Case Report: Optimizing Daily Function for People with Below-elbow Limb Deficiency with the SoftHand Pro

Amanda Theuer
Mayo Clinic, USA, theuer.amanda@mayo.edu

Sasha Blue Godfrey
Istituto Italiano di Tecnologia, Italy, sbgodfrey@gmail.com

Kristin Zhao
Mayo Clinic, USA, zhao.kristin@mayo.edu

Ryan Breighner
Mayo Clinic, USA, breighner.ryan@mayo.edu

Manuel Catalano
Istituto Italiano di Tecnologia, Italy, manuel.catalano@gmail.com

See next page for additional authors

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Abstract

Background: Innovation in prosthetic devices for adults with upper limb loss is necessary to meet the demand for effective devices to optimize participation in daily activity. We evaluate the SoftHand Pro (SHP) as a terminal device to determine the application of this biologically-inspired prosthetic hand for use for a person with transradial limb deficiency.

Method: This case study describes and measures the first use of the SHP by an individual with transradial limb deficiency in their home environment. This paper reports the features and functionality of the SHP prototype and provides recommendations for changes to further optimize function.

Results: The participant found the simple mechanics, durability, and ease of use of the SHP to be beneficial. She praised the SHP's positive impact on quality of life and suggested areas for optimization. Objective assessments of dexterity and function showed improvements.

Conclusion: Using a biologically-inspired myoelectric hand provides an opportunity for intuitively controlled grasp of common large and small objects. The simplicity of use and the lightweight, durable design of the SHP has the potential to provide a positive impact on quality of life, and this case study has provided valuable feedback to further improve the hand and enable larger at-home trials.

Keywords

amputation, assistive technology, prosthetics, upper limb

Cover Page Footnote

Complete Author List

Amanda Theuer, Sasha Blue Godfrey, Kristin Zhao, Ryan Breighner, Manuel Catalano, Marco Santello, Antonio Bicchi, and Karen L. Andrews

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Amanda Theuer, MOT; Sasha Blue Godfrey, PhD; Kristin Zhao, PhD; Ryan Breighner, PhD; Manuel Catalano, PhD; Marco Santello, PhD; Antonio Bicchi, PhD; Karen Andrews, MD

DOI: 10.15453/2168-6408.1602

In 2005, 8% of the 1.6 million people in the US with limb loss were adults with a major upper limb amputation. Projections estimate that by the year 2050 there will be 288,000 adults with upper limb loss (Ziegler-Graham et al., 2008). Upper limb loss impacts both an individual's daily activities and appearance. Behrend et al. (2011) found that only 62% of individuals with upper limb loss use a prosthetic device. Zlotolow and Kozin (2012) postulated that adults will use upper extremity prostheses if they perceive improvement from wearing them. They also reported that adults desire social integration, improved self-image, and improved aesthetics from their upper limb prostheses (Zlotolow & Kozin, 2012).

The optimal prosthetic device should have the ability to enhance and improve function without sacrificing quality, durability, or appearance. Many prostheses require significant training, are costly, and weigh so much that the user is not comfortable with regular wear. Nothing has yet to replicate and replace the function of a hand. Advanced prosthetic technology is imperative to meet the unique needs of individuals with limb loss. The evolution of the SoftHand Pro (SHP) takes steps to provide an individual with a prosthesis that is simple and intuitive to use with a lightweight, durable design.

The SHP is the prosthetic evolution of the robotic hand Pisa/IIT SoftHand, which was designed to be robust and easy to control as an industrial gripper while exhibiting versatility in grasping similar to that of a human hand (Catalano et al., 2014). The design allows hyperextension of the digits without damage. It is powerful with a durable structure obtained through the use of innovative articulations and tendons made of synthetic material replacing conventional joint design (Catalano et al., 2014). The SHP design allows each joint to move in response to activation and modify its trajectory in response to the object being grasped and the surrounding environment. The resulting grasp pattern is adapted to the specific target object, simplifying control and efficiency of use.

This article presents the results of a participant with transradial limb deficiency who used the SHP in her home environment for 1 week after training and assessment of use. The resulting feedback from the participant is summarized and discussed as suggestions for the team to further improve the SHP. Our findings confirm our hypothesis: A robotic hand has the capacity to be a strong and simple-to-use prosthetic device for people with transradial limb deficiency. The SHP currently is not commercially available, and the timeline for potential consumer access is unknown.

Design, Weight, Cosmesis

Biologically inspired, the SHP hand approximates a medium to large adult male hand shape and size. The SHP has a square hand base (palm) and fingers sized larger, more similar to an adult male. The weight of the SHP hand is approximately 520 g or 1.15 lb (without the wrist, socket, and external battery). The total weight of the hand, wrist, socket, and external battery is 1028 g or 2.27 lb. The hand is mounted to a custom socket by a certified prosthetist. The SHP uses a rechargeable lithium-polymer battery worn in a holster on the upper arm. A fabric commercial work glove with textured rubber fingertips is used to protect the SHP. The SHP is not water resistant (see Figure 1).

Figure 1
The SHP Glove Without Covering

Grasp

The SHP exhibits coordinated motion at multiple joints during grasping of a wide variety of object shapes and sizes (see Figure 2). The hand is flexible, allowing it to adapt to environmental constraints. If the user keeps the index finger in the extended position against an external surface while activating the flexion or close signal, this configuration can be used to perform activities that require a single digit to push a button or switch.

Figure 2

The SHP, with Glove Covering, Demonstrates Grasp Coordinated by Multiple Joints

Control of Powered Movement

Users control prosthetic movements with electromyography electrodes placed on the flexors (close signal) and extensors (open signal) of the forearm, previously calibrated to ensure appropriate activation and control. The SHP was designed anthropomorphically with 19 degrees of freedom arranged in four fingers and an opposable thumb. It uses one actuator to maximize simplicity and usability.

Method

This study was carried out following institutional review board approval. Recruitment was based on known available participants in the region. The participant is a 54-year-old female with a left transradial limb deficiency (congenital), currently using a myoelectric prosthesis less than half of the time at home. She does not use a prosthetic device the other half of the time. She was involved in 8 hr of familiarization and training with the SHP prior to preassessment. Training included verbal education on the principles of the SHP function, visual demonstration of the SHP function, participant trials picking up objects of different sizes in various planes, managing bimanual activities, and engaging in activities of daily living. Assessments were completed using her current myoelectric device and with the SHP pre and post use of the SHP in the home environment for 1 week. The Canadian Occupational Performance Measure (COPM) scores were calculated with her current myoelectric device and compared to the SHP after use in the home environment.

The participant had the SHP for 1 week between pre and post assessments. She was instructed to wear the device often, use the device as able in activities of daily living, and avoid wearing the device during tasks that would involve liquids and/or water. She used the SHP while digging in the garden, using garden tools, in bimanual activities, grasping vegetables, and carrying buckets and baskets. She opened and closed jars, lifted full jars of sauce, and manipulated objects in her kitchen required to complete various tasks. The participant played cards with her family, held the cards in the SHP, and placed cards in the discard pile with her intact hand. She was particularly interested in the ability of the SHP to grasp very small objects, including pennies, bottle tops, and paper clips. The participant engaged in regular exercise, including weight lifting, and eagerly tested the durability and strength of the SHP grasping weights and bars during exercise.

Dexterity Assessment

Two dexterity measures were used: the Box and Block (Mathiowetz et al., 1985) and the Jebsen Hand Function Test (JHFT) (Dromerick et al., 2008; Resnik & Borgia, 2012; Resnik & Borgia, 2014). The Box and Block test has been used as an outcome measure of hand function in upper limb prosthetics with good responsiveness to change in test retest environments and good reliability/validity with upper limb prosthetic users (Resnik & Borgia, 2012; Resnik & Borgia, 2014). The Box and Block consists of a
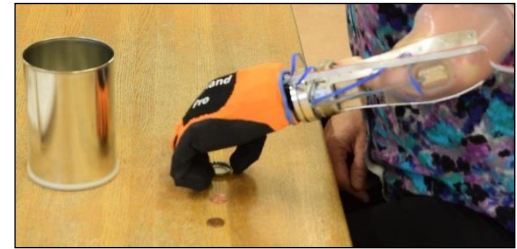
box with a center partition with 1-in. blocks on one side. A subject is asked to use their prosthetic terminal device to grasp one block at a time, transport it over the partition without hitting the partition, and release the block on the opposite side. The number of blocks transported to the other side in 60 s is counted and reported (Desrosiers et al., 1994; Mathiowetz et al., 1985). Normative data available for a normal female 50 to 54 years of age is right hand mean 77.7 (standard deviation 10.7) blocks and left hand mean 74.3 (standard deviation 9.9) blocks (Mathiowetz et al.,1985).

The JHFT is a dexterity test that evaluates the time needed to perform seven hand-related tasks, including: (a) printing a 24-letter, third grade reading difficulty sentence; (b) turning over 7.6 x 12.7 cm (3 x 5 inch) cards in simulated page turning; (c) picking up small common objects (including pennies, paper clips, and bottle caps) and placing them in a container; (d) stacking checkers; (e) simulated feeding; (f) repeatedly lifting a bean with a spoon and placing the bean in a can; (g) moving large empty cans; and (h) moving large 1 lb cans. The subtests are scored separately by recording the number of seconds required to complete each task. Unlike the traditional use of the JHFT, in our study, each subtest was terminated at 2 min if the subject was not successful in completing the task in that time frame. The JHFT has been used in studies of prosthetic function and found to be most useful when adapted time limits were capped at 2 min, noting that the page turning task has a potential ceiling effect and the subtest of lifting heavy and light cans is most responsive to change (Dromerick et al., 2008; Resnik & Borgia, 2012; Resnik & Borgia, 2014). The JHFT was performed with her current myoelectric device and with SHP pre and post.

Functional Assessment

The Activities Measure for Upper Limb Amputees (AM-ULA) is an outcome assessment tool for adults with upper limb amputation that reflects skill in prosthetic use in daily functional activities (Resnik et al., 2013). It is known to have high statistical integrity, including internal consistency, test-retest reliability, and good interrater reliability. The assessment requires a professional to provide a rating score based on task completion, speed of completion, movement quality, skillfulness of prosthetic use in control of voluntary grip function, and independence during observation of the prosthetic user's performance of the task. The assessment's final score ranges from zero to 40, with higher scores revealing improved or better functional performance. The tasks include: brushing hair; donning a shirt overhead; removing a shirt overhead; buttoning a shirt; engaging and zipping a zipper; donning socks; tying shoes; picking up and using a fork, cup, and spoon; pouring liquid from a cup; folding a towel; cutting paper with scissors; using a hammer to pound a nail in a piece of wood; dialing a cell phone; turning a door knob; and reaching overhead (Resnik et al., 2013). The pouring liquid task was omitted because of institutional review board restrictions that did not permit the device to be used near liquid because of safety concerns between an electronic device and liquid. The AM-ULA was completed with pre and post the week of home use with the SHP.

Self-Report Assessment

The COPM is a semi-structured interview in which the participant is guided to determine important tasks in daily life and proceeds to rate the current performance and satisfaction with that performance on a scale of 1 to 10. 1 indicates poor performance and low satisfaction, respectively, while 10 indicates very good performance and high satisfaction (Law et al., 2005). Our participant was asked to identify areas of importance to her and then rate performance and satisfaction with her current myoelectric device (pre) and with the SHP (post) after the week of use. An average COPM score of the

performance and satisfaction across areas of importance was calculated (Law et al., 2005) for the current myoelectric device (pre) and the SHP (post) and compared.

The Quick Disabilities of the Arm, Shoulder and Hand Outcome Measure (QuickDASH) is a self-report, 11-item questionnaire intended to measure physical function and symptoms of a person with disorders of the upper limb (Beaton et al., 2005). Each QuickDASH item requires a rating from 1 (*no difficulty*) to 5 (*unable*). The final score is obtained by dividing the sum of the ratings by the total number of responses, subtracting one, and multiplying by 25 for the final score. A score of 100 indicates the greatest amount of limitation or disability. A score of 0 indicates no limitation or disability at all (Beaton et al., 2005).

Results

Data from SHP use pre and post at-home use for 1 week was obtained and analyzed. There was a decrease in the number of blocks moved in 1 min in the Box and Block test post SHP (five) versus pre SHP (eight). In the JHFT testing with her current prosthesis, the task was terminated at 120 s because of failure to pick up any of the small objects. Results of the JHFT pre and post SHP at home indicated success in picking up small objects; the time to pick up small objects increased between pre and post SHP testing, and the demonstrated skill and control in picking up those objects improved (see Figure 3). The AM-ULA score pre was 17.5/40 and post was 18.75/40; a result closer to 40 indicates improvement. The QuickDASH pre was 25 and post was 22.7 following a week of use.

Figure 3
Jebsen Hand Function Test
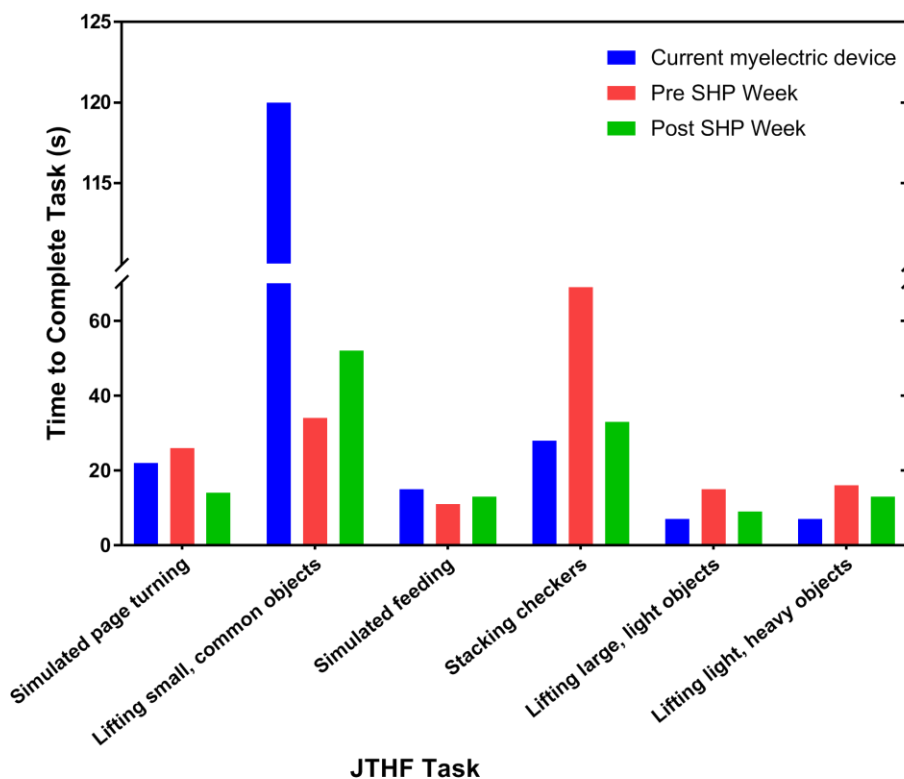
Note. Time (in seconds) to complete each task (task terminated at 120 s if unable to complete in that time).

Data was compared between the participant's current myoelectric device and the post SHP at-home use testing. The JHFT results compared to her current device, after a week, showed with the SHP she completed page turning, lifting small objects, and simulating feeding in a comparable or slightly less amount of time. Stacking checkers time was slightly greater with the SHP (33 s) than with her current device (28 s). Lifting cans took longer with the SHP than with her current device by 2 s for light cans and 6 s for heavy cans. The results of the AM-ULA between her current device and the SHP were similar (18.23/40 and 18.75/40, respectively). The COPM revealed the participant rated both perceived performance and satisfaction at 7.6 and 5.3, respectively, with the SHP compared to her current terminal device, which she rated for perceived performance and satisfaction at 6 and 4.67, respectively (see Figure 4). According to the COPM manual, a change of two or more points is representative of an important change (Law et al., 2005).

Figure 4
Canadian Occupational Performance Measure
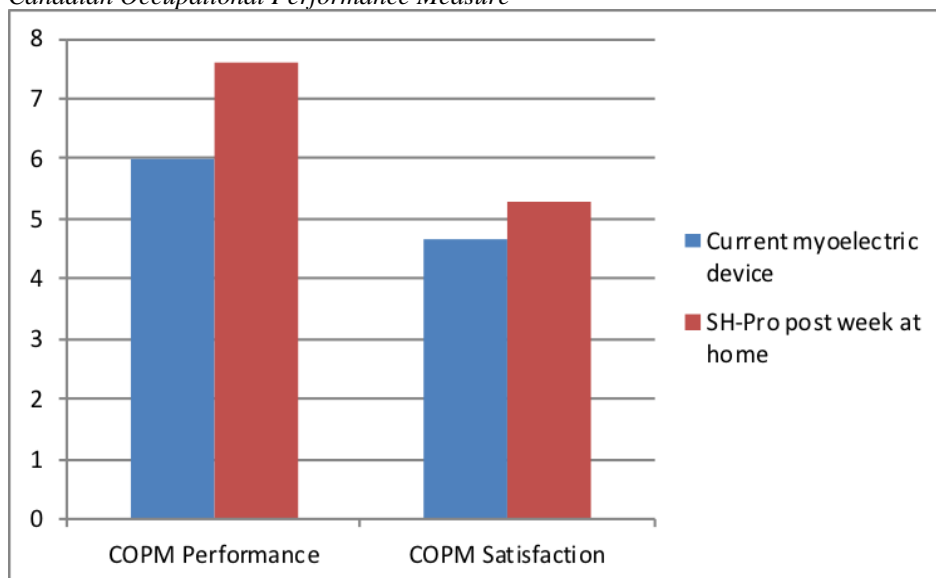
Note. The participant reported perceived performance and perceived satisfaction pre and post. 0 = *Not performing/Not satisfied* and 10 = *Performing very well/Very satisfied*.

Patient Perceptions and Feedback

The participant praised the grasp of the SHP provided to cut food or meat and was satisfied with the fork stabilization of the SHP while using her intact limb to manipulate the knife. She successfully cut vegetables, prepared sauces, and canned vegetables with ease and efficiency. She was pleased with the SHP grasp of a bar while completing weight lifting exercises. She was successful with picking up small items but would prefer smaller or more slender digits.

The participant reported frustration attempting to repeat the same grasp pattern for the same task or object at a different time. She had success in picking up objects at different times of the day or over the course of a few days, but the grasp pattern was not always the same as it had been previously when she picked up an object. This created some hesitation when approaching a familiar object based on the potential unknown deviation from the previous grasp pattern for the object. During strenuous activities that required a long hold or grasp of an object, such as holding a weight during exercise repetitions, she would have preferred to have the option to lock or turn off the device to grasp and maintain a grasp

without risk of unintentional activation or opening. She recommended optimizing the materials to be as lightweight as possible. She suggested a focused study of the pattern of movement of the third, fourth, and fifth digits because she felt these digits close (flex or curl) at a much faster rate or too early compared to the other digits. This inhibited grasping an object in her preferred manner (or at all) less than half the time, but often enough to be reported as bothersome. When playing cards, the participant found that the most successful position used to hold the cards (arm resting on table, SHP nearly in supination or palm up position) did not position the cards at the most optimal visual viewing angle. The participant reported that this angle was successful, but she did not like the visual appearance of the position of the playing cards.

Discussion

The participant reported overall satisfaction with the features of the SHP, successful application of the SHP in daily tasks in the home environment, and no adverse events or concern when using the device. The participant was pleased with the intuitive nature of the device. Timed results, participant performance, and satisfaction reportedly improved. On occasion, timed results were impacted by the participant's precision and accuracy (improved observably), which slowed her time to complete the task in posttest data. During the Box and Block test the subject picked up fewer blocks in the post test and explained that she was trying to use a "pretty grasp" rather than move at a rapid pace, which impacted results, and repeated trials were excluded because of potential practice effect and/or fatigue.

Our results support bioinspired technology, using soft synergies, provides the potential to optimize prosthetic hand design. This is the first study to assess the use of a SHP in a participant's home. The SHP is designed with the purpose of being robust and simple to control while exhibiting high grasping versatility similar to that of the human hand (Catalano et al., 2014). Of particular relevance in its design is the very soft, safe, powerful, and extremely strong structure obtained through the use of innovative articulations and tendons replacing conventional joint design (Catalano et al., 2014). Although the SHP uses only one motor, it preserves the ability to achieve most grasping tasks.

Based on our results and the feedback from the participant, the SHP has the potential to provide a positive impact on quality of life. The adaptability of the grasp patterns can reduce the cognitive requirement to operate the hand, potentially reducing the amount of time required for training, and improve user success in daily function. Personal success, sense of achievement, and independence has the potential to positively impact psychological well-being. This study provided the unique opportunity to refine and develop this technology for use by a wider population. There are potential future improvements to be addressed based on the feedback, such as a durable protective covering, lighter materials to reduce weight of device, smaller digits, and a locking option to reduce error in activation during heavy lifting.

Limitations

The limitations of this study include the participation of a single subject with only 7 days of home-use, allowing only trends in data to be assessed, and the restriction against SHP use around liquids imposed by the institutional review board. It is limiting that with the one participant, the results of the AM-ULA, QuickDASH, and COPM satisfaction results did not reach minimal clinically important difference. The AM-ULA minimal clinically important difference is 3.7 points (Resnik et al., 2013), and the QuickDASH is between 11 and 17.18 (Gabel et al., 2009; Polson et al., 2010). The COPM satisfaction and performance difference in rating between the two terminal devices is less than two points, which is the important difference published in the manual (Law et al., 2005). Limitations existed

because of this participant's test and performance anxiety. The participant's test anxiety and self-limiting of tasks because of concern for damaging the device despite assurances to use the device as any other prosthetic device may have impacted the results. The SHP does not have an ideal covering, which could both provide protection from moisture and liquids and improve the grasp of small objects with a textured material at the tip of the digit. Despite this limitation, the participant reported improvement in picking up paper clips as compared to the prosthesis she typically uses in daily activities. Finally, the subject wore her existing prosthesis less than half of the time; wearing the SHP for more hours of the day could have biased the findings.

We have evaluated additional subjects in a controlled lab environment in a separate study (Godfrey et al., 2018). This is the only study to evaluate the SHP outside of the laboratory.

Conclusion

The results of one participant using the SHP for 1 week are promising. The objective results neither negate nor strongly support the hypothesis as compared to the positive subjective report of the participant. Therefore, this case study supports the qualitative hypothesis of the authors that a biologically inspired prosthetic hand, the SHP, is a viable and desirable prosthetic component to optimize function for persons with transradial limb loss or deficiency. Further objective assessment of the SHP is required to provide significant quantifiable results.

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