Inconspicuous Ankle Foot Orthosis Device for Teen

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Client: Debbie Eggleston

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Problem Statement

Ankle foot orthoses (AFOs) are essential for providing dorsiflexion and mediolateral support during the swing phase of walking. However, conventional AFOs are often bulky and limit natural ankle mobility, making them less practical for everyday use. There is a need for an AFO design that balances effective support with comfort and flexibility. This project focuses on creating a discreet and lightweight foot brace specifically designed to support a teenager diagnosed with facioscapulohumeral muscular dystrophy (FSHD).

Design Specifications

- Provide dorsiflexion support to prevent foot drop
- Prevent ankle inversion
- Have a slim, lightweight, and flexible design
- Stay within an initial prototype budget of $300
- Allow customization to meet individual user needs
- Ensure the brace is easy to put on and take off
- Fit comfortably within shoes

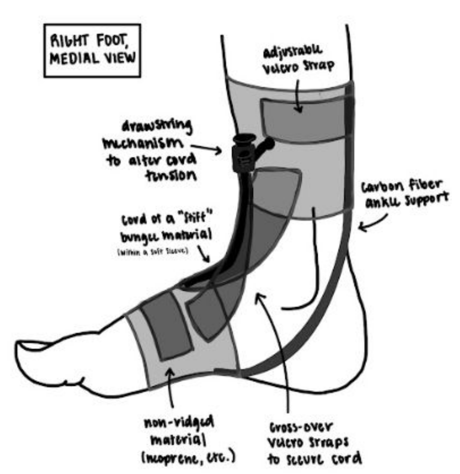


Figure 1: Initial Brace Idea

Background Information

Facioscapulohumeral muscular dystrophy (FSHD): Genetic disorder causing progressive muscle weakness [1]

Client: Debbie Eggleston, a physical therapist and activist for FSHD

Patient: A high school student with FSHD, concerned about the visibility of an AFO and its potential impact on her daily activities

Impact: This device is designed to provide discreet support for teenagers with FSHD, addressing their unique needs and filling a critical gap in research and resources available for this age group.

Existing AFOs:

- Rigid AFO [2]
  - No range of motion
- Flexible AFO [3]
  - Bulky but provides some ankle flexibility
  - Reduces Three-Point-System
- Passive Dynamic AFOs (PD-AFOs) [4]
  - Flexible and sleek but expensive and difficult to fit in everyday shoes
  - Thermoplastic material


Figure 2: Rigid AFO [2]


Figure 3: Flexible AFO [3]


Figure 4: Passive Dynamic AFOs [4]

References

[1] Facioscapulohumeral muscular dystrophy (Fshd). (n.d.). Muscular Dystrophy UK. Retrieved October 3, 2024, from https://www.musculardystrophyuk.org/conditions/a-z/facioscapulohumeral-muscular-dystrophy-fshd/
[2] Rogati, G., Caravaggi, P., & Leardini, A. (2022). Design principles, manufacturing and evaluation techniques of custom dynamic ankle-foot orthoses: A review study. Journal of Foot and Ankle Research,15, 38. https://doi.org/10.1186/s13047-022-00547-2
[3] A Professional Guide for Everyone wearing an Ankle-Foot Orthosis (AFO)," Feb. 24, 2022. https://alcammedical.com/ankle-foot-orthosis-afo/
[4] "Thermoplastic AFO | Dynamic Medical." Accessed: Dec. 04, 2024. [Online]. Available: https://dynamicmedical.ae/product/thermoplastic-afo/
[5] "Home," Runeasi. Accessed: Dec. 04, 2024. [Online]. Available: https://runeasi.ai/
[6] W. N. Mascarenhas, C. H. Ahrens, and A. Ogliari, "Design criteria and safety factors for plastic components design," *Materials & Design*, vol. 25, no. 3, pp. 257–261, May 2004, doi: https://doi.org/10.1016/j.matdes.2003.10.003.

Final Design

- **Design Features:**
  - Compression sock with gel pads for comfort
  - Foot brace with PLA-reinforced carbon fiber piece (tailored to the users dimensions) for strength, stability, and durability
  - Adjustable bungee cord system for customizable support; excess cord tucks into side fabric for comfort
- **Usage:**
  - Easy to use: wear the compression sock first, then the foot brace; adjust cords and straps as needed
  - Ideal for indoor use, allowing mobility without bulky AFOs
- **Key Benefits:**
  - Prevents falls, minimizes foot inversion, and supports dorsiflexion
  - Practical, user-friendly design tailored for everyday wear
  - Can be used with or without a shoe, dependent on the users needs


Figure 5: Final Design on Mold of Patient


Figure 6: Final Design on Team Member's Foot for testing

Runeasi Testing and Results

Runeasi is a system that develops gait assessments based on biomechanic sensor data

- Collected data during three-minute walking intervals on a treadmill, repeated for three trials under each condition: no brace, brace with support, and brace without support

Overall Effects of the Brace on Gait and Comfort of Healthy Individuals?

Pain Levels:

- Measured before, during, after each walking trial
- On a scale from 0 (no pain) - 10 (extreme pain); **pain levels never exceed 1**

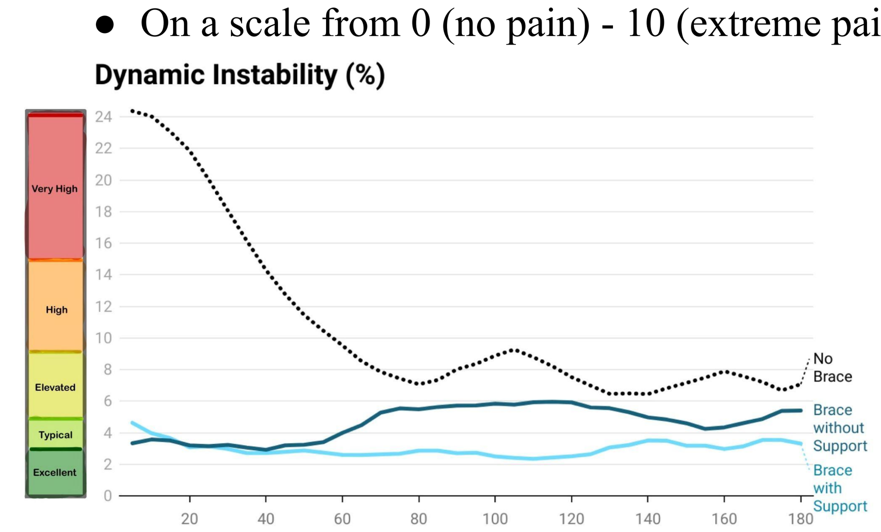


Figure 7: Graph of Dynamic Instability over Time for 3 Conditions

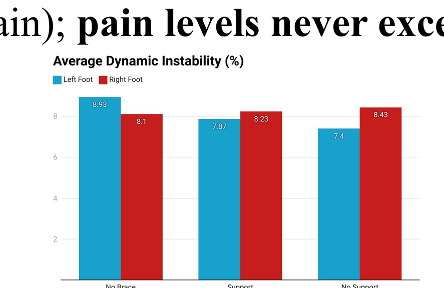


Figure 8: Average Dynamic Instability across Conditions

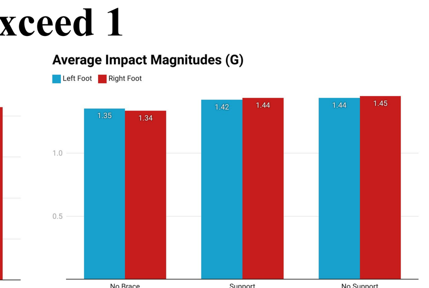


Figure 9: Average Impact Magnitudes across Conditions

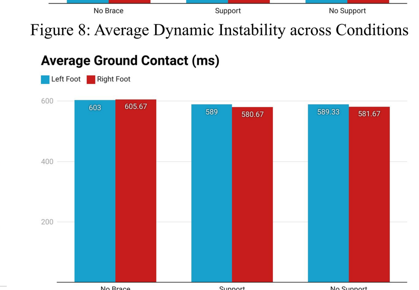


Figure 10: Average Ground Contact across Conditions

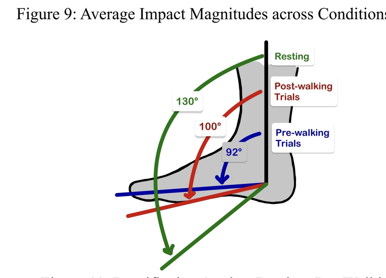


Figure 11: Dorsiflexion Angles: Resting, Pre-Walking, Post-Walking Trails

Dynamic Instability (%): proportion of hip movement in the mediolateral direction during landing
Ground Contact Time (%): total duration the foot is in contact with the ground
Impact Magnitude (%): vertical impact that reached the pelvis immediately after ground contact [5]

Key Findings:

- The brace caused minimal discomfort
- Over time, the brace reduced variability in gait between the left and right foot
- No significant differences were observed in dynamic instability, impact magnitude, or ground contact across tested conditions
- The bungee tension angle decreased by 8° after 30 minutes

Acknowledgements

The team would like to extend their appreciation to Dr. Coventry for his continued guidance and support throughout this process. Additional thanks goes out to Dr. Puccinelli, Mikel Joachim, BME faculty, and the UW Makerspace and Design Lab for their collaboration during the fabrication process.

Solidworks Testing and Results

- Red regions have FoS below 2
- Recommended FoS for plastic components between 1.5 and 2 [6]
- Singular red region at edge has a FoS of 1.7
- Majority of structure has FoS above the recommended threshold; likelihood of failure under these conditions appears low

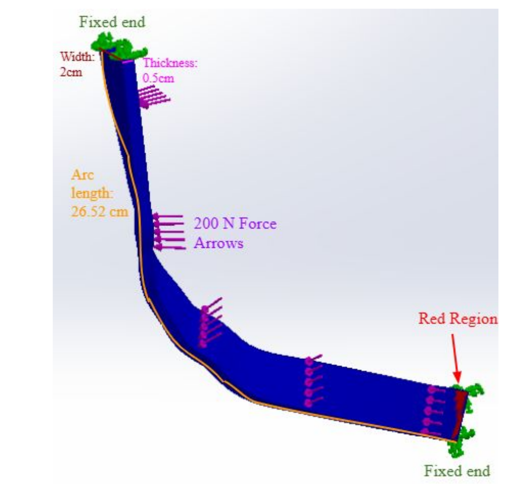
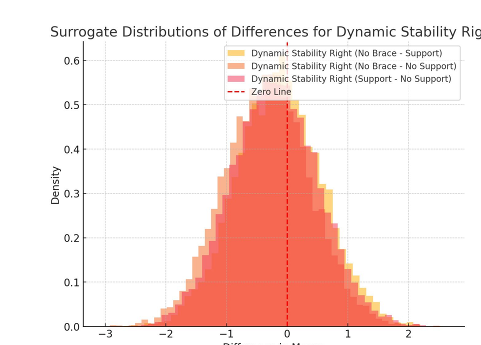
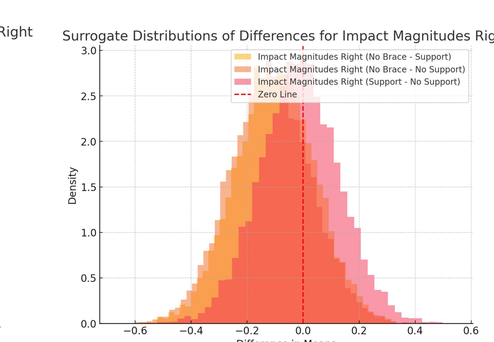


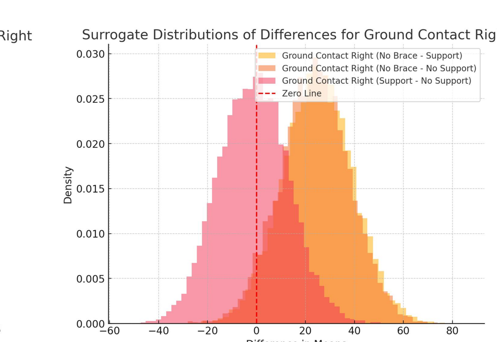
Figure 12: Solidworks Model for PLA + CF Piece

Bayesian Estimation - Statistics

- Bayesian estimation measured the posterior distribution of gait-related parameters (ex dynamic stability, impact magnitudes, ground contact, and cadence) for different conditions (No Brace, Support, No Support)
  - Quantified how likely it was that the gait parameters differed across conditions, considering both data and uncertainty


Figures 13: Difference in means plots for significance for dynamic stability


Figures 14: Difference in means plots for significance for impact magnitudes


Figures 15: Difference in means plots for significance for ground contact

Discussion

Complications and Solutions

- The bungee cord pulled up the compression sleeve instead of the foot
  - Used a firm neoprene strap to attach the bungee cord
- Normal cord lock was not securing the bungee cord in place
  - Used a lock lace and sewed upside down to maintain tension in the bungee cord
- The lock lace did not adhere to the fabric with E6000 glue
  - A 3D-printed part was designed to fit the lock lace, providing an increased contact surface for glueing and sewing

Testing

- Overall, the brace with or without the support did not significantly impact gait patterns
  - This matches our hypothesis because the testing was done on a healthy individual
- Overall, majority of the support will be able to withstand a load of 200 N applied to the inner face of the support with the recommended factor of safety

Future Work

Device Prototyping:

- Order an ankle brace to replace neoprene straps and compression sleeve
- Attach the bungee cord to the brace to ensure the bungee cords stay flush with the brace
- Fabricate the support using carbon fiber and conduct material testing
- Assemble the full prototype

Runeasi Testing

- Conduct Runeasi testing using the full prototype on our patient
- Compare results between no prototype, full prototype with a shoe and without a shoe