Cover Page

Official Title of the Study: To Assess the Utility of the Point Digit in a Clinical Take-home Study

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Protocol #:
Project Title: The Point Digit: A Family of Ratcheting Prosthetic Finger Technology
Principal Investigator: Levin Sliker
Version Date: 8/2/2018

I. **Hypotheses and Specific Aims**: The purpose of this research is to study the use of passive prosthetic devices. The design of passive prosthetic devices for amputees will be tested by human subjects for strength, function, and durability. The hypothesis of the study asks whether certain design features can withstand activities of daily living. Examples of activities include lifting objects, pouring water, turning keys, etc.

II. **Background and Significance**: There are approximately 500,000 people living with minor upper limb loss in the USA [1],[2]. Minor upper limb loss (also partial hand amputation) is defined as the amputation of the bones distal to the wrist joint. While the field refers to these types of amputation as 'minor,' it can be a severe disability, especially if the amputation involves the thumb and/or multiple digits. In fact, partial hand amputees self-report a higher level of disability compared to other major unilateral upper limb amputees [3]. Furthermore, it was reported that fewer than half of partial hand amputees were able to return to the same job after amputation and most found that the prosthetic devices were insufficient to meet the demands of their work [4]. Amputation can cause physical, psychosocial, and economic damage to an individual and can lead to depression, anxiety, loss of self-esteem, and social isolation [5],[6]. While the number of individuals with partial hand amputation is 10 times more than all other categories of upper limb amputation combined, the state of available technology for this underserved patient population is relatively poor [7].

Current partial hand prostheses are limited in several ways. First, they generally lack robustness, and there are frequent reports of devices breaking under normal use. Second, most current options offer a one-size-fits-all approach, which limits the acceptance by people who want a prosthesis that matches their original finger size. A complete lack of prosthetic finger options can occur for women with smaller anatomical size. Third, rotation of the finger about the anatomical center of rotation of the metacarpophalangeal (MCP) joint is not possible with current options resulting in a prosthesis that is frequently too long. Fourth, current prostheses require the use of the opposite hand to operate the device. There is a need for a durable, scalable, anatomically suitable for women, single-handedly operable prosthetic finger.

[1] K. Ziegler-Graham, E. J. MacKenzie, P. L. Ephraim, T. G. Travison, and R. Brookmeyer, "Estimating the prevalence of limb loss in the United States: 2005 to 2050," Arch. Phys. Med. Rehabil., vol. 89, no. 3, pp. 422–429, 2008.
[2] M. P. LaPlante and D. Carlson, "Disability in the United States: Prevalence and Causes, 1992. Disability Statistics Report 7.," Aug. 1996.
[3] J. Davidson, "A comparison of upper limb amputees and patients with upper limb injuries using the Disability of the Arm, Shoulder and Hand (DASH)," Disabil. Rehabil., vol. 26, no. 14–15, pp. 917–923, Jul. 2004.
[4] H. Burger, T. Maver, and Č. Marinček, "Partial hand amputation and work," Disabil. Rehabil., vol. 29, no. 17, pp. 1317–1321, Jan. 2007.
[5] D. Desmond and M. MacLachlan, "Psychological issues in prosthetic and orthotic practice: A 25 year review of psychology in Prosthetics and Orthotics International," Prosthet. Orthot. Int., vol. 26, no. 3, pp. 182–188, Dec. 2002.

[6] C. M. Parkes, “Psycho-social Transitions: Comparison between Reactions to Loss of a Limb and Loss of a Spouse,” Br. J. Psychiatry, vol. 127, no. 3, pp. 204–210, Sep. 1975.
[7] Committee on the Use of Selected Assistive Products and Technologies in Eliminating or Reducing the Effects of Impairments, Board on Health Care Services, Health and Medicine Division, and National Academies of Sciences, Engineering, and Medicine, The Promise of Assistive Technology to Enhance Activity and Work Participation. Washington, D.C.: National Academies Press, 2017.

III. Preliminary Studies/Progress Report:

IV. Research Methods

A. Outcome Measure(s):

Outcome measures include completion rate, completion time, SHAP score, DASH score, box and blocks test, clothespin test, and other measures of function. These metrics quantify the performance of prosthetic devices.

B. Description of Population to be Enrolled:

The subject population will consist of a convenient sample of people. The subjects will have various ethnicity, age, and gender. An estimated total of 30 subjects will be enrolled. The subjects must be normal intact individuals and/or persons with amputation who are able to understand and follow directions in English, assessed by their ability to respond during the recruitment and consent process. Exclusion criteria include any subjects that are not able to understand the procedures and/or are less than 18 years of age.

C. Study Design and Research Methods

The experiments will take place at the Point Designs LLC headquarters, at partner clinics, and/or at home. The participant will come up to 3 times for up to 4 hour sessions. During this session the participant will be asked to perform activities of daily living in a laboratory setting. The only devices/materials coming into contact with the participant will be standard of care orthopedic/prosthetic equipment including gauze, casting tape, medical tape, prosthetic sockets. Risks from the above devices are possible minor skin discomfort. Standard of care procedures will be used to mount the prosthetic device. A training period will be followed by several tests to measure the function of the prosthetic device. Different versions of the device may be presented to the subject in a randomized order.

D. Description, Risks and Justification of Procedures and Data Collection Tools:

Risks from the above devices are possible minor skin discomfort. If you feel that you have been harmed while participating in this study, you should inform Levin Sliker at 720-600-4753 immediately.

E. Potential Scientific Problems:

Potential scientific problems include a lack of subjects with amputation and/or a lack of ability to perform the activities of daily living with the prosthetic devices.

F. Data Analysis Plan:

Data will be processed with standard statistical methods using MATLAB (Mathworks, Inc.) in order to produce the metrics described previously (completion rate, completion time, etc.)

G. Summarize Knowledge to be Gained:

The development of more functional/robust prosthetic devices will augment the quality of life for people with amputation.

H. References:

N/A