresponded to great function. Usage data was recorded on the embedded controller. Because the study device included different degrees of freedom than their prescribed prosthesis, participants were allowed to continue use of this device. We did not track use of their prescribed prosthesis.

4) Post-Home Trial Assessments: Following each home trial, participants returned to the lab for assessments. Since there is not one upper limb outcome measure that captures all prosthetic function [37], we tested a suite of outcome measures in order to get a more representative picture of how differences in grip control effected prosthesis control. These measures included:

- Southampton Hand Assessment Procedure (SHAP) evaluates unilateral hand function [38]. Abstract object manipulation and activities of daily living are timed by the subject. Scores are compared to a normalized, able-bodied control score of 100.
- Jebsen-Taylor Hand Function Test evaluates hand function. Seven hand-related tasks utilizing common items such as cards, cans, paper clips, and coins are timed [39].
- Assessment of Capacity for Myoelectric Control (ACMC) evaluates control a myoelectric hand. An observational assessment of the ability to control gripping, holding, releasing and coordinating 30 items is scored on a 4-point capability scale [40], [41]. Rasch analysis converts capability ratings to a single measure of each user's functional ability.
- Modified Box and Block Test of Manual Dexterity evaluates gross manual dexterity. One-inch blocks are moved one at a time from one side of a box to the other over a wooden partition [42]. The final score is the number of blocks transferred in 1 minute, typically averaged over three trials.
- Activities Measure for Upper Limb Amputees (AM-ULA) evaluates the performance of daily functional activities using the prosthesis and is graded on a scale of 0-4 (unable to excellent) [43].

A higher score for the SHAP, ACMC, AM-ULA, and Box and Blocks and a lower score for the Jebsen-Taylor indicated better function or control.

Since commercially available pattern recognition systems provide users the advantage of recalibrating at any time, this important feature was included during home trial and assessment. To parallel clinically available direct control, control parameters were only modified during their prosthetic or laboratory visits. If the clinicians and/or participant agreed modifications of their direct control settings were necessary prior to starting outcomes, changes were made. For both styles of control, no changes to grip configurations were made once home trial ended and outcomes began.

B. Data Analysis

During the home trial, prosthesis daily usage data was logged on the device. Measures included the duration of time the prosthesis was turned on, which grip(s) were used and the speed at which the hand was commanded to move. From these data, we calculated average daily wear time as the total number of hours the device was turned on divided by the total number of days the device was turned on. For pattern recognition control, the number of times the prosthesis was recalibrated and the raw EMG recorded during calibration were logged. Since the configured grips for each user were selected based on the most functional grips for their own activities of daily living, the time spent in each grip was ranked in order of descending usage and the percentage of time spent in each grip was calculated.

EMG recorded during pattern recognition calibration was analyzed to measure offline classification accuracy. A leaveone-out-cross-validation analysis was performed across all calibrations performed in each quarter of the home trial. Confusion matrices for each subject were created in order to investigate whether there were trends in accuracy of different grips and whether those trends remained varied across the duration of the home trial.

Calibration EMG data were also used to investigate potential signal noise and user timing issues that may have occurred at home. Signal noise issues included higher presence of 60 Hz noise (i.e., higher baseline signal noise), poor skin/electrode impedance matching, intermittent electrode contact, faulty wire. User timing issues included non-trivial muscle activity recorded during the no movement/rest portion of the calibration (i.e., amplitude near equivalent to the lowest amplitude grip muscle pattern), missing contractions (e.g., no muscle activity during an expected movement portion of the calibration), and/or calibration timing issues (e.g., one muscle contraction(s) recorded across two different calibrated movements, or when muscle contraction starts too early or ends too late).

To compare cumulative wear time, average daily wear-time, number days powered on and number of configured grips, between direct and pattern recognition control, we performed a repeated measures analysis of variance (ANOVA) with subject as a random factor, control type (DC, PR) and order as fixed factors. To compare outcome measures between direct and pattern recognition control, we performed a repeated measures

TABLE II HOME USE DATA

Metric	Direct Control	Pattern Recognition Control	
Number of grips configured*	4.8 [0.5]	3.8 [0.7]	
Home trial length, days	75.5 [12.6]	68.6 [8.6]	
Days powered on	48.9 [13.3]	47.5 [15.9]	
Cumulative hours powered on	216.7 [55.7]	247.4 [60.6]	
Overall user rating	7.5 [0.7]	8.0 [0.9]	
[1=poor, 10=great]			
1 st quarter	7.0 [1.3]	7.5 [1.5]	
2 nd quarter	7.5 [1.3]	8.1 [0.9]	
3 rd quarter	7.6 [0.5]	8.2[0.7]	
4th quarter	7.5 [0.5]	8.3 [0.8]	
Overall Classification Accuracy, %	n/a	81.5 [7.1]	
1 st quarter		81.8 [6.1]	
2 nd quarter		80.8 [9.1]	
3 rd quarter		82.7 [9.3]	
4th quarter		84.8 [5.6]	

*indicates significant difference between control, p<0.05

analysis of variance (ANOVA) with subject as a random factor, control type (DC, PR) and order as fixed factors, and the average daily wear time, testing order, and control condition of the users' prescribed prosthesis as a covariate. As the average daily wear-time was found to be non-significant, it was removed from the model.

III. RESULTS

A. Home Usage

Participants reported successfully using the multiarticulating hand prosthesis for similar activities across the duration of the study protocol for both control conditions. These activities included housework (e.g., washing and folding laundry, sweeping, mopping, vacuuming), meal preparation, self-care (e.g., dressing, grooming, cutting food), yardwork (e.g., mowing lawn), grocery shopping, and for employment including office work (e.g., filing papers, typing) and holding small tools for maintenance work. Usage data logged on the device during the home trials showed no significant difference in cumulative hours powered on or on the average daily on time between control conditions (Table II) (p > 0.05). Participants rated their overall prosthesis function for direct control as 7.5 [0.7] and for pattern recognition as 8.0 [0.9]. These ratings remained fairly consistent across the duration of the home trial, with pattern recognition increasing slightly each quarter (Table II). At the conclusion of the study, seven of the eight subjects (all except TR3) stated they preferred pattern recognition over direct control.

The three most commonly configured grips, were power, thumb precision pinch closed, and standard 3 jaw chuck closed (Fig. 2A). On average, more grips were configured for direct control (Table II, p = 0.02); however, while using the multi-articulating hand at home, participants demonstrated broader usage of grips in pattern recognition compared to direct control (Fig. 2A & 2B). Participants spent 83.0% [1.9] of the time at home in a single grip (i.e., most-used grip) for direct control,



Fig. 2. Home use grip usage including A) configured grips for each subject displayed with the percentage of usage time associated with direct control and pattern recognition control and B) average grip usage across all users with grips ranked in descending usage order for direct control and pattern recognition. Grey shading indicates results from direct control and blue shading indicates results from pattern recognition control.



Fig. 3. Outcomes using direct (*grey*) and pattern recognition (*blue*) control. The ACMC showed significantly improved control for pattern recognition compared to direct control (*p < 0.05).

11.5% [1.3] of the time in their second most used grip, and 4.1% [1.1] of the time in their third most used grip. For pattern recognition control, usage at home was spread out across a larger number of grips with approximately 56.1% [6.6] of the time spent in the preferred grip, and 23.4% [3.5] and 16.5% [3.4] of time spent in the 2nd and 3rd most used grips, respectively.

B. Outcome Measures

Testing order and control of the users' home prescribed prosthesis were found to be not significant and therefore these covariates were removed from the model. Analyzing outcome measures showed significant differences between control conditions (Fig. 3); users scored significantly better control with pattern recognition compared to direct control (DC: 48.3 [3.4]; PR: (58.7 [2.2], p = 0.017). The Box and Blocks (DC: 35.9 [2.6]; PR: 37.7 blocks [2.9]; p = 0.75), AMULA (DC: 19.7 [0.5]; PR: 21.1 [1.0]; p = 0.16), Jebsen-Taylor (DC: 264.5 sec [22.6]; PR: 226.4 sec [17.7], p = 0.35), and SHAP (DC: 36.6 [2.3]; PR: 35.4 [2.5], p = 0.697) showed no significant

differences between control. For pattern recognition control seven of eight users recalibrated in between tasks in the assessments an average of 3.9 [3.5] times. For direct control a prosthetist adjusted settings (gains or thresholds) for one of eight users prior to beginning outcomes.

C. Signal Quality During Pattern Recognition Calibration

During the pattern recognition home trial, the amount of times users calibrated their prosthesis was highly variable. Median value was 18.0 with an interquartile range of 11.75 to 36. TR5 only calibrated one time at home and TR2 calibrated his prosthesis the most often with 97 calibration sessions at home. An example of raw EMG recorded during calibration of four grip patterns with no signal quality issues identified is shown in Fig. 4A. The figure additionally shows examples of various types of signal noise (Fig. 4B) and user timing (Fig. 4C) issues identified during analysis. Fig. 5 displays, in counts per user, how many times both noise and user timing issues were identified.

D. Calibration Offline Classification Accuracy

Figure 6 displays the offline accuracy confusion matrices and the grips identified via home logs as difficult to control in real-time of each user across each quarter of the home trial. The majority of grips for all users had accuracies above 70% with many in the 85% to 95% range. Average classification accuracy across all users 81.5% [7.1].

IV. DISCUSSION

To the authors knowledge this is the first multi-user study to evaluate multi-grip control at home with two different myoelectric control strategies. While pattern recognition control did not increase the total number of grips a user had access to, users did access more varied grips with pattern recognition compared to direct control. Due to using natural muscle contraction patterns paired with similar prosthesis



Fig. 4. Example EMG calibration data from all 8 signals recorded during home use. A) Data recorded from one user calibrating 4 grips (Key, Power, Tripod Closed, and Precision Pinch Closed) grips with no issues identified. Other calibrations demonstrate examples of B) signal noise and C) user timing issues.



Fig. 5. Number of calibrations per subject where any issues (*top*), signal noise issues (*middle*), and user timing issues (*bottom*) were identified. The number of calibrations was highly variable between subjects.

grips, pattern recognition may encourage users to access a more useful or functional grip for their activities of daily living. These data, recorded at home, provide an insight into how an individual truly translates at home what is setup for them in the laboratory or clinic.

During our in-lab clinical testing, users showed a significant improvement of 21% (representing an average score increase of 10.4 [2.9] in the ACMC. The ACMC was included because of its ability to measure skill in prosthesis control and flow of movement including the user's ability to grasp, release, and hold items in multiple planes of movement [40]. For this test, users are encouraged to use their prosthetic hand as much as possible throughout the assessment. The significant increase found in this study may be a result of users accessing and therefore having more practice with more grips using pattern recognition control. In contrast, a case study using four grips of the i-Limb Ultra hand showed better prosthesis performance in the ACMC with direct control compared to pattern recognition following five days of pattern recognition home use [29].

In contrast to user preference which indicated 7 of 8 participants favored consistently rated pattern recognition higher than direct control while at home and the same subjects preferring pattern recognition at the end of the study, the other outcomes assessed showed no difference between control types. For some tests, this is not surprising. For example, the Box and Blocks task does not require changing grips; there would be no reason to believe that performance would be different between control types but including this comparison was still important. One might expect pattern recognition to perform more poorly if misclassification caused the hand to change grips erroneously. Our results confirm that pattern recognition did not degrade simple one degree of freedom hand movements. For the SHAP, it is possible to achieve high scores by performing compensatory movements or completing components of the test without using the most functionally appropriate grips. For this study in direct control the hand started in the users default grip (i.e., power grip for the majority of users) and with pattern recognition the hand started in a relaxed hand open position where users had to perform the muscle contraction of the grip they desired. For either control style, there is the possibility some participants just completed the task with whichever grip was selected first. One study showed that users could perform well in the SHAP using only a single degree of freedom terminal device [44] which requires no grip switching. The AM-ULA evaluates skillfulness and speed of movement and we expected a difference between the two control strategies. For this test, a user completes a series of activities of daily living in which they are either encouraged to use their prosthesis to complete bilateral tasks and asked to use only their prosthesis to complete unilateral tasks and ask time is not measured or constrained [43]. The AM-ULA trended towards improved control with pattern recognition but this potential difference was not statistically significant. Perhaps other outcome measures that explicitly measured body compensations, such as the Gaze and Movement Assessment [45], or inclusion of a powered wrist rotator, may reveal more notable differences between control types.

The choice of not using a powered wrist rotator likely impacted overall performance for both conditions. Controlling a powered wrist via direct or pattern recognition might have contributed to additional differences seen during outcome measures. For direct control users would need to access the wrist via either another myoelectric switch (or replace a grip with wrist control). With pattern recognition control users could implement seamless sequential control to go back and forth between hand and wrist movements. This choice may have especially impacted the three subjects who use a powered wrist with their prescribed device. Pre-positioning of the passive wrist rotation was allowed prior to starting tasks, however was not allowed to complete the task. For example, SHAP page turning, they were allowed to pre-position the hand/wrist after the timer was started but not use the passive wrist to complete the turning of the page. For the ACMC, pre-positioning was allowed throughout the evaluation. Although reliable and accurate control of the wrist in combination with multiple grips still remains rather challenging regardless of control modality, preliminary work on intact-limbed individuals demonstrates





improved performance with additional degrees of freedom at the wrist [46]. Additionally had we measured users' baseline control with their prescribed prosthesis we may have been able to better define changes in control due to study prosthesis components.

The pattern recognition portion of the study provided a unique opportunity to evaluate EMG and user calibrations during home use. An offline analysis of these calibrations showed that users were fairly accurate with their grip control (average 81.5%) and that this remained fairly constant throughout the duration of the home trial. The grips users felt hard to control (Fig. 6) weren't always the grips with the lowest accuracy. This is likely the difference between offline analysis of these calibration sessions and real-time control. Unfortunately we were unable to measure misclassification during home use without constant knowledge of the users' intent. One novel study with a similar pattern recognition control subjectively logged errors and the user's intended grip via a button during real-time home use of four grips of the i-Limb Ultra [29]. The user reported four to six errors in grip control across five consecutive days. While something similar could have been helpful in this study, the logging of errors in this way likely interfered with natural use.

It is hard to determine if or how much the individuals' choices to calibrate both at home and during outcomes effected their control and whether recalibration truly was necessary. Users may have chosen to recalibrate because of poor control (potentially due to fatigue, arm position, etc) or simply because they were used to recalibrating often. The benefit of pattern recognition is that it not only provides this choice to the user, letting them feel more in control of their own device, but also that the calibration procedure doesn't take long (under a minute, with less time when less grips are configured).

Early concerns regarding clinical viability of pattern recognition included potential difficulties maintaining quality EMG signals on more than the two channels necessary for direct control. While the reliance on clean EMG signals and the potential for signal noise via faulty wires or the electrodeskin interface (e.g., electrodes picking up 60 Hz interference or poor electrode impedance matching [47]) are well known in the field, data of how often these signal characteristics occur during home use has thus far been unreported. In this study we confirm that while maintaining good electrode connection with eight bipolar EMG channels is difficult, the EMG still resulted in usable pattern recognition control as evidence by the fact that even with some signal issues, pattern recognition control was at least as good as, or for some outcomes significantly better than, direct control.

While certain calibrations demonstrate EMG quality below laboratory-based standards, many of these calibrations still result in satisfactory prosthesis control. Usage at home likely depends more on the consistency of these issues; an intermittent signal issue, or one that was present during calibration but then resolves itself during use, can lead to poor control whereas a consistent signal issue, or one that is consistently present during calibration and subsequent use may be unnoticeable to the user. This idea was reinforced during an in-lab test demonstrating that amputee users maintained prosthesis function following simulated signal issues on at least two of the eight available signals [48].

Similarly user timing issues do not automatically imply poor control. Many users are in fact encouraged to move their arm freely around the workspace during each movement of calibration, including rest [49]. Finding the right balance of optimal movement is critical. Too much activity during rest, especially if the overall magnitude of EMG activity recorded is at or above the magnitude of EMG activity for a desired motion class, raises the threshold for the pattern recognition controller to be able to distinguish motion from no motion [50]. This has the potential to make activating an intended motion difficult, since the threshold for movement can become high. But the right amount of arm movement for the rest or the "no motion" portion of calibration can raise the motion threshold just enough to reduce inadvertent movements of the prosthesis. Alternative approaches to automatic categorize training data as corresponding to a resting or active category could help mitigate these issues.

An important finding from the at-home calibrations was that identifying signal or timing issues closer to their onset could further improve user pattern recognition control and user experience. These study data were stored on the prosthesis during the 8-week home trial and thus unavailable for real-time analysis and feedback. Since completing this study, mobile phone applications have become available to inform users of calibration quality immediately and provide signal quality indicators to both the user and clinician [51]. An even more powerful alternative would be a cloud-connected health system whereby a clinical or research team could remotely access device data in a timely manner such that a resolution could be proposed; a prosthetist can remotely identify poor fit issues and faulty wires [52] and recall the study participant or just the device to address the issue(s), a therapist can identify user calibration issues in order to provide subject-specific training to improve their muscle contraction timing, or, if accessible, device settings can be remotely adjusted. Furthermore, purely knowing the number of times a user has calibrated can be important to a clinician. For example, had this been in place for this study, a therapist could have intervened to question why TR2 was calibrating so often (97 times during the 8-week home trial) or why TR5 had only calibrated one time in 8 weeks (even if only to confirm continued function). TR2's high number of calibrations was due to poor control caused by electrode liftoff; TR2 often calibrated five to eight times in a row before he reached out to the occupational therapist and/or prosthetist for assistance. Once study personnel were aware of the electrode liftoff and socket fit issues they attempted to resolve them but ongoing fit issues remained during the first half of his home trial. Once these issues were finally resolved TR2's number of calibrations drastically decreased; during the last half of the home trial, TR2 only calibrated on 4 separate days. TR5 chose not to calibrate over the majority of the home trial because he was happy with the daily performance of the prosthesis.

Our study on the comparison of direct control to pattern recognition had some limitations. All users had access to their prescribed prosthesis but we did not track how often these devices were used during the home trials. Four of the eight participants (TR3, TR5, TR10, TR11) reported regularly switching back to their prescribed device (body powered or ETD) mostly to complete heavy duty tasks or tasks that were too rough on the multi-grip hand. For the other four, two participants (TR2 and TR4) did not switch to their prescribed device because it remained ill-fitting during the study and we are unsure of the remaining two (TR1 and TR7). Switching may have caused an additional cognitive burden for users when their prescribed prosthesis was configured under the opposite control type as the study prosthesis. Although the order of control conditions was randomized and order found to be not significant, users may still have been learning how to use the multi-articulating hand and/or the control throughout the 8-week trial or learning the outcome measures. It was found that able-body participants did better at performing the SHAP after completing it five days in a row [53], although it is unclear the impact when assessments were completed 2-3 months apart. Another limitation of the study was the low number of enrolled subjects likely reduced our power for detecting changes between control conditions.

The electronic usage data was limited due to the type of data logging available. We were unable to distinguish between *wear* time (i.e., wearing the prosthesis) and *use* time (i.e., using the prosthesis to accomplish a task) and instead were able to record *on* time (i.e., prosthesis powered on). These three measurements are different and we are unable to know if *wear* or *use* time differed by control condition. Similarly, while we measured the time spent in each grip we were unable to distinguish how the grips were being used, if switching most often occurred between more similar grips (e.g., 3 jaw chuck closed and precision pinch closed) or more different grips (e.g., precision pinch and lateral grasp) and if that varied by control condition.

V. CONCLUSION

This study provided critical insight into the control and home use of multi-articulating hand prosthesis. Users demonstrated broader use of a variety grips at home and significant improvements in the ACMC outcome measure while controlling their prosthesis with pattern recognition compared to direct control. At-home pattern recognition calibration data revealed that although signal noise and user timing issues were identified on some calibrations, overall EMG quality was sufficient to provide users with control performance at or better than direct control. Since these data were collected in home they provide a more accurate story of how well EMG signals can be maintained during true daily use. Additionally, these calibration sessions highlight an opportunity for near realtime analysis and user feedback that could provide additional information to resolve device or user errors and/or accelerate user training.

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DISCLOSURE

Coapt LLC was launched in 2012 and has a technology transfer and license agreement with the Shirley Ryan AbilityLab for the development of certain control technologies. T.A. Kuiken and L.J. Hargrove in the Center for Bionic Medicine at Shirley Ryan AbilityLab are responsible for the design, conduct and reporting of this research, and also have financial, management and ownership interests in Coapt LLC, which manufactures the device being tested in this research. These interests have been fully disclosed to Shirley Ryan AbilityLab and Northwestern University, and there is a conflict of interest management plan in place relative to this research study.

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