DEVELOPMENT OF A MINIATURE RATCHETING PROSTHETIC DIGIT FOR SMALL ADULTS AND CHILDREN WITH PARTIAL HAND AMPUTATION

Jacob L. Segil[1,2], Stephen Huddle[3], Richard F. *ff.* Weir[1,3]

[1]*Rocky Mountain Regional VA Medical Center*

[2]*University of Colorado Boulder*

[3]*University of Colorado | Anschutz Medical Campus*

ABSTRACT

The loss of digits from the hand is the most common upper limb amputation but there is a lack of commercially available prosthetic digits to replace what was lost. The lack of prosthetic options is especially severe for small adults of children with hand sizes that are too small for existing prosthetic componentry. Here we describe the design of a miniature ratcheting prosthetic digit for small adults and children with partial hand amputation. The design features are discussed and mechanical testing of the digits was performed. The results indicate that the miniature digit can withstand heavy-duty loads and has a failure strength of over 275 lbs while sized for a 5th percentile female hand or an 8-year old child. Soon, this miniature digit will hopefully serve a population of people with partial hand amputation that have been underserved up to this point in time.

INTRODUCTION

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]**.

Figure 1: A depiction of the miniature digits spanning lengths of 55mm (little finger) to 75mm (middle finger) on a full hand model.

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 men and 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, single-handedly operable prosthetic finger which is anatomically suitable for small adults or children.

The lack of prosthetic limb systems for small adults and children with upper limb amputation is a problem within our field. Even data concerning the prevalence of upper limb loss among women in particular is lacking **[7]**. Ziegler et al. estimated limb loss in the United States in 2008 and determined that women comprised 35% of all persons with upper and lower limb loss **[1]**. More specifically, Atkins et al performed a thorough survey of persons with upper-limb loss in 1996 and found that women comprised 22% of persons with upper limb loss **[8]**. Based on this percentage (22% women) while the majority of people with upper limb amputation are male, there is still a large population of women, approximately 110,000 women **[1], [2]** who are in need of better prosthetic options at the finger level.

The differences between male and female hand anatomy are great; a 50th percentile female middle finger length (101mm) is equivalent to the 1st percentile male middle finger length (102mm) **[9]**. Also, the 1st percentile male middle finger length (102mm) is 13mm longer than the 1st percentile female middle finger length (89mm). These differences essentially preclude the use of most current partial hand prosthetic devices for women who are not in the 5th percentile or greater. With this effort, we sought to design a miniature prosthetic finger with 55mm length that would provide a valuable device for 5th percentile women and 5-year-old children (Figure 1) **[10]**.

DESIGN METHODS

The design of the miniature digit was based upon our prior work on the *Point Digit* now commercialized by Point Designs LLC (Lafayette, CO). The miniaturization of the digit affects the function of the mechanical systems within it. Multiple mechanisms within the current design were scaled with the size of the finger including 1) the ratchetting mechanism, 2) the bump release mechanism, and 3) the push-button release mechanism. The tolerances involved were redefined for the miniature mechanisms to provide the same amount of reliability and function using a repeatable manufacturing method. The bump release unlocks the ratchetting mechanism allowing the spring to bring the finger to full extension. The "props" within the bump release mechanism are used to unlock the ratchetting mechanism bringing the finger to full extension.

The current, full-sized Point Digit weight specification is no more than 70 g (1/8 lb.) based on an estimate of anatomical weight where the hand makes up 0.75% of body weight [11]. In the case of a 175 lbs. male whose hand would weigh about 1.25 lb., and assuming the palm makes up 50% of that weight, each finger and thumb would be 1/8 lb. (~66 g). The Point Digit prototype weighs between 45 g (80 mm length) to 55 g (120 mm length), satisfying the weight requirement for male hands. We sought to reduce the weight of the Point Digit by 50% to a weight of 25g in order to fit women with body weight as little as 90 lbs. To achieve this, we will print the finger in titanium as well as light-weighting the componentry using direct metal laser sintering techniques.

EXPERIMENTAL METHODS

We evaluated each finger on a bench-top material-testing machines (MTS) and custom finger cyclers to establish if the design meets specifications. To create a clinically-ready prosthetic finger, we need the miniature digit to be durable, robust, and able to withstand high forces. The mechanical testing spanned static loading conditions, dynamic loading conditions, and dynamic unloaded conditions. Each test was conducted with loads applied to the palmar surface of the distal phalange, the palmar surface of the medial phalange, and lateral surface of the distal phalange. The static loading test applied loads of 66N on the palmar and lateral surface of the distal phalange as this is the minimum a prosthetic hand should be able to generate [12] and loads of 98N on the palmar surface of the medial phalange as this is approximately the weight of a bag of groceries (10kg). After achieving this minimum specification, each finger was tested to failure with loads applied to each finger surface. The dynamic loading test applied a repetitive fatigue load of the same magnitude of the static loading testing at a rate of 1Hz for 10,000 cycles. The dynamic unloaded test cycled the digit through 250,000 flexion and extension cycles. This simulated the unloaded use of the digit over 3 years of use assuming ~30 grip changes per hour, 8 hours of wear time per day, and 365 days of use per year. A custom made cycle testing machine used an actuator to flex the digit into full-flexion and then relied on the spring-back mechanism within the digit to fully extend the digit. This test ensured the mechanism can withstand long-term use while maintaining the ratcheting and spring-back functions. The successful completion of these specifications will match the mechanical specifications of the Point Digit.

RESULTS

A battery of verification tests was performed to ensure that all design specifications of the miniature prosthetic digit had been met. In all tests, the digit met or exceeded the specification (Table 1). In some cases, the digit exceeded the specification by several factors. The miniature digit met the mass and length requirements of a 5th percentile female as well as a 5-year old child. In the most demanding test, the static load test at the distal tip of the finger, the static strength of the Point Digit at the distal fingertip exceeded the specification by 18 times (1,242 N compared to 66 N, 279 lb compared to 15 lb). The dynamic load tests were all successful in that the digits did not show any visible signs of wear, damage, or loss of function. The dynamic cycle test was not completed at the time of this publication, but has proceeded without adverse events at this time. These results indicate that the miniaturization of the digit did not cause a decrease in mechanical performance of the mechanisms involved in the ratcheting prosthetic digit.

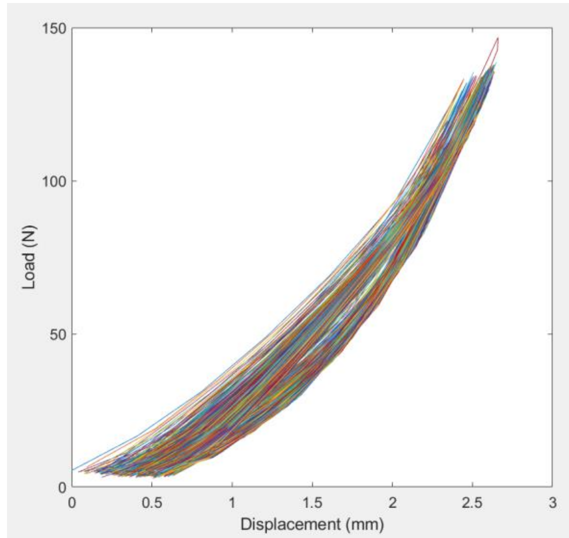

Figure 2: Exemplary data from the dynamic load test applied to the medial phalange. 500 loading cycles are shown out of the 10,000 cycles performed.

Table 1. Mechanical Testing Results

	Mass	Length	Dynamic Cycle Test	Dynamic Load Testing (10,000 cycles @ 1Hz)			Static Load Testing (Load to failure)		
				Distal	Medial	Lateral	Distal	Medial	Lateral
Specification	25g – 35g	55mm – 75mm	250,000 cycles	66 N	98 N	66 N	≥66 N	≥98 N	≥66 N
Testing Result	30g	55mm – 75mm	N/A	10,000 cycles at 66 N	10,000 cycles at 98 N	10,000 cycles at 98 N	1,242 N	≥200 N	≥200 N
Meets Specification	✓	✓	--	✓	✓	✓	✓+++	✓+	✓+
Exceeds Specification by	--	--	--	1x	1x	1x	**18.8x**	2x	2x

DISCUSSION

The mechanical design of miniature prosthetic fingers for small adults and children with partial hand amputation requires a great reduction in size of the internal mechanisms involved in the devices. This work details the creation of a robust device which can withstand heavy-duty use for these under-served patient populations. A battery of mechanical tests confirmed that the miniature digit could withstand clinically-relevant loads and cycles of use. The success of this mechanical design was accomplished using rapid-manufacturing technology like direct-metal laser sintering 3D printing. This manufacturing method enables complex componentry to be created with internal geometries and in-situ functions that are not possible with other manufacturing techniques. Furthermore, the 3D printing technology allows for the digit to be easily scaled between 55mm – 75mm and thereby produce appropriate lengths for a variety of patients. Future work will produce miniature digits for small adults in a laboratory testing session as well as a take-home clinical trial. Then, relevant outcome measures will be produced in order to detail the utility of the miniature digit during activities of daily living.

ACKNOWLEDGEMENTS

This work is support by the Department of Veteran Affairs Rehabilitation Research and Development (RR&D) Service Merit Review (1 I01 RX002830).

REFERENCES

[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*. 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, doi: 10.1080/09638280410001708940.

[4] H. Burger, T. Maver, and Č. Marinček, "Partial hand amputation and work," *Disabil. Rehabil.*, vol. 29, no. 17, pp. 1317–1321, Jan. 2007, doi: 10.1080/09638280701320763.

[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, doi: 10.1080/03093640208726646.

[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, doi: 10.1192/bjp.127.3.204.

[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.

[8] D. J. Atkins, D. C. Y. Heard, and W. H. Donovan, "Epidemiologic Overview of lndividuals with Upper-Limb Loss and Their Reported Research Priorities," *J. Prosthet. Orthot.*, vol. 8, no. 1, p. 2, 1996.

[9] A. R. Tilley and H. D. Associates, *The Measure of Man and Woman: Human Factors in Design*. Wiley, 2001.

[10] B. Hohendorff, C. Weidermann, K. J. Burkhart, P. M. Rommens, K. J. Prommersberger, and M. A. Konerding, "Lengths, girths, and diameters of children's fingers from 3 to 10 years of age," *Ann. Anat. - Anat. Anz.*, vol. 192, no. 3, pp. 156–161, May 2010, doi: 10.1016/j.aanat.2010.03.002.

[11] C. W. Heckathorne, "Components for adult externally powered systems," *Atlas Limb Prosthet. Surg. Prosthet. Rehabil. Princ.*, vol. 2, pp. 151–174, 1992.

[12] E. Peizer, D. W. Wright, C. Mason, and C. Pirrello, "Guidelines for standards for externally powered hands," *Bull. Prosthet. Res.*, vol. 10–12, no. Fall, pp. 118–155, 1969.