Individualized Finger Prostheses, Team Phalange Flexors

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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 has three main components working together to recreate flexion and extension, facilitated by the movement of a patient's residuum. The base of the prosthesis, which is custom-made by the client, acts as a socket and anchors the prosthesis to the phalange of the patient. This base must then connect to a skeleton-like mechanism, which is the principal challenge of the design. This mechanical skeleton will therefore mimic the functionality and structure of the distal inter-phalangeal joint and its corresponding tendons and ligaments. Lastly, a cosmetic sleeve will slide over the mechanical unit of the prosthesis, making the artificial phalangeal segment appear natural. In addition, all three 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 silicon 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 3D printer technology and ABS plastic. PMMA may also factor into the design, as it is a readily available and inexpensive biomaterial in Mr. Gion's supplies. 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.

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 use a suction cap at the end of the residual. This means that the user might not be able use quite the same amount of force. 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, but is not expected to be used 24 hours per day.

h. *Size:* The size of the prosthesis should be small enough to be concealed underneath a cosmetic coating without looking too bulky or unnatural. Anthropometric data suggests that the length of female versus male phalanges are significantly different. Consequently, our design will be customizable to fit either. Measurements taken from the customers hands will be used to determine the length of different components. We aim to match the exact dimensions of any possible customer.

i. *Weight:* Keeping user comfort in mind, the weight of the assembly should be kept to a minimum. Using lightweight materials such as ABS plastic 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 be compatible with Dr. Gions existing materials which includes PMMA and silicone.

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.

2. Production Characteristics

a. *Quantity:* Our client has only requested one functional model to be used for the index or middle fingers. 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 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 $10 for 3d printing material.

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 anatomic capabilities as possible, and resemble a human finger while flexing. For production, he would like something that can be replicated quickly (possibly by a 3D printer) 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. With an internal, skeleton-like mechanism to provide flexion and extension, the team can devise an outer shell or filling that will maintain the finger's shape during movement. This outer component should therefore be highly customizable and easily manufactured in Mr. Gion's lab setting.

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. [1]

Works Cited:

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