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Force Characterization and Manufacturing of a Dynamic Unilateral Clubfoot Brace

Brittney D. Fouse

Sam J. Rasinske

Stevie R. Snodgrass

Jacob R. Cornwell

Michelle Lo

See next page for additional authors

Authors

Brittney D. Fouse, Sam J. Rasinske, Stevie R. Snodgrass, Jacob R. Cornwell, Michelle Lo, Clint M. Meekins Jr, Leigha R. Southall, and Tim Howell

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What is Clubfoot?

Clubfoot is a birth defect that affects 1 in every 1000 children worldwide. It is characterized by a baby's foot being twisted inward and upward because the tendons of the foot are shorter than usual.

The current treatment for clubfoot is the Ponseti Method, which consists of a corrective phase of five different casts, followed by a maintenance bracing phase.

Maintenance Braces

Boots-and-Bar or Steenbeek Brace
(Current Method)
- 5 year treatment
- Bilateral (both feet)
- Uncomfortable
- Limits mobility
- Inhibits muscle growth
- Has more social stigma

Cunningham Brace
- Replaces the Boots-and-Bar brace
- 2-3 year treatment
- Unilateral (one foot)
- Promotes comfort
- Allows mobility and muscle growth
- Can be hidden to reduce social stigma
- Reports a high compliance (88%)

Force Testing with the Cunningham and Steenbeek Brace

The team has designed an electronic force testing system to characterize the biomechanical forces of the Cunningham Clubfoot Brace. The system uses capacitance force sensors to collect force data (Figure 1). The components are attached to the brace with Velcro, custom 3D-printed boxes, and binder labels (Figure 2).

Figure 1: Capacitance force sensors used on both braces

After analyzing force data collected during a trip to Mr. Cunningham's clinic (Figure 3), it was observed that a clubfoot patient at the beginning of maintenance bracing exerted lower forces than one further into maintenance bracing (Figure 4). These preliminary results support Mr. Cunningham's explanation of the brace's functionally (i.e., the brace exerts greater force to match the foot's tendency to relapse) and encouraged the team in their force testing endeavors.

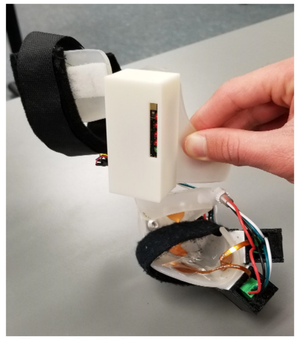

Figure 2: Cunningham brace with force testing system applied.

Figure 3: One of Mr. Cunningham's patients wearing the force testing system on their brace.

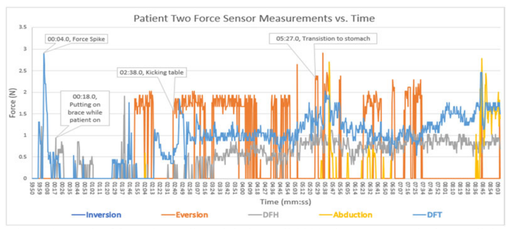

Figure 4: Graph of force data collected during Fall 2021 trip to Mr. Cunningham's clinic in Maine.

The team plans to compare the forces of the Cunningham and Steenbeek brace. The force testing system has been adapted for the Steenbeek brace to accomplish this comparison (Figure 5). Using data collected with the force testing system, the team will test the null hypothesis that the Cunningham brace exerts less force than the Steenbeek brace. The team hopes that the data will provide quantitative support for the Cunningham brace as an alternative to the Steenbeek.

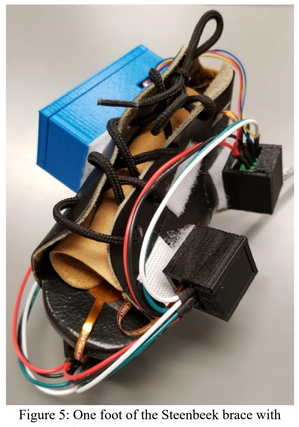

Figure 5: One foot of the Steenbeek brace with force testing system applied.

Sustainable Manufacturing

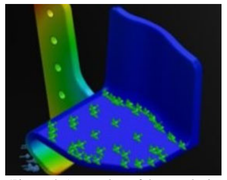

Figure 6: Screenshot of data analysis performed on the thigh piece in Solidworks

The Cunningham Brace is currently manufactured using a vacuum molding procedure. Mr. Cunningham is looking into injection molding to streamline the process, yet he is unsure how the material properties will change the functionality of the brace. This year we have been testing the material properties of the current vacuum molded polypropylene material, the standard polypropene, and the injection molded material by using a computer simulator (Solidworks) (Figure 6).

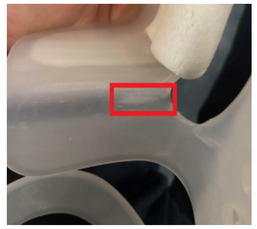

Figure 7: Photo of the thigh piece after fatiguing

We have also been focusing on the sustainability aspect of the brace, given that the current brace fatigues at the knee. This is depicted by a white line on the crease of the thigh piece (Figure 7). This analysis is done by using a linear actuator, in combination with a switch to apply repetitive force. This research will help Hope Walks determine how often they can reuse the brace before it no longer provides the necessary forces to correct clubfoot.

Conclusion

With the goal of validating the Cunningham brace, the team has chosen to test the experimental hypothesis: the Cunningham brace exerts more or the same magnitude of forces than the Steenbeek brace. These forces will be measured with the capacitance force sensor system in our upcoming trip to Kenya. Additionally, the team is conducting research to assess the material properties of the Cunningham brace to best help Kenya understand its mode for reuse and Mr. Cunningham in his decision to injection mold the brace as a way to maximize production.

Future Directions

Visit to Kijabe, Kenya in June 2022
- Collect force testing data from clubfoot patients in Steenbeek and Cunningham braces using the force testing system.
- Receive feedback from our clients
- Learn more about the clinical study in Kenya

Fall 2022 Work Cycle:
- Analyze testing data to help solidify hypothesis
- Testing with non-clubfoot children in both braces to be used as a control
- Continuation of fatigue analysis and brace reusability
- Further research on material properties of the brace

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