

The Point Digit II: Mechanical Design and Testing of a Ratcheting Prosthetic Finger

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ABSTRACT

Introduction:

People with partial hand loss represent the largest population of upper limb amputees by a factor of 10. The available prosthetic componentry for people with digit loss provide various methods of control, kinematic designs, and functional abilities. Here, the Point Digit II is empirically tested and a discussion is provided comparing the Point Digit II with the existing commercially available prosthetic fingers.

Materials and Methods:

Benchtop mechanical tests were performed using prototype Point Digit II prosthetic fingers. The battery of tests included a static load test, a static mounting tear-out test, a dynamic load test, and a dynamic cycle test. These tests were implemented to study the mechanisms within the digit and the ability of the device to withstand heavy-duty use once out in the field.

Results:

The Point Digit II met or exceeded all geometric and mechanical specifications. The device can withstand over 300 lbs of force applied to the distal phalange and was cycled over 250,000 times without an adverse event representing 3 years of use. Multiple prototypes were utilized across all tests to confirm the ability to reproduce the device in a reliable manner.

Conclusions:

The Point Digit II presents novel and exciting features to help those with partial hand amputation return to work and regain ability. The use of additive manufacturing, unique mechanism design, and clinically relevant design features provides both the patient and clinician with a prosthetic digit, which improves upon the existing devices available.

INTRODUCTION

There are approximately 500,000 people living with minor upper limb loss in the USA.^{1,2} Although 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. For example, the loss of both the index and middle fingers results in 40%, 36%, and 22% impairments of the hand, upper extremity, and whole body, respectively.³ Amputation can cause physical, psychosocial, and economic damage to an individual and can lead to depression, anxiety, loss of self-esteem, and social isolation.^{4,5} Although 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. Further, prosthetic solutions for partial hand amputations are typically considered only after reconstructive surgical procedures have failed.⁶

Current commercial products for people with partial hand amputations do not satisfy all of the needs of these patients (Fig. 1).⁷ Full-length prosthetic fingers are categorized into three major types: 1) passive, 2) body-powered, and 3) powered prosthetic fingers. Passive prosthetic digits can be positioned into various degrees of flexion using external forces from the contra-lateral hand and/or external objects. Body-powered prosthetic fingers are positioned using the residual digit if/when available. Powered prosthetic fingers use electric motors along with electromyographic sensors and other electronics to position the prosthetic digit. The use of each type of digit for any given person with partial hand amputation is a clinical decision based upon the needs and desires of the patient.

There are strengths and weaknesses of each type of prosthetic finger. Passive fingers can be made as a cosmetic device that simply produces a facsimile of the finger (referred to as a silicon restoration). Cosmetic silicone finger extensions can also provide function for improving finger spread and reach, thereby enabling the possibility to type on a keyboard, play an instrument, or grasp objects. There are a number of cosmetic silicone finger restoration providers, including ARTech Laboratory, Touch Bionics (livingskin), and American Hand Prosthetics. Studies have shown that the cosmetic

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Prosthetic Options for MCP Level Partial-Hand Amputations						
Product	Point Digit II	TITAN	M-Finger	iDigits Quantum	VINCENTpartial passive	VINCENTpartial active
Company	Point Designs LLC	Partial Hand Solutions LLC	Partial Hand Solutions LLC	Touch Bionics	Vincent Systems GmbH	Vincent Systems GmbH
Image						
Actuation Method	Passive	Passive	Body-Powered	Motorized	Passive	Motorized
Strength	308 lb	Unavailable	Unavailable	5 kg	Unavailable	Unavailable
Number of Sizes	6 stock + custom	3	5	4	6	4
Anatomical Flexion	✓	✗	✗	✗	✗	✗
Anatomical MCP Center of Rotation	✓	✗	✗	✗	✗	✗
One-Handed Operation?	✓	✗	--	--	--	--
Number of Locking Positions	11	3	--	--	--	--
Aesthetic Options	2 Finishes (gunmetal/polished)	1 Finish	--	--	--	--

FIGURE 1. Prosthetic options for people with metacarpophalangeal (MCP) level partial-hand amputations. Six products are compared across the actuation method, perceived strength, number of sizes, anatomical flexion capability, anatomical MCP center of rotation capability, one-handed operation ability, number of locking positions, and aesthetic options.

result associated with a silicone restoration can have a positive effect on an individual’s self-image.^{8,9} These same studies showed, however, that a silicone restoration was not durable enough for individuals hoping to return to jobs involving manual labor. Other passive fingers attempt to address this issue by using a ratcheting or position mechanisms to lock the digit into a flexion position; examples include the TITAN finger (Partial Hand Solutions) and the VINCENT partial passive (Vincent Systems GmbH). Passive fingers are often seen as being difficult to operate since they typically require the use of the contra-lateral limb to position the digit.

Body-powered fingers provide an intuitive positioning method that couples the flexion of the wrist/digit to control the flexion of the prosthetic device. Body-powered prosthetic fingers are difficult to fit to the residual limb and can cause excessive fatigue because of the poor mechanical advantage created by the prosthetic fitting. Body powered devices for full finger amputations such as the M-Finger (Partial Hand Solutions) and X-Finger (Didrick Medical) can articulate, but require motion from either the wrist or an adjacent intact digit to function. The MCP Driver (Naked Prosthetics) is available for people with intact metacarpophalangeal (MCP) joints and uses the residual finger to actuate the prosthetic device.

Powered fingers use myoelectric control methods that utilize the muscle activity within the residual limb to control the position of the digit in a volitional manner. Powered fingers and their ancillary components are expensive, fragile, and cumbersome. The electrically powered i-limb digits (Touch Bionics) and the VINCENT partial active (Vincent Systems GmbH) use battery-powered motors within each digit to power the flexion of the finger. Electromyographic

sensors situated on the residual limb provide volitional control signals to a motor controller, which translates those signals into flexion/extension commands. These current options do not provide the durability needed for many users and therefore have not satisfied all patients.

In general, current prosthetic fingers for MCP level amputations are limited in several ways. First, they generally lack robustness, and there are frequent reports of devices breaking under normal use. This concern is related to the need for a high strength to weight ratio. In fact, the reduction of weight is cited as the highest priority for upper limb amputees.¹⁰ However, the reduction of weight of prosthetic components typically comes with a loss of functionality or robustness. Second, current passive prostheses require the use of the contra-lateral hand for operation (a lack of unilateral use). The ability to position the prosthetic digit into flexion in a seamless manner is important for performing activities of daily living and thereby returning to work. Third, anatomical rotation about the MCP joint is not possible with current options. Current finger prostheses place the most proximal rotational axis of the prosthetic finger around the artificial MCP joint instead of the person’s MCP joint. This results in a prosthesis that is frequently too long and nonanthropomorphic and negatively affects the ability to grasp objects efficiently. This issue affects a large number of people with partial hand amputations and results in a reduction in the number of people who use prosthetic finger systems. Fourth, most current options offer a one-size-fits-all approach, limiting the acceptance by people who want a prosthesis that matches their original finger size. Proper finger lengths positively affect the ability to form stable grasps and improve the aesthetic appearance. There are other prosthetic finger components that can be sized in a

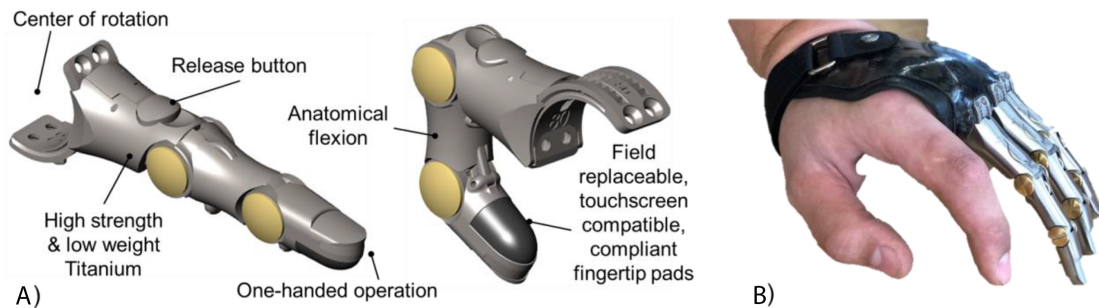


FIGURE 2. (A) Features of the Point Digit II include anatomically appropriate center of rotation and flexion, high strength-to-weight ratio, single-handed operation, and integrated fingertip pads. (B) Example of a three finger Point Digit II fitting including prosthetic socket, mounting bracket, and Point Digit II devices.

customizable fashion like the MCP Driver (Naked Prosthetics) and the X-Finger (Didrick Medical), but neither are for MCP level amputation. The TITAN finger (Partial Hand Solutions) provides 3 lengths (85 mm, 89 mm, 92 mm), which does not span the entire range of finger sizes necessary for all male and female partial hand amputees.^{9,11}

This work studies the Point Digit II prosthetic finger solution from Point Designs LLC (Lafayette, CO). The Point Digit II is a passive prosthetic finger for MCP level amputation (Fig. 2A). A spring-loaded ratcheting mechanism enables the unilateral positioning (one-handed operation) of the finger into 11 unique positions of flexion. The user can position the device into any of the 11 positions by pressing the device against an object, tabletop, or their own body. The 11 distinct positions enable the securement of objects of a variety of sizes especially for patients using multiple devices (see fitting shown in Fig. 2B). The extension of the Point Digit II can occur in two ways: 1) a self-locking button releases the ratchet and extends the finger or 2) the full flexion of the finger causes the finger to spring-back to full extension. By allowing external features to position the finger in both flexion and extension, the contra-lateral limb is not required for use of the Point Digit II. A kinematic linkage system couples all three joints of the Point Digit II, flexing them at an anatomically appropriate rate. The linkage system ensures a finger that behaves similar to the intact limb while maintaining mechanical strength. The Point Digit II provides an anatomically appropriate center of rotation about the former MCP joint. This feature ensures a clinically sound system that easily integrates into a prosthetic socket as shown in Fig. 2B. A mounting bracket provides a method for prosthetists to install the Point Digit II into the prosthetic socket and ensure appropriate positioning of the finger with respect to the physiological limb. It is manufactured using a direct metal laser sintering 3D printing process using high-strength and low-weight titanium to ensure comfort and robustness. Finally, fingertip pads provide a compliant surface to improve grip stability and provide a touchscreen compatible surface. The field replaceable nature of the fingertip pads ensures streamlined clinical care, which does not require additional appointments

for the replacement of the fingertip pads. In this study, the Point Digit II was tested across a battery of mechanical tests. The results are presented and followed by a discussion on the different prosthetic finger designs in the field today.

METHODS

The mechanical properties of the Point Digit II were studied using both static and dynamic testing procedures. The Point Digit II was designed to be durable, robust, and able to resist high forces. The design requirements included that the Point Digit II is able to resist at least 66 N applied to the fingertip, as this is the minimum a prosthetic hand ought to be able to generate.¹² When fully flexed, the finger should be able to hold a bag of groceries or about 10 kg (22 lbs) without failing. Finally, the mechanism was considered durable if it was capable of enduring ~250,000 extension-flexion-extension cycles, which represents approximately 3 years of use assuming 30 grasps per hour over an 8 hour work day.¹² The specific mechanical tests and detailed specifications are presented in the test plans below. No ethics committee or institutional review board was contacted because of the lack of human subjects required in this study.

Static Load Test Plan

To test the finger's ability to withstand static load, the finger was oriented in a material testing machine (MTS) so that the MTS loads the palmar side of the fingertip. The finger experienced a 66 N load applied at 1 lbs/s five times and confirmed to be able to withstand the load. Next, the test finger was mounted into a second fixture so that the MTS could load the medial phalange. The finger experienced a 10 kg (98 N) load five times and was confirmed to withstand the load on the medial phalange. Finally, the finger was tested to failure by loading the palmar side of the fingertip. This battery of tests was repeated with five different fingers in total to establish consistency across assemblies. Similar procedures were repeated for the lateral load tests where the procedures were implemented with the loading along the medial-lateral plane as opposed to the palmar-dorsal. This test studied the

mechanical strength of the Point Digit II assembly in different loading planes and locations to ensure a robust and durable prosthetic device.

Static Mounting Tear-out Test Plan

The tear-out strength of the mounting screws was determined by fabricating a custom mount for the Point Digit II. The custom mount had four holes with depth equal to that of the holes on the mounting bracket. Identical M2 Torx screws used to mount the Point Digit II to the mounting bracket were used to mount the Point Digit II to the custom mount. The base of the mount was clamped in the MTS, and the distal phalange of the Point Digit II was clamped in the opposing jaws. The MTS applied a tensile force on the finger-mount assembly until tear-out occurred. We conducted this test on five finger-mount assemblies to establish consistency. This test determined the attachment strength between the prosthetic finger and the prosthetic socket during use.

Dynamic Load Test Plan

Point Digit II's are regularly subject to repetitive, low forces like lifting a bag of groceries. Therefore, we performed various dynamic loading tests to assess durability and longevity. First, the Point Digit II was oriented in the MTS machine so that load can be applied to the palmar side of the fingertip similar to the static load procedure. Then, a load of 10 kg (98 N) was applied 10,000 times at a rate of 1 Hz. Second, the Point Digit II was fully flexed and oriented in the MTS so that a load can be applied to the medial phalange. Then, a load of 10 kg (98 N) was applied 10,000 times at a rate of 1 Hz. Third, the Point Digit II was fully extended and oriented in the MTS so that a lateral load was applied to the distal phalange. A load of 10 kg (98 N) was applied 10,000 times at a rate of 1 Hz. These three dynamic load tests were conducted with five unique Point Digits in order to establish consistency across prototypes. After the testing, each digit was disassembled and inspected for damage. This test plan mimicked an accelerated use case where multiple years of use were presented to the digit in a short period of time.

Dynamic Cycle Test Plan

To test the reliability of the mechanisms within the digits, another five test fingers were fabricated and tested in a custom cycling machine (Fig. 3). The machine used rotational motion to flex the fingers through their range of motion and then engage the "spring-back mechanism" which extended the digit back to a neutral position. We performed the dynamic cycle test to 250,000 cycles at 1.7 Hz and then proceeded to failure. The same cycling machine tested the durability of the compliant, high-friction surfaces on the fingertips. The machine struck the fingertip once per cycle to simulate everyday contact. The metric for passing this test was full finger function after 250,000 cycles, and reasonable fingertip wear (no underlying surfaces exposed). The dynamic cycle test

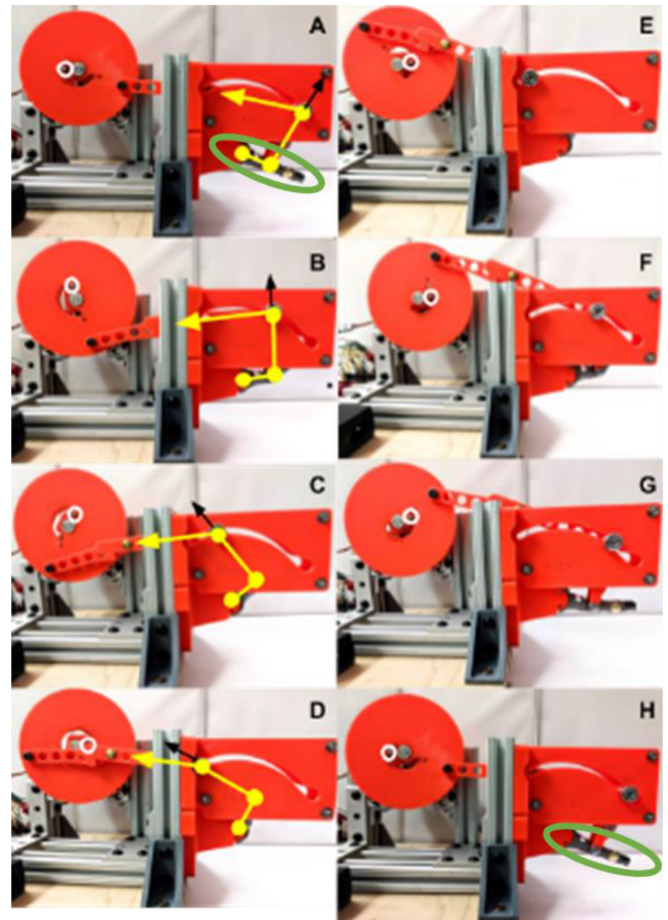


FIGURE 3. Cycling machine. (Left Column) A Point Digit II during various stages of flexion. The circle in panels (A) and (H) identifies the Point Digit II within the cycling machine. The digit then passes behind the red linkages in panels (B)-(G). The dotted lines represent the proximal phalange and linkage that attaches to the PIP joint. The arrow indicates the direction of the applied force and the black arrow indicates the direction of the resultant force that the digit experiences. (Right Column) A Point Digit II during various stages of free extension via spring-back.

plan ensured the reliability of the ratcheting mechanisms, spring-back mechanisms, and fingertip pads.

RESULTS

The Point Digit II prototypes were fabricated and subjected to the battery of mechanical tests. Table 1 presents the test results for each testing procedure including the number of samples tested, the average testing result, the standard deviation of the testing result, whether the test met the specification, and the amount the result exceeded the specification. A checkmark indicates the result met the specification, and the use of "+" indicates that the result exceeded the specification. The factor by which the result exceeded the specification is provided as the multiplicative value. In all tests, the Point Digit II met or exceeded the specification. In some cases, the Point Digit II exceeded the specification by several factors.

TABLE I. Mechanical Testing Results

	Mounting tear-out testing	Fingertip cycle test	Dynamic cycle test	Dynamic load testing (10,000 cycles @ 1 Hz)	Static load testing (load to failure)
Specification	196 N	250,000 cycles	250,000 cycles	Distal 66 N	Distal ≥66 N
# Samples	5	5	5	5	5
Avg. testing result	3,863 N	263,581 cycles	263,581 cycles	10,000 cycles at 66 N	1,370 N
Standard deviation	±285 N	±11,837 cycles	±11,837 cycles	n/a	±246 N
Meets specification	✓ + + + +	✓ +	✓ +	✓	✓ + + + +
Exceeds specification by	<u>19.7x</u>	1.1x	1.1x	1x	<u>20.7x</u>
				Medial 98 N	Medial ≥98 N
				5	5
				10,000 cycles at 98 N	≥200 N
				n/a	n/a
				✓	✓ +
				1x	2x
				Lateral 98 N	Lateral ≥98 N
				5	5
				10,000 cycles at 98 N	≥200 N
				n/a	n/a
				✓	✓ +
				1x	2x

Static Load Test Plan

The static loading procedure was implemented on the distal and medial phalange on the palmar surface and the distal phalange in the lateral surface. In all prototypes tested, the static strength of the Point Digit II at the distal fingertip exceeded the specification by 20 times (1,370 N compared with 66 N, 308 lbs compared with 15 lbs). The robustness of the Point Digit II surpasses all of the specifications and will provide people with partial hand amputation a robust prosthetic device. Similarly, the medial phalange of the finger will be able to support the weight of a grocery bag (98 N) since it withstood loads greater than 200 N across all assemblies. The lateral loading test showed that the device can withstand loads greater than 200 N when applied laterally to the distal phalange. This result proves that the digits can withstand typical lateral loading scenarios like pressing upon a table surface or using a door handle.

Static Mounting Tear-out Test Plan

A tear-out test was performed to verify the strength specification of the mounting system. Again, the device exceeded the specification by nearly 20 times (3,863 N compared with the 196 N, 868 lbs compared with 44 lbs). These loads are not probable in everyday use and depict a prosthetic mounting system that will withstand any loading scenario that a patient will see in everyday practice. Furthermore, the mounting system has superior strength to the digit and therefore can be trusted to transmit those loads through the prosthetic componentry and into the prosthetic socket.

Dynamic Load Test Plan

After the dynamic load cycling, each digit was examined for wear, damage, and function. The metric for passing this test was full finger function and no damage after the dynamic load cycling. In all cases, the digits withstood the dynamic cycling without notable change in performance or damage. The fatigue loading applied to the mechanisms could have caused wear along the sliding surfaces and/or fatigue to the linkage pins, ratcheting teeth, or other loaded surfaces. However, no visible wear was present and the functionality of the digit was maintained.

Dynamic Cycle Test Plan

An unloaded cycle was performed to verify the lifespan specification for both the fingertip and the digit. After cycling, the digits and fingertip pads were examined for wear and functionality. Five Point Digit IIs were cycled (extension-flexion-extension) 250,000 times without failure (average of 263,581 ± 11,837 cycles) and the fingertip pad maintained its surface properties. No underlying surfaces were exposed because of the abrasion. The successful dynamic cycle test results indicate that the lifetime of the mechanisms will last approximately 3 years of use without failure.

DISCUSSION

The results of the mechanical tests of the Point Digit II confirm that the design meets and exceeds all specifications. This empirical evidence proves the viability of the Point Digit II to withstand the rigors of heavy-duty use for patients. In the most important case, the static load test at the distal tip of the finger, the Point Digit II should be able to resist at least 66 N (15 lbs) applied to the distal fingertip. The tests showed its ability to withstand 20 times that amount, 1,370 N (308 lbs). This amount of force on the fingertip will not occur regularly and may only occur during impact loading scenarios like hammering a nail. The Point Digit II was designed for heavy-duty users who will require the use of hand-tools and other machinery, which will impart large impact loads on the prosthesis. The static load test results verified that the Point Digit II will provide a durable prosthetic system to ensure that these patients can return to work, utilize hand tools, interact with heavy machinery, and withstand large impact loads.

The manufacturing of the Point Digit II is novel compared with others in the field today. First, the main components are 3D printed out of titanium using a semi-hollow structure resulting in a device that is both low weight and high strength. The weight of the Point Digit II ranges from 30-36 g and meets the anatomical equivalent.¹³ The balance of both strength and weight distinguish the Point Digit II from other commercially available options. The TITAN from Partial Hand Solutions (Fig. 1) comprises of machined titanium components, which do not have hollow internal structures like the Point Digit II.⁹ Then, other products like the M-Finger (Partial Hand Solutions), iDigit (Touch Bionics), and VINCENT partial passive (Vincent Systems GmbH) use plastic componentry that cannot withstand the large static loads.⁹

Design features like the novel ratcheting mechanism, curved knuckle track, and linkage system to couple the three joints of the digit are unique to the Point Digit II compared with other prosthetic finger options. The ratcheting mechanism in the Point Digit II enables one-handed use. An opposing surface is used to flex, lock, and extend the Point Digit II throughout 11 distinct positions, not the contra-lateral hand. This design feature distinguishes the device from the TITAN from Partial Hand Solutions, which requires the use of the contra-lateral hand to unlock and position the digit. Furthermore, the passive design as opposed to body-powered devices allows the device to be used by patients without residual digits, which have sufficient range of motion to control a body powered device like the MCP Driver from Naked Prosthetics.¹¹ The knuckle track and linkage bars result in anatomical flexion and rotation about the MCP joint (Fig. 2A,B). These geometric features of the Point Digit II distinguish it from all other products in the market by providing an anatomically appropriate center of rotation about the former anatomical MCP joint as well as both distal joints in the digit. MCP joint rotation is important for both functional and aesthetic reasons. The Point Digit II achieves rotation about the patient's MCP

joint through a curved proximal knuckle track. The curved knuckle track creates a virtual center of rotation that is located about the former MCP joint as opposed to having a center of rotation that is distal to the residual limb like with the TITAN, iDigit, and/or VINCENT partial, which is the case for all other commercially available prosthetic fingers.¹¹ This feature is most critical when there are intact digits on the same residual limb as is shown in Fig. 2B. The Point Digit II can be mounted on the residual limb in an anatomically appropriate location that ensures that the intact digits and prosthetic digits can conform around an object in harmony. If the prosthetic componentry is mounted distal to the residual limb, then the grasping of objects can be ineffective and cumbersome. Furthermore, the kinematic linkage system in the Point Digit II couples the three joints of the digit unlike all other products. Other products fuse the distal two joints of the digits (PIP and DIP joints) into a single phalange like the TITAN and the VINCENT partial passive devices. This reduces the ability of the user to conformally grasp an object and can lead to unstable grasps where only some of the digits are in contact with the object. The kinematic linkages in the Point Digit cause flexion across all three joints, which mimics the effects of intact physiology. The rigid nature of the linkage bars provides increased strength in flexion as opposed to cable driven systems like the body-powered M-finger. The design features of the Point Digit II integrated geometric and kinematic design features in order to address clinical needs of both the patient and prosthetist alike.

CONCLUSION

A heavy-duty prosthetic finger for people with partial hand amputation must be able to withstand everyday loads and contain mechanisms that can withstand the lifetime of the prosthesis. Here, the Point Digit II prototype was mechanically tested and was shown to meet or exceed all specifications. In the future, the Point Digit II will be studied in a take-home clinical trial. The clinical trial will provide further justification for the use of the Point Digit II by recording outcome measures before and after 8 weeks of use. Then, the verification of the mechanical design of the Point Digit II will be complemented by the validation of the prosthesis during the clinical trial. These pieces of evidence will be provided to patients, clinicians, and other healthcare representatives in order to confirm the efficacy of the Point Digit II. These efforts will hopefully ensure widespread adoption of the device to enable increasingly more people with partial hand amputation to regain what was lost.

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CONFLICT OF INTEREST

Co-author B.P. is employed by Point Designs; co-authors L.S., J.S., R.W., and S.H. are major stockholders in Point Designs.

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