

Individualized Finger Prosthesis

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Abstract

As biomedical technology continues to develop, finger prostheses have become an increasingly viable solution for individuals that have suffered a finger amputation. Typically, prosthetic fingers are either mechanical or cosmetic; as such, patients have to choose between a prosthesis that is actively functional but very obvious or an extension that is passive yet inconspicuous. In collaboration with the client, Mr. Greg Gion, the members of team Phalanx Flexors devised a two-part assembly, consisting of a mechanical element that would be encapsulated by a hollow version of the realistic silicone finger prostheses that Mr. Gion crafts at Medical Art Prosthetics. As a skilled silicone prosthetist and founder of Medical Art Prosthetics, the “finger sleeve” was left entirely up to Mr. Gion, and thus the challenge of the final design was to create a minimal mechanism that would replicate both flexion and extension of the most distal phalangeal joint. The final prototype consisted of five 3D printed pieces and two metal pins, the former produced by the Arm-10 3D desktop printer through Digital Light Processing (DLP) stereolithography. The mechanism itself relies on the opposing motion that naturally occurs when one end of the lever arm is fixed to the underside of the joint proximal to the amputation; when this joint is bent, the other end of the lever arm is pushed forward. From this, the mechanism was designed to “pull back” on another piece that successfully recreated flexional motion. Additionally, mechanical extension was concurrent with the extension of finger. Three-point transverse MTS testing proved that the mechanism would withstand normal daily use when compared to experimental force values exerted by a finger. While the mechanics of the design functioned as intended, further optimization of both the size and material used would greatly improve the strength and appearance of the prosthesis when both the mechanical and cosmetic parts are assembled.

Abstract	2
Introduction	4
Background	4
Preliminary designs	6
Design 1: The Links	6
Design 2: Leverage Joint	6
Design 3: Push/Pull	6
Design 4: Levers	6
Design 5: Gear System	7
Preliminary Design Evaluations	7
Design Matrix	7
Summary of Design Matrix	8
Final Design	9
Testing	10
Results	12
Fabrication & Development	13
Materials	13
Methods	13
Discussion	14
Conclusion	15
Appendix	16

Introduction

Each year, around 61,000 Americans lose at least one finger in a partial hand or finger amputation. The causes of these amputations are widespread, ranging from work-related accidents to cardiovascular diseases, infections, and nerve injuries [1]. Unfortunately, current partial phalange prosthetics on market either do not restore function of the lost fragment, or are bulky and undesirable to wear for affected individuals. Creating a prosthetic device that can restore some of the function of the lost phalange fragment while looking inconspicuous to the wandering eye is essential to help amputees return to a more normal hand function. Today, prosthesis companies such as Medical Art Resources, Inc. produce cosmetic finger prostheses composed of silicone that slides over the residual finger. These prostheses are undetectable to the eye, but do not provide any additional function to the affected finger, causing awkward hand gestures in everyday life [2]. In contrast, more functional-based prosthesis companies, such as Naked Prosthetics, provide a more functional artificial phalanx that is more tailored to the everyday tasks of individuals. However, these prostheses are composed of carbon fiber or other highly functional material and look alien on the hands of patients [3]. There seems to be a gap in available products for individuals that want a bit of function out of their prosthetic finger without the conspicuousness of a functional prosthetic.

Background

Mr. Greg Gion, our client and owner of Medical Art Prosthetics, tasked us with designing a functional skeletal structure that can be placed over the residuum of an amputated finger. Specializing in realistic cosmetic prosthetics, Mr. Gion desired something that could be covered with a silicone finger sleeve to create a final product that was not only functional, but appeared realistic as well. Aside from this, our client also wanted our design to be simple enough that specialized designs could be made for each customer and printed off in his lab. He also expected the device to last from three to five years, but no strenuous activity, such as weightlifting, to be placed onto the device. Further specifications for our design can be found in the PDS in the appendix.

The complex and precise movement of the human fingers is regulated by muscles in the forearm and tendons in the hand that control the movement of each joint. Each of the fingers contains three tendons that each play a key role in flexion or extension. These tendons are the flexor digitorum superficialis, which flexes the middle phalanx, the flexor digitorum profundus, which flexes the distal phalanx, and the extensor digitorum communis which is the sole tendon responsible for extending the finger. As a team, it is our responsibility to first recreate the structure lost in an amputation and then try to replicate the function of these tendons.

Finger	tip – soft tissues of the tip of the distal phalanx (mm)	distal phalanx (mm)	medial phalanx (mm)	proximal phalanx (mm)	metacarpal (mm)
I	5.67±0.61	21.67±1.60	-	31.57±3.13	46.22±3.94
II	3.84±0.59	15.82±2.26	22.38±2.51	39.78±4.94	68.12±6.27
III	3.95±0.61	17.40±1.85	26.33±3.00	44.63±3.81	64.60±5.38
IV	3.95±0.60	17.30±2.22	25.65±3.29	41.37±3.87	58.00±5.06
V	3.73±0.62	15.96±2.45	18.11±2.54	32.74±2.77	53.69±4.36

Table 1. This table shows the average phalanx and metacarpal lengths in the hand taken from the x-ray images of 66 undeformed hands. As found in [4], the data shown is in the form of average±one standard deviation.

For our design to look as natural as possible, it also needs to be as anatomically correct as possible. Table 1 from Buryanov and Kotiuk [4] shows the average lengths of the phalanges and metacarpals located in the hand. This information proved useful during the preliminary design process and throughout the production of the prototype.

Preliminary designs

Design 1: The Links

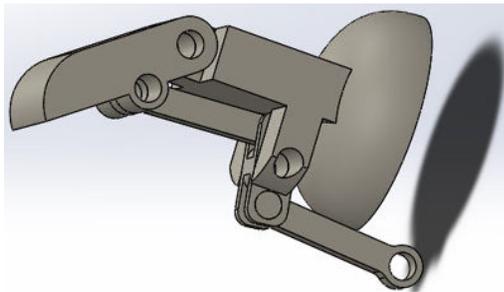


Figure 1. When a patient bends their finger, the rightmost link hits the more proximal finger segment and forces a bend in the prosthetic distal end. By manipulating the relative sizes of the links, our client can change the force necessary to initiate prosthetic movement and the range of motion achievable by the total finger system.

Design 2: Leverage Joint

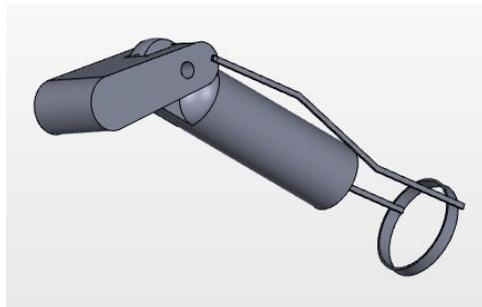


Figure 2. The wires depicted in this design attach to a ring just below the proximal joint of the residuum of the finger. The rod will be directly attached to a cap covering the residuum. As the proximal joint bends, the force from the wires creates a moment in the lever acting as the distal phalanx. This leverage causes the device to bend downward, and the subsequent extension of the proximal joint will in turn cause the lever to extend.

Design 3: Levers

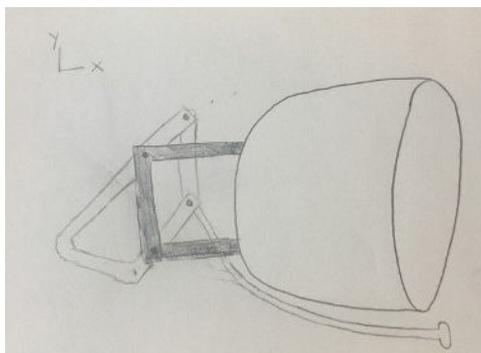


Figure 3. This design uses a push/pull system to control the flexion and extension of the prosthesis. As the lever on the bottom of the prosthesis is pushed to the left, it causes a moment imbalance at the two pins holding the mechanism onto the anchor frame. As the lever on the bottom is retracted back to the right, these moment imbalances reverse, causing extension of the joint.

Design 4: Push/Pull

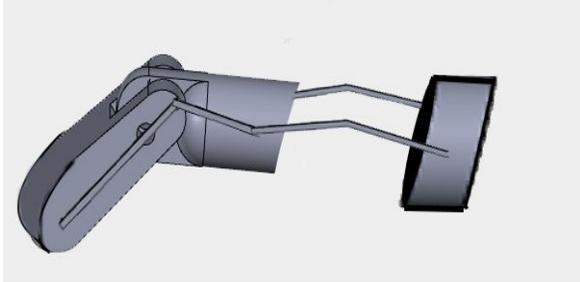


Figure 4. This design incorporates both a push/pull design centered on a ring the patient wears and a lever mechanism resting on the anterior surface of the amputated finger. By use of a moment arms the device will be able to flex based on the patient's articulation of their finger. The design features a built in spring to assist with extension of the finger following flexion.

Design 5: Gear System

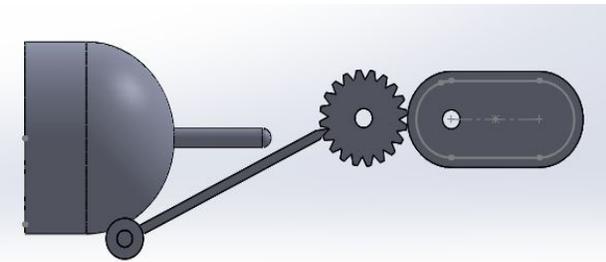


Figure 5. This design consists of a lever connected to the finger cap, and two fixed gears. When the residuum flexes, the extension on the tip of the the finger cap increases the moment arm, which pushes the lever in the downward direction, causing a counterclockwise rotation of the left gear. The left gear then causes the right gear to rotate clockwise about its fixed point. In this design, the left gear resembles the knuckle, and the rightmost gear mimics the distal portion of the index finger.

Preliminary Design Evaluations

Design Matrix

	Weight	Links		Two Bar Push / Pull		Leverage Joint	
Ease of fabrication	20	4/5	16	4/5	16	4/5	16
Functionality	20	4/5	16	4/5	16	3/5	12
Simplicity of design	15	4/5	12	3/5	9	4/5	12
Estimated lifespan	15	4/5	12	4/5	12	3/5	9
Weight	10	4/5	8	5/5	10	4/5	8
Safety	10	5/5	10	5/5	10	4/5	8
Cost	10	5/5	10	5/5	10	4/5	8
Total			84		83		73

Table 2: Design Matrix

Summary of Design Matrix

When choosing how to evaluate designs three fundamental questions arose: “Does the design work?”, “How easily can it be fabricated?”, and “Which design will benefit the patient the most?” With these guidelines in mind the above criteria and weighting scales were developed. The team individually assessed each design and data was collected on the averages. Due to the competitiveness of our designs, some design ideas were within fractions of a point from each other. In the interest of neater viewing, these fractions were rounded to the nearest integer in the table above. The proposed final design remained the same after rounding.

Final Design

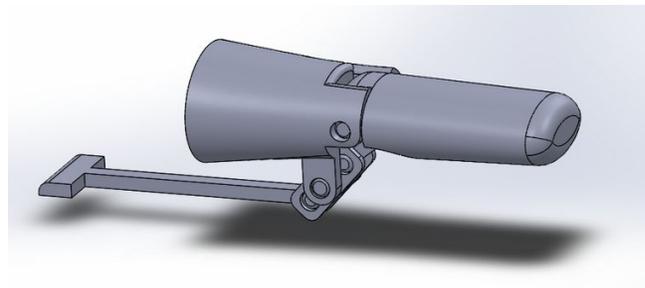
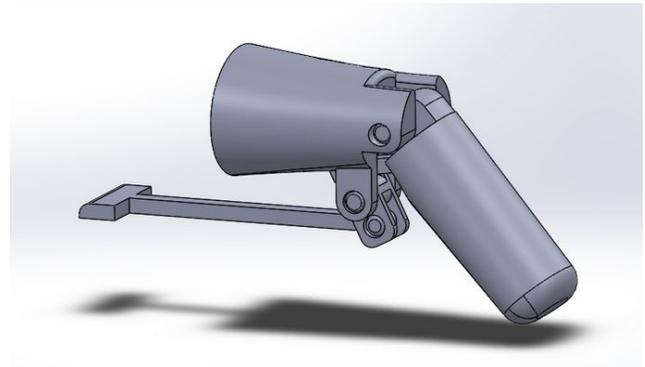


Fig. 6,7, and 8: Final Design

Based on the evaluation of our design matrix and having fabricated a working prototype, the design “Links” was selected as the proposed final design. It was remodeled in solidworks and revised over multiple iterations after printing and recognizing flaws. Using the basic concept of the “links”, a more fingerlike shape was developed and a more efficient packaging of the mechanism was added to the bottom. In addition, the fingertip was integrated into the end of the cap, furthermore reducing size. Adding the fingertip to the assembly is essential in keeping the design lifelike, but can still be customized to our clients needs. By simply adjusting dimensions in the model to match the user’s finger, the fit can be flawless. In addition, if the finger is partly cured while on the finger, it will solidify with further accuracy. In future work, a laser scanned residuum can be imported into the software to provide a perfect cast-like fit.

The mechanism itself consists of five 3D printed pieces and two metal pins. To actuate the mechanism, one end of the lever arm is fixed to the underside of the joint proximal to the amputation; when this joint is bent, the other end of the lever arm is pushed forward. This distal end of the lever arm rotates an axial piece that pulls the solid distal end inwards, therefore recreating flexion. Since the initial lever arm is fixed to the proximal joint, the mechanism achieves extension along with the natural extension of the finger.

Testing

The prosthesis will endure daily challenges over a long lifetime as it is expected to perform for the patient every single day. To ensure the resiliency and performance of the product, the prosthesis will be subjected to different quantitative tests. These tests will measure the operational characteristics of the prosthesis, measuring overall strength, endurance, and failure points. Although the mechanical element will not be expected to experience extreme stresses throughout daily usage, it must maintain functionality under reasonable stresses and temperatures associated with daily tasks. The following tests were conducted using three 3D printed prosthetic prototypes, which all had the same dimensions, plastic materials, printing resolutions, and ultraviolet curing exposures.

Mechanical Testing:

The highest priority of the design is to ensure that it indeed functions properly while encased within the silicone finger sleeve. As such, MTS compression testing was conducted to confirm the mechanical element's viability and limitations of use. While not expected to experience such extreme stresses, the device should be able to withstand benchmark tests to ensure proper functionality throughout a wide range of activities.

A three point MTS transverse load compression test was first conducted at room temperature (21C) to see the failure strength of the prosthesis in the transverse plane. Since most of the daily stresses on the fingers are loaded transversely rather than axially, a transverse loading test was determined better fit for failure testing rather than an axial test. The prosthesis having an overall height of 12mm, the MTS compression test was set to a 6mm strain with a 6mm/min strain rate. The MTS compression drop height was not set to the full 12mm of the height of the prosthetic since failure was expected much before a 100% strain. Below is an image of the orientation of the mechanical element within the MTS machine.

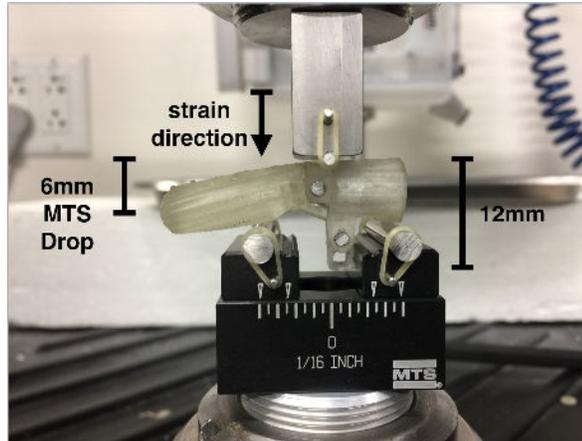


Figure 9: 3 point MTS transverse load compression test at room temperature

Thermal Testing:

In addition to ensuring adequate performance with regards to transverse stresses at room temperature, the prosthesis must also be able to withstand various loadings at temperature fluctuations experienced throughout everyday life. During instances of heat exposure, such as grabbing a hot cup or cooking, the mechanical element should not melt or experience excessive thermal expansion that would hinder the performance of the prosthesis. Additionally, during instances of cold exposure, such as scraping ice off of a windshield on a cold winter day, the mechanical element must not contract to such a degree that would hinder the performance of the product. The mechanical element must exhibit resiliency at these temperature fluctuations and maintain its structural integrity without significant deformation or loss of yield strength.

In order to mimic temperature changes throughout everyday tasks, the mechanical elements were subjected to varying thermal baths kept at constant temperatures. First, to mimic heat exposure, the mechanical element was subjected to three consecutive 30 second intervals of a hot water bath. This bath was filled with deionized water and heated to a constant temperature of 50 degrees Celsius. Directly after exposure to the hot water bath, the mechanical element underwent the same 3 point MTS transverse load compression test as described above. Second, to mimic cold exposure, the mechanical element was subjected to three consecutive 30 second intervals of an ice bath. This bath was filled with deionized water but included tap water ice cubes due to lack of access of deionized ice. Directly after the mechanical element was exposed to the cold exposure, the same 3 point MTS transverse load compression test was executed, as described above.

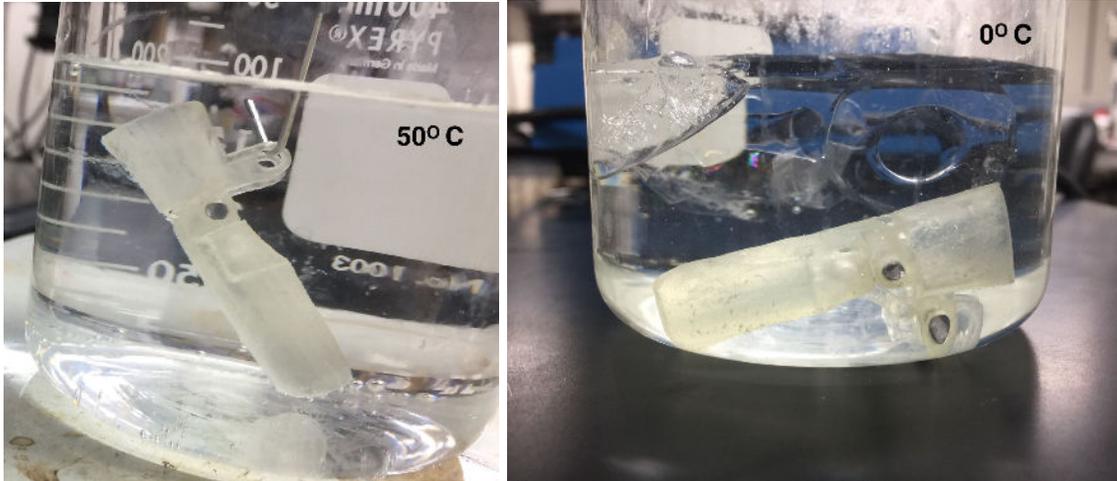


Figure 10, 11: Left: Mechanical element subjected to the hot water bath. Right: Mechanical element subjected to the ice bath.

Results

The 3 point MTS transverse load test conducted on the three specimens provided failure loads and stresses throughout the temperature range expected throughout daily tasks. The mechanical element failed either at the finger cap or the top joint, where the stresses were most concentrated. Below is a graph of the failures of the three elements at different temperatures, along with the respective deflections experienced.

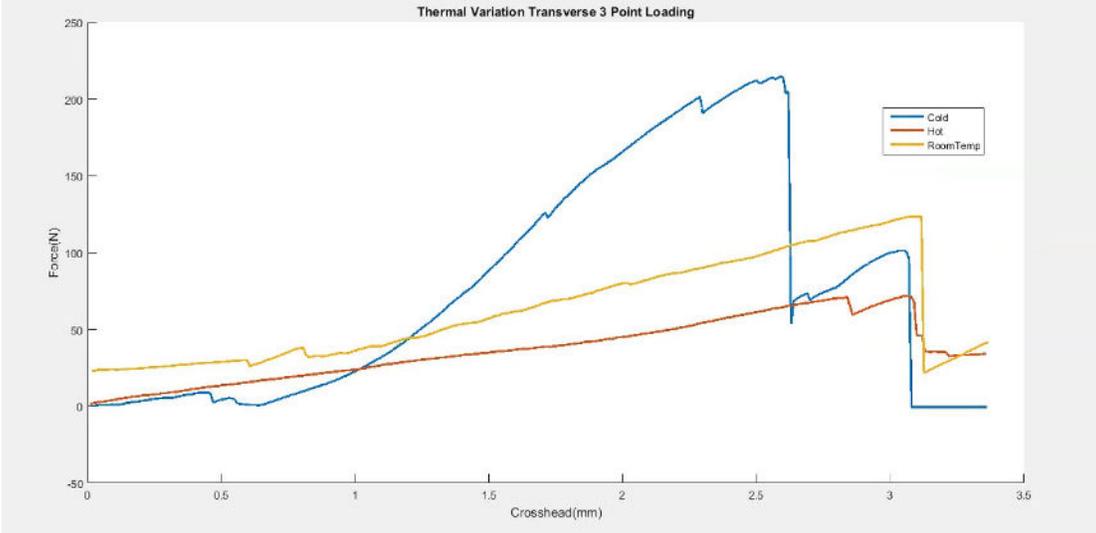


Figure 12: graphical representation of the crosshead-load differences throughout normal operating temperatures of the mechanical element.

From the data gathered from the MTS compression tests, it was concluded that the mechanical element is indeed able to withstand daily stresses involved with everyday tasks. The baseline room temperature compressive test exhibited an ultimate loading of approximately 110N for the mechanical element. As temperatures were dropped, this ultimate loading was increased to a value of approximately 220N. Conversely, as temperatures were increased, the ultimate loading was decreased to a value of approximately 60N. Since a gallon of milk has a weight of roughly 38N, the mechanical element should withstand everyday tasks such as carrying groceries as long as the prosthetic does not warm up significantly. Additionally, a loss in ductility was observed as temperatures dropped. This creates a much more brittle mechanical element at lower temperatures.

Across the three thermal tests that were conducted, it was concluded that the standard deviation of the failure load is 66.833 Newtons. This fluctuation in failure load capacity of the mechanical element can cause a large change in performance depending on the operating temperature of the prosthetic. Below is the equation used to calculate this standard deviation.

$$\sigma_{SD} = \sqrt{\frac{1}{N} \sum_{i=1}^N (x_i - \mu)^2}$$

The diagram illustrates the components of the standard deviation equation. Three arrows point from text labels below to parts of the equation:

- An arrow from "number of thermal tests" points to the variable N in the denominator.
- An arrow from "failure load" points to the variable x_i in the summation term.
- An arrow from "mean failure load" points to the Greek letter μ in the summation term.

Figure 13: calculation of standard deviation of the failure loads.

Fabrication & Development

Materials

As mentioned before, the body of the mechanical element in the finger prosthesis is most easily fabricated through 3D printing technology. The Arm-10 3D printer uses a photo-curable resin, which quickly dries when exposed to the UV light source below the printing platform. There are a couple variations to the imageCure™ standard resin that can be used; both the PRH35-ST2 and PRH35-ST are highly recommended and manufactured by the Roland DGA company. This stereolithographic resin is primarily composed of bisphenol A, ethoxylated, dimethacrylate (80-90% by weight) and rapidly polymerizes under heat and UV light (Reference). The end product has the appearance of white translucent plastic.

It is structurally advantageous to use a harder material for the internal pins of the mechanism; for the purposes of the team's prototyping, we cut "typical" steel nails to size.

The fabrication and materials involved with silicone finger sleeve is solely up to Mr. Gion's discretion.

Methods

The Arm-10 machine is designed to be simple to use. After installation of the required software and drivers, the model is loaded onto a virtual plate and printed. It is necessary to consider the structural integrity of the part as it is being printed. Since the part is still flexible until cured, supports must be added to ensure there is no movement during the print cycle and that parts with gaps can be supported correctly (Fig. 14). The print time depends on the height of each layer and the cure time applied to that layer. Printing times can range from 2 hours with 0.15 mm layer height to 5+ hours with sub 0.05 mm layer height. We chose a 0.1 mm layer height with default curing times based solely on ease of iteration. Future work includes testing structural differences between settings. To release the part from its printing platform. The supports are cut away and carved down to the piece. It is washed in ethanol to remove excess resin and cured in a UV light chamber for ~10 minutes. The piece is then slightly sanded in binding regions to ensure proper function of the mechanism.

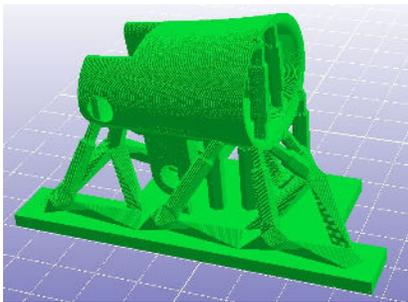


Figure 14: A rendering of the "Cap and Base" part of the assembly with automatically generated supports.



Figure 15: Arm-10 3D printer by Roland DGA

Discussion

With the failure of the mechanism occurring at a higher force value (see Results) than the target force (around 40N), the mechanical element was proven to be able to perform throughout everyday tasks, granted that excessive stresses are not placed on the element.

However, the results of our testing do have potential sources of error. First, the MTS compression tests conducted on the mechanical elements were executed at a speed of 6mm/min. This speed is much slower than the speed the prosthesis is expected to function at in daily tasks. The loading and unloading at higher rates could cause a much higher magnitude of stress within the mechanical element, causing it to fail much faster than seen within the results. The MTS compression tests were not able to be performed at the rates seen in everyday life due to the brittle nature of the mechanical element material, and the safety hazards associated with having projectile pieces within the laboratory. For this reason, the tests were not able to be conducted faster than 6mm/min.

In regards to thermal testing, the ice bath that was used in the cold exposure tests had deionized water, but the ice cubes were from tap water. As the ice melted, the water in the bath was no longer deionized. This is a discrepancy with regards to the completely deionized hot water bath. The impurities in the water could have melted and reacted with the resin of the mechanical element, causing skewed data. Third, the hot water bath MTS compression test snapped the mechanical element at the finger cap, while the cold water and room temperature tests snapped the mechanical element at the top joint of the prosthesis. The differences in failure points might lead to discrepancies of placement and force application of the MTS machine, causing skewed results as well.

Lastly, any variation in the production of the prosthetics, including creation within the 3D printer as well as assembly and cutting of the pieces out of the 3D printer can cause variations with the samples that were tested, leading to a skew of the data.

Conclusion

Finger prostheses are provided for people who may have lost a finger due to amputation or accident. These products are forced into one of two categories: aesthetic or functional. This team was tasked with designing a product that can achieve both and, within a \$10 budget, develop a process that can be reproducible for our client. Furthermore, the team was responsible for creating a test that would allow prosthesis properties to be evaluated against those of existing phalanges.

The design achieved the goal, but there is much to be improved. Overall, The prosthesis is functional and could be utilized for basic tasks. However, with the addition of the silicone sleeve, its function is greatly reduced unless sleeve material is removed from the bottom near the mechanism. Future versions should house the mechanism in a small shell or reduce its size to prevent binding with the material. To improve the workflow of our client, it would help to include automation in the modeling process. A macro can be written using Visual Basic and Solidworks to automatically adjust the size of the prosthesis using relative dimensions of the features of the model. This allows a user with no experience in 3D modeling to automatically generate a fitting model in almost no time. Using this macro, our client can automatically integrate laser scan results directly to the model. Finally, further testing should be done with print settings to optimize the structural integrity of the prosthesis such as layer height, cure times, etc.

With regards to testing, although the mechanical element of the prosthesis was able to withstand the basic stresses of everyday tasks, there are many activities that would cause failure in the mechanism. This is mainly due to the material and dimensional constraints imposed by both the 3D printer as well as the anatomy of the finger. To improve the durability and structural strength of the mechanical elements, improving the materials used to create the prosthesis as well as tweaking the design could offer a stronger and more resilient prosthetic. The mechanical element could also undergo more vigorous compressive testing, including a much faster strain rate transverse load test as well as an axial compressive test. The addition of

a pinch grip test could prove useful in measuring the ability of the prosthetic to be used in more fine motor skill tasks, such as writing or basket weaving.

References

- [1] Amputee Coalition Organization. *Limb Loss Awareness Month*. Amputee Coalition, 2013.
<http://www.amputee-coalition.org/events-programs/limb-loss-awareness-month/>
- [2] Brown University Department of Biology and Medicine. *Statistics on Hand and Arm Loss*.
Brown University, 2003. <http://www.aboutonehandtyping.com/statistics.html>
- [3] Medical Art Resources, Inc. *Martin Defatte for Platypus Advertising Design*. Medical Art
Resources, 2016. <http://www.medicalartresources.com/services-directory/finger-toe-2/>
- [4] A. Buryanov and V. Kotiuk, "Proportions of hand segments," *Int. J. Morphol.*, Kiev, Ukraine,
Rep. 28(3):755-758, 2010.
- [5] Naked Prosthetics, Inc. *It's All About Function*. Naked Prosthetics, 2016.
<http://www.npdevices.com/>

From Appendix:

- [6] Jan de Cubber, "Finger or Toe Prosthesis", US Patent Application Publication,
Patent# PCT/EP05/07503, PDF, 2007

Appendix

1. Product Design Specifications -

Function:

Our client, Dr. Gregory Gion, has tasked us with the design and fabrication of a functional, cosmetic finger prosthesis to replace the distal joint of the index finger. The design should be useful for everyday tasks and small enough to be hidden beneath a cosmetic sleeve

which is individually crafted by our client. The product should be completed by the end of the Fall 2016 semester.

Client requirements:

The client is looking to prototype a cosmetic finger prosthesis that possesses active function capabilities. This prosthesis will consist of two main components with movement facilitated by the motion of the patient's residuum. The principal challenge of the design is to create a skeleton-like mechanism that will mimic the functionality and structure of the distal inter-phalangeal joint and its corresponding tendons and ligaments. After the mechanism is created, a cosmetic sleeve will slide over the mechanical unit of the prosthesis, making the artificial phalangeal segment appear natural. In addition, all parts of the prosthesis must be easily reproduced within the client's laboratory.

Design requirements:

1. Physical and Operational Characteristics

- a. *Performance requirements:* The device should be worn throughout the entire day, but must also be removable when desired. The prosthesis should be able to perform both passive and active functions of phalanges, including simple tasks such as picking up a coffee cup or handwriting. However, it is not expected to be used under severe stress, such as weightlifting.
- b. *Safety:* Due to the prolonged contact with the skin, both the cosmetic sleeve and the finger cap must be biocompatible. In the past, Dr. Gion has used silicone for both solid and hollow prosthetic fingers and surgical plaster casts or PMMA for finger caps. These materials are already known to be biocompatible and durable, and therefore can be similarly used in the team's design. The mechanical element itself must be durable, non-porous, and non-corrosive to accommodate normal instances of stress while maintaining mechanical integrity during exposure to water or perspiration.
- c. *Accuracy and Reliability:* The entire assembly should be easily duplicated to serve the needs of a variety of patients. After modeling the mechanical elements in SolidWorks, repeatability of fabrication is most easily achieved using the client's existing ARM-10 desktop 3D printer and compatible resin. Using anthropometry of the hand as a baseline, the length and diameter of the assembly can be tailored to an individual's particular phalange dimensions.
- d. *Life in Service:* The prosthetic must continuously function for up to 16 hours a day under normal activity levels to provide the patient with proper flexion and extension. Service may include occasional cleaning or refitting of mechanical components. Ideally, the

assembly will maintain mechanical integrity for at least 3-5 years which is the approximate lifetime of the existing silicone sleeve.

- e. *Shelf Life:* The product will be made to order and used immediately so there will be no pre-use storage requirements. As far as storage in between use, as long as the device is stored in a cool dry area, it will be able to last its full life in service.
- f. *Operating Environment:* The product will not be exposed to many extreme circumstances. Daily activity may include manageable loads, low temperature (in the local area), and moisture. The latter being the most important; in accordance with the client's aesthetic cover, the product should hold up to repeated exposure to wetness. Additionally, it is important that the design be resistant to corrosion resulting from moisture and cleaning.
- g. *Ergonomics:* The customer will likely use this product for everyday activities. Unlike strictly functional prostheses that are often attached with supports, the aim of this product is to utilize the existing suction capabilities of the silicone sleeve to keep the mechanical component in place throughout the day. This means that the user may not be able to experience extreme forces, however, this shouldn't hinder them when performing basic biomechanical motions. The range of motion should be comparable to an existing finger. Additionally, the attachment should allow all day comfort.
- h. *Size:* The size of the prosthesis should be small enough to be concealed underneath a cosmetic coating without looking too bulky or unnatural. The dimension should also mimic that of a natural index finger. Since our client deals with a large age range of clients, and therefore, various residuum sizes, our design will be customizable to fit any patient. Measurements taken from the customers hands will be used to determine the length of different components. We aim to provide a fit for any possible customer.
- i. *Weight:* Keeping user comfort in mind, the weight of the assembly should be kept to a minimum. Using lightweight materials for the mechanical element would be ideal to decrease additional strain in the knuckle from lifting the prosthetic.
- j. *Materials:* Corroding metals should not be used for the purpose of creating a long lasting prosthesis. A durable, and easily machinable material must be chosen for the mechanical portion of the design. The material chosen for the mechanical portion of the prosthesis must also be compatible with Mr. Gions existing materials which includes PMMA and silicone. Ideally, the material(s) chosen will already be available in Mr. Gions office or be quickly and easily attainable.
- k. *Aesthetics, Appearance, and Finish:* Because the prosthesis will be covered by a sleeve, our aesthetic concern is the bulkiness of our design. The client described prosthetics as an "artform," so the mechanical element will be as thin as possible for optimal discretion

and realistic appearance. During flexion of the device, the prosthetic needs to maintain a natural look and mimic the actual anatomical tendencies of the human finger.

2. Production Characteristics

- a. *Quantity:* Our client has only requested one functional model to be used for the index finger. However, he has expressed interest in self manufacturing additional units, so process design is necessary. Being able to produce a large amount of units efficiently without error in our client's office space is a crucial concern.
- b. *Target Product Cost:* As our client intends to produce this product in house, it is important that the costs be justifiable in terms of materials used. Valid tradeoffs include material strength, mechanical simplicity, and reproducibility. Our client stated that other functional prostheses may cost more than \$10,000 and he would like to be extremely competitive. He has granted us a budget of \$500 for the semester but we aim to limit the unit cost to under \$10 to produce a single unit with 3d printing technology.

3. Miscellaneous

- a. *Standards and Specifications:* The prosthesis must comply with the beneficiary's requests, and instructions for fabrication, assembly, and operation will be provided.
- b. *Customer:* Mr. Gion's clients are looking for finger replacements that are unnoticeable as well as functional. The client would like the mechanical unit to function as an anatomical finger while visually resembling a human finger. For production, he would like something that can be replicated quickly in as little as a day.
- c. *Patient - related concerns:* Our design is not intended to enter the body in any way, so sterilization should be of little issue. Mr. Gion sees patients with a wide range of injury, as well as finger length and diameter. Our design should be highly customizable and easily manufactured in Mr. Gion's lab setting to ensure that products for patients of all different finger types and extents of amputation can be produced.
- d. *Competition:* Upon searching through a patent application and publication database, a prosthetic finger similar to this design project was found. The prosthetic by Jan de Cubber is designed to replace the entire finger through an internal, skeleton-like structure. Her design incorporates a socket, bone anchor, and spring loaded joints in the fingers. Like ours, it can be covered with a cosmetic sleeve. However, the aforementioned prosthetic options in the general biomedical market do not commonly offer this combined mechanical and aesthetic solution. Therefore, Ms. Cubber's designs are worthy of inspiration towards the team's original approach toward the design of a prosthetic distal phalangeal segment [6].

2. Bill of Materials

Part Name	Description	Part Number	Purchased Place	Cost	Quantity	Total Amount
resin for ARM-10 3D printer	Resin used to 3D print the mechanism and the supports	PRH35-ST2	https://www.rolanddgastore.com/product.aspx?zpid=32894	\$89.99	Approx 40g of resin	\$10.28
#11-1/2 x 2-1/2 in. 8-Penny Hot-Galvanized Steel Box Nails (1 lb.-Pack)	Nails used to replace the moment link pin and the base pin for extra stability	Model # 8HGBX1 Internet #202308599 Store SKU #446386	Home Depot: http://www.homedepot.com/p/Grip-Rite-11-1-2-x-2-1-2-in-8-Penny-Hot-Galvanized-Steel-Box-Nails-1-lb-Pack-8HGBX1/202308599	\$4.24	2 nails	\$0.0584
					Total	\$10.29

Table 3: Materials needed to create a single mechanism and the total cost to produce a single mechanical unit.