Implant-retained finger prosthesis

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Abstract

The project involves the improvement the connecting mechanism and substructure for implant-retained finger prosthesis. The current slip-cover device that holds the prosthetic by suction fails to function as a real finger, thus new prosthetic implantation approach is preferred. The proposed prototype consists of the Allen wrench connecting mechanism and the Solid Works displaying the “spring-loaded mechanical joint” substructure. The design indicates that the implant-retained finger prosthesis has a stronger connection mechanism, and is able to regain certain original functionality.

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Problem statement

The main focus of our project is to create a connecting mechanism that will improve upon the functionality of prosthetic fingers. Currently, in the United States the only FDA approved connecting mechanism is a slipcover device that is held onto the amputated finger through suction. The current suction mechanism of prosthetic fingers has little to no practical function. We want to add functionality to the prosthetic without making it any less aesthetically pleasing. In other countries osseointegration, a procedure similar to that of dental implants, is used for prosthetics. Osseointegration will be the basis of our design, where a metal abutment will be fused with the remaining bone of the amputated finger. Building off of this, we will need to propose an idea for a better connecting mechanism and a better substructure.

Background

Problem motivation

The final device is expected increase the motility and functionality of the implant-retained finger prosthesis compared to the current model. The incorporation of a new substructure is expected to improve prosthetic motility. The enhanced connecting mechanism should allow the patients to easily remove and clean their prosthesis. By coming up with this new device, and involving a surgeon in our work, we hope to raise awareness to the FDA to pass more finger prosthesis.

Clinical problem

It is highly probable that a simple accident that will cause one to have a life-long lasting effect. An injury such as a loss of one finger is considered as a significant functional, life-long deficiency (Michael& Buckner 1994). One way to restore the functionality of the lost digit is by replacing the amputation with prosthesis. According to Michael& Buckner (1994), prosthesis can restore a "near-normal function" of the original finger. Moreover, as long as 1cm of the mobile phalanx remains at the amputated region, the restoration of active grasp finger is feasible (*ibid.*).

Traditional prosthetic finger

The traditional method of prosthesis is replacing the lost finger with an artificial digit. The artificial digit is made of silicone elastomer, which its chemical name is polysiloxane. Silicone elastomer of a prosthetic finger is sculpted custom made to suit every individual. Multiple layers of clear silicone overlap each layer, and the flesh-like color is gradually added to customize the skin color for the patient (*ibid.*). Since silicone is a high chemically stable material, it has a high overall durability and stain resistance relative to any other current finger prosthesis material (*ibid.*).

The adhesive vacuum allows the prosthesis to remain on the finger. Other medical adhesions are provided to enhance the adhesiveness. Decorative rings near finger joints are also used to cover up the margin between the amputation and the prosthesis. However, this type of weak adhesion force often results in missing prosthesis, since the prosthesis has a high tendency to be released from the amputation. Moreover, this poor adhesive ability limits the force that the prosthesis could withstand before detachment. Thus, pure silicone elastomer prosthetic finger has mainly cosmetic purposes and low functionality.

Implant-retained finger prosthesis

A second prosthetic mechanism called implant-retained prosthesis is introduced to solve the problems of simple silicone prosthesis. This method was originally used in Australia, Europe, the UK and South Africa (meeting with G. Gion, 2007). A metal piece is inserted and then implanted into the terminal bone of the amputation, which is called osseointegration. This metal abutment insertion provides a more solid anchor to which the silicone elastomer attaches to. This attachment is relatively stronger than pure vacuum adhesion, which allows the patient to exert more force with the prosthesis. Thus, implant-retained has a higher prosthesis functionality, which could possibly regain the confidence of the patients.

Osseointegration

Osseointegration is the attachment method used in implant-retained prosthesis. It was originally discovered by Per-Ingvar Branemark in his research, which studied blood flow in rabbit bone (Fairley 2006). By the end of his study, a titanium (Ti) implant chamber used in the study tightly integrated with the rabbit bone (*ibid.*). The discovery of metal integrating into the bone (osseointegration = bone-integration) was then used in other medical fields, such as dentistry fixation and maxillofacial reconstruction (Aydin et al. 2007). Two surgeries are required for a complete osseointegration implantation. The first surgery involves the implantation of a Ti abutment into the remaining skeleton at the amputation (Fairley 2006). The surgery wound would heal after approximately 3 to 6 months depending on the wound size (*ibid.*). After healing, the wound is then re-exposed with the Ti bolt attached to the bone. Finally the silicone elastomer segment is attached to the Ti bolt (*ibid.*).

Design Constraints

Due to the necessity for osseointegration, the implanted abutment will be made out of a metal like titanium which will fuse with the digit bone. The outer prosthetic silicone skin must be anti-corrosive and non-toxic to allow the patient use of this prosthetic finger for things like eating and grooming. Furthermore, the entire prosthetic must be easy to disassemble and clean for

hygienic purposes, as well as for the ease and comfort of the patient. In order to maintain visual consistency with the real hand parts, the prosthetic must have similar properties of a real finger such as size, weight, and shape. This requires that the substructure created will be small enough that the prosthetic outer skin will easily cover and conceal any protruding edges and abnormal features of the substructure. The prosthetic finger, together with the substructure and outer prosthetic skin, must be able to withstand weathering, temperature variations, and forces normally experienced by a human finger.

Current device

Our client uses the only FDA approved device in his work, which is a silicone elastomer cover. This method involves a slip-cover that holds the prosthetic on by suction. The slip-cover is placed over the rigid substructure. Although this device allows the prosthetic to look and feel exactly like a real finger, the internal substructure is rigid, so the patient is unable to mimic normal hand movement.

Competition

Currently, there are methods being used in other countries to retain finger prosthetics through implants, as well as an interest group in Minnesota. There are several companies that design implant-retained substructures. The current design of a slip-cover is mostly for looks, and has little to no motility. Despite not having approval in the United States, there are other devices used in other countries that could count as international competition.

The X-Finger, a very advanced prosthesis, only involves human work, rather than robotic work to function. It is made out of steel and blue plastic, allowing the patient to play golf or lift objects. The mechanism almost flawlessly mimics normal hand movement by using the remaining part of the digit to contract and retract the finger. Despite the high functionality of this device, it is extremely costly (thousands of dollars per digit) and it only works when part of the finger remains.

Alternate *connection* design descriptions

Four alternative designs to connect terminal bone to the prosthesis were proposed. All these designs involve an installation of a titanium abutment into the terminal bone via osseointegration.

(DSN#1)-Screw n' Clip

The first design was aptly named the "Screw n' Clip" mechanism, which functions with the installation of a spring-loaded shaft in the terminal end of the titanium osseointegrated abutment with peripheral clip wells. The prosthesis threaded terminal end is screwed into the threaded well

while the lateral clips are aligned with the clip wells. Once the prosthesis has been fully screwed in, the clips are pinched and the prosthesis is pushed downwards into the spring-loaded shaft. The clips are then released simultaneously with the prosthesis and the mechanism will lock into position (Figure 1).

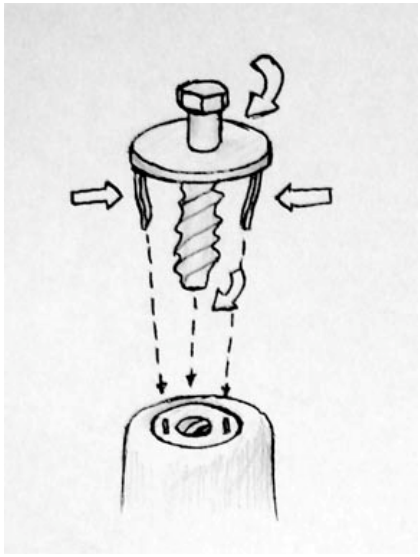


Figure 1: Screw n' Clip mechanism

This design was developed to provide a smooth, tight fit between the prosthesis and terminal bone that was both structurally stable and could resist a large amount of external shear and normal forces. However, the downside to this mechanism is that the terminal abutment shaft would be hard to install due to its complicated construction while the prosthesis could prove a challenge to remove.

(DSN#2)-Magnet and Clip

The second design called the "Magnet and Clip" mechanism, functions with the installation of a simple titanium osseointegrated abutment with peripheral clip wells. The prosthesis magnetic terminal end is aligned and attached to the oppositely magnetized well in the abutment, while the lateral clips are aligned, pinched and inserted into the clip wells. Once the magnet and clips have been properly inserted, the clips are released simultaneously to lock the mechanism into position (Figure 2).

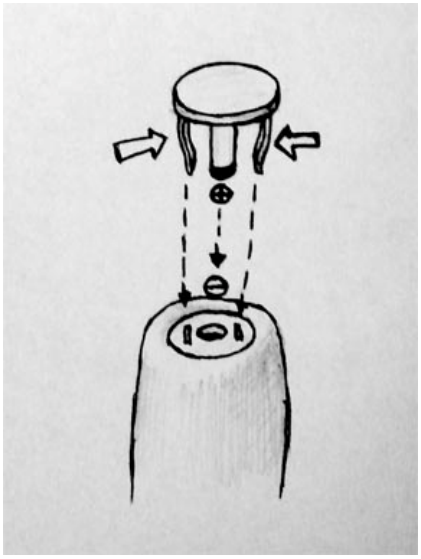


Figure 2: Magnet and Clip mechanism

The function of this design was to provide a smooth, aesthetic fit in conjunction with a simple construction and easy to install and remove mechanism that could resist a small amount of external forces. However, the downside to this mechanism is that prosthesis would have a rather low resistance to shear and normal forces, resulting in the prosthesis being more subject to falling off because it is less structurally stable.

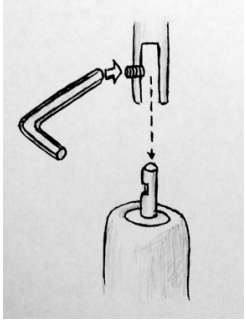


Figure 3: Allen Wrench mechanism

(DSN#3)-Allen Wrench

The third design “Allen Wrench” mechanism functions with the installation of a simple titanium osseointegrated abutment that extends beyond the length of the terminal bone and is fitted with a slot. The prosthesis terminal end has a similar slot and acts as a shaft for the abutment, whereby the prosthesis end is slid over the abutment and the slots are aligned. Once aligned, a bolt is inserted between the slots and is tightened with an Allen Wrench to lock the mechanism into position (Figure 3).

The function of this design was to provide a solid fit that had an easy to install and remove mechanism and could resist a large amount of external forces. However, the downside to this mechanism is that the prosthesis has a non-uniform structure and thus could interfere in designs to make the prosthetic more natural looking. The construction for this design might be somewhat complicated and the removal of the prosthesis could pose a difficulty, should the Allen Wrench be misplaced.

(DSN#4)-Reverse Screw n’ Clip

The fourth design is the “Reverse Screw n’ Clip” mechanism, which functions with the installation of a simple titanium osseointegrated abutment that extends beyond the length of the terminal bone with a flared, conical tip. The prosthesis terminal end has two spring-loaded buttons with two valves that act to allow insertion of the abutment as long as the buttons are depressed. Once, inserted, the pressure applied to the buttons is released to hold and lock the mechanism into position (Figure 4).

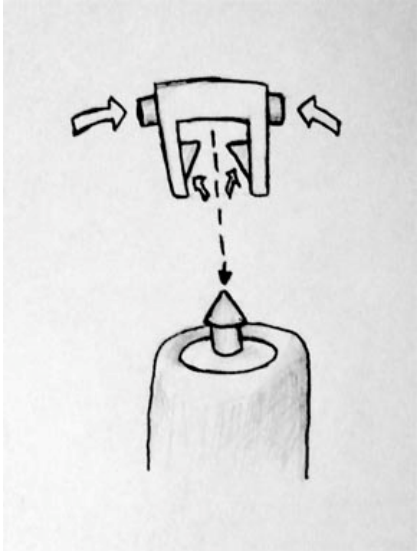


Figure 4: Reverse Screw n’ Clip mechanism

The function of this design was to provide a smooth, tight fit that was both easy to remove and could resist a large amount of external forces. However, the downside to this mechanism is that the prosthesis terminal end is hard to install because of its complicated construction and small parts. Furthermore, the construction for this design might be structurally unstable because the mechanism is top heavy with respect to the terminal bone abutment, resulting in increased loading of the connection. If the loading is too great, resistance to external forces may decrease and difficulties in lifting the finger with the attached prosthesis may be observed.

Alternate *substructure* design descriptions

The purpose of the substructure is to regain some functionality and motility of the finger. The substructure can be secured to the osseointegrated abutment by one of the previous attachment designs. The life-like prosthetic silicone skin will cover the substructure, which will represent the bones of the prosthetic finger.

(DSN#5)-Spring-Loaded Sac

The first substructure design was named the "Spring-Loaded Sac," which describes the connection between two solid bone-like segments. The joint is supported by two or more elastic fibers on the front and back sides of the hand, to allow passive displacement of the prosthetic finger in terms of flexion and extension. The spring located in the center of this design returns the displaced prosthetic to a relaxed angle that is realistic for a finger at rest (Figure 5).

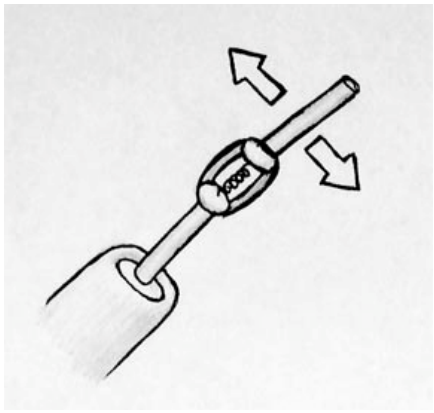


Figure 5: Spring-loaded sac mechanism

The purpose of this design was to create a moveable joint that allowed passive flexion and expansion while providing some amount of passive resistance. The difficulties that come up with this design include assembling small parts that are elastic enough to withstand force without tearing, yet plastic enough to naturally react to normal finger forces.

(DSN#6)-Mechanical Joint with Spring

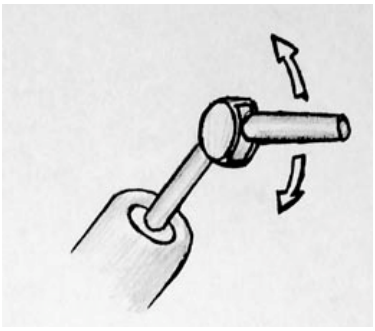


Figure 6: Mechanical ioint with spring mechanism

The next substructure design alternative is called the "Mechanical Joint with Spring." This design describes a round joint casing attached to the unmovable portion of the finger prosthetic, and an enclosed round joint that connects to the distal end of the substructure. The outer joint casing has built-in mechanical limits as to how far the prosthetic can undergo flexion and extension. The joint itself will also include a spring to resist normal finger forces while the substructure passively displaces (Figure 6).

The function of this design is identical to the previous substructure design: to allow passive displacement while exhibiting normal finger-like resistance. The difficulties of this design include assembling small enough parts which maintain typical relaxed finger properties, including limits

of flexion and extension.

(DSN#7)-Flat Piece

The third substructure design alternative, named simply the "flat piece," consists of a sturdy, flat piece of metal or dental acrylic that is firmly connected to the implanted abutment and bent at a natural angle of a finger at rest. The shape of this design leaves no room for rotational movement of the prosthetic skin when its cross-sectional area is comprised of a small height and large width. There are no moving parts to this design, so a great deal of gripping force can be produced by the living portion of the finger (Figure 7)

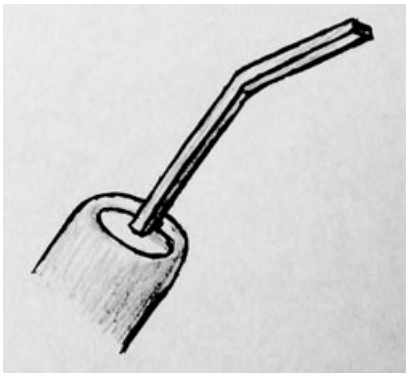


Figure 7: Flat Piece mechanism

The purpose of this design is to provide a cheap, simple, and realistic look of a relaxed finger while allowing no movement for maximum gripping force. The problems with this design include a large amount of wear and tear experienced by the prosthetic skin, as well as no realistic movement of the prosthetic finger.

(DSN#8)-Articulation Mechanism

The final design alternative, called the "Articulation Mechanism," consists of movable parts that undergo active flexion when the entire wrist is flexed. Small straps are fastened to the distal end of the substructure, wound around the underside of the mechanical joints, brought around to the backside of the hand, and fastened down by the wrist. When the wrist undergoes flexion, the straps are pulled taught and the substructure exhibits active displacement in terms of finger flexion. When the wrist is aligned longitudinal to the forearm, no tension exists in the straps and the finger is able to undergo passive displacement (Figure 8).

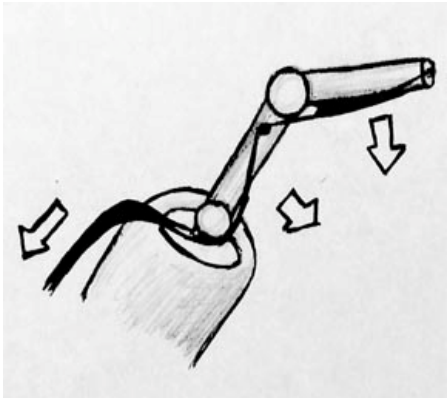


Figure 10: Articulation Mechanism

The purpose of this design is to create a substructure that fits beneath a prosthetic skin and allows active displacement and gripping force when the wrist is flexed. The problems with this design include creating something so complex without falling apart, as well as difficulties involved with

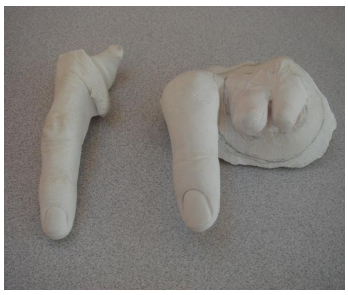
having straps fastened to the wrist that do not look natural.

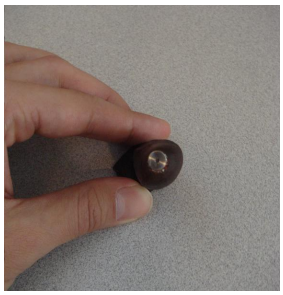
Final design

Prototype Fabrication

After careful consideration of functionality, practicality of implementation given the restraints of time, budget and materials, for each of our design ideas, a specific substructure, connection device combination was chosen. This combination was fabricated as a physical prototype along with two intermediary prototypes showing the abutment installation and the intended connection mechanism. In addition, a 3D simulation of the final prototype was constructed in Solidworks computer software.

The final design prototype was constructed such that it modeled the left ring finger of an actual customer of our client. A casting mold was provided for insertion angle and finger segment length references to aid in the construction of the prototype. The first step of the prototype fabrication was to install a small titanium 'temporary' abutment provided by our client into a molded acrylic bone made from dental acrylic. Dental acrylic finger models are shown in (Figure 9) below. Since actual bone was not used, it was assumed that the dental acrylic used was somewhat similar to bone and therefore the installed abutment represented the whole osseointegrated portion of the prosthetic finger prototype. Due to the limitations of finding a screw and drill bit small enough to compensate for the threaded well in the abutment, the prototype plan of action had to differ a little. Instead, the titanium abutment itself was installed into a separate dental acrylic finger model to be exhibited as an intermediary prototype (Figure 10). For the final prototype however, a steel screw (screw head removed) was fixed into the dental acrylic and fasted with superglue at an angle natural to the formation of a finger, thus the osseointegrated portion of the prosthesis was represented by a screw jutting out from the terminal bone abutment.





From left to right:

Figure 9: Dental Acrylic finger models specific to real life customer of client

Figure 10: Intermediary Prototype of terminal bone with installed temporary titanium abutment

Figure 11: Intermediary Prototype of Allen Wrench installation using bent galvanized metal sheet

For the connection mechanism, we decided upon the “Allen Wrench” idea and it was implemented into our prototype through the use of a hexagonal steel rod and a steel cover shaft that installed flush over the rod and extended over a segment of finger. The Allen Wrench mechanism was coupled (attached) with the screw protrusion from the dental acrylic via the threaded steel hexagonal rod. However, due to the fact that the majority of the cover shafts utilized were of hardened steel molds, the Allen Wrench could not be fully applied because the hardened steel could neither be drilled through nor cut with the machine shop equipment available for us. Thus, a sheet of galvanized metal was bent into the shape of a hexagonal cylinder that could easily slide over and provide a tight secure fit for the hexagonal rod. Through this, holes orthogonal to the long axis of the shaft were simultaneously drilled and threaded into both the folded sheet and hexagonal rod whereby a tiny screw was inserted to complete the Allen Wrench (Figure 11). The final prototype implemented this same idea with an added polysiloxane covering (Figure 12) for the purpose of coating the shaft region during the silicone casting process.

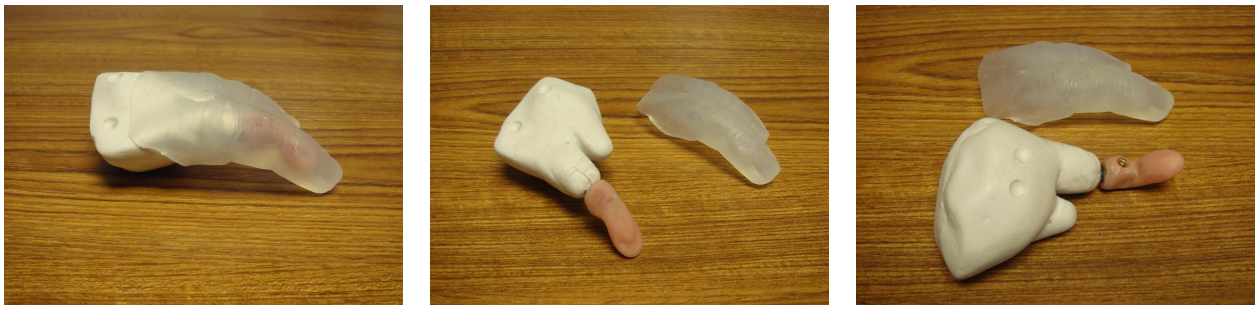


Figure 12: Final Prototype: Side View (*left*), Silicone Casting Removed (*center*), Exposed Allen Wrench (*right*)

For the substructure, we wanted to emulate as closely as possible the skeletal structure of a finger chose to continue with the “spring-loaded mechanical joint” as our final design. However, in the interest of saving time and focusing on the development of the connection mechanism for the prototype, a flat, yet somewhat stiff galvanized metal sheet covered in the extended polysiloxane layer used for the Allen Wrench was used as a simplified representation of the “spring loaded mechanical joint” as seen in Figure 12 In other words, the ‘flat piece’ substructure mechanism design was implemented for the current prototype fabrication for simplicity of application reasons.

Prototype 3D Simulation in Solid Works

In order to enhance the understanding of our prototype, and provide the client with a 3-D model in which he could show future surgeons, several Solid Works images of our prototype were

constructed. In order to provide the greatest possible accuracy, the exact angles and measurements were taken from the competed prototype and used to create the models.

Figure 13 created in Solid Works was the hexagonal rod piece. This rod screws into the abutment connected to the patient's hand. Another hole on the side of the hexagonal piece allows for a patient to use an Allen wrench to tighten and adjust the substructure, which is fitted over the hexagonal piece. Also shown in the figure is a screw that simulates the abutment that the hexagonal piece screws onto. This model is exactly to scale with the actual prototype.

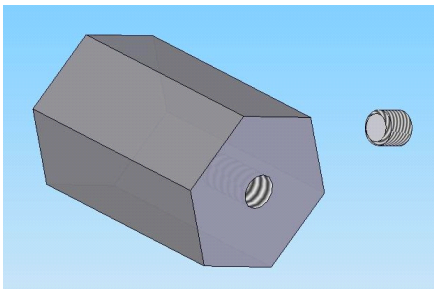


Figure 13: Hexagonal rod piece

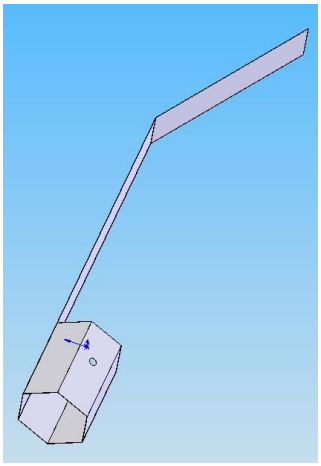


Figure 14: Hollow hexagonal sleeve

Figure 14 created in Solid Works is of the substructure with a hollow hexagonal sleeve. This sleeve fits perfectly over the previous Solid Works model and is connected with a small screw in the side of the structures. The long extended portion represents a very simple version of a possible substructure. In this version, the metal is bent at a natural angle in order to provide a patient with a comfortable resting position for their prosthetic.

Further work needs still needs to be implemented in Solid Works. Testing of the substructures was unable to be completed in the short amount of time given; however, Solid works has very complex testing programs, which would help to find the best types of material to use for the separate pieces. In addition, a simulation has yet to be created in which the client could distribute to prospective surgeons.

Final Project Design Overview

The objective for fabricating the final prototype was to machine the available components together (Figure 15) into an easily removable yet sturdy connection mechanism for the purpose of providing a solid and stable prosthesis connection that promoted hygiene and regular sanitation of the terminal bone abutment. Thus we felt that a combination of the Allen Wrench and Spring Loaded Mechanisms was the most functional and feasible theoretically. However, due to our time

constraints and machining capabilities, it was determined that the best mode of operation for this design project prototype was to fabricate the next best alternative, which was functional, feasible and very practical. In conclusion, the combination of the Allen Wrench mechanism with the flat piece substructure for the final design prototype worked in favor of success for the team project.

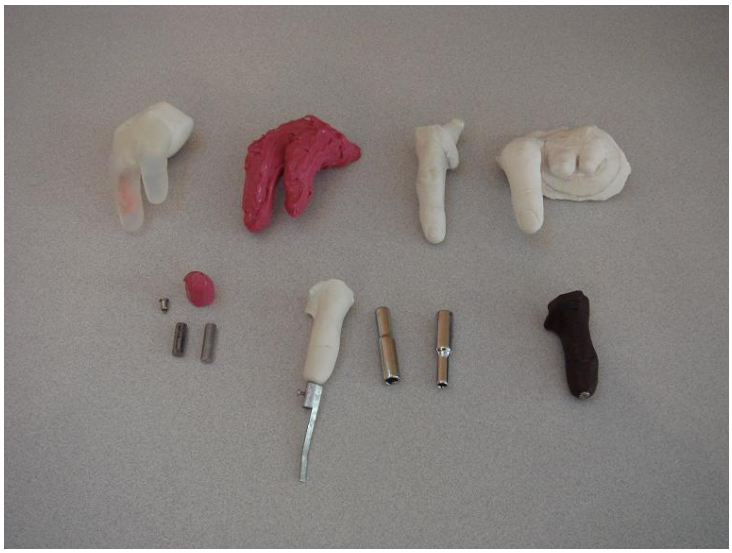


Figure 15: *(Top Left to Bottom Right)* Final Prototype, Finger Casting Cover, Acrylic Model Index Finger, Acrylic Model of intact middle finger with ring and pinky finger terminal bones, Titanium Abutment with casting cap and hexagonal rods, Intermediary Prototype (Allen Wrench), Cover Shafts, Intermediary Prototype (Installed Abutment)

There are a multitude of different medical cases for which each finger prosthetic and subsequent attachment would need to be individually customized and designed for. For the large majority of amputations the mechanical finger joint design should not have to be individually customized, however lengths would vary from patient to patient and therefore they must be taken into consideration. The connection mechanism, however, requires customization from one patient to another due to the varied nature of amputations and genetic bone formations. A personally customized silicone cover, that emulates skin, will be placed over the skeletal substructure to form an almost unintelligible natural aesthetic look to the appended finger prosthesis or prostheses as seen in Figure 16. The dimension and weights of each finger should match general anthropometric data (i.e. *length of the 3rd phalanx = 0.254*total length in cm*) with specific lengths and bone mass of the patient concerned. With these pieces of information integrated into the fabrication process of the final prototype, an accurate and natural looking finger prosthesis may be constructed, resulting in a potentially satisfied patient, a contented client and an accomplished BME design team.

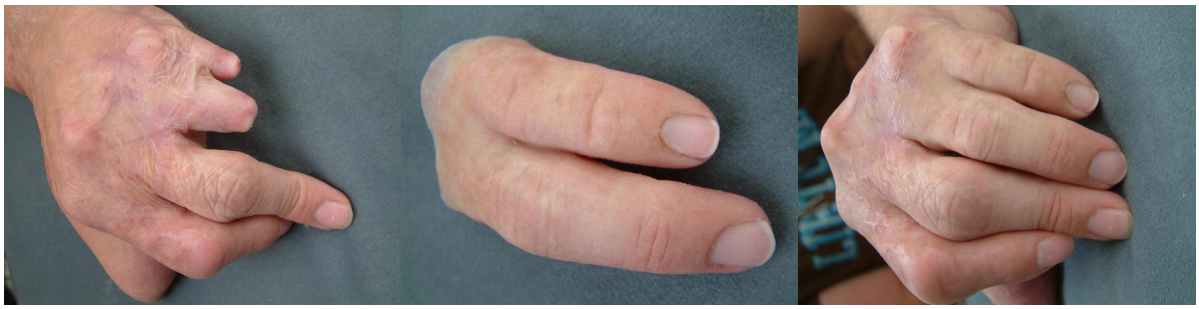


Figure 16: The currently applied suction-based finger prostheses used in the US

Materials list

As aforementioned most of these finger prosthetics will be customized. Therefore, there are not consistent dimensions that can be listed for our design report other than it will be designed to match the remaining fingers of the patient. The primary materials that will be used in the design are steel, dental acrylic, polysiloxane and titanium. The steel will be used for the skeletal center and joints. The dental acrylic will be molded around the steel rods. Polysiloxane will be used for the pseudo skin cover. The titanium ends of both the finger prosthetic and abutment will act as male and female nodes, where the male node is the abutment and its respective female node will be a shaft-like structure embedded within the housing at the terminal end of the finger prosthesis.

Conclusions and Future Work

Through the discourse of this design course, several advancements have been made to further interest and research in the field of implant-retained finger prosthetics. A hand surgeon has been contacted and has shown some interest in pursuing further work in this area along with our client, who intends to advance this technology into the future of finger prosthetics. In doing so, some ethical considerations come into play, as this procedure is not approved by the Food and Drug Administration (FDA). Our client will have to work with the hand surgeon and come up with a usable prototype as well as a willing patient in order to have this research reviewed by a committee authorized by the FDA. This process must take every action to ensure the patient's safety. Whoever decides to go through with this procedure must be entirely informed of the risks of surgery and other processes involved, as well as the discomfort and other possible side-effects that belong to this type of process. Fortunately, since this type of implant-retained prosthetic technology has been utilized in dentistry and maxillo-facial implants, there has already been research and experiments of this nature, and will not be such a new process. Future considerations for the design course involve more precise computer simulations. These simulations need to be the exact dimensions and shapes required for a finished product, as they will be used to fabricate the pieces out of titanium (something our group was unable to do in the short time-period).

Furthermore, testing of this finished device should be done to ensure proper function and usability. Our group was unable to test the prototype due to the cheap materials used for a more “proof of concept” prototype. Using the real device, testing would allow knowledge of how the prosthetic handled a wide range of stresses, temperatures, pressures, and contact with everyday chemicals and compounds. As for the present, the final prototype created has allowed people to see what this area of prosthesis technology has to offer to those who are less fortunate. With an implant-retained finger prosthetic, people with one or more missing fingers will be able to do many things that they haven’t been able to do before, such as type normally on the computer, draw or write with their normal hand, or even something as amazing as playing the piano one more time.

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Appendix

Product Design Specification for BME 200/300 group 28E: Prosthetic Finger Device
(as of *December 12, 2007*)
Group members: Richard Bamberg, Karen Chen, Dustin Gardner, Alex Kracht, and Allison McArton

Function
The focus of this project is to design a substructure and connecting mechanism for an implant-retained finger prosthetic. Currently, the only method used in the United States is a slip-cover which holds the prosthetic onto the remaining portion of an amputated finger. New approaches have been used in other countries which involve implanting an object through the distal end of a partial digit bone. The object is such that a prosthetic finger with a solid substructure can be attached in order to achieve increased motility and use of the prosthetic finger without having any parts fall off. Our team is to design a prosthetic finger substructure and connection apparatus which will successfully match these characteristics.

Client Requirements
- Either new or improved attachment system from current system
- Either new or improved prosthetic substructure from current system
- Computer simulation of final design
- Interested in experimental work with hand surgeon
- Budget of $500

Design Requirements
Due to the necessity for osseointegration, the implanted abutment will be made out of a metal like titanium which will fuse with the digit bone. The outer prosthetic silicone skin must be anti-corrosive and non-toxic to allow the patient use of this prosthetic finger for things like eating and grooming. Furthermore, the entire prosthetic must be easy to disassemble and clean for hygienic purposes, as well as for the ease and comfort of the patient. In order to maintain visual consistency with the real hand parts, the prosthetic must have similar properties of a real finger such as size, weight, and shape. This requires that the substructure created will be small enough that the prosthetic outer skin will easily cover and conceal any protruding edges and abnormal features of the substructure. The prosthetic finger, together with the substructure and outer prosthetic skin, must be able to withstand weathering, temperature variations, and forces normally

experienced by a human finger. The finger prosthesis may be constructed out of solid silicone polyurethane or a combination of silicone polyurethane with a dental acrylic sub-structure to strengthen the prosthesis for better durability. Medical improvements on this design have also requested by the client such that better flexibility around joint portions of the prosthesis could be present to improve durability, responsiveness and support of the implant-retained finger prosthesis.

1. Physical and Operational Characteristics

a. Performance requirements

The device is meant to effectively connect the prosthetic finger to the hand, providing durability for usage while still allowing the patient to easily remove the finger.

b. Safety

This device must be able to easily be removed so that the patient can easily clean the prosthetic finger. In addition, the material used for the device must not create any physical reactions.

c. Accuracy and Reliability

The device will be used daily by patients so normal wear and tear will occur on the actual prosthetic. The device used to connect the prosthetic to the hand must be able to keep the prosthetic in the correct position when in use. Also, the device should be easily removable for cleaning and comfort purposes.

d. Life in Service

The connecting mechanism must be able to withstand normal finger usage over the course of a day. The life-limiting factor of this device would be the degradation on the actual prosthetic.

e. Shelf Life

The shelf life of this product is rather long. Metal for finger implant is usually titanium (Ti), and the half-life of Ti is 63 years. The silicone rubber (polysiloxane) has relatively long lasting characteristics. This product will be able to remain new and unused for a minimum of 63 years.

f. Operating Environment

Silicone rubber will be exposed in the air, since it is the material that covers the amputation. Ti will be implanted inside the finger, thus it will not be exposed to the air most of the time.
Silicone rubber is able to operate at a large temperature range, from -40C to 200C.
Ti has a high melting point of 1668 C. Thus, these materials will not self-deform under room

temperature, at human body temperature, or during the summer time.
Silicone rubber is highly inert, thus it does not react with most chemical and humidity. Ti also has a great resistance to corrosion; therefore it will be able to withstand the acidity and water of the human body.
The shear modulus of Ti is 44GPa, thus it has a high shock loading. Also, the tensile strength of silicone rubber is 11N/mm. Silicone rubber will endure 490% of elongation before breaking.

g. Ergonomics
This product should not generate a torque that is greater than the torque of regular finger muscles. For the best use of this product, the patient should not be using this prosthesis to pick up loadings heavier than 1 kg.

h. Size
The size of this product is roughly the size of a human finger length. This product will not excess 3 inches in length, and 1 inch in cross section diameter. It should be highly portable when attached to the human amputation.

i. Weight
The weight of this product should not exceed 50 grams in order to remain its high flexibility and light loading.

j. Materials
The prosthetic skin is made of solid silicone polyurethane and will be molded and provided by the client. The solid substructure can either be made of dental acrylic or produced by the client, or it can be made of any solid plastics or metals and developed by the team. The implanted wells are typically made of titanium and may possibly be given to us by an interested hand surgeon.
The materials used must be strong enough so that normal forces experienced by the finger will be supported. The materials must be able to withstand prolonged friction and daily wear and tear.

k. Aesthetics, Appearance and Finish
The prosthetic skin will be colored and designed by the client. Our only concern is to come up with designs which will look natural and not display prosthetic camouflaging flaws.

2. Production Characteristics
a. Quantity
There are not too many people that get prosthetic fingers or would want to undergo a cosmetic

surgical procedure, but if this device were to gain FDA approval, the few hundreds of those who wants it would need to have them custom-designed to fit the customer's look.

b. Target Product Cost

For this design semester, the team will attempt to create either a full-scale or larger-scale prototype with a budget of around $500. A professionally crafted model of this kind would cost someone a lot of money, including surgical costs. Insurance companies typically do not cover cosmetic surgery.

3. Miscellaneous

a. Standards and Specifications

Concerning FDA approval, there have been similar implant procedures, such as dental implants, which have been approved in the US, but finger prosthetic implants are not one of them. We will be working on a prototype, as well as raising awareness about the topic.

b. Customer

The design of this device is intended to increase motility and usage while concealing the imperfections. The device should be easy to clean, helpful to the customer, and also durable so that the prosthetic will last longer.

c. Patient-related Concerns

One problem that was brought up is that insurance companies have recently changed their standards and now consider finger prosthetics to be cosmetic. Lowering materials costs will help patients afford this convenience. Also, the device to be designed must be easy to sterilize and maintain to prevent infections.

d. Competition

Currently, there are methods being used in other countries to retain finger prosthetics through implants, as well as an interest group in Minnesota. There are several companies that design implant-retained substructures.