Cunningham Clubfoot Brace
School of Science, Engineering, and Health Symposium 2018
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Introduction

Figure 1: Clubfoot vs Normal Foot

Clubfoot is a fairly common congenital foot abnormality in which the baby’s foot is twisted out of shape because the tendons are shorter than usual. The current treatment for clubfoot is the Ponseti Method, which consists of a corrective phase of 5 different casts, followed by a maintenance bracing phase.

The current method for maintenance is the boots-and-bar method, which has several disadvantages. The 5-year treatment period limits mobility, prevents muscle strengthening, and leads to increased social stigma and discomfort.

The Cunningham Maintenance Brace is a design that replaces this method and reports a high success rate (90%). It promotes comfort, allows mobility and muscle growth, has a shorter treatment time (2-3 years), and is unilateral.

Figure 2: Ponseti Method

Figure 3: Boots-and-Bar brace
Figure 4: Cunningham Brace

The goal of our project is to improve the reproducibility of the Cunningham brace by making the brace locally manufacturable at a lower cost. In addition, we will conduct biomechanical force testing to characterize the performance of the original and 3D printed braces.

Manufacturing Processes

Current Method
The current molding process takes around 5-6 hours to produce one polypropylene brace. It is labor intensive, has significant material waste, lack of precision, and requires expert skills or training.

Figure 5: Current Vacuum Molding Process

Wrapping Method
A redesigned manufacturing method involving cutting, heating, and wrapping polypropylene around a mold is being explored. This could reduce labor and material waste and allow for better reproducibility.

Figure 6: Wrapping Polypropylene around a mold

3D printing
3D printing currently takes around 12 hours per brace and requires minimal labor. It decreases material waste, helps with production precision, and minimizes training. We are working with Alloy 910, a flexible and stiff material that has replicated the force characterization. It also opens the option for custom sizing.

Figure 7: 3D Printed Brace in Alloy 910

Fasteners
Currently, the machine screws used to assemble the Cunningham brace make up 67% of the cost of the entire brace. The goal was to determine if the 3D printed brace would successfully survive for a significant period of time.

Figure 8: Full brace assembled with fasteners

Testing
A testing apparatus was constructed to test the correctional forces of the brace. The apparatus can both stretch and rotate the brace and be used in fatigue testing.

Figure 10: The constructed testing apparatus with brace.

Physical Testing
Rotational forces display a strong linear relation with the angle of brace rotation. The results indicate the new 3D printable materials and designs are comparable to the original brace.

Figure 11: Axial and Rotational forces after fourteen hours of varied degrees of rotation

Fatigue Testing
The brace was set up in the testing apparatus where it was twisted and stretched for several hours. The forces were monitored and analyzed over time and then compared to the original brace. The goal was to determine if the 3D printed brace would successfully survive for a significant period of time.

Figure 12: Fatigue testing for Alloy 910, showing consistent forces over a span of 1250 cycles.

Conclusion

In the efforts to replicate the Cunningham Clubfoot brace via 3D-printing and also provide a quality clubfoot brace solution to CURE International, we have made some major progress in both manufacturing process research and replication testing of the brace. We believe that as we gather data and conduct additional analysis, testing, and research, we will be able to successfully reproduce Cunningham’s current design while being compatible with the priorities of CURE International (local manufacturing, cost reduction, and validation of efficacy.)

Future directions

Kenya Trip:
- Communicate and interact with the CURE Clubfoot Kenya (CCK) team
- Suggest new manufacturing processes and learn about the progress of the clinical study

Fall:
- Continue exploration of the wrapping process and 3D printing modifications
- Biomechanical research and analysis with physical testing

Acknowledgements

Mr. Tim Howell and Dr. Emily Farrar for the guidance throughout the project.
Mr. Jerald Cunningham and Mr. Scott Reichenbach for their expert advice and guidance.
Luke Redcay, Paul Stoltzfus, and Vy Ho for their friendships and brilliant engineering ideas.