Creating an evidence-based training protocol for upper limb bypass prostheses

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INTRODUCTION

Over the last 10 years, interest in the field of upper limb prostheses has increased tremendously, with publications on the topic nearly doubling. Potentially important to the continuation of this trend is the use of bypass prostheses in human subject research. A bypass prosthesis allows a non-disabled user to activate a specific type of terminal device with similar body motions that an amputee would use to operate a custom-made prosthesis. Several studies have used body-powered and myoelectric-controlled upper limb bypass prostheses to allow for a direct comparison between prosthetic hand and intact hand performance, and to increase the number of readily available subjects to obtain greater statistical power [1-6]. Similar to custom-made prostheses for amputees, bypass prostheses require significant training for proper use. However, standardized bypass training protocols don't yet exist. Additionally, training for amputees typically occurs in a rehabilitation setting with a specialized occupational therapist, a resource that may not be easily accessible to researchers [7]. The development of a standardized, quantitative training protocol would allow for more widespread use of bypasses in research by reducing the training expertise barrier and could improve confidence in the translatability of performance results obtained from able-bodied bypass prosthesis users to upper limb amputee prosthesis users.

Explicit scripting of training tasks from existing studies and rehabilitation guidelines can readily produce standardized content. However, quantitative assessments to benchmark competency are less established [8]. The Southampton Hand Assessment Procedure (SHAP) is one of a few quantitative assessments developed specifically to assess upper limb prosthesis function relative to normal hand function [9]. The SHAP, while originally designed for and validated in the myoelectric user population, can be applied to body-powered users with some minor changes as described in the methods section. The assessment itself is a compilation of self-timed abstract object tasks and activities of daily living (ADLs). Times for each task are transformed into individual scores, which can track performance throughout a training program.

The current study presented in this paper focuses on training of able-bodied subjects in the use of a body-powered bypass prosthesis. Details of the standard training protocol developed for this purpose are provided, as well as a preliminary analysis of performance for each subject. Specifically, we were interested in assessing performance as a function of training session to recommend the minimum number of sessions required for subjects to become proficient in the use of the device prior to enrollment in an upper limb bypass prosthesis study.

METHODS

Subjects

For the current study, 4 right-handed subjects (3 female, 1 male; mean age 28.75 ± 3.20 years) with no upper limb disability were asked to participate in the bypass training. Advanced Arm Dynamics (Dallas, TX) provided the body powered bypass prosthesis, featuring a Hosmer 5X hook terminal device (Figure 1). The bypass prosthesis was designed with a distal offset of 12 cm. Two rubber bands were maintained for all subjects to generate passive closure of the hook. The study was approved by the Institutional Review Board (Research Involving Human Subjects Committee) of the U.S. Food and Drug Administration (RIHSC #14-086R). All subjects provided written informed consent prior to participating in the study.

Figure 1. Body powered bypass prosthesis

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Session 1	Session 2	Sessions 3, 4, 5
1. Device orientation	1. Use checkpoint	1. Use checkpoint
2. Use checkpoint	2. Random order object manipulation	2. Random order object manipulation
3. Blocked order object manipulation	3. Free training	3. Free training
4. Free training	4. Blocked order ADLs	4. Random order ADLs
5. mSHAP	5. mSHAP	5. mSHAP

Figure 2. Session structure

Training Protocol

Subjects completed 5 training sessions, each approximately 2 hours long, over an average span of 22 days. The content of the sessions is organized into device orientation, use checkpoint, basic object manipulation, free training, ADLs, and the modified SHAP (mSHAP). Figure 2 shows the structure of each session. A more detailed description of the training content is provided below.

Device Orientation

Device orientation introduced the componentry of the device, the ability to change the orientation of the terminal device (TD), and the body control motions used to open and close the TD.

Use Checkpoint

A short quiz was used to ensure memorization of the device orientation content and required subjects to demonstrate TD adjustments, the various body control motions, and TD opening and closing in various situations.

Basic Object Manipulation

Basic object manipulation tasks were adapted from existing experimental protocols and were based on three main functions of the prosthesis: direct grasping (DG), indirect grasping (IG), and fixation (FIX) [10]. DG and IG tasks were completed using three distinct objects (a foam ball, a wooden block, and a metal can). FIX tasks were completed using three distinct task designs (using a ruler, using a zipper, and unbuttoning). Subjects initially performed four trials per object/task design in a blocked order beginning with IG, then DG, then FIX. In all following sessions, two trials per object/task combination were performed in a random order. A table template was used to standardize the initial and final locations of objects.

Free Training

Free training was a 10-minute period (five min standing; five min seated) of unstructured time for the subject to experiment with the prosthesis. Subjects were encouraged to interact with a variety of objects placed on the table ranging from binder clips to a Rubik's cube.

ADLs

Eight ADLs from the Activities Measure for Upper Limb Amputees (AM-ULA) [11] and 4 additional ADLs (using a fork, using a spoon, using a tape measure, and opening a bag) designed by the FDA research team were used during a 20-minute ADL section of training sessions. ADLs were considered either unilateral or bilateral. In initial ADL training, two trials per ADL were performed in blocked order with unilateral tasks preceding bilateral tasks. In following sessions, two trials per ADL were performed in random order. In both cases, as many ADLs as time allowed within the 20-minute period were performed.

mSHAP

The SHAP was altered to accommodate its use with body-powered bypass prostheses, creating the modified SHAP (mSHAP). Modifications included the elimination of three tasks from the protocol as well as an adapted scoring system based on a weighted linear index of functionality (*wLIF*) [12]. Two tasks, "remove jar lid" and "food cutting", were eliminated due to an inability to complete the tasks with the body-powered bypass prosthesis during initial testing. This change prompted the elimination of an additional task, "pick up coins", to maintain a proportional representation of prehensile patterns (PPs) within the procedure. These changes necessitated the use of a transparent scoring system so that procedural changes could be reflected in the scoring equations. The linear scoring system for the SHAP, presented by Burgerhof et. al, was used [12]. The system was used as outlined in the reference except for changes to the weighting of LIF_{PP} in the calculation of *wLIF*, due to changes in the number of tasks.

The following equation was used, where *wLIF* represents the overall performance score and each subscript of LIF on the right-hand side of the equation represents the type of grasp typically employed for task completion.

$$wLIF = \frac{1}{25}(3 * LIF_{spherical} + 3 * LIF_{tripod} + 6 * LIF_{power} + 5 * LIF_{lateral} + 5 * LIF_{tip} + 3 * LIF_{extension})$$

While we understand a hook, unlike a hand, can only employ a single grip the representation of grasp types or PPs was important to maintain a realistic variety of tasks. Times were recorded for each mSHAP task and then scored and compiled into LIF_{PP} scores and then into an overall *wLIF*.

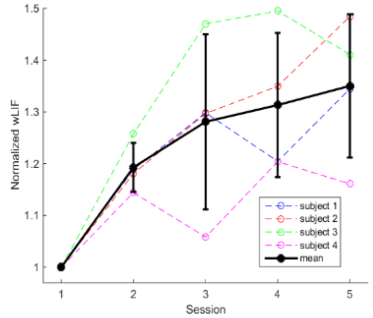

Figure 3. Normalized *wLIF* subject and average scores across 5

RESULTS

The subjects' performances improved from a mean *wLIF* of 53.84 ± 11.14 to 71.86 ± 10.74 between the first and fifth sessions. A Friedman test confirmed significant difference across these two sessions with a p-value of 0.0146. Normalizing to the 1st session score, the progression of each subject and the mean score with standard deviations can be seen in Figure 2. All subjects improved their scores from session one to session two by an average of 20%, with little variation in the amount of improvement. However, variability in scores from baseline measurements increased through sessions 3 – 5, with some subjects declining in performance compared to previous assessments. While limited by the small sample size, the beginning of an expected plateau in performance is evident.

Additionally, responsiveness of the mSHAP to the standard training protocol was evaluated by computing the effect size, or standardized response mean [13]. This metric was calculated to demonstrate the impact of each session on performance gains and quantify the amount of change from session to session. The following equation was applied to consecutive sessions:

$$ES = \frac{mean(T_{s,i-1} - T_{s,i})_{total\ group}}{std(T_{s,i-1} - T_{s,i})_{total\ group}}$$

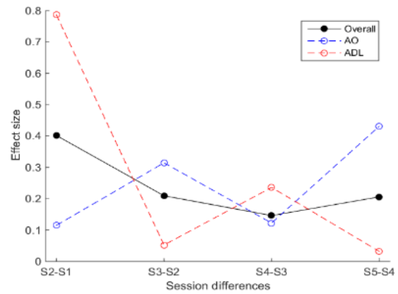

Figure 3. Effect size overall and broken into ADL and Abstract object tasks across 5 sessions

In this equation, $T_{s,i}$ represents the vector of task scores for all subjects for a particular session, *i,* where *i* goes from 2 to 5. ES represents the effect size for the performance scores between sessions *i* and *i – 1*. Results of this analysis can be seen in Figure 3. Consistent with the plateau effect in Figure 2, diminishing effect size is seen with additional sessions. The effect size can be further divided into the contributions from the abstract object tasks and the ADL tasks. Interestingly we found that effect size is far more variable in the ADL tasks compared to the abstract objects.

Using the Friedman test, the mSHAP was further broken down into individual tasks for analysis. Comparing mean scores from all subjects between sessions for each task, significant differences were found only for the "heavy power", "carton pour", and "door handle" tasks from 1st to 5th session. Of note, both "heavy power" and "door handle" fall under the power PP, which as a group showed a significant difference in LIF_{PP} between 1st and 5th sessions. The same analysis showed significiant differences in the spherical LIF_{PP} between 4th and 5th sessions, tripod LIF_{PP} between 1st and 4th sessions, and tip LIF_{PP} between 1st and 4th sessions.

DISCUSSION

Preliminary results for this study demonstrate significant improvement in performance, as measured by the mSHAP, across five of our training sessions. Importantly, the beginning of a plateau effect in performance can be seen. With a greater number of subjects and an extended amount of sessions observation of this plateau effect can determine up to how many hours training in this format remains effective. Additionally, the analysis of individual tasks and PP scores can help attribute progress to the development of specific skills or could point to potentially insignificant mSHAP tasks. This could eventually be used to guide individualization of training aspects by focusing on development of lacking PP skills while still maintaining a standardized, quantitative approach. It could also be used to further modify and improve the mSHAP.

To address these points future work will focus on expanding the current data set for more high-powered analyses. One specific point of analysis will focus on establishing a threshold difference in *wLIF* scores between subsequent sessions that would indicate the subject has reached their performance potential. This would create a quantitative indication to stop training and would clear subjects for researchers' intended upper limb bypass studies.

Disclaimer: The mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as an actual or implied endorsement of such products by Department of Health and Human Services.

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