BME Design-Fall 2024 - ANYA HADIM
Complete Notebook

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GRACE NEUVILLE

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Team contact Information

GRACE NEUVILLE - Sep 18, 2024, 12:20 PM CDT

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Project description

Presley Hansen - Sep 12, 2024, 12:50 PM CDT

Course Number: Section number 304

Project Name: Inconspicuous Ankle Foot Orthosis (AFO) for teen

Short Name: AFO Group

Project description/problem statement:

Ankle foot orthoses (AFOs) are engineered to provide dorsiflexion support during the swing phase of walking. This device is mainly used for treatment of muscular dystrophies and for this project in particular, we are focusing on young individuals diagnosed with Facioscapulohumeral Dystrophy (FSHD), the most common kind of muscular dystrophy. The team is aiming to design a brace for teens to aid in ankle dorsiflexion for safer walking, while being easily concealable and flexible enough to allow for functional ankle range of motion. The key objectives of this device include positioning the ankle in adequate dorsiflexion, maintaining a narrow, thin, and discreet design, and ensuring sufficient flexibility to minimize any restriction of movement.

About the client: Debbie Eggleston

LE Medical History - Maggie

Alex Conover - Sep 18, 2024, 7:12 PM CDT

Download

Pediatric_FSHD_Data_-_Maggie_Ankle_info.xlsx (255 kB)

MD and orthotist notes

Lucia Hockerman - Sep 22, 2024, 1:28 PM CDT

Title: Email sent from Deggie, MD and orthotist note overview

Date: Sent to the team 9/21/2024: covers info from 11/7/2023 to 9/5/2024

Content by: Various doctor notes from orthotics and prosthetic centers

Present: N/A

Goals: Understand the specific details of Maggie's condition so we can design an AFO customized to Maggies needs.

Content: Events from least to most current

11/7/2023: UM Orthotics and Prosthetics Center (UMOPC)

- Discussed with patient and her mom could not guarantee delivery of custom foot orthotic before the end of year - proceeded with foot orthotics at UMOPC

- 14 year old female, Deggie states Maggie is experiencing ankle weakness with foot drop. Did not want to go with AFO but a custom foot orthotic*.

*Differences between AFO and custom foot orthotic: AFO offers more comprehensive support, addressing both ankle and foot issues, while a custom foot orthotic focuses on correcting foot alignment and function but does not control ankle or leg movements (normally a insole that fits inside the shoe).

- Patient is active in horseback riding. Wears a size 8.5-9 in shoes

Assessment:

- Skin cool, dry and intact (people with FSHD could have loose skin, dry/pale skin (due to poor blood flow), INCREASES irritation --> we should mention this in PDS.

- Hypermobile ankles and feet: increases range of motion in the joints which can impact gait

- Appears to be Pes cavus while seated: pes cavus = high arches of the foot, possible contracted toes, arch remains rigid despite the lack of weight (does not flatten)

- Arches drop during weight-bearing

- Pronation of both lower extremities, right side is greater than left: the amount of which the foot rolls inward (normally around 15%), assuming Maggie has over-pronation?

- Bilaterial hindfoot valgus: hindfoot (the heel region) tilts outward in relation to the lower leg. The heel rolls inward (eversion), causes the arch to collapse and ankle becomes misaligned

1/15/2024: fit and delivery of custom orthotic

Reports no change in condition from previous assessment. Orthoses are fit to shoes for Maggie (Adidas size 8.5).

Orthotic design: Functional - 3/4 length orthotic with extra deep heel cup, high medial and lateral flanges and full length 1/8"/1/16" EVA topcover

9/5/2024: University of Michigan Pediatric Neurology Clinic

Doctor recommends AFO, but Maggie is not ready yet. Open to using, just not at school.

Assessment:

BUE: strength 5/5 throughout except right shoulder abduction to 90 but 4/5 within range,
RLE HF 5/5, HA 5/5, KE 5-/5, KF 5-/5, DF 4/5
LLE HF 5/5, HA 5/5, KE 5-/5, KF 5-/5, DF 4+/5
Active DF left +10, Right -15
Passive DF 15 left, 10 right
Left dorsiflexion 4/5, Right dorsiflexion 3/5. Facial muscle weakness (unable to keep air in cheeks, purse lips).
Gait: Left supinates, lateral border initial contact, mild circumduction left , good knee control
Difficulty with heel walking left
Difficulty with maintaining knee flexion in single leg stance left

Impression & Plan:
Magdalena Eggleston is a 15 y.o. female with a history of FSHD-1 who presents for follow up of rehab needs.

- continue PT
- AFOs ordered, please trial different options
- Night static progressive AFO placed.

Debbie's added comments: even worse MMT. Refer to PT note. She says it's 2+. If these doctors were right, she wouldn't need an AFO.

BUE: strength 5/5 throughout except right shoulder abduction to 90 but 4/5 within range, (did not test all of the individual scapula and stabalizing muscles today)
RLE HF 5/5, HA 5/5, KE 5-/5, KF 5-/5, DF 3/5
LLE HF 5/5, HA 5/5, KE 5-/5, KF 5-/5, DF 4/5
Active DF left +10, Right -15
Passive DF 15 L, 10 R.
Facial muscle weakness (unable to keep air in cheeks, purse lips).
Gait: Left foot supinates with lateral border initial contact, mild circumduction on left but good knee control. Has difficult time with heel walking on left. Able to go on toes b/l. Can tandem. Difficulty with single leg stance on left.

Debbie's added comments: the testing is not accurate. Her DF strength is less than 3 because she can go full ROM anti-gravity.

Conclusions/action items: Apply this knowledge to our design ideas

09/18/2024 1st Meeting with Ms. Eggleston

Alex Conover - Sep 18, 2024, 10:58 AM CDT

Title: First Client Meeting

Date: 09/18/2024

Content by: Alex Conover

Present: All present

Goals: Meet with Ms. Eggleston (our Client) and discuss design, PDS, and other important information.

Content:

These are the questions and answers from our meeting with the client:

Questions:

1. When leveraging aesthetics with function and support, is there one you would like to take higher priority?
    - Cares about the function the most, allows her to do heel strike so she doesn't fall while not limiting other activities.
    - Rather it be medially than laterally
    - Would you like the brace to be easily hidden by clothing or even when exposed (match skin color etc.)?
        - Hidden inside the shoe.
        - Often wears leggings, jeans, pants, easier to hide underneath
        - More info coming soon from Maggie
2. From your expertise, do you have any material suggestions?
    - Carbon fiber
    - Plastic (thick and rigid) - hinges may be less inconspicuous
3. What common problems do you see with traditional AFOs for individuals diagnosed with FSHD?
    - Too rigid, restricts full range of motion, aren't able to walk around and do day to day activities
4. Would you like this AFO to be designed for both the left and right leg?
    - Right leg is most important
    - Left scapula weakness
    - Asymmetrical disease, has left scapular weakness, right tibialis anterior weakness
5. Is this AFO specifically for Maggie? Or is there a specific age range for our target audience?
    - Will benefit Maggia Initially
    - Applying to somebody else will be the next step
6. What is our budget for this project?
    - 200/300 average, if we think it won't be useful, flexible budget
    - Value of an AFO is 1000, would only pay if we would design something that would work to that regard
    - Initial Budget is $300

<u>Other notes from the meeting:</u>

Physical therapist she has 4 kids her oldest started having postural problems so she took her to doctors and then rehab therapists and found out she has FSHD. Facial weakness, can't pucker her lips or hold air in her mouth. Has a hard time raising her arms. More recently, she has a foot drop and her hamstrings are getting weaker. No clinical trials include children.

She's never had an AFO before.

- Dorsioflexion is the most important criteria, not rigid
- Plantarflexion not as important
- Allow Heelstrike (inhibit falling)
- Unilateral - add something medially, not laterally perhaps.

- Hinges and straps on the shoe - are super helpful, but very bulky. Design something about the inside? Interior (beneath the shoe) perhaps is a better idea.

Cannot do antigravity dorsiflexion
Inserts?

- Very social, doesn't want to draw attention, Sophomore in HS. It was diagnosed in 8th grade, she played softball, track, cross country, etc. She was very physical, very active, and athletic, but it is harder to do so now.
- Doesn't want to draw attention to her condition to avoid attention in public, bullying etc.
- Heading to Virginia next week - PT work. She can ask specific questions - 25th for clinical trials to train PT's. She will send us the notes from the PT stuff.
- Don't be afraid to nag, send her an email tomorrow morning to remind for the email about Maggie's open dates.

Additional Questions:

1. Measurements for the prototype?

- Keep Wednesdays at 9 am… maybe - will depend on schedules. Will keep in contact regarding times to meet (including when Maddie is free)

Conclusions/action items:

- Research ways to take Maggie's measurements most effectively (actually measuring: what specific places; or mold: cheap, easy way for them to do at home)
- Discuss with Coventry about testing plans with Maggie and finalize what testing will look like/what we need to get done beforehand
- Meet with Maggie over Zoom about her specific requirements
- Gather specific information from Maggie's PT appointment

09/30/2024 - 2nd Meeting - Maggie

Alex Conover - Oct 02, 2024, 1:32 PM CDT

Title: Second Client Meeting/Meeting with Maggie

Date: 09/30/2024

Content by: Lucy Hockerman

Present: All present

Goals: Meet with Ms. Eggleston (our Client) and Maggie to discuss our designs, PDS, and other important information.

Start with introductions:

- Names, something else?
- Our design process:
    - We will be constantly changing the prototype. So the ideas we will show you might change a lot once we get feedback, research more, and begin testing.
    - We are making this for you! So be completely honest, you won't hurt our feelings. Don’t be scared to say something if you want the design to be changed or it is not to your liking. Our goal is to make a brace that is supportive, but that you are confident and comfortable in.

Show design ideas:

Walk her through each design (three people each take one design)

- Important points with each design
- Pros and cons
- Design 1
    - Likes that it is like a knee brace
    - Medial versus lateral with inversion/rotation of ankle?
- Design 2
    - Likes the athletic look
    - Add something more rigid to the bottom
    - Likes the strap fed through ankle
- Design 3
    - Would rather have it medial

Ask initial questions about ankle mobility:

We are just trying to understand how you feel when walking, so we can get a better understanding on the type support we need to focus on for our design.

- What physical activities do you do during a typical day?
    - In your lower legs, what bothers you most during a typical day?
    - Ankle inversion, has been falling
- How much control do you have moving your foot up and down?
- Do you have any difficulties moving your foot side-to-side?

- What problems do you notice most when you walk?
- What do you hope to be able to do with the brace that you can’t/are having trouble with doing currently?

Ask initial questions about aesthetics:

- What is your preference of how the brace looks?
- What shoes are you hoping to wear with this brace?
- Do you want it to go over your pants or under?
- Color preference?
-

Get feedback:
What do you like/dislike about the designs?
Do you have a favorite?

Notes:
Most important is functionality, try and have be more discreet than normal AFOs
Had a couple falls recently, for sure needs an AFO
Hinge design: looks kinda like an athletic brace
Lately the foot (inversion - lateral side of the foot is stressed), rolling the ankle inwards
Like the strap is close to the skin for design 2
Research: why AFO has joints lateral than medial
Maggie fell during competition, might not be a foot drop problem, might not

- **Can the design go into the boot?**

Will send dates about testing and Maggie's trip to Madsion

Like:

- **More non-rigid material, try to avoid**
- **Likes the 2nd design with carbon fiber support on medial side (less of an adjustment)**
- **Maybe combine 1 and 2 (dorsiflexion support with bungee and medial/lateral support with the circular hinge)**
- **Start with a black material**
- **Mostly tennis shoes, and common shoes (asked for photos)**
- **Think about incorporating the custom orthotics (would not need plantar support) and avoid the carbon fiber sole**

Send out an email to go over
Still doing equestrian, bowling, driving with left foot

Debbie: Peter Adamczyk

Conclusion/action points: write a email reminding what we discussed/what we need from maggie (photos of shoes, measurements, send new version of our final design, dates for maggie's visit in late October/early November), create solidwork design of foot support.

11/25/2024 - 3rd Meeting with Debbie

ANYA HADIM - Nov 25, 2024, 1:45 PM CST

Title: 3rd Meeting with Debbie

Date: 11/25/2024

Content by: Alex Conover

Present: All present

Goals: Update Debbie on the design

Content:

- Good looking (not like an immovable brace), more like a recovering athlete (good feedback)

- Eventually adding the pieces to make the bungee less visible (straps sewed together)

- Testing is good

- Zoom into the final presentation

- further patenting and updating later semesters, if we get that far

- carbon fiber medio lateral support is important as falls have been increasing

- grip on the bottom to help with falling?

-can be worn around the house since support does not allow it to fit in a shoe

Conclusion/action points:

Keep working on final deliverables, and deliver a time to Debbie for when we're presenting on Friday, December 6th.

09/13/2024 Advisor Meeting 1

Alex Conover - Nov 15, 2024, 2:56 PM CST

Title: First Advisor Meeting

Date: 9/13/2024

Content by: Alex Conover

Present: All members

Goals: Meet with our Advisor and receive updates

Content:

- Researching, we are working on our research, and we haven't started working on the actual design yet due to not meeting with our client.

- PDS work is divided up but not starting on the client part yet due to not working with them yet.

- Aesthetics chat:

- implantable medical devices tend to have more usage "set and forget", versus the exterior devices. Patient compliance is higher with implantable medical devices.

- Trade-off with effectiveness and efficacy versus aesthetics

- Establish a metric/standard to describe to the client. Effectiveness vs aesthetics. 80% effective vs very visible, 60% effective vs hidden. Quantify with the client ASAP.

- Client relationships are very important, we seem to have a good one.

- Carbon fiber is a great material, but it is very expensive, and can leave microfibers as skin irritants

- adding to bulkiness, it may need a buffer

- haptics - how to interact with the client's skin to make sure there is no irritation.

- divide and conquer - machining, testing, etc. Min/max the results.

- Question for the client about patents: independent from university: pay, unless you are a first-time patent applicant. (a substantial amount of money). If we were to publish a patent. This link can help with this stuff, also when finding patents, etc: https://patents.justia.com/

- PDS is a living breathing document, work on the design process, don't worry too much about filling out the paperwork for the grades. The outline is online. Fill in every section, whether it is relevant or not.

- Can email to Dr. Coventry to review before grading, and send it in by Wednesday (9/18).

Conclusions/action items:

Begin working and researching the PDS, and meet with our client on Monday at 9 am!

09/20/2024 Advisor Meeting 2

Alex Conover - Sep 20, 2024, 1:17 PM CDT

Title: First Advisor Meeting

Date: 9/20/2024

Content by: Alex Conover

Present: Dr. Coventry, Presley, Alex, Grace

Goals: Meet with our Dr. Coventry to receive updates and ask questions

Content:

Fusion360 is the software to use AutoCAD/Solidworks to share designs. (Free because of UW Madison)

- Also relating to Maggie's trip, what preparations do you suggest so everything goes as smoothly as possible and we make the most out of it?
- Start designs as soon as possible (in Solidworks with simulations)
- Once we get designs, go through iterations which will decide where we go
- "Design matrices are stupid" - Dr. Coventry
- Spend more times on singular design instead of design matrix and explain this in final meeting because they will agree when grading
- Fixed design vs jointed design in matrix (add measurements to designs)

- Are there any materials you suggest would be optimal for our prototype over others considering our budget (carbon fiber vs plastic)? How should we go about acquiring these materials (makerspace or ordering)

- People in makerspace who know how to work with carbon fiber
- Carbon fiber best bet because of flexibility
- Build initially with something cheaper and easy to obtain (goal to get to carbon fiber)
- Put into CAD for material strength estimates
- Analog to carbon fiber that is a little cheaper?

- Thoughts on a jointed AFO vs a less bulky design (jointed would give optimal function but be much less inconspicuous, seems that the client cares more about functionality but Maggie cares more about aesthetics how do you recommend we place more weight/importance to)

- Possible for hinge design with less bulk
- Don't trade functionally too much
- Brace needs to do a lot more work with tone → do research on this (hop onto PubMed → braces without muscle tone → where to place stability points)
- Low profile circular joints (inner and outer joint)

- What do you think about the budget in general?

- Feasible budget especially for development
- Might need a little more for development for new materials
- Fusion 360 to share designs easily → get for free on computer through uw-madison

Conclusions/action items:

Start designing prototypes for the design matrix, and continue research on hinges and materials.

09/27/2024 Advisor Meeting 3

Lucia Hockerman - Sep 27, 2024, 1:01 PM CDT

Title: Third advisor meeting

Date: 9/27/2024

Content by: Lucy Hockerman

Present: Dr. Coventry, Presley, Alex, Grace, Anya, Lucy

Goals: Meet with our Dr. Coventry to receive updates and ask questions

Content:

- Start build SolidWorks before measurements (just get a start on it and add dimensions later)

- The balance between visual vs function, two different clients (Maggie and Debbie): say to Maggie "we are concerned about function, but tell us what you want aesthetically." We need function, but what do you want it specifically to look like. Aesthetics might just weigh more than functions (Maggie needs to like it to wear it)

- Design patent: could focus on aesthetics

- Combine ideas from design matrix based on the function requirements of Maggies specific leg

- BPAG meeting overview: could submit a request to cover the cost (need to talk to client more about)

- Client: Debbie ; Patient: Maggie

- All teammates should complete the HIPPA human testing training

- Let Maggie know we are learning and testing and the prototype will change

- Set a goal but be aware things might change

- Cross compare the conflicting PT notes with Maggie's personal experience

- Think about embodiment, how can we create a device that works in tandem with her needs/image. Goal is to help Maggie feel more comfortable and confident with her disease

- Wearables are not for the future, but for the discreteness

- Spend time on SolidWorks for winning design

- Each team gets 50 dollars for the makerspace (materials), and its free to use.

- In presentations: show that you are physically doing design, not paperwork. Talk about function vs aesthetics.

Conclusions/action items:

- Ask client specific questions about function (where do you need support the most) vs aesthetics (what do you like it to look like).

- Ask Debbies connection to UW-Madison

- Prepare questions about Maggie's walking ability/ankle mobility

10/18/2024 Advisor Meeting 4

ANYA HADIM - Oct 20, 2024, 12:21 PM CDT

Title: Advisor Meeting

Date: 10/18/2024

Content by: Anya Hadim

Present: whole group

Goals: update our advisor on our fabrication plan

Content:

-likes the cord lock idea, thinks its worth trying

-might be fail or pass but good idea to try

-more inconspicuous and the client will like more

-discussing failure modes: drop a weight and slowly raise the height for carbon fiber attachment

-custom foot pads for Maggie?

- For sewing: research strong knots/sewing patterns that are used in surgery and/or industry

Conclusions/action items:

Begin fabrication of the prototype, try sewing the cord lock, perform weight testing on the carbon fiber piece, ask about custom foot pads for Maggie.

10/25/2024 Advisor Meeting 5

Lucia Hockerman - Oct 25, 2024, 12:57 PM CDT

Title: Advisor Meeting 5

Date: 10/25/2024

Content by: Lucy Hockerman

Present: Whole Group

Goals: Update our advisor on our prototypes and problems

Content:

- With the issue concerning the pulling of material: increase surface area by potentially adding a wrap around the foot. Distribute the force across the brace (brainstorm different places). Add a farther position from the heel to increase the torque.

- For show and tell: split room into two. One half of team will stay and one will go around and give feedback to other teams. Need to prepare a one minute elevator pitch (little background, but mostly about the design and its problems). For the pitch, add points that facilitate conversations.

- Funding got approved! Maybe? Props to ALEX for killing the funding proposal! Have around $300 (maybe a little more) for spending.

- To work the carbon fiber, you could epoxy it in a mold. If/when we get to this stage, it is dangerous to work with carbon fiber.

- Maggie is confirmed to come Nov. 9th: make reservation on where to meet, consider a meal, talk with Pucc about hosting protocol. Ask about specific cut-off for times.

Conclusions/action items: Finish SolidWorks/prototype for show and tell and prepare an elevator pitch/split up teams.

11/08/2024 Advisor Meeting 6

Alex Conover - Nov 08, 2024, 2:30 PM CST

Title: Advisor Meeting 6

Date: 11/08/2024

Content by: Lucy Hockerman

Present: Whole Group

Goals: Update our advisor on our prototypes and problems

Content:

- From coventry: he team is doing well and will have enough for final deliverables

- Suggested fabric glue. Coventry is a skateboarder! He uses E600 which is a flexible fabric glue

- In terms of testing, quantify is good to have. MTS testing of bungee cord? Should look into to see if it possible with a bungee cord. Research the shock cord and try and find its max tensile strength

- Next week is tong lecture: shorten meeting to 15 mins after tong lecture (meet from 1:15-1:30)

- Dental rubber maybe for a cast fill, or epoxy resin stuff. This something to research and purchase --> amazon or in person at hobby lobby.

Conclusions/action items: Buy mold materials and begin testing!

11/15/2024 Advisor Meeting 7

Alex Conover - Nov 15, 2024, 1:42 PM CST

Title: Advisor Meeting 7

Date: 11/15/2024

Content by: Alex Conover

Present: Whole Group

Goals: Update our advisor on our prototypes and problems

Content:

- main data takeaway: didn't change much from grace's normal walking (didn't make it worse), but did feel better.

- excellent data collection

- did we expect a numerical difference? muscle activation for us vs maggie (healthy control is valuable information)

- more surface area for plastic cord lock - distributing forces evenly

- sewing it will help counteract the torque acting on it.

Worth having a final prototype?

- specify what we used for what in final presentation

- is it worth our time? Should we make a final brace with our time remaining? If we cannot, then don't order another brace.

- if the brace would help the story overall, then go for it.

Quick pour - harder to work with, just follow instructions

- will need the mold release agent

- use rubber to mix

Testing 2x?

- new changes in forces, we should test again (adding the plastic piece) - quantify data.

- not the end of the world if we can't test again.

Conclusions/action items:

Conduct final testing, prepare final prototype.

11/22/2024 Advisor Meeting 8

Lucia Hockerman - Nov 22, 2024, 12:58 PM CST

Title: Advisor Meeting 8

Date: 11/21/2024

Content by: Lucy Hockerman

Present: Whole Group minus Anya

Goals: Update our advisor on our prototype and testing (part two)

Content:

- Discussed epoxy problems: can't find it.

- Dr. P is requesting posters at 10 am on December 6th (the morning of presentations)

- Relative deflection from control left foot: bayesian t-test for low samples. Will send online website for calculations.

- Is there significance compared to control? Bayesian uses a prior assumption and looks at the distributions of data. Looks at the percentages the data overlaps. Control as no brace on the right foot.

- Biased opinions from Grace, but her opinions is still helpful

- Based on Impact mag, Grace mentioned that the higher number might be a good sign because there is more weight on heel than toes

Bayesian : https://www.sumsar.net/best_online/

- Leave sample sizes as is (2000)

- Can plug in sample groups as you go - order does not matter

- For solidworks testing: increase forces until a failure point at different points --> find the max forces

- For presentation: go through client needs and go through how you meet them.

Conclusions/action items: Look a testing more, make mold and finish up the semester!

12/11/2024 Advisor Meeting 9 - Final Meeting

Alex Conover - Dec 11, 2024, 3:58 PM CST

Title: Final Advisor Meeting

Date: 12/11/2024

Content by: Alex Conover

Present: Entire Group and Dr. Coventry

Goals: Final Meeting with our Advisor

Content:

- Dr. Coventry said this was the best presentation he saw during our poster session 12/06 (yay!)

- Also agreed with our sentiment, everyone did really good work

- Add Coventry on Linkedin - Happy to work with us and help us, especially with networking and as a resource

- get the HIPPA training done, as well as other certifications necessary to continue testing

- Our progression throughout the semester is commendable, a working prototype is wonderful

- if you decide to continue the project, you get back on and you don't have to fight for it

- sophomore options are still in the question - list who is going to stay on, if necessary

- As we go through the program, keep this semester in mind. This was top-tier communication; this should be the standard. (both sides of the coin), carry it forward, give it forward, keep up the great attitudes and everything.

- Reach out if you need anything!

Conclusions/action items: Finish and turn in the final deliverables.

Design Matrix - 09/24/2024

GRACE NEUVILLE - Oct 01, 2024, 1:21 PM CDT

Title: Design Matrix

Date: 09/24/2024

Content by: Grace Neuville

Present: Team

Goals: Create a design matrix that reflects the most important design specifications from the PDS. Weight each criterion based on how important it is to our client. Then, score each design out of 5 based on how well they fulfill each criterion.

Content:

Scoring Criteria

Scoring Criteria

Support (20%) - Support is weighted at 20% because our design must support the position of the foot and ankle, as this is one of the main functions of an ankle-foot orthosis. Our client wants the orthosis to support the heel and allow for heel strike while also providing some mobility. A higher score represents a design that offers more support for the foot and ankle.

Discreetness (20%) - Discreetness is weighted at 20% because it is very important to our client that the ankle-foot orthosis is discreet. Our client is a sophomore in high school and does not want to draw attention to her ankle. The AFO should fit inside a shoe and underneath jeans or leggings. A higher score represents a more discreet design.

Safety (15%) - Depending on the materials chosen for our design, there may be potential safety hazards. It is important that the ankle-foot orthosis is made from durable materials. If the AFO were to break, it must be ensured that it would not harm the user, which is why safety is weighted at 15%. Additionally, we must consider the effects of microplastics or any skin irritation that could be caused by the device. A higher score represents a design that is likely to be safer for the user.

Flexibility (15%) - The design and material used should be flexible enough to allow for functional ankle range of motion, which is why flexibility is weighted at 15%. It must be flexible enough to ensure that other activities, such as squatting or descending stairs, are minimally impacted. A higher score represents a more flexible design.

Ease of Attachment and Removal (10%) - Since this device will be used daily, it is important that it is easy for the user to put on and take off. It is only weighted at 10% because a device that is harder to attach and remove can still be functional, flexible, and safe, supporting the client's main requirements. A higher score represents a design that is easier to attach and remove.

Customizability (10%) - A customizable AFO ensures a proper, comfortable fit. Customizability helps prevent discomfort and enhances functionality for ankle range of motion. An adjustable design ensures it remains effective as the user’s needs evolve. A higher score represents a more customizable design. Customizability is weighted at 10% because, while important, it is more critical for the device to be functional and discreet for the user.

Cost (5%) - Considers the amount of money needed to fabricate and maintain each design. Low scores indicate a higher cost and higher scores indicate a lower cost. Cost is only weighted at 5% because the client is flexible with the budget depending on the necessity and functionality of the design.

Ease of Manufacture (5%) - Considers how easy each design is to fabricate, including the accessibility of materials, machinery, and the time required for fabrication. A higher score indicates greater ease of manufacture. Ease of manufacture is weighted at only 5% because, although the design needs to be practical to produce, there is considerable flexibility in the time, materials, and fabrication processes that can be used.

Design Matrix Table

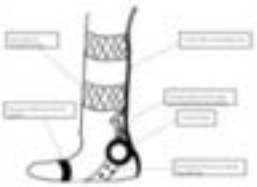
Criteria	Weight	Design 1 Hinge Design Score |	Weighted Score	Design 2 Bungee Brace Design Score |	Weighted Score	Design 3 Strap Design Score |	Weighted Score
							
Support	20	3/5	12	3/5	12	5/5	20
Discreetness	20	3/5	12	5/5	20	4/5	16
Safety	15	3/5	9	4/5	12	4/5	12
Flexibility	15	4/5	12	5/5	15	3/5	9
Customizability	10	4/5	8	5/5	10	3/5	6
Ease of Attachment and Removal	10	2/5	4	3/5	6	4/5	8
Cost	5	4/5	4	5/5	5	4/5	4
Ease of Manufacture	5	5/5	5	4/5	4	3/4	3
Total	100		66		84		78

Figure 1. *Design Matrix Table*

Design Matrix Discussion

Support - Design 3 offers the most support because the orthosis covers ¾ of the bottom of the foot and travels about halfway up the calf, which will fully support the ankle. Design 1 and Design 2 do not support the ankle as much because it allows for more mobility. The hinge in Design 1 and the bungee system in Design 2 will allow for plantar flexion.

Discreetness - Design 2 is the most discreet because it will easily fit inside a shoe and underneath pants. The strap gives a sock-like appearance, so this device would not draw too much attention. Design 2 is slightly more discreet than Design 1 because of the circular hinge and additional strap. However, both designs would fit underneath pants and inside a larger shoe.

Safety - Design 2 and Design 3 were ranked the highest for safety for different reasons. Design 2 is safe because of the soft material so it will not harm the user. Whereas Design 3 could potentially break and harm the user, but the design is the most supportive and durable because of the carbon fiber design. Design 1 is the least safe because the design could break and harm the user because of

the plastic design, and there could be microplastics. Additionally, it is not as supportive because of the hinge mechanism, so the user, depending on muscle strength, could potentially miss a heel strike.

Flexibility - Design 2 is the most flexible design because the bungee system allows for plantar flexion, and the soft fabric material is less rigid than plastic or carbon fiber. Design 1 is slightly more flexible than Design 3 because the hinge mechanism allows for more mobility; however, they are both rigid because of the use of plastic and/or carbon fiber.

Ease of Attachment and Removal - Design 3 is the easiest design to use, as it will only contain straps to attach to the leg, which will be made of a stretchy, flexible material, such at TPU filament, or another type of 3D printing filament for ease of use and ease of construction. Design 1 has many moving parts that could make the attachment more difficult. Design 2 will have a lace-up design, or a bungee-like cord through the sleeve, which may be difficult to get on due to the lack of dorsiflexion in the patient.

Customizability - Design 2 will be the most customizable, both in terms of level of stability and support and in exterior aesthetics. Design 2 can be tightened to various levels of support, while still maintaining an inconspicuous profile, and would be color-customizable. Design 1 scored the next highest, as it also has a high level and range of support available, but would be less inconspicuous due to the hinge, and not as customizable exteriorly. Design 3 scored the lowest, as it is the simplest, and provides the least amount of customizable support. It maintains a decent level of inconspicuousness, but cannot be customized exteriorly any more than the color of the straps.

Cost - Design 2 will be the most cost-effective. Our budget for the initial project is $300; Design 1 potentially involves more testing and prototyping due to the hinge mechanism, and Design 3 would be the most expensive because of the cost of carbon fiber.

Ease of Manufacture - Design 1 would be the easiest to manufacture. The hinge would provide some level of difficulty, but there is no other technical level of difficulty beyond basic machining. Design 2 would involve lots of experimenting to design the best bungee mechanism inside of the base, but overall would still be less difficult than Design 3. The 3rd design would involve the manufacturing of carbon fiber, which none of us have the current skill-set to do, and would need to learn; therefore, giving design 3 the lowest and design 1 the highest score.

Conclusions/action items:

Continue to define and discuss designs.

Expenses Table

Alex Conover - Dec 11, 2024

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Ankle Brace - Component 1										
Ankle Brace	Cloth brace	**Abiram**		Amazon		10/10/2024	1	$14.88	$14.88	Link
Gel padding	medical grade padding	**Shechekin**		Amazon		10/10/2024	1	$15.81	$15.81	Link
Gel sock	Compressive sock to support the carbon fiber	**KEMFORD**		Amazon		10/10/2024	1	$15.95	$15.95	Link
Plastic cord locks	End of the bungee	**Heado US**		Amazon		10/10/2024	1	$3.98	$4.20	Link
Nylon Fabric	fabric/cloth to sew carbon fiber	**MYUREN**		Amazon		11/6/2024	1	$12.61	$12.61	Link
Bungee pt 2	stronger bungee to support better dorsiflexion	**LuckyStraps**		Amazon		10/23/2024	1	18.99	$20.03	Link
Bungee	thinner bungee	**Huouoo**		Amazon		10/25/2024	1	$6.32	$6.32	Link
Mini caribener	small sized caribener to hold bungee	**REI**		REI		11/4/2024	1	$6.00	$6.00	**In-store**
Shock cord	thinner and stronger bungee	**REI**		REI		11/4/2024	1	$5.95	$6.61	**In-store**
Lock laces	lock laces to fix the slipping problem of the plastic cord lock	**Lock Laces**		Amazon		11/4/2024	1	$12.65	$12.65	Link
Fabric Glue	glue to attach the cord locks to the fabric	**E6000**		Amazon		11/08/2024	**1**	$8.14	$8.14	Link
Needles and Thread	Stronger needles and thread to attatch various fabrics	**Basic Home**		Amazon		12/03/2024	**1**	$8.43	$8.43	Link
Carbon Fiber piece - Component 2										
3D printing prototype	3D printing of back support	**Bambu printer**		Makerspace		11/8/2024	1	1.4	$1.40	***cover**
3D printing prototype - 3 variants	3D printing of back support	**Bambu printer**		Makerspace		11/12/2024	1	3.8	$3.80	***cover**
3D printing prototype	3D printing of back support	**Bambu printer**		Makerspace		11/13/2024	1	1.71	$1.71	***cover**
Lock lace piece	3D printing the lock lace piece	**Bambu printer**		Makerspace		11/18/2024	1	0.23	$0.23	***covere by our given $5 per tear**
3D Printing Final Prototype	3D printing of back support	**Shen Printer**		Makerspace		12/3/2024	1	1.57	$1.57	***cover**
Epoxy Mold - Component 3										
Epoxy	Take cast of the leg	**Easy Pour Epoxy**		Amazon		11/14/2024	1	$39.97	$39.97	Link
Mold release Agent	PVA release agent - Prevent bonding to the cast	**Mrealeazy**		Amazon		11/14/2024	1	0	$0.00	***Used**
								TOTAL:	**$189.02**	

10/12/2024 - Fabrication Draft

Alex Conover - Oct 06, 2024, 7:44 PM CDT

Alex Conover - Oct 12, 2024, 3:28 PM CDT

Title: Fabrication Draft

Date: 10/12/2024

Content by: Alex Conover

Present: all

Goals: Create a preliminary fabrication plan

Content:

- Order Materials (completed 10/09/2024)

- Decide if we were going to 3D print or fabricate the support of the AFO

- Begin the process to fabricate the support piece

    - 3D print in Makerspace, or work with metal in the TEAM lab

- Fabricate the brace with the gels to prevent irritation

- Put together the 2 pieces to create the initial prototype

Conclusions/action items:

Flesh out a solid idea for both pieces of fabrication, and create a more full version of fabrication with specific steps.

Fabrication Plan - prototype

ANYA HADIM - Oct 20, 2024, 12:39 PM CDT

Title: Fabrication Plan - first prototype

Date: 10/15/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: create a fabrication plan for the initial prototype

Content:

The carbon fiber attachment will be designed in SolidWorks and subsequently 3D printed at the UW-Makerspace using the Markforged Onyx Pro printer. The material will undergo an initial testing evaluation on Solidworks prior to being printed (see testing section for more details). This preliminary testing will assess the strength, flexibility, and overall functionality of the carbon fiber component in the device.

The ankle brace and bungee cord will be purchased (see BPAG cost sheet for pricing details), but the bungee cord will be customized to meet the specific dimensions and support requirements of the patient. The cord will be cut and modified to optimize the level of tension needed to assist with walking. These modifications will be made based on assumptions and initial bungee cord testing and then fine-tuned after an in-person testing session with the patient (see the Testing and Results section for more detailed procedures). To ensure ease of adjustability, the bungee cord will be threaded through a plastic cord lock, which will also be purchased and integrated into the design.

To assemble all components, the gel-padded compression sock will remain separate, as an additional layer of comfort and support for the user. The gel pads will be sewn on the sock based on the patient's pressure points after testing. The carbon fiber attachment will be securely sewn onto the foot sleeve brace using purchased sheets of nylon fabric. This will hold the carbon fiber in place without adding unnecessary bulk or restricting movement. This assembly will be completed using the sewing machines available at the UW-Makerspace. The plastic cord lock will be sewn onto the top portion of the foot sleeve, while the bungee cord —once placed under tension—will be threaded through the cord lock, ensuring adjustability. The bungee will then be covered and secured using diagonal Velcro straps, which wrap across the front of the ankle to stabilize the brace. The bottom of the bungee cord will be sewn to the front of the brace, approximately 15.24 centimeters from the top, using additional nylon fabric for extra support and reinforcement.

Once fully assembled, the user will be able to put on the brace by first slipping on the compressive sock, followed by sliding the brace onto their foot, both processes like a regular sock. The bungee cord can then be tightened to the user's preference using the cord lock, and the Velcro straps will be fastened as the final step. The design prioritizes simplicity, speed, and ease of use, as the AFO will be worn daily and taken on and off frequently. This streamlined assembly and adjustment process ensures that the device will be comfortable, user-friendly, and highly functional for everyday use.

Conclusions/action items:

fabricate the initial prototype using these instructions.

Bungee cord fabrication

ANYA HADIM - Nov 01, 2024, 10:50 AM CDT

Title: Bungee cord fabrication

Date: 10/20/2024

Content by: Anya Hadim

Present: Anya and Alex

Goals: Sew the bungee cord onto the foot sleeve and thread it through the plastic lock

Content:

We cut the bungee cord to the length of the foot sleeve, then trimmed it to 2/3 of that size to have sufficient tension. Alex sewed the bungee cord 2 inches out from the top of the foot sleeve (toe side), and the plastic cord lock 2 inches down from the top of the sleeve (shin side). We then tested how it worked and felt all together by trying the foot sleeve on and testing different levels of tightening the bungee cord and how it affected our foot/walking/gait support.

Conclusions/action items:

Discuss with group and have a team meeting about: adding fabric on top of the bungee cord at the front of the foot sleeve, attaching the plastic cord lock in a more inconspicuous way (so that it isn't sticking out/moving around), purchasing a stronger bungee cord of the same thinness, sewing the foot straps to the foot sleeve. Purchase fabric to pull through the plastic lock and attach it down to the foot sleeve and sew that way as it will be more supportive. Doing two bungee cords on either side of the foot rather than one in the front for more support? Compression sock not supportive enough? Add a clamp or adjustable strap at the top of the carbon fiber attachment.

11/01/2024 - First Rigid Support Fabrication: SOLIDWORKS

Lucia Hockerman - Nov 15, 2024, 5:28 PM CST

Title: Rigid Support Fabrication in SOLIDWORKS

Date: 11/01/2024

Content by: Lucy Hockerman

Goals: Fabricate the rigid support of our design in SOLIDWORKS to 3D print and eventually sew into our bungee brace

Content:

Initial SOLIDWORKS problems: After initial time on SOLIDWORKS, there was problems creating a curve (specific to Grace's dimensions) in 3 different planes. Met with the Design Lab (Jack Sperling) for SOLIDWORK design assistance.

Solution: Utilize the "Curve Through XYZ Points" function on the program. This allows to input specific 3D measurements and the system generates a 3D curve following along the inputed dimensions.

3D measuring (grace's dimensions) -

1.) Draw a line along the medial side of the left foot to map a desired path starting at the bottom the calf muscle (posterior), beneath the ankle joint, and ending underneath the footpad. Set the x, y and z coordinates to match on solidworks. In increments down the y axis every 1 cm, took measurements in x and y directions.

Measurements:

y (up down)	x (out of foot)	z (down foot)	
7	0	0	
0	0	0	
-1	0.5	0	
-2	0.75	0	
-3	1	-0.5	
-4	1	-1	
-5	1	-1.5	
-6	1	-2.5	
-7	1	-3.25	
-8	1	-4.5	
-8.4	1	-5.5	x=5
-8.8	1.25	-6.5	z=12.5
-9.2	1.25	-7.5	x=-5/12.5z-8
-9.6	0.75	-8.5	
-10	0.5	-9.5	
-10.4	0.83	-10.5	
-10.8	1.16	-11.5	
-11.2	1.49	-12.5	

2.) Plugged in measurements to solidworks program to create line path. Extruded a circle along the path to create a bent-like pipe shape.

SOLIDWORKS 3D printed: white support along the side of foot

Conclusions: Adjust dimensions around the ankle joint and make it a flat, rectangular shape for next print.

11/13/2024 - prototype 2 fabrication

Presley Hansen - Nov 15, 2024, 5:00 PM CST

Title: Prototype 2 Fabrication

Date: 11/13/2024

Content by: Presley Hansen and Alex Conover

Present: Presley and Alex

Goals: To start fabricating prototype 2

Content:

- Alex sewed the fabric onto the strap to secure the bungee cord beneath it

- Used the E6000 fabric glue to secure the cord lock to the strap

- Need to buy stronger needles and thread

Procedure:

The bungee was cut to an adjustable length, then the center of the wraps was measured, and the bungee cord was sewn into the center across a width of about 2.5 inches. A piece of fabric was cut to increase the surface area being pulled up by the bungee. The initial plan was to sew the entire piece of fabric with the bungee into the wrap, but that was taking too long, and we were running low on thread, so we decided to glue the fabric down. We also glue the cord lock down on both sides, leaving the front and back open for the bungee cords to go through. We used the E6000 fabric glue and clamps to hold the various pieces into place, as it needed 8 hours to set. We will be continuing prototyping methods to attach the cord lock since it was not stable in the initial fabrication.

The sewing of the bungee cord was successful but the lock lace did not stay in place with the glue. A new piece will be 3D printed to secure the lock lace in place. The bungee cord was temporarily secured with the upper strap so the prototype could undergo gait testing as shown in Figure 1 below.

Figure 1: Prototype 2 used for gait testing

Conclusions/action items:

Buy stronger needles, buy stronger thread, and maybe explore what ECB offers in that department before purchasing.

Final prototype testing will commence this Friday, 11/15/2024.

Update: 3D print a new mechanism to secure the lock lace because the glue was unsuccessful

11/08/2024 - Updated Rigid Support Fabrication

GRACE NEUVILLE - Nov 15, 2024, 3:51 PM CST

Title: Updated Rigid Support Fabrication

Date: 11/08/2024

Content by: Grace

Present: Self

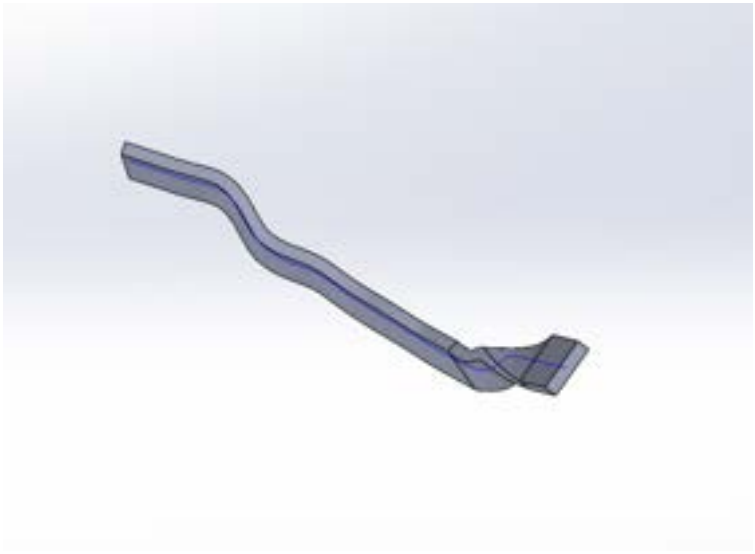
Goals: Design a support that will be flat against the foot, rather than circular.

Content:

Measurements were taken again on Grace's foot and then were plotted in SolidWorks using the curve path function. 3 different styles were designed and then 3D printed to see which type was the best.

Rectangular Sweep Twisty

This part was made using the rectangular sweep function of a rectangle (2 cm x 0.5 cm) with a 90 degree twist.



Rectangular Sweep 2

This part was again made using the rectangular sweep function (2 cm x 0.5 cm), but was done in 3 different steps. This was done so the top section could be facing fully forward (against the calf), the middle section could be a 90 degree twist (around the ankle), and the bottom section could be facing the side (against the side of the foot). This would hopefully allow the support to be comfortably resting against the foot at all sections.

Rectangular Sweep 2 with Foot Plate

This part was made just as Rectangular Sweep 2, but another rectangular sweep was added at the bottom to create a foot plate. This will offer more surface area and hopefully more comfortability. The new section was again made through the sweep function with a 90 degree twist.

All 3 parts were printed on a Bambu labs 3D printer in PLA.


slanted


weird bump

Conclusions/action items:

Rectangular Sweep Twisty: calf section is slanted due to the 90 degree twist in the sweep. The curve path is not accurate to the foot.

Rectangular Sweep 2: calf section is straight. The twist around the ankle bumps too far out. The curve path is not accurate to the foot.

Rectangular Sweep 2 with Foot Plate: foot plat is not accurate to the foot's dimensions. It printed out thin.

All 3 parts are not what we were hoping for. A new support will need to be fabricated.

11/13/2024 - Updated Rigid Support Fabrication

GRACE NEUVILLE - Nov 13, 2024, 9:15 PM CST

Title: Updated Rigid Support Fabrication

Date: 11/13/2024

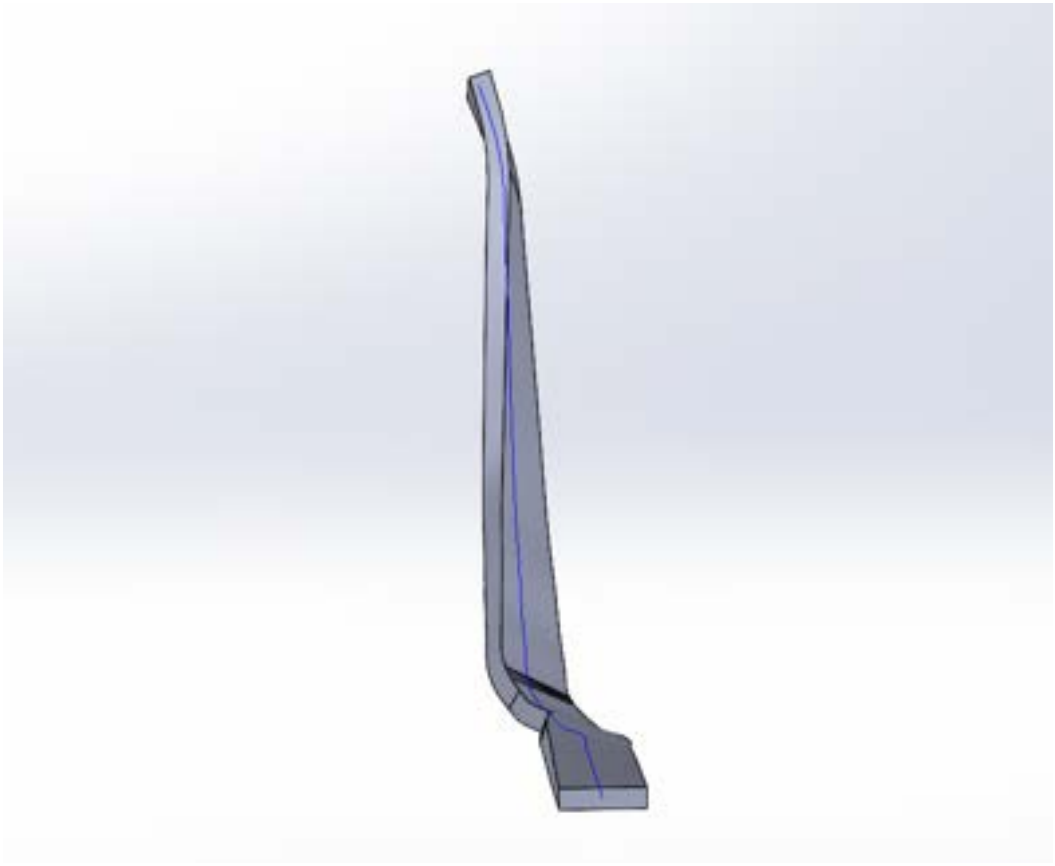
Content by: Grace

Present: Self

Goals: Update the curve path so that it more comfortably sits against the foot.

Content:

The curve path was edited so that the weird bump near the arch of the foot was omitted. The best support design was the rectangular sweep twisty because it was the most comfortable design.



This part was again printed on a Bambu Labs 3D printer with PLA.

Conclusions/action items:

Pick up part and assess from there.

11/30/2024 - Final Prototype Support

Alex Conover - Dec 05, 2024, 12:03 AM CST

Title: Final Prototype Support

Date: 11/30/2024

Content by: Grace

Present: Self

Goals: Create a support using Maggie's dimensions like the previous rigid support

Content:

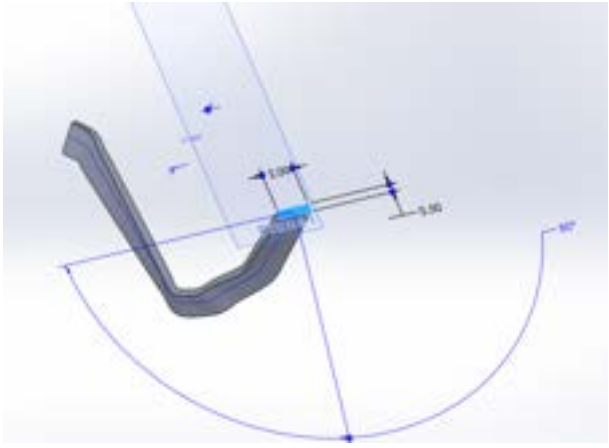
- this support was created just as the updated rigid support (11/13/2024) but with using Maggie's dimensions

- First, I sketched the coordinate points on Maggie's cast

- I used these points for the curve path

- Then I did the same rectangular sweep as the previous rigid support

- This will be 3D printed using plastic with reinforced carbon fiber



Conclusions/action items: We will need to print

12/04/2024 - Final Prototype Work

Alex Conover - Dec 11, 2024, 2:49 PM CST

Title: Final Prototype Work

Date: 12/04/2024

Content by: Alex Conover

Present: Self

Goals: Complete the fabrication of the Brace

Content:

Prior to meeting with the team, I fixed the sewing/gluing on the top of the foot part of the brace, where the bungee is sewed into the straps, The bungee is sewed down with fabric, but only the bungee was sewed into the straps, and the extra fabric increasing the surface area was glued. The extra fabric was starting to lift, so I sewed it down so that way it would be extra secure, and for sure not go anywhere for our final design.

Met with the team to determine the final placings of the gel paddings, as well as confirm the final design.

These were the steps taken to ensure the fabrication went smoothly:

1. Used the resin cast to determine the exact placements of the gel on the ankle, as well as consulting Grace to be sure of the placement

2. Sewed in the gel padding to the first sleeve, the skin-tight one, so that they wouldn't move when placed with the rest of the brace. They were sewed in with the thinnest thread, and only in 1 place, because the skin-tight sleeve is very elastic, and I didn't want to accidentally limit the flexibility due to poor sewing.

3. Sewed the skin-tight sleeve to the gray sleeve. This allowed for the padding to sit below the first layer, so it couldn't be altered by every day movements. They were sewed together at the top and the bottom for optimal usage.

4. Sewed the straps with the bungee attached to the gray sleeve. I sewed around the cord lock on the top part. This was mainly to sew into place, so surface area attachments weren't a huge issue here. I sewed around the entire cord lock, ensuring that the bungee was not sewn into the straps. Then, on the bottom part, I sewed completely around the fabric piece and made sure the straps were secure to the sleeve.

Below are all 4 views of the nearly completed brace:

5. After conferring with the team, the sleeve for the carbon fiber support was sewn into the straps. It was just big enough to hold the support in place.

Conclusions/action items:

Complete poster, complete final deliverables, make sure the ball is rolling on the final report.

11/15/2024: Pt.1 Runeasi Testing Protocol/Results

Lucia Hockerman - Nov 15, 2024, 5:07 PM CST

Title: Runeasi Testing Protocol and Results

Date: November 15, 2024

Content by: Lucy

Present: Grace, Anya, Lucy

Goals: Conduct testing through Runeasi to gain insightful and quantitative data on how the our initial prototype affects gait. Using a prototype tailored to Grace's dimensions, we will hopefully gain understand on how the brace affects healthy individuals in both comfort and biomechanical aspects.

Content:

Testing Criteria and Scales:
Relative Values:

Impact Magnitude (%): Vertical impact that reaches the pelvis immediately after the foot hits the ground. Linked to ground reaction forces on the body.
<1.1%: excellent, 1.1-2.1%: typical, 2.1-3.5%: elevated, 3.5-5.8%: high, >5.8%: very high

Dynamic Instability (%): The proportion of hip movement in the medio-lateral direction during landing. Captures how much energy is wasted by movements that are not contributing to forward propulsion. Linked to fatigue.

<2.3%: excellent, 2.1-5.0%: typical, 5.0-9.2%: elevated, 9.2-15.5%: high, >15.5%: very high

Ground Contact Time (%): Total duration the foot is in contact with the ground.

<0.5%: excellent, 0.5-1.2%: typical, 1.2-2.3%: elevated, 2.3-3.9%: high, >3.9%: very high

Absolute Values:

Impact Magnitude (G): vertical impact that reaches the pelvis immediately after the foot hits the ground. Linked to ground reaction forced on the body

(speed dependent - no absolute benchmarks)

Dynamic Instability (%): The proportion of the high movement in the medio-lateral directions during landing. Captures how much energy is wasted by movements that are not contributing to toward propulsion. Linked to fatigue.

< 8.8%: excellent, 8.8-11.1%: typical, 11.1-14.0%: elevated, 14.0-19.6%: high, >19.6%: very high

Ground Contact Time (ms): The total duration the foot is in contact with the ground.

Testing Protocol:
- Using a walking speed of 1 m/s for 3 mins on the treadmill, collect 3 trials bare foot and 3 trials with brace.
- Measure using Runeasi system: records information during walking duration, results listed below.
- Brace configuration: Compression sleeve, two gels: at medial edge near foot pad and back of calf, compression sleeve, rigid support, brace straps + bungee cord (bungee held in place by top brace strap: the lock cord attached with fabric glue to the straps failed before testing began)
- 5 minutes between no brace and brace trials. Took measurements of resting foot angles:

Without brace resting, elevated foot drop: -20 deg

With brace resting, elevated foot drop: 0 deg (angle of ankle joint is 90 deg)

Results:

Without Brace:

Trial 1:

Testing Variable	Left Foot	Right Foot
Dynamic Stability	8.4 %	7.3 %
Impact Magnitude	1.37 G	1.35 G
Ground Contact	605 ms	607 ms

Cadence: 112

Duration: 3:05

Trial 2:

Testing Variable	Left Foot	Right Foot
Dynamic Stability	8.6 %	8.6 %
Impact Magnitude	1.35 G	1.33 G
Ground Contact	596 ms	599 ms

Cadence: 113

Duration: 3:05

Trial 3:

Testing Variable	Left Foot	Right Foot
Dynamic Stability	9.8 %	8.4 %
Impact Magnitude	1.34 G	1.33 G
Ground Contact	608 ms	611 ms

Cadence: 110

Duration: 2:55

Pain levels:

Trial	Pre - Pain level	During - Pain level	Post - Pain level
One	0	0	0
Two	0	1 (left foot)	0
Three	0	2 (left foot)	0

Pain Scale: 1 - 10; 10 most imaginable pain, 0 no pain

With Brace:

Trial 1:

Testing Variable	Left Foot	Right Foot

Dynamic Stability	8.2 %	8.1 %
Impact Magnitude	1.36 G	1.37 G
Ground Contact	587 ms	951 ms

Cadence: 115

Duration: 3:05

Trial 2:

Testing Variable	**Left Foot**	**Right Foot**
Dynamic Stability	8.4 %	8.2 %
Impact Magnitude	1.38 G	1.36 G
Ground Contact	594 ms	608 ms

Cadence: 112

Duration: 3:05

Trial 3:

Testing Variable	**Left Foot**	**Right Foot**
Dynamic Stability	8.0 %	8.1 %
Impact Magnitude	1.37 G	1.38 G
Ground Contact	598 ms	598 ms

Cadence: 114

Duration: 3:05

Pain levels:

Trial	**Pre - Pain level**	**During - Pain level**	**Post - Pain level**
One	1 (discomfort from compression tightness)	1 (discomfort from compression tightness)	1 (discomfort from compression tightness)
Two	1 (discomfort from compression tightness)	1 (discomfort from compression tightness)	1 (discomfort from compression tightness)
Three	1 (discomfort from compression tightness)	1 (discomfort from compression tightness)	1 (discomfort from compression tightness)

Pain Scale: 1 - 10; 10 most imaginable pain, 0 no pain

Grace’s thoughts throughout walking:

Trial one: It is nice, feels like less effort to lift the right foot. Walking

Trial two: Wishes the brace is on the left foot also. Feeling very comfortable

Data collection: Averages

Dark green represent "excellent" range. Blue line is left leg and red line is right leg.

Conclusions/action items: overlap brace/without brace data to better visualize the impact of the brace on dynamic stability and impact magnitude.

Conduct a second round of testing with the securely attached bungee cord lock.

11/20/2024 - Solidworks Analysis of 3D Plastic Part

Presley Hansen - Nov 20, 2024, 3:15 PM CST

Title: Solidworks Analysis of 3D Plastic Part

Date: 11/20/2024

Content by: Presley Hansen

Present: N/A

Goals: To stress test the 3D plastic part in solidworks

Content:

1. Open SimulationXpress Analysis Wizard from the Evaluate tab
2. Add fixture to top and bottom of part
3. Add 1000N (double body weight) compression force to side of part (pushing outwards from inside)
4. Add PLA material (need to make custom material)
5. Run simulation
6. Need to lower mesh density in order to successfully run simulation

Report attached

Conclusions/action items: There are some possible spots that need to be watched for failure but the force applied will likely not approach the value of 1000N

Presley Hansen - Nov 20, 2024, 3:16 PM CST

Download

FinalSupport1.11.docx (483 kB)

11/21/2024: Pt. 2 Runeasi Testing Protocol/Results

Lucia Hockerman - Dec 01, 2024, 11:39 AM CST

Title: Runeasi Testing Pt. 2

Date: November 21, 2024

Content by: Lucy Hockerman

Present: Anya, Grace, Lucy

Goals: Conduct Runeasi testing again with the sewed on Lock Lace and run trials with and without rigid support.

Content:

Runeasi System Protocol:

- Attach it to the back of the hip (synchrom)
- Linked to the runeasi app
- The email is joachim@ortho.wisc.edu
- Password: Topo3437!
- Click on the client
- Check that theres a connected bluetooth sensor : click on icon to manage the sensor
- Click start test
- Choose running or walking
- Treadmill walk
- Start
- Get dashboard and a score
- Look at individual metrics : click on expert center
    - Dynamic stability: medial lateral measure
    - Impact loading: how many Gs of force you're experiencing peak vertical forces
    - Impact duration: impulse of how long that force was applied for
    - Ground contact: how long foot was on the ground
    - Cadence: total steps
    - Flight ratio: what percent of gait cycle are you in stance vs in gait (state)
- Info and knowledge: describes all of the metrics in more detail
- App with the black icon
- 3 trials of 3 mins

Absolute Value Data Definitions:

Impact Magnitude (G): vertical impact that reaches the pelvis immediately after the foot hits the ground. Linked to ground reaction forced on the body

(speed dependent - no absolute benchmarks)

Dynamic Instability (%): The proportion of the high movement in the medio-lateral directions during landing. Captures how much energy is wasted by movements that are not contributing to toward propulsion. Linked to fatigue.

< 8.8%: excellent, 8.8-11.1%: typical, 11.1-14.0%: elevated, 14.0-19.6%: high, >19.6%: very high

Ground Contact Time (ms): The total duration the foot is in contact with the ground.

Testing Protocol:
Using a walking speed of 1 m/s for 3 mins on the treadmill, collect 3 trials without support and 3 trials with support and measure using Runeasi (without shoes). 5 minutes between with/without brace trials (measured foot angle)

Right foot angle (before walking trials): 92 deg from vertical (CW)
Right foot angle (after 3 walking trials) : 100 deg from vertical (CW)
Resting left foot angle: 130 deg from vertical (CW)

Date: November 21, 2024
With Rigid Support:
Compression sleeve, gel at medial edge near foot pad, ankle bone, and back of calf, compression sleeve, ridgid support, brace straps + bungee held from cord lock.

Trial 1:

Testing Variable	**Left Foot**	**Right Foot**
Dynamic Stability	7.6	8.3
Impact Magnitude	1.42	1.44
Ground Contact	583	573

Cadence: 117
Duration: 3:05

Trial 2:

Testing Variable	**Left Foot**	**Right Foot**
Dynamic Stability	7.9	8.3
Impact Magnitude	1.41	1.43
Ground Contact	593	583

Cadence: 115
Duration: 3:00

Trial 3:

Testing Variable	**Left Foot**	**Right Foot**
Dynamic Stability	8.1	8.1
Impact Magnitude	1.44	1.44
Ground Contact	591	586

Cadence: 115
Duration: 3:00

Pain levels: With rigid support

Trial	**Pre - Pain level**	**During - Pain level**	**Post - Pain level**
One	0.5	0.5	0.5
Two	0.5	0.5	0.5
Three	0.5	0.5	0.5

Pain Scale: 1 - 10; 10 most imaginable pain, 0 no pain

Thoughts:
0.5 pain from general compressive discomfort
The glue on the base of the foot is coming off (mostly lateral side)

Without Rigid Support:

Compression sleeve, gel at medial edge near foot pad, ankle bone, and back of calf, compression sleeve, brace straps + bungee attached with cord lock

Trial 1:

Testing Variable	Left Foot	Right Foot
Dynamic Stability	7.9	9.0
Impact Magnitude	1.48	1.46
Ground Contact	580	574

Cadence: 117
Duration: 2:55

Trial 2:

Testing Variable	Left Foot	Right Foot
Dynamic Stability	7.2	8.3
Impact Magnitude	1.42	1.45
Ground Contact	588	580

Cadence: 116
Duration: 3:00

Trial 3:

Testing Variable	Left Foot	Right Foot
Dynamic Stability	7.1	8
Impact Magnitude	1.41	1.44
Ground Contact	600	591

Cadence: 114
Duration: 2:50

Pain levels: Without rigid support

Trial	Pre - Pain level	During - Pain level	Post - Pain level
One	0.25	0.5	0.5
Two	0.5	1.0	1.0
Three	1.0	1.0	1.0

Pain Scale: 1 - 10; 10 most imaginable pain, 0 no pain

Thoughts:
Way more comfortable without support, still lifts up foot.

Medial/lateral support feels similar to the support on (the same range of motion)

With shoe: does not support foot drop as well

0.25 pain: compression

0.5/1.0 pain: strap below hurts a bit

Maybe consider sewing the bungee cord at a location of the strap where the ends of the strap would not lie on the bottom of the foot

Conclusions/action items: Analyze data conclude helpful findings to present in our final poster presentation and mention in final report

10/11/2024 - Bungee Cord Testing

Alex Conover - Oct 12, 2024, 3:30 PM CDT

Title: Bungee Cord testing

Date: 10/11/2024

Content by: Lucy, Anya

Present: All

Goals: Conduct preliminary testing for the bungee cord application of the brace

Content:

Date of testing: October 11th, 2024
Bungee Cord Strength Testing Protocol

1. Obtain several different bungee cord with varied strengths and lengths:
    - List cords tested here - blue, purple, black

2. Secure the bungee cord around the top of foot right below the foot pad, wrap around ankle once and tighten up the calf
3. Take measurements of the resting foot angle without ground support
4. Rate the comfort on a scale of 1-10 in tension of the bungee cord during walking by taking five consecutive strides
5. Note any other discomfort
6. Repeat on the remaining 4 teammates

Results
Purple cord (176 max lb)
Trial one (alex):
Normal resting angle: 20 °
Cord displacement: 11.25 - 4 = 7.25 in
Bunge resting angle: 10 °

Trial two (grace):
Normal resting angle: 16 °
Cord displacement: 7.4 - 3.5 = 4 in
Bungee resting angle: 10 °

Trial three (presley):
Normal resting angle: 15 °

Cord displacement: 11 - 3.5 = 7.5 in
Bunge resting angle: 10 °

Trial four (anya):
Normal resting angle: 11 °
Cord displacement: 6 - 3 = 3 in
Bunge resting angle: 10 °

Results
Black cord (significantly less than 176 max lb)
Trial one (anya):
Normal resting angle: 11 °
Cord displacement: 6.5 - 2 = 4.5 in
Bunge resting angle: 10 °

Trial two (presley):
Normal resting angle: 15 °
Cord displacement: 6.5 - 2 = 4.5 in
Bungee resting angle: 10 °

Trial three (alex):
Normal resting angle: 20 °
Cord displacement: 7.0 - 1.5 = 5.5
Bunge resting angle: 10 °

Trial four (grace):
Normal resting angle: 16 °
Cord displacement: 8.5 - 1.0 = 7.5
Bunge resting angle: 10 °



Conclusions/action items:

Continue to conduct testing for our various parts in the AFO.

12/01/2024: Compilation of Runeasi Data

Lucia Hockerman - Dec 09, 2024, 8:32 PM CST

Title: All raw data and testing compilation of Runeasi Data

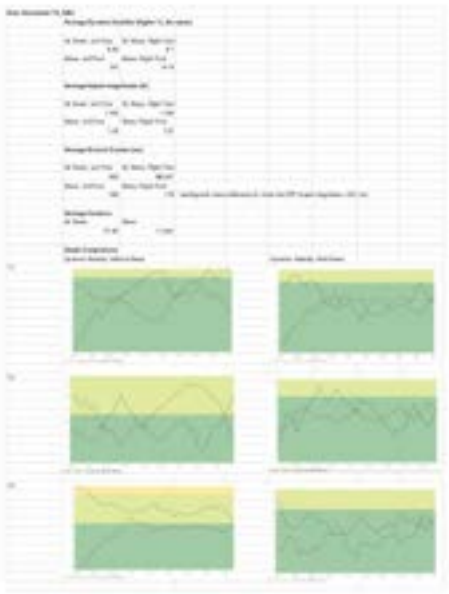
Date: December 9, 2024

Content by: Lucy Hockerman

Goals: Show the raw data and graphs made for the testing sections of the report and presentation

Content:

Lucia Hockerman - Dec 01, 2024, 11:45 AM CST



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Runeasi_Testing_-_11_15_2024.pdf (2.73 MB)

Lucia Hockerman - Dec 01, 2024, 11:46 AM CST

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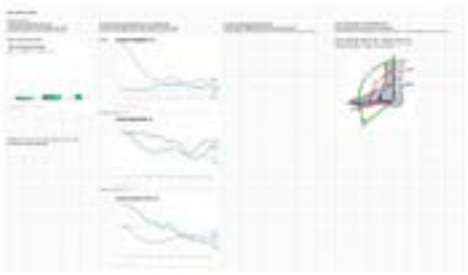
Runeasi_Testing_-_11_21_2024.pdf (2.96 MB)

Lucia Hockerman - Dec 09, 2024, 8:32 PM CST



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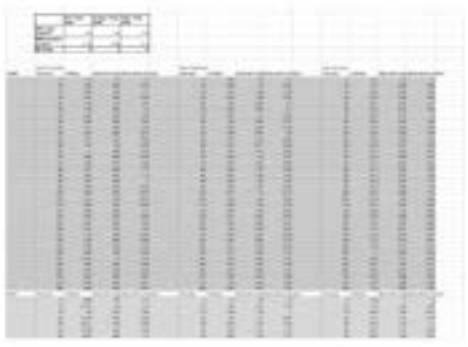
Runeasi_Testing_-_Conclusions.pdf (402 kB)

Lucia Hockerman - Dec 09, 2024, 8:32 PM CST



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Runeasi_Testing_-_Raw_Data_used_in_Conclusion.pdf (99.1 kB)

12/02/2024: Updated Solidworks Analysis of Part

Presley Hansen - Dec 02, 2024, 6:35 PM CST

Title: Updated Solidworks Analysis of Part

Date: 12/02/2024

Content by: Presley Hansen

Present: N/A

Goals: I need to lower the force applied on the part to about 200 N and analyze the factor of safety.

Content:

The SimulationXpress Analysis Wizard in SolidWorks was utilized to evaluate the structural integrity of the 3D-printed PLA prototype. This simulation aimed to identify potential failure points and optimize the rigid support design for durability and performance prior to patient use. Fixtures were added to the top and bottom of the part to simulate its interaction with other components of the final design. A 200 N load was applied to the face of the part that aligns with the inside of the foot, reflecting the forces expected during ankle inversion. In addition, PLA was selected as the material for analysis. Figure 1 illustrates the SolidWorks model, with red regions indicating areas where the factor of safety (FoS) is below 2. The recommended FoS for plastic components typically ranges between 1.5 and 2, ensuring sufficient safety margins under anticipated loading conditions. Due to inversion at the ankle, the majority of the load is concentrated near the center of the piece, reducing stress around the edges while increasing it near the midpoint.

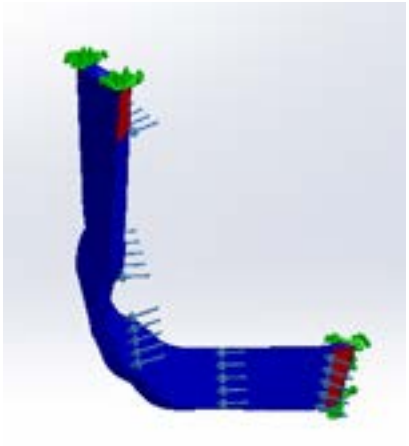


Figure 1: SolidWorks part showing red regions where factor of safety is below 2

Conclusions/action items: The analysis showed that a 200 N force results in minimal areas of concern, with the majority of the structure maintaining a FoS above the recommended threshold; the likelihood of failure under these conditions appears low.

12/4/2024 - Statistics

ANYA HADIM - Dec 04, 2024, 1:59 PM CST

Title: Bayesian Estimation Statistics

Date: 12/3/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: Run Bayesian estimation statistics test on all of the raw data collected during the runeasi training

Content:

Average values from raw data:

Condition	Dynamic Stability Left	Dynamic Stability Right	Impact Magnitudes Left	Impact Magnitudes Right	Ground Contact Left	Ground Contact Right	Cadence
No Brace	8.93	8.10	1.353	1.336	603.00	605.67	111.67
Support	7.867	8.233	1.423	1.436	589.00	580.67	115.67
No Support	7.40	8.433	1.436	1.450	589.33	581.67	115.67

Bayesian posterior distributions:

Bayes' theorem:

$P(\theta|D) \propto P(D|\theta) \cdot P(\theta)$

Prior Distribution ($P(\theta)$): Represents initial beliefs about the parameter (ex mean Dynamic Stability).

Likelihood ($P(D|\theta)$): Describes how likely the observed data is, given the parameter.

Posterior Distribution ($P(\theta|D)$): Combines the prior and the likelihood to give the updated belief about the parameter after observing the data.

Posterior mean:

$$\mu_{\text{posterior}} = \frac{\mu_{\text{prior}}/\sigma^2_{\text{prior}} + \sum \text{data}/\sigma^2_{\text{likelihood}}}{1/\sigma^2_{\text{prior}} + n/\sigma^2_{\text{likelihood}}}$$

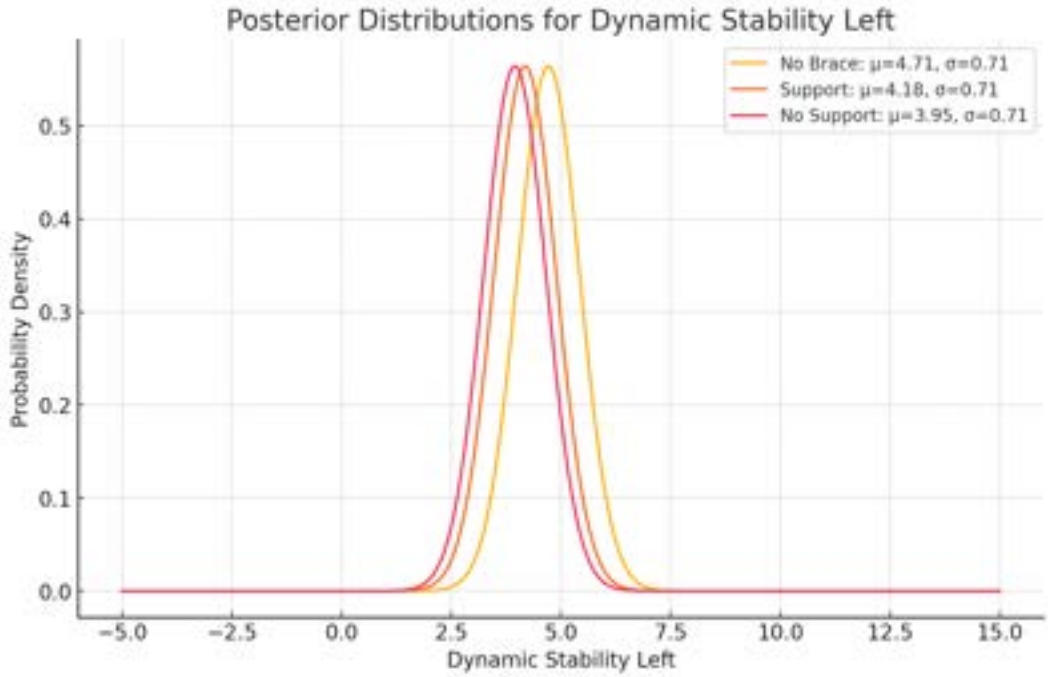
Posterior variance:

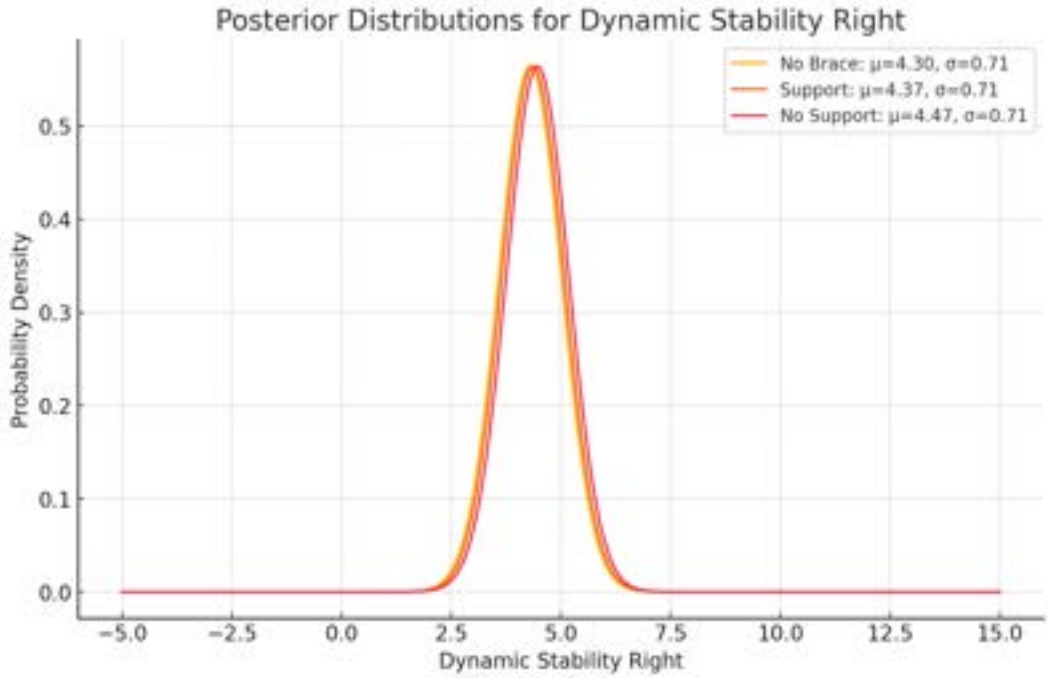
$$\sigma^2_{\text{posterior}} = \frac{1}{1/\sigma^2_{\text{prior}} + n/\sigma^2_{\text{likelihood}}}$$

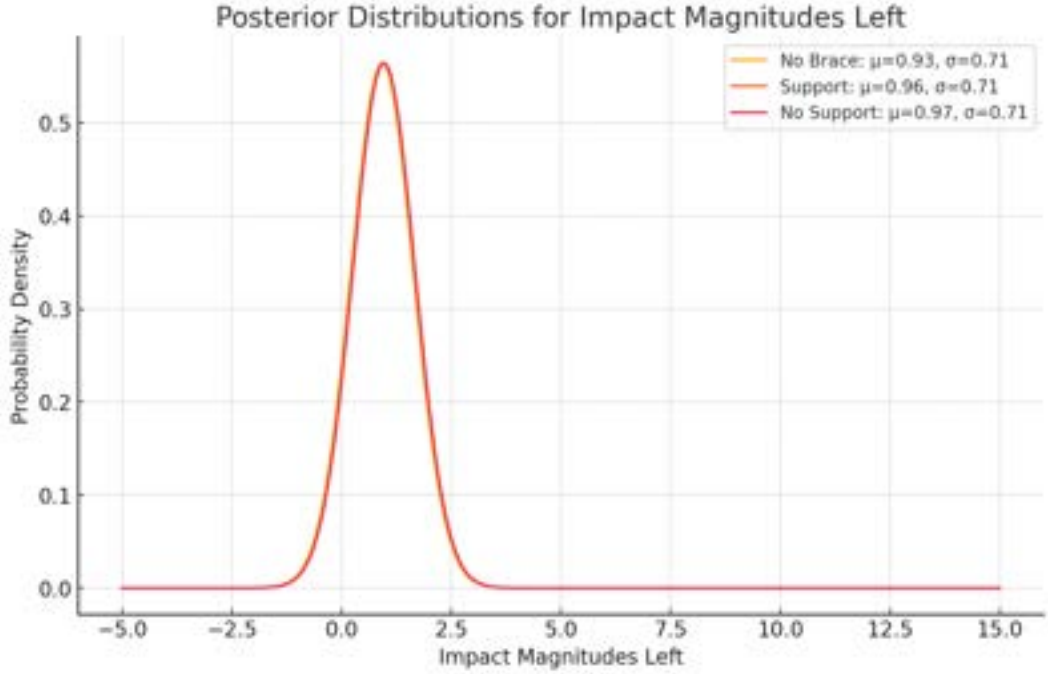
Posterior standard deviation:

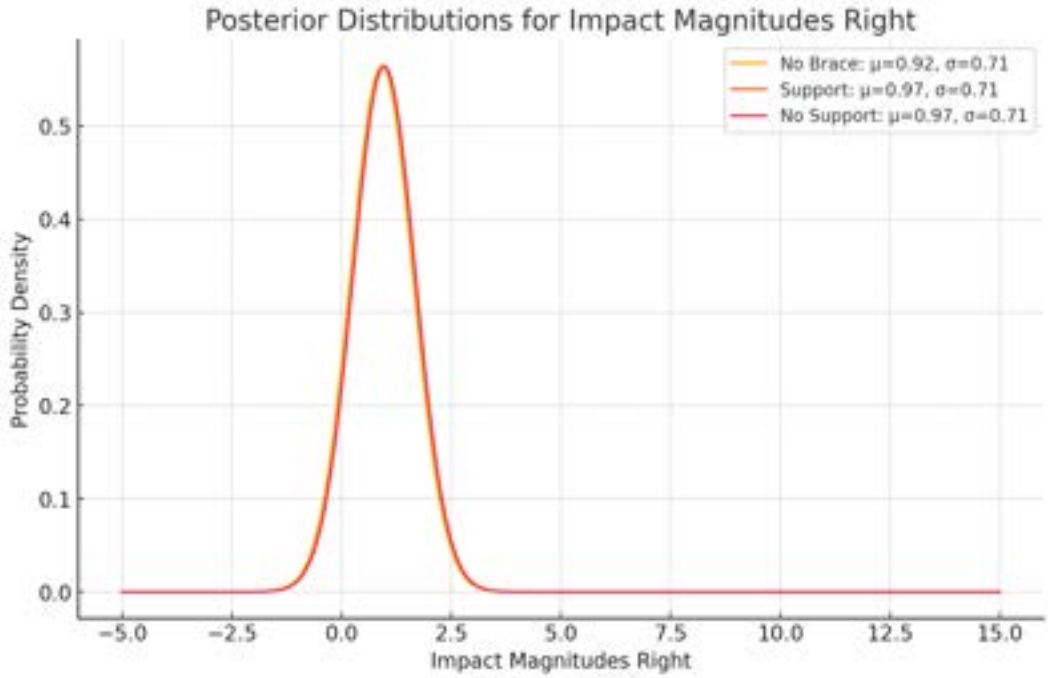
$$\sigma_{\text{posterior}} = \sqrt{\sigma^2_{\text{posterior}}}$$

Prior Mean (μprior): 0.5 (represents an initial neutral belief).
Prior Standard Deviation (σprior): 1 (indicates uncertainty in our initial belief).
Likelihood Standard Deviation (σlikelihood): 1 (assumes observed averages are not highly variable)



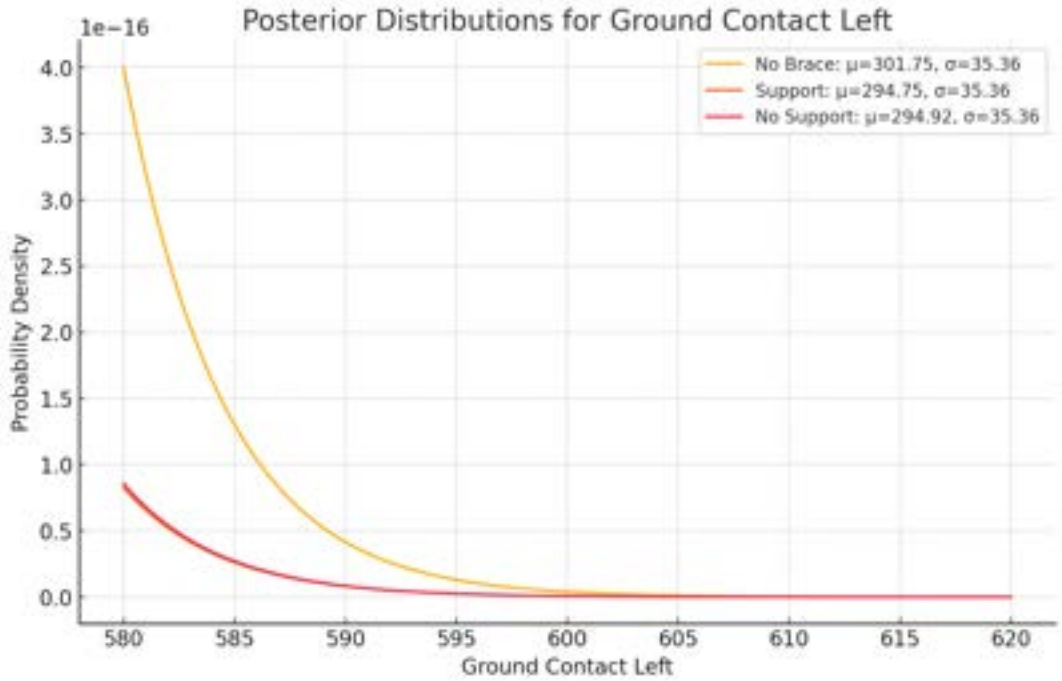

Posterior Distributions for Dynamic Stability Right
No Brace: μ=4.30, σ=0.71
Support: μ=4.37, σ=0.71
No Support: μ=4.47, σ=0.71
Probability Density
0.0
0.1
0.2
0.3
0.4
0.5
−5.0
−2.5
0.0
2.5
5.0
7.5
10.0
12.5
15.0
Dynamic Stability Right

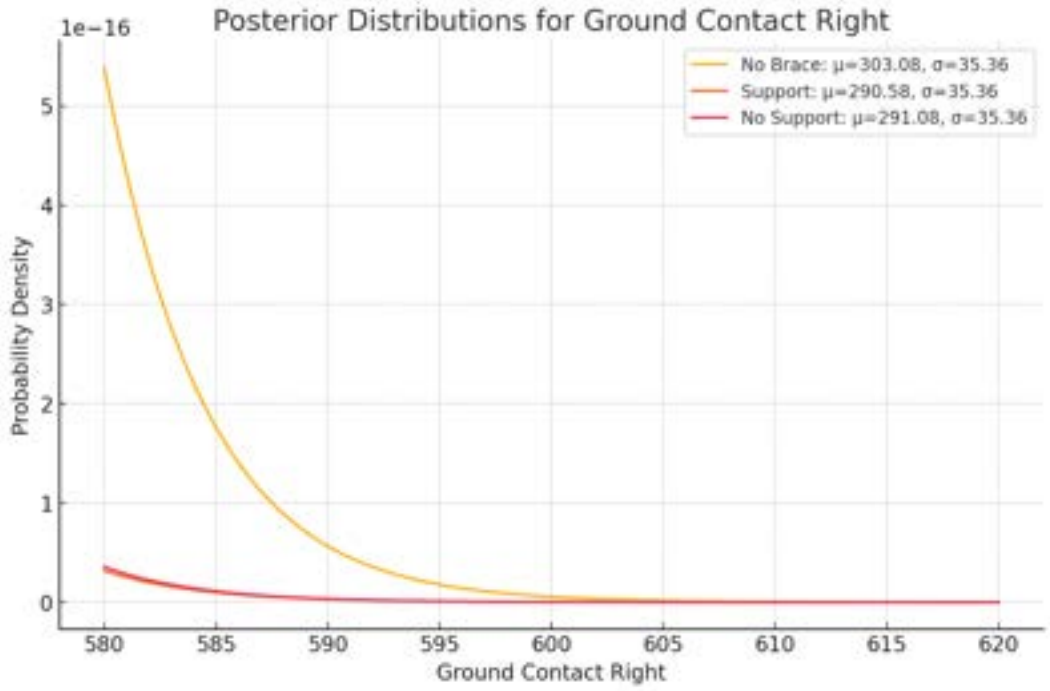

Posterior Distributions for Impact Magnitudes Left
No Brace: μ=0.93, σ=0.71
Support: μ=0.96, σ=0.71
No Support: μ=0.97, σ=0.71
Probability Density
0.0
0.1
0.2
0.3
0.4
0.5
−5.0
−2.5
0.0
2.5
5.0
7.5
10.0
12.5
15.0
Impact Magnitudes Left

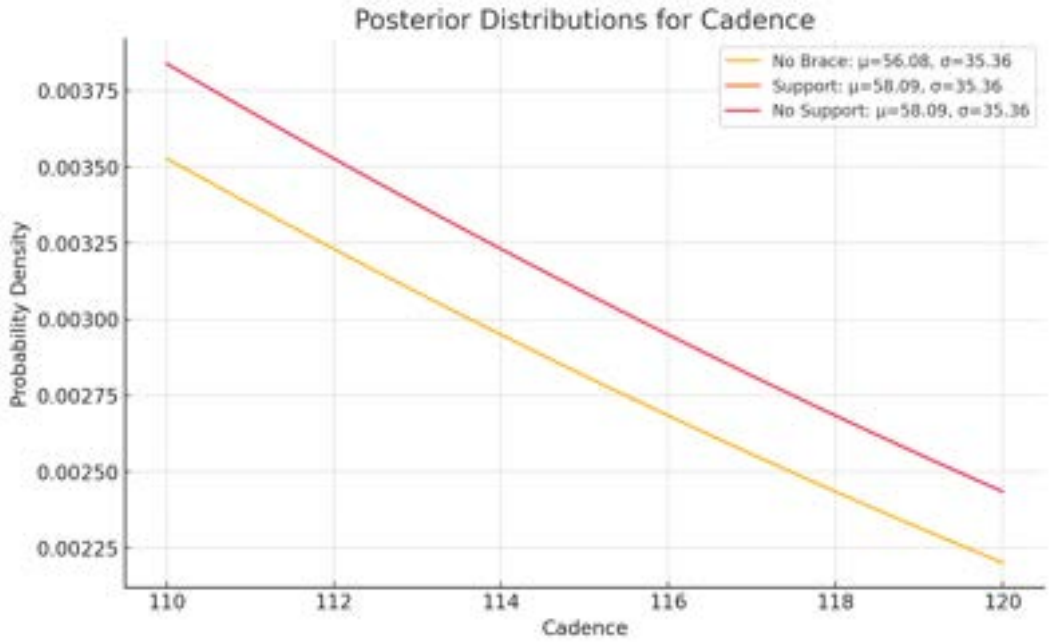


Adjustments for ground contact and cadence:

*increased the prior and likelihood standard deviation to 50 to better reflect the scale of the observed values and account for variability in larger values.







Conclusions:

Dynamic Stability

- **Left and Right Foot**:
  - The posterior distributions for Dynamic Stability across all three conditions (No Brace, Support, No Support) have nearly identical means and significant overlap.
  - This indicates that the conditions provide comparable stability, with no condition clearly outperforming the others.

Conclusion: There is no significant difference in Dynamic Stability across the three conditions for both feet.

Impact Magnitudes

- **Left and Right Foot**:
    - All three conditions have very close posterior distributions with significant overlap.
    - Differences in means are minimal, suggesting little to no practical difference in impact magnitudes among the conditions.

Conclusion: None of the conditions clearly outperforms the others in reducing impact magnitudes.

Ground Contact

- **Left and Right Foot**:
    - No Brace consistently shows higher ground contact times, indicating longer foot-ground interaction.
    - Support and No Support have similar, shorter ground contact times, with overlapping distributions.

Conclusion: No Brace promotes longer ground contact, while support and no support favor quicker ground interaction.

Cadence

- No Brace has a slightly lower cadence compared to Support and No Support, which show almost identical posterior distributions.
- Higher cadence in Support and No Support may reflect a faster or more efficient gait pattern.

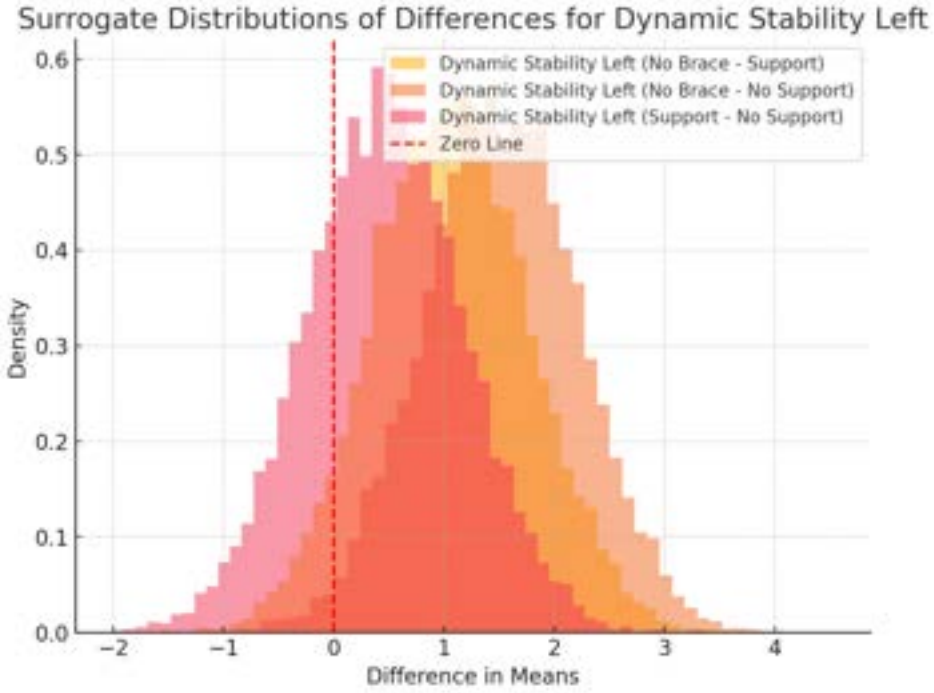
Conclusion: Support and No Support promote higher cadence, while No Brace results in slightly slower steps.

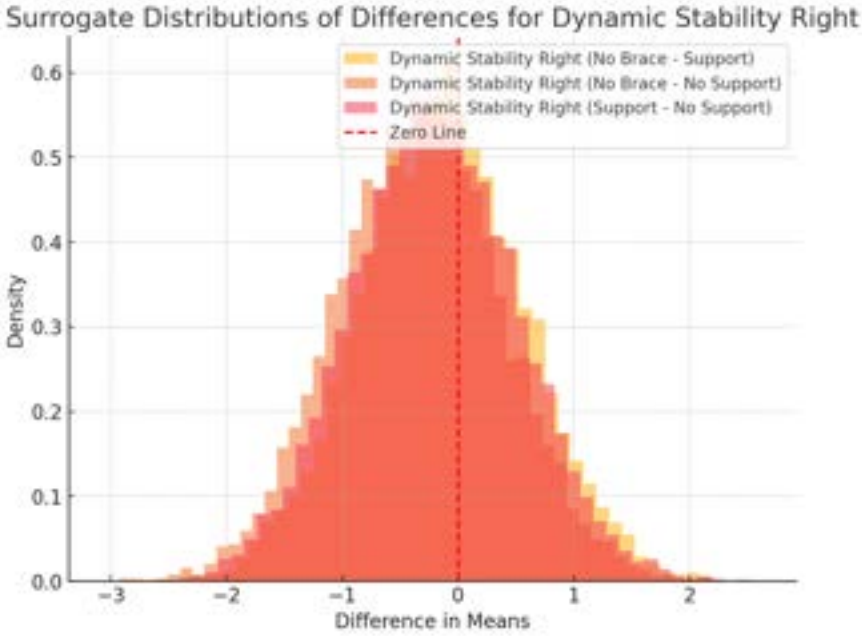
Updated Overall Conclusion

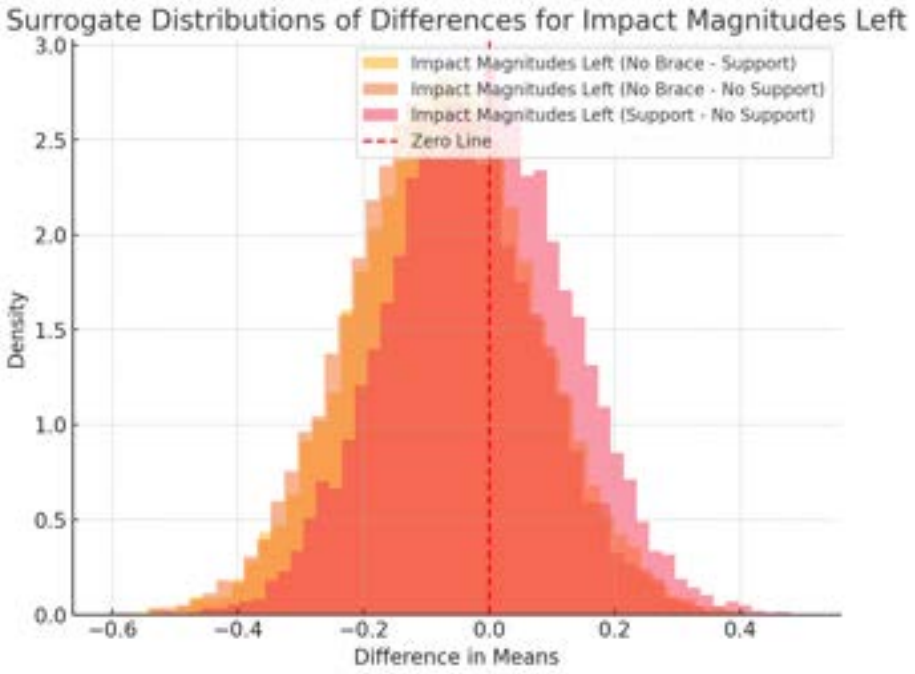
1. **No Brace**:
    - Promotes longer Ground Contact but results in slightly lower Cadence.
    - Comparable to other conditions in Dynamic Stability and Impact Magnitudes.
2. **Support**:
    - Promotes higher Cadence and shorter Ground Contact.
    - Comparable to others in Dynamic Stability and Impact Magnitudes.
3. **No Support**:
    - Performs similarly to Support in all metrics, with no significant differences.

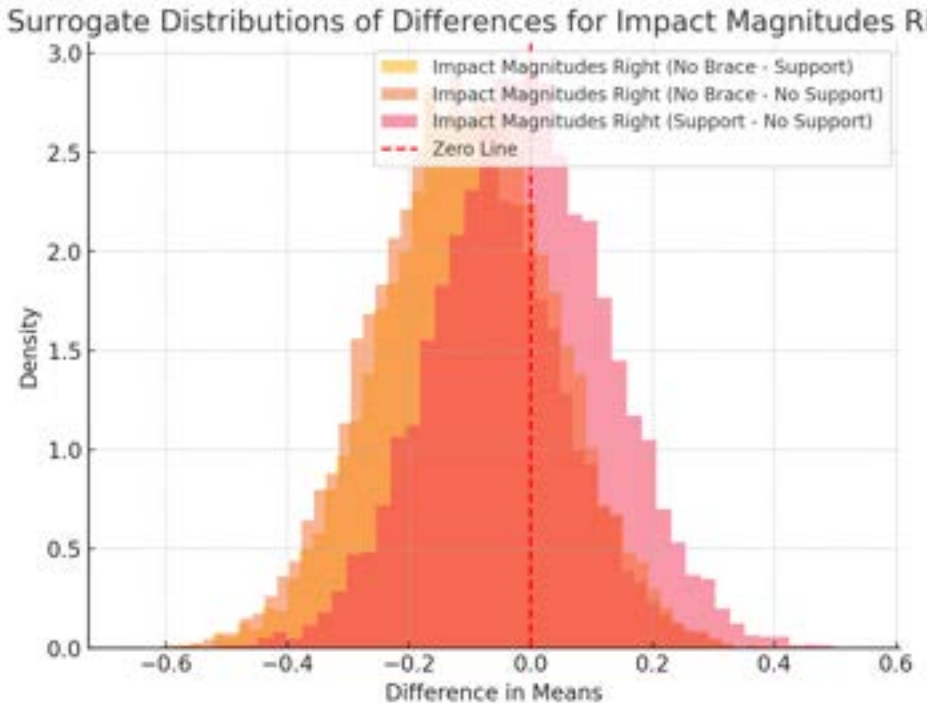
Since Grace does not have foot drop, these results align with our hypothesis, as the brace did not negatively affect her dynamic stability or impact magnitude. When considering ground contact and cadence, the results demonstrate significant improvement with the brace compared to without it, as the brace facilitates shorter ground contact times and promotes a faster, more efficient gait pattern. Additionally, no significant differences in performance were observed between the support and no support conditions.

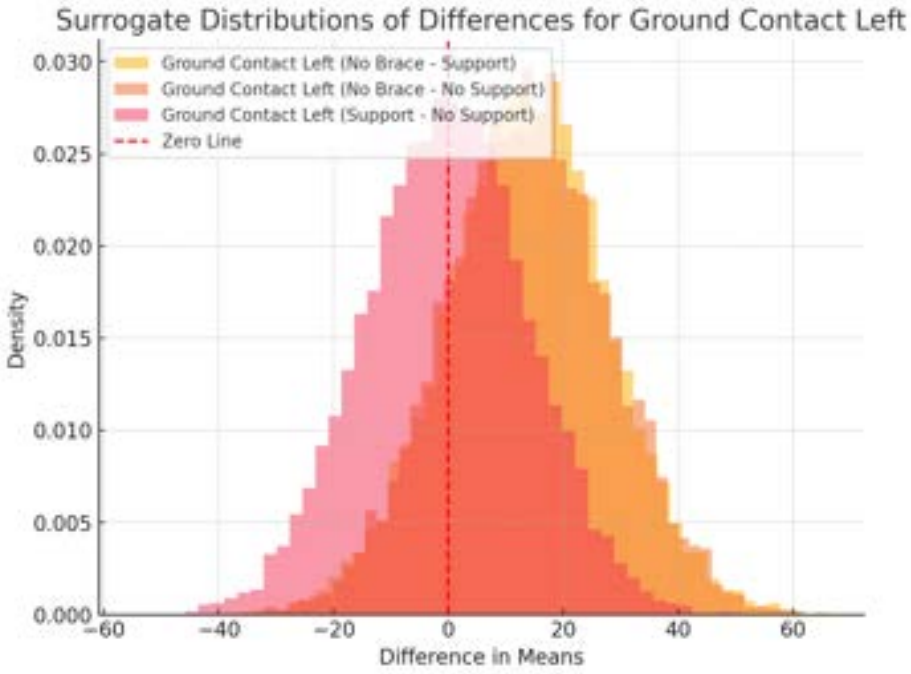
Testing significance:

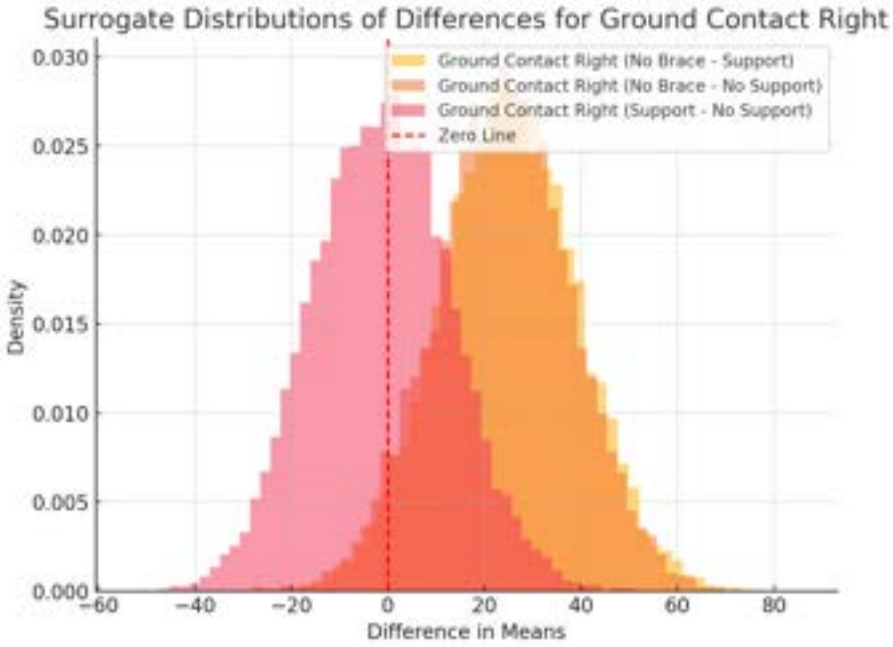

Surrogate Distributions of Differences for Dynamic Stability Left
Dynamic Stability Left (No Brace - Support)
Dynamic Stability Left (No Brace - No Support)
Dynamic Stability Left (Support - No Support)
Zero Line
Density
Difference in Means
0.0
0.1
0.2
0.3
0.4
0.5
0.6
−2
−1
0
1
2
3
4

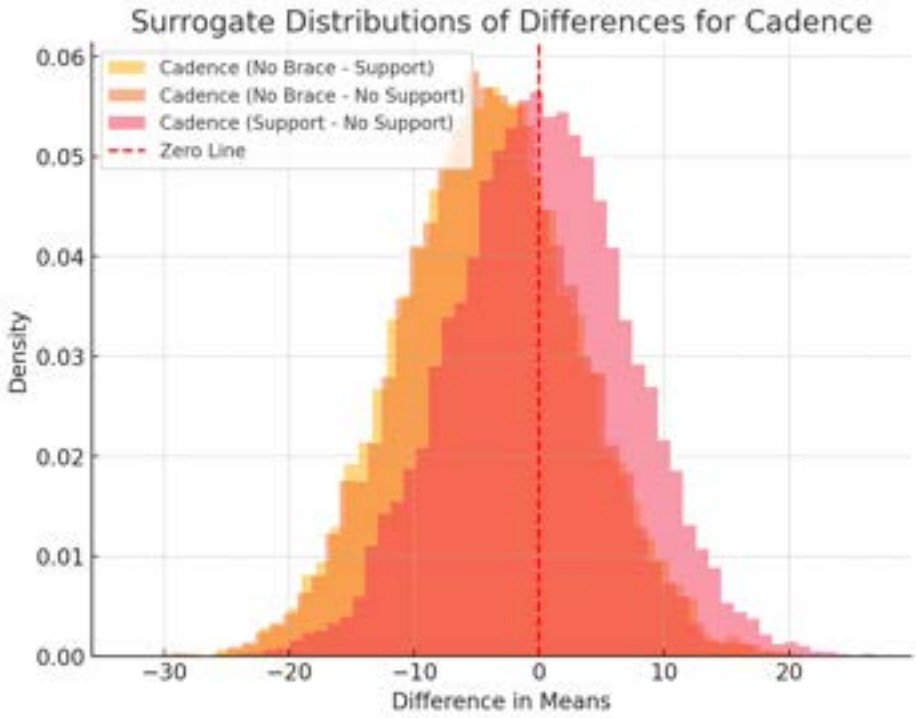

Surrogate Distributions of Differences for Dynamic Stability Right
Dynamic Stability Right (No Brace - Support)
Dynamic Stability Right (No Brace - No Support)
Dynamic Stability Right (Support - No Support)
Zero Line
Density
Difference in Means
0.0
0.1
0.2
0.3
0.4
0.5
0.6
−3
−2
−1
0
1
2


Surrogate Distributions of Differences for Impact Magnitudes Left
Impact Magnitudes Left (No Brace - Support)
Impact Magnitudes Left (No Brace - No Support)
Impact Magnitudes Left (Support - No Support)
Zero Line
Density
Difference in Means
3.0
2.5
2.0
1.5
1.0
0.5
0.0
−0.6
−0.4
−0.2
0.0
0.2
0.4


Surrogate Distributions of Differences for Impact Magnitudes Right
Impact Magnitudes Right (No Brace - Support)
Impact Magnitudes Right (No Brace - No Support)
Impact Magnitudes Right (Support - No Support)
Zero Line
Density
Difference in Means
3.0
2.5
2.0
1.5
1.0
0.5
0.0
−0.6
−0.4
−0.2
0.0
0.2
0.4
0.6


Surrogate Distributions of Differences for Ground Contact Left
Ground Contact Left (No Brace - Support)
Ground Contact Left (No Brace - No Support)
Ground Contact Left (Support - No Support)
Zero Line
Density
0.030
0.025
0.020
0.015
0.010
0.005
0.000
−60
−40
−20
0
20
40
60
Difference in Means


Surrogate Distributions of Differences for Ground Contact Right
Ground Contact Right (No Brace - Support)
Ground Contact Right (No Brace - No Support)
Ground Contact Right (Support - No Support)
Zero Line
Density
0.030
0.025
0.020
0.015
0.010
0.005
0.000
−60
−40
−20
0
20
40
60
80
Difference in Means



Updated conclusions:

Dynamic Stability Left:

- No Brace - Support: Not significant (credible interval includes zero)
- No Brace - No Support: Significant (credible interval does not include zero)
- Support - No Support: Not significant (credible interval includes zero)

Dynamic Stability Right: All comparisons are **not significant** (credible interval includes zero).
Impact Magnitudes (Left & Right): All comparisons are **not significant** (credible interval includes zero).
Ground Contact (Left & Right): All comparisons are **not significant** (credible interval includes zero).
Cadence: All comparisons are **not significant** (credible interval includes zero).

Although most of the results are not significant, this aligns with our hypothesis, as Grace does not have foot drop. The brace was not expected to significantly alter her gait, and the results confirm that it did not negatively impact her dynamic stability, impact magnitudes, or overall gait patterns. Specifically, the lack of significant differences across most metrics suggests that the brace neither hindered nor substantially improved her gait mechanics compared to the support and no support conditions. This is consistent with the expectation that the brace would not dramatically influence gait parameters in individuals without specific impairments like foot drop.

Conclusions/action items:

Conclusions from the results written above. Add these graphs, results, and conclusions to the poster and final deliverables.

10/05/2024 - PDS Version 1

Presley Hansen - Oct 05, 2024, 9:07 PM CDT

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Team_AFO_Group_PDS_Version1_1_.pdf (285 kB)

12/11/2024 - Final PDS

ANYA HADIM - Dec 11, 2024, 4:30 PM CST

Product Design Specifications

Function/Problem Statement:

Ankle foot orthosis (AFO) are engineered to provide dorsiflexion support during the swing phase of walking. This device is usually used for the treatment of muscular dystrophy and this project in particular is focused on young individuals diagnosed with Pseudocephalomuscular Dystrophy (PMD), the most common kind of muscular dystrophy. The main aim to design a brace for the patient to aid in ankle dorsiflexion for safer walking while being easily removable and flexible enough to allow for a functional ankle range of motion. The key objectives of this device include prioritizing the ease in adequate dorsiflexion, maintaining a secure, fast, and discreet design, and ensuring sufficient flexibility to minimize any restriction of movement.

Client requirements:

The client requests that the AFO (Ankle Foot Orthosis) support dorsiflexion while remaining flexible enough for the patient to carry out their daily activities and live a typical teenage life. Additionally, the client prefers the AFO to be discreet, fitting inside a shoe and maintaining versatility. The AFO should also enable heel strike, prevent foot drop, and reduce the risk of falls for the patient.

Recommended additional requirements:

The AFO will be designed to accommodate teenagers as there are currently no clinical trials available for young individuals.

Design requirements:

1. Physical and Operational Characteristics
   a. Performance requirements
      i. The AFO must be designed to be discrete and resilient material while providing strong support for ankle dorsiflexion and must enable movement in posterior/plantar grid [1]. It should mimic normal gait, allowing for a 20° range of ankle dorsiflexion to facilitate foot clearance [2], with movement angle characteristics maintained within a torque range of +/-0.9Nm. Additionally, the

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12/11/2024 - Final Report

ANYA HADIM - Dec 11, 2024, 4:37 PM CST

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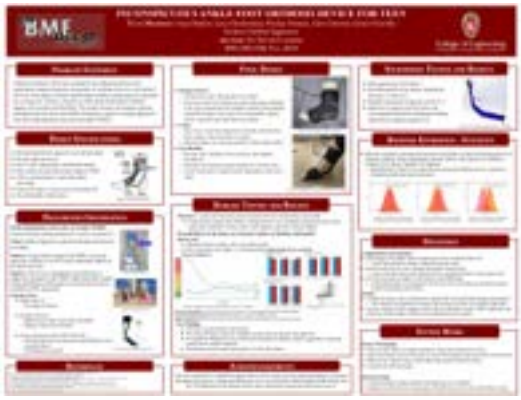
Team_AFO_Group_Final_Report.pdf (6.34 MB)

12/11/2024 - Final Poster

ANYA HADIM - Dec 11, 2024, 2:48 PM CST



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Team_AFO_Final_Poster.pptx.pdf (2.91 MB)

Team Meeting 1 9/12/2024

Alex Conover - Sep 25, 2024, 1:44 PM CDT

Title: Team Meeting

Date: 9/12/2024

Content by: Anya Hadim

Present: whole group

Goals: Write out progress report, discuss preliminary research, follow up with client on what time to meet (preferably early next week), write down project information (summary, objective), send progress report to client advisor and post to website

Content:

Progress report was finished, and research was shared.

Conclusions/action items:

Research standards and patents, work on each individual part for PDS, meet with client, continue baseline research.

Team Meeting 2 9/18/2024

ANYA HADIM - Sep 18, 2024, 7:57 PM CDT

Title: Team Meeting 2

Date: 9/18/2024

Content by: Anya Hadim

Present: whole group

Goals: Review PDS corrections and finalize our first draft.

Content:

See PDS section.

The group went over the corrections sent by our advisor and corrected each of our parts in the product design specifications. We also reviewed and summarized the meeting we had with our client earlier this morning.

Conclusions/action items:

Submit our first draft of the PDS.

Team Meeting 3 9/23/2024

ANYA HADIM - Sep 25, 2024, 10:26 PM CDT

Title: Team Meeting 3

Date: 9/23/2024

Content by: Anya Hadim

Present: whole group

Goals: Brainstorm design ideas and discuss research

Content:

Brainstormed different design ideas and split up Solidworks designing.

Notes:

-carbon fiber

-avoid full coverage of the ankle

-be able to fit in shoe so that it is more inconspicuous

-straps made out of nylon mesh? so that it is more concealable

-TPE filament - good bond, flexibility, elasticity

-created a list of measurements for the client to adequately measure Maggie's foot and ankle for our prototype

- Leg Measurements

Length of the leg (bottom of foot to directly below kneecap)

Diameter Directly Below the kneecap (Top of the leg)

Diameter of the Thickest part of the calf (Mid leg)

Diameter Where the achilles meets the calf (bottom leg)

- Ankle Measurements

Diameter of the thinnest part of the ankle (where you can feel the achilles

Diameter Across the middle of the ankle, through the joint

Diameter of the middle of the foot

- Foot Measurements

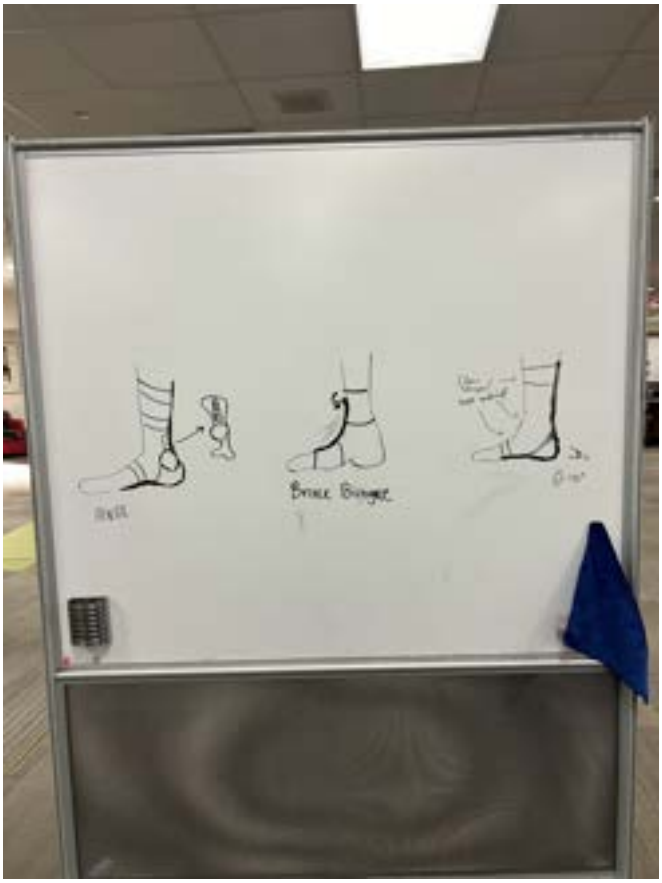
Length of the foot

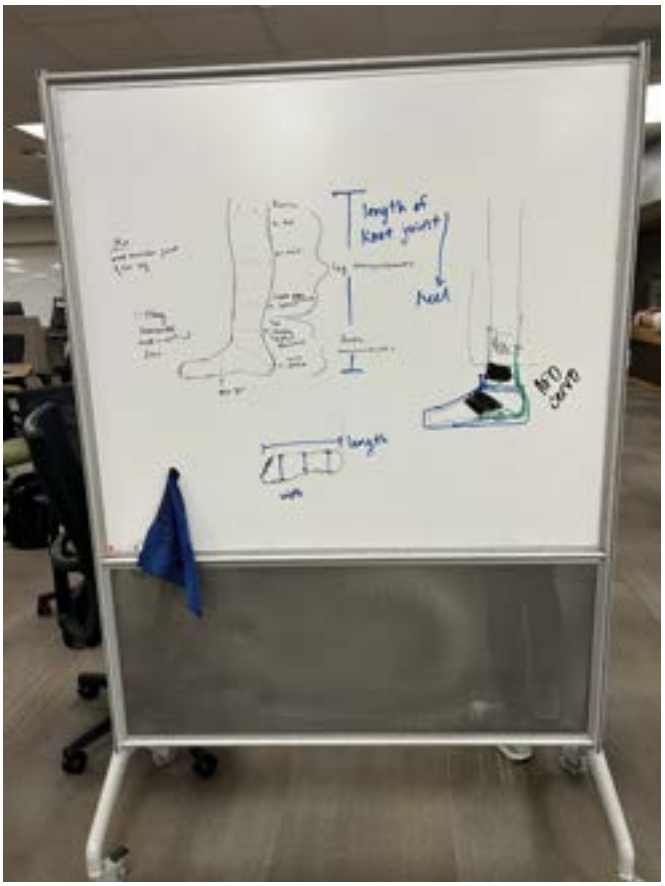
Width of the foot (where the metatarsals meet the phalanges)

Width of the foot (midsole area)

Width of the foot (at the heel)

-we also decided the criteria for the design matrix and decided the weight for each





Conclusions/action items:

Sketch the designs on solidworks for the design matrix and stress testing. Fill in the criteria for each design on the design matrix.

Team Meeting 4 10/3/2024

Lucia Hockerman - Oct 03, 2024, 4:32 PM CDT

Title: Team Meeting 4

Date: 10/3/2024

Content by: Lucy Hockerman

Present: Presley, Alex, Grace, Lucy

Goals: Practice presenting/walk though preliminary presentation sections. Make edits on content, check rubric requirements, and ensure we are in the correct time restraint

Content:

We all went through our sections. The total time was 12 minutes and 30 seconds (2 minutes and 30 seconds over allotted time).

Some edits discussed:

- In background/motivation: don’t mention that the patent is Debbie's daughter, but it is okay to mention her gender (she/her)
- In pre-existing design: include dynamic AFOs and citations
- Everyone should practice their section tonight and ensure their part is around 2 mins (not over)
- Design 2: mention it does not support inversion, only dorsiflexion
- Design 3: carbon fiber material is for the final prototype
- Customizability: mention her foot insole and how to incorporate that in the design
- Grace and Alex switch back and forth when speaking - need to change this
- Final design: explain it looks like an ankle brace, explain the carbon-fiber support a little more (solidworks is a rough estimate)
- Future work: test in person with the patient

Conclusions/action items: Meet again to practice with the group at 11 before presentations and then present to our class!

Team Meeting 10/4/2024

ANYA HADIM - Oct 12, 2024, 2:57 PM CDT

Title: Team Meeting pre client zoom

Date: 10/4/2024

Content by: Anya Hadim

Present: whole group

Goals: Prepare our questions for our clients daughter and present our design ideas to get intel from her on what she wants.

Content:

Practiced presenting each of our designs for the client and her daughter. Discussed and finalized all of our questions to ask her.

Conclusions/action items:

Meet with the client and her daughter and finalize/make changes to our design with their inputs/opinions considered.

Team Meeting 5 10/6/2024

ANYA HADIM - Oct 06, 2024, 7:46 PM CDT

Title: Team Meeting

Date: 10/6/2024

Content by: Anya Hadim

Present: whole group

Goals: discuss fabrication plans

Content:

-research about making braces vs buying them

-discussed drawstring idea vs the original knob bungee design

-decided to move to drawstring rather than knob bungee design

-hide the drawstring in a pocket

-deadlift straps with neoprene

Conclusions/action items:

Fill out preliminary report, send client final design, order materials needed

Team Meeting 6 10/09/2024

Lucia Hockerman - Oct 09, 2024, 8:49 PM CDT

Title: Fabrication/Testing meeting

Date: 10/09/2024

Content by: Lucy Hockerman

Present: whole group

Goals: Discuss fabrication/testing plans

Content:

- Considering making the "carbon-fiber" support out of metal but want to avoid welding training and two separate parts. Now considering finding the strongest material to 3D print for the initial prototype.

- Alex discussed we will have to get reimbursed for everything we buy for the prototype

- Look over possible material to order on amazon: we decided to purchase an ankle brace (with crossover velcro straps), gel padding, inner foot sleeve and cord lock contraption.

- We discussed how we would fabricate our AFO and possible failures: i.e. how the ridged bar can be a problem with the brace

- We made plans to meet before our advising meeting to test different bungee stiffness and how that affects foot dorsiflexion support

Conclusions/action items:

Complete preliminary report, start bungee cord testing, finish SolidWork "carbon fiber" design

Team Meeting 7 10/11/2024

ANYA HADIM - Oct 12, 2024, 2:53 PM CDT

Title: Team Meeting 7

Date: 10/11/2024

Content by: Anya Hadim

Present: whole group

Goals: conduct bungee cord strength testing

Content:

Each team member took turns doing the bungee cord strength test. First, the angle of our feet were measured using a protractor at resting position. Then, we wrapped the bungee cord around the top of our arch and measured the displacement of the cord between resting position and 10 degree dorsiflexion. The results were recorded.

Conclusions/action items:

Use this data to choose the most effective bungee cord for our design.

Team Meeting 8 10/18/2024

ANYA HADIM - Oct 20, 2024, 12:57 PM CDT

Title: Team Meeting 8

Date: 10/20/2024

Content by: Anya Hadim

Present: whole team

Goals: Discuss and split up fabrication for the first prototype

Content:

We received all of the materials, we discussed how we're going to assemble everything.

Carbon fiber attachement:

- Presley and Lucy meeting with Jack to finish Solidworks design and run testing on it
- 3D print first prototype
- Need Grace's dimensions (after advisor meeting)
    - Foot sleeve dimensions:
        - Back of shin from max length of brace __ cm down to height right below the ankle bone:
        - The end point of the ankle measurement in above measurement diagonally to the start of the arch:
        - End point of the above measurement across the bottom of foot:

Sewing:

- Anya and Alex go to ehall and sew

Todo: talk to someone in the Makerspace for carbon fiber attachment replacement

Conclusions/action items:

Anya and Alex will conduct the sewing for the bungee cord and plastic lock, Lucy and Presley will seek Solidworks help at the makerspace for the carbon fiber attachment.

Team Meeting 9 10/20/2024

ANYA HADIM - Dec 11, 2024, 2:49 PM CST

Title: Team Meeting 9

Date: 10/20/2024

Content by: Anya Hadim

Present: Anya and Alex

Goals: begin fabrication of the foot sleeve component

Content:

Anya and Alex sewed the bungee cord and plastic lock onto the foot sleeve. See fabrication for more details.

Conclusions/action items:

Test the design on Grace and implement changes based off its performance.

Team Meeting 10 10/23/2024

ANYA HADIM - Oct 23, 2024, 8:47 PM CDT

Title: Team Meeting

Date: 10/23/2024

Content by: Anya Hadim

Present: whole group

Goals: brainstorm alternatives to fix the issue that came up during the fabrication of the prototype (the foot sleeve slides up instead of creating tension in the foot.

Content:

Ideas: pulley system, have bungee cords on either side

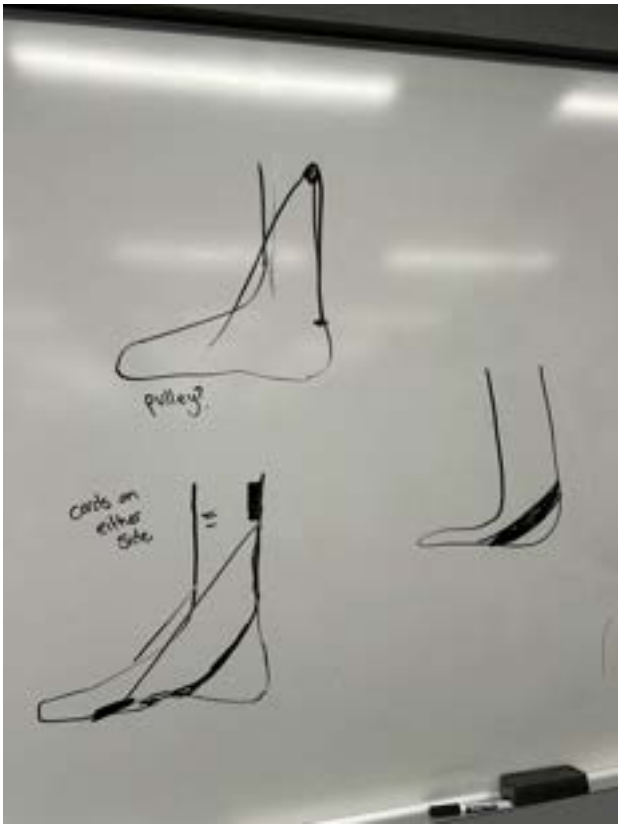
having them on either side - might as well just do a full carbon fiber support so does not make sense to do that

decided to purchase a stronger foot brace and a stronger bungee cord, keeping the same design

lucy took Grace's measurement for the solidworks carbon fiber piece

-sewed bungee cord and plastic lock onto the straps of the foot sleeve material to see if the more durable material will work better with our original design mechanism

-purchased stronger bungee cord and researched stronger foot braces



new problem - plastic cord lock not strong enough?

^will try with stronger bungee to see if that will fix the problem first

Conclusions/action items:

Try re-sewing with stronger bungee cord, purchase stronger material foot brace for more support, complete Solidworks design and print 3D part.

Team Meeting 11 10/31/2024

ANYA HADIM - Oct 31, 2024, 1:33 PM CDT

Title: Team Meeting

Date: 10/31/2024

Content by: Anya Hadim

Present: Anya, Alex

Goals: Assess the new bungee cords and sew to the prototype to create an updated prototype for show and tell

Content:

-assessed the new bungee cords, the stronger ones are very hard to pull - might be too strong

-decided not to sew because we have a problem with the plastic cords now slipping/not being strong enough

-researched stronger plastic locks and other possible methods

-REI looks like it has much stronger locks if we want to keep the same mechanism

Conclusions/action items:

Go to REI and look at the plastic locks available and bungee cords

Team Meeting 12 11/1/2024

ANYA HADIM - Dec 11, 2024, 2:50 PM CST

Title: Team Meeting

Date: 11/1/2024

Content by: Anya Hadim

Present: Anya, Grace, Lucy, Alex

Goals: pick up 3D printed part, practice show and tell pitch, discuss next steps for fabrication

Content:

-brainstormed how to make the inside of the part flat (sanding potentially?)

-practiced show and tell pitch

-the dimensions of the carbon fiber attachment need to be closer/more accurate

Prototype for show and tell on Grace's foot with first PLA printed carbon fiber attachment:

Ideas for bungee cord problem:

-coating on the bungee cord to prevent slipping

-different kind of plastic cord lock (stronger one, loop one, other designs like the shark one)

-increasing the surface area of the bungee cord (different problem than the slipping)

Conclusions/action items:

Prepare pitch for show and tell, continue brainstorming ways to fix the slipping problem for the bungee cord.

Team Meeting 13 11/6/2024

ANYA HADIM - Nov 06, 2024, 5:53 PM CST

Title: Team Meeting 13

Date: 11/6/2024

Content by: Anya Hadim

Present: whole group

Goals: continue fabrication of prototype

Content:

- took closer measurements of Grace's foot for the Solidworks piece

-final print will be made out of: Markforged Onyx Pro printer Onyx Filament which is a high strength thermoplastic composed of nylon mixed with chopped carbon fibers. This combination results in parts that are 1.4 times stronger and stiffer than ABS, offering excellent heat resistance, chemical resistance, and a superior surface finish.

(https://www.matterhackers.com/store/l/markforged-onyx-filament/sk/MUJD90ET)

Individual goals/tasks:

Anya - figure out reimbursement, update BPAG sheet and purchase remaining materials (fabric)

Alex - sew locklaces

Grace - new measurements and reprint carbon fiber piece

Lucy - research and schedule runeasi testing

Presley - conduct solidworks testing on the piece

Team timeline:

Sunday 11/10: Grace's prototype working and completed, purchase final foot brace

next week:

-Grace runeasi testing

-mold creation

-reprint carbon piece with Maggie's dimensions

Week 18-22:

-assemble final prototype

-final deliverables

-final adjustments

Conclusions/action items:

Complete goals and tasks above.

Team Meeting 14 11/8/2024

Alex Conover - Nov 14, 2024, 11:56 AM CST

Title: Team meeting 14

Date: 11/8/2024

Content by: Anya and Alex

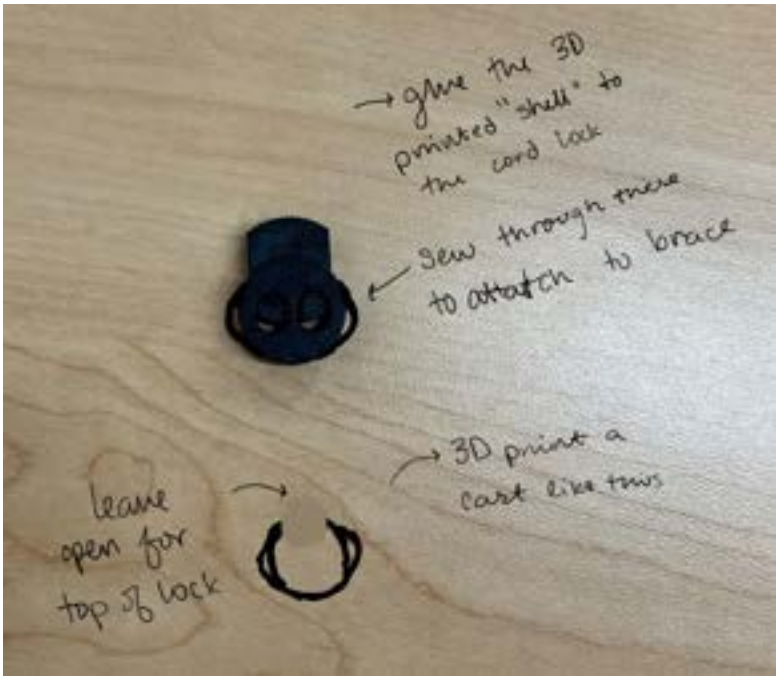
Present: Anya and Alex

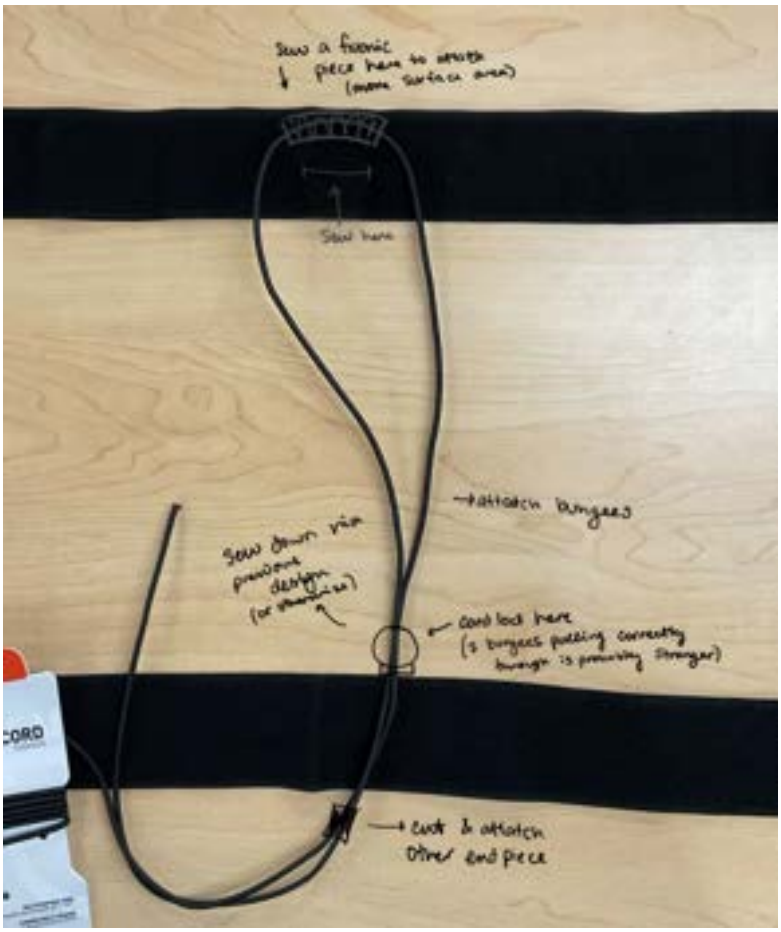
Goals: Progress on sewing and plastic lock mechanism

Content:

Brainstorming ways to secure the locklaces:

-3D printing or attaching 2 loops to the sides of the lock and sewing it





Conclusions/action items:

Ask Coventry and team on their input for attaching the lock lace to the brace.

Team Meeting 15 11/10/2024

ANYA HADIM - Dec 11, 2024, 2:51 PM CST

Title: Team Meeting 15

Date: 11/10/2024

Content by: Anya Hadim

Present: whole group

Goals: Set fabrication goals for the week

Content:

This week's goals:

-Anya, Lucy, Grace testing on Friday

-Alex and Presley fabricate brace

-create mold on Sunday

Tasks:

-double check glue with Dr. P

-pick up part

-Presley email Debbie about cast

-purchase mold filling

-Presley conduct stress testing on Solidworks

-Alex

Found mold kit for cast (see BPAG materials/cost sheet for more information)

Conclusions/action items:

Complete tasks labeled above in the content section.

Team Meeting 16 11/17/2024

ANYA HADIM - Nov 17, 2024, 7:26 PM CST

Title: Team Meeting 16

Date: 11/17/2024

Content by: Anya Hadim

Present: whole group

Goals: create a timeline plan for fabrication for the week

Content:

Plan for the week:

-schedule final meeting with the client and invite them to the final presentation: Presley

Round 2 of testing with Grace: Thursday 12:15-1 followup with Lucy on time Anya Lucy Grace

-Lucy 3D print part tomorrow morning

-mold Wednesday night: Anya, Lucy, Presley, Alex

-Presley Solidworks testing

-split up work for final deliverables

Conclusions/action items:

Complete all the tasks for the week.

Team Meeting 17 11/23/2024

GRACE NEUVILLE - Nov 23, 2024, 12:40 PM CST

Title: Team Meeting 18

Date: 11/23/2024

Content by: Grace

Present: Grace, Presley, Alex, and Lucy

Goals: Meet with team and fabricate the epoxy mold from the cast.

Content:

- we mixed 500 ml of hardener and 500 ml of resin in a bucket

- we stirred for ~5 minutes with a spatula being sure to scrape the edges of the bucket

- we sprayed the cast with silicone mold release right before pouring in the resin

- Then we poured in the resin with the toe part of the cast clamped shut

- the resin began to seep through the wholes of the cast, and we were unable to make the mold

Conclusions/action items: The resin mold did not work with the cast. We will take measurements from the outside of the cast as approximate measurements for the support. The cast is about 2 mm thick, so it should not affect the measurements significantly.

Team Meeting 18 12/02/2024

Alex Conover - Dec 02, 2024, 4:15 PM CST

Title: Team Meeting 19

Date: 12/02/2024

Content by: Alex

Present: Everyone

Goals: Meeting to hash out the details of the week

Content:

- this week we're printing the brace (Tuesday morning?)
- decide who will present what in the presentation
- add solid works testing to lab archives (Presley)
- finalize the brace with maggies dimensions, add sewing in the gels, and the bungee places.
- Meet Wednesday at 3:30 to finalize the brace - Wendt Commons?
- Reimburse Debbie for the shipping costs of the brace?
- finish the project for Wednesday so we can send it to Coventry.

Conclusions/action items:

Complete the final presentation by Wednesday to send to Dr. Coventry can look over it for us; meeting on Wednesday at 3:30 in Wendt Commons to finish the brace.

Team Meeting 19 12/04/2024

Alex Conover - Dec 11, 2024, 2:49 PM CST

Title: Team Meeting

Date: 12/04/2024

Content by: Anya Hadim and Alex Conover

Present: Anya, Lucy, Alex, Grace

Goals: complete presentation and assemble final design

Content:

Met together to mitigate final deliverables work

Lucy, Anya, and Grace worked to decipher the statistics data, as well as work on the poster.

Alex did the sewing of the brace, detailed in the fabrication section.

Goal was to finish the poster so we could send it to Coventry - the poster was eventually finished and sent to him later in the evening.

We also checked the fit of the printed piece with the brace, at it fits relatively well, but minor adjustments could be made to make it a better fit to our patients ankle.

Conclusions/action items:

Finish reprinting (if necessary)

receive feedback from Dr. Coventry, update poster

print poster, (Lucy in her Lab)

FSHD Background

ANYA HADIM - Oct 12, 2024, 3:10 PM CDT

Title: Background on FSHD Research

Date: 9/11/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: Conduct background research on FSHD because the target demographic for this device is for those diagnosed with this muscular dystrophy. The client ideally wants the AFO to allow active concentric ankle movements in those who have this and reduce the necessity for eccentric muscle contractions while also preventing foot slap.

Content:

-Facioscapulohumeral muscular dystrophy shrink and weaken the muscles of young individuals

-symptoms appear before 20 years old and slowly worsen with age, severity varies but normal life span remains

-caused by gene mutations (autosomal dominant inheritance pattern)

-no cure for the disease, physical therapy is the biggest key along with anti-inflammatory medicines, scapular fixation surgery, and support devices (hence the AFO)

-As FSHD worsens with age, symptoms worsen with the most common ones being:

-difficulty lifting feet (important to know and cater for with the brace), swayback in the lower back, hip weakness

Facioscapulohumeral Muscular Dystrophy in Children | Johns Hopkins Medicine

-muscle groups affected: face, shoulder girdle, lower extremity affected all asymmetrically

-most common type of muscular dystrophy

-appears less in women compared to men (women diagnosed at a later age with less severe pathology)

-affects distal-most muscles first

-contractures do not surround weak muscle groups like they do in other dystrophies (affect all especially smile, tense, head and neck)

-treatment showed improvement in muscle function for those engaged in a 6-month program of combined aerobic and strength training

-main complications are chronic pain and impaired daily functioning

Facioscapulohumeral Muscular Dystrophy - StatPearls - NCBI Bookshelf (nih.gov)

-asymmetric muscle involvement

-progression of weakness is slow and follows a descending pattern into the distal lower extremities

-early onset makes up for 21% of the total FSHD population

-scapular fixation is common safe and effective once patients achieved skeletal maturity (but there are no other direct treatments for any other part of the body making the AFO critical for the lower extremities of patients)

-New emerging treatments:

Oligonucleotide-Based Gene Therapy : targets specific genes for treating infectious and genetic diseases

Reduce Muscle Inflammation by Immune Modulatory Agents

Improve Muscle Mass and Pathology by Activating Compensatory Pathways

Others: exercise therapy, cell therapy, studies of compounds that target molecular pathways and are misregulated by DUX4

A Pediatric Review of Facioscapulohumeral Muscular Dystrophy - PMC (nih.gov)

Conclusions/action items:

Use this knowledge to design the ankle brace according to our client's disorder. Ask about severeness and more specific details during client meeting.

Gait effects and assessment

ANYA HADIM - Oct 12, 2024, 3:12 PM CDT

Title: Gait effects and testing for AFOs

Date: 9/20/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: conduct research on gait effects for AFOs and how to test it (for testing section)

Content:

Orthotic Assessment (should do these for testing):

Passive assessment: range of motion, muscle power, proprioception, sensation, leg length

Active assessment: level of mobility, gait pattern, compensation mechanisms of instability, risk of injury, pain

Common Gait cycle complications:

true equinus: hip and knee are extended

jump gait: anterior pelvic tilt and lumbar lordosis

apparent equinus: increased hip and knee flexion

crouch gait: excessive hip and knee flexion

Changes in gait due to: Pain, Joint ROM limitations, Muscle weakness/ paralysis, Neurological deficit, Sensory deficit, Leg length

Foundations for Ankle Foot Orthoses - Physiopedia (physio-pedia.com)

Conclusions/action items:

Use this information to plan gait testing with our AFO.

Competing Design

ANYA HADIM - Dec 11, 2024, 2:58 PM CST

Title: Competing Designs

Date: 9/15/2024

Content by: Anya

Present: Anya

Goals: Identify other AFO Designs that currently exist.

Content:

Three main types of AFOs: flexible, rigid, jointed

Flexible:

-flexibility around the ankle area

-cutting away part of the device around the ankle which reduces surface area and reduces Three Point Pressure system (not suitable for patients with mediolateral instability)

-useful for those that have increased uncontroled movement in the ankle joint with good mediolateral stability

-encourages natural gait pattern, easier to get up and out of chairs, stairs, and children to play on floor and move

Criteria:

drop foot - corrects the position to plantigrade but allows movement through midstance, makes more natural gait pattern but allows foot to clear the ground

mobile foot/ankle

no tendency to valgus or varus

also known as posterior leaf spring (PLS) because there is a spring at the back of it, commonly used short-term

Rigid:

-orthotic device allows for no movement

-used in more severe situations, allows the Three-Point Pressure System to function in the optimal way

-important to conduct gait analysis when constructing these devices

-ground-reaction AFO is the same as a rigid but with an anterior shell attached to spread the load to the front of the shin which extends the knee and maintains the ankle in plantigrade position

Criteria:

flex at knee, muscle tightness, dynamic/fixed, crouch/equinus gait, hyper-extension, escape valgus

Jointed:

-made with a moving part that hinges at the ankle joint

-allows motion at the ankle joint while still offering the correction that the Three-Point Pressure System offers

-optimizes gait pattern

cons:

-bulkier (difficulty with footwear)

-noisy

-parts can break

advantages:

-full ROM (walking up and down stairs, getting up from a chair, moving around the floor)

Types: AFO - Ankle-Foot Orthosis
GRAFO - Ground Reaction Ankle-Foot Orthosis
DAFO - Dynamic Ankle-Foot Orthosis
SMO - Supramalleolar Orthosis
Custom made: manufactured using a plaster cast

Off-the-shelf: designed in small medium and large but usually need adjustments depending on the person, mostly manufactured from a plaster model, polypropylene/lamination/carbon fibre

Foundations for Ankle Foot Orthoses - Physiopedia (physio-pedia.com)

Conclusions/action items:

Use these competing designs to draw inspiration for our design based off what works and what doesn't work. Also use to differentiate our design from what already exists.

Stabilizing Joint

ANYA HADIM - Oct 12, 2024, 3:15 PM CDT

Title: Research on AFO fabrication

Date: 9/13/2024

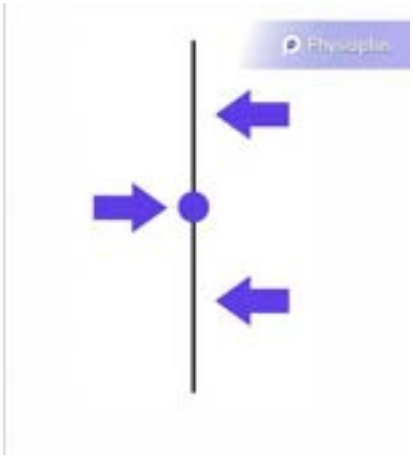
Content by: Anya Hadim

Present: Anya Hadim

Goals: Research how building AFOs work from competing designs

Content:

Three-Point Force system - used to stabilize a joint or segment to reduce angular rotation



- force is applied medio - laterally or antero - posteriorly

Critical to creating an orthosis:

1. Primary force is applied at the joint to be corrected

2. Counterforces are applied above and below the primary force

3. Sum of all these forces should be 0

4. Pressure = Force / Area

5. The longer the lever arm/orthosis is the further away the points of force are = the bigger the correction will be

Pressure can be reduced using this ^ and **can be used to reduce discomfort when wearing an orthosis**

Positioning:

Most important factors: least painful position, best position possible (closest to neutral), highest functional level

Conclusions/action items:

Use this technique to build our AFO.

Building AFO

ANYA HADIM - Oct 12, 2024, 3:17 PM CDT

Title: Building AFO research

Date: 10/1/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: learn about how AFOs are most commonly built

Content:

Building AFO:

-mold of the patient's foot and ankle is made using a plaster cast

-3D printing is most commonly used but it is difficult to maintain the optimum foot position long enough to take an accurate scan

Updated 10/12/2024

Fabrication plan:

Conclusions/action items:

use this information when considering our fabrication plan

Circular Hinge Research

ANYA HADIM - Sep 30, 2024, 8:33 PM CDT

Title: Circular Hinge Research

Date: 9/30/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: Research circular hinges, specifically from AFOs to draw inspiration for a design.

Content:

-Hinges allow for movement that is entirely restricted with completely rigid AFO designs which are what most commonly exist (walking, running, playing sports etc)

-5/8s rings are used distally at the ankle joint open anteriorly

-threaded rods are the simplest method to build rings

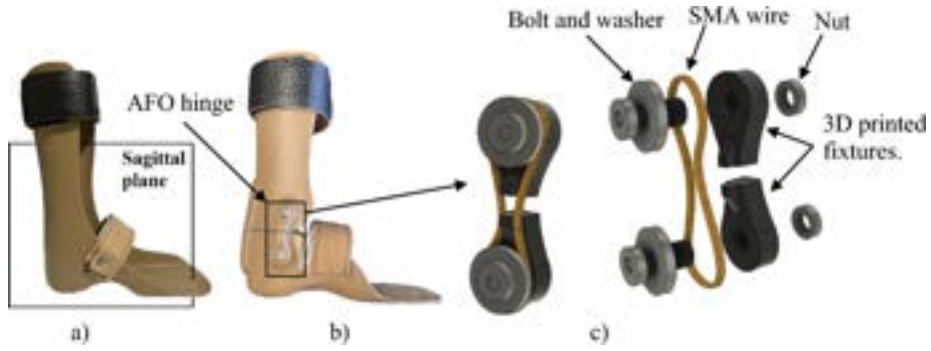
- **Types of Motion**:
    - **Longitudinal Motion**:
        - Required in cases like compression (arthrodesis) or distraction osteogenesis (limb lengthening).
        - Achieved using threaded rods and compression/distraction nuts.
        - Nuts have quarter-turn markers; one full rotation = 1 mm of travel, often used in bone transport.
        - **Telescoping rods**: An alternative option, pre-assembled with a threaded rod inside.
            - Slotted windows and markings allow measurement of travel over time.
- **Multiplanar Motion**:
    - Combines rotational, translational, sagittal, or coronal plane movements.
    - Achieved with **hinged struts**, which incorporate hinges at both ends and a central compression/distraction mechanism.
        - Used for multiplanar correction with gradual lengthening.
        - Newer versions include quick-release mechanisms for temporary adjustments and locking collars for stabilization.
- **Virtual Axis Concept**:
    - Newer approach where struts move in an infinite number of planes.
    - Struts can be used with software programs to plan and guide the correction process.

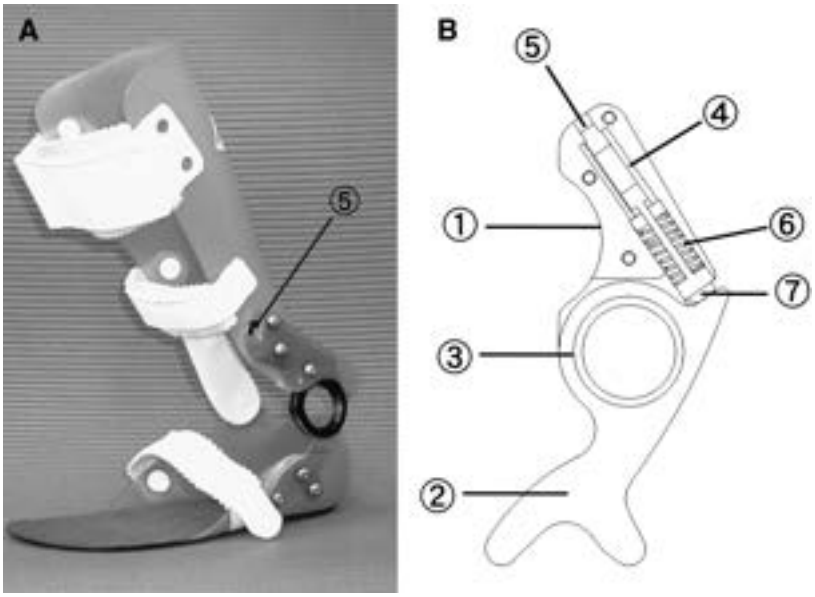
Key Devices:

- **Threaded Rod with Compression/Distraction Nut**: Simplest tool for longitudinal motion.
- **Telescoping Rods**: Allow for measurement of travel over time.
- **Hinged Struts**: For multiplanar corrections, with features like quick release and locking collars for stabilization.

- **Virtual Axis Struts**: Used in conjunction with software to plan multiplanar motion corrections.

[Circular External Fixation Components and Design Considerations | Musculoskeletal Key]





Conclusions/action items:

The hinge is a good idea for a design that will provide the flexibility and range of motion that the client wants. However, it could add some unwanted bulkiness. This information will be used to construct a hinge design that will hopefully adhere to both of these criteria adequately.

Materials Research

ANYA HADIM - Oct 12, 2024, 5:41 PM CDT

Title: Design Materials Research

Date: 9/30/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: Searching for a clear mesh material to make the straps out of to keep the prototype as conspicuous as possible

Content:

benefits of mesh fabric: comfortable, soft, breathable, waterproof, durable, versatile

Nylon mesh:

low elongation, strong, high temperature resistant, makes clothes visually appealing and lightweight

Tulle mesh:

lightweight, low GSM, net-form material

Power Mesh:

Nylon and spandex blended stretchy material, breathable, strong, elastic, sheer appearance

Powernet Mesh:
good material for dense clothes

Polyester mesh:

light, retains a lot of moisture

What is Mesh Fabric? Different Types of Mesh Fabric (textileindustry.net)

Updated 10/12/2024:

Nylon is specifically selected for its low elongation, strength, high-temperature resistance, and ability to make the brace visually appealing and lightweight. Polyester, known for its durability and strength, is ideal as it retains its shape and resists wrinkles, shrinking, and environmental elements like water and wind, which is crucial since the device will frequently be exposed to outdoor conditions. Latex contributes flexibility, durability, and excellent resistance to liquids, making it an effective barrier against moisture while maintaining overall strength.

https://www.rtprototype.com/what-is-polyester/

Latex Polymer: Benefits, Uses, and Environmental Impact (polymer-process.com

Conclusions/action items:

Powermesh would be the best kind to use for our design given its properties matching our clients needs best.

Cast Mold Research

ANYA HADIM - Dec 11, 2024, 3:00 PM CST

Title: Cast Mold Research

Date: 11/18/2024

Content by: Anya Hadim

Present: Anya

Goals: conduct research to find the best material to make our cast mold successfully.

Content:

1. Silicone Rubber

Best for: Prototyping, low to medium production runs, and casting resins or other soft materials.

Pros: Highly flexible, excellent detail reproduction, heat and chemical resistant, easy to work with.

Cons: Not as durable for long-term use or high-volume production.

2. Epoxy Resin

Best for: Medium production runs and when strength and detail are needed.

Pros: Good detail reproduction, customizable properties (can be mixed with fillers for added strength), relatively cost-effective.

Cons: Less flexible than silicone, potential for cracking if not reinforced properly.

3. Urethane Rubber

Best for: Creating molds for casting concrete, plaster, or other rigid materials.

Pros: Strong and durable, good tear resistance, good flexibility.

Cons: May have more shrinkage over time compared to silicone.

4. Aluminum

Best for: High-volume production and processes involving high temperatures (e.g., injection molding).

Pros: Good thermal conductivity, lightweight, durable, and easy to machine.

Cons: Higher initial cost, less detailed than silicone or epoxy, not as resistant to abrasive wear as steel.

5. Tool Steel

Best for: Very high-volume production and high-pressure molding (e.g., injection molding).

Pros: Extremely durable, capable of producing millions of cycles, highly resistant to wear and tear.

Cons: Expensive, requires specialized machining and maintenance, heavy.

6. 3D Printed Materials

Best for: Rapid prototyping and low-volume production.

Pros: Customizable, quick production, relatively low cost, good for creating complex geometries.

Cons: Limited durability, material properties vary widely based on the type of 3D printer and material used (e.g., resin, ABS, PLA).

7. Plaster or Gypsum

Best for: Making simple, inexpensive molds for low-temperature casting (e.g., slip casting ceramics).

Pros: Cheap, easy to use and work with, good for educational or artistic applications.

Cons: Fragile, not suitable for high temperatures or high production volumes.

Recommendations Based on Application:

Low to Medium Production, High Detail: Use silicone rubber or epoxy resin.

High Production, High Durability: Use aluminum or tool steel.

Prototyping or Complex Shapes: Use 3D printed materials or silicone rubber.

Silicone rubber is often the most versatile material due to its balance between flexibility, detail reproduction, and ease of use. For high-volume, industrial-scale production, tool steel or aluminum molds are the most cost-effective over time, despite their higher initial investment.

Conclusions/action items:

Based off this research and our advisor's recommendations, the team will be using epoxy resin to make the mold for our cast.

Standards

Alex Conover - Oct 12, 2024, 3:13 PM CDT

Title: Standards

Date: 9/17/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: Find standards that our design has to follow/adhere to

Content:

When testing the AFO, the team must abide by ISO Standard 2267:2016.

This standard outlines a specific testing procedure for ankle-foot devices and foot units used in external lower limb prostheses. This standard tests how the prosthetic device performs under repeated, cyclical loading conditions that simulate the forces and motions experienced during the complete stance phase of walking—from the moment the heel strikes the ground to the moment the toe leaves the ground (toe-off). The testing will provide performance characteristics of the prosthetic device such as its strength, durability, and service life, ensuring the prosthesis meets quality and safety standards.

The device will be classified as a Class 1 Medical Device. The device does require pre-market approval from the FDA.

Our device will need to fall under Code of Federal Regulations Title 21, Section 890.3475.

This defines a limb orthosis as a medical device worn on either upper or lower limbs to support, correct, prevent deformities, or to align body structures to improve bodily function. Examples of limb orthoses are as follows: a whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.

ISO Standard 8549-3:2020

Defines orthosis as an externally applied device utilized to compensate for impairments in the structure and function of the neuromuscular and skeletal system; ankle-foot orthosis is defined as an orthosis that encompasses the ankle joint and the whole or part of the foot.

ISO Standard 8551:2020

Covers functional deficiencies in prosthetics and orthotics. The standard provides guidelines for the person to be treated with an orthosis, the clinical objectives of treatment, and the functional requirements of the orthosis.

When testing the AFO, the team must abide by ISO Standard 2267:2016.

This standard outlines a specific testing procedure for ankle-foot devices and foot units used in external lower-limb prostheses. This standard tests how the prosthetic device performs under repeated, cyclical loading conditions that simulate the forces and motions experienced during the complete stance phase of walking—from the moment the heel strikes the ground to the moment the toe leaves the ground (toe-off). The testing will provide performance characteristics of the prosthetic device such as its strength, durability, and service life, ensuring the prosthesis meets quality and safety standards.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=IQO

https://www.iso.org/obp/ui/en/#iso:std:iso:8549:-3:ed-2:v1:en

https://www.iso.org/obp/ui/en/#iso:std:iso:8551:ed-2:v1:en

https://www.iso.org/standard/70203.html#:~:text=ISO%2022675%3A2016%20primarily%20specifies%20a%20cyclic%20test%20procedure

Conclusions/action items:

Consider these standards when designing our prototype and final design.

Patents

ANYA HADIM - Oct 13, 2024, 8:44 PM CDT

Title: Patents for AFOs

Date: 10/1/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: Research existing patents on AFOs

Content:

US4289122A

- The device is an ankle-foot orthosis made from thin polypropylene.
- It includes a foot section and a leg section, which are hinged together at the ankle.
- The design promotes dorsiflexion (upward foot movement).
- A flange at the bottom of the leg section overlaps the foot section, limiting plantar flexion (downward movement) and preventing foot drop.

US8075633B2

- The AAFO dynamically adjusts joint stiffness during the walking cycle to treat gait issues like drop foot.
- During controlled plantar flexion, stiffness is biomimetically adjusted to avoid forefoot collisions.
- In late stance, stiffness is minimized to allow natural powered movements.
- During the swing phase, a spring-damper system aids in lifting the foot for toe clearance.
- Clinical studies on drop foot participants showed reduced foot slap, improved plantar flexion, and more natural swing-phase motion compared to normal gait.

US4289122A - Ankle-foot orthosis - Google Patents

US8075633B2 - Active ankle foot orthosis - Google Patents

Conclusions/action items:

Use this information to design our product based on what now exists and works.

Brainstorming - design ideas

ANYA HADIM - Nov 15, 2024, 2:51 PM CST

Title: Individual prototype brainstorming

Date: 10/2/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: Brainstorm a prototype then meet with the group to share ideas

Content:

Circular hinge design : mesh straps over the top, carbon fiber piece on the back, circular hinge joint that allows for walking, supportive strap on the top of the foot.

Conclusions/action items:

Meet with team to share ideas and construct a prototype.

11/10/2024 - Runeasi Training

ANYA HADIM - Nov 15, 2024, 2:40 PM CST

Title: Runeasi Training

Date: 11/10/2024

Content by: Anya Hadim

Present: Anya, Lucy

Goals: Learn how to use Runeasi software/program for testing

Content:

Steps:

- Attach it to the back of the hip (synchrom)
- Linked to the runeasi app
- The email is joachim@orthowisc.edu
- Password: Topo3437!
- Click on the client
- Check that theres a connected bluetooth sensor : click on icon to manage the sensor
- Click start test
- Choose running or walking
- Treadmill walk
- Start
- Get dashboard and a score
- Look at individual metrics : click on expert center
    - Dynamic stability: medial lateral measure
    - Impact loading: how many Gs of force you're experiencing peak vertical forces
    - Impact duration: impulse of how long that force was applied for
    - Ground contact: how long foot was on the ground
    - Cadence: total steps
    - Flight ratio: what percent of gait cycle are you in stance vs in gait (state)
- Pdf report
- Info and knowledge: describes all of the metrics in more detail
- App with the black icon
- 3 trials of 3 mins
    - Pain level
    - Carbon fiber piece uncomfortable

Parameter measures:

Impact Magnitude (%): Vertical impact that reaches the pelvis immediately after the foot hits the ground. Linked to ground reaction forces on the body.
<2.7%: excellent, 2.7-5.9%: typical, 5.9-10.7%: elevated, 10.7-17.9%: high, >17.9%: very high

Impact Duration (%): The time it takes for the impact shockwave to reach the pelvis. Indicates capacity of the legs to absorb shocks. Longer impact durations correspond to a better shock absorption.
<3.2%: excellent, 3.2-6.8%: typical, 6.8-12.5%: elevated, 12.5-20.9%: high, >20.9%: very high

Dynamic Instability (%): The proportion of hip movement in the medio-lateral direction during landing. Captures how much energy is wasted by movements that are not contributing to forward propulsion. Linked to fatigue.
<2.1%: excellent, 2.1-4.8%: typical, 4.8-8.3%: elevated, 8.3-14.1%: high, >14.1%: very high

Testing Protocol:
Using a walking speed of 1 m/s for 3 mins on the treadmill, I collected 3 trials without brace and measured using Runeasi (without shoes). 5 minutes between with/without brace trials (measured foot angle)

Conclusions/action items:

Conduct testing on Grace using this information

Lecture 1 9/11/2024

ANYA HADIM - Sep 11, 2024, 11:01 PM CDT

Title: Lecture 1 - BME Career Prep

Date: 9/11/2024

Content by: Anya

Present: Anya

Goals: Take notes on the lecture from Stephanie in career services,

Content:

Speaker: Stephanie Salazar Kann

Job Search tips: keep track of everything, quality of source, connect before becoming a candidate, follow-up after applying

-recommends looking into coops

-ecs.wisc.edu/resources - find the excel tracker sheet to track the jobs and internships you apply to

-career fair is giving a leg up - chosen to recruit from UW Madison

-keep an open mind

Resume tips:

-tailor resume to the position

-create balance to show your full experience

-hold off on applying until after career fair

Career fair advice:

Identify your purpose - more than just an internship, looking beyond the obvious - overlap with other disciplines, research the employer - feedback from our partners, develop your value added statement - why you?

Come prepared do your research know what youre talking about

differentiate yourself - design classes way more over MechEs - value added "I've had 4 semesters of intensive design experience - tell them about all the skills you acquired doing your projects"

-start with Handshake then move to Linkedin

Citations:

Conclusions/action items:

Use this advice to apply for internships, attend the career fair.

Lecture 2 9/18/2024

ANYA HADIM - Sep 18, 2024, 1:56 PM CDT

Title: Lecture 2

Date: 9/18/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: Learn how to explore your leadership style

Content:

How do you define a leader?

I define a leader as someone who is a hard worker, motivated, determined, and confident; but at the same time knows how to collaborate, work and listen with others, can stay organized and manage a group effectively.

What do you feel are important qualities in a leader?

Openmindedness, honesty, humbleness, strength, compassion, determination, motivation, communication, confidence

Common qualities of a leader: self-awareness, vision, transparency, communication, decision making, empathy

Styles - examples of leadership style

- power model of leadership: being in control, hierarchy, authority, command

- Servant Leadership: thought process, defining qualities, being of service to others, empathetic, empowering, shared decision making

- Authentic Leadership: transparency, genuineness, honesty

People-oriented leader: hold the team together, get to know everyone as individuals, building trust and inclusive environment

Process-Oriented: sets the pace for the team; willing to work alongside everyone create systems and process so work gets done efficiently

thought oriented: sees big picture, open to new innovation ideas

impact-oriented: sets the bar high inspires others to follow your cause and mission

leading others starts with leading yourself

explore and define how you want to lead: self-assess, observe and reflect, seek out feedback

Goal setting: start small, slow down, focus on one element to practice, look for mentors, ask questions, partner with others, consider tracking your progress

Set team goal: The design team will collaborate nicely, listen to each others thoughts and ideas and consider all of them equally and fairly, help each other in tasks and work efficiently together getting everything done in time successfully.

Set self goal: I would like to be a team leader that everyone enjoys working with and feels heard, seen, and appreciate equally and fairly. I also hope to make everyone enjoy the project and want to work hard on it because they like what they're doing.

Conclusions/action items:

Use these tips to be the most effective team leader possible for my group. Work towards achieving the team and self goal.

Lecture 3 9/25/2024

ANYA HADIM - Dec 11, 2024, 3:01 PM CST

Title: Post Grad Advising Planning

Date: 9/25/2024

Content by: Anya Hadim

Present:

Goals: Learn about how to plan career post grad

Content:

Speaker: John Pucinelli

-use your undergrad to "build a story" get experiences specifically in what you want to do not just what you get (get involved in research in what you want to pursue)

-what does your ideal position/company look like

-connect with alums on Linkedin

-think about letter writers: get 3 strong references

Writing a personal statement: avoid including things that don't have any relevance to each other, don't just regurgitate what you did, don't say you'll do "whatever" be specific

Instead: start with what you want to do - thesis statement

show how the experiences you have relate to the field

be very specific in matching your skills to what they are specifically looking for and talk about how you match those exact key words they are looking for

defend your plan with your life experiences - Most recent first

CV to some extent in paragraph form but tie it specifically to the position you're applying for

Graduate School options

Masters, industry focused, generally 1 year, 20-30% get one and some go on to getting an MD or PhD

recommends applying for PhD and getting a masters along the way

PhD: desire to be your own researcher, write research grants, work in academia, lead projects in industry, startups and consulting

generally >3.5GPA and 75%ile Quantitative GRE

MS: opens doors for more opportunities, higher starting salary, another opportunity for summer internships, can co-op during the MS as well, time to find your dream job, will make you more desirable

MS options within BME:

Research - 1.5-2 years, for those continuing on for a PhD, thesis required

Accelerated program - 1 year, coursework only, independent study allowed, funding like TA or RA or PA

BME innovation, design, and entrepreneurship - 1 year accelerated, project based (project required), partnership with B-school, funding same as accelerated

Special for BME students: no need for recc letter, no CRE or MCAT scores, no transcript, easy to meet deadline and application is reviewed separately

Masters elsewhere: Meng, MS in Global Health, MS in other Eng departments, MBA

Duke has a similar program (requires project) look for programs that have projects

use your PI at madison for connections or collaborators

Beyond the classroom: research is required, volunteer, shadow physicians, patient contact time, reference letters, use your design experiences

Conclusions/action items:

Create a post grad plan using this information. Do more research on a masters and see how it could fit into my future career moving forward.

Lecture 4 10/2/2024

ANYA HADIM - Oct 02, 2024, 2:02 PM CDT

Title: Lecture 4

Date: 10/2/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: Learn about peer mentoring

Content:

Speaker: Tracy Puccinelli

Why are we mentoring BME 200 students:
-teaching them things about design

-get them more comfortable with the design process

-prepping them to teach others how to do it

-helping others reinforces what you know and helps you learn and grow

-additional instructional and emotional support for students

-peer mentors are more approachable, mentees are more willing to ask questions

-share experiences (courses, coops, internships, research, etc)
-increases belonging

-mutual benefits (transferrable skills)

transferrable skills: leadership, communication, active listening, study practices, self-awareness, interpersonal skills

General Benefits of Mentoring

Increased self-esteem/confidence, increased patience, build positive habits, foster personal growth, help identify gaps in your own knowledge, sense of accomplishment

What does it mean to be a "good mentor"?

-teach things rather than doing them yourself

-be considerate

-listen to others

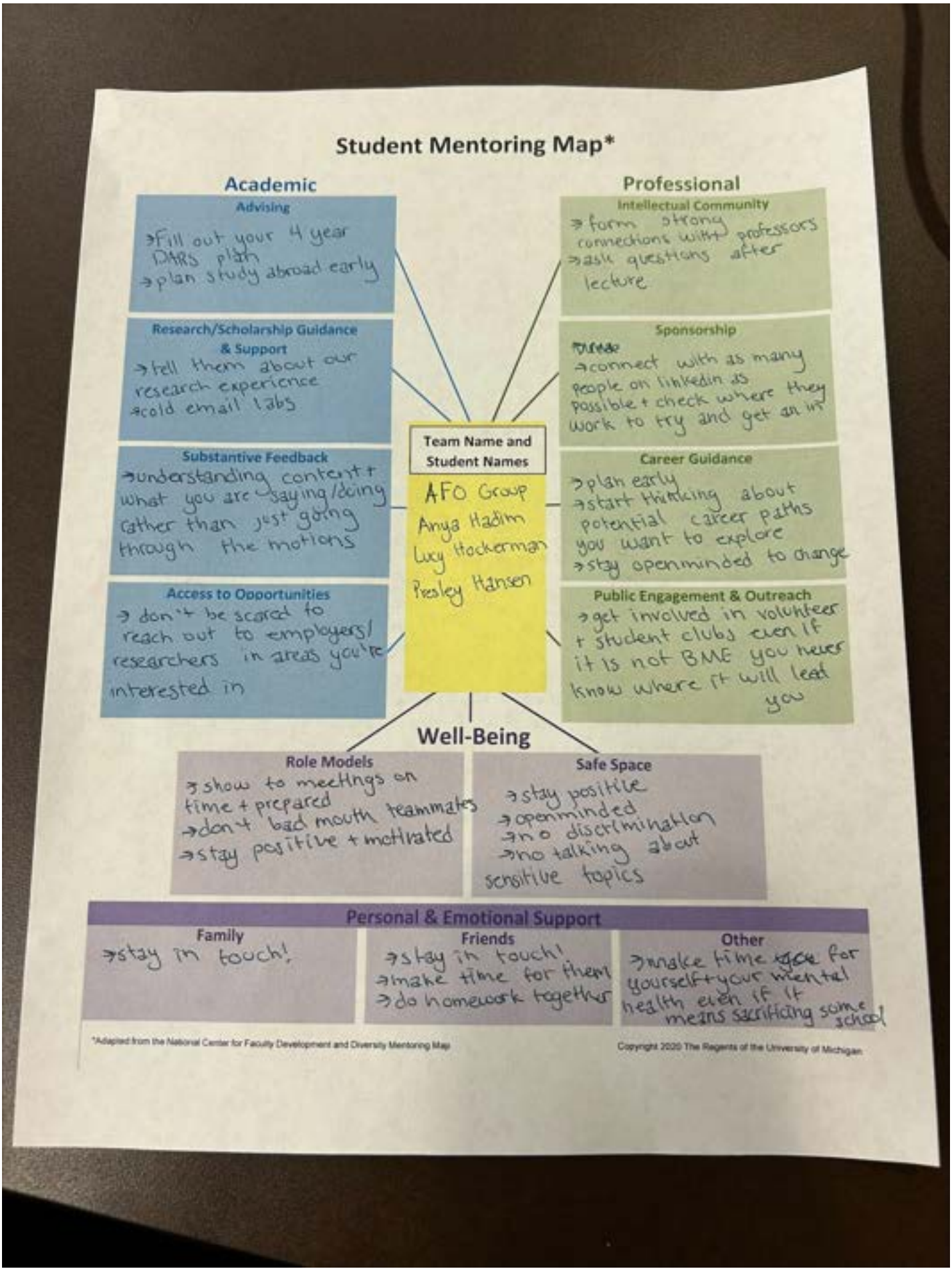
-respect others

-good listening

-support

-be available

I wish I knew in BME 200: run DARS early, get involved in research, plan your track early



Conclusions/action items:

Apply these skills to mentoring the 200s this semester

Lecture 5 10/9/2024

ANYA HADIM - Oct 09, 2024, 2:06 PM CDT

Title: Lecture 5

Date: 10/9/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: Learn about sustainability engineering and its importance/purpose

Content:

Speaker: Andrea L. Hicks

nutrification: too many nutrients, occurs when switching from something fossil based to bio based

disposable vs reusable blood pressure cuffs

consider how sustainability fits into our project? Our device is reusable, however it is important for us to choose environmentally friendly materials when building it because when considering future work, if it was ever put in the market and had to be made in large quantities, we have to consider its environmental impact.

-recycled 3D printing material

Conclusions/action items:

Incorporate sustainable aspects to our design into our project.

Lecture 6 10/16/2024

ANYA HADIM - Dec 11, 2024, 3:02 PM CST

Title: Lecture 6

Date: 10/16/2024

Content by: Anya Hadim

Present:

Goals: learn about patenting and IPs

Content:

Wharf: enables UW Madison research to solve world problems

-provides financial support, mentoring, help, support for patenting and licensing

technology transfer: moving research results from campus out into the market, secures IP rights and commercial licenses

Intellectual property overview

Four common types: patents, copyrights, trademarks, trade secrets

other: biomaterials, technique and know how, data

Overview of non-patent IP

Copyrights: protection for creative works that are expressed in a tangible medium, a wide range of subject matter, including software code

trademarks: protection for names, marks, logos, dress, etc. , requires use in commerce, source-identifying function

trade secrets: can be used to protect anthing of value, protection is good so long as the concept is not generally known

Patents Generally

a patent is a property right, granted by a governmental agency (US Patent and trademark office, no global patent)
patent holder has right to exclude others from making, using, selling, or importing the claimed invention

3 different types of US patents: design (15-year term), plant (20 year term, asexually reproducing, non-tuber), utility (provisional (1 year), non provisional (20 year term)

utility (non provisional):
takes 2-5 years to issue after filing, costs about 30K

requirements for patenting:

eligible: cannot be a product of nature, abstract idea, or natural phenomenon

novel: must be new

non-obvious: cannot be simple modification or combination of existing concepts

enabled and described: must provide enough detail to teach others how to make or use the invention

Warf receives about 400 new innovation disclosures each year

disclosing: describe the innovation, identify its advantages and potential applications, name contributors, provide funding and public disclosure details

Meeting with Warf: describe the innovation in more detail, ask questions about warf and patenting processes, discuss next steps

IP considerations: IP protection, breadth and strength of IP protection, public disclosure, stage of development

licensing considerations: applications, likelihood of identifying a commercial partner, likely return from licensing

Marketing and Licensing

licensing the IP is the next step in transferring the technology

market analysis

market status - established, emerging, new

size and type - large and growing, medium and contracting, etc.

potential licensees - companies in the market

license negotiation

type and terms - exclusive and field limited, sublicensing, etc.

consideration - upfront payment, royalties, reimbursement

ongoing

technology development, enforcement, amendment, termination

Value of licensing

Benefits to the company: reduced R&D costs, improved time to market, opportunity to enter new markets and expand company quickly, new features or products provide additional revenue opportunities

Determining the value: technology application, key selling points/features/benefits, technology trends, market size, trend, competition, industry standards/historical deals

AI and IP

patents: can AI invent? (no) limited to US only? (no) can AI assist in inventing? yes

copyright: original works of human authorship, AI must be incidental to conception and creation, original conception by human master mind, combinations of derivative works requires more than de minimis contribution from human

Conclusions/action items:

Consider patenting our design given this information and knowledge. Our design is not non obvious.

Lecture 7 10/23/2024

ANYA HADIM - Oct 23, 2024, 8:23 PM CDT

Title: **Institutional Review Boards and Clinical Translation**

Date: 10/23/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: Learn about IRBs

Speaker: **Dr. Jennifer Fenne, PhD**

Key points:

Unethical research --> ethical principles --> human research regulations

Infamous studies that are examples of unethical research: Nazi prisoner experiments, Hepatitis studies at Willowbrook State School for children, Milgram shock experiments at Yale, Tusckegee syphilis study**.**

Belmont principles: Respect for Persons, Beneficence and Justice

Regulation for protection of human "subjects": department of Health and Human Services (DHHS) aka "the common rule" and the FDA

UW-Madison IRB:

- Minimal Risk Research IRB (MRR IRB): biomedical, education, and social/behavioral sciences research. Secondary analysis of data, survey research, behavioral health interventions, evaluations of educational practice

- Health Sciences IRB (HS IRB): biomedical, interventional, any risk level. All FDA regulated and VA regulated research

Do I need an IRB? No - because our product is not generalizable. We are only creating an AFO for one patient with no intent to mass produce

Subject: an individual on whom or on whose specimen an investigated device is used on

Preparing for an IRB review

- Complete required training for researchers through CITI

- Complete annual outside activities reports

- Identify appropriate principle investigator and study team

- Collect preliminary (non-human) data and background information

- Develop a research question and steps to answer it

- If evaluation device effectiveness and/or safety, consult UW's FDA regulated Research Oversight Program

- Consider research participants details (how many, why, how to minimize risks, where to recruit, etc.)

Application system: Arrow (protocol based vs non protocol based)

Resources: irb.wisc.edu

IRB for Beginners Workshop 10/24 10:00 -11:00 am

Conclusion: Confirm our group does not need to get approval from the IRB

Lecture 8 10/30/2024

ANYA HADIM - Dec 11, 2024, 3:03 PM CST

Title: Lecture 8

Date: 10/30/2924

Content by: Anya Hadim

Present: Anya Hadim

Goals: learn about how to navigate FDA requirements

Content:

Speaker: Jake Rome

FDA Regulations:

Defining a Medical Device - decide first if you have a medical device

medical device: anything that affects health that is not a drug or an antibiotic

traditional or non-traditional

once you define something as a medical device the regulations start there

Classes of marketed medical devices:

device classes: class 1, 2, 3

risk: low, moderate, highest

marketing: exempt from premarket approval, 510(k) showing substantial equivalence, premarket approval

examples: band aids, floss, tongue depressor, BP cuffs, sutures, catheters, pacemakers, vascular stents

regulatory controls:

general controls: registration and listing, good manufacturing practice, general labeling, adverse event reporting

special controls: performance standards, special labeling requirements, post market surveillance, potential data requirements

Class 2:
premarket approval: data to show safety and effectiveness

Risk level: moderate risk (higher risk than class 1)

regulatory requirements: must follow general and special controls, including performance standards, post market surveillance and specific labeling requirements

approval process: submission of a 510(k) application to show substantial equivalence; may be exempt

Class 3:

risk level: high

regulatory requirements: must follow general controls and additional stringent requirements such as clinical trials to demonstrate safety and efficacy

approval process: PMA submission, which involves a comprehensive FDA review of safety and effectiveness data before marketing

market submission types

510 (k) exempt : registration and listing only

510 (k) -premarket notification (substantial equivalence)

PMA-premarket approval

-full safety and effectiveness submission

-manufacturing details

DeNovo classification

-novel medical devices, no legally marketed predicate

Conclusions/action items:

Use this information to properly classify our device and familiarize ourselves on the FDA regulations that are placed on it as a result of its classification.

Lecture 9 11/6/2024

ANYA HADIM - Dec 11, 2024, 3:04 PM CST

Title: FDA Structure and Advanced Therapeutics

Date: 11/6/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: learn about the FDA framework with advanced therapies

Content:

FDA structure and advanced therapeutics

Device (CDRH): PMA, 510(k), IDE

drug (CDER): NDA, IND

Biologic (CBER): BLA, IND

Genome Editing: target a precise genome locus and delete, insert, or change existing seuences

Gene Delivery: transfer molecular tools and assembled gene systems into the cell

Cell therapy: use expanded cells to transfer medicinal bio-activity to regenerate damaged tissue or restore health

dramatic implications

minimally manipulate? homologous use? Combined with another article? Systemic effect or dependent on metabolic activity of the cells?

-351 products are regulated as drugs and/or biologics while 361 products are largely unregulated

351 products have way more tests, trials, and restrictions to adhere to (much more regulated)

a target product profile allows you to determine: when to use a product, why to use a product, and how to use a product

patient identification: indication

patient benefits: efficacy profile

patient risks: safety profile

has to make a clear case that it is medically and commercially compelling

considerations when developing a 351-Regulated CGT

nonclinical: non-glp nonclinical studies and pilot tox studies

quality: CMC development

GLP: very expensive

clinical: phase trials

career options within a regulated environment: chemistry, manufacturing, controls

characterization and analytics, process development, manufacturing, management systems

Conclusions/action items:

Use this information to help design devices in school and beyond properly under the FDA constraints.

Lecture 10 11/13/2024

ANYA HADIM - Nov 13, 2024, 2:10 PM CST

Title: Lecture 10

Date: 11/13/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: Learn about all the stages of medical device design from fabrication to commercial selling

Content:

Medical device FDA Pathways

Device classification: Class 1, Class 2, Class 3

510(k) exempt, premarket notification 510(k) - must prove substantial equivalence to existing approved device

510(k) de novo - class 1/2 devices with no predicate

-FDA regulatory process takes time 75-180 days always double your estimate when planning for it

Steps from approval to adoption

clinical studies - FDA approval - CPT codes - CMS National insurance decisions - standards of practices - national regional buying groups - regional/local IDNs, hospitals - hospital/IDN value analytics groups - product evaluations - regional/just in time distribution - product implementation

Stakeholders:

administrative: purchasing, materials, IT, billing, value analytics

patient point of cars: MDs, RNs, RPh, Labs, OR, ER, OT

National/regional groups:

IDNs, Buying groups, distribution

trickle-down influence for new technology

National policy, standards of practice and clinical practice guidelines - health system and provider - payor

-the more specific you can be the better!

-start with a detailed patient (or diagnonsis) flow/care pathway

-explore pain points and gain creators

-expand your knowledge of the procedure or diagnosis payment

-examine about how products or therapies are adopted locally and nationally

-understand the impact of outside organizations

-consider unique purchasing and distribution organizations

Discovery to product mentorship and funding available

Conclusions/action items:

Use this knowledge moving forward with our careers following medical device design and creation

Tong Lecture 11/15/2024

ANYA HADIM - Nov 15, 2024, 1:19 PM CST

Title: Tong lecture

Date: 11/15/2024

Content by: Anya Hadim

Goals: Learn about the innovation process for Tasso

Speaker: Eriwn Berthier and Benjamin Casavant (PhD)

Key points:

Introductions: Both had unique ways to get into UW-Madison PhD program, they emailed professors in labs that research their interests - both ended up in a lab focusing around microfluidics. Benjamin Casavant completed his undergrad at Berkely in biomedical engineering. Eriwn completed schooling in France.

Together started a company, with the idea to perform a blood collection at home.

Initially: scraped together materials and asked around to start building prototypes. They reached out to the law & entrepreneurship clinic and they provided them with their first patent and other legal advice/documents. Got "scrappy" with funding opportunities - cracked out grants (wrote a ton) and eventually awarded a grant. Had a great idea, got the ability to defend their idea and pitch it to receive a grant.

Evolutionary of the technology: vacuum in the device (reached out to a professor doing OCG imaging to show the blood flow in capillaries). Learned more effective way to retrieve blood - you have to kill one prototype to make a better one.

"You can pick someone to do a lancet once, you can't trick them to do it twice" -- worked with this person to alter the product to his needs

USADA was also looking to switch anti-doping to blood but everyone hates needles and lancets even more: MLB (player unions agreed to this), UFC, cyclism converted to Tasso

Work with the people that had a problem, focusing on that specific problem and once that problem is solved, you get very good reviews from influential people (you cannot solve everything at once: one step at a time).

Innovation takes effort! Lots of different prototypes.

COVID shutdown: companies cancelled all the contracts to conserve money. Slowed down Tasso for a bit, but then people are interested in COVID antibody testing --> at home testing! Got a crazy influx for orders, needed a new building and more space to keep up with the demand.

Quality is key. One costumer that has a bad experience, will kill you. Develop systems to check and double check quality fast.

Culture of the company matters! Create an environment where people problem solve and "point in the same direction" to reflect the values of the company.

FDA: sold the collection tube and device separate to avoid super hard clearance (Class II IVD). Instead the lancet device only needed class I medical device (became the first company to get a lancet device approved separately). Be smart with the FDA!

If you have an idea that you believe in, go for it. People here want to help - there are lots of experts around. You will run into bumps in the road, but lean on others.

Naming of the company: Tasso is Italian for Badger!

Conclusion: If you have an idea, go for it.

Lecture 11 11/20/2024

ANYA HADIM - Dec 11, 2024, 3:06 PM CST

Title: Lecture 11 - How New Product Development Works in the Medical Device Industry

Date: 11/20/2024

Content by: Anya Hadim

Present:

Goals:

-understand how new products are selected and prioritized

-understand how NPD projects are managed and resourced

-define common hurdles/barriers

Content:

Speaker: Russ

How New Product Development Works in the Medical Device Industry

Smith & Nephew: orthopedic implants

Gyrus ENT (now Olympus): ENT implants and instruments

Cardinal Health: surgical products, environmental technologies, orthopedics

Hollister: ostomy products

TIDI Products: surgical and patient safety products

NPD in the medical device industry:

highly regulated - FDA and other regulatory bodies have a significant impact

expensive - requirement for verification and validation is a cost multiplier

resource intense - involves sizeable teams to execute projects

competitive - competition is fierce

Selecting and prioritizing projects:

corporate business strategy - define how the business will sustain itself

product portfolio review

project review

budgeting and resource allocation - allocate budget and resources based on project prioritization

Types of NPD projects

-line extensions

-product improvements

-new to company

-new to world

Managing NPD: Stage - Gate process

stage 0: idea

-choose area of opportunity

-review market trends and or competitive threats

-conduct primary and secondary market research

-identify customer unmet needs

-create high level "back of the napkin" ideas

stage 1: exploration

-define problems to be solved and customer requirements

-review, refine, screen list of ideas from stage 0 for exploration

-create concepts for 8-10 ideas

-define problem statement *** super critical, ask a lot of questions from the customer and ask why

stage 2: concept development

-get one leading concept based on all the feedback you received from client

stage 3: design development

-move to functional prototype

-continue iterative design process including initial testing and reviews with customers

-confirm regulatory pathway

-begin formal design control documentation

stage 4: design confirmation

-conduct extensive verification and validation testing

-finalize product and component drawings/models

-accelerate manufacturing process development along with plans for quality control

-freeze design at the end of this stage

-submit FDA documentation

stage 5: design transfer and commercialization

-complete any remaining testing

-make final design changes

-build molds assembly/test equipment

-create instructions for use and user manuals

-develop service plan and resources

-finalize go-to-market strategy and start limited release (if applicable)

Conclusions/action items:

Relate this information to our project to see how the process would be were it to be commercialized. Use this information moving forward with real world medical device projects.

09/08/2024 - Ankle Foot Orthosis Vocabulary

Presley Hansen - Sep 11, 2024, 11:43 PM CDT

Title: Vocabulary Research

Date: 09/08/2024

Content by: Presley Hansen

Present: N/A

Goals: Gain a better understanding of the basic vocabulary regarding Ankle Foot Orthosis (AFO)

Content:

Ankle dorsiflexion: the movement of the foot that brings the toes closer to the knee [1]

gait: a person's manner of walking

AFOs: Ankle foot orthoses are external biomechanical devices utilized on lower limbs to stabilize the joints and improve the gait and physical functioning of the affected lower limb. AFO is used as supportive devices and aid for walking through different gait stages by providing foot clearance by limiting or assisting ankle range of motion (ROM). [2]

Ambulation: the ability to walk

gait cycle: The basic unit to characterize the way of walking. Made up of two phases: stance and swing

Swing phase: the period when the foot is in the air

concentric contractions: a type of muscle contraction that occurs when a muscle shortens while generating force

Loading phase of gait: Loading response occurs while both limbs are on the ground, leading into the next segment of the phase, where body weight is transferred, and the opposite leg is elevated.

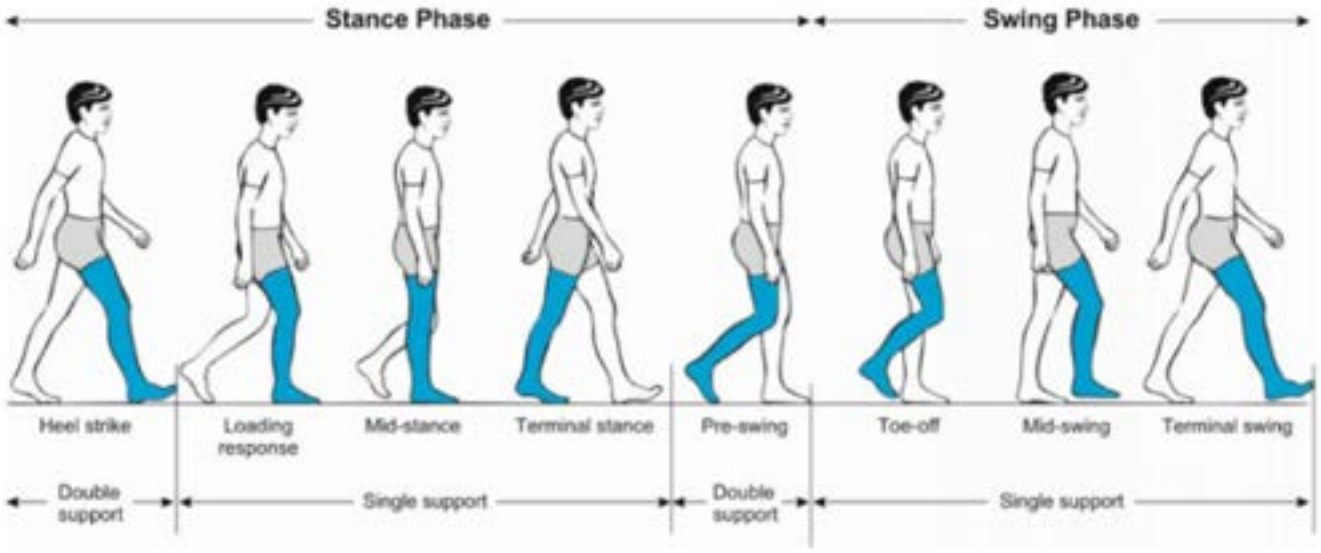


Figure 1: Gait cycle phases [3]

Foot slap: Also known as foot drop, slapping gait, or step-page gait. Foot drop is a condition that makes it difficult to lift the front of the foot, which can cause the foot to slap the ground when walking. [4]

References:

[1] "Tulsa Spine and Rehab," *Tulsa Spine and Rehab*, Feb. 2023. https://tulsaspineandrehab.com/spinecast/ankle-dorsiflexion/#:~:text=Ankle%20dorsiflexion%20is%20a%20fancy (accessed Sep. 08, 2024).

[2] "Introduction to Ankle Foot Orthoses," *Physiopedia*. https://www.physiopedia.com/Introduction_to_Ankle_Foot_Orthoses

[3] Researchgate, "Researchgate," *ResearchGate*, 2024. https://www.researchgate.net

[4] "Foot drop - Symptoms and causes," *Mayo Clinic*. https://www.mayoclinic.org/diseases-conditions/foot-drop/symptoms-causes/syc-20372628#:~:text=Foot%20drop%20makes%20it%20difficult

Conclusions/action items: learn more about types of AFOs; possibly learn about characteristics of the gait pattern; research Facioscapulohumeral Dystrophy (FSHD)

09/08/2024 - Types of AFOs

Presley Hansen - Sep 11, 2024, 11:44 PM CDT

Title: Types of AFOs Research

Date: 09/08/2024

Content by: Presley Hansen

Present: N/A

Goals: To learn about different types of AFOs

Content:

Traditional plastic AFO[1]:

- provides maximum medial/ lateral joint stability
- better for short-term use
- easy to apply, cover a variety of needs, and are an economic choice
- can be customized by heat molding
- difficult to insert in shoes

Figure 1: Traditional plastic AFO [2]

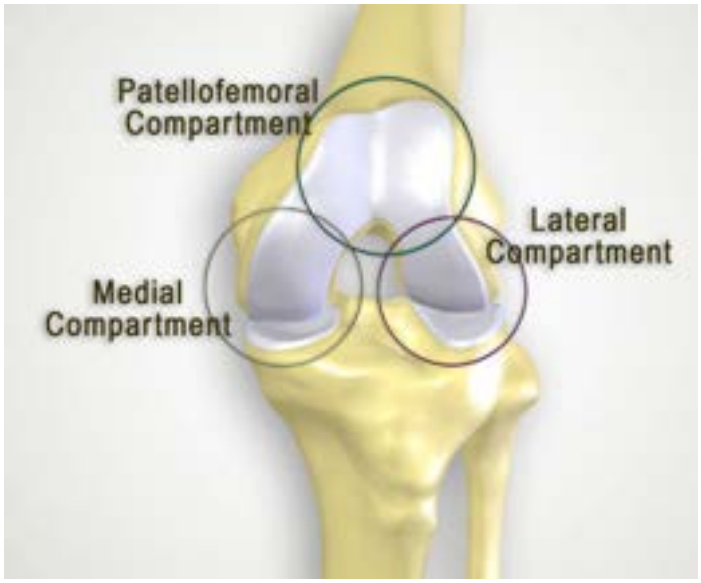


Figure 2: Medial and lateral knee joint locations [3]

Swedish AFO[1]:

- They have a lower profile than traditional AFO (less noticeable/easier to conceal) and an easy shoe fit
- can also be customized by heat molding
- Provide moderate lateral stability
- Assist with static ankle dorsiflexion and are suitable for the moderately active person
- They have free cub space for the heel and calf muscle so they are comfortable in use

Figure 3: Swedish AFO [4]

Carbon Fiber AFOs[1]:

- modern dynamic, semi-flexible, lightweight
- 10-15 degree tilting on footplate staring at the metatarsal heads (midfoot)
- Open heel and low profile design to help avoid the pressure and contact with critical pressure points of foot (also to add stability and strength)
- lateral support to control the medial instability, ankle pronation (the amount that the foot rolls inward toward the arch) and ankle eversion (involves tilting the sole of the foot outward).
- They are the best choice for an active person to encourage the normal gait pattern and control torsion forces

Figure 4: Carbon Fiber AFO [5]

References:

[1] "Introduction to Ankle Foot Orthoses," *Physiopedia*. https://www.physiopedia.com/Introduction_to_Ankle_Foot_Orthoses

[2] "Custom AFOs," *Acor.com*, 2024. https://acor.com/products/axis-afo-plastic-afos (accessed Sep. 08, 2024).

[3] "Understanding Knee Arthritis | Hofmann Arthritis Institute," Jun. 21, 2021. https://hofmannarthritisinstitute.com/understanding-knee-arthritis/

[4] “1600 Swedish AFO - Ortho Active,” *Ortho Active*, Jan. 08, 2024. https://orthoactive.com/product/1600-swedish-afo/ (accessed Sep. 08, 2024).

[5] “Carbon Fiber AFO – Rapid Orthopedic Supplies.” https://rapidortho.com/product/carbon-fiber-afo/

Conclusions/Action Items: Research Facioscapulohumeral Dystrophy (FSHD)

09/08/2024 - Facioscapulohumeral Dystrophy (FSHD)

Presley Hansen - Sep 11, 2024, 11:45 PM CDT

Title: Facioscapulohumeral Dystrophy (FSHD) Research

Date: 09/08/2024

Content by: Presley Hansen

Present: N/A

Goals: To learn more about FSHD

Content:

- FSHD is a genetically acquired disease that leads to progressive muscle weakness and severely decreased functional capacity in affected individuals

- inherited in an autosomal dominant fashion (A child has a 50% chance of inheriting a mutated gene from a parent with the condition) that affects skeletal muscle tissue in affected individuals.

- FSHD characteristically starts proximally in the face and spreads distally to affected muscle groups

- FSHD is one of the most prevalent types of muscular dystrophy currently known

- The onset of physical exam findings in FSHD can occur across an individual's entire lifespan but most frequently occur in the second decade of life

- There are currently no disease-modifying treatments for FSHD.

- care for FSHD is primarily in the context of physical therapy, rehabilitation exercises, and assistive devices

- While the overall lifespan in these patients is not affected, roughly 20 percent of affected individuals will experience disability significant enough to require wheelchair use during the course of the disease

References:

C. Fecek and P. D. Emmady, “Facioscapulohumeral Muscular Dystrophy,” *PubMed*, 2021.
https://www.ncbi.nlm.nih.gov/books/NBK559028/

Conclusions/Action Items: To learn about FSHD more specifically in teens and in regards to the ankle and foot

09/10/2024 - Powered AFO

Presley Hansen - Sep 11, 2024, 11:46 PM CDT

Title: Powered AFO research

Date: 09/10/2024

Content by: Presley Hansen

Present: N/A

Goals: To learn more about AFOs that will help ankle dorsiflexion

Search Term: ankle braces for ankle dorsiflexion; PubMed

Link: https://pubmed.ncbi.nlm.nih.gov/37864265/

Content:

- Study: Ten foot drop patients with hemiparesis (a condition that causes a loss of strength or weakness on one side of the body) were fitted with a custom AFO with an adjustable calf brace and portable air compressor for ankle dorsiflexion assistance in the gait cycle during the swing phase. All subjects walked under two different conditions without extensive practice: (1) barefoot and (2) wearing a powered AFO. Under each condition, the patients walked back and forth on a 9-m track with ten laps of level ground under the supervision of licensed physical therapists. The lower-limb joint and trunk kinematics were acquired using 12 motion-capture cameras.

- Results: kinematic asymmetry decreased in the three lower-limb joints after ankle dorsiflexion assistance during the swing phase. The average ankle-joint angle increased after using the AFO during the entire gait cycle. Also, The knee-joint angle showed a slight increase while using the AFO. [1]

Figure 1: AFO air-compression design [1]

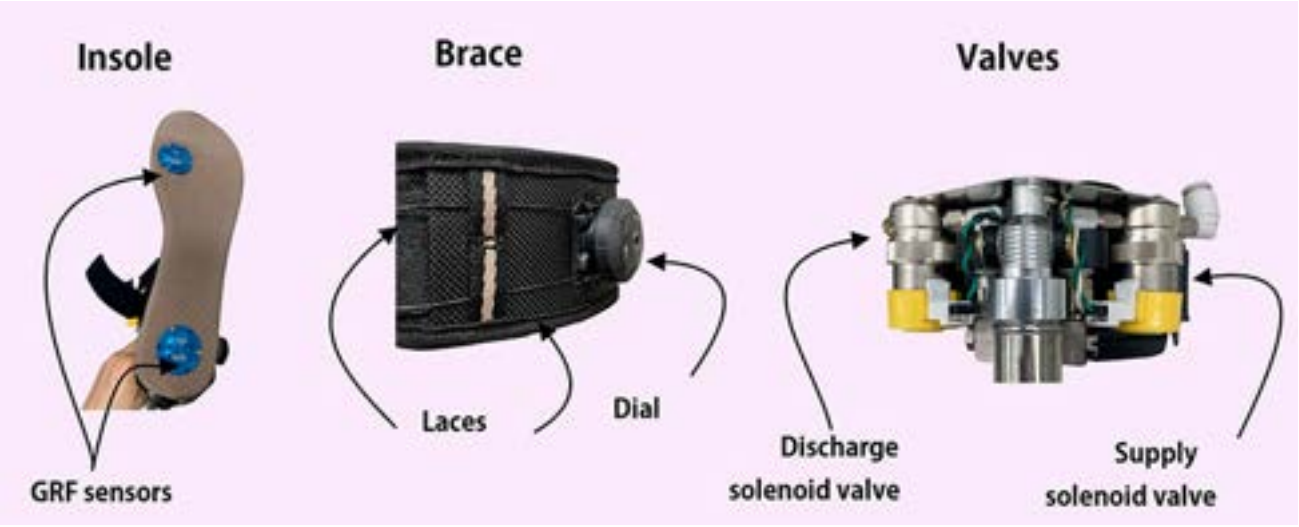


Figure 2: AFO design for insole, brace, and valves [1]

References:

[1] Weon Ho Shin *et al.*, "Ankle dorsiflexion assistance of patients with foot drop using a powered ankle-foot orthosis to improve the gait asymmetry," *Journal of Neuroengineering and Rehabilitation*, vol. 20, no. 1, Oct. 2023, doi: https://doi.org/10.1186/s12984-023-01261-1.

Conclusions/Action Items: Learned about an interesting AFO design incorporating a pneumatic actuator and how that study was carried out.

09/23/2024 - Adjustable Foot Drop Brace

Presley Hansen - Oct 05, 2024, 9:39 PM CDT

Title: Adjustable Foot Drop Brace

Date: 09/23/2024

Content by: Presley Hansen

Present: N/A

Goals: To explore current AFOs on the market and see if any features can be implemented into our design.

Content:

Figure 1: Adjustable Foot Drop Brace at Walmart [1]

Figure 2: Adjustable Foot Drop Brace With Shoe On [1]

Citation:

[1] "Foot Up AFO Foot Drop Brace Adjustable Ankle Foot Orthosis Support for Men & Women and Kids - Improve Walking Gait, Achilles Tendon, Hemiplegia, Stroke & Pain Relief - Comfort fit for Right, Left," *Walmart.com*, 2023. https://www.walmart.com/ip/Foot-Up-AFO-Drop-Brace-Adjustable-Ankle-Orthosis-Support-Men-Women-Kids-Improve-Walking-Gait-Achilles-Tendon-Hemiplegia-Stroke-Pain-Relief-Comfort-fi/1719792090 (accessed Oct. 06, 2024).

Conclusions/action items: This design is comfortable for the user, supports ankle dorsiflexion, and looks similar to an athletic brace which could limit questions regarding its functionality (improve discreetness). The main problem with this design is that the strap connects to the outside of the shoe which is not very discreet. This gave us inspiration for one of the designs in our design matrix, the Bungee Brace. We can change the strap to a bungee cord that trails along the top of the foot so it can still tighten to a favorable level of dorsiflexion and be concealed inside the shoe. The other problem with this design is that it does not support anke inversion. We created a final design that combined aspects of the three designs in the design matrix so there is sufficient ankle dorsiflexion and minimal/no ankle inversion. The final design is described under the Design Ideas folder (labeled Final Design Idea).

09/17/2024 - AFO Standards

Presley Hansen - Sep 17, 2024, 9:45 PM CDT

Title: AFO Standards

Date: 09/17/2024

Content by: Presley Hansen

Present: N/A

Goals: To find AFO-related standards and include in the PDS

Content:

- ISO Standard 8549-3:2020 defines orthosis as an externally applied device utilized to compensate for impairments in the structure and function of the neuromuscular and skeletal system; ankle-foot orthosis is defined as an orthosis that encompasses the ankle joint and the whole or part of the foot [1].

- ISO Standard 8551:2003 covers functional deficiencies in prosthetics and orthotics. The standard provides guidelines for the person to be treated with an orthosis, the clinical objectives of treatment, and the functional requirements of the orthosis. The initial objective is accomplished by outlining the procedures and terms to describe the patient's medical condition. The second objective is to standardize the definition of “clinical objectives” in orthotic treatment which are listed as nine fundamental objectives. The last part of the standard outlines the procedures and terms to describe the “functional requirements” of the orthosis that are necessary to meet the previously established clinical objectives [2][3].

Citations:

[1] Iso.org, 2024. https://www.iso.org/obp/ui/en/#iso:std:iso:8549:-3:ed-2:v1:en (accessed Sep. 18, 2024).

[2] Iso.org, 2024. https://www.iso.org/obp/ui/en/#iso:std:iso:8551:ed-2:v1:en (accessed Sep. 18, 2024).

[3] A. Nouri, L. Wang, Y. Li, and C. Wen, “Materials and manufacturing for ankle-foot orthoses: A review,” *Advanced Engineering Materials*, vol. 25, no. 20, Jul. 2023, doi: https://doi.org/10.1002/adem.202300238.

Conclusions/action items: Found two ISO standards that related to AFOs. Add to the PDA and continue research.

09/23/2024 - Design Idea Sketches

Presley Hansen - Sep 24, 2024, 4:32 PM CDT

Title: Design Idea Sketches

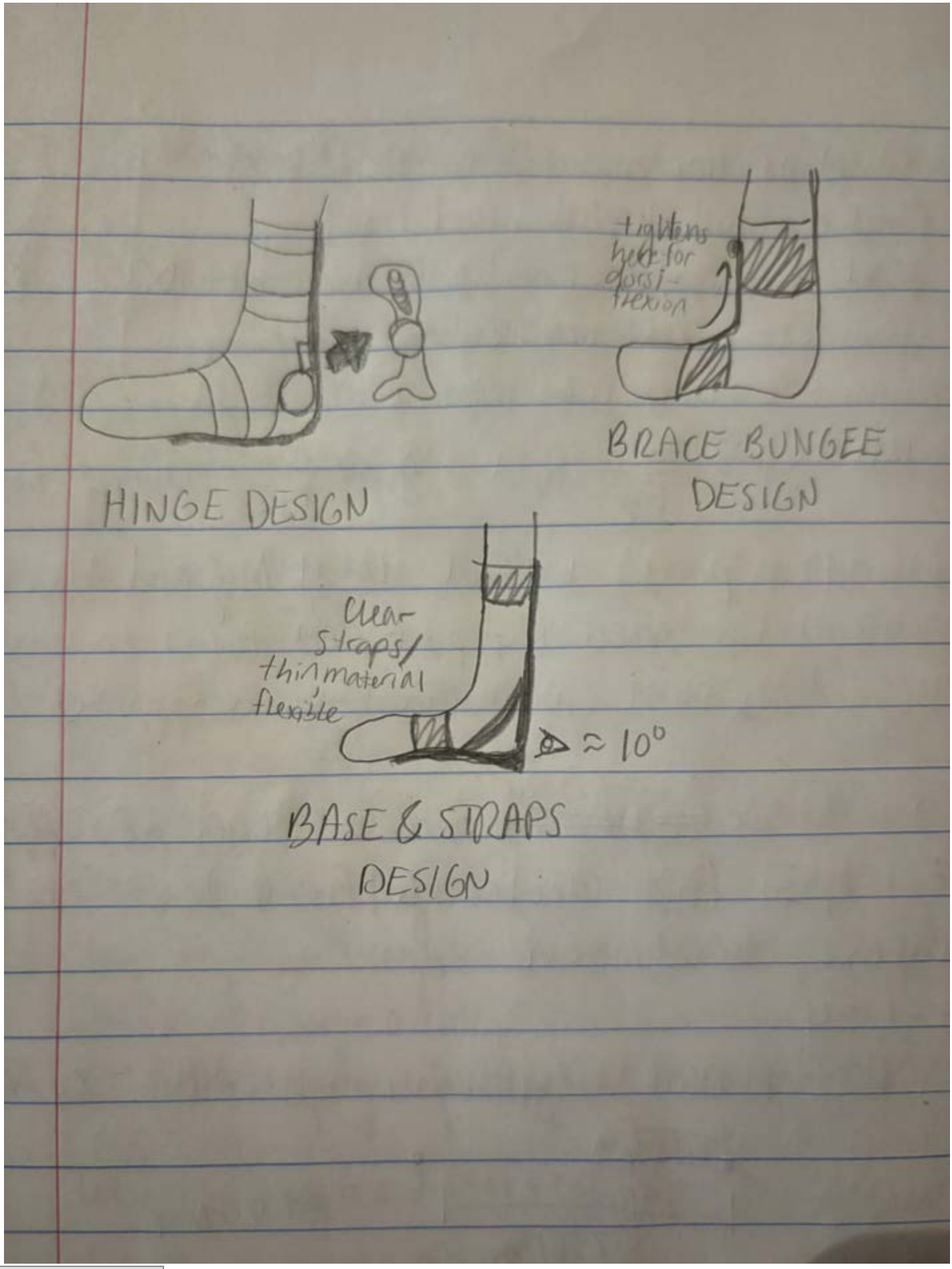
Date: 09/23/2024

Content by: Presley Hansen

Present: All team members

Goals: Work with team to come up with three solid design ideas to include in the design matrix.

Content:



Conclusions/action items: Came up with 3 AFO designs; after discussing with Maggie, completing the design matrix, and completing testing in Solidworks, we can choose the best design or combination and start looking further into materials.

09/30/2024 - Final Design Idea

Presley Hansen - Oct 05, 2024, 10:35 PM CDT

Title: Final Design Idea

Date: 09/30/2024

Content by: Presley Hansen

Present: N/A

Goals: To come up with a final design that incorporates the three designs from the design matrix.

Content:

Figure 2: Medial View of Carbon Fiber Support in Solidworks

Figure 1 shows the final design idea. This incorporates the bungee brace design because of its comfort and flexibility for ankle dorsiflexion. It also adds the part of the carbon fiber support of the strap brace design. Carbon fiber provides more support for the user and prevents ankle inversion through the section that travels medially. Figure 2 shows the solidworks design for the carbon fiber support (made by Lucy and Anya). This should be stress-tested and analyzed in Solidworks. This can be incorporated with the patients current orthotic insoles as well.

Conclusions/action items: Stress testing in Solidworks

10/01/2024 - Material Ideas and Research

Presley Hansen - Oct 05, 2024, 10:13 PM CDT

Title: Material Ideas and Research

Date: 10/01/2024

Content by: Presley Hansen

Present: N/A

Goals: To find possible materials for the design ideas.

Content:

The bungee brace design consists of a rotator dial with a bungee cord, adjustable velcro straps, and a non-rigid material for the straps themselves. Neoprene could be a good non-rigid material to use because it is a synthetic rubber which will provide flexibility and comfort. Neoprene is stronger and more resistance to water, oils, and solvents than natural rubber [1]. Neoprene is also resistant to temperature ranges between -35°C and +100°C and resistant to damage from twisting and flexing [2].

The strap brace design consists of a carbon fiber body which has excellent stiffness and strength. This helps provide better stability to the ankle and foot [3]. Carbon fiber is more flexible than other plastics so the anke can still dorsiflex but it is more rigid than other materials so it can provide support. The downside to carbon fiber is that it is very expensive. Another component of the design is the straps made of TPE filament. TPE stands for Thermoplastic Elastomer and is a rubber that has both thermoplastic and elastomer properties [4]. This rubber can be 3D printed and is very flexible which will be ideal for the straps. These straps can also be made clear which makes the design more discreet.

Citations:

[1] "Neoprene," *Chemical Safety Facts*, Oct. 14, 2022. https://www.chemicalsafetyfacts.org/chemicals/neoprene/

[2] "What is neoprene rubber used for?," *Aquaseal Rubber Ltd*, Mar. 03, 2021. https://www.aquasealrubber.co.uk/general/what-is-neoprene-rubber-used-for/

[3] "Benefits of Carbon Fiber AFOs," *thriveorthopedics.com*, Jan. 30, 2023. https://thriveorthopedics.com/blogs/news/benefits-of-carbon-fiber-afos

[4] "TPE vs. TPU: Differences and Comparison," *www.xometry.com*. https://www.xometry.com/resources/3d-printing/tpe-vs-tpu-3d-printing/

Conclusions/action items: Neoprene and TPE could be good materials to move forward with. Carbon fiber is a good final prototype material but for an initial prototype, something cheaper with similar properties should be used.

09/28/2024 - HIPAA Certification

Presley Hansen - Sep 28, 2024, 3:46 PM CDT

WISCONSIN
UNIVERSITY OF WISCONSIN–MADISON

This certifies that Presley Hansen has completed training for the following course(s):

Course	Assignment	Completion	Expiration
2023-24 HIPAA Privacy & Security Training	HIPAA Attestation	9/27/2024	

09/29/2024 - Human Subjects Research Certificate

Presley Hansen - Sep 29, 2024, 10:50 PM CDT

CITI PROGRAM

Completion Date 29-Sep-2024
Expiration Date 29-Sep-2027
Record ID 65507280

This is to certify that:

PRESLEY HANSEN

Not valid for renewal of certification through CME.

Has completed the following CITI Program course:

Basic/Refresher Course - Human Subjects Research
(Curriculum Group)
UW Human Subjects Protections Course
(Course Learner Group)
1 - Level 1
(Stage)

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09/11/2024 - BME Career Prep

Presley Hansen - Sep 11, 2024, 11:47 PM CDT

Title: BME Career Prep

Date: 09/11/2024

Content by: Presley Hansen

Present: Presley Hansen

Goals: To get ready for the career fair and job searching

Speaker: Stephanie Salazar Kann

Content:

Job search tips:

- Keep track of what you do (ECS tracking sheet- ecs.wisc.edu/resources)

- Quality of source matters - Handshake, LinkedIn, Indeed...

- Connect BEFORE you are a candidate - use your people! --> go to the career fair to get a leg up

- Applying is step 1 - follow-up is required (2-3 weeks*) --> follow up with specific person you talked to

- Think beyond the title - focus on skills, industry, exposure

- It takes time!

Resume Tips:

- Tailor your resume to the position - quick changes

- Create balance - show a full picture of your experience

- "Flawless" product - ATS proofed resume is do-able

    - Use MS Word

    - No columns, charts, colors

    - Design projects WITHOUT years or semesters - what did you do?

    - Technical skills and coursework

    - Jobs - Organization + Location, Position title + Dates

- Lots of ECS help still available before the fair

- be prepared to apply online but don't actually send the resume until you have talked to the organization at the fair - you might get tips or specific advice at the fair

- DON'T PUT ANYTHING IN HEADER

Cover Letter Tips:

- ALWAYS based on the job posting

- Custom to each job

- Don't need for career fair

Career Fair Advice:

- Identify your purpose - more than just an internship
- Looking beyond the obvious - overlap with other disciplines
- Research the employer - feedback from our partners
- Develop your "value added" statement - why you?

Don't get caught up in job posting titles

Career Fair is Sept 16-Sept 19

Each day has different employers!

11am-5pm

EH Lobby, ME Lobby, ECB Lobby

Look at BME, ME, and EE!!

Internships abroad:

- International internship program: they have a database to log into and search around the world
- Resumes are not the same everywhere else

Conclusion/Action Items: Finalize resume!

Presley Hansen - Sep 11, 2024, 11:40 PM CDT

This was submitted on time, but we set up the wrong notebook and had to make a new one. We transferred over the documents but the time stamps are wrong.

09/18/2024 - Leadership Lecture

Presley Hansen - Sep 18, 2024, 2:02 PM CDT

Title: Leadership Lecture

Date: 09/18/2024

Content by: Presley Hansen

Present: N/A

Speaker: Dr. Angela Kita

Goals: To learn about exploring your leadership style

Content:

- We talked about whether we feel like we are leaders and what we feel are important qualities of a leader

- Some qualities include confidence, knowledge, communication, organization, empathy, and facilitation

- Top answers online: self-awareness, having a vision, being transparent, communication, decision-making, empathy

- Three examples of leadership styles:

- Power model: "Someone has to take control here, and it should be me."; only certain people are born to lead; being in control is the most important thing

- Servant leadership: "It's not about me and my needs, the needs of my followers is most important"; being of service to others, sharing power, listening and understanding; shared decision making, empathetic, empowering

- Authentic leadership: "By being my genuine self, I will gain and build trust"; building self-esteem and self-awareness; emotional intelligence. honestly, transparency

- People-oriented leader: glue that holds the team together; gets to know everyone

- process-oriented leader: sets the pace for the team and is willing to work alongside everyone

- thought-oriented leader: sees the big picture and anticipates the future

- impact-oriented leader: you set the bar high and push for excellent performance

- leading others starts with leading yourself

- how do you want to lead? self-assess, observe and reflect, and seek out feedback

Conclusions/action items: Learned more about what makes a leader and how we can become better ones.

09/25/24 - Fall Post Graduate Planning

Presley Hansen - Sep 25, 2024, 2:09 PM CDT

Title: Fall Post Graduate Planning Lecture

Date: 09/25/24

Content by: Presley Hansen

Present: N/A

Goals: Learn about post-graduate planning

Speaker: John Puccinelli

Content:

- Use your undergraduate experience to build a story

- Think about letter writers or references early - 3 strong ones

- Start with what you want to do - thesis statement (your narrow experience(s) and how that applies to your broad interest; specific to each position or place to which you apply)

- Check key words that they are looking for for job application and tailor to resume

- Defend your plans with your life experiences

- MS is a stepping stone for industry because it opens doors, higher starting salary, time to find dream job

- Acccelerated program (1 year): can be coursework only and can pay for tuition through being a TA

- A lot of information was given about Medical school and PhD's, but I am planning on going straight to industry.

- After 5 years, 6 credits don't count towards accelerated masters program anymore (30 credits instead of 24)

Conclusions/action items: Learned about tips for applying to jobs and about the specific masters and medical school programs here

10/02/2024 - Near Peer Mentoring

Presley Hansen - Oct 02, 2024, 2:08 PM CDT

Title: Near Peer Mentoring Lecture

Date: 10/02/2024

Content by: Presley Hansen

Present: N/A

Speaker: Prof. Tracy Puccinelli

Goals:

Content:

- Mentoring BME 200 students helps us learn how to teach and solidify what we know

- easier to confide in us compared to professors/advisors

- coursework is more fresh in mind

- additional instructional and emotional support for students

- peer mentors are more approachable, mentees are more willing to ask questions

- share experiences (Courses, internships, research, etc.)

- increases belonging

- mutual benefits (transferrable skills)

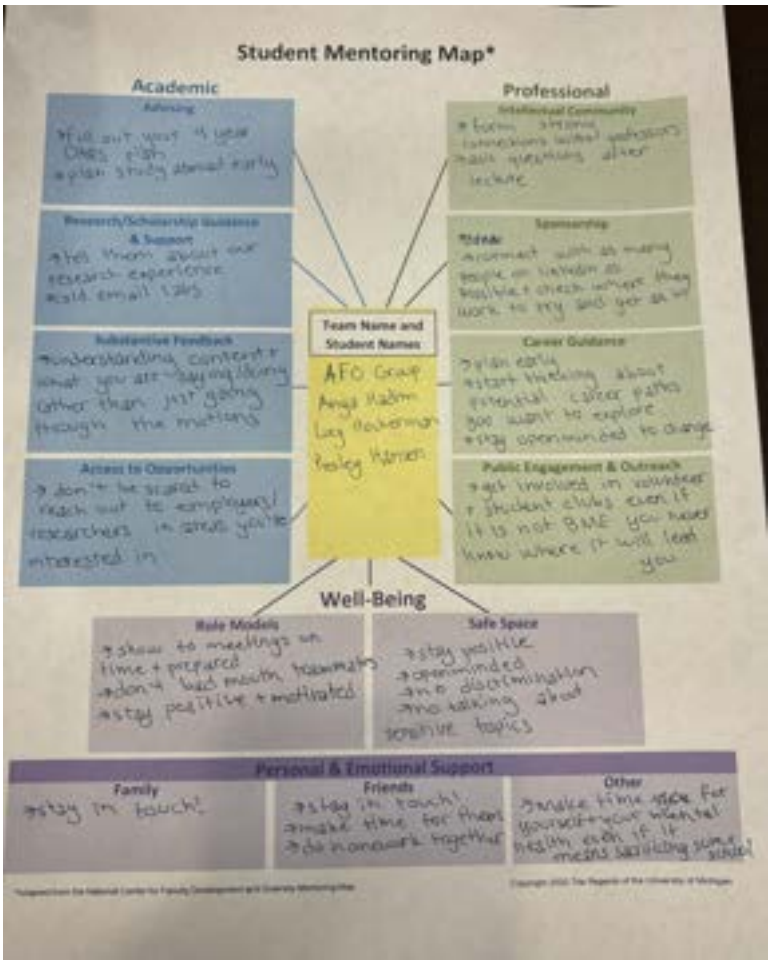
- Transferable skills like leadership, communication, active listening, study practices, self awareness, interpersonal skills

- general benefits of mentoring like increased self esteem/confidence, increased patience, build positive habits, foster personal growth, help identify gaps in own knowledge, sense of accomplishment

- What does it mean to be a good mentor? building trust, psychological safety, reliability, support/enthusiasm, being available, transparent, humanizing their challenges: be the coach, good listening

- how to listen effectively: get rid of distractions, stop talking, act like you're interested, look at the other person, get the main idea, ask questions, check for understanding, react to ideas, not to the person

mentor map:



Conclusions/action items: Brainstormed what it means to be a good peer mentor and make a mentor map

10/09/2024 - Sustainable Engineering

Presley Hansen - Oct 09, 2024, 2:25 PM CDT

Title: Sustainable Engineering Lecture

Date: 10/09/2024

Content by: Presley Hansen

Present: Presley Hansen

Speaker: Andrea Hicks

Goals: To learn about sustainable engineering

Content:

- Circle economy

- life cycle assessment: resources --> processing--> manufacturing --> distribution --> use --> end of life

- think about sustainability fits into your project --> our device is already reusable but we should pick an environmentally friendly material in case this product will ever be mass produced

Conclusions/action items: Though about how sustainability fit into our project

10/16/2024 - Patents and Licensing with WARF

Presley Hansen - Oct 16, 2024, 2:06 PM CDT

Title: Patents and Licensing with WARF

Date: 10/16/2024

Content by: Presley Hansen

Present: Presley Hansen

Speaker: Justin Anderson

Goals: To learn about patents and licensing

Content:

- WARF enables UW-Madison research to solve the world's problems

- WARF is a nonprofit supporting organization governed by a board of UW-Madison alumni with expertise in a variety of fields

- WARF works to facilitate securing IP rights and commercial licenses

- Four common types of IP: Patents, copyrights, trademarks, and trade secrets

- Other, WARF IP: Biomaterials, technique and know how, and data

- Copyrights: Protection for creative works that are expressed in a tangible medium

- Trademarks: Protection for names, marks, logos, dress, etc.

- Trade secrets: can be used to protect anything of value

- Patent: A patent is a property right, granted by a governmental agency

- Patent holder has right to exclude others from making, using, selling, or importing the claimed invention

- Three different types of U.S. patents: design (15-year term), plant (20-year term), and utility (provisional and non-provisional term)

- Requirements for patents include: Must be eligible, must be novel, most be non-obvious, must be enabled and described

- WARF receives about 400 new innovation disclosures each year

- Can AI invent? No!

Conclusions/action items: Learned about WARF, and types of IP

10/23/2024 - Do I need an IRB?

Presley Hansen - Oct 23, 2024, 2:09 PM CDT

Title: Do I need an IRB?

Date: 10/23/2024

Content by: Presley Hansen

Present: Presley Hansen

Goals: To learn about human participants research requirements

Speaker: Jennifer Fenne

Content:

- IRB = Institutional Review Board

- unethical research --> ethical principles --> human research regulations

- Infamous studies like WWII Nazi prisoner experiments, Hepatitis studies at Willowbrook State School for Children, Milgram shock experiments at Yale, Tuskegee Syphilis Study. etc.

- instituded by Common Rule and FDA regulations

- Minimal Risk Research IRB (MRR IRB) and Health Sciences IRB (HS IRB) at UW-Madison

- Research means a systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

- Human subject means a living individual about whom an investigator conducting research obtains information through interventions or obtains identifiable private information or identifiable biospecimens

- complete required training for researchers through CITI (Human Subjects Protection Training, HIPAA Privacy and Research training, Conflict of Interest training, Good clinical practice training)

- PBA components:

- Protocol document, informed constent forms, recruiting tools, screening scripts, written assessments

- IRB review process: UROC review, SRC/PRMC review, pre-review by IRB staff, review at IRB meeting, committee determination

Conclusions/action items: learned about human participants research requirements

10/30/2024 - Navigating FDA Device Requirements

Presley Hansen - Oct 30, 2024, 2:10 PM CDT

Title: Navigating FDA Device Requirements

Date: 10/30/2024

Content by: Presley Hansen

Present: Presley Hansen

Speaker: Jake Rome

Goals: Learn about FDA Regulated Research and how it applies to our design process

Content:

- Classes of Marked Medical Devices:

- class 1 --> low risk --> exempt from premarket approval (i.e. band-aids)

- minimal potential for harm, mostly exempt from premarket notification and quality system requirements, must follow certain general controls like labeling, record retention, and complaint files, approval process is self registration and listing with the FDA

- class 2 --> moderate risk --> 510k showing substantial equivalence (i.e. BP cuffs, sutures, etc.)

- must follow general and special controls which can include performance standards, post-market surveillance, and specific labeling requirements; approval process is submission of a 510k application to show substantial equivalence (may be exempt)

- class 3--> high risk --> premarket approval

- risk - sustain or support life, implanted, or potential for unreasonable risk; must follow general controls and additional stringent requirements, such as clinical trials to demonstrate safety and efficacy; PMA submission which involves a comprehensive FDA review of safety and effectiveness data before marketing

- Regulatory Controls Key Elements: General controls, special controls, premarket approval

- 510k exempt, 510k premarket notification, PMA premarket approval, de novo classification

- Quick search to classify your medical device, 510k device lookup, PMA devices - through FDA, medical devices, databases

Conclusions/action items: Learned about class of marked medical devices, searching things up through FDA, etc.

11/06/2024 - Bringing biologics to market

Presley Hansen - Nov 06, 2024, 2:23 PM CST

Title: Bringing biologics to market

Date: 11/06/2024

Content by: Presley Hansen

Present: Presley Hansen

Speaker: William Murphy

Goals: Learn about bringing biologics to market including FDA Structure, advanced therapeutics, etc

Content:

- Device (CRH): PMA, 510k, IDE

- Drug(CDER): NDA, IND

- Biologic (CBER): BLA, IND

- Genome editing, gene delivery, and cell therapy

- U.S. laws --> regulations (CFR Title 21) --> FDA guidance

-351 products are biologic, required for marketing, indicated for a specific therapeutic use, potency assured, purity assured, novel design, high barrier to entry, randomized controlled trials, 12 years marketing exclusivity

- 361 products are HCT/P, not required for FDA approval, no clinical claims, bot tested in potency, not tested in purity, commodity design, low barrier to entry, no clinical data requirements, no marketing exclusivity

- "each stage of the product development cycle faces its own risks and challenges, and proper management of these risks in vital for successful commercialization."

- A target product profile (TPP) is your product vision

- GLP: Good laboratory practice

- CMC: Chemistry manufacturing controls

Conclusions/action items: Learned about bring biologics to the market

11/13/2024 - Medical Device Innovation

Presley Hansen - Nov 13, 2024, 2:20 PM CST

Title: Medical Device Innovation

Date: 11/13/2024

Content by: Presley Hansen

Present: Presley Hansen

Speaker: Aimee Arnoldussen

Goals: To learn about medical device innovation from prototype to commercial clinical use

Content:

- There are different medical device FDA pathways with 3 device classifications, etc.

- Breakthrough devices program

- Medical Device Process at a Glance: Innovation Idea and development --> human testing data acquisition with IRB oversight --> FDA regulatory process --> reimbursement or financial incentive --> sales

- Clinical studies --> FDA approval --> CPT codes--> cms national insurance decisions --> standards of practices --> national regional buying groups --> regional/local IDNs, Hospitals --> Hospitals/IDN value analytics groups --> product evaluations --> regional/just in time distribution --> product implementation

- if we define value more broadly as improving patient outcomes while making it more affordable to deliver those outcomes, there is a wider range of possibilities for product developers, providers and payers to collaborate, and signs of progress are easier to find

- national policy, standards of practice and clinical practice guidelines --> health system and provider --> payor

- existence of codes do not equal financially favorable

- innovate.wisc.edu

- nerve ninja is class 1 device

Conclusions/action items: Learned about medical device innovation

11/15/2024 - Tong Lecture

Presley Hansen - Nov 15, 2024, 12:46 PM CST

Title: Tong Lecture

Date: 11/15/2024

Content by: Presley Hansen

Present: Presley Hansen

Goals: To learn about starting a business from scratch (specifically Tasso in this case)

Content:

- Tasso creates at-home diagnostic access (blood sampling kit)

- Realized people don't want to go in to get blood draws because of far drive, waiting room, pain, etc. ---> can make an at-home sample?

- resources around uw-madison university for starting a business --> law and entrepreneurship clinic

- SBIR grants

- you have to kill products to get to a better product but you have to do so in a careful way (think of the people currently using it)

- listen to the people out there who want the technology

- "you can trick someone to do a lancet once, you can't trick them to do it twice"

- MLB, UFC, cyclism converted to Tasso

- Tasso developed a tamper-proof security case to solve the chain-of-custody problem

- USADA was looking to switch anti-doping to blood but everyone hates needles and lancets even more

- COVID caused huge backlog --> needed to scale up

- when you scale up, quality is key (that one customer who has a bad time tells other people and then you are out --> better to negotiate)

- Class II IVD is super hard clearance; Class I medical device has super easy clearance

- Read the labels - easy to over analyze what regulators say they "want" to do

- first landset cleared this way (being clever in regulatory strategy)

- Tasso is Italian for badgers! Where name comes from!

Conclusions/action items: Learned a lot about the start up of Tasso

11/20/2024 - New Product Development

Presley Hansen - Nov 20, 2024, 3:12 PM CST

Title: New Product Development

Date: 11/20/2024

Content by: Presley Hansen

Present: Presley Hansen

Speaker: Russ Johnson

Goals: Learn how new product development works in the medical device industry

Content:

- NPD in the medial device industry is: highly regulated, expensive, resource intense, and competitive

- corporate business strategy --> product portfolio review --> project review --> budgeting and resource allocation

- types of NPD projects: line extensions, product improvements, new-to-company, new-to-world (left to right is increasing risk, cost, etc)

- managing NPD: State-gate process: stage 0 is ideation, stage 1 is exploration, stage 2 is concept development, stage 3 is design development, stage 4 is design confirmation, stage 5 is design transfer and commercialization, post market surveliance

- "cloud" --> "funnel" --> "tunnel"

- stage 0: Ideation: choose area of opportunity, review market trends and/or competitive threats, research, consumer unmet needs, etc.

Conclusions/action items: Learned how new product development works in the medical device industry

09/08/2024: The affects of FSHD on ankle mobility

Lucia Hockerman - Sep 12, 2024, 9:46 AM CDT

Title: The affects of FSHD on ankle mobility

Date: Sept. 8, 2024

Content by: Lucy Hockerman

Present: N/A

Goals: Understand and learn how Facioscapulohumeral muscular dystrophy (FSHD) affects ankle mobility

Content:

There are several impacts FSHD has on ankle strength and stability. The severity of the effects depends on the individual and the disease progression.

Listed below are several impacts on leg and ankle mobility:

1.) Due to lack of muscle and control, individuals struggle lifting their foot in an ankle dorsiflexion-like manner. This causes a symptom called "foot drop" while walking [1].

2.) In addition to "foot drop", as the disease progresses the ankle gets weaker causing additional mobility problems. In addition to problems with dorsiflexion, plantarflexion (pointing toes downward) could be affected [2].

3.) To compensate for the lack of ankle/foot control, walking patterns might change and become irregular. Common changes might include relying more on glutes/iliopoas muscles because calf and ankle tend to become affected by FSHD earlier in its progression. The affects FSHD has on gait cycle is not well researched and still remains partially unknown [2].

There is also a higher risk of falling due to lack of balance and muscle strength.

Sources:

[1] Facioscapulohumeral muscular dystrophy (fshd). (n.d.). Muscular Dystrophy UK. Retrieved September 8, 2024, from https://www.musculardystrophyuk.org/conditions/a-z/facioscapulohumeral-muscular-dystrophy-fshd/

[2] Rijken, N. H., van Engelen, B. G., de Rooy, J. W., Weerdesteyn, V., & Geurts, A. C. (2015). Gait propulsion in patients with facioscapulohumeral muscular dystrophy and ankle plantarflexor weakness. *Gait & posture*, *41*(2), 476–481. https://doi.org/10.1016/j.gaitpost.2014.11.013

Conclusions/action items: Some main goals outlined for this project is to prevent eccentric muscle contractions, yet support active concentric ankle movement. Researching more on eccentric/concentric ankle/foot movements will be beneficial to understanding the expectations of the project. Additionally, next steps will include researching more about FSHD, specifically about the disease's stages and progressions.

09/08/2024: Stages and Progression of FSHD

Lucia Hockerman - Sep 12, 2024, 9:47 AM CDT

Title: Stages and progression of FSHD in ankle mobility

Date: Sept. 8, 2024

Content by: Lucy Hockerman

Present: N/A

Goals: Understand the stages of FSHD to clarify specific limitations of walking in the targeted group for our AFO project.

Content:

Facioscapulohumeral muscular dystrophy (FSHD) in its early stages does not commonly begin in the lower leg muscles but occurs as the disease progresses.

Once the disease progresses to the lower legs, some common stages/symptoms include (in order from earliest to latest occurrence):

1.) Onset of foot drop: weakness develops in the ankle dorsiflexors (specifically in the tibialis anterior muscle) [1]

Depiction of Tibialis Anterior muscle [2]

2.) Increased weakness in ankle and foot occurs slowly over years but can spread to other muscles that control ankle movements including the calf.

3.) Increase step to clear toes from ground. Increased hip and knee flexion during swing phase of walking.

Advanced stages: require ankle-foot orthoses or even knee-ankle-foot orthoses might be necessary. About 20% of FSHD patients will eventually require a wheelchair [1]

Overall, the progression varies between individuals. There are no exact "stages" or progression for FSHD. Our clients will have advanced FSHD where they would benefit from a AFO, but will not be in need of an ankle, foot and knee orthoses.

Citations:

[1] Fecek C, Emmady PD. Facioscapulohumeral Muscular Dystrophy. [Updated 2023 Jun 26]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK559028/

[2] Patient, R. M. (n.d.). Tibialis anterior | rehab my patient. Retrieved September 8, 2024, from https://www.rehabmypatient.com//knee/tibialis-anterior

Conclusions/action items: Prepare some client questions and continue a general baseline research.

09/17/2024: PD-AFO review

Lucia Hockerman - Sep 22, 2024, 9:44 PM CDT

Title: Design principles, manufacturing and evaluation techniques of custom dynamic ankle-foot orthoses: a review study

Date: Sept. 17, 2024

Content by: Lucy

Goals: Explore the costs and benefits of custom AFOs as apposed to standard off-the-shelf designs. Hopefully this will give the team insight on how we can tailor an AFO specifically to Maggie's needs.

Content:

Overview: the most common types of AFOs provide the most stability and strong resistance.

A most common AFO = strong resistance to ankle plantarflexion

There is an option to choice a passive dynamic AFO (PD-AFO) for patients with less severe ankle weakness.

Passive dynamic characteristics:

- Flexible calf shell (can bend and absorb energy in the stance phase of walking --> energy can be used for released support during the push-off phase)

- Foot drop = lack of control in dorsiflexor muscles (flex the foot upward)

Figure 1: Specific dorsiflexor muscles; source: https://teachmeanatomy.info/lower-limb/muscles/leg/anterior-compartment/

- Plantarflexion: opposes dorsiflexion (pointed foot downward)

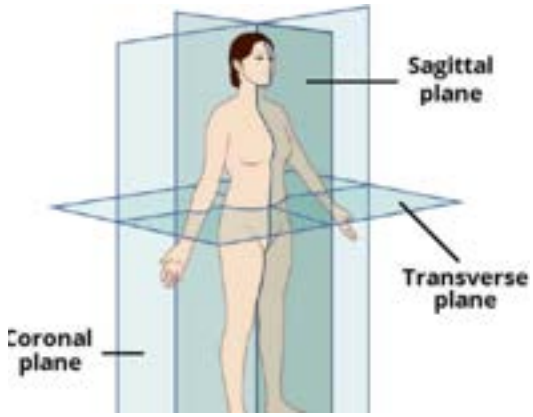


Figure 2: anatomical planes for reference: source: https://teachmeanatomy.info/the-basics/anatomical-terminology/planes/

PD-AFO characteristic: flexible in sagittal plane (allows left to right movement)

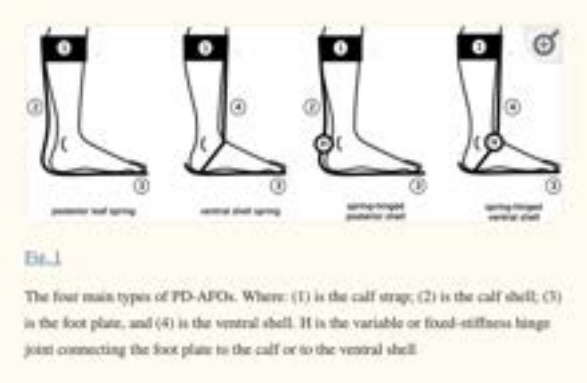


Fig. 1

The four main types of PD-AFOs. Where: (1) is the calf strap; (2) is the calf shell; (3) is the foot plate, and (4) is the ventral shell. H is the variable or fixed-stiffness hinge joint connecting the foot plate to the calf or to the ventral shell

Active AFOS: powered by actuators

- 3D printing is now the most popular method for an customized AFO

Geometry acquisition:

- modeled by hand vis thermal molding (liquid plaster)

- 3D digital replica of the patient's geometry through 3D scanning, computer tomography and optical motion capture systems (this would be a final prototype problem)

Customization criteria:

- the modular intrepid dynamic exoskeletal orthosis (IDEO) : commercial customizable PD-AFO

- Optimizing the stiffness of the calf shell is a popular way to increase stiffness

Production (3D printing): Selective laser sintering, fused deposition modeling/fused filament fabrication (stereolithography and multi jet fusion are less frequently used)

Mechanical testing: studies investigated the stiffness properties in plantar-dorsiflexion in the range 20 deg plantar to 30 deg dorsiflexion. Assed calf shell, displacements during AFO deflection.

To test dorsiflexion: hold calf and apply force to replicate movement --> resistance to dorsiflexion = .12 - 8.9 N*m/deg

Functional evaluation:

- Carbon-fiber was found to be the most used material along with plastic (nylon and polyamide) and thermoplastic (polypropylene and polyurethane)

- Most common task investigated: walking (some stairs, or inclined walk). Spatio-temporal parameters and lower limb joint kinematices and kinetics (sagittal plane) were recorded and analyzed

*reference table one in article

Citations:

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

Conclusions/action items:

Finish first draft of PDS and research more about modular intrepid dynamic exoskeletal orthosis (IDEO)

09/29/2024: FSHD AFO overview

Lucia Hockerman - Sep 29, 2024, 12:17 PM CDT

Title: AFO types

Date: 09/29/2024

Content by: Lucy

Goals: Wanted to ensure the options of AFO types for individuals because my group is considering a leather/non-ridged design.

Content: The video just gave a brief overview for all AFO types, sharing pros and cons for each type. This informs me that all AFOs have the potential for helping someone with FSHD. The type chosen relies on the individual and their needs/what is recommended by medical workers.

The video talks about the AFO designs already discussed in my previous, so I will not summarize that information.

One consideration that the video mentioned was driving ability. Maggie is 15 and will start driving soon, so this is an important consideration.

Video link: https://www.fshdsociety.org/2022/05/30/about-ankle-foot-orthoses-afos/

Conclusions/action items: Complete my preliminary presentation part, research material for bungee brace design.

09/29/2024: Boa tighten and release mechanism

Lucia Hockerman - Sep 29, 2024, 1:02 PM CDT

Title: BOA Fit Systems

Date: 09/29/2024

Content by: Lucy

Goals: Research possible dial tightening devices for the bungee brace design idea

Content:

The BOA system consists on a dial to turn clockwise to tighten skinny wires/cord. You press down and turn to tighten and it has a fast release by pulling up. The device is used in all sorts of shoes/athletic wear. The company already has several patents for designs. I could not find more information behind the fabrication and specific mechanisms.

Link: https://www.boafit.com/en-us/innovation

Conclusions/action items: This idea is great and would allow for quick emergency release. I am concerned about the thickness of the cord. Our design will require a thick and supportive cord, which might be a problem and require a different tightening mechanism. This will require more research on other options.

10/12/2024: MTS testing

Lucia Hockerman - Oct 12, 2024, 11:12 PM CDT

Title: BME 201 Lab 12 Mechanical Testing Background

Date: October 12, 2024

Content by: Lucy

Goals: Understand the types of MTS testing in ECB so we can preform mechanical testing once we 3D print to quantify max loadings

Content:

- Important to compare young's modulus properties of competing designs to the young's modulus of our prototype

- Before starting any testing, it is important to know about some mechanical properties of your sample (such as max possible load) before testing to properly set up the machine. There are many options for the load cells but you never want to exceed their maximum load and want to avoid a less desirable signal by measuring a load out of range.

- A compressive force can be performed using a universal testing machine (MTS machine Criterion C43) with appropriate compression platens. Most samples tested are cylindrical or a rectangular prism in shape - this will be a problem for us in our design!

- Always identify the emergency stop and wear safety glasses!

- In the BME teaching lab, they have fixtures for tensile testing, compression testing, and bending (3 and 4 point bending)

- Tension grips: we should not have to test in tension because AFO are mostly exposed to compression

- Bend fixtures: to obtain point bending (4 or 3 point)

- Our design will require custom fixtures to fully support our design through MTS testing. The provided clevis adapters will have to securely attach to a test fixture that attaches to our prototype for compression/tensile testing

Conclusions/action items: Due to the BME teaching lab resources and our limited time this semester, we might have to only conduct point bending testing. Discuss with team about findings

Link: https://docs.google.com/document/d/1Yw0sxH4qmYrd2itBNUWt2Tt5-knWrqAIt7FwaCmA6rQ/edit

10/12/2024: 3 vs 4 point bending test

Lucia Hockerman - Oct 12, 2024, 11:24 PM CDT

Title: 3-point or 4-point Bending Test

Date: October 12, 2024

Content by: Lucy

Goals: Understand the difference between 3 and 4 point testing to decide what to test on our prototype

Content:

- 3 - point bending test: produces its peak stress at the material mid-point and reduces stress elsewhere

- 4 - point bending test: produces peak stresses along an extended region of the material hence exposing a larger length of the material

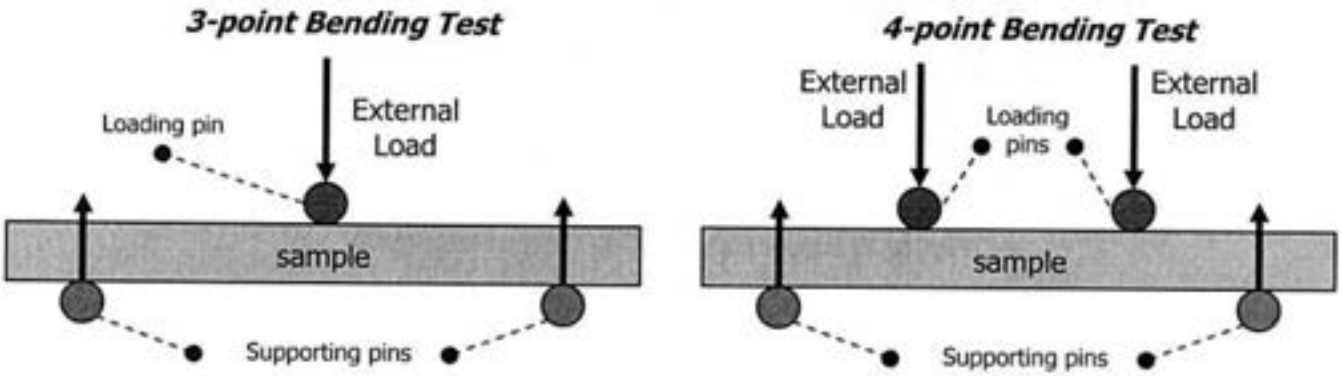


Figure 1. Schematic of flexure tests (3-point and 4-point bending test)

You still have to take geometry into account for point bending test

Conclusions/action items: Discuss with the team about performing MTS testing. Is it worth testing just the material considering our resources?

Link: https://www.biomomentum.com/wp-content/themes/biomomentum/library/images/zoho/Publications/MA056-SOP11-D%20v2%20Mach-1%20-%203-point%20or%204-point%20Bending%20Test.pdf

10/13/2024: Learning about OpenSim

Lucia Hockerman - Oct 13, 2024, 8:17 AM CDT

Title: Webinar - ESB Webinar Series - Jumping into Musculoskeletal Modeling with OpenSim

Date: October 13, 2024

Content by: Lucy

Goals: There is a possibility we could use the Opensim 3D motion capture for our testing,

Content:

- OpenSIm can model a variety of biological and mechanical structures in humans and animals: Has biological joints, muscle-tendon dynamic. Can measure assistive devices (orthotics)

Link with demo: https://www.youtube.com/watch?v=SlGXLS5m27A

- How to plan a demo:

1.) Identify the type of simulation required: based on the types described, inverse kinematics seem to best fit our groups needs.

Inverse Kinematics: key factors to consider are geometry of the anatomical features and the model's degrees of freedom. Our group will only focus on the ankle joint. For accurate data, properly include 3D marker coordinates:

- Use enough markers to define body segments.
- Include extra markers to account for occlusion (marker places on the body is temporarily blocked or hidden from the motion capture cameras).
- Place markers on bony landmarks near joints for scaling, and away from joints for motion tracking.
- Capture images and videos of subjects with the marker set, and record static poses for scaling.
- Measure segment lengths and height for further scaling assistance

Summary of different types of simulations:

Simulation:	Model Requirements:	Data Requirements:
Inverse Kinematics	Accurate Skeletal Anatomy	3D Marker Coordinate Data
Inverse Dynamics	Accurate Skeletal Anatomy, Inertial Parameters	3D Marker Coordinate Data, External Force Data, Subject Mass
Static Optimization/Forward Dynamics	Accurate Skeletal Anatomy, Inertial Parameters, Accurate Muscle Anatomy/Parameters	3D Marker Coordinate Data, External Force Data, Subject Mass, EMG*, Imaging*, Strength Test Results*

*Recommended but not required

Conclusions/action items: Write about this as a possibility for testing. Not sure if we will be allowed to use this equipment, but worth mentioning as it will provide more useful information.

Link: https://opensimconfluence.atlassian.net/wiki/spaces/OpenSim/pages/53090652/Planning+an+OpenSim+Simulation

10/13/2024: 6MWT

Lucia Hockerman - Oct 13, 2024, 8:28 AM CDT

Title: Six Minute Walk Test

Date: 10/12/2024

Content by: Lucy

Goals: Explore simple testing to analyze gait and test or AFO

Content:

Overview:

- Developed by the American Thoracic Society, introduced in 2002

- A sub-maximal exercise test assessing aerobic capacity and endurance

- Measures distance covered in 6 minutes to compare changes in performance capacity

Intended Population:

- Applicable for ages 2-65+ across various conditions, especially cardiopulmonary issues

- Evaluates functional capacity involving multiple systems (pulmonary, cardiovascular, neuromuscular, metabolic, etc.)

- Used for conditions such as arthritis, fibromyalgia, multiple sclerosis, Parkinson's disease, stroke, spinal cord injury, **muscle disorders**, and more

Equipment:

- Stopwatch, measuring wheel, cones, optional pulse oximeter, and Borg Breathlessness Scale (won't have or need in our testing set-up)

Set-Up:

- 30-meter unimpeded walkway with cones at each end

- Chairs placed along the stretch for resting

Instructions for Participants:

- Walk as far as possible in 6 minutes, turning at the cones

- May slow down, stop, and rest but resume walking when able

Standard Encouragement:

- Provided at specific intervals during the test (e.g., 5, 4, 3 minutes remaining, etc.)

Interpretation:

- Improvement in distance indicates better mobility

- A difference of 45 meters post-training indicates significant improvement

- Useful in assessing conditions like Duchenne/Becker muscular dystrophy, spinal muscular atrophy, and neuromuscular junction dysfunction

- Data on fatigue can be inferred by comparing distance walked in the first and last minutes of the test

Conclusions/action items: include this into the report as one way to assess the effectiveness of the device

11/4/2024: Runeasi research

Lucia Hockerman - Nov 04, 2024, 5:00 PM CST

Title: Runeasi Research

Date: 10/12/2024

Content by: Lucy

Goals: The team might have access to a device called Runeasi. Before I reach out about using this device, research is required to determine if the device can provide useful data on a healthy individual with and without the brace - considering the patient is no longer coming in town.

Link: https://runeasi.ai/

Content:

Single biomechanics sensor on the lower back to track the acceleration of body's center of mass. Interprets metric in a client-friendly report

Possibly helpful data Runeasi could provide in initial testing: Walking gait assessment: detect movement dysfunctions

- Dynamic stability: represents the proportion of hip movement in the medio-lateral direction (side to side) during ground contact. It captures how much energy is wasted that is not contributing to forward movement

- Impact loading: measure the impact reaching lower back immediately after the foot hits the ground. Split into two sections: impact magnitude and impact duration (timing component that indicates the rate of loading - explains how well the load is absorbed by the lower legs). A longer impact duration suggest better shock absorption

- **Symmetry:** measures the symmetry difference between both feet

Single score calculated (%) based on dynamic stability, impact loading, and symmetry

Misc. data: duration of exercise, speed cadence, inclination

Easy to compare between different trials (with and without brace), can graph trends throughout the session

Conclusions/action items: There is data we can potentially use for our testing. Without an individual with foot drop of ankle inversion, there is a challenge to gather useful data on a person with an average gait. Symmetry seems to be the most potentially helpful data collection. With Grace, we can measure her baseline walking score and compare her symmetry to her walking score with the brace on her right foot. This could give the group information on undesired gait effects of the brace. In addition to this testing, the group will have to preform more testing to analyze how the brace improves foot drop (relates to tension in the bungee) and prevents inversion (stability of the rigid piece).

09/29/2024: Bungee Brace

Lucia Hockerman - Sep 29, 2024, 11:35 AM CDT

Title: Design matrix 2: bungee brace

Date: 09/25/2024

Content by: Lucy

Present: Discussed during the whole team meeting

Goals: Go over group member designs and choose 3 for our design matrix.

Content:

This is an AFO brace that leans more on the aesthetic part and less on the functionality. The non-ridged material is less restrictive and noticeable, but will have to discuss with Debbie if it allows for enough support.

Conclusions/action items: With the other 2 designs, show these to Maggie and ask for her opinions

Runeasi Training

Lucia Hockerman - Nov 15, 2024, 5:35 PM CST

Title: Runeasi Training

Date: 11/10/2024

Content by: Lucy

Present: Anya, Lucy

Goals: Learn how to use Runeasi software/program for testing at the Badger Athletic Program (Mikel Joachim)

Content:

- Attach it to the back of the hip (synchrom)
- Linked to the runeasi app
- The email is joachim@orthowisc.edu
- Password: Topo3437!
- Click on the client
- Check that theres a connected bluetooth sensor : click on icon to manage the sensor
- Click start test
- Choose running or walking
- Treadmill walk
- Start
- Get dashboard and a score
- Look at individual metrics : click on expert center
    - Dynamic stability: medial lateral measure
    - Impact loading: how many Gs of force you're experiencing peak vertical forces
    - Impact duration: impulse of how long that force was applied for
    - Ground contact: how long foot was on the ground
    - Cadence: total steps
    - Flight ratio: what percent of gait cycle are you in stance vs in gait (state)
- Pdf report
- Info and knowledge: describes all of the metrics in more detail
- App with the black icon
- 3 trials of 3 mins
    - Pain level
    - Carbon fiber piece uncomfortable

Conclusions/action items:

Conduct testing on Grace using this information on Friday

09/11/2024: BME Career Preparation and Advice

Lucia Hockerman - Sep 12, 2024, 9:49 AM CDT

Date: Sept 11, 2024

Title: BME career prep

Speaker: Stephanie Salazar Kann

Key points:

- Keep track about what you apply to (including internships, co-ops, full-time)

- ECS.wisc.edu/resources : to keep track of what you are applying to

- Connect with organization before you become an applicant: use the career fair for this!! All connects are good connections

- With editing resumes, emphasize skills the company favors

- Build resume in microsoft word. Don't use templates but can download a starting point on word

- Do not need cover letter for career fair

- Handshake logic: jobs cannot pick more than one category for several things on handshake, don't focus on brief categories but the descriptions

- Get handouts from Ehall

- Follow up with the internships that you really enjoy first

Needed action:

- Edit resume and go to a building workshop

- Grab last career fair map

- Research companies and go to career fair

09/18/2024: Exploring your leadership style

Lucia Hockerman - Sep 18, 2024, 2:01 PM CDT

Date: Sept 18, 2024

Title: Exploring your leadership style

Speaker: Dr. Angela Kita, PhD

Key points:

Important qualities of leaders (from class): confident, knowledgable, open-minded

Anatomy of a good leader: self-awareness, vision, transparent, communication, decision-making

Leadership styles:

1.) Power model: in control, only certain people are born to lead

2.) Servant leadership: it is about the needs of followers, people above you, listening and understanding, sharing power

3.) Authentic leadership: transparency, genuineness, honesty

People-oriented leader: glue that holds the team together, get to know everyone as individuals. Skilled at building trust and an inclusive environment

Impact-oriented leader: set the bar high and push for excellent performance

Thought-oriented leader: sees big picture, open to new ideas, anticipates the future

Process-oriented leader: sets the pace, creates systems and processes

To leader others, you need to lead yourself

Goal setting: start small, slow down, focus on one element to practice, look for mentors

Team goal: Cohesive team with motivated team members. I would like everyone to have the comfort to express their ideas. I want to create an environment were people are intristically motivated by the project itself, not by the grade.

Self goal: I would like to develop decisiveness in decision making. I might not know all the answers, but I want to trust myself to be confident in my initial thoughts.

9/25/2024: Advising 2

Lucia Hockerman - Oct 02, 2024, 2:24 PM CDT

Date: Sept 25, 2024

Title: Advising pt 2

Speaker: Dr. Puccinelli

Key points:

- Run your 4 year DARS!

- Refer to the engineering advising page for helpful links

- Use undergrad experience to "build a story"

- It is never too late to research what you would like to do and start building a story

- Consider masters programs (usually only one year and makes you stand out as a employer in the industry world, higher starting salary)

- Try and find that balance between class, research experiences, leadership, and extracurricular activities

Conclusion/to-do: continue internship search

10/02/2024: Near peer mentoring

Lucia Hockerman - Oct 02, 2024, 2:06 PM CDT

Title: Near peer mentoring

Date: 10/02/2024

Content by: Myself

Present: Anya and Presley

Goals: Learn about peer mentoring

Speaker: Dr. Tracy Puccinelli

Key points:

Why am I mentoring: getting sophomores more comfortable with the design project, helping others helps you, learning how to work on a team.

- Additional instructional and emotional support

- More approaching, mentees are more willing to ask questions

- Learning more about my leadership style

- Increased self-esteem, confidence and patience

- Identify gaps in your own knowledge

What does it mean to be a "good mentor": considerate towards their opinions, listen and respect, be inviting

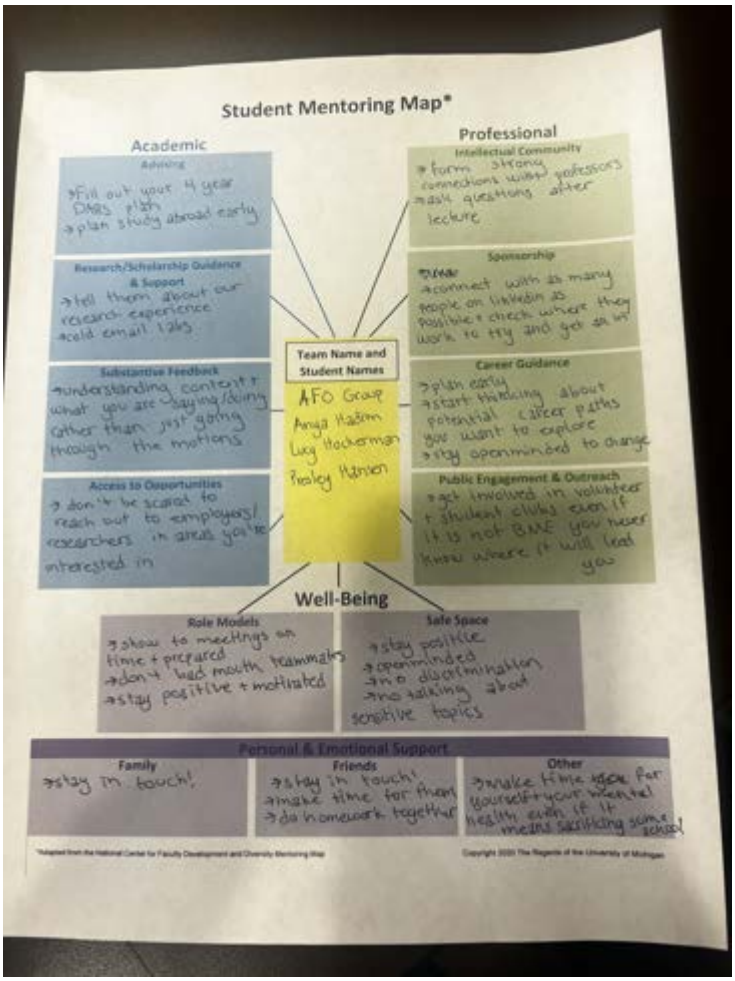
- Building trust

- Transparent

- Humanizing their challenges: Be their coach

What do you wish you knew in BME 200: complete DARs (4 year plan) and plan ahead, deadlines come up quick important for time management, you will fail, put everything in lab archives, don't be afraid to ask questions

Mentor map:



Conclusions/action items: Think more crucially about how to be a good mentor during the rest of the semester.

10/09/2024: Sustainability

Lucia Hockerman - Oct 09, 2024, 2:07 PM CDT

Title: Sustainability

Date: 10/09/2024

Content by: Myself

Present: Anya and Presley

Goals: Learn why we should care about sustainability as engineers

Speaker: Prof. Andrea L. Hicks

Key points:

- Life cycle assessment: look at the environmental impact of a design throughout its WHOLE lifetime. Use this to bring awareness to the effects of the products, so one can limit the impacts on the environment.

- In a product, you have to consider all materials/parts of the design

- There is a rise in popularity for single-use medical devices. People believe this will prevent infection, but the bacteria content is basically the same with a well-sterilized reusable medical devices.

- Sustainability is not only about environmental impact but also resiliency

- How does sustainability fit into my AFO project: our project is to make a brace for repeated use and for a specific client, but if this design was ever to go on the market, we need to think about how the materials we use can effect the environment. Also, our group should think about the parts more opt to wear down (i.e. velcro, drawstring mechanism, and bungee cord) and how to increase their resiliency.

Conclusions/action items: During fabrication, continue to think about how our design will be sustainable

10/16/2024: Patent and Licensing with WARF

Lucia Hockerman - Oct 16, 2024, 2:02 PM CDT

Title: Patent and Licensing with WARF

Date: 10/16/2024

Content by: Myself

Present: Anya and Presley

Goals: Learn about patents and the process of creating one for your device at UW-Madison

Speaker: Jeanine Burmania and Justin Anderson

Key points:

- Technology transfer: moving research from campus out into the market. WARF works at this interface to facilitate securing IP rights and commercial licenses.

- Intellectual Property: set of rights that exist for products of the mind

Four common types:

1.) Copyrights: protection for creative works (wide range of subject matter, including software)

2.) Trademarks: logos, marks, etc. (requires use in commerce)

3.) Trade secrets: can be used to protect anything of value

4.) Patent: each country has its own patent system, all information discuss specific for the USA:

- a property write, granted by a governmental agency

Three different types of patents: design, plant, utility (WARFs focus)

Utility (provisional) patents: issued for the invention of a new and useful process, machine, manufacture, or composition of matter (often takes 2-5 years to issue after filing)

Requirements for patents:

1.) Eligible (cannot be a product of nature, abstract material, or natural phenomenon)

2.) Novel (must be new)

3.) Non-obvious (it cannot be simple modification or combination of existing concepts)

4.) Enables and described (must provide enough detail to teach others how to make or use the invention)

WARFs process applicable points: have a year from public viewing (preliminary presentation), patent the most finalized version of the design

Conclusions/action items: Discuss with team if our final design could pass in the patent process

10/23/2024: IRB

ANYA HADIM - Oct 23, 2024, 8:22 PM CDT

Title: Institutional Review Boards and Clinical Translation

Date: 10/23/2024

Content by: Myself

Present: Anya and Presley

Goals: Learn about IRBs

Speaker: Dr. Jennifer Fenne, PhD

Key points:

Unethical research --> ethical principles --> human research regulations

Infamous studies that are examples of unethical research: Nazi prisoner experiments, Hepatitis studies at Willowbrook State School for children, Milgram shock experiments at Yale, Tusckegee syphilis study**.**

Belmont principles: Respect for Persons, Beneficence and Justice

Regulation for protection of human "subjects": department of Health and Human Services (DHHS) aka "the common rule" and the FDA

UW-Madison IRB:

- Minimal Risk Research IRB (MRR IRB): biomedical, education, and social/behavioral sciences research. Secondary analysis of data, survey research, behavioral health interventions, evaluations of educational practice

- Health Sciences IRB (HS IRB): biomedical, interventional, any risk level. All FDA regulated and VA regulated research

Do I need an IRB? No - because our product is not generalizable. We are only creating an AFO for one patient with no intent to mass produce

Subject: an individual on whom or on whose specimen an investigated device is used on

Preparing for an IRB review

- Complete required training for researchers through CITI

- Complete annual outside activities reports

- Identify appropriate principle investigator and study team

- Collect preliminary (non-human) data and background information

- Develop a research question and steps to answer it

- If evaluation device effectiveness and/or safety, consult UW's FDA regulated Research Oversight Program

- Consider research participants details (how many, why, how to minimize risks, where to recruit, etc.)

Application system: Arrow (protocol based vs non protocol based)

Resources: irb.wisc.edu

IRB for Beginners Workshop 10/24 10:00 -11:00 am

Conclusion: Confirm our group does not need to get approval from the IRB

10/30/2024: Navigation FDA device requirements

Lucia Hockerman - Oct 30, 2024, 2:04 PM CDT

Title: Navigation FAD device requirements

Date: 10/30/2024

Content by: Myself

Present: Anya and Presley

Goals: Learn about FDA device requirements

Speaker: Jake Rome

Key points:

Medical device: anything that affects health that is not a drug or antibiotic (very broad for a reason)

Device classification review:

Class 1: Low risk. exempt from premarket approval, band-aids, floss, etc.

Class 2: Moderate risk, 510k showing substantial equivalence, BP cuffs, sutures, catheters, etc.

Class 3: High risk, premarket approval, pacemakers, etc.

Regulatory control key elements: general controls, specific controls, premarket approval (data to show safety and effectiveness)

Marketing submissions: 510K exempt (registration and listing only), 510k-premarket notification (substantial equivalence), PMA-premarket approval (full safety and effectiveness submission, manufacturing details), De Novo Classification (novel medical devices no legally marketed predicate)

Check the lecture slides for helpful links

Conclusion: Prepare and go to show and tell

11/06/2024: Bringing Biologics to the Market

Lucia Hockerman - Nov 06, 2024, 2:06 PM CST

Title: The Framework Guiding Advanced Therapeutic Product Development

Date: 11/06/2024

Content by: Myself

Present: Anya and Presley

Goals: Learn about

Speaker: Prof. William Murphy, PhD

Key points:

Drugs: produced in a chemical environment

Biologic: living thing or produced by a living thing

Look to "design of early phase CGT trials guidance" for documentation on how to perform initial testing. This is save companies money on studies by having awareness what will not be accepted by the FDA.

361 products "minimal manipulation productions": do not have to go through the whole process to demonstrating safety and efficacy.

351 products "complex manipulation productions": will be regulated like a traditional biologic due to the potential risk.Products that are classified at 351 products and are the first of its kind will gain market exclusivity for 12 years (corner the market)

It is extremely important to be able to distinguish between studies that are **"on the critical path"** vs **"good research projects."**

Target Product Profile (TPP): when to use it, why to use it, how to use it, patient identification, patient benefits, patient risks, medically and commercially compelling?

Career Options within a Regulated Environment: chemistry, manufacturing, controls (lots of career options involved in this)

Conclusion: meet with team to complete prototype two and start testing.

11/13/2024: Medical Device Innovation from Prototype to Commercial Clinical Use

Lucia Hockerman - Nov 13, 2024, 2:02 PM CST

Title: Medical Device Innovation From Prototype to Clinical Use

Date: 11/13/2024

Content by: Myself

Present: Anya and Presley

Goals: Learn about how to overcome difficulties when bringing a prototype to commercial clinical use

Speaker: Aimee Arnoldussen, PhD

Key points:

Medical Device Process at a Glance:

1.) Innovation Idea and Development

2.) Human Testing Data Acquisition with IRB Oversight: controlled and affected by the IRB

3.) FDA regulatory Process: device classification (class I, II, III) will require different approval

Breakthrough device program: timely access to medical devices for life-threatening or irreversibly debilitating diseases/conditions. Program to expedite development, assessment and review.

4.) Reimbursement or Financial Incentive

5.) Sales

Workflow: patient care pathway as a starting point

Consider the stakeholder and who the product directly helps and who will actually want to invest

Value based healthcare: improving patient outcomes while making it more affordable to deliver those outcomes

Value drivers to discover: economic, clinical and mission impact

Evidence more compelling than "hand-waving" benefit assumptions

Existence of codes do not equal financially favorable!

Innovate.wisc.edu: resources for innovators and entrepreneurs - on campus and beyond

Conclusion: meet with team to complete prototype two and start testing on Friday. Update notebook by writing fabrication protocol

11/15/2024: Tong Lecture

ANYA HADIM - Nov 15, 2024, 1:18 PM CST

Title: Tong lecture

Date: 11/15/2024

Content by: Myself

Goals: Learn about the innovation process for Tasso

Speaker: Eriwn Berthier and Benjamin Casavant (PhD)

Key points:

Introductions: Both had unique ways to get into UW-Madison PhD program, they emailed professors in labs that research their interests - both ended up in a lab focusing around microfluidics. Benjamin Casavant completed his undergrad at Berkely in biomedical engineering. Eriwn completed schooling in France.

Together started a company, with the idea to perform a blood collection at home.

Initially: scraped together materials and asked around to start building prototypes. They reached out to the law & entrepreneurship clinic and they provided them with their first patent and other legal advice/documents. Got "scrappy" with funding opportunities - cracked out grants (wrote a ton) and eventually awarded a grant. Had a great idea, got the ability to defend their idea and pitch it to receive a grant.

Evolutionary of the technology: vacuum in the device (reached out to a professor doing OCG imaging to show the blood flow in capillaries). Learned more effective way to retrieve blood - you have to kill one prototype to make a better one.

"You can pick someone to do a lancet once, you can't trick them to do it twice" -- worked with this person to alter the product to his needs

USADA was also looking to switch anti-doping to blood but everyone hates needles and lancets even more: MLB (player unions agreed to this), UFC, cyclism converted to Tasso

Work with the people that had a problem, focusing on that specific problem and once that problem is solved, you get very good reviews from influential people (you cannot solve everything at once: one step at a time).

Innovation takes effort! Lots of different prototypes.

COVID shutdown: companies cancelled all the contracts to conserve money. Slowed down Tasso for a bit, but then people are interested in COVID antibody testing --> at home testing! Got a crazy influx for orders, needed a new building and more space to keep up with the demand.

Quality is key. One costumer that has a bad experience, will kill you. Develop systems to check and double check quality fast.

Culture of the company matters! Create an environment where people problem solve and "point in the same direction" to reflect the values of the company.

FDA: sold the collection tube and device separate to avoid super hard clearance (Class II IVD). Instead the lancet device only needed class I medical device (became the first company to get a lancet device approved separately). Be smart with the FDA!

If you have an idea that you believe in, go for it. People here want to help - there are lots of experts around. You will run into bumps in the road, but lean on others.

Naming of the company: Tasso is Italian for Badger!

Conclusion: If you have an idea, go for it.

11/20/2024: How New Product Development works in the Medical Device Industry

Lucia Hockerman - Nov 20, 2024, 2:07 PM CST

Title: How New Product Development works in the Medical Device Industry

Date: 11/20/2024

Content by: Myself

Present: Anya and Presley

Goals: Learn about how new product development (NPD) works at most medical device companies

Speaker: Russ Johnson, PhD

Key points:

NPD in the medical industry is: highly regulated, expensive, resource intense and competitive

Selecting and prioritizing projects: corporate business strategy --> product portfolio review --> project review --> budgeting and resource allocation

Type of NPD projects: line extensions, product improvements, new-to-company, new to world

Successful development and launch of new products involves a well coordinated, cross-functional team.

Stage-gate process: stage 0 (ideation: the cloud) --> stage 1 (exploration) --> stage 2 (concept development: build business model and get approval) --> stage 3 (design development) --> stage 4 (design confirmation) --> stage 5 (design transfer and commercialization) --> post market surveillance

Throughout the stage process, the go/no-go decision will check if there should be continuation between each stage.

Companies have a stage-gate process to ensure there will be increase funding return.

Case study: OR Fluid Management System

Goal: Provide clinicians with an innovative solution for high fluid volume collection during surgical procedures

Stage 0 (Ideation): choose an area of opportunity, review market trends, conduct research, talk with clinicians to discuss unmet needs, create high-level idea sketches

Stage 1 (exploration): define problem to be solved and customer requirements, refine ideas, create 8-10 concepts, develop high-level business case (market size/value proposition), conduct preliminary technical scouting and intellectual property landscaping

Stage 2 (concept definition): based on customer interviews and use-case assessments, select 2-3 to 1 leading concept, develop robust business case, conduct IP examination

Next, gate review: "go/no-go" business decision

Stage 3 (design development): move to functional prototype, the cyclic design process, begin formal design control documentation (FDA class 2 and 3, risk management)

Stage 4 (design confirmation): conduct extensive verification and validation testing, finalize product and component drawings/models, accelerate manufacturing process. "freeze" design, submit regulatory documentation (FDA 510(k))

Stage 5 (design transfer and commercialization): complete any remaining testing, make final design changes, build mold/assembly, create user manuals, etc.

Post Market Surveillance: monitor the market with the device and project teams report out to stakeholders

Conclusion: Meet with the team to conduct testing part 2 and create the mold before thanksgiving break.

09/08/2024: Lower Body Anatomy and Why an AFO?

Alex Conover - Sep 12, 2024, 10:52 AM CDT

Title: Lower Body Anatomy and Why an AFO?

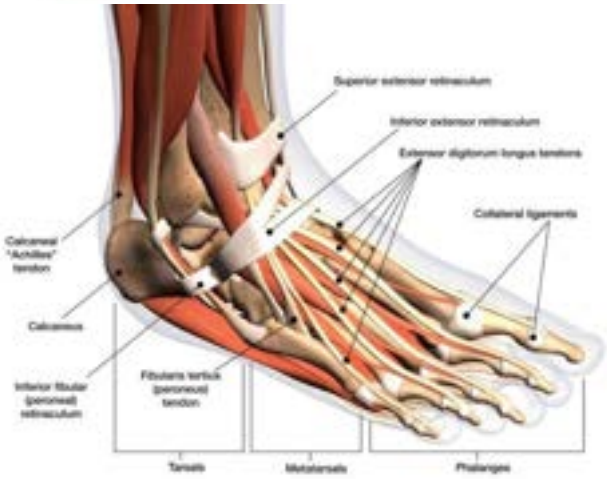
Date: 9/8/2024

Content by: Alex Conover

Goals: Refresh the human anatomy of the lower body.

Content:

The bottom half of the human body is an incredibly complex machine. Logged here are anatomical images of the anatomy below the knee as a reminder of what muscles, tendons, ligaments, and other pieces of the body are located in the lower legs.



A foot drop is a condition where the patient has difficulty lifting up the front part of their foot. It results in dragging the foot along the group when walking, which can disrupt the normal gait of the patient. A foot drop is generally an inclination of an underlying neurological, muscular, or anatomical problem. A foot drop can be temporary, but can also be permanent. This may help decide if the patient needs a brace or more invasive biomechanics technology.

Factors that increase the likelihood of foot drop include:

- Foot crossing, which can compress the peroneal nerve of the uppermost leg

- Prolonged kneeling or squatting can also compress the nerves

- wearing a leg cast also can compress the nerves

Other causes of foot drop include:

- Spinal cord or brain injury, or stroke can cause foot drop

- cerebral palsy: a group of disorders that affect a person's ability to move, maintain balance, and posture.

- ALS: Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, is a fatal neurological disorder that affects the nerve cells in the brain and spinal cord that control voluntary muscle movement and breathing.

- Multiple sclerosis: a chronic disease that affects the central nervous system, damaging the brain and spinal cord.

- Various other muscle or nerve disorders

- any damage to the peroneal nerve, which controls the raising and lowering of the foot, can result in foot drop.

References:

“Filling a Prescription for an Ankle Foot Orthosis (AFO).” Edited by Elevate Staff, *Filling a Prescription for an Ankle Foot Orthosis (AFO)*, Elevate, 2023, www.elevatemovement.com/guides/filling-afo-prescription.

“Foot Drop.” Edited by Mayo Clinic, *Mayo Clinic*, Mayo Foundation for Medical Education and Research, 5 Jan. 2023, www.mayoclinic.org/diseases-conditions/foot-drop/symptoms-causes/syc-20372628.

Manganaro, Daniel. “Anatomy, Bony Pelvis and Lower Limb: Ankle Joint.” *StatPearls [Internet].*, U.S. National Library of Medicine, 23 May 2023, www.ncbi.nlm.nih.gov/books/NBK545158/.

Conclusions: It's likely that our client has a foot drop, and experiences a loss of movement. This research was to understand why someone may need an AFO.

Action Items: Continue to refresh on anke and lower limb anatomy, as well as meet with our client to determine the best way to create this brace for them.

09/08/2024: AFO Research

Alex Conover - Sep 12, 2024, 10:51 AM CDT

Title: AFO Research

Date: 9/8/2024

Content by: Alex Conover

Goals: Understand what Ankle Foot Orthosis is, and what types of devices there are

Content:

AFO's (Ankle foot orthoses) are external biomechanical devices designed to stabilize the joints and improve the gait of one's lower limbs. It aims to assist with all levels of movement, including dorsiflexion, plantar flexion, and help improve balance. The ultimate goal of an AFO is to return the patient to their previous level of motion, or increase their level of motion.

There are many different types of AFO's:

Traditional Plastic AFO

- provides maximum medial and lateral joint stability

- great for short term usage, cheap to manufacture

- easy to apply and easily moldable to the patient.

- difficult to fit into shoes

Swedish AFO

- Also easy to mold to patient via heat molding

- can more easily fit into shoes

- weaker support in the medial area when compared to the plastic AFO

- more suitable for moderately active people

- have greater room for ankle and calf muscle, can be easier to use

Carbon Fiber AFO

Carbon Fiber AFO

- Most modern and flexible design, semi-flexible

- Low profile design, easier to fit into shoes, avoids pressure points in the foot and ankle

- greatly stabilizes and strengthens the joints

- lateral support to control medial instability and there are medial supports for patients with lateral instability

- best choice for restoring a normal gait pattern for an active person

To fit an AFO there will be multiple measurements done, as well as various rounds of fitting and shaping to make sure the braces fit perfectly to each patient.

An assessment of the patient is also done to determine if they require an AFO, and what type of AFO. A patient's medical history is reviewed, as well as their primary pathology and a current diagnosis of their condition. To determine the type, a patient's occupation, ADL activities, mobility status, and level of independence is considered to decide which type of brace they may require. The strength of the muscles is important to the type of brace, as well as the condition of the skin and surrounding areas. Gait analysis, posture, balance, and functional strength also play a major role in determining the type of brace.

References:

Shreif, Khloud. “Introduction to Ankle Foot Orthoses.” *Physiopedia*, Physiopedia, 3 Aug. 2022, www.physio-pedia.com/Introduction_to_Ankle_Foot_Orthoses.

https://www.physio-pedia.com/Introduction_to_Ankle_Foot_Orthoses

Conclusions: AFOs provide stability and strength to patients with otherwise impaired lower body movement. The type of device is determined on a case-by-case basis and is highly individualized depending on the patient's needs.

Action Items: Determine the best device for our client, and find a way to adapt it to make it inconspicuous and useful for the client.

10/06/2024 - Carbon Fiber Pricing and Types

Alex Conover - Oct 06, 2024, 10:31 PM CDT

Title: Alex Conover

Date: 10/06/2024

Content by: Alex Conover

Present: Alex

Goals: Discover the different types of carbon fiber on the market and their pricing

Content:

Unidirectional Carbon Fiber - stronger, stiffer, more resistant to stretching, more expensive.

- typically twice as long as woven CF (fiber wise)

- stiffer than woven carbon fiber; 5 times stronger than steel, 2 times as stiff

- typically used in automobiles, boats, and bicycles

- lighter than woven CF

- All fibers are aligned in the same direction, vs random in Woven CF

- Better choice for components under a lot of stress/duress

- more economical

- great at strength in 1 direction, weak in multidirectional stuff

Woven Carbon Fiber -

- better for wrapping around the complex curves of a joint area

- strength in all areas, from all directions

- its all so dang expensive

https://www.grainger.com/category/raw-materials/fiberglass-carbon-fiber-composites/high-strength-carbon-fiber-reinforced-plastics/carbon-fiber-sheets?attrs=Thickness%7C0.125+in&filters=attrs%2CwebParentSkuKey&searchQuery=carbon+fiber&webParentSkuKey=WP14796353%7CWP14796357&sst=4&ts_optout=true

Woven sheets are appearing 30 dollars more expensive than unidirectional, but we may want to consider the benefits vs trade-offs before purchasing.

Unidirectional Carbon Fiber 12in x 12in .125in thickness = $155.46

Woven Carbon Fiber 12in x 12in .125in thickness = $188.96

So expensive.

References:

"What Are Unidirectional Carbon Fiber Fabrics?" *Fibre Glast Developments Corp*, https://www.fibreglast.com/product/What-are-Unidirectional-Carbon-Fiber-Fabrics. Accessed 7 Oct. 2024.

Conclusions/action items:

Carbon Fiber is very expensive, submit a referral for it to be covered by the university this week and continue to research products.

10/12/2024 - Expenses 1

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Ankle Brace - Component 1										
Ankle Brace	Cloth brace						1	$11.90	$11.90	https://www.amazon.com/dp/B074PWC89V?ref=cm_sw_r_cso_sms_apin_dp_4A7FNN5T1YBVSZNCNVPH&ref_=cm_sw_r_cso_sms_apin_
Strong glue	medical grade glue								$0.00	
Gel padding	medical grade padding						1	$14.99	$14.99	https://www.amazon.com/dp/B0BG46QQD4?ref=cm_sw_r_cso_cp_apin_dp_JKJRKB
Gel sock	Compressive sock to support the carbon fiber						1		$0.00	
Plastic cord locks	End of the bungee						1	$3.98	$3.98	https://www.amazon.com/Cord-Upgraded-Fastener-Shoelaces-Drawstrings/dp/B08JTZPQRY/ref=l5KIUe8VocNtt7ttoaU5KP5L-v5EZ5bMu9Asr9uFocExq9kdp17f6eavPiue9N5Y83saBjH9iNNE3oS O3ijVUbPKrd6UhYNgeeiQFq5_pDaHseB0.TSc33ZsZGH-3bmWYlmbwayRanr4NpFKnaE9SvO5M
Fabric	fabric/cloth to sew carbon fiber								$0.00	
Bungee	Bungee to support dorsiflexion - use what we have								$0.00	
Carbon Fiber piece - Component 2										
Carbon Fiber (N/A)									$0.00	
Metal for prototype	Fabrication of back support								$0.00	
3D printing prototype	3D printing of back support								$0.00	
Category 3										
									$0.00	
									$0.00	
								TOTAL:	**$30.87**	

09/16/2024 - Standards

Alex Conover - Oct 12, 2024, 3:12 PM CDT

Alex Conover - Oct 12, 2024, 3:15 PM CDT

Title: Standards

Date: 9/17/2024

Content by: Anya Hadim

Present: Anya Hadim

Goals: Find standards that our design has to follow/adhere to

Content:

When we test the AFO, we must keep in mind the ISO Standard 2267:2016.

The device will be classified as a Class 1 Medical Device, and the device does require pre-market approval from the FDA.

Our device will need to fall under the Code of Federal Regulations Title 21, Section 890.3475.

This defines a limb orthosis as a medical device worn on either upper or lower limbs to support, correct, prevent deformities, or to align body structures to improve bodily function. Examples of limb orthoses are as follows: a whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=IQO

Conclusions/action items:

Keep these standards in mind when constructing our AFO.

09/23/2024 - Design Idea Sketches

Alex Conover - Sep 25, 2024, 1:41 PM CDT

Title: Team Design Meeting

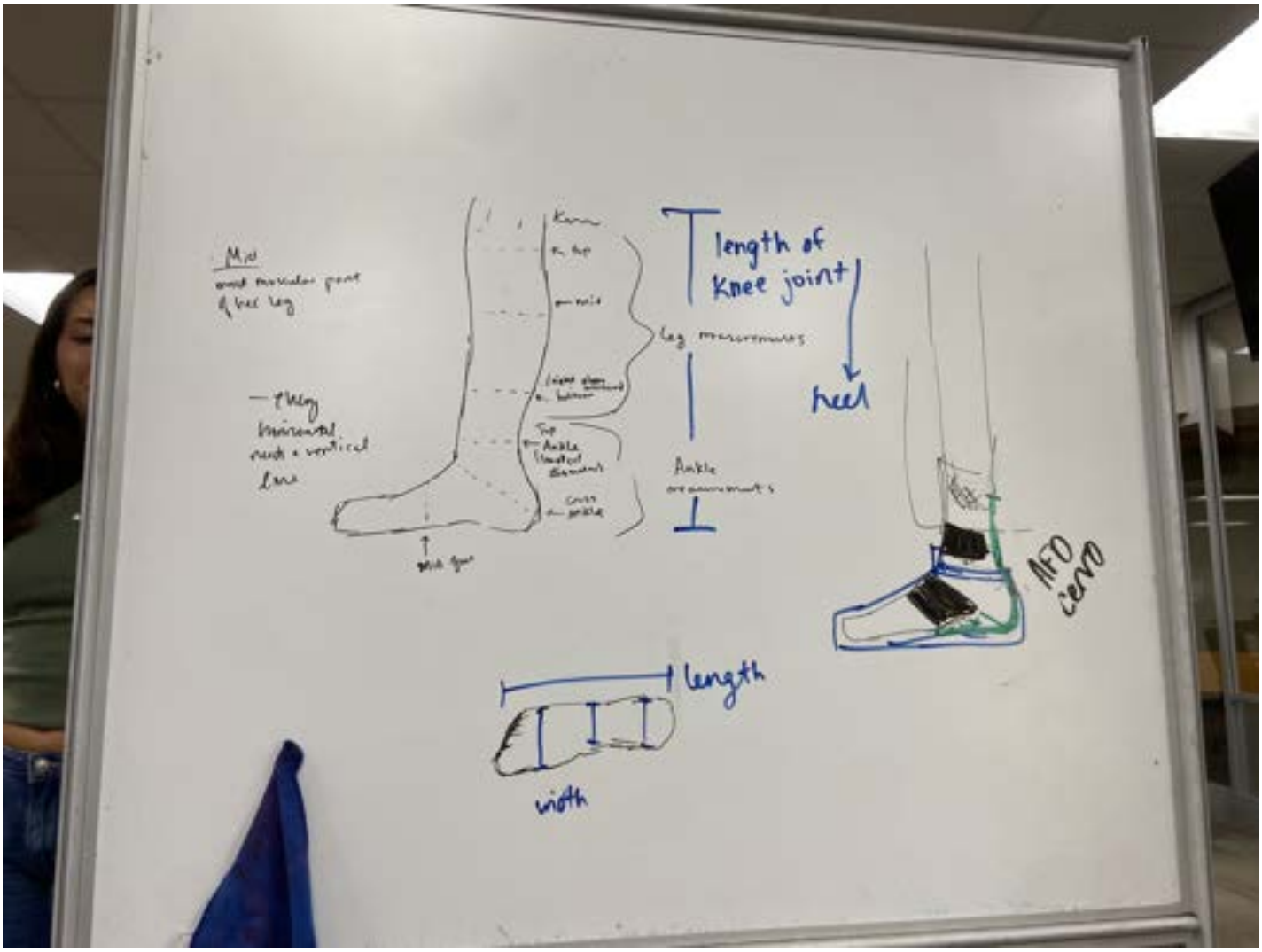
Date: 09/23/2024

Content by: Alex Conover

Present: All team members

Goals: Come up with 3 solid ideas for the design matrix, and ask our Client for measurements

Content:



Conclusions/action items:

Sketch design 3, start and continue research on manufacturing, with 3D printing in the maker-space and carbon fiber manufacturing.

Also complete the lab certifications.

09/27/2024 - BPAG Meeting

Alex Conover - Sep 27, 2024, 12:29 PM CDT

Title: BPAG Meeting 1

Date: 09/27/2024

Content by: Alex Conover

Present: Alex Conover

Goals: Understand the BPAG requirements

Content:

- see PDF, slides linked below:

https://docs.google.com/presentation/d/1afzZducXt7gQVMzRxzyJ6cwwz9kEzfxt0djJqp8hhZc/edit#slide=id.p1

Conclusions/action items:

Start the process of asking our Client for payment methods.

Alex Conover - Sep 27, 2024, 12:29 PM CDT

Download

BPAC_meeting_9-27.pdf (3.76 MB)

11/15/2024 - Tong Lecture

Alex Conover - Nov 15, 2024, 12:45 PM CST

Title: Tong Distinguished Entrepreneur Lecture

Date: 11/15/2024

Content by: Alex Conover

Present: everyone (separately, all together in lecture)

Goals: Learn about Tasso and their Entrepreneurship in the Tong Lecture

Content:

- Tasso is an at-home diagnostic access - a lab device to take your info and send it back without having to go into the office.

- BME background, UW and elsewhere - emphasis of reaching out

- 10 million blood draws per year in the US (nobody likes it) - how would you solve this issue? Get people the care that they need

- just start prototyping! just do it.

- use your resources, they used the university information and (law and entrepreneurship clinic) to create their company

- don't be afraid to "kill" your project when necessary; if it's not working, try something new! Technology evolves, evolve with it. Do it the right way.

- find a key customer: instead of applying a sales pitch, cater directly to the patient/customer

- quality, culture, HR - super important

- lots and lots of testing - 100s of devices a month through testing

- FDA regulations: Class 2 IVD, diagnostic product, 1-2 million dollar clinical trial, 18 months in testing: Class 1 medical device is super easy to clear through FDA (appropriate quality, $100,000 cost)

- Read what regulators say they "want" to do

- stay innovative, you want new and creative ideas, so keep the ideas flowing

- Tasso is Italian for badger, that's why they named the company Tasso.

Conclusions/action items:

Attend team meeting with our advisor today.

Gait Cycle - 09/08/24

GRACE NEUVILLE - Sep 18, 2024, 12:24 PM CDT

Title: Gait Cycle

Date: 9/8/2024

Content By: Grace Neuville

Present: N/A

Goals: Understand the phases of the Gait Cycle, so we can understand how our AFO needs to help our client in each phase.

Contents:

There are two main phases during the Gait Cycle: Stance and Swing. Stance is when the chosen limb is in contact with the ground. Swing is the period when the foot is in the air.

Figure 1. Diagram showing the steps of a Gait Cycle.

The swing and Stance phase can be further broken down into 8 additional phases:

Phase 1- Initial Contact

- Knee is extended
- Dorsiflexed neutral
- Heel makes contact with floor

Phase 2- Loading Response

- Body weight transferred to forward limb
- Knee is flexed

- Initial double stance period until other limb is ready for pre swing

Phase 3- Mid Stance

- First half of single limb support
- Other limb is in mid-swing
- Foot is stationary
- Hip and knee extend
- Until body weight is aligned over forefoot

Phase 4- Terminal Stance

- Other limb is in terminal swing as it moves past forefoot
- Ends once other foot touches ground

Phase 5- Pre swing

- Terminal double support
- Foot responds with plantar flexion
- Opposite limb in loading response

Phase 6- Initial Swing

- Foot is lifted
- Hip and knee flexion
- Ankle partially dorsiflexes
- Ends once foot is in front of planted foot

Phase 7- Mid Swing

- Hip flexion
- Dorsiflexing to neutral
- Limb is in front of planted limb

Phase 8- Terminal Swing

- Begins with knee flexion
- Remains dorsiflexion neutral
- Other limb is in terminal stance
- Ends once foot touches floor

Citations:

A. Kharb, V. Saini, Y. K. Jain, and S. Dhiman, “A Review of Gait Cycle and Its Parameters,” vol. 13, Jul. 2011.

Conclusions/Action Items: In the Gait Cycle, there are 8 unique phases, and we must consider the different flexions of the feet, hip, and knee during each phase. Refer to the Gait Cycle while brainstorming which AFO will accommodate our client the best. Understand how the ankle, hip, and knee are positioned, and what our client needs during each phase.

GRACE NEUVILLE - Sep 18, 2024, 12:25 PM CDT

Download

Review_of_Gait_Cycle_and_Its_Parameters.pdf (431 kB)

AFO Types - 09/08/24

GRACE NEUVILLE - Sep 18, 2024, 12:26 PM CDT

Title: AFO Types

Date: 9/8/2024

Content By: Self

Present: N/A

Goals: Understand the properties of different types of AFOs that we can then implement in our project.

Content:

Ankle Foot Orthosis are used to maintain the alignment of the ankle and foot as well as to stabilize the ankle and foot. It works to prevent and correct ankle and foot deformities. They also help prevent the foot from being dragged on the ground, and help the user maintain a stable posture.

Plastic AFO (PAFO)

- Common
- thermoplastics such as polypropylene
- Low cost, appealing, easy to clean
- Solid or hinged versions

Figure 1. **(A): solid ankle-foot orthosis, (B): posterior leaf spring orthosis, (C): hinged ankle-foot orthosis, and (D): patellar tendon-bearing ankle-foot orthosis.**

Solid AFO (SAFO) (A/B)

- Limits ankle joint movement
- foot drop, weak dorsiflexion and/or plantarflexion, ligament injury about the ankle, mild knee instability, and valgus/varus
- Posterior leaf spring orthosis:

- allows for more movement
- leaf-like corrugations near the ankle to strengthen ankle and act as a spring
- patients with mild cramps, cerebral palsy, stroke
- limitations in controlling valgus/varus

Hinged AFO (HAFO) (C)

- Allows some ankle movement
- Increases plantarflexion and dorsiflexion
- Easier to walk on uneven surfaces
- Walk more normally
- Used in patients with control in knees and mediolateral stability in ankle

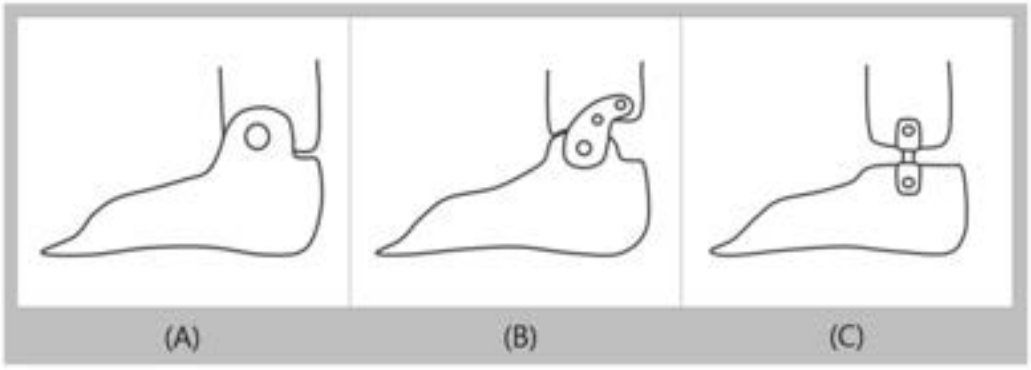


Figure 2. **(A): overlap joint, (B): Oklahoma joint, and (C): Gillette joint.**

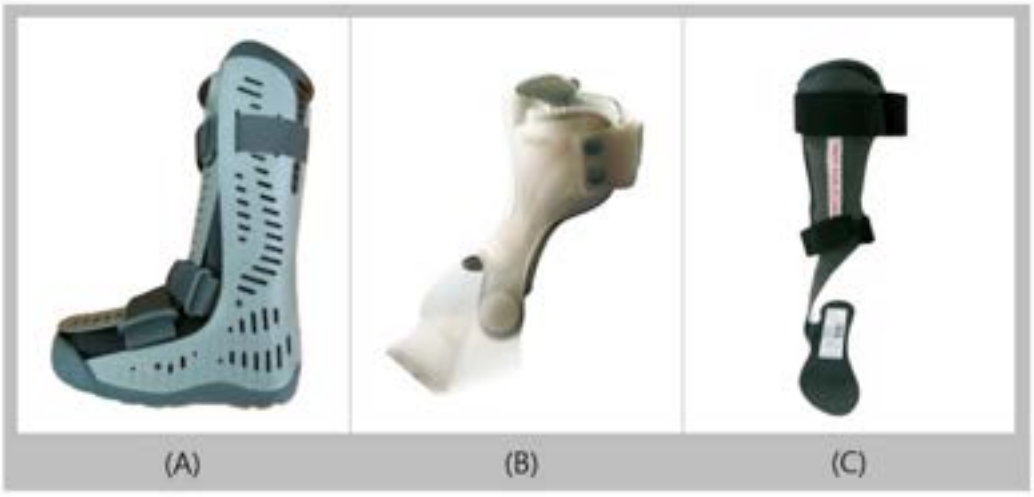


Figure 3. **(A) Boot (B) UD-Flex (C) Carbon Fiber AFO.**

UD-Flex (B)

- Open heel
- Allows contact with ground: natural walking
- Users can wear normal shoe size
- Consistent 5 degree dorsiflexion

Carbon Fiber AFO (CFAFO) (C)

- high stiffness
- high tensile strength
- resistance to high temperatures
- low weight
- Similar to PLSO
- Heel is open
- Thin shell
- Used for foot drop, limb proprioception deficiency, M-L instability, mild knee instability, Charcot–Marie–Tooth disease, and poliomyelitis, where no spasticity is evident

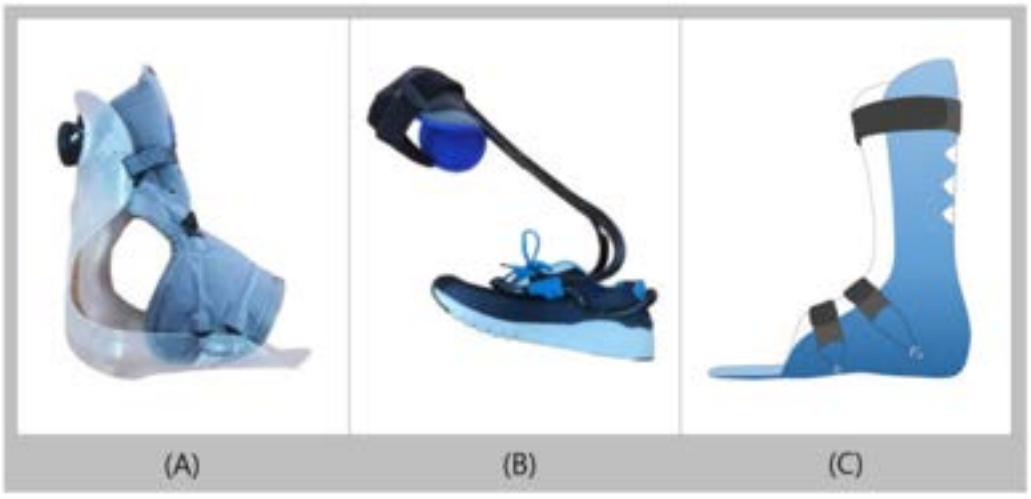


Figure 4. **(A) AFO Servo (B) TurboMed (C) 3D Printed AFO.**

AFO servo (A)

- Fabric in the front plastic in the back
- Mild foot drop

- No studies done on effectiveness…

TurboMed (B)

- Attached to exterior of various types of shoes
- Made of plastic
- Good for uneven ground
- weakened dorsiflexor, foot drop, hemiplegia, or peroneal nerve palsy caused by stroke, cerebral palsy, and multiple sclerosis
- Fear is that plastic will not withstand with the applied load

3D printed AFO (C)

- Can be uniquely made for patients
- Rapid production
- Easily duplicated
- nylon-based polymer
    - high level of stiffness and impact strength
- thermoplastic polyurethane
    - non-toxic and highly flexible
- foot drop, Charcot–Marie–Tooth disease, and plantar fasciitis caused by conditions such as stroke, cerebral palsy, and multiple sclerosis

Citations:

Y. J. Choo and M. C. Chang, “Commonly Used Types and Recent Development of Ankle-Foot Orthosis: A Narrative Review,” *Healthcare*, vol. 9, no. 8, p. 1046, Aug. 2021, doi: https://doi.org/10.3390/healthcare9081046.

Conclusions/Action Items: Plastic AFOs are the most commonly used because of their low cost and durability. However, recently developed AFOs are more durable than plastic ones; however, there is not as much research on how affective they are. Meet with client to understand what her needs are, so we can properly decide which AFO(s) would be appropriate.

PD-AFO - 10/13/24

GRACE NEUVILLE - Oct 13, 2024, 11:51 AM CDT

Title: Passive-Dynamic AFO

Date: 10/13/2024

Content by: Self

Present: N/A

Goals: Understand more about PD-AFOs because they are a more discreet option.

Content:

- **Passive-Dynamic AFOs**
  - allow for more dorsi/plantar flexion
  - calf shell bends and stores elastic energy during stance phase
    - releases that elastic energy during push-off phase
  - suitable for less severe foot drop patients
  - most commonly 3D printed

[1]

[2] Front View of a Passive-Dynamic AFO

References:

[1] G. Rogati, P. Caravaggi, and A. Leardini, “Design principles, manufacturing and evaluation techniques of custom dynamic ankle-foot orthoses: a review study,” *Journal of Foot and Ankle Research*, vol. 15, no. 1, May 2022, doi: https://doi.org/10.1186/s13047-022-00547-2

[2] P. Caravaggi *et al.*, “Development of a Novel Passive-Dynamic Custom AFO for Drop-Foot Patients: Design Principles, Manufacturing Technique, Mechanical Properties Characterization and Functional Evaluation,” *Applied Sciences*, vol. 12, no. 9, p. 4721, May 2022, doi: https://doi.org/10.3390/app12094721

Conclusions/action items: PD-AFOs are discreet and offer more flexibility; however, they should be used in patients with slight foot drop. Add this information into current devices in preliminary report.

Patent US 12042417 - 09/13/24

GRACE NEUVILLE - Sep 18, 2024, 12:32 PM CDT

Title: Ankle Foot Orthosis and Method of Manufacturing Patent

Date: 09/13/2024

Content by: Self

Present: N/A

Goals:

Content:

Patent US 12042417

- Aims to address underlying conditions as well
    - Valgus or varus deformities
    - Instability of the ankle/knee
- Aims to have a degree of adjustability
- Includes multiple variants
- Foot plate
- Spiral strut attached to the rear of the foot plate
    - Spirals at 65 degrees over less than 160mm
- Includes a cuff to adjust the height

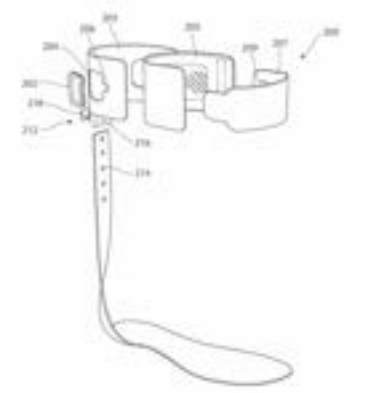


Figure 1. Diagram showing the various components of a posterior ankle foot orthosis variant.

Citations:

Ankle Foot Orthosis and Methods of Manufacturing, by A Thor. et al. (2024, Jul. 23). US012042417B2. [Online]. Available https://patents.google.com/patent/US12042417B2/en?oq=US+12042417

Conclusions/action items: This design of an AFO is unique because it has an adjustable strap and a spiral strut. This can help us brainstorm designs for our AFO that meet our clients' requirements: having the strut medially versus laterally.

Limb Orthosis Standard - 09/13/24

GRACE NEUVILLE - Sep 18, 2024, 12:33 PM CDT

Title: Limb Orthosis Standard

Date: 09/13/2024

Content by: Self

Present: N/A

Goals: Understand what a limb orthosis is classified as.

Content:

§ 890.3475 Limb orthosis

Limb orthosis is identified as a medical device worn on either upper or lower limbs to support, correct, prevent deformities, or to align body structures to improve bodily function. Examples of limb orthoses are as follows: a whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.

Citations:

Limb Orthosis, 21 CFR 890.3475, 2001 (accessed Sep. 13, 2024).

Conclusions/action items: Use this classification of a limb orthosis and apply it as we design our ankle foot orthosis.

Testing Elastic Fabrics Standard - 09/19/2024

GRACE NEUVILLE - Sep 19, 2024, 4:11 PM CDT

Title: Testing Elastic Fabrics Standard

Date: 09/19/2024

Content by: Self

Present: N/A

Goals: Learn more about standard testing procedures for elastic fabrics. Can use this to test different elastic fabrics if we choose to incorporate them in our design.

Content:

ASTM D5278/D5278M-09(2017)

Standard Test Method for Elongation of Narrow Elastic Fabrics (Static-Load Testing)

- This standard discusses testing methods for elastic fabrics that are natural or man-made by elastomers. This static load testing procedure determines elongation characteristics of such fabrics.

Citations:

Standard Test Method for Elongation of Narrow Elastic Fabrics, ASTM D5278/D5278M-09, 2017 (accessed Sep.19, 2024).

Conclusions/action items: If we choose to incorporate elastic fabrics into our AFO design, we can apply this testing procedure.

FEA Test - 09/18/24

GRACE NEUVILLE - Sep 18, 2024, 6:57 PM CDT

Title: FEA Versus F-D Curve Test on CF and Thermoplastic AFOs

Date: 09/18/24

Content by: self

Present: N/A

Goals: Understand more about the differences between carbon fiber and thermoplastic AFOs. Learn more about testing strategies that we can later apply to our design.

Content:

Study Purpose:
To use FEA (Finite Element Analysis) Modeling to predict how AFOs will react to loads and compare with bench-top testing. This Study tests 2 carbon fiber AFOs and 1 Posterior leaf spring (thermoplastic) AFO.

Background Information:

- Posterior leaf spring AFO
    - Low energy storage
    - Low energy return capabilities
    - Unable to assist with propulsion during walking
    - Easy and quick fabrication
        - Thermoplastic used in this study:
        - AFO3: Polypropylene (¼ in.)
            - Hyper-elastic (1) and viscoelastic properties (2)
            - Density: 0.9 g/m^3
            - Young modulus (3): 2400 Mpa (4)
            - Poisson ratio (5): 0.43
            - Tensile strength: 30 MPa
- Carbon fiber AFO
    - Improve ankle plantar-flexor power (by 15-97%)
    - Improve plantar-flexor ankle joint moment (by 7-27%)
    - Improve walking speed by (6-30%)
    - improved stride length (by 4-9%)
    - Decrease energy cost (by 12%)
    - Cannot be remolded if modifications are required
    - Difficult and expensive to fabricate; fabrication steps:
        - Layering sheets or plies of CF, then impregnating them with resin
        - Cure resin at high temperatures
        - Standard layering: fiber structures of Std 2x2 twill weave
            - AFO1:
                - Shank (18 layers)
                - Mid-foot (9 layers)
                - Toe (4 layers)
            - AFO2:
                - Shank (24 layers)
                - Mid-foot (9 layers)

- Toe (4 layers)

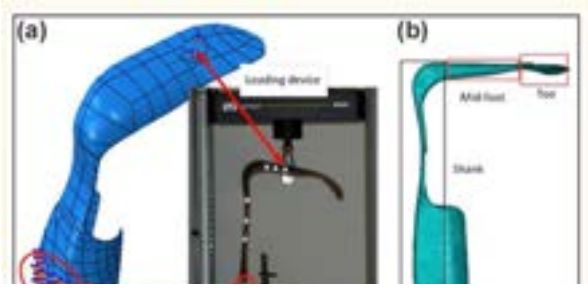


Figure 2. Model displaying the bench-top testing set-up.

- FEA Modeling
  - Assumed CF as a shell composite
  - For CF AFOs: stress in the composite is equal to the sum of all stresses in the fibers and in the resin:
    - $$\sigma_t = (1 - \sum_{1}^{n} \rho_f^i)\sigma_r + \sum_{1}^{n} \rho_f^i \sigma_f^i$$
      - t= total stress in the composite material; f= fiber stress tensors; r= resin stress tensors; = volume fraction; f= fiber; r= resin; i=ith direction; n=total number of fibers
  - Goal is to predict bench-top test results, therefore used same loads and loading rate

Results:

- CF had a relatively linear F-D loading curve with high stiffness
  - Reached 1000 N with little deformation (approximate amount of force on an AFO for a 225 lb. man)
  - AFO2 fracture occurred at a load of 1970 N
    - fracture was at the mid-shank region
  - FEA was able to accurately predict the Energy Return Rate for both AFO1 and AFO2
- Thermoplastic nonlinear behavior with low stiffness
  - Reached 150 N before undergoing significant deformation
  - FEA was unable to accurately predict the Energy Return Rate for AFO3

Figure 3. Bar graph comparing the Energy Return Rate (%) results from the bench-top study, in blue, and FEA model, in red, for three different AFOs.

Limitations of this study:

- Inaccuracy of FEA predicting mechanical properties of the thermoplastic AFO at high loads
- Loading method used in bench-top testing does not accurately represent how the AFO is used during gait

Conclusions:

- CF AFO returned more than 88% energy from a 1000 N load
- Thermoplastic AFO returned 77.4% of energy from a 150 N load
- FEA model accurately predicted the behavior of the CF AFO

Vocab:

1. Hyper-elastic: ideally elastic, can undergo deformation and remain elastic
2. Viscoelastic: exhibiting both elastic and viscous behavior
3. Young Modulus: measures tensile and compressive strength of a material when force is applied lengthwise.
4. Mpa: megapascal (10^6 times the si unit for pressure)
5. Poisson ratio: deformation perpendicular to the loading force. (typical range is 0-0.5, rigid-soft)

Citations:

D. Zou *et al.*, “Experimental and computational analysis of composite ankle-foot orthosis,” *Journal of Rehabilitation Research and Development*, vol. 51, no. 10, pp. 1525–1536, 2014, doi: https://doi.org/10.1682/jrrd.2014-02-0046. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5976490/

Conclusions/action items:

Bench-top testing is a good method to determine F-D data to determine Energy Return rates. Carbon fiber AFOs are more durable and improve functionality of the ankle compared to thermoplastic AFOs. Discuss findings with team and determine if carbon fiber is a feasible option for our project given that it is expensive and difficult to fabricate.

Testing AFOs and Muscle Tone - 09/23/2024

GRACE NEUVILLE - Sep 23, 2024, 1:07 PM CDT

Title: Testing the Influence of AFOs on Muscle Tone

Date: 09/23/2024

Content by: Self

Present: N/A

Goals: Understand how AFOs can help with individuals with muscle tone.

Content:

AFOs that help with muscle tone are called "tone-reducing AFOs". These AFOs work to:

- Influence the positive support reflex or tonic reflex:
    - Presses reflexogenous areas on the plantar surface of the foot
    - Suppressed by offloading them
- Toes are either extended or horizontal
    - Elevated by 10 degrees, or 0.5 cm
- Ankle joint kept at 90 degrees with the subtalar joint in a neutral position

In this study, AFOs were tested on patients with muscle tone:

AFO designs	References
AFO type	
NAAFO	Zachazewski et al.[11]; Harris and Rieffle[14]; Bronkhurst and Lamb[15]; Diamond and Ottenbacher[17]; Dieli et al.[20]; Radtka et al.[21]; Iwata et al.[24]; Nash et al.[29]
AAFO	Crenshaw et al.[22]; Ibuki et al.[30]
SMO	Harris and Rieffle[14]; Hylton[16]; Embrey et al.[18]; Mueller et al.[19]; Crenshaw et al.[22]; Romkes and Brunner[23]; Näslund et al.[25]; Lam et al.[26]; Bjornson et al.[27]; Näslund et al.[28]
NAFO	Ford et al.[13]
Toe extensor	
Extended	Zachazewski et al.[11]; Bronhorst and Lamb[15]; Embrey et al.[18]; Dieli et al.[20]; Crenshaw et al.[22]; Iwata et al.[24]; Nash et al.[29]
Horizontal	Hylton[16]; Mueller et al.[19]; Radtka et al.[21]; Romkes and Brunner[23]; Näslund et al.[25]; Lam et al.[26]; Bjornson et al.[27]; Näslund et al.[28]; Ibuki et al.[30]
Metatarsal head	
Loaded	Zachazewski et al.[11]; Crenshaw et al.[22]
Unloaded	Ford et al.[13]; Bronkhorst and Lamb[15]; Hylton[16]; Mueller et al.[19]; Dieli et al.[20]; Radtka et al.[21]; Crenshaw et al.[22]; Romkes and Brunner[23]; Näslund et al.[25]; Lam et al.[26]; Bjornson et al.[27]; Näslund et al.[28]; Nash et al.[29]; Ibuki et al.[30]
Ankle alignment	
90° with subtalar neutral	Zachazewski et al.[11]; Bronhorst and Lamb[15]; Diamond and Ottenbacher[17]; Dieli et al.[20]; Radtka et al.[21]
Free PF/DF with subtalar neutral	Hylton[16]; Mueller et al.[19]; Romkes and Brunner[23]; Näslund et al.[25]; Lam et al.[26]; Bjornson et al.[27]; Näslund et al.[28]
PF/DF with sutalar, midfoot, forefoot neutral	Ford et al.[13]
Free DF with 90° PF stop	Crenshaw et al.[22]; Ibuki et al.[30]
Medial-lateral stability	Hylton[16]; Embrey et al.[18]; Mueller et al.[19]; Romkes and Brunner[23]; Näslund et al.[25]; Lam et al.[26]; Bjornson et al.[27]; Näslund et al.[28]
Heel	
Loaded	Bronkhurst and Lam[15]
Unloaded	Hylton[16]; Mueller et al.[19]; Radtka et al.[21]; Romkes and Brunner[23]; Näslund et al.[25]; Lam et al.[26]; Bjornson et al.[27]; Näslund et al.[28]; Ibuki et al.[30]
Tendon insertion	
Loaded	Zachazewski et al.[11]; Nash et al.[29]
Hylton's design (DAFO)	Hylton[16]; Mueller et al.[19]; Romkes and Brunner[23]; Näslund et al.[25]; Lam et al.[26]; Bjornson et al.[27]; Näslund et al.[28]

AFO, ankle-foot orthosis; AAFO, articulated ankle-foot orthosis; DAFO, dynamic ankle-foot orthosis; DF, dorsiflexion; NAAFO, nonarticulated ankle-foot orthosis; NAFO, neurophysiological ankle-foot orthosis; PF, plantarflexion; SMO, supramalleolar orthosis.

Clinical effect	References
Gait	
Increase in walking velocity	Diamond and Ottenbacher[17]; Dieli et al.[20]; Iwata et al.[24]; Nash et al.[29]
Increase in step or stride length	Diamond and Ottenbacher[17]; Dieli et al.[20]; Radtka et al.[21]; Lam et al.[26]; Nash et al.[29]
Decrease or increase in cadence	Diamond and Ottenbacher[17]; Dieli et al.[20]; Radtka et al.[21]; Iwata et al.[24]
Reduction in excessive knee flexion	Embery et al.[18]
Improvement in foot floor contact/loading pattern/support	Mueller et al.[19]; Dieli et al.[20]
Improvement in ankle kinematics	Zachazewski et al.[11]; Radtka et al.[21]
Reduction in positive support reflex	Zachazewski et al.[11]; Bronkhorst and Lamb[15]
Reduction in time spent at double stance phase	Nash et al.[29]
Balance, posture, function	
Improvement in balance, posture and standing	Harris and Rieffle[14]; Hylton[16]; Näslund et al.[25]
Improvement in Gross Motor Function Measure	Bjornson et al.[27]
Neurophysiological effect	
No reduction in Hmax: Mmax ratio or median frequency	Lam et al.[26]; Ibuki et al.[30]
Better modulation of EMG activity at gastrocnemius	Nash et al.[29]
Carryover effect	
Potential carryover effect	Bronhorst and Lamb[15]; Mueller et al.[19]

EMG, electromyography; Hmax:Mmax, the ratio of maximum Hoffman reflex amplitude to maximum muscle response amplitude.

Conclusions:

- Extensions of the toes: articles varied in opinion:
  - 10 degree elevation, 0.5 cm elevation, hyperextended, or horizontal.
- Loading on the metatarsal heads:
  - most suggested using plastar model rectifications to relieve loading from the metatarsal heads
  - using felt that extended from under the toes to underneath the metatarsophalangeal joints helped prevent plantar grasping
  - 0.5 cm of elevation beneath the metatarsal heads attempted to reduce tone in plantarflexion and inversion
- Alignment of the ankle:
  - most AFOs the ankle joint was kept at 90 degrees
  - most had subtalar joint positioned in neutral
  - DAFOs allowed for free plantar/dorsiflexion ankle movement
  - neurophysiological AFOs positioned the subtalar, midfoot, and forefoot in their neutral position, and ankle movement was dependent on the stiffness of the orthoses
  - articulated AFOs ankle joint kept at 90 degrees, controlled plantarflexion and free dorsiflexion

- Loading on the Heel:
  - most AFOs relieved loading on the heel
- Loading on the Tendon Insertion:
  - loading was applied medially and laterally to the Achilles tendon insertion area
- Comparison with standard AFOs:
  - did not show conclusive evidence that AFOs with tone-influencing designs were superior

Citations:

Kobayashi, Toshiki PhD; Leung, Aaron K.L. PhD; Hutchins, Stephen W. PhD. Design and Effect of Ankle-Foot Orthoses Proposed to Influence Muscle Tone: A Review. *JPO Journal of Prosthetics and Orthotics* 23(2):pp. 52-57, 2011. doi: 10.1097/JPO.0b013e3182173a61. Available: https://journals.lww.com/jpojournal/Fulltext/2011/04000/Design_and_Effect_of_Ankle_Foot_Orthoses_Proposed.2.aspx

Conclusions/action items: Use the conclusions of this study to help design our AFO, and choose what aspects will help our client.

Brainstorming Designs - 09/20/2024

GRACE NEUVILLE - Sep 24, 2024, 1:47 PM CDT

Title: Brainstorming Designs

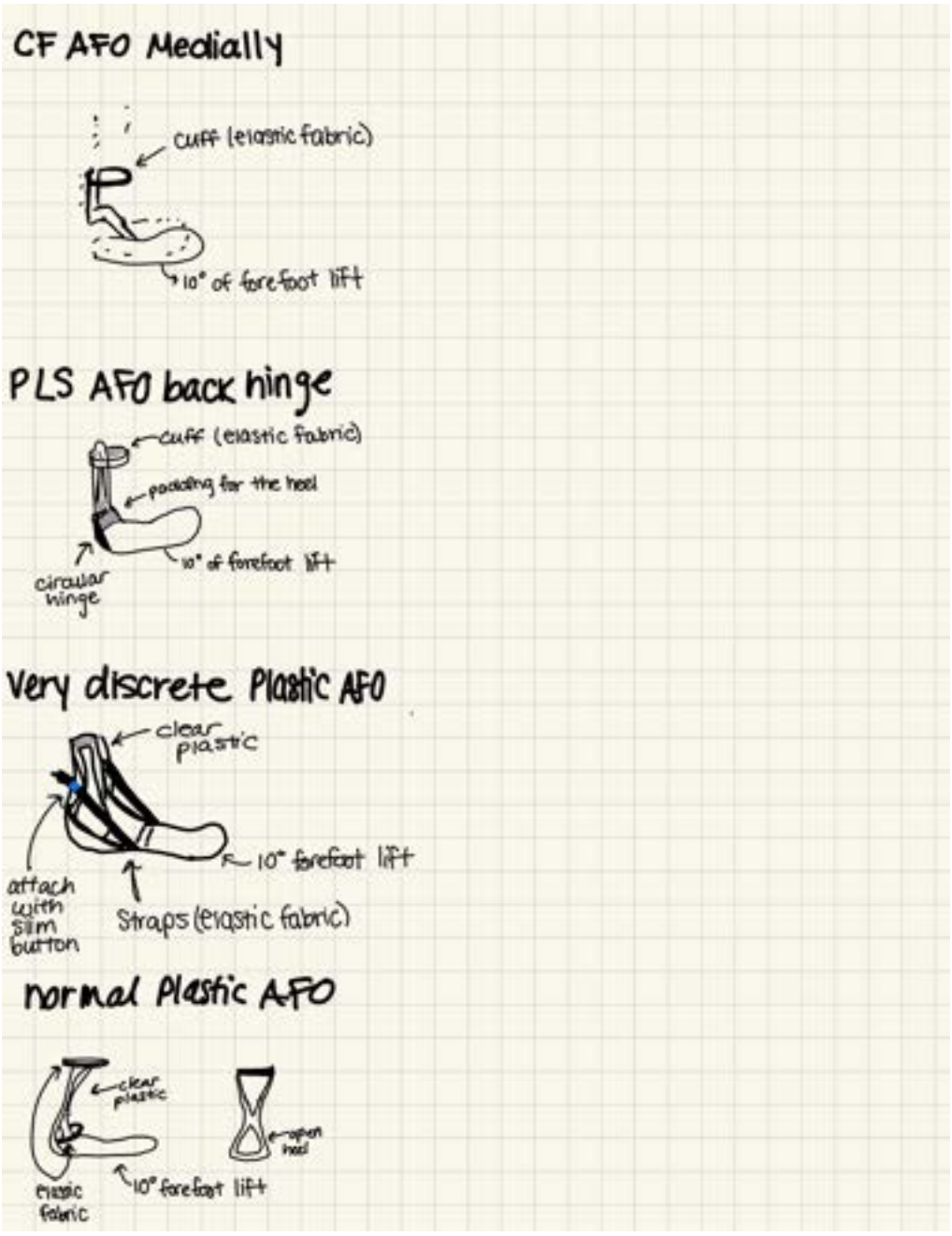
Date: 09/20/2024

Content by: Self

Present: N/A

Goals: Brainstorm designs that take into account our client's requirements and the product design specifications.

Content:



Descriptions:

CF AFO Medially

- Slim cuff made of elastic fabric
- strut begins on the medial side of the foot, then twists up and ends at the back of the leg
- End goal is to be made of carbon fiber
- 10 degrees of forefoot lift to help with dorsiflexion
- expensive

PLS AFO Back Hinge

- Similar to PLS AFOs because of the back leaf-like slits and made of thermoplastic
- Has a circular hinge at the ankle to allow for some plantar flexion movement
- Has padding near the ankle to help with comfortability
- 10 degrees of forefoot lift to help with dorsiflexion
- cheaper
- may be uncomfortable
- bulky

Very Discrete Plastic AFO

- Similar to AFO servo, but does not have the fabric in the front
- Replaces the fabric with two elastic fabric straps
- elastic straps allows for some plantar flexion movement
- straps attach with durable buttons, various button locations adds customizability
- made from clear plastic
- open heel for comfortability
- 10 degrees of forefoot lift to help with dorsiflexion
- cheaper
- discrete because it is shorter, mostly hidden in shoe
- little research on how effective, because of the shorter design

Normal Plastic AFO

- slim cuff made from elastic fabric
- additional elastic fabric strap near ankle for support
- clear plastic design for discreetness
- open heel for comfortability
- 10 degrees of forefoot lift to help with dorsiflexion
- cheaper
- not as discrete

Conclusions/action items: The Very Discrete Plastic AFO is the most discrete option, and should be easy to manufacture; however, not sure on how effective it would be because of its short, discrete nature. The CF AFO Medially matches what our client is looking for; however, the carbon fiber is expensive, so need to use a plastic that is similar to carbon fiber. The PLS AFO Back Hinge and Normal Plastic AFO designs are the least discrete but may be the most effective at supporting dorsiflexion and plantar flexion movements. Meet with team to discuss design ideas. Create design matrix to weigh the pros and cons of each design. Present them to our client to decide which design to move forward with. Continue to do research on materials.

HIPPA Training - 10/22/24

GRACE NEUVILLE - Oct 30, 2024, 5:34 PM CDT


Grades for GRACE NEUVILLE

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CITI Human Subjects Research Training - 10/22/24

GRACE NEUVILLE - Oct 30, 2024, 5:35 PM CDT

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Biosafety Training - 09/03/24

GRACE NEUVILLE - Oct 30, 2024, 5:38 PM CDT

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Chemical Safety Training - 09/02/24

GRACE NEUVILLE - Oct 30, 2024, 5:39 PM CDT

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Chemical_Safety_Training.pdf (86.4 kB)

Tong Lecture Notes - 11/15/24

GRACE NEUVILLE - Nov 15, 2024, 12:48 PM CST

Title: Tong Lecture Notes

Date: 11/15/2024

Content by: self

Present: N/A

Goals: Take notes during Tong Lecture

Content:

Starting a business:

- Think about how health care can be improved
- Take the leap and start brainstorming and prototyping
- Find resources and make connection to help build the business
- Find funding opportunities and write as many grants as possible - helps alleviate pressure and conduct testing
- Continuously improve products and kill previous products when needed in a careful way - do not want to upset existing customers
- Find key customers and focus on solving one of their problems
- Scale up while still making sure quality of the product is preserved and focusing on team culture
- FDA regulatory process: make sure to look closely at labels and how they can be applied to your device for easier clearance

Conclusions/action items: If you have an idea and believe in it then go for it.

2014/11/03-Entry guidelines

Alex Conover - Sep 25, 2024, 1:39 PM CDT

Use this as a guide for every entry

- Every text entry of your notebook should have the **bold titles** below.
- Every page/entry should be **named starting with the date** of the entry's first creation/activity, subsequent material from future dates can be added later.

You can create a copy of the blank template by first opening the desired folder, clicking on "New", selecting "Copy Existing Page...", and then select "2014/11/03-Template")

Title: Descriptive title (i.e. Client Meeting)

Date: 9/5/2016

Content by: The one person who wrote the content

Present: Names of those present if more than just you (not necessary for individual work)

Goals: Establish clear goals for all text entries (meetings, individual work, etc.).

Content:

Contains clear and organized notes (also includes any references used)

Conclusions/action items:

Recap only the most significant findings and/or action items resulting from the entry.

2014/11/03-Template

Lucia Hockerman - Sep 29, 2024, 11:29 AM CDT

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items: