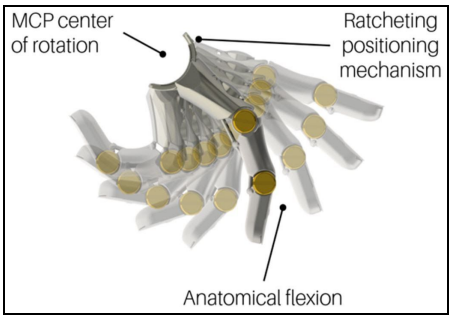
I. Problem Description

Partial hand amputations affect many people across the world; in the United States alone, as many as 45,000 partial hand amputations occur annually [1]. Point Designs LLC is an American based company that produces prosthetic fingers for people with finger amputations to give function and form. The company has an already established customer base in the United States with plans to expand into the European market. To expand, the prosthesis must be narrowed on the lateral sides of the proximal phalanx, and be produced at a lower cost. This will allow the prosthesis to be sold at a competitive price point while also allowing it to function in a cosmetic covering. The purpose of this project is to design and fabricate an affordable and realistic prosthesis for Point Designs LLC at a price reduction of 30-50%.

Figure 1. Patient with a partial hand amputation [2].

II. Solution Concept



The Point Digit is a mechanically-based finger that has ten different lockable positions. A torsion spring is located in the proximal interphalangeal (PIP) joint to return the finger from any of the lockable positions back to its original position. The finger can return to its original position once fully flexed or with the use of the spring back button that is located on the proximal phalange. This prosthesis should share the same functionality as the current Point Digit from Point Designs LLC shown in Figure 2.

Figure 2. Current Point Digit [3].

Additionally, the prosthesis will be designed to be functional in a cosmetic covering. To achieve this, the proximal, medial and distal components will be redesigned in order to be more life-like inside a cosmetic covering as shown in Figure 3. Redesigning the prosthesis will also allow the spring-back mechanism to function properly within the cosmetic covering, as the current version cannot overcome the additional resistance of the cosmetic covering.

Figure 3. Cosmetic Covering [3].

III. Reduction to Practice

The prosthesis is designed in a way that minimizes cost and maximizes the compatibility with a cosmetic covering. The prosthesis features simplistic geometry for the medial and distal portions that can be easily manufactured. This reduces the manufacturing cost along with making the device lighter. Plastic pieces surround the medial and distal sections of the design which eliminates pinch points. A newly designed spring can store ~300% more energy in full flexion

than the original spring; this will allow the device to overcome the resistance provided by the cosmetic covering. The volume of the prosthesis is reduced by ~30%. This not only improves the function within a cosmetic covering but also reduces the cost of manufacturing.

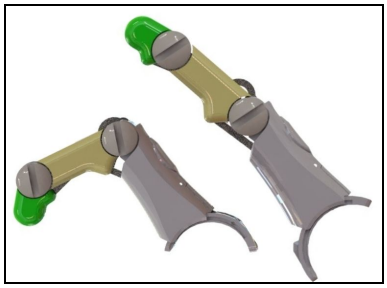


Figure 4. SolidWorks Render.

IV. Pathway to Implementation

Milestone 1

- 3D Print all Components
  - Metal & Plastic
- Fabricate New Spring

Milestone 2

- Verification of Final Design

Milestone 3

- Validation Testing

Milestone 4

- Present Design
  - Capstone Expo
  - International Conferences

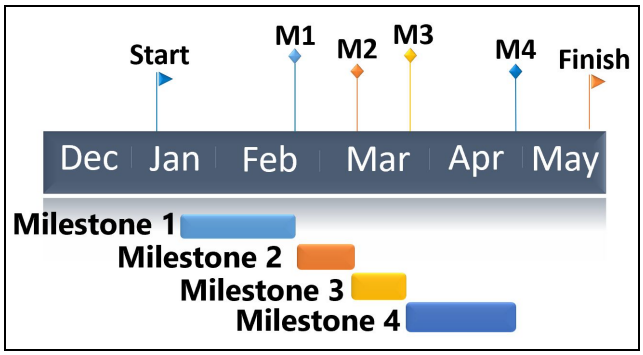


Figure 5. Spring Milestone Schedule.

A manufacturing procedure will also be produced in order to optimize the price of fabrication. Once the manufacturing procedure is finalized, the team will produce a final prosthesis made from production-quality materials. The manufacturing process includes 3D printing in both metal and plastic materials. The final prosthesis will undergo verification and validation testing. This includes verifying that the spring inside the prosthesis is strong enough to withstand the cosmetic covering and that the prosthesis can undergo successful cyclical testing. In the final milestone, the team will present at the Capstone Design Expo, along with presenting at conferences internationally. The FDA classification of a prosthesis is a Class I medical device. Due to this type of prosthesis being a Class I medical device, the FDA pathway that the prosthesis follows is a 510(K) exempt pathway. This design and current products of Point Designs are patent protected and have full rights to any new prosthesis created by the team.

References

[1] "Epidemiology of Finger Amputations in the United States From 1997 to 2016," Journal of Hand Surgery Global Online , 25-Mar-2019. [Online]. Available: https://www.sciencedirect.com/science/article/pii/S2589514118300379. [Accessed: 07-Sep-2019].

[2] Vergara, E."Second toe-to-hand transplantation: A surgical option for hand amputations" Research Gate,11-Nov-2019 [Online] Available: https://www.researchgate.net/figure/Female-patient-33-year-old-with-partial-amputation-of-thumb-and-4th-finger-and-almost_fig3_281342930

[3] "Point Designs LLC," *Point Designs LLC*. [Online]. Available: https://www.pointdesignsllc.com/. [Accessed: 13-Nov-2019]