Product Design Specification for BME 200/300 group 28E: Prosthetic Finger Device

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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.

Establish environmental conditions while in storage, shelf-life of components such as batteries, etc.

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.

(I can't find the atm pressure that both materials can withstand)

Establish the conditions that the device could be exposed to during operation (or at any other time, such as storage or idle time), including temperature range, pressure range,

humidity, shock loading, dirt or dust, corrosion from fluids, noise levels, insects, vibration, persons who will use or handle, any unforeseen hazards, etc.

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.

Establish restrictions on the interaction of the product with man (animal), including heights, reach, forces, acceptable operation torques, etc…

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.

Establish restrictions on the size of the product, including maximum size, portability, space available, access for maintenance, etc.

i. Weight:

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

Establish restrictions on maximum, minimum, and/or optimum weight; weight is important when it comes to handling the product by the user, by the distributor, handling on the shop floor, during installation, etc.

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 and 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.