INSTRUMENTING CLUBFOOT BRACE TO DEFINE PROPER FIT

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ABSTRACT

Clubfoot is a congenital condition characterized by the inward twisting of a baby's foot. One significant challenge in treating clubfoot is ensuring that the corrective brace fits properly, especially as the child grows. This project aims to address this challenge by embedding flexible sensors into a brace liner to gather pressure data and measure the forces between the brace and the foot. This project addresses the current lack of quantified data to define a satisfactory fit for clubfoot braces. By investigating the relationship between brace fit and the forces exerted by the foot, we provide numerical data to guide proper brace adjustment and ensure effective clubfoot treatment. This additional medical evaluation will further validate a baby's brace fit, as well as contribute to the assessment of the foot condition by healthcare professionals.

1. PROBLEM STATEMENT

It is difficult to determine when a clubfoot brace fits properly, especially as the child grows. The goal of this project is to embed flexible sensors in a brace liner to collect pressure data and quantify the forces between the brace and the foot.

2. USER/APPLICATION

The target users for our product will be doctors who specialize in treating clubfoot. The data collected will be analyzed by doctors to help them numerically understand what is happening between the baby's foot and their clubfoot brace.

3. BACKGROUND RESEARCH

3.1 What is Clubfoot?

Clubfoot is a condition some babies are born with that makes their feet point inwards and downwards. It does not usually hurt the baby, but if it is not treated early, it can make walking difficult and uncomfortable as they grow up. With proper treatment, most children with this condition can participate in physical activities with little trace of deformity (OrthoInfo).

Clubfoot tends to affect males more than females, with a ratio of about 2.5 to 2.8 males for every female (Boden et al.). The incidence of clubfoot varies across different countries and regions, usually ranging from 1 to 1.5 cases per 1000 live births, but in some areas, it can as high as 3 per 1000 live births (Boden et al., Harnett et al., Jowett et al.). Notably, approximately 80% of children born with clubfoot worldwide come from low and middle-income countries (Clubfoot Training Project).

3.2 Ponseti Method

The first treatment for clubfoot is the Ponseti method, where doctor's gently stretch and adjust the baby's foot using manipulation and casting. They put on a long cast that covers the foot from the toes to the thigh. They do this each week, stretching and repositioning the foot until it greatly improves. It usually takes about 6 to 8 weeks for most babies to see great progress in their foot. Typically, casts are changed every week, and the last cast stays on for three weeks (Stanford Children's Health).

3.3 Boots and Bar Brace & Application

Even after successful correction with casting, clubfoot can tend to return naturally. To correct the foot position, the baby will need to wear a brace, often called "boots and bar," for several years. This brace maintains the foot at the proper angle to preserve the correction. During the initial three months, the baby will wear the brace around 23 hours a day. Over time, the prescribed wear time is gradually reduced until it is only needed to be worn overnight and during nap times. There are various types of braces available, including shoes, sandals, or custom-made footwear connected to a bar. The bar itself can be solid (causing both legs to move together) or dynamic (allowing each leg to move on its own) (OrthoInfo).

***Figure 1**: Side view and front view of Dobbs clubfoot boot (KiddFoot)*

Doctors teach parents the proper application of the clubfoot brace for their child, which involves several essential steps. In Figure 1, there is a tongue in the middle that must be pulled up high to secure the ankle strap around the heel within the boot to allow the ankle strap to firmly secure the heel at the back of the foot. Parents can visually confirm this proper foot positioning through two holes at the back of each boot (SickKids).

Doctors mark the insole to guide the correct foot placement, and as the child grows, this marking must be adjusted accordingly. Securing the ankle strap through the designated slot and marked hole, while avoiding overtightening, is crucial. Running a finger along the boot's side after fastening the straps

and laces will indicate that the boot is not too tight, yet tightened enough (SickKids).

To assess circulation, gently pressing the skin after opening the sock at the toes should briefly cause it to turn white before returning to a healthy pink color. Additionally, ensuring the heel stays firmly positioned without sliding during a gentle tug of the boots is essential. Any backward movement of the toes within the boot might indicate an issue with the brace being loose, requiring a refitting attempt (SickKids).

3.4 Problem Formulation

One common problem encountered in dealing with clubfoot is the inconsistent application of the brace by parents. To better understand the reasons behind this inconsistency, research was conducted through forums to explore the challenges parents face regarding their child's clubfoot condition and brace usage. Babies often feel uncomfortable and sometimes pain when they wear clubfoot braces. On the NoSurgery4Clubfoot website, a mother shared her story about her daughter's clubfoot. She said, "Once we put on the Foot Abduction Bar, my little girl got a sore on her heel from a blister." Unfortunately, the doctors could not do much, and using padding did not help, so the child had to deal with the discomfort. It turns out she was slipping in her shoe, causing the blisters due to friction. In many cases, like this one, parents do not put the braces on correctly. Severe skin problems like sores or ulcers from bracing are uncommon and usually happen when the straps are pulled too tightly. Skin irritation can be prevented by teaching parents the correct way to put on the brace's shoes. (Boughton)

Following this, research was conducted to define a "good fit." Although doctors can visually and physically assess whether the baby's feet are properly positioned in the clubfoot brace, there's a notable absence of quantified data to define what constitutes a satisfactory fit. The relationship between the brace fit and the forces exerted by the foot onto the brace has not yet been investigated. As a result, there's a lack of numerical data to indicate the necessary forces from the foot onto the brace that signify proper tightening and effectiveness of the brace. It is important for doctors and researchers to have an additional medical assessment to validate a baby's fit in a brace as well as the condition of the baby's foot.

4. DESIGN CONSTRAINTS

4.1 Why Dobbs Clubfoot Brace?

Dr. Melinda Sharkey and Dr. Leila Alvandi from Montefiore Medical Center provided us with a Dobbs clubfoot brace. Utilizing the Dobbs brace as the foundational model for design parameters and prototype evaluation, the experimental setup and brace liner were designed.

4.2 Areas of Interest For Foot

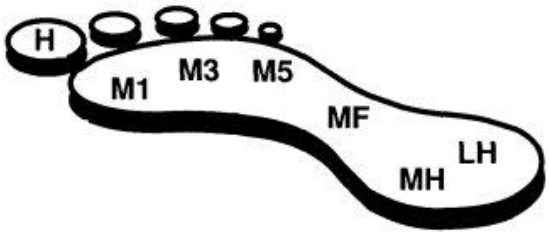


Figure 2*:Schematic foot print with anatomical regions of interest. MH, medial heel; LH, lateral heel; MF, midfoot region; M1, first metatarsal head; M3, third metatarsal head; M5, fifth metatarsal head; H, hallux (Hennig et al)*

An ideal fit entails the baby's foot positioned towards the rear of the boot, while signs of recurrence involve slight inward twisting and foot lifting off the platform (KidsHealth, Ponseti). These conditions narrowed down the areas of interest on the brace platform.

Figure 2 depicts a footprint with labeled anatomical points. This diagram identifies key areas on the foot where pressure measurement are crucial: the first and fifth metatarsal heads and the space between the medial and lateral heels, as illustrated above. When assessing the fit of a clubfoot brace, gathering force data at specified points is crucial. A proper fit entails the heel of the foot positioned at the boot of the boot. Conversely, signs of a poor fit include excessive pressure on the first metatarsal head compared to the fifth metatarsal head, or vice versa, since it suggests foot rotation and improper fit. Additionally, if the foot is reverting back to a clubfoot position, it suggests an inadequate brace fit.

4.3 Requirements of Prototype

The objective of the prototype is to identify the optimal placements for the sensor in order to determine what pressures constitute a "good fit". It is important that the prototype does not add too much thickness, which could affect how well the Dobbs brace fits. The piezoresistive sensors need to measure forces within the range produced by a baby's foot while being flexible and appropriately scaled to fit within the brace's platform. The sensors are adjustable, so it can be placed in different positions, and securely adheres to the base of the boot. A coordinate system implemented in the design will maintain consistency by showing the specific position of the sensors. The circuit board is wired to be modular, therefore more sensors can be added to collect data from all points of interest simultaneously. Wires running from the sensors to the circuit board do not interfere with the functionality of the boot and the foot.

4.4 Requirements of Final Product

The goal of the final product is to collect force data that quantifies both good and bad fit. The final product will have a similar configuration to the prototype. To maintain the integrity of the Dobbs brace fit and ensure longevity, it's crucial that the final product is made from soft yet durable materials. The piezoresistive sensors should be firmly secured in the brace liner to collect force data. The overall product should be designed in a way that is easy for doctors to use.

5. SENSOR CHOICE

Sensors were needed to measure the forces produced from the foot onto the brace. The research paper, "Foot Placement Characteristics and Plantar Pressure Distribution Patterns During Stepping on Ground in Neonates," was used to determine the force range the sensors experienced from a baby's foot. The study investigated how newborn babies place their feet and distribute pressure when taking supported steps. Researchers found that heel initial contact reached a maximum force of $3\frac{N}{cm^2}$; the midfoot initial contact reached a maximum force of $2\frac{N}{cm^2}$; and the forefoot initial contact also reached a maximum force of $2\frac{N}{m^2}$. Although the tests of motion that will be conducted for this current project does not account for a baby walking, this paper is helpful to determine the maximum force the sensors will experience. (Sylos-Labani, F et al)

Figure 3: SEN0294 DigiKey Piezoresistive Sensor (Sen0294 DFRobot)

A sensor is required to measure the forces between the medial and lateral heels. Illustrated in Figure 3, the piezoresistive sensor features an 18.3 cm diameter and a pressure measuring range spanning from 20 g to 6 kg, allowing it to accurately measure the maximum force exerted during a baby's heel contact. Its dimensions and flexibility are suitable for seamless integration into the heel section of the brace platform, ensuring compatibility with both the prototype and final product. Furthermore, the sensor's affordable cost of $5 makes it easily replaceable if needed.

Figure 4: SEN0297 DigiKey Piezoresistive Sensor (SEN0297 DFRobot)

A sensor is required to measure the forces at the first and fifth metatarsal heads. Illustrated in Figure 4, the sensor features a 1 cm diameter and a pressure measuring range spanning from 30 g to 1.5 kg, allowing it to accurately measure the maximum force exerted during a baby's forefoot contact. Choosing sensors from the same manufacturer ensures their seamless integration and circuit board implementation. This also guarantees consistency in desired features like flexibility and affordability across all sensors.

6. PROTOTYPE

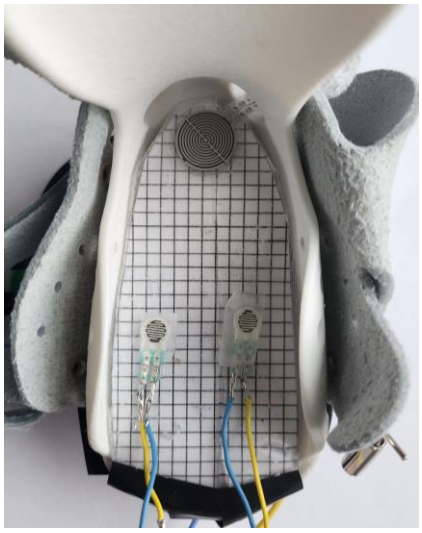


Figure 5: Prototype Integrated In Brace

In Figure 5, there is a coordinate placed on the platform of the brace to define where each sensor is in relation to the brace platform. Clear tape was placed on top of the coordinate to adhere the sensors to the coordinate. The SEN0294 piezoelectric sensor is placed at the heel section of the platform and two SEN0297 piezoelectric sensors are placed at the forefoot section of the platform. Wires were soldered to the sensors to connect them from the brace to the circuit.

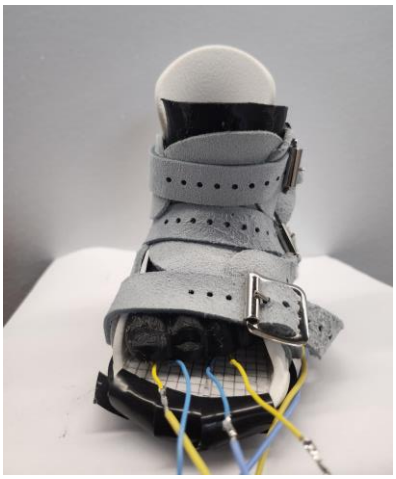


*Figure 6: Prototype Setup with 3D Printed Baby Foot *Need picture of this with cleaner background**

In Figure 6, the prototype setup displays a 3D printed baby foot secured within the brace. It is created from TPU due to its relatively soft texture. While it does not perfectly mimic the feel of a baby's foot, the chosen wall thickness allows it to somewhat resemble it. Sensor positions were identified by observing where the baby foot makes contact with the brace, both at the forefoot and heel.

6.1 Procedure For Data Collection

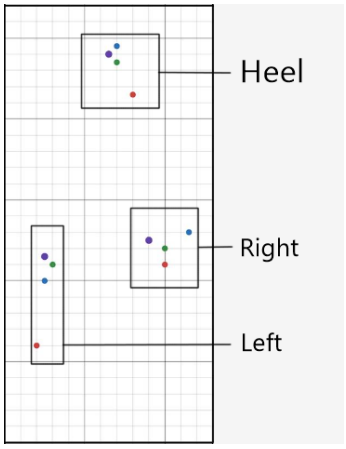


Figure 7: Data Positions Tested

Figure 7 illustrates the coordinates of various sensor positions tested. The positions were defined by the center of each sensor. The first sensor configuration is marked in red, the second in blue, the third in green, and the fourth in purple. These sensor placements were positioned within a relative radius of the foot contact areas to the platform.

Each sensor configuration underwent testing with different brace fittings and foot positions, including those for a good fit, foot rotation (both counterclockwise and clockwise), and forward translation of two units respective to the grid. A good fit was determined from doctor's instructions, which means, good fit was qualitatively determined using holes within the brace where the heel of the foot should align with the brace. Foot rotation and forward positioning indicated poor fits. Rotation of the foot was set at 15 degrees in both counterclockwise and clockwise directions relative to the platform, while the forward position referred to platform coordinate units. Five trials were conducted for each brace fitting.

During testing, sensors were initially placed on the platform, and Arduino was used to run the code for collecting pressure and analog data. Microsoft Excel's Data Streamer feature was then utilized to collect the data. Subsequently, the baby foot was positioned in the brace according to the specific trial's brace fit, with consistent tightening of the straps across all sensor configurations tested. Upon completing a one-minute trial, the brace was unstrapped, and the baby foot removed. To initiate a new trial, the baby foot was taken out of the brace and strapped back in.

7. SENSOR PLACEMENT DATA

7.1 Results

After collecting data from all three sensors in different configurations, the next step was to analyze the data. The objective of data analysis was to determine which sensor position is optimal to differentiate good and bad fit. There was a total of five trials for each fit orientation for every sensor position. Therefore, there is a total of 20 trials conducted for each tested position. The resulting data used for analysis is the average pressure values across all trials for each fit orientation (good fit, forward position, clockwise rotation, and counterclockwise).

To begin the process of data analysis, the raw data from the sensor needed to be filtered and organized for data visualization. Initially, the sensor reading returned an analog value, which needed to be converted to a pressure value. Therefore, the raw data was filtered and averaged across all data to achieve the values shown in table 1.

Table 1: Average Pressure readings for fit orientation and their differences

Position 3	CCW	CW	ff	gfit	gfit-ff	gfit-CW	gfit-CCW
Heel (grams)	82.94	15.04	4.45	69.58	65.14	54.54	13.36
Left (grams)	23.68	0.00	0.00	1.50	1.50	1.50	22.17
Right (grams)	0.00	37.18	0.00	15.24	15.24	21.93	15.24

Table 1: The average pressure values for each sensor vs. the fit orientations and their differences for position 3. (CCW: counter clockwise, CW: clockwise, ff: forward position) The last three cells contain the differences between the good fit and all the bad fit orientations.

The final table as shown above for all the data displays all the average pressure values for position 3. Using the differences between the good fit and all the respective bad fit orientations,

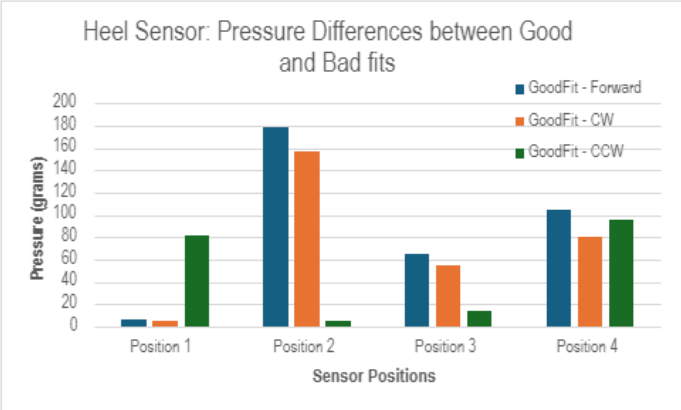


Figure 8: The average pressure difference recorded between good and all bad fit orientations at the heel sensor for all tested positions.

In Figure 8, the pressure differences between good fit positions and bad fit positions were plotted for the heel. For heel sensor placement, the best position was determined by looking at the consistency within the data and largest difference in pressure for when the foot was placed two spaces forward in the brace according to our grid (Goodfit–Forward). This criterion would provide information on where the sensor will best be able to pick up pressure readings relatively consistently. Based on this criterion, Position 4 had data that was all within similar ranges while having one of the highest difference in pressure when compared to the other positions.

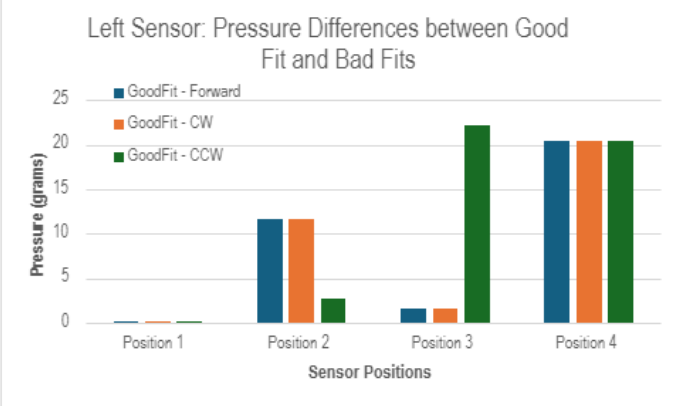


Figure 9: The pressure difference between good and bad fit for the left sensor at different positions.

In Figure 9, the pressure differences between good fit and bad fit were plotted for the left sensor. For left sensor placement, the best position was determined by looking at the largest difference in pressure for when the foot was rotated counter-clockwise (Goodfit–CCW). This criterion would define where the sensor is able to characterize a counter- clockwise rotation of the foot, hence making it easier to differentiate when the foot is in a bad position and when it is in a good position in that particular area. Based on this criterion, Position 3 had the largest difference in pressure when compared to the other positions.

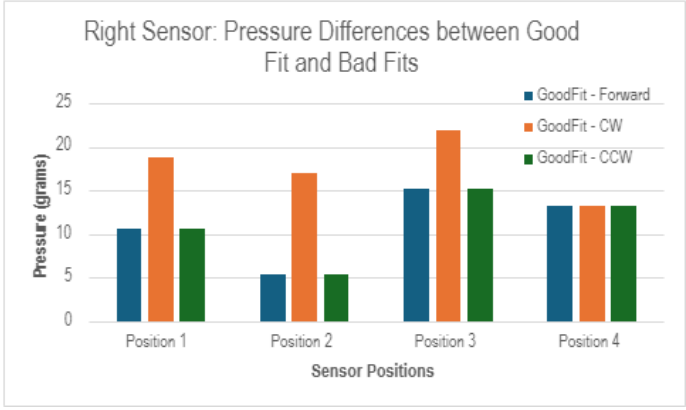


Figure 10: The pressure difference between good and bad fit for the right sensor at different positions.

In Figure 10, the pressure differences between good fit and bad fit were plotted for the right sensor. For right sensor placement, the best position was determined by looking at the largest difference in pressure for when the foot was rotated clockwise (Goodfit–CW). Similar to the left sensor placement, this criterion would define where the sensor is able to characterize a clockwise rotation of the foot, hence making it easier to differentiate when the foot is in a bad position and when it is in a good position in that particular area. Based on this criterion, Position 3 had the largest difference in pressure when compared to the other positions.

7.2 Sources of Error

Despite testing four different sensor configurations, there was no systematic approach to determining the positions for each sensor test. The sensor positions were chosen based on their proximity to the areas where the foot makes contact at the heel, first metatarsal head, and fifth metatarsal head. Initially, the left and right sensors were placed in an area below the rest of the positions tested, as the initial plan was to test the area under the toes. However, after observing the data from the first position, it was decided to select the area under the balls of the foot for collecting data.

Human error impacted the data collection process. The prototype was placed on a desk, which, while relatively stable, could have experienced minor shifts in movement that might have impacted the readings. Although efforts were made to maintain consistent angles for counterclockwise and clockwise rotations indicating a bad fit, there are inherent limitations when reading a protractor with the human eye. Additionally, while a timer was used to track one minute of data collection, it was observed that the data collection did not cease precisely after one minute; instead, slightly more than a minute of data was collected. As a result, some trials were recorded for slightly longer durations than others, leading to inconsistencies across trials.

8. FINAL BRACE LINER

The liner has a stainless-steel sheet base as it serves as a rigid platform for the sensors. Over this base, EVA foam is shaped to cover the stainless-steel sheet foundation. EVA was chosen over alternative materials after evaluating it based on attributes such as flexibility, moisture management, and cost-effectiveness. Assembly of the liner involved the use of Barge, a contact cement, to bond the EVA and silicone components together. The liner was then put together using Barge (contact cement) as adhesive between the EVA and the Silicone. The sensor placement was marked using our previous coordinate system sheet and stamps. These stamps, as seen in Figure 11, were 3D printed and pressed into the EVA to indicate the center of each of the sensors for accurate positioning. The sensors were secured in place using double sided tape to prevent damage to the wiring and electrical components as seen in Figure 12. Finally, to encase all the layers and sensors in place, a cotton fabric was sewn around the perimeter of the sensor with an opening in the toe area for the wires to protrude from as shown in Figure 13. This fabric also further ensures comfort and packages all the layers together.

Figure 11: 3D printed stamps.

Figure 12: Sensor placement in EVA foam.

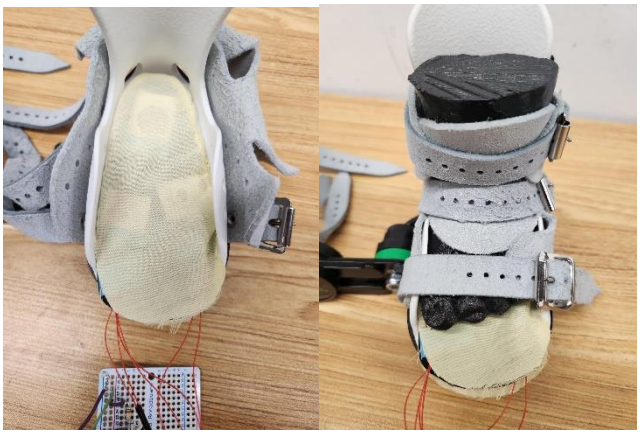
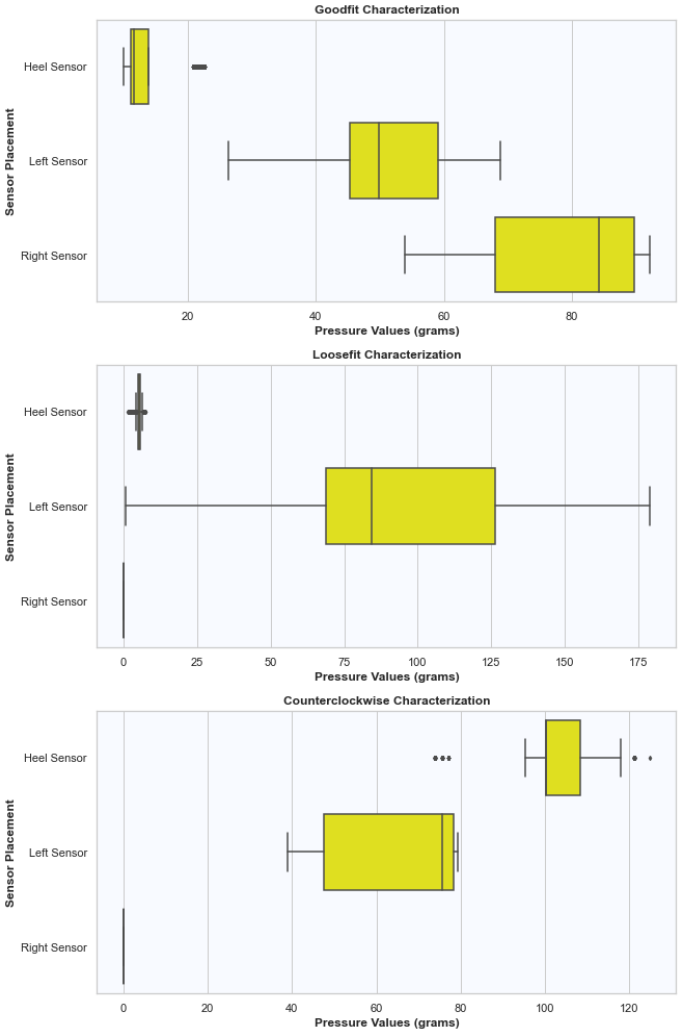
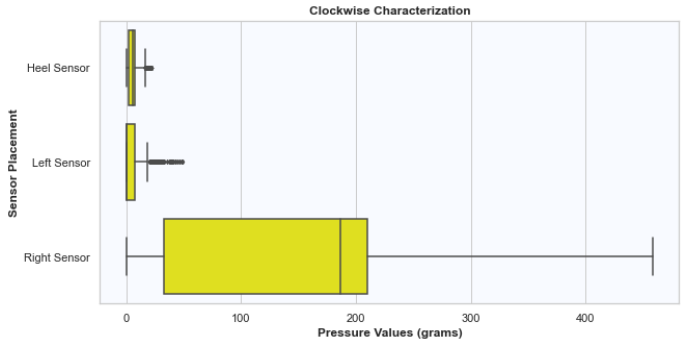


Figure 13: Top view of liner placement in size 2 dobbs brace (left) and TPU baby foot strapped into the size 2 dobbs brace with the liner (right).

9. FINAL DATA COLLECTION

9.1 Results





9.2 Discussion

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9.3 Sources of Error

While there were many measures taken to ensure consistency during data collection, there are also inevitable sources of error. Many of these errors were human error. Similar to the test set up with the prototype, the final liner was tested on a desk. This time the brace was also laid down on its side, so there could have been a minimal rotation of the boot and the liner could have slightly shifted in the brace since it was oriented vertically. All these minor movements could have impacted readings. Although efforts were made to maintain consistent angles for counterclockwise and clockwise rotations indicating a bad fit, there are inherent limitations when reading a protractor with the human eye. Furthermore, the sensors chosen could not read as accurately at lower pressures, so the data may be higher or lower than expected.

10. CONCLUSION

Place conclusion here.

11. FUTURE WORK

As discussed previously,

- Minimizing Error
  - More Trials
  - Recording data where sensors are fully reset for each other
- Testing
  - Human testing
  - Involve testing that would include movement of babies and how that might give indication to proper fit
  - Testing for the pressure felt on the foot could be done to see whether the straps on the boot are too tight (this could be done with a barometer on a balloon).
- Sensors
  - More consistent sensors, sensor speced for lower range of pressures (more expensive though)
  - Grid sensors could give better results for full mapping of foot (might not be needed though)
- Liner
  - Ethylene-vinyl acetate (EVA) is already FDA approved for medical devices -- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=177.1350
    - **CFR - Code of Federal Regulations Title 21**
    - "Ethylene-vinyl acetate copolymers may be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:" (several conditions that we can say are discussed in this document)
    - There is anti-microbial EVA which could be better for insoles
  - Silicone is also already an approved FDA material:
    - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=177.2600&SearchTerm=silicone
  - We need to get approval for this device as it would be classified as a Class I medical device (most likely). Class I devices are low-risk devices.
    - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm
    - A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act) that is not subject to premarket approval.
- Circuits and Packaging
  - Battery Codes/Requirements:
    - Referred to as the "bible" of medical electrical equipment standards, ANSI/AAMI ES 60601-1 outlines the general requirements for basic safety and essential performance of medical devices that require an electrical outlet or a battery.
    - Clause 15.4.3.4 in the standard requires lithium batteries to comply with IEC 60086-4, Primary Batteries – Part 4: Safety of Lithium Batteries or IEC 62133, Secondary Cells and Batteries Containing Alkaline or

Other Non-acid Electrolytes. The former outlines tests and requirements for primary lithium batteries to help ensure their safe operation under intended use and reasonably foreseeable misuse. The latter specifies requirements and tests for the safe operation of portable sealed secondary lithium cells and batteries containing non-acid electrolyte under intended use and reasonably foreseeable misuse.
        - IEC 62133, Secondary Cells and Batteries Containing Alkaline or Other Non-acid Electrolytes
        - IEC 60086-4, Primary Batteries – Part 4: Safety of Lithium Batteries
        - IEC 60086-5, Primary Batteries – Part 5: Safety of Batteries with Aqueous Electrolyte
        - IEC 62485-X, Safety Requirements for Secondary Batteries and Battery Installations
        - UL 1642, Lithium batteries
        - UL 2054, Household and Commercial Batteries
            - (https://www.csagroup.org/article/making-sense-regulations-medical-device-batteries/)
    - Microcontroller
        - ESP32-C3- WROOM-02, has WiFi and Bluetooth capabilities already built into the microcontroller.
        - Quite small ($18.0 \times 20.0 \times 3.2\ mm^3$) and could easily be added onto the brace.
        - https://www.espressif.com/sites/default/files/documentation/esp32-c3-wroom-02_datasheet_en.pdf
    - PCB
        - A PCB is needed to connect all the sensors to the microcontroller and can be easily printed making it perfect for mass production
    - Op Amp and Low Pass filter to lower noise of readings
        - There is no need for a low pass filter or Op amp at this point because we are recording the average values for the pressure values over time. The low pass filter will be required to remove noise from the circuit if we are
        - If we decide that time dependent data is needed for future testing, then these can easily be implemented at a rate which is consistent with nyquist theory (filtering frequencies 2 times the sample rate).

*Talk about using FDA approved materials
*Talk about advanced/more precise sensors to implement if given a bigger budget
*More Refined

ACKNOWLEDGEMENTS

The authors thank Dr. Rosen and Dr. Lima for their guidance and feedback throughout this capstone project. The authors also thank Dr. Melinda Sharkey and Dr. Leila Alvandi from Montefiore Medical Center for providing a Dobbs clubfoot brace.

REFERENCES

[1] "Clubfoot," OrthoInfo, American Academy of Orthopaedic Surgeons, April 2023, orthoinfo.aaos.org/en/diseasesconditions/clubfoot/#:~:text=Clubfoot%20is%20a%20deformity%20in,An%20infant%20with%20clubfoot.

[2] Boden, R.A., Nuttall, G.H., & Paton, R.W. (2011). A 14-year longitudinal comparison study of two treatment methods in clubfoot: Ponseti versus traditional. Acta Orhopaedica Belgica, 77(4), pp. 522-528.

[3] Harnett, P., Freeman, R., Harrison, W.J., Brown, L.C., ; Beckles, V. (2011). An accelerated Ponseti versus the standard Ponseti method. The Journal of Bone ; Joint Surgery, 93, pp. 404-408.

[4] Jowett, C.R., Morcuende, J.A., ; Ramachandran, M. (2011). Management of congenital talipes equinovarus using the Ponseti method. The Journal of Bone & Joint Surgery, 93, pp. 1160-1164.

[5] Clubfoot Training Project. Chapter 2 Africa Clubfoot Training Basic & Advanced Clubfoot Treatment Provider Courses - Participant Manual. University of Oxford: Africa Clubfoot Training Project, 2017.

[6] "KiddFoot," Kiddfoot. Dobbs ADM Clubfoot Braces (Boots and Bars), Kiddfoot, kiddfoot.com/boots-and-bar-system?orderby=6&pagenumber=2&viewmode=list.

[7] SickKids staff, "Clubfoot: Treatment with a Boots and Bar Orthosis," AboutKidsHealth, January 24, 2012, www.aboutkidshealth.ca/article?contentid=1192&language=english.

[8] Boughton, Barbara, "Keeping Kids in Braces Can Prevent Clubfoot Relapse," Lower Extremity Review Magazine | Rehabilitation • Trauma • Diabetes • Biomechanics • Sports Medicine, March 2, 2016,

lermagazine.com/issues/february/keeping-kids-in-braces-can-prevent-clubfoot-relapse.

[9] "The Ponseti Method - Clubfoot Program - Stanford Children's Health," Stanford Children's Health, www.stanfordchildrens.org/en/service/clubfoot/ponseti-method

[10] "Clubfoot," OrthoInfo, American Academy of Orthopaedic Surgeons, April 2023, orthoinfo.aaos.org/en/diseases--conditions/clubfoot/#:~:text=Clubfoot%20is%20a%20deformity%20in,An%20infant%20with%20clubfoot.

[11] "Bracing for Clubfoot." *Physiopedia*, www.physio-pedia.com/Bracing_for_Clubfoot#:~:text=Essential%20features%20of%20the%20brace,the%20affected%20side%20or%20sides.

[12] Hennig, Ewald M., and Dieter Rosenbaum, "Pressure Distribution Patterns Under the Feet of Children in Comparison With Adults," Foot & Ankle, vol. 11, no. 5, April 1991, pp. 306–11, https://doi.org/10.1177/107110079101100507.

[13] "The Ponseti Clubfoot Brace: Tips for Parents (for Parents)," KidsHealth, The Nemours Foundation, February 2022, kidshealth.org/en/parents/ponseti-brace-tips.html.

[14] Ponseti, Ignacio V., "Relapsing Clubfoot: Causes, Prevention, and Treatment," The Iowa Orthopaedic Journal, U.S. National Library of Medicine, 2002, www.ncbi.nlm.nih.gov/pmc/articles/PMC1888384/#:~:text=A%20relapse%20is%20detected%20when,the%20sole%20of%20the%20foot.

[15] Sylos-Labini, F., et al. "Foot Placement Characteristics and Plantar Pressure Distribution Patterns during Stepping on Ground in Neonates." *Frontiers in Physiology*, vol. 8, 2017, pp. 784-784. [National Institutes of Health (.gov)] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5641324/.

[16] "Sen0294 DFRobot | Sensors, Transducers | DigiKey." *DigiKey*,www.digikey.com/en/products/detail/dfrobot/SEN0294/10136556.

[17] "Sen0297 DFrobot | Sensors, Transducers | DigiKey." *DigiKey*,www.digikey.com/product-detail/en/dfrobot/SEN0297/1738-SEN0297-ND/10136551.

[18] "CFR - Code of Federal Regulations Title 21." *Accessdata.Fda.Gov*, www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=177.2600&SearchTerm=silicone. Accessed 14 Apr. 2024.

[19] "CFR - Code of Federal Regulations Title 21." *Accessdata.Fda.Gov*, www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=177.1350. Accessed 14 Apr. 2024.

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