Product Design Specifications - September 22, 2017

Title: Medical Arts Prosthetics: Individualized Functional Finger Prosthetic

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Function: The goal of this project is to design and manufacture a mechanical prosthetic finger to fit inside a realistic silicone covering. The final prototype should be an individualized finger prosthesis that is affordable, aesthetically and mechanically functional. Ideally it will restore flexion and extension movement of an amputated residual finger, while still being able to fit inside a realistic silicone sleeve. The client desires that the prototype be 3D-printable.

Client requirements:

1. Prosthetic must give the user enough gripping force to wield small objects
2. Prosthetic will initially be made for amputees who have residuum of proximal phalange.
3. Prosthetic must look realistic (client stresses that aesthetic beats functionality)
4. Prosthetic must be *relatively* durable (client stresses that patients aren't usually hitting the prosthetic against hard objects). However, the prosthetic can't be brittle to the extent that small trauma causes fracture.
5. Prosthetic will be made for only one digit.
6. Prosthetic must weigh similar to human finger.
7. Prosthetic must be 3D-printable.

Design requirements:

1. Physical and Operational Characteristics

a. **Performance requirements:** The goal is to create an aesthetically similar and functional device that can not only give enough range of motion to the amputee but also be durable enough to withstand the forces a typical finger is subjected to. The device needs to be able to withstand the forces similar to those exposed to the tendons in a finger, the forces on the muscles, the forces between the bones, the forces at the joints, and the forces during pressing with the fingertip as well as the forces during extension and flexion of the fingers. Biomechanical analysis based on the amputee's needed finger dimensions should be calculated [1]. The device must allow for the gripping of small objects as well.

b. **Safety:** This device must follow Class 1 medical device guidelines, as it is not surgically implanted, and is not a life-sustaining device.

c. **Accuracy and Reliability:** Prosthetic must be aesthetically indistinguishable from a human finger and must be comfortable for the patient. Ideally, the prosthetic must have smooth, rigid contractions comparable to a finger.
d. **Life in Service:** The finger prosthetic is needed to be used for multiple hours a day for the rest of the device's lifetime. A finger prosthetic typically lasts between one to three years so this device should last at least for a year to be comparable to competitors [2].
e. **Shelf Life:** The inter mechanical finger prosthetic should be removable for repair but should not come off during daily activities. However, if removed for repair, it should have a life time shelf life at room temperature. The external silicone sleeve should not be stored under high temperature and UV light.
f. **Operating Environment:** The purpose of the device is to closely mimic the appearance of a natural finger. With this in mind, the operating environment will vary based on the lifestyle of the patient, and according to the client, the device would withstand conditions with minimal risk of large trauma. The device will need to maintain function within the full ranges of temperature and humidity found in their local climate, throughout all seasons. It will also likely have to be able to withstand, without any damage, submersion in water, as well as contact with many common cleaning supplies. The product will likely also encounter a lot of dirt and grime, which will need to be easily removed.
g. **Ergonomics:** The device must fit comfortably yet firmly on finger residuum when in use. This means that, if force is applied to the finger, it must not shift or bend backwards in an unnatural way, and provide tactile feedback of forces to the user. Ideally, the device will be capable of flexion and extension along with the rest of the fingers on the patient; this must be done by purely mechanical means.
h. **Size:** The device must be the exact size such that when it is inserted into the silicone sleeve, the entire assembly is identical in size and geometry to the desired human finger. Based on literature search, the average lengths of distal phalanx, medial phalanx and proximal phalanx are 23 mm, 25 mm and 43 mm, accordingly. And the angles of rotation at the distal phalangeal joint, the medial interphalangeal joint are 78 degree and 105 degree, accordingly. These numbers describes the boundary range of motion of a real human finger, the prosthesis can meet most daily motion requirements with a smaller range of rotation.
i. **Weight:** The optimal weight of the device, as it will be made to specific dimensions of a patient, will be the closest approximation to the patient's original finger. If the human hand can be approximated per anthropometric tables to .6% of the human body mass, with an approximate density of 1.16 kg/l, it could be approximated that the patient's finger will be slightly less than .1% of their body weight. A more accurate approximation could be made creating a cylinder with density of 1.16 kg/l using the length and width of one of the patient's fingers as dimensions. The weight of the silicon cover, created by the doctor, would be subtracted from this approximation, and this would give the target weight.

j. **Materials:** This device will act as a structural framework for a silicone mold of a human finger, which will be attached to a mount on the residuum of the patient's finger. In this case, the device will not come in contact with the patient, and so biocompatibility is not a concern. The ideal materials used will be one that allows for the manufacturing techniques required by the geometry, with a density low enough to mimic the weight of a finger, and with a strength that mimics or exceeds that of bone. This will likely lead us to using a plastic, and if 3D printing is the chosen means of manufacturing, it will be a thermoplastic polymer such as polyamide, polylactic acid, ABS, or acrylonitrile Butadiene Styrene.

k. **Aesthetics:** The design is desired to look closely like a real finger in appearance. As a result the mechanical component of the device must not be visible below the silicone sleeve; any fittings to finger residuum must either be covered by the sleeve or of a color similar to the patient's flesh. The frame should support the sleeve to be the same size as a normal finger when in use.

2. Production Characteristics

a. **Quantity:** One
b. **Target Product Cost:** The prototype must be made within a budget of $500. The final product should have costs comparable to similar products on the market.

3. Miscellaneous

a. **Standards and Specifications:** This device is a mechanical prosthetics finger that would fit in a silicone prosthetics sleeve. The final prototype should ideally restore the independent flexion and extension function to mimic a real finger. This finger prosthesis must fit on the amputated finger of the patient and provide the gripping function at the distal phalange. The final prototype would likely be classified as a class I medical device that is a hand, external limb mechanical component device which is not implanted and does not provide life-sustaining function [3]. This device would be exempted from 510(k) snf GMP.

b. **Customer:** Mr. Gregory Gion is the client for this project. He required that the mechanical structure of this finger prosthesis must provide the user enough gripping force to wield small objects. He also expressed preference in accurate appearance, moderate durability and relative lightweight of this finger prosthesis design.

c. **Patient-related concerns:** This device is a reusable mechanical finger prosthesis that restores basic function of the amputated finger. The external silicone sleeve should not be stored under high temperature and UV light. The internal mechanical skeleton should be safe and durable to use, but the user should be aware of the possibility of material fatigue

and fracture, and avoid excessive motion with the prosthesis like heavy lifting and pulling. The prosthetic should also be comfortable for the user to use.

d. **Competition:** There are some similar mechanical finger prosthetics products that exist on the market. One of our strong competition would be the PIPdriver made by the NAKED prosthetics™ [4]. This device is customized to fit and suit the amputated end of finger and made from medical grade nylon 12. It has a cage-like structure, a slender and sleek design, and a silicone rubber tip pad which allow comfortable wearing and enables near-normal finger flexion. Another strong competition would be a patented mechanical prosthetic finger device [5]. This patented design utilizes unique connections between the distal phalange, middle phalange and proximal phalange that provides patients with natural movability and full dexterity. It also incorporated a touch screen mechanism at the end of the prosthetic that allows users to interact with touch screens. These two products are well structured and highly functional. However, due to their complexity in structure, none of them would fit in the silicone external sleeve required by our client.

References

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