Implant-retained finger prosthesis

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Abstract

The goal of this project is to improve the connecting mechanism and substructure for an implant-retained finger prosthesis. Currently, the only method used in the United States is a slip-cover device which holds the prosthetic on by suction. New approaches have been used in other countries that 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.

Table of Contents

Problem statement

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.

Background

Problem motivation

The final design for this project should increase the motility and durability of the implant-retained finger prosthesis as compared to current model used in the United States. By incorporating a new substructure, the prosthetic would have motility, unlike the rigid model currently used. In addition, the new connecting mechanism would allow a patient to easily remove and clean their prosthesis. Each individual substructure would have to be customized to imitate the size of the patient's actual fingers. 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

Accidents occur in every day life, and there is a high possibility that the injury causes 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.*).

Option one – prosthetic finger

The traditional method of prosthesis is by replacing the lost finger with an artificial digit. The artificial digit is made of silicone elastomer, which its chemical name is polysiloxane. Normally, the 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.

Option two – 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

Since osseointegration involves an implanted metal into the human body, the metal for osseointegration is limited to stable metals such as Ti. The prosthetic finger (silicone) need to be anti-corrosive and also food safe. Also, the size and the weight of the prosthesis need to be to scale of the original finger. The artificial finger needs to be able to withstand weathering, high and low temperatures, and tensions and compressions.

Current device

Our client currently uses the only FDA approved device in his work. 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 employed in other countries for implant-retained finger prosthetics, 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 almost entirely for aesthetic purposes, and has little or 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 design descriptions

The goal for this project is to construct a large-scale model and simulation model of our final design. The final design could be focused in two areas of finger prosthesis functionality, provided that time permits. The first focus would be in constructing a working terminal bone attachment mechanism for a finger prosthesis that could employ some method of osseointegration. The second focus would be the construction of a finger prosthesis substructure mechanism that will allow displacement of prosthesis limb segments to allow more functionality to the prosthetic device. Several ideas for improving the current finger prostheses models used by our client were brainstormed and four ideas for each focus were developed, presented, and critically evaluated. The ideas were channeled towards providing a solid, easy-to-remove and force-resistant fit between the prosthesis and terminal joint abutment or a prosthesis substructure with improved functionality, flexibility and natural appearance.

Alternate connection design descriptions:

The four alternate designs for terminal bone attachment mechanisms that were drawn, discussed and evaluated upon by the group all consisted of 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. See **Figure 3** below:

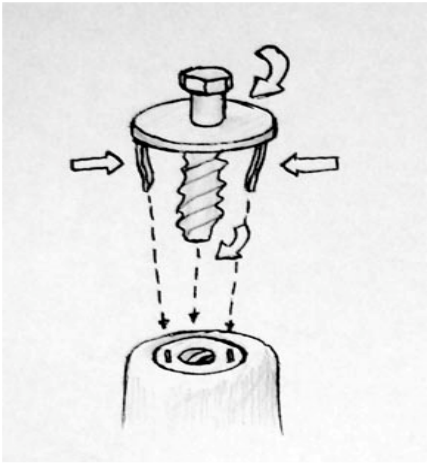

Figure 3: *Screw n' Clip* mechanism

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. See **Figure 4** below:

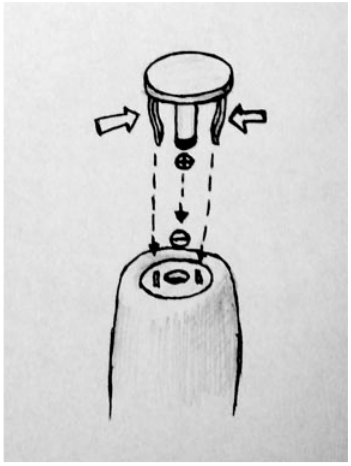

Figure 4: *Magnet and Clip* mechanism

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.

(DSN#3)-Allen Wrench

The third design, named the “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. See **Figure 5** below:

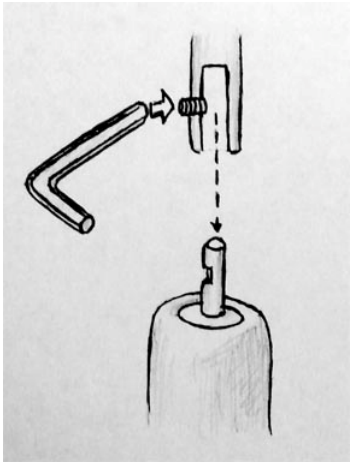

Figure 5: *Allen Wrench* mechanism

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, named the "Reverse Screw n' Clip" mechanism, 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. See **Figure 6** below:

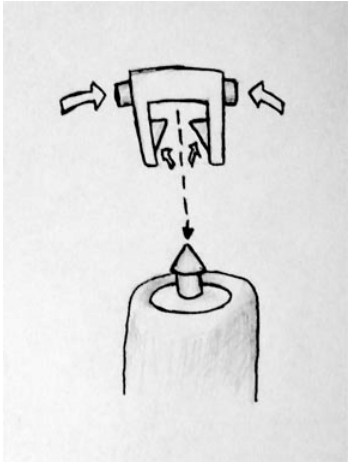

Figure 6: *Reverse Screw n' Clip* mechanism

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.

Design ideas

The alternative design solutions proposed for the connection mechanism of the prosthetic finger used in the design matrix involved osseointegration of a titanium abutment into the terminal bone of an amputated finger. Different abutments and prosthesis terminal housings were compared and the 'Allen Wrench' mechanism was ultimately chosen because it was the most feasible. The 'Allen Wrench' mechanism was the most stable mechanism that provided a solid fit to the finger. Moreover, due to the nature of the shaft mechanism within, it became the most resistive to external loads of shear and normal forces, which would allow a greater amount of functionality in conjunction with an alternative substructure. Following closely behind this mechanism was the 'Screw and Clip' mechanism, which was both highly resistive to external forces and stable, however its feasibility was rated as secondary due to its complexity to remove. Although it would not seem hard to remove a prosthetic finger with this connection mechanism using two hands, one had to think about removing the prosthesis with a single hand. It was here that the 'Allen Wrench' mechanism emerged the victor because it encompassed attributes of being a stable, highly force-resistant mechanism with a solid fit, that is both easy to install and remove.

Design matrix

The design matrix included four different connection designs that all employed the use of osseointegrated abutments as a function of the design. The designs were labeled as follows: 1) Screw n' Clip, 2) Magnet and Clip, 3) Allen Wrench, 4) Reverse Screw n' Clip. Considerations included in the design matrix included Functionality (weighted 30%), Durability (weighted 25%), Cost effectiveness (weighted 10%), and Feasibility/Practicality of design (weighted 35%). The most weight was place on feasibility and functionality of design because the client stressed his desire for a more practical, force resistant finger prosthesis that could have an element of increase function for daily life, while maintaining a natural look. Durability of the device was also very important, however it was outweighed by functionality and feasibility because osseointegrated designs are still in the trial stages and have yet to be improved upon. Cost Effectiveness did not seem to carry as much importance because the client was more concerned with what was devised rather than its cost.

As a result of comparing all the designs to one another, the clear winner for the alternative connection design was the 'Allen Wrench' because it received the highest ratings in all fields and thus the highest overall score.

	Functionality (30pts)	Durability (25pts)	Cost Effectiveness (10pts)	Feasibility (35pts)	Total (100pts)
Screw and Clip Mechanism	24	20.5	7.2	28	79.7
Magnet and Clip Mechanism	15.6	13	7.2	25.2	61
Allen Wrench Mechanism	24	22	8.2	30.8	85
Reverse Screw Clip Mechanism	22.8	17	6	21	66.8

Alternate substructure design descriptions:

The substructure design alternatives that were manifested by the team all 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. The following designs were evaluated against each other by all team members.

(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. See **Figure 7** below:

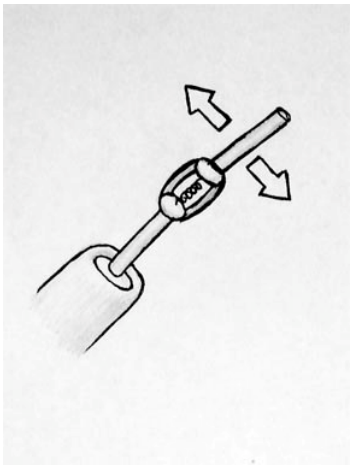

Figure 7: *Spring-Loaded Sac* mechanism

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

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. See **Figure 8** below:

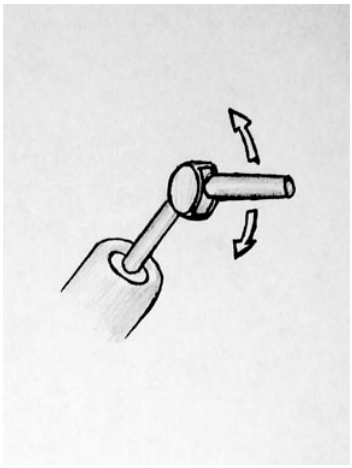

Figure 8: *Mechanical Joint with Spring* mechanism

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. See **Figure 9** below:

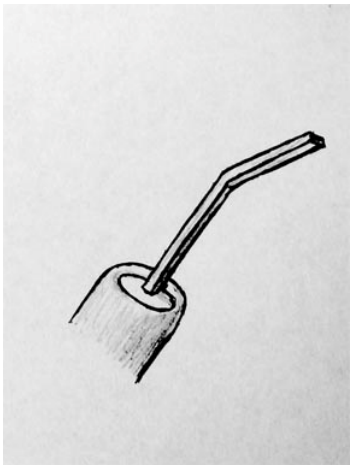

Figure 9: *Flat Piece* mechanism

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. See **Figure 10** below:

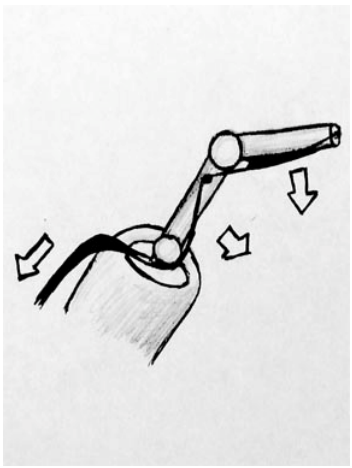

Figure 10: *Articulation Mechanism*

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.

Design Ideas

The four design alternatives involved creating substructures that connected to the implanted abutment, provided framework for a prosthetic skin covering, and either exhibited no movement, passive displacement of the joint angle, or active displacement in terms of finger flexion and extension. These designs were compared and contrasted, and the two top designs included the "Mechanical Joint with Springs" and the "Flat Piece," with the former achieving highest ratings. The "Mechanical Joint with Springs" appears to be easy to create and produce, and allows a natural look and reaction to typical finger forces. This design is also very sturdy due to its metal parts and solid joint-angle limits, which means increased durability and longer usage. The runner-up of these designs, called the "Flat Piece," is simple, cheap, and allows effective gripping force. However, these features also make the prosthetic skin that covers this substructure more prone to wear and tear, since there is no displacement of the joint-angle whatsoever. From these features, the "Mechanical Joint with Spring" design has been chosen as the best idea for an implant-retained prosthetic finger substructure.

Design matrix

The design matrix used for the substructure design alternatives contains the exact same categories, with the same weighted values, as the previous connection design alternatives design matrix. This similarity is expressed due to the close relationship between the connection and substructure mechanisms and their equal effects on the overall function and feasibility of the design prototype. As all of the substructure design alternatives were compared and contrasted by each team member, it is clear that both the "Mechanical Joint with Spring" and "Flat Piece" design ideas scored high, with the "Mechanical Joint with Spring" mechanism achieving the highest approval of the design matrix. See graph below:

	Functionality (*30pts*)	**Durability (*25pts*)**	**Cost Effectiveness (*10pts*)**	**Feasibility *(35pts*)**	**Total (*100pts*)**
Spring-loaded Sac	24	15.63	6	22.75	68.38
Mech. Joint w/ Spring	26.25	19.75	7	27.13	80.13
Flat Piece	18.75	22.5	8.75	29.75	79.75
Articulation Mech.	23.25	13.75	5.5	18.38	60.88

Final design

After careful consideration of each of our design ideas we have chosen to further pursue a specific substructure, connection device combination. For the substructure, we have chosen to pursue the "spring-loaded mechanical joint." For the connection, we decided on the "Allen wrench." We feel that the combination of these two mechanisms is the most functional and feasible.

The substructure will primarily consist of dental acrylic with a steel rod center, which will act as the skeletal structure of the finger. The steel center will run throughout the prosthetic connecting each steel joint and attachment device together. Dental acrylic will be placed between the joints surrounding the steel. The connecting side of the acrylic skeleton will have a well where the osseointegrated abutment, attached to the terminal finger bone, will be able to slide into. The shaft and well will have a square shape that allows for easy alignment of the prosthetic and screw hole. Due to the infinitely many different finger amputations the attachment will be customized to each customer. For the large majority of amputations the mechanical finger joint should not have to be individually customized. A personally customized polysiloxane cover, that emulates skin, will be placed over the skeletal substructure.

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.

Future work/research

For the remainder of the semester we will be focusing on creating a working large-scale model of the prosthetic, creating a computer simulation of the prosthetic, as well as contacting a hand surgeon to see if he thinks our proposed design is functional and feasible. In doing so, we would hope that whomever we have managed to establish contact with would shed some light on thoughts and impart valuable knowledge pertaining to osseointegration installation upon us so that we may fit our designs accordingly. We have neither the resources nor the budget yet to create the intricate pieces that will be involved in the prosthetic finger, however the plan is to create a working large-scale model that can be presented both to our client and advisors during final presentations, along with a computer simulated model of each design mechanism. The simulated models will be used to clearly define and exhibit the simulated range of movements and applied loads that can be observed. This will accomplish a better understanding of our designs and lend credibility for future work in this field. For now, however, we will concentrate on researching and designing the specifics for the spring loaded joints.

References

Aydin, C., Karakoca, S., & Yilmaz, H. (2007). Implant-retained digital prostheses with custom-designed attachments: A clinical report. *Journal of Prosthetic Dentistry, 97,* 191-195. Retrieved October 9, 2007.

Fairley, M. (2006). Osseointegration: In the wave of the future? *The O&P Edge,* Retrieved September 13, 2007.

Gion, Gregory. (2007). Meeting, October 2007.

Michael, J. W., & Buckner, H. (1994). Options for finger prostheses. *JPO, 6*(1), 10. Retrieved September 13, 2007.

Appendix

Product Design Specification for BME 200/300 group 28E:
Prosthetic Finger Device
(as of October 24, 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
According to the client, the implant-retained finger prosthesis must hold firmly to the terminal amputated portion of the finger. This could be done either through a sleeve concept or through osseo-integration. The prosthesis should also be easy enough to remove such that maintenance and hygiene may continue, unimpeded and unobstructed. However, the implant must not detach too easily when certain external forces and shear forces are applied to the finger prosthesis. As such, the finger prosthesis must also maintain an element of support functionality and fulfill the aesthetic requirement of resembling a real finger in appearance, function and attachment.
Our client wants the group to devise a new attachment system or build upon the existing system, in conjunction with a simulator model. The simulator model is necessary to obtain a clearer interpretation of what reactions occur when the prosthesis undergoes kinetic motion, and thus correct errors prior to implementation.
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 want 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.