CroBro

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Executive Summary

In addition to the 795,000 people that experience a stroke every year ("Stroke Facts", 2017), there are millions of others living in the United States who are diagnosed with multiple sclerosis, cerebral palsy, and other conditions that cause weakness or near paralysis in a person's leg. Most of these people wear an L-shaped brace that goes around their ankle called an Ankle Foot Orthosis (AFO), making AFOs the most commonly used orthotic in the United States ("Neuromuscular Mobility Treatment."). While the AFO does a lot to support the user's weakened leg, its bulkiness and rigidity makes it difficult for users to independently don their shoes on top of their AFO.

Because of this, Lauren Henderson, an occupational therapist working at the Shirley Ryan AbilityLab, commissioned Team 11-1 to create a device that would allow AFO users to independently don their shoes in combination with their orthotic.

CroBro

In response, Team 11-1 created a set of instructions for users to give to shoe repair shops to modify their shoes into CroBros. Intended for athletic shoes, this modification makes the shoe donning process easier by adding a slit to the inner side of their shoe. A leather flap, lined with weather resistant velcro, covers this slit and provides durability and adjustability.

Specifically, CroBro modifications have the following benefits:

- **Easy foot access.** The slit in the side of the shoe provides a large opening for the foot and AFO to slide in without getting caught on the shoe's tongue, heel, or other loose elements.
- **Independence.** The modified shoes allow users to don their shoes with little to no assistance from others, promoting independence and self-confidence.
- **Minimalist appearance.** Because there is only a simple flap covering the slit along the inner-facing side, the shoe maintains most of its standard appearance, including its laces and outward-facing designs.
- **Ease of fabrication.** The instructions contain multiple diagrams, detailed text, and accurate measurements, making it easy for the shoe repair shop to understand how to perform the modification.
- **Adaptability.** Due to the simplicity of the design, the CroBro modification can be adapted for many sizes of athletic shoes.

Although CroBro meets many of its major requirements, it can still be improved greatly. With more development, the CroBro could become a kit that allows users to independently modify their own shoes, increasing accessibility, affordability, and simplicity. Additionally, a tab or loop could be added to the flap to help those with less dexterity open and close the shoe. It would also be ideal for the CroBro to become adaptable to non-athletic shoes.

Introduction

In the United States alone, around 19.4 million people live with leg impairments from stroke, multiple sclerosis, cerebral palsy, and numerous other conditions. According to the Centers for Disease Control and Prevention, over 795,000 Americans experience a stroke every year (2019), which can result in long-term side-effects that impair motor function and cognitive abilities. Hemiplegia, for example, renders half of a person's body weak or paralyzed. A 2019 study estimated that in 2017, around 1 million people lived with multiple sclerosis in the United states, which is double the estimate from a 1975 study ("Landmark Study Estimates," 2019). This disease attacks the central nervous system, causing the person to lose control over parts of their body. As a result, many of these people are prescribed to wear Ankle Foot Orthoses (AFO), an L-shaped brace that provides rigid support for the foot and increases toe clearance during the swing phase of the gate. Although effective, wearing an AFO comes with many negatives. The rubbing between the plastic and the skin can lead to skin inflammation ("Use and Care of Your Ankle-Foot Orthosis"), the bulky design of the AFO draws attention, and the process of putting an AFO on can be difficult.

Consequently, there are plenty of workarounds and blogs devoted to daily living with an AFO, such as trend-able.com and biotechpossibilities.com. They teach AFO users how to clean their AFO, choose what socks to wear, check for pressure points, and much more. However, one of the largest issues that hasn't been fully addressed is donning a shoe over an AFO. The weakness in that leg means AFO users cannot forcibly adjust their feet into their shoes. The shape of the AFO locks the user's foot into a 90 degree angle. These limitations, combined with the narrowness of the shoe's opening and the slackness of the shoe's fabric causes the heel of the AFO to often get caught on the back of the shoe and the user's toes to get caught on the tongue of the shoe. Although blogs and physicians recommend sizing up in shoes, the opening is still not large enough, and most of these problems persist.

Upon seeing this need first-hand, occupational therapist Lauren Henderson from the Shirley Ryan AbilityLab asked DTC Team 11-1 to design a device in ten weeks that would allow users to independently don their shoes over their AFO (See Appendix A for a detailed project definition).

A variety of products currently attempt to assist with the difficulty of donning a shoe over an AFO. The Original AFO Assist is one such product, providing a docking station for donning both the AFO and the shoe over top of it ("Sammons Preston AFO Assist"). However, the client indicated that she'd never seen such a device used in hospitals despite her experience in numerous places. Another device used to ease the process is a foot funnel ("FootFunnel Long Shoe Horn"). This is a plastic piece that is inserted into the shoe over the heel. It both decreases friction when sliding the foot into the shoe and increases the shoe's opening by preventing the heel from being collapsed. While very useful, the foot funnel doesn't completely solve the problems associated with donning a shoe over an AFO. The other notable solution on the market is an external AFO ("Turbomed Orthotics - The Most Advanced Foot Drop Brace"). This is an AFO that fits on the outside of the users shoe, allowing use with a variety of footwear. This requires a

fundamental change in the type of AFO used however, and users typically have personalized AFOs. (More detail on these solutions, including images can be found in Appendix B.)

With these issues in mind, the CroBro and the CroBro instruction set were created. The CroBro is a modified shoe with a slit and a velcro flap to cover it, and the instruction set is a set of instructions to give to a shoe repair shop in order to create a CroBro.

The rest of this report goes into detail of the process in which Team 11-1 addresses the AFO donning issue. It will specify the targeted user audience, outline the major requirements that this device must meet, explain the rationale behind each feature of this design, and conclude with the limitations and directions for future designs.

Users and Major Requirements

Primary Users: AFO Wearers

The device must be designed to be used by anyone who wears an AFO on a daily basis. This includes patients with hemiplegia who have paralysis on one side of their body. AFO wearers who are recovering from stroke commonly have cognitive impairments and weak core strength (Appendix C).

Secondary Users: Caretakers

Caretakers are responsible for taking care of the patient, so they are in charge of performing actions that the patient cannot on their own. These tasks include creating/purchasing the device as well as transporting the device if needed. Overall, the device should reduce the patients reliance on their caretaker.

Stakeholders: Shoe Repair/Sales & Occupational Therapists

Shoe shops may be contacted to order or alter shoes and stand to financially benefit from the final product.

Occupational therapists strive to increase independence in daily activities of AFO wearers. The device gives these patients the ability to don their shoes on their own, assisting occupational therapists in helping their patients reach the end goal of complete independence (See Appendix F for the full user, stakeholder, and context assessment).

Major Requirements

Simplicity: The client mentioned that stroke patients often have cognitive impairments, making it difficult for them to learn complex tasks (Appendix D). Therefore, the patient ideally should be able to operate the device by simply looking at the design without going through prior education of its functionality. At worst, the user should be confident in operating the device after a maximum of five minutes of guidance.

Aesthetics: Users made it clear during testing that modified shoes should be aesthetically pleasing to encourage wear (Appendix J). Ideally, the modified shoe should be indistinguishable from an unmodified pair of running shoes.

Accessibility: Patients with hemiplegia have full mobility in only half of their body (Appendix B), so the device should only require one arm and one leg to operate. Otherwise, the patients with hemiplegia would need a caretaker to help them operate the device, limiting independence.

Durability: The end goal for many AFO wearers is to regain enough control to resume normal, daily functioning, including walking. Thus, the design must be durable enough to withstand frequent use multiple times a day. If the device is used outside, it must also be able to endure the wide range of possible temperatures, terrains, and other conditions of the surrounding environment.

Clarity: In order to ensure that the device functions properly, instructions for creating/using the device must be clear and devoid of any ambiguity.

Cost: The client indicated that because of the already high costs associated with medical treatment, the shoe modification must cost no more than $100 (Appendix D).

Safety: As a general rule, designs that are unsafe are better left unused. The most significant safety risks in regards to a design dealing with footwear are tripping hazards. In order for a design to be safe, it must not increase the user's risk of tripping.

Design Concept and Rationale

Team 11-1 has two major deliverables — the CroBro shoe prototype and the Handbook for making a CroBro.

CroBro

The CroBro is a shoe modification that gives the user more room to insert their AFO and foot into a shoe. Its core feature is a cut that is made along the inward-facing side of the shoe which grants the user's foot more space to operate in during donning. A leather patch is sewn onto the top flap to cover the cut, while velcro is attached to either side to close off the opening. The design is compatible with any running shoe.

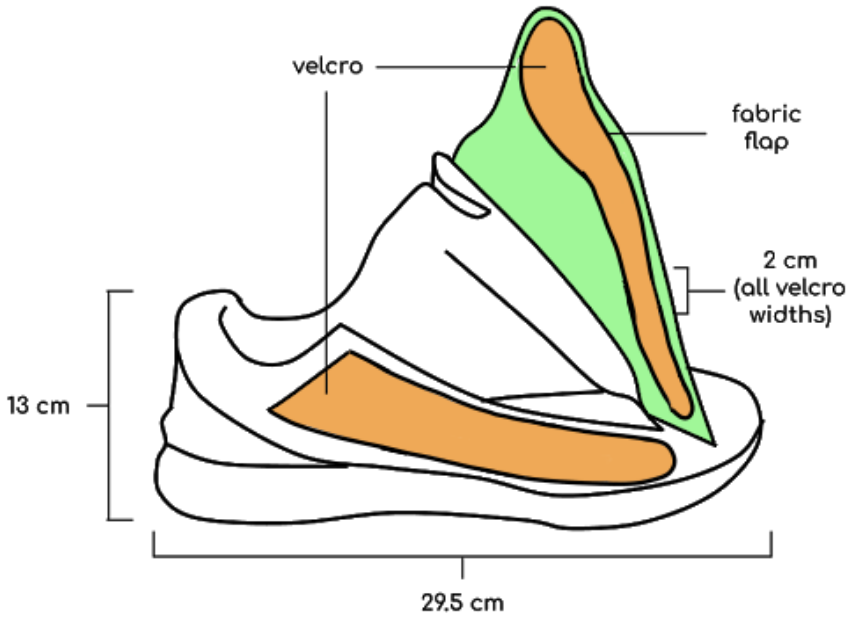

Figure 1: The Velcro Burritoe (CroBro). Graphic by Katrina Baniak and Hannah Huang.

Donning Instructions:

1. Enter the cross-legged position, placing the AFO leg over the other leg.
2. Open velcro flap.
3. Insert foot with AFO fully into shoe.
4. Pull velcro flap closed.

Design Subsystems, Important Features, and Key Decisions

Shoe Modification Rationale

Shoe modifications were concluded to be the best design choice, as all Team 11.1's previous non-shoe mockups were unwieldy and difficult to operate (See Appendices G, H, and I for more detail on mockup testing). Shoes often come in different shapes, materials, and forms, and different shoes introduce different challenges to the donning process. Shoe modifications, however, allow us to physically alter the shoe to a desired design. Instead of trying to overcome a shoe's inherent tensions and other attributes, shoe modifications give us the ability to remove those tensions in the first place.

For instance, during user testing, we observed that the rigidity between a shoe's heel and the rest of the opening made it extremely difficult to insert one's foot (Appendix E). By making a cut along the side of the shoe, the incision relieves that pressure, slightly weakening the structural integrity to make it much easier to insert. A non-shoe device would have to find a workaround for the stiffness of the shoe, a much more difficult and complex task.

1. Inner-Facing Flap

Design Specifications:

The flap is produced by making a curved incision using shears along the inner-facing side of the target shoe. The cut starts roughly two-thirds of the way from the back of the shoe opening to the start of the opening. It curves forward and down until it stops so that there is 10% - 15% of the length of the shoe still remaining to the shoe's tip. A curved, oblong patch is then fitted and sewn onto the top flap to cover the incision line and provide a surface for velcro to be attached on later. This leather flap was 3.25'' by 8.5'' in our CroBro prototype, but the exact dimensions will vary to a small degree depending on the shoe.

Rationale:

The flap is designed to open up the shoe to give the user more open area to work with throughout the donning process. Compared to other potential shoe modifications, this design was the simplest and most aesthetically pleasing. In the entire design, the flap is the only moving part, allowing the shoe to be put on with just a single hand. Furthermore, the attached flap conceals both the incision and the velcro closing mechanism that holds the upper and lower portions of the flap together. This disguises the shoe modification to great effect (Appendix L). The use of leather not only added to the inconspicuousness of the design, but also provided durability (see Appendix N for recommendations from shoe repair shops).

The incision must be made on the inward-facing side, as that side is exposed to the user when oriented in the cross-legged position. This also shares the added benefit of visually obscuring the modification, as the inward-facing side can only be seen clearly from certain angles compared to the outward face.

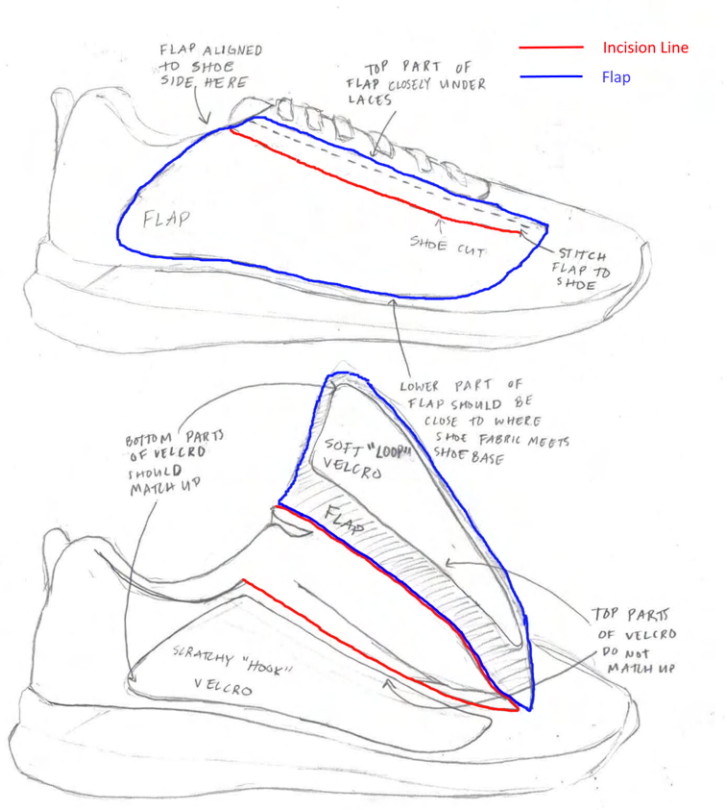

Figure 2: Shoe Diagram with Marked Incision Line and Flap. The diagram above illustrates the the flap and incision line positions relative to the shoe in our prototype. Graphic by Hannah Huang and Andy Xu.

2. Velcro Patch

Design Specifications:

The velcro patches are cut with scissors and are sewn on using a patching machine with the fuzzy side on the bottom and the coarse side on top. We used specialized weather-resistant velcro that works in conditions from -20 °F to 200 °F (Appendices O and P). The velcro patch in the prototype was 1.25'' by 7.125'', though this varies slightly between different shoe types and sizes.

Rationale:

The velcro serves to attach the open ends of the fabric together to close off the incision. A velcro patch was used on both sides of the opening instead of horizontal or vertical stripes in order to maximize the connecting surface area of the two velcro patches, increasing the integrity of the connection. Velcro patches are also easier to align. Velcro was used as it provided an intuitive mechanism by which users could open and close the flap. Velcro already appears commonly in commercial shoe products, proving that it is an effective technology. Additionally, the large velcro patches offer a small

amount of flexibility to increase or decrease the overall fit of the shoe, as the intersection of upper and lower flaps can be freely adjusted depending on the user's needs.

The velcro was chosen over a zipper because from user testing of past mockups, the zipper often got stuck, did not allow for adjustability, and was hard to use for those with limited dexterity (Appendices J and K).

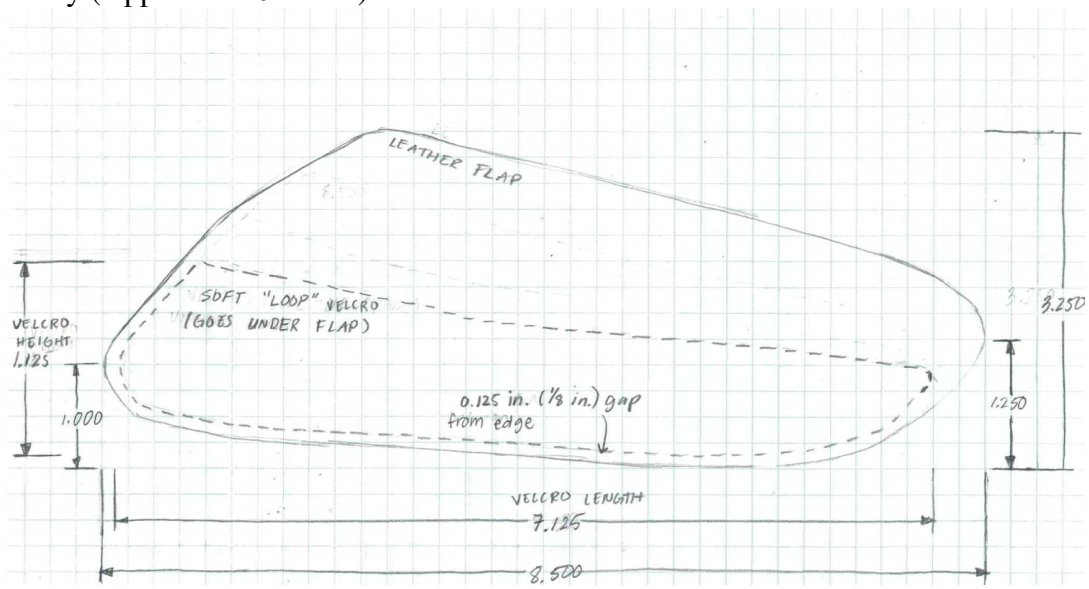

Figure 3: Leather Flap and Weather-Resistant Velcro. The diagram above illustrates the dimensions of the flap and the velcro in our prototype. Graphic by Hannah Huang.

Benefits

- *Free:* CroBro gives AFO wearers increased freedom in putting on their shoes. This empowers the user in granting them more control over their daily lives while taking stress off of caretakers.

- *Portable:* CroBro does not require the user to carry around any independent parts in order to don shoes because the solution is integrated into the shoe itself.

- *Intuitive:* CroBro's only mechanic, the velcro flap, is something an overwhelming majority of adults in the United States know how to operate. Velcro is by design extremely lightweight and easy to use.

- *Discreet:* The color of the leather flap can be especially chosen to match the color of the rest of the shoe. The flap itself conceals the velcro patches. Consequently, the modification does not draw unwanted attention to itself.

- *Accessible:* CroBro can be operated with a single hand.

- *Durable:* CroBro's leather and weather-resistant components are designed to withstand a wide range of conditions. Additionally, the use of very few parts reduces the likelihood of components breaking.

Handbook

The handbook is an instruction for users to communicate with the shoe repairer to modify an existing running shoe into a CroBro. The Handbook consists of Script, a step-by-step instruction for users, and Diagrams that gives instructions for shoe repairers to modify the shoe.

Design Subsystems, Important Features, and Key Decisions

1. Script

Design Concept:

The script guides the user in what materials to buy, how to find a shoe repair shop, and how to ask the shoe repair shop to carry out the CroBro modification (Appendix Q).

Rationale:

Without the script, the user would not know what specific materials to buy. They may also not know how to ask the shoe repair shop to perform the CroBro modification. By giving the user a detailed description of everything they need to do, this provides clarity and allows the user to closely replicate our CroBro prototype.

2. Diagrams

Design Concept:

The diagrams are geared towards the shoe repair store, giving them detailed instructions to create the CroBro on any athletic shoe that they may be given. Earlier versions of all of the diagrams (except the picture of the finished CroBro) were used in the original instructions given to the shoe repair shop to fabricate the CroBro prototype (see Appendix Q for full handbook).

Rationale:

The labeled diagrams describe the instructions for how to perform the shoe modification much more clearly than just words. This ensures that the instructions are as straight-forward as possible and prevents errors in the modification as a result of miscommunication. One of the most important diagrams is the flap pattern, which includes instructions on how to scale it for different shoe sizes. This pattern allows for this flap to be put on athletic shoes of all sizes.

Benefits

- *Easy to follow:* Detailed step-by-step instructions let the user know what to do for each step, making the Handbook easy to follow. The Diagrams provides the shoe repairer an easy to follow visual instruction.

- *Customized*: The Handbook can be used by any users and can provide instructions for modifications of different types of running shoes.

Limitations and Directions for Future Development

The CroBro concept provides AFO users with easy foot access to the shoe and independence when donning the shoe. The modified shoe CroBro is intuitive to use and the modified part is inconspicuous. The handbook provides the shoemaker a clear instruction on how to modify a shoe into CroBro. The shoemaker Chris who made the first CroBro complimented our handbook on its ease to follow. Future teams should focus both on how to improve the design of CroBro and the content of the handbook.

CroBro Design

1. **Waterproof**

   The CroBro our team designed is not as waterproof as the original shoe. This is because when the velcro is closed, there will be a gap between the velcro (hook part) and the fabric at the front of the shoe that is not sealed. This gap may allow water permeate when the user is walking in the rain, snow or through a puddle.

Figure 4: The Gap Between Fabric and Velcro (Hook Part). Picture by Sam Huang.

Future teams may attach a piece of velcro (loop part) on the front edge of the incision so the velcro may close fully. Future teams may also make multiple other designs that seal the gap between velcro (hook part) and the fabric. Then teams should conduct multiple tests on whether the water will come in through the velcro when walking in rain or snow, or walk through a puddle, and making further adjustments on the CroBro accordingly.

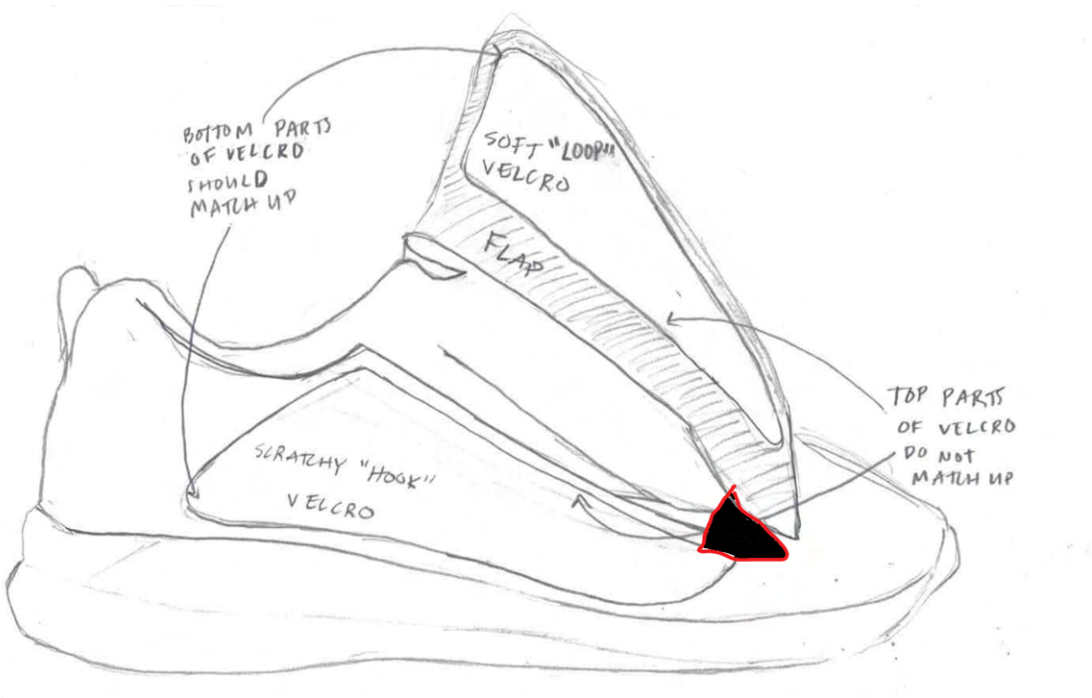

Figure 5: Fabric (Loop Part) on the Front Edge of the Incision. The drawing illustrates the location of the reinforcing fabric, marked by the red triangle. Graphic by Hannah Huang and Sam Huang.

2. **Incision Line**

   The CroBro our team built is made from a New Balance running shoe which only has two layers of fabric on the side of the shoe. Thus, the layers will not easily detach with simple gluing and the addition of the velcro lining. However, some other shoes may have more layers of fabric on the side of the shoe, which may detach easily without proper reinforcement (Appendix N).

   Future teams should design a proper lining to reinforce the incision edge of the CroBro. The lining should cover the entire incision edge and the material should be as comfortable as the original fabric of the shoe. Teams should take into account that the lining should not affect the surface area of the velcro (loop part) significantly.

3. **Strength of Velcro**

   The CroBro our team made reflects a design concept that provides users easy foot access to the shoe, and our team members can operate it with one hand. However, we have not tested whether the velcro chosen has the desired strength for users with hemiplegia.

   Future teams should do further research on the strength of the velcro and make CroBro prototypes with velcros of different strengths. They should test these CroBros with users with hemiplegia and determine what is the acceptable strength of the velcro for them. They should also consider whether the velcro will be

strong enough to hold the shoe close in daily use in choosing the velcro with optimal strength.

4. **Durability**

   Due to the time constraint, the durability of the glue and the leather flap are not tested. Future teams should research on glue and leather options, including how many years the leather can be used and time for the glue to lose its stickiness. The team should make sure the material they choose is washable or give clear instructions for users on how to clean the CroBro Design. In addition, the team should test the durability of other materials for the flap, such as marine vinyl (see Appendix M for fabric recommendations from Vogue Fabrics).

5. **Comfort Level**

   Time constraint did not allow our team to conduct enough tests on the comfort level of CroBro. Future teams should do multiple testing on different AFO users to find out whether the materials used and the structure of CroBro is as comfortable as a normal shoe. The testing should last at least a day and involve all kinds of daily activities.

6. **Hook and Loop**

   When the flap is closed, the hook on the flap may stick onto the sock. This may damage the sock when the user is opening the flap. Future teams may attach the loop part onto the flap, making the flap not sticky to the socks. Future teams may also search for other types of velcro that is not sticky to the socks but remain hook part on the flap.

7. **Tongue**

   The tongue is not stabilized, so it sometimes falls down and gets in the way when the user is putting the foot into the shoe. Future teams may attach the tongue onto the upper part of the shoe so the tongue will not fall down when the flap is opened. They should test on how to attach the tongue onto the upper part of the shoe, possibly using glue or sewing.

Handbook

1. **Aesthetics of the Design**

   Our CroBro prototype attached a black flap onto a black running shoe, which makes the modification inconspicuous for other people (See Appendix L for Performance Testing Activities with CroBro). However, if the shoe to be modified have a bright color or originally has a special color design, the flap should be designed accordingly.

   Future teams should do research on what colors leather options have, their cost and what kind of colors the shoe repair stores usually have. Teams should also do research on other proper materials for the flap that can have special color design

and how to order them. The instructions for how to choose and order proper materials for flap should be included in the Handbook.

2. **Modification for Other Kinds of Shoes**

   The Handbook our team provided is only designed for running shoe modification. Users may also wish to wear other kinds of shoes such as boots and sneakers.

   Future teams should develop instructions for how to modify each kind of shoes and include these instructions in the Handbook. Teams should follow a similar procedure of how our team develops the instruction for modifying the running shoe and direction for future development for CroBro.

3. **Handbook and Kit for Users**

   The current Handbook is designed for experienced shoemakers, so the user has to find a shoemaker to modify the shoe. However, some users may wish to modify the shoe themselves to save money.

   Future teams should develop a Handbook for inexperienced users to modify a shoe into CroBro. This instruction should not involve in the usage of special machines that people do not normally have. A knitting package includes basic tools and materials to make CroBro can also be developed along with the Handbook for users' convenience.

Conclusion

The CroBro meets the needs of AFO users in donning their shoes over their AFOs with a simple, yet effective design. The CroBro is effective in the following ways:

- **Ease of access to shoe.** The slit in the side of the shoe provides a large opening for users to insert their foot into the shoe. It eliminates the struggle of standardl shoes, allowing users to more effectively don the shoe over their AFO.
- **Simple and intuitive use.** User testing proved that the velcro flap is immediately understandable and easy for a user to maneuver.
- **Increased user independence.** The modified shoe allows users to don their shoe with little to no assistance from others, giving them independence in an essential part of their daily routine.
- **Minimalist modification.** The simple design of the flap and strategic positioning (on the shoe's inner side) disguises the modification, allowing users to go about their lives without calling extra attention to their AFO or condition.
- **Adaptable for various shoes.** The adaptability of the CroBro plans mean that a user can have their choice of athletic shoes modified. This allows them to maintain freedom of choice and a level of personalization of their footwear.

The CroBro instruction set could be very easily be adopted by a number of rehabilitation clinics or individual users. The instruction set is adaptable and simple for a user to give to any shoe repair shop. With these instructions and a nearby shoe repair shop, any AFO user would be able to modify a pair of athletic shoes to suit their needs.

Although the CroBro has numerous design successes, it would benefit from future testing - especially in regards to durability. One of the main concerns of the design is whether the modification compromises the structural stability of the shoe in the long term. The durability of the shoe, as well as ways to improve this quality, should be explored. Additionally, the CroBro instruction set could potentially be adapted to footwear other than just athletic shoes, expanding the freedom of choice for users.

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Appendices

Appendix A: Project Definition

Project Name: AFO and Shoe Donning Device
Client: Lauren Henderson - Shirley Ryan AbilityLab
Team Members: Katrina Baniak (TBT3), Hannah Huang (PM4), Sam Huang (SR4), Andy Xu (TBT4)
Date: 11/19/2019

Mission Statement

To design and create a safe, intuitive, and affordable device that allows users to independently don their ankle foot orthosis (AFO) and shoe.

Project Deliverables

- Final report to be printed and bound
- Presentation and poster for the Design Expo
- Physical prototype of modified shoe (CroBro)
- General instruction for the shoemaker to modify the shoe

Constraints

- Prototype is due November 22, 2019, all other deliverables are due on December 7, 2019
- Project budget is $100
- Device must accommodate an AFO
- AFO cannot be changed or modified

Users and Stakeholders

• AFO wearers who need help donning shoes

• Lauren Henderson, occupational therapist, works with hemiplegia patients regularly

User(s) Profile

Our user demographic includes adults that wear an AFO and can cross the AFO wearing leg over their other thigh in a seated position. Of the specific users we tested, one experienced hemiplegia from a stroke, one had near paralyzed legs from multiple sclerosis, and the last had weakened legs from multiple myeloma. Due to their conditions, users have very little core strength and cannot easily lean over on their own to reach for their shoes.

User Scenario

After Ms. Henderson raised Izzy's bed and brought Izzy's foot closer to Izzy's body for better access, Izzy began her attempt to put the shoe on over the AFO. Izzy is post second stroke and has been using her AFO for around two years. The stroke rendered the left side of her body immobile and weakened her core so much that she could not sit up on her own. At home, her family assisted her in putting on the AFO and shoe,

but Izzy was asked to attempt the process independently. After Izzy attempted for a few minutes, Ms. Henderson took over the process, as it was that clear Izzy wasn't experiencing success. Izzy had to lie still as Ms. Henderson attempted to push Izzy's AFO-clad foot into the shoe. Izzy made a few comments about it hurting during the process and Ms. Henderson adjusted, but Izzy was relatively helpless throughout the entire ordeal.

Table 1: Requirements and As-Built Specifications for CroBro Design

Requirements	**As-Built Specifications**
The process of using the device should be quick to use. ● *Rationale:* A device that is slow will likely not be utilized by the user. ● *Target Specification:* The device should minimize the time the user takes the don shoes. The donning process should preferably take no longer than 32 seconds—this is how long it took user Joe to don his shoe without a device and with minimal help (refer to Appendix J).	User testing has not yet been completed with the final product, but detaching and reattaching velcro is a fairly quick process and should help to speed donning. Our performance testing indicated that operating the flap took no longer than a few seconds (refer to Appendix L).
This device should be easy to use. It should lack small parts and limit the number of steps for use. ● *Rationale:* As a result of a stroke, people may experience lack of coordination and muscle weakness (refer to Appendix B). Therefore, the user may lack fine motor skills to operate a complicated device and may become exhausted or frustrated with having to perform too many steps. ● *Target Specification:* ○ At most, the user must be able to operate the device in fewer than 8 steps—this is the amount of steps the Burritoe required which Dan found confusing during user testing (refer to Appendices I and K). ○ No maneuverable part should be bigger than 1 cm. In one	CroBro requires only four steps to operate: 1) Enter the cross-legged position 2) Open velcro flap 3) Fully insert the foot and AFO into the shoe 4) Close flap In an earlier mockup of this device, it had a zipper, which user Joe said was too small (Appendix J). The final prototype replaced this zipper with a flap to improve ease of use; however, not enough user testing was completed to test how easily the flap could be opened or closed. Our performance testing indicated that operating the flap was not a major issue (refer to Appendix L).

user testing, Joe said the zipper for the Burritoe was too small for other users (refer to Appendix J for Joe's comments and Appendix H for specifics of the Burritoe).	
The device needs to be intuitive. ● *Rationale:* Patients with hemiplegia often also have cognitive impairments which affect their ability to learn complex tasks (refer to Appendix D). ● *Target Specification:* ○ The user should ideally be able to use the device without any prior knowledge of its function. At most, the user must be able to operate the device in under four minutes—this is how long user Joe and user Izzy attempted to don their shoes before giving up (refer to Appendix E). It is reasonable to assume that they wouldn't attempt a new device for longer. ○ The user should be able to meet the above specification with no explanation provided.	User testing has not yet been completed with the final product, but at the second user testing 2, the user almost immediately figured out how to use the earlier prototype. He commented on how much he liked the velcro mechanism multiple times and was pleasantly surprised when the shoe managed to slide on.
The device must be able to be operated with at most one hand and one leg without the help of a caretaker. ● *Rationale:* Patients with hemiplegia only have full mobility in one side of their body (refer to Appendix B for more information on the effects of hemiplegia). Also, as per the client's wishes, the device is intended to give the patient absolute freedom in donning their shoes (refer to Appendix D for goals set by Ms. Henderson). ● *Target Specification:* ○ The device must function fully even if the user has complete paralysis on one side of their	This target has not yet been tested by an actual user. However, at the last user test the user was very close to meeting this target with a too-small shoe mock-up of our design. From our own proxy user testing, the shoe was easily be put on with a single hand once in the cross-legged position. The tongue would sometimes get caught underneath the foot if not careful, and occasionally the sticky top velcro patch would adhere to the user's socks (refer to Appendix L).

body. ○ The user must be able to use the device to completely don shoes without external help.	
The device must last for many uses. ● *Rationale:* The device is intended for daily use, and frequent replacements are impractical. ● *Target Specification:* ○ The device should last for between 1,000 to 1,500 miles of walking (Pribut, 2019). ○ The device must be fully functional for at least 6 - 9 months (Pribut, 2019). ○ The device must function correctly in temperatures of 55 ºF to 78 ºF, the range of indoor temperatures ("Indoor Space Temperature Guidelines"). ○ Ideally, the shoe would accommodate usage in temperatures ranging from a low of -18 ºF which is the recommended lowest temperature for exercise by Mayo Clinic ("Winter fitness: Safety tips for exercising outdoors", 2019) to 104 ºF which is the temperature at which the human body started to suffer from heatstroke ("How to keep cool during hot-weather exercise", 2017).	The shoes use weather-resistant velcro functions from -20 ºF to 200 ºF. Thus, it perfectly meets the lower bound -18 ºF and the upper bound of 104 ºF. It follows that it also does meet the indoor temperature requirements. Also, because the shoe was fabricated with the help of a professional shoe repair shop, it is reasonable to infer that this device will last for many uses. Although there was no available information regarding the exact mileage of the New Balance 009 V1 Sneaker, it was rated 4 out of 5 stars by 117 users, which indicates that its durability is around the range of an average sneaker. That said, more user testing must be done to fully test the mileage of the individual shoe shoe as well as the CroBro design ("New Balance Men's 009 V1 Sneaker").
The device must be comfortable to use. ● *Rationale:* Users are unlikely to adopt uncomfortable devices (refer to Appendix K). ● *Target Specification:* ○ The device must use soft or smooth materials. ○ The device must not be too tight as to cause discomfort for	This shoe is a men's extra-wide size 12 New-Balance 009 V1, a well-known sneakers brand. The velcro flap allows for adjustment of the tightness of the shoe, and the leather modification is smooth. In addition, the velcro was specifically placed so that the user would not experience discomfort from the sharp velcro hooks.

cut of blood flow when used.	
The device must be safe to use. ● *Rationale:* Any device that presents a great risk for injury is better left unused. ● *Target Specification:* ○ The device must not have sharp edges. ○ The device must not be a tripping hazard. ○ The user must not fear using the device in any way.	The shoes does not expose any sharp edges, as all the parts are relatively soft. There is little risk for the material to penetrate or damage the skin in any way. Additionally, because the modification is performed on the side of the shoe, it does not increase the user's risk of tripping. This conclusion is further supported by our own user testing. Judging from our personal reactions to the final product, there should be little fear in donning the shoe (refer to Appendix L).
The device must be affordable for the user. ● *Rationale:* The patient must already pay the medical costs associated with therapy for hemiplegia, so the device should not be too much of a financial burden. ● *Target Specification:* ○ According to Client Interview, the desired cost for the user of the device should be lower than $100 (refer to Appendix D). Ideally, the cost should be below $90 which is the price of the "Original AFO Assist" which Mrs. Henderson mentioned was too expensive (refer to Appendix D). Since our product is a shoe modification design and handbook, the cost here refers to the average price a shoe repair store charged to modify a shoe according to the Handbook. The cost here also includes the price of the materials the user has to buy. As the fact that the user has the shoe already, the cost of buying the shoe does not take into account.	The modification costs roughly from $67 - $117 not including the cost of the shoe. The wide range of prices across different shoe repair shops is reasonable for the variability in cost of the CroBro. Therefore, the CroBro may or may not meet the target specification depending on the shoe repair vendor. Ideally though, cost would be even lower than this in order to make them more affordable for users.

Table 2: Requirements and As-Built Specifications for CroBro Handbook

Requirements	As-Built Specifications
The instructions set should be easy to follow. ● *Rationale:* Handbook should provide easy to follow instructions that will cause minimal misinterpretation for both users and shoemakers ● *Target Specification:* ○ The instruction should contain the information for users to find and choose a shoe repair store, and how to communicate with a shoemaker to modify their shoes ○ Step-by-step instructions for how to make a CroBro from an existing shoe ○ A list of material to use and to purchase ○ Use the same font or fonts in the same size in the same way throughout the entire text. Also, use the same diction throughout the text ○ Use clear images as and only as supplements to facilitate the audience's comprehension of the text. ("Rhetorical technical communication: Exploring the gaps, connections, and new boundaries between the fields through an analysis of instruction manuals", 2016)	The Handbook should be easy to follow because we provide the users with a step-by-step ordering process, a script for communicating with the shoemaker and a list of material to purchase. But the Handbook has yet to be tested by a user, so further testing should be conducted. The Handbook is most likely easy to follow for the shoemaker as well because it provides modification instruction with clear images. This is supported by the shoemaker from the National Shoe Service who said 'it is easy to follow' when the team got back the CroBro from him. However, only one shoemaker has used the Handbook, so further testing should be conducted.
The instructions set should be customizable. ● *Rationale:* ○ The instruction can give	The instruction should be customizable because the Handbook specified how to determine the size of the flap for different shoe sizes. It also specified the

users and shoemakers instructions on how to modify different running shoes ● *Target Specification:* ○ The instructions should include a list of materials to use and purchase for users and shoemaker for different running shoes ○ The instructions should give the shoemaker a general instruction for how to modify user's shoe, taking into account the variation of shoe size and shoe color. This is necessary because the users' shoes also vary in size and color.	approximate position of incision on a shoe and the shape of the velcro. The actual position of the incision and the shape of the velcro can be adjusted by the shoemaker on different shoes. But the Handbook has only been tested on modifying the men's extra-wide size 12 New-Balance 009 V1, so more testing on using this Handbook to modify different types of shoes needs to be done to draw a more solid conclusion.

Appendix B: Hemiplegia, Ankle Foot Orthoses, Past/Existing Solutions, and Shirley Ryan AbilityLab

Hannah Huang, Katrina Baniak

Hemiplegia

Because all of our users have hemiplegia, learning about hemiplegia was one of the most important steps into understanding our users. From this research, we found limiting factors for our design, but also user strengths that we could utilize.
We found information from stroke.org, Encyclopedia Britannica, and contact.org.

Defining Hemiplegia

Hemiplegia is defined as one-sided paralysis, unlike hemiparesis which is one-sided weakness ("Paralysis", 2019). Paralysis occurs on the side opposite of body where the stroke occurred ("Paralysis", 2019). The most common cause of hemiplegia is a stroke (The Editors of Encyclopaedia Britannica, n.d.). Hemiplegia is usually caused by an injury to a part of the brain that controls movement ("What is hemiplegia?", n.d.).

Other Symptoms of Strokes

Other post-stroke paralysis symptoms include spasticity/stiff muscles, weakness, incoordination, sensory deficits, balance problems, and foot drop (a condition where one can't raise the front part of the foot to walk, resulting in dragging) ("Paralysis", 2019). Those suffering from hemiplegia suffer from varying degrees of severity for each of these symptoms ("What is hemiplegia?", n.d.).

Ankle Foot Orthoses (AFOs)

Our client asked us to design a product that will help the users don both their shoe and ankle foot orthosis (AFO). In order to create such a product, we had to research the specifics of AFOs and read about the experiences of those who wear AFOs.
This information comes from three sources: alimed.com, a study called "The impact of ankle–foot orthoses on toe clearance strategy in hemiparetic gait: a cross-sectional study," Merriam Webster, and the official website of Fairview Health Services.

What an AFO is and How it Works

An orthosis is any device that supports or treats weak or paralyzed parts of the body ("Orthotic"). An AFO is a device made to support the affected leg by controlling the position and motion of the ankle with the added benefit of correcting deformities ("AFOs," 2014). It also provides toe clearance when the leg is swinging, preventing the toe from getting caught and prevents the user from falling (Pongpipatpaiboon, 2018). An AFO typically creates an L-shape from around foot and ankle to just below knee ("AFOs," 2014).

Figure 6: AFO. The image above shows a traditional AFO design. ("AFOs," 2014)

Types of AFOs ("AFOs," 2014)

a. Design
    - Traditional: Maximum stability, one large piece without holes for ventilation
    - Swedish: Typically less noticeable, has more airflow, more cooling and comfort, more customizable to fit different people and shoes; heat molding

b. Material
    - Carbon Fiber: dynamic, flexible, good for active patients, promotes a natural walking pattern, accommodates for large range of calf sizes, open heel to eliminate pressure sores
    - Hard Plastic: Accommodates for diverse needs, can have maximum or minimum stability, very customizable; heat molding and trimming, reliable, economical for a variety of needs, good for short term use

Wearing an AFO ("Use and Care of Your Ankle-Foot Orthosis")

1. Wear socks that reach top of AFO
2. Donning AFO Method 1:
    a. Put AFO into shoe
    b. Put foot into AFO and shoe
    c. Tie shoes then fasten velcro
3. Donning AFO Method 2:
    a. Put AFO on first
    b. Put foot and AFO into shoe
    c. Tie shoes then fasten velcro
4. Always wear AFO with a shoe or else it may cause injury

Past/Existing Solutions

While researching about past and existing devices for donning AFOs and shoes, we focused on the advantages and disadvantages of each. We hope to incorporate whatever worked into our design, while learning from whatever did not work.

We found these products on the official Home Heart Beats website, limbionics.org, and YouTube. We used YouTube because watching the process of donning a shoe was more descriptive than reading about it.

Table 3: AFO Donning Assistive Devices

Name	Price	Description	Advantages	Disadvantages
The Original AFO Assist (Home Heart Beats, LLC. 2018)	$89.99	This device features a docking station allowing for a variety of donning positions for both the AFO and shoe.	Fit to be used by a variety of users with different methods of donning AFOs and shoes	Bulky, complicated, some ways of using it require a wall, expensive ($90)
Footfunnel Shoe Horn (Products, I. 2011)	$9.99	This is a plastic funnel device put on the heel of the shoe, allowing the foot to more easily be placed into the shoe.	Gives more space to allow heel of foot to go into shoe	Foot mainly gets caught on the tongue of the shoe
Non-Slip Mat (Home Heart Beats, LLC. 2018)	$9.16	This mat is placed on the floor to reduce sliding during the donning process.	Provides stability while donning shoe without the use of a wall or heavy object, cheap ($7)	Need to use it with some other device, only used to stabilize the device on the floor
Turbomed AFO (Stresing, B., 2018)	Unknown Price	This is an AFO that fits on outside of the user's shoe, allowing it to be utilized with a variety of footwear. "This external foot drop brace will allow running, walking, hiking	User doesn't need to buy new shoes, will make the process of donning shoe and AFO much easier, makes walking a lot easier too	Price not there, but probably very expensive

		in mountain[s] as long and as far as you want without any discomforts."		

Figure 7: The Original AFO Assist. The figure illustrates one potential use of the AFO Assist. ("Sammons Preston AFO Assist")

Figure 8: The Foot Funnel Shoe Horn. The shoe horn is placed into the heel of the shoe and can be removed by pulling on the black string. ("FootFunnel Long Shoe Horn")

Figure 9: Non-Slip Mat. The photo illustrates a traditional non-slip mat. ("Tenura Anti-Slip Fabric Roll")

Figure 10: Turbomed AFO. The photo illustrates how the extern AFO wraps around the shoe. ("Turbomed Orthotics - The Most Advanced Foot Drop Brace")

Shirley Ryan AbilityLab

Research on the Shirley Ryan AbilityLab gave our team insight into the resources that are available for both us and our users.
All of this information comes from the Shirley Ryan AbilityLab official website.

What the Shirley Ryan AbilityLab (SRAL) Does ("Shirley Ryan AbilityLab")

A research hospital where clinicians, scientists, innovators and technologists work together to provide physical medicine and rehabilitation to a variety of patients

The Legs and Walking Lab ("Shirley Ryan AbilityLab")
As one of the five ability labs in Shirley-Ryan Lab, the legs and walking lab is designed for patients and research participants with diagnoses affecting lower-body function due to brain or spinal cord injury and diseases of the nerves, muscles and bones. Researchers and clinicians focus on advancing trunk, pelvic and leg function, movement and balance *Rehabilitation Engineering Center* ("Shirley Ryan AbilityLab"). Through collaboration between engineers, designers, roboticists, and wheelchair technicians, the lab modifies commercial products and creates custom equipment.

Related Services ("Shirley Ryan AbilityLab")
The "Prosthetics and Orthotics" department builds devices to fit patients' needs. The "Nursing" department helps patients who are affected by physical conditions or mental illness gain independence.

Conclusions

Given the background research findings presented above, the team has concluded the following:

- Device must be able to use with one hand
- Device should be used in sitting position since they should not be standing with an AFO on
- More information must be acquired about SRAL prosthetic lab during user observation
- More information must be procured about the specific problems with donning AFO and shoe

Appendix C: Core Strength Secondary Research

Katrina Baniak

Introduction

Throughout the user testing process, the users encountered had a variety of core strength levels depending upon what phase of rehabilitation the user was in. This variation in core strength and sitting balance influenced what position the users donned their shoes in, and therefore has great significance to the design of our device. The key objectives for this research were to find:

- Demographics on what percentage of patients have what level of core strength
- Recovery period for core strength
- Amount of core strength that can be regained during rehabilitation

Methods

This research was conducted using the nusearch database, searching using the following list of keywords and their various permutations:

- Stroke, Hemiplegia, Seizure
- Mobility, Flexibility, Range of Motion, Movability, Freedom
- Strength, Power, Support, Core, Abdominal

The date range searched was limited to the past fifteen years in order to only include relatively up to date information while not limiting the search too extensively. Inclusion factors for this search included english language only, and research relating to humans and stroke patients only. Exclusion factors included sources not written in english, and research relating to organisms other than humans or non-stroke patients. Four relevant articles were found in the course of the research on this subject.

Results

The most helpful sources found can be split into sources relating to the core strength of patients post-stroke and sources relating the effects of various treatments on core strength rehabilitation in stroke patients. The first category looks at the core strength of stroke patients in general, not in relation to improvements seen through rehabilitation, but rather how it compares to the core strength of those that haven't suffered a stroke. The second focuses on the positive effects specialized treatments have had on the core strength of patients post-stroke when compared to standard treatment methods.

Core Strength Post-Stroke

In a study that sought to evaluate the trunk strength of stroke patients, the Trunk Control test and Trunk Impairment Scale were used to gauge results of over fifty stroke patients in various stages of a rehabilitation program (Verheyden et al., 2006). The study found that measures of trunk performance were significantly related with balance, functional ability, and gait, with a special significance given to the sitting balance subscale of the Trunk Impairment Scale (Verheyden et al., 2006). The study showed that core strength is very clearly impaired in most stroke patients, at least to some degree, using results from both scales (Verheyden et al., 2006).

Another study examined the link between strength and balance post-stroke, a relationship previously thought to be weak (Wagatsuma et al., 2017). The study showed through a number of strength and balance assessments that core strength, along with leg strength, is strongly associated with gait stability in post-stroke patients (Wagatsuma et al., 2017).

Treatment Effects

Various studies have compared conventional treatments to other methods in order to determine which treatment plans improve core strength most during rehabilitation. When conventional core stabilization was compared with dynamic neuromuscular stabilization, the latter was shown to yield greater improvement in control and balance, highlighting the importance of core stabilization exercises in post-stroke recovery (Lee et al., 2018). Conventional core stability exercises, in combination with conventional rehabilitation, has also been shown to improve trunk control, balance, and daily living activities (Ting-ting et al., 2018).

Analysis

The research in these studies is mainly applicable in deciding upon the design scenario for our project. Patients with greater core strength, and thus sitting balance and the ability to sit up, have been shown to also have greater balance and gait stability. The patients that can sit up and use a device geared towards a sitting situation are also the ones that are likely to have greater independence within their lives. This is important to keep in mind as the core strength we chose to design for will influence our user's needs in regards to independence amongst other categories.

The other significance of this research is found in the treatment effects section, showing that trunk control improves over time with the use of core stability exercises during rehabilitation. At a certain point, most users will gain back some of their trunk control, meaning that a device for use by sitting is a realistic design solution. At some point throughout the rehabilitation process, the majority of users will regain the core strength required to use a device geared towards a user sitting up.

Conclusions and Recommendations

The research found relating to core strength yielded two important pieces of information for the project: patients with greater core strength have greater balance and gait stability (qualities important for independence post-stroke), and rehabilitation (especially that involving core strengthening exercises) has been shown to help patients regain trunk control and balance. The first piece of information means that users that have the core strength required to use a sitting device are also the more independent users. The second indicates that most users will eventually be able to use a sitting device. Next steps for this line of research could include:

- Locate exact statistics on what percentage of core strength post-stroke patients regain
- Interview physical therapists to find more information on core strength rehabilitation

Appendix D: Initial Client Interview with Lauren Henderson

Date: 09 - 30 - 2019
Time: 6:30 pm - 7:00 pm
Location: Hive Annex (2340) - Ford Motor Company Engineering Design Center - Phone Call
Team members in attendance: Andy Xu, Hannah Huang, Sam Huang, Katrina Baniak
Other key attendees: Nathan Arnold, Katz Kadlic, Konyin Okubadejo

Client / Design Problem Overview

- Ms. Lauren Henderson
- Occupational Therapist, MS
- Shirley Ryan AbilityLab

Our client Ms. Lauren Henderson is an occupational therapist with Shirley Ryan AbilityLab. She evaluates and treats individuals with hemiplegia on pediatric and adult inpatient floors. She has advanced competencies in helping patients with hemiplegia to use orthoses, including the Ankle Foot Orthoses. In her extensive experience with AFO wearers, she observed that patients find it incredibly challenging for to don their shoes themselves over their AFO. This increases the workload of caregivers and reduces patients' independence in their daily activities. Our client wants us to build a device to help AFO users with hemiplegia to don their shoes independently.

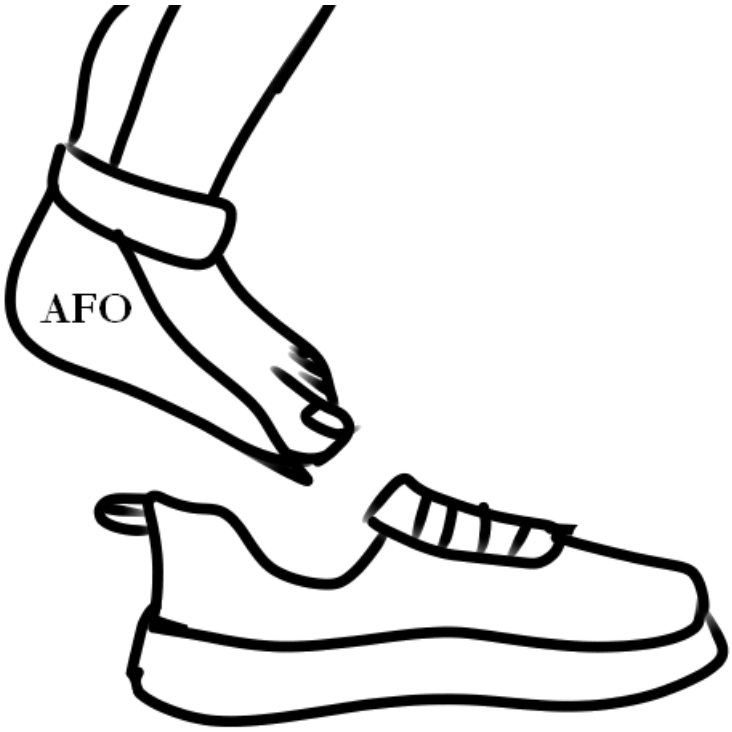


Figure 11: Problem Description. Diagram shows the issue of inserting the user's foot and AFO into the shoe. Drawing by Katrina Baniak.

Users

Demographic Information

A. *Patient Type:* People with Hemiplegia
B. *Age:* Mostly Adult Males
C. *Conditions:* Weakness on one side of the body, Cognitive impairments
D. *Relevant Medical Devices Used:* AFOs

Hemiplegia Background

Patients often recover from leg paralysis before arm paralysis. The one-sided weakness or paralysis exists on a spectrum of severity. The majority of those with hemiplegia are people who have had strokes.

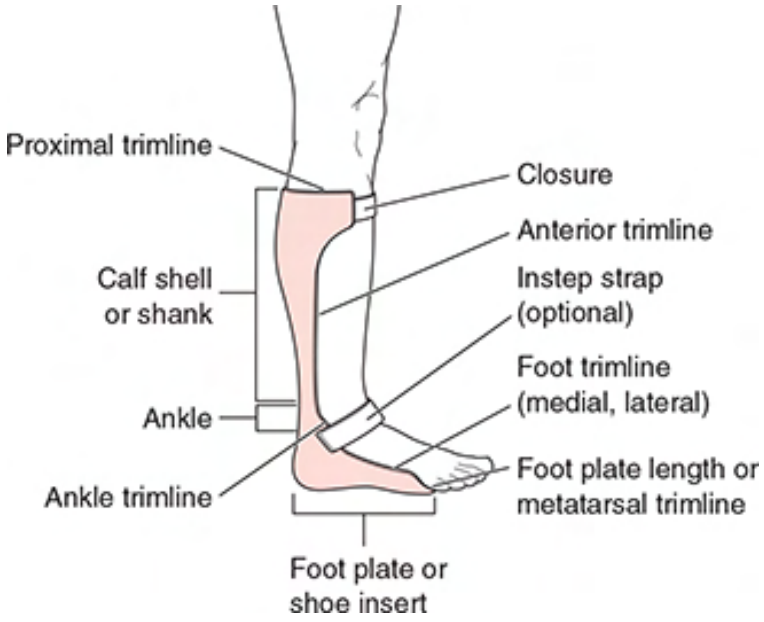


Figure 12: AFO Overview. Diagram shows a standard AFO on a user. Individual parts of the AFO are labeled along the sides of the diagram. [Online Image] Retrieved September 30, 2019 from https://fadavispt.mhmedical.com/content.aspx?sbookid=1865&sectionid=140944581

Table 4: Solutions Attempted by Client

Solution Name	Description	Why Solution was Ineffective
Long Handled Shoe Horn $25	Curved metal stick inserted into heel of shoe to help with foot insertion	Tongue pinched down into shoe, Shoe slides around, Requires a hand to operate shoe horn
Reacher $8	Effectively a long pair of tweezers that holds the shoe in place	Tongue pinched down into shoe, Shoe slides around, Requires a hand to operate reacher
Original AFO Assist $90	Plastic device with slanted shoe stabilization station to hold shoe in place	Too costly, Not widely available

Figure 13: Original AFO Overview. Image shows the "Original AFO Assist" and how it functions. [Online Image] Retrieved September 30, 2019 https://www.wrightstuff.biz/original-afo-assist.html.

Client Preferences

Our interview with Ms. Henderson gave us a list of goals for our final product:

- Can be used on floor in absence of a wall
- Under $100
- Requires little to no knowledge to operate
- Can be used by patients with different AFO size
- Can be used by the patient without the help of a caretaker

Conclusions and Next Steps

The interview made it clear that the device developed should be learned easily, focused on helping the user achieve independence, and accommodate users of varying abilities. Existing solutions on the market, such as the "Original AFO Assist" are too much of a financial burden on patients. Our next steps are as follows:

- Conduct user observation on 10/6/2019
    - Develop a detailed plan of what information we need to gather during the user observation
    - Interview the user about their experience with donning shoe
- Brainstorm design concepts
- Narrow down design options

Appendix E: User Observation of Joe and Izzy

Date: 10/6/2019
Time: 3:45 - 4:15
Location: Shirley Ryan Ability Lab
Team members in attendance: Andy Xu, Hannah Huang, Katrina Baniak, Sam Huang
Other key attendees: Nathan Arnold, Katz Kadlic, Konyin Okubadejo

Objective

To observe the challenges accompanying the shoe donning process and to make qualitative observations about materials in the environment surrounding the user as well as quantitative observations on the duration of shoe donning.

Observation Conditions

Two patients, patient Joe and patient Izzy, were observed during the session, and both patients were reclined in bed in their respective rooms. The first user, Joe, had never tried to don shoes with an AFO before, while the second user, Izzy, possessed some experience. Overall, both users appeared relaxed. Joe seemed enthusiastic about the observation, while patient Izzy was more timid, likely due to the language barrier existing between her and the rest of the group. All in all, both patients were extremely helpful in demonstrating the challenges of putting on their shoes and providing verbal responses to our questions.

Session Overview

1. Introduction to client to ask preliminary questions and go over plan for visit
2. Introduction to Joe explaining purpose of visit, including asking for permission to record
3. Observation and visual recording of Joe's behavior using two separate donning strategies
    a. Put AFO on foot, then slide both into shoe
    b. Slide AFO in shoe, then insert foot
4. Collection of qualitative information about the room environment and shoe types
5. Interview of user Joe and client
6. Repeat steps 2 - 5 with user Izzy

Table 5: User Overview

User Name	Relevant medical history	Experience with AFO
Joe	Multiple Sclerosis	No experience
Izzy	Stroke two years ago and recently	Two years of experience

Observation Session 1: Joe

Interview

Joe was very forthright about his lack of experience with putting on shoes in his AFOs, so many of our questions were directed to our client Lauren. Our initial questions centered around the context surrounding the shoe donning process, such as the patient's seated orientation and the types of AFOs used. Lauren made sure to address that hemiplegia also affects the patient's abdominals, so some users may not have the strength to sit upright in a chair while donning shoes. Joe did not have hemiplegia, though he still lacked the strength to fully stabilize his upper body. Despite this, Lauren did mention how Joe was unusually flexible, and that most patients cannot bring their leg very far up toward their chest area. She then reiterated how patients often need to get shoes a few sizes larger than normal and that the soles are removed to make more room for the AFO. When asked about which of the two methods Joe prefered to use to put on shoes, he responded with the method of placing the AFO in the shoe and sliding his foot into both.

Table 6: Task Breakdown for Joe Donning his Shoes

	Task	Process	Comments	Time (minutes)
1	Donning an AFO	Joe inserts his leg into the AFO and fastens the leg and ankle straps with Laurne's help	None	1
2	Reorienting Weak Leg	Joe supports his weak right leg with his stronger left arm and brings it so it is resting on his left leg	"Not everyone is this flexible"	0.5
3	Sliding Foot + AFO into Shoe	Joe tries to maneuver his bent right foot into the shoe, but the tongue gets caught and the AFO is just a bit too large to fit; even with Lauren's help, it is difficult to get his foot in	"[The AFO] makes my foot feel wider." "Even with a shoe horn, I don't think I could." "It's already hard just to get it in."	5 (did not complete)
4	Sliding Foot into AFO + Shoe	Joe tries to maneuver his bent right foot into the AFO and shoe, but the angle of the opening is just a little too tight and tongue gets caught.	"It's easier [than the first method]."	4 (did not complete)

Figure 14: Joe Struggles to Don his Shoe over an AFO for the First Time. Note how much larger the heel of the AFO is compared to Joe's shoe. Usually, patients are advised to go up one or two shoe sizes when wearing an AFO; however, Joe hasn't gotten an AFO yet, so his shoes are his regular shoe size.

Figure 15: The Nurse tries to Don Joe's Shoe. In this image, the nurse is trying to help Joe put his shoe on for the second time. She uses the method of putting the AFO into the shoe and then trying to the foot into both the shoe and AFO. Notice that the user holds his leg to help force his foot into the shoe.

Observation Session 2: Izzy

Interview

Although Izzy has had her AFO for two years, she admitted that she has never put it on by herself. Because she had so little abdominale strength and only one fully capable arm, she said it was too hard to put the shoe on without help. When asked if she had ever tried putting the AFO into the shoe and then putting them both on, she told us that yes, and it was in fact much harder that way.

Izzy tries to don the shoe after putting on AFO

Lauren helped Izzy to put AFO on her left leg, and put half of her foot into the shoe. Then Lauren bend her leg and repositioned her foot aside her knee so that Izzy can reach the shoe. After that, Izzy tried to don the shoe by pulling the ring on the back of the shoe but failed. Lauren then used the other approach by putting the AFO into the shoe first. However, the angle for Izzy to don the shoe was too steep, which makes the process even harder. After twenty seconds of trying, Izzy gave up eventually.

Table 7: Task Breakdown for Izzy Donning her Shoes

	Task	Process	Comments	Time (minutes)
1	Donning an AFO	Lauren helps bring Izzy's leg up and puts on the AFO for her; Izzy points toward the AFO to signal that the top leg strap is too tight	"Dolor" (indicating pain)	2
2	Sliding Foot + AFO into Shoe	Lauren holds Izzy's back upright while Izzy tries to shimmy the shoe into her foot; rigidity and length of AFO appear to be the main issue		5 (did not complete)
3	Sliding Foot into AFO + Shoe	Lauren tries to push Izzy's into the AFO + Shoe combination, but her foot is not flexible enough to fit		4 (did not complete)

Figure 16: Lauren Helps Izzy Put on her AFO. The picture shows Lauren is helping Izzy to put on the AFO by bringing her leg up.

Figure 17: Izzy Donning her Shoe. Izzy sits on the bed with her leg bent so her hand can reach the shoe. She tries to pull the back of the shoe, but do not have enough core strength. Prior to this image, Lauren had to elevate the back of Izzy's bed to get her to this position.

Figure 18: Izzy Sliding her Foot into AFO + Shoe. Lauren helps Izzy to slide her foot into the AFO+shoe combination. However, the angle sliding in is too steep which makes it even harder than the previous approach.

Data Collection

Table 8: User Observation User Data

Users	Time to Don Shoes	Required Help of Caretaker?	Pairs of Shoes in Room	Same Shoe Size for Both Shoes
Joe	Incomplete	Yes	4	Yes
Izzy	Incomplete	Yes	1	Yes

Table 9: User Observation Device Data

Device	Dimensions
Long Handled Shoe Horn	62 cm by 3.5 cm
Reacher	66 cm by 9.5 cm

Figure 19: Long Foot-Funnel Shoe Horn and Reacher. The above image shows a size comparison of the shoe horn and the reacher.

Client Interview

Some clarification questions were addressed to the client after the observations to elucidate further information about the problem description. Lauren clarified that the price range of the final product should be under $100 and that the hingeless AFOs often work slightly better than their hinged counterparts. The hinged AFOs, however, do allow for greater freedom in the user's foot.

Analysis and Implications for the Design

Table 10: Critical Observations and Potential Responses

Observation	Opportunity	Possible Follow-up
Users had poor sitting balance	Provide method that allows user to be laying down	Make device useable for bed-donning
Heel of AFO made foot too bulky to slip in	Widen shoe opening	Incorporate a device similar to a shoe funnel
Ms. Henderson had to pull back tongue of shoe with every attempt	Get shoe's tongue out of the way to allow easier access	Hooks or sticky tape to secure tongue back
Required a lot of maneuvering to put on shoe with caretaker's assistance	Device needs to be stable in place	Affix device securely to a fixed structure (like the bed or a chair)
Many users wanted to keep shoes in their original size rather than sizing up (as recommended)	Create a device allowing for same shoe size to be used with AFO	A shoe expander or some wearable technology that decreases friction

Following the user observation the key conclusions that we gleaned were:

- Putting on the AFO is much harder for the user than background research and the client interview indicated. Neither user was able to put on the AFO and shoe without assistance in any amount of time.
- The two users observed had to put on their AFO sitting down due to poor sitting balance. They were unable to sit up and lean over to put on their shoes any other way.
- The ability and strength of users vary widely. Joe experienced weakness/paralysis in both his legs, but not his arms. Izzy experienced weakness/paralysis on half of her body, having use of one leg and one arm. There are a large number of user situations to keep in mind.
- The users gave up fairly quickly, so our device needs to be extremely easy to use and figure out or else there is a high chance that the users will simply quit.
- Putting on the shoe over the AFO took a lot of maneuvering and force on Ms. Henderson's part. We will need to keep this in mind in regards to the stability of our design.

Ideas that we need to keep in mind for the next observation session are:

- It would be helpful to measure the foot with and without the AFO on in order to see how much wider the foot actually gets, testing out Joe's claims.
- Do the majority of patients still put on their AFO lying down due to poor sitting balance?
- What does the process look like when a user is using an appropriately large shoe?

Appendix F: User, Stakeholder, and Context Assessment

The objective for our team is to design and produce a device to assist patients with hemiplegia in donning their shoes. The device needs to be cost-effective, simple, and usable without the help of a caretaker. The table below lists the users/stakeholders involved in this project and our team's interpretations of their roles and preferences.

Table 11: Needs, Motivations, and Context Assessment

Users / Stakeholders	**Motivations**	**Interactions with Design**	**Wish list**
Patients: People with Hemiplegia	Greater independence in donning shoes, Reduce costs	Deploying it, using it, transporting/storing it	Can be used in absence of wall, Portable, Simple/Intuitive, Also helps with donning AFO
Patients' families/ caretakers	Greater comfort in seeing patients become independent, manage their own equipment	Helping patients transition into using the device on a daily basis	Patients do not need assistance from families/ caretaker anymore
Occupational therapists	Increase patient independence in activities of daily living	Teach patients to use the device	Empower patients in being able to direct their own lives
Manufacturers	Exploit an opportunity in a largely underserved market	Fabrication	Achieve economies of scale

Appendix G: Mockups — Round 1

(10/11/2019)

Objective

The mockups in this round meant to test the feasibility of our design ideas of shoe donning devices for people with hemiplegia. These mockups address the need for expanding or stabilizing the shoe during the shoe donning process for people who can use only one hand and one leg. Our mockups are all works-like mockups, aiming to demonstrate our design concepts and help us to test their basic and most important functions. For the fact that these mockups do not have the full functionality, users have to use them under the aid of a caretaker.

Mockup 1 - AFO Dock

This works-like mockup demonstrates the structure to help the user to stabilize the shoe on the floor. It consists of a foam-core as a base, a rubber-tube semi-ring as a stabilizer, and an elastic cord to hold the semi-ring. The user is expected to put the shoe on the pedal with the shoe front inside semi-ring. The semi-ring will prevent the shoe from sliding forward when the user dons the shoe. When the user dons the shoe, there will be a force pushing the shoe downward that causes the shoe slightly sink into the foam core, providing an additional force preventing the shoe slide aside. However, this mockup only has a pedal, so the caretaker has to hold the pedal at the right angle and position for the user.

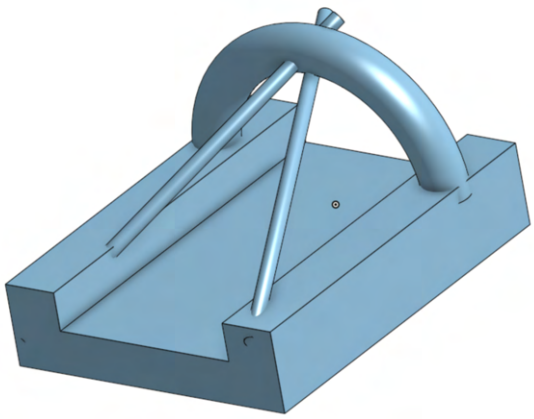


Figure 20.a: Mockup 1 — Docking Station (Left). The photograph features the pedal of the docking station, as well as materials used: foam core, rubber tube, and elastic cord.
Figure 20.b: Mockup 1 — Docking Station Image (Right). The image features the plan for the pedal of the docking station prior to build.

Questions for Mockup to Answer

- Will the shoe move forward when donning the shoe?
- Will the shoe slide aside when the user is donning the shoe?
- Will the foam core be solid enough for the pedal?

Mockup 2 - Pull N' Expand

This works-like mockup demonstrates the structure to help the user to expand the collar and the tongue of the shoe. The Pull N' Expand consists of two strings, four clamps that attach to each end of the string, and a wood fastening lock. The user is supposed to put the wood lock on the bottom of the shoe and attach each clamp to the tongue, the rear, and both sides of the collar of the shoe. When the user fastens the string using the wood lock, the clamp will be pulled outward so the collar and the tongue will be expanded.

Figure 21.a: Mockup 2 — Pull N' Expand (Top). The photograph pictures the Pull N' Expand when it is attached to the shoe. It is made of string, clamps, and wood.

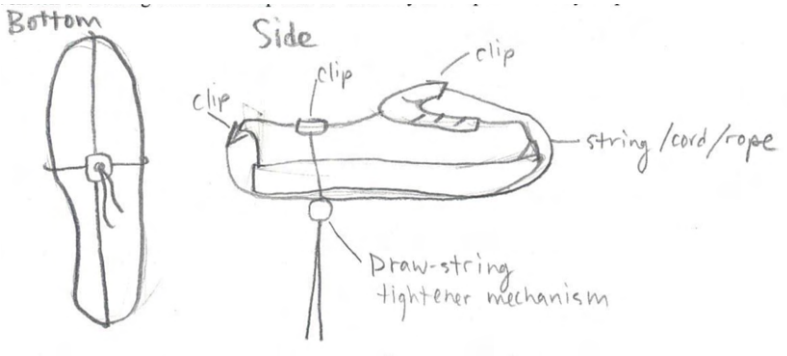


Figure 21.b: Mockup 2 — Pull N' Expand Sketch (Bottom). The drawing features the structure of the Pull N' Expand in a preliminary sketch. Graphics by Katrina Baniak.

Questions for Mockup to Answer

- Will the clamp expand the collar and tongue?
- Will the device be stable when the user is donning the shoe?
- Will it be difficult for the user to pull the string using the wood lock?

Mockup 3 - Leg Latch

This works-like mockup demonstrates the structure to help the users to expand the collar and the tongue of the shoe, and provide additional force for shoe donning. The Leg Latch consists of a leg band made of elastic rubber, two elastic cord attached to the leg band, and clips on the end of each cord. The leg band fixes the device on the user's leg while the clips will expand the collar and the tongue. When the user dons the shoe, the elastic cord attached to the rear of the shoe will pull the shoe toward the user, providing additional force for shoe donning.

Figure 22.a: Mockup 3 — Leg Latch (Above). This picture features how the user is supposed to use the Leg Latch.

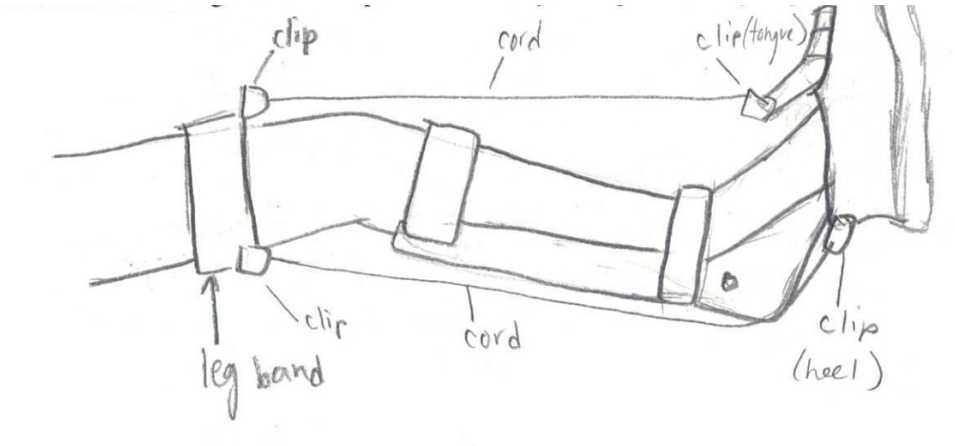


Figure 22.b: Mockup 3 — Leg Latch Sketch (Below). The drawing features the structure of the Leg Latch in a preliminary sketch prior to build. Graphics by Katrina Baniak

Questions for Mockup to Answer

- Will the clip and the cord expand the collar and the tongue?
- Will the cord provide additional stability for shoe donning?
- Will the rubber band be able to fix the device on the leg?

Mockup 4 - Flappy Shoe

This works-like mockup is our first attempt at modifying an existing shoe directly to ease the donning process. Our shoe is cut along the outside to create a flap that can be opened to allow for easy access into the inner shoe. Velcro was attached to the top and bottom flaps to make the closing the flap as easy as slapping the flap back into place. We tested our initial mockup design with a size 11 men's New Balance running shoe.

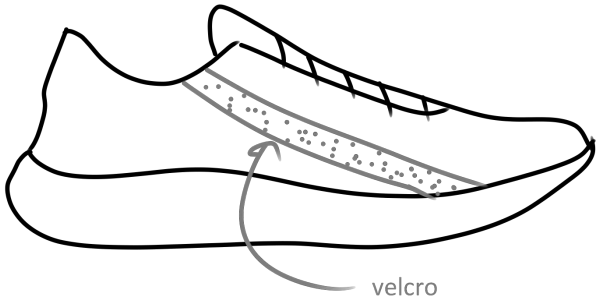


Figure 23.a: Mockup 4 — Flappy Shoe Sketch (Left). This sketch features the general design concept for the flappy shoe. Graphics by Katrina Baniak.
Figure 23.b: Mockup 4 — Flappy Shoe Photograph (Right). The image above illustrates the positions of the velcro strips on both flaps when the top flap is opened fully. Since the hot glue did not adhere to the fabric effectively, one of the velcro strips had fallen from its position on the top flap.

Questions for Mockup to Answer

- Does modifying the shoe compromise its structural integrity?
- Can the user put the shoe on with one hand?
- How difficult is it to modify a shoe? Can it be done in a short time-span?

Appendix H: Mockups — Round 2

(10/20/2019)

Objective

This round of mockups aims to improve the mockups from the last round. The Leg Latch mockup is eliminated because the device is too complicated to set up and the elastic cord provides the users minimum assistive force for shoe donning. We improved the structure and material used of AFO Dock and Pull N' Expand mockups to increase the stability of the devices. The hook-and-loop has been changed to zipper because the hook-and-loop may detach when the user is walking. In addition to that, the hook is hard to be attached to the loop when the foot is in the shoe. These mockups are all works-like and have the full functionality for users to interact with.

Mockup 5 - AFO Dock V2

The AFO Dock in this round is a device to assist the user in stabilizing the shoe on the floor and adjust the shoe donning angle. The device consists of a base, a pedal, and a supporting board. The user should first put the shoe on the pedal and use the hook to expand the tongue. Then the user should adjust the angles by placing the supporting board into different slots.

Figure 24.a: Mockup 5 — AFO Dock. The AFO dock in this round is made of wood with a rubber semi-loop as the previous mockup. The picture shows a shoe fixed on the pedal with the angle adjusted to the second-lowest position.

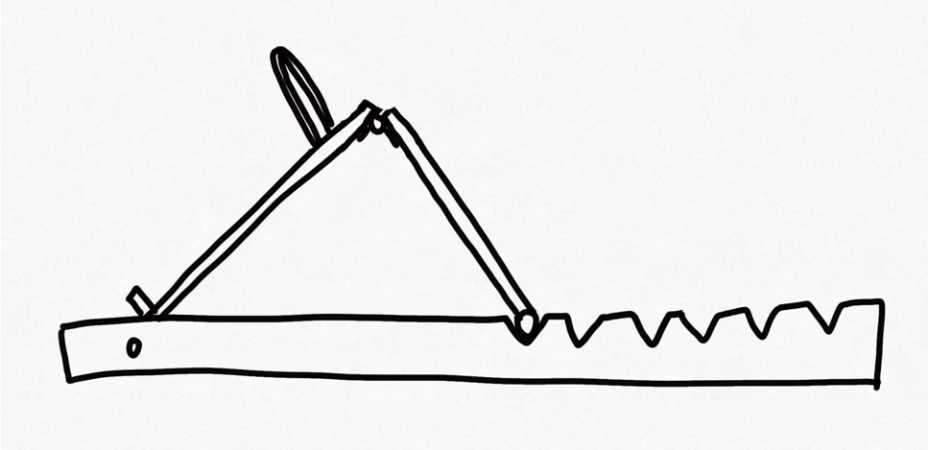


Figure 24.b: Mockup 5 — AFO Dock Diagram. The drawing illustrates the structure of the device from the side. Graphic by Sam Huang.

Questions for Mockup to Answer

- Will the shoe slide aside when the user is donning the shoe?
- Will the user be able to slide the foot into the shoe at the angles provided?
- Will the device slide on the floor?

Mockup 6 - Pull N' Expand V2

This work-like mockup consists of a metal frame with a panel that rises up in front of the shoe. The frame consists of two guide walls and a folded metal back to keep the shoe in place. Embedded in the panel is an elastic "tongue-puller" that attaches onto the tongue of the shoe and pulls it back to allow for more access into the shoe.

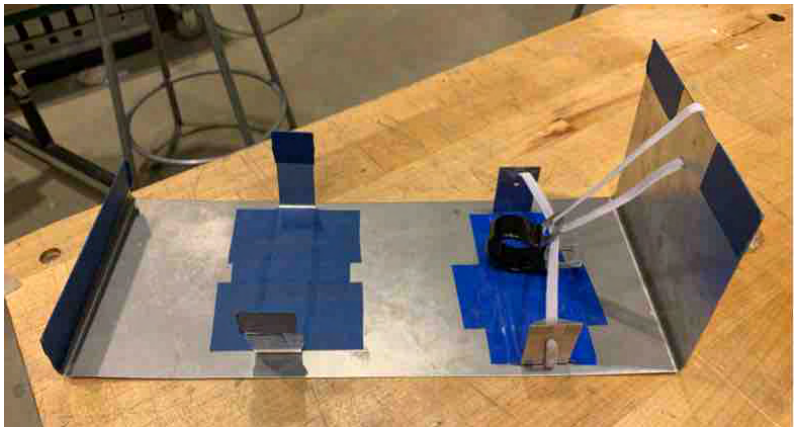


Figure 25.a: Mockup 6 — Pull N' Expand V2. The Pull N' Expand v2 is made of metal sheet so it is light enough for one-hand use. The shoe show be placed so that the tip of the shoe is facing the tongue puller.

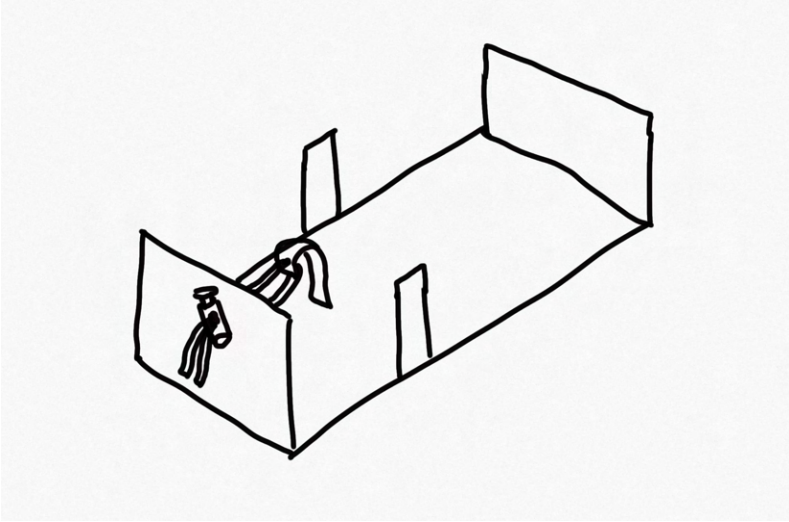


Figure 25.b: Mockup 6 — Pull N' Expand V2 Diagram. The drawing shows the structure of Pull N' Expand V2 in its simplest form.

Questions for Mockup to Answer

- Is metal a good material to use?
- How effective is the "tongue-puller" system?
- Do the one-size-fits-all guide walls stabilize the shoe or is a more adjustable system needed?

Mockup 7 - Burritoe

This works-like mockup attempted to remedy the problems faced in with the Flappy Shoe in the previous round of mockups. In this iteration, zippers (zipper pull tab was 1 cm) were attached along with the flaps with fabric glue to ensure the flap is closed fully after the user's foot is inserted. Snowboard bindings were also placed at the top of the opening to assist in pulling the flap back over. The cut was done along the inside edge this time to test if this position was better for foot insertion.

Figure 26: Mockup 7 — Burrito. The image above illustrates the snowboard binding process. The top binding attaches into the strap and locks into place as it is slid down. This holds the flap into place as the zipper is closed.

Questions for Mockup to Answer

- Will the snowboard binding system help with folding the flap back over?
- Can the user put the shoe on with one hand?
- Should we place the flap cut on the right or on the left?

Appendix I: Mockups — Round 3

(11/02/2019)

Objectives

This round of mock-ups aims to improve the mock-ups from the previous round according to the user testing result. Our team abandoned the AFO dock design because it is impractical to design a docking station with desired mechanical structure. The user testing shows that the paddle should slide back toward the user's foot as the angle of the panel is lowered. Thus, the device will involve in sophisticated mechanical and perhaps electrical structures which reduce the reliability of the device. Also, the AFO Dock will be large compared to other mock-ups, which makes the device not portable and cannot be operated by the user alone. The mockups in this round are all works-like.

Mockup 8 - Pull N' Expand V3

The user testing result shows the Pull N' Expand V2 is too big to operate for the user sitting in a chair or wheelchair, so it may collide with the armrest of the chair or wheelchair. To address this problem, we reduced its size and made it into cross-shaped. Another problem found in user testing is that the device does not have a handle. We designed an adjustable handle on the back of the device, and the user may also use any branch of the cross as a handle. We also include a rubber band to hold the shoe tight onto the device so the shoe may not slide away when donning the shoe. The user is supposed to put the shoe on the device, attach the "tongue-puller" and don the shoe.

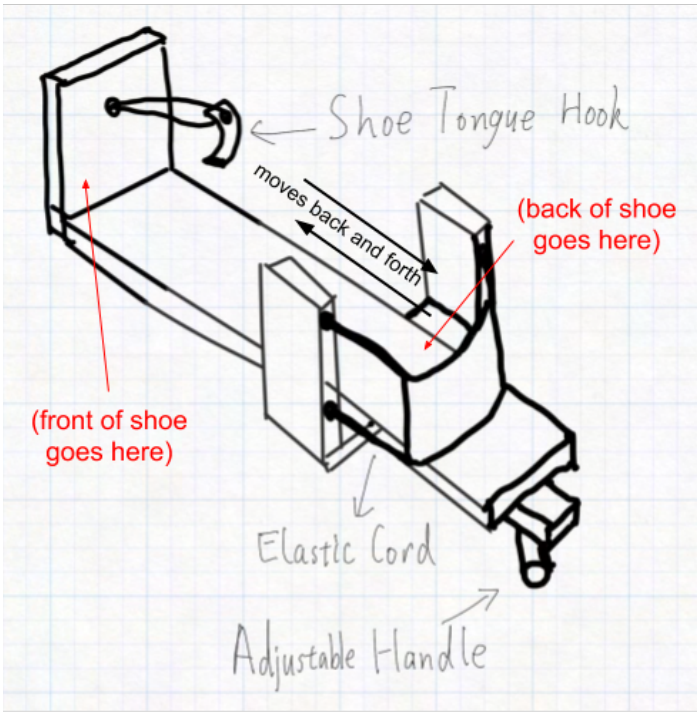


Figure 27a: Mockup 8 - Pull N' Expand V3 Diagram. The drawing illustrates the structure of different parts of the device. Drawing by Sam Huang.

Figure 27b: Mockup 8 - Pull N' Expand V3. The picture shows how the mock-up actually look like. The handle is beneath the cross and a metal sheet wall is added to stabilize the shoe. Picture by Sam Huang.

Questions for Mockup to Answer

- What is the optimal position to place the handle?
- How effective the handle in helping the user don the shoe?
- Will the rubber band be too tight so the user may find it difficult to put the shoe in?

Mockup 9 - Burritoe V2

From the user testing, we found that the zipper may be stuck halfway, and the snowboard binding latch has problems getting off and is also very bulky. So we used a bigger zipper to make it easier to pull and replace the latch with a string fastener that could loop around the shoe while the user is donning it so that it does not get in the foot's way.

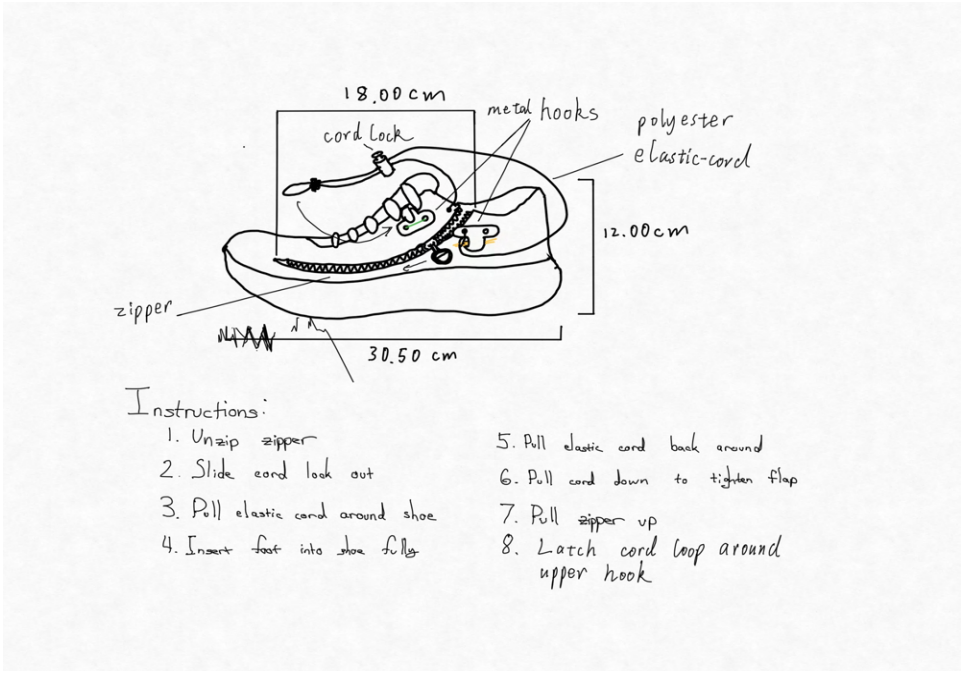


Figure 28a: Mockup 9 - Burritoe V2 Diagram. The drawing shows the position of the string and tightener and the zipper. Drawing by Katrina Baniak.

Figure 28b: Mockup 9 - Burritoe V2. The picture shows the front view of the Burritoe. Two metal hooks are used to stable the string after the user puts the shoe on. Picture by Sam Huang.

Questions for Mockup to Answer

- Whether the user can don the shoe by one hand?
- Whether the device is intuitive to the users?
- Whether the hook is enough to stabilize the string when the user is walking?

Mockup 10 - Flappy Shoe V2

The velcro in Flappy Shoe V1 is too small and not adjustable, so it may easily detach after foot with AFO is put in. This Flappy Shoe V2 improved the Flappy Shoe V1 by features an extra length of stretchy fabric that will be able to fold over the shoe and adjust to different shoe widths.

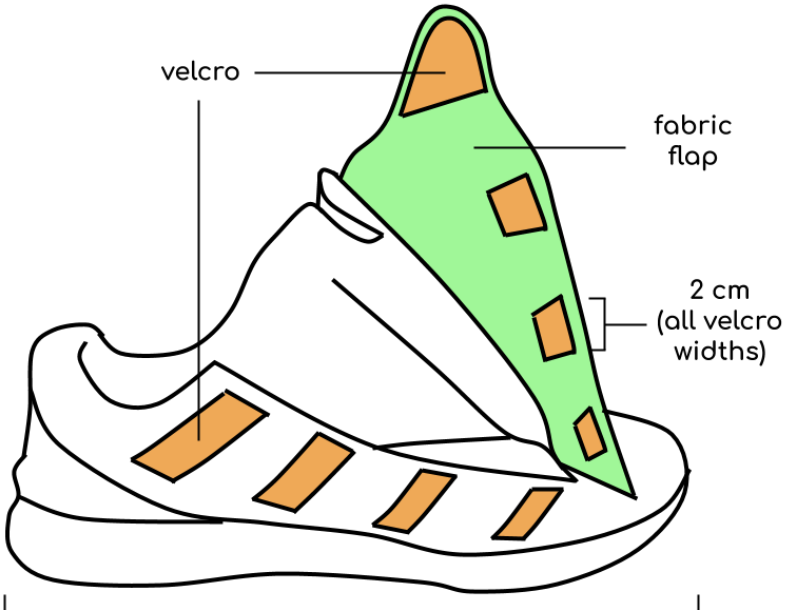


Figure 29a: Mockup 10 - Flappy Shoe V2 Diagram. The drawing indicating the shape of the flap and the position of the velcro on the shoe and the flap.

Figure 29b: Mockup 10 - Flappy Shoe V2. The picture shows how the Flappy Shoe looks like when it is opened.

Questions for Mockup to Answer

- Whether the velcro is strong enough to hold the shoe closed?
- Whether the user can close the velcro properly with one hand so the hook and loop are precisely attached?
- Will the velcro detach from the shoe after opening and closing several times?

Appendix J: User Testing 1

Date: 10/20/19
Time: 3:45 - 4:30 PM
Location: Shirley Ryan AbilityLab
Team members in attendance: Hannah Huang, Sam Huang, Andy Xu
Other key attendees: Nathan Arnold, Katz Kadlic, Lauren Henderson

Objective

1. Determine if devices were helpful in donning shoes
2. See if designs were intuitive to the user
3. Observe where the user struggles with the devices
4. Gain user feedback to improve on the designs

Testing Conditions

- Sitting in a wheelchair. Although this was advantageous to us because our designs were mostly made for the sitting position, we did not anticipate that his feet would be elevated off the ground.
- High privacy levels, low noise levels (low volume TV going on in the background), average lighting levels. The user seemed pretty relaxed and comfortable in this environment. This could have made him more participatory and was why we were able to get so much feedback.
- Resting the whole day (Sunday is his rest day), meaning his performance was under optimal energy levels. This could have caused him to try harder and not give up as much. Our data would reflect nearly the best case scenario for our designs.

Testing Session Overview

1. Gave an overview of each of our mockups to Ms. Henderson
2. Reintroduced ourselves to Joe, whom we had previously observed
3. Briefly explained each mockup and asked the user to interact with them
4. Asked the user questions about the mockups
5. Video recorded the user's interaction with mockups, as long as his responses to them
6. Observed the client donning his shoe without any device
7. Post-test interview of users

User Testing 1 User Overview

A. *Name:* Joe
B. *Relevant Medical History:* Multiple Sclerosis
C. *Type of Shoe:* Sketchers Slip-On extra-wide
D. *Shoes Over Regular Size:* Yes
E. *AFO Foot:* Both

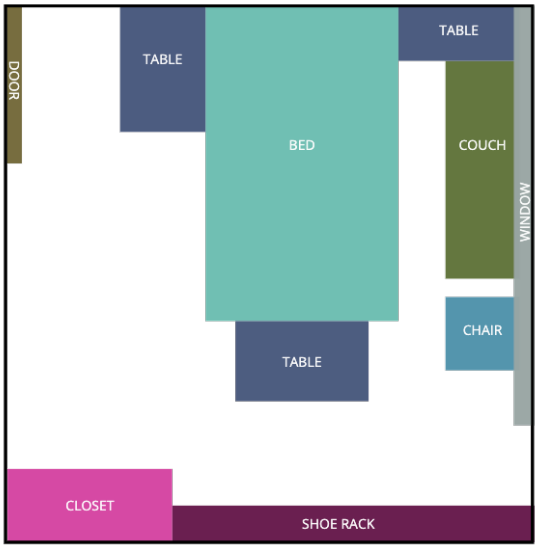


Figure 30: Floorplan. Tests were conducted at the Shirley Ryan AbilityLab in the user's room on floor 24. This floor also contains the legs and walking lab for patients who are going through leg-related physical therapy. However, our tests were all limited to his room, next to his bed.

Test 1 — Shoe Donning: Mockups 1 - 3

Table 12: Shoe Donning—Joe

Mockup Name	Posture	Process	Comments	Successful?	Time (seconds)
Without any device	Sitting	With Ms. Henderson's assistance, Joe crosses one leg over the other on his lap and then wiggles the shoe onto his foot.	"I usually have leg loops" (which is why Ms. Henderson had to help him, but he could presumably do it without her help, too)	Yes	32
Burritoe	Sitting	Ms. Henderson unzips shoe and lets Joe try to wiggle it on. With some help and a lot of effort, the shoe slides in, though the flap is too small to	"[The shoe] is just too small for me. This is a great idea, the zipper	No	120

		completely slide back over.	just has to be bigger." Make the shoe wider.		
Pull n' Expand	Sitting	Sam inserts the foot-funnel shoe horn, slides Joe's shoe into the device, and offers it to Joe for use. Joe is unable to slide his foot in so Sam raises the device, but little progress is made.	"Yeah, that's about as far as it can go. AFOs are not easy guys."	No	120
AFO Dock	Sitting	The shoe with the foot-funnel shoe horn is placed into the dock at the highest possible setting. Joe is able to get half his foot in, though when the angle is gradually reduced, his foot slides out.	"As the angle lowers, the shoe is coming off my foot… There has got to be a way for it to drop the angle and have it come back in"	No	180

Figure 31: Joe Dons Shoe Without Any Device. In the photo above, Joe pulls his leg up to his body (with the help of Ms. Henderson), crossing one leg over the other. He uses his

hands to wiggle the shoe over his AFO and foot to make up for the lack of force in his legs.

Figure 32: Joe Slips on the Burrito. The flap shown above is too short to fold over Joe's foot. As a result, the zipper was stuck in the photo above. Picture by Hannah Huang

Figure 33: Joe Tries the Pull n' Expand. Sam props up the device while Joe tries his best to insert his foot, though his foot gets stuck in the position shown above. Picture by Hannah Huang

Figure 34: Joe Uses the AFO Dock. Sam and Hannah stabilize the device, while Joe tries to don his shoe. As the docking panel is lowered, the shoe gets further and further from Joe's foot. Picture by Hannah Huang

Figure 35: Joe Uses his Leg Loop to Lift his Leg. After wrapping the loop around his leg (which would ideally go under the AFO, but he put them over just for example purposes) Joe was able to lift his leg upwards with his arms.

Interview

At the beginning of the session, Joe had new shoes and two new AFOs, which he had a bit of practice with since we last saw him. He told us the best part of his slip-on Sketchers shoes was the "extra wide" feature, that made all the difference in accommodating for the AFO's width; thus, for the shoe modification, he recommended that we made the shoe itself wider. He had a lot of ideas about each device, most of which are listed in Table 2. He told us that when he gets back to his normal life, he will want to take the AFO

whenever he can, like when he sits at work all day. Near the end, he showed us the process in which he would put on his shoes by himself, but because he didn't have his leg loops, Ms. Henderson helped him put up his leg. Afterwards, he briefly showed us how he would put on his leg loops and how they are used (he didn't show us in depth because it would require taking off his AFOs). The leg loops are strips of fabric that go around his legs and have velcro adjustments. These strips have fabric handles, which he pulls to bring his legs into different positions.

- "The key is the width [of the shoe]."
- "If I'm at work, sitting at the desk all day, I'm not wearing AFOs—and I'm definitely not wearing Frankenstein shoes. I'm wearing my regular comfortable gym shoes."

Analysis and Implications for Each Design

Table 13: Analysis and Implications of Designs

Design	Analysis and Implications
Burritoe	Zipper needs to be larger to allow for easy fastening Shoe flap closing process needs to be refined because the current system with snowboard bindings is difficult to use Larger and wider shoe should be modified next time for testing
Pull n' Expand	Handle needs to be attached to back to improve ease of use More appropriate for use in cross-legged position than on the ground
AFO Dock	Device should slide back toward the user's foot as the angle of the panel is lowered Device needs some material underneath to keep in from moving during the donning process The device is very big and bulky and will not be portable

General insights:

- Joe had minimal strength in his legs and was limited in his ability to push his feet down into the shoe
- Wheelchair is slightly elevated, so future designs should take that added height into account
- Joe wanted to be able to take the AFO off whenever he wanted, so whatever device should take into account portability
- Joe made a comment about not wanting to stand out, so this device must either be inconspicuous as to not draw attention, or be aesthetically pleasing as to not embarrass the user.

Appendix K: User Testing 2

Date: 11/10/19
Time: 1:00-1:30 PM
Location: Shirley Ryan AbilityLab
Team members in attendance: Katrina Baniak, Hannah Huang, Sam Huang, Andy Xu
Other key attendees: Nathan Arnold, Lauren Henderson

Objective:

1. Determine if round two mock-ups were helpful in donning shoes
2. See if designs were intuitive to the user
3. Observe where the user struggles with the devices
4. Gain user feedback to improve on the designs
5. Decide upon a single design direction to proceed with for the prototype

Testing conditions

- Sitting in a wheelchair, preparing for a later physical therapy session. The visit was slightly unexpected for the user and he had an upcoming physical therapy session just after our user testing. As a result, the session was slightly rushed, and while all devices were tested this may have affected the testing.
- High privacy levels, low noise levels (low volume TV going on in the background), average lighting levels, presence of enthusiastic wife. The user seemed pretty relaxed and comfortable in this environment. This could have made him more participatory and was why we were able to get so much feedback.

Testing session overview

1. Gave an overview of each of our mockups to Ms. Henderson
2. Introduced ourselves to Dan, our user for this testing
3. Briefly explained each mockup (Flappy Shoe and Burritoe) and asked the user to interact with them
4. Asked user specific questions about the mockups as well as asking for general feedback
5. Video recorded the user's interaction with mockups, as well as his responses to them
6. Post-test interview with Ms. Henderson

User overview

Dan

- Age: 74
- Shoe size 11 (normally), 12 (to compensate for AFO)
- Has Multiple Myeloma
- AFO wearing leg (left) can move up and down, but still not a lot of strength
- Not very flexible, can't get into a cross-legged position
- Been going into treatment for multiple myeloma since his retirement in 2014
    - This cancer was a result of the effects of Agent Orange during the Vietnam war

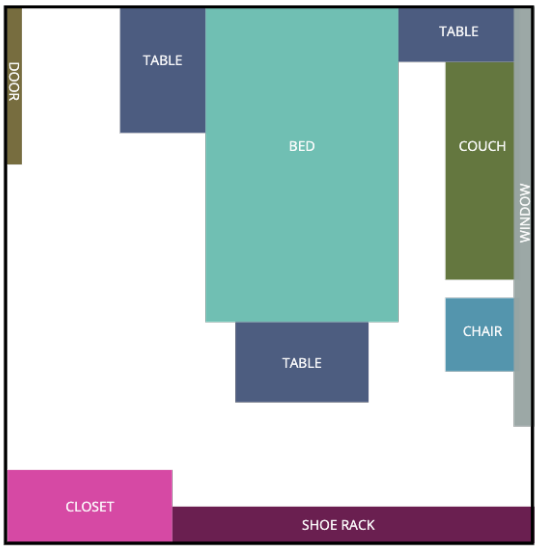


Figure 36: Floorplan. Tests were conducted at the Shirley Ryan AbilityLab in the user's room on floor 24. This floor also contains the legs and walking lab for patients who are going through leg-related physical therapy. However, our tests were all limited to his room, next to his bed. Floorplan by Hannah Huang.

Figure 37: Testing Environment. This is the room in which we tested our mock-ups. Dan sat in his wheelchair beside his bed, while his wife sat on the couch next to the window.

Table 14: Shoe Donning—Dan

Mockup	Posture	Process	Comments	Successful?	Time (minutes)
Flappy Shoe	Sitting	While Dan held his leg up, Ms. Henderson pushes the shoe onto his foot. Then, she folds the velcro flap over his AFO and shoe, which does not go over all the way.	"If that was a size 12, I could get the shoe on with this [the shoe horn]." "If this was the right size, I could probably do it, so that's a great idea." Mrs. Henderson - "We're going to have to get you more flexible."	Somewhat -> shoe size was too small	4

Burritoe	Sitting	Dan immediately asks for the directions to be repeated. He wraps his right hand underneath his right thigh and pulls his leg up. Holding onto the drawstring with his right hand to keep the shoe against his foot, he uses a shoe horn with his left hand to push his foot fully into the shoe. Dan once again requests instructions. After they are given, he bends over and uses both hands to pull the cord lock down. When Ms. Henderson tries to pull the zipper up, the zipper breaks off, as the flap is too small to pull over.	"My toes are cramped." "I'm not supposed to BLT: bend, lift, or twist." Ms. Henderson - "Oh my gosh, I broke your project."	Somewhat -> shoe size was too small & zipper broke	2

Flappy Shoe

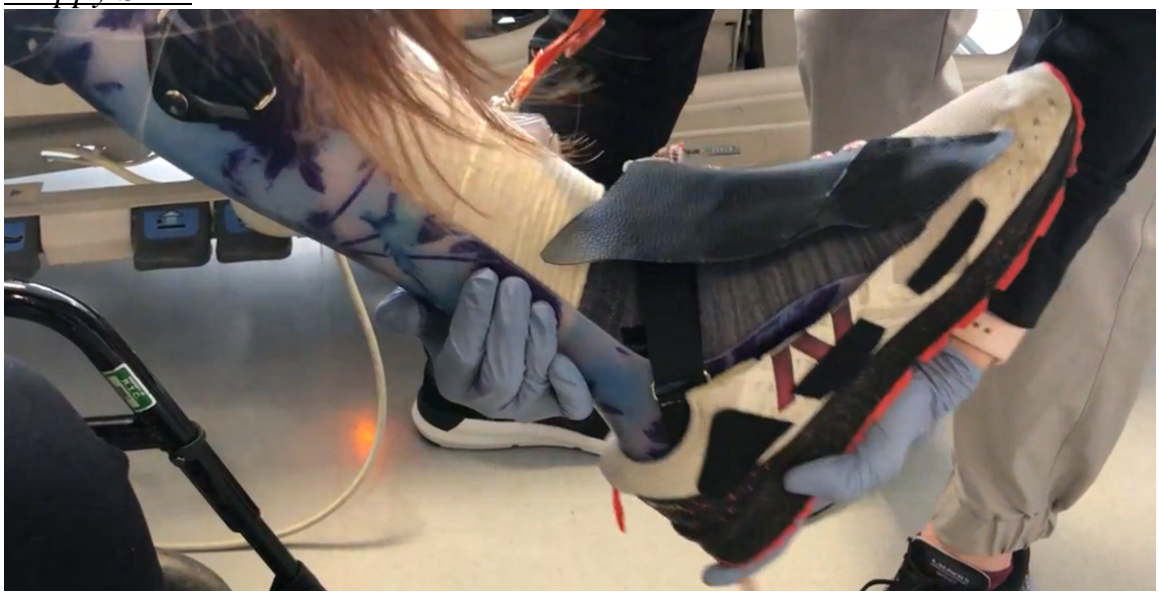


Figure 38: Ms. Henderson Inserts Dan's Foot into Flappy Shoe. Dan did not have the strength or flexibility to enter the cross-legged position so he required Ms. Henderson assistance to don the shoe. Overall, the shoe slipped on without too much effort.

Figure 39: Ms. Henderson Closes the Velcro Flap. Even though the shoe was a size too small, the velcro flap still managed to close though not fully.

Burritoe

Figure 40: Dan Supports his Right Leg while Donning the Burritoe. Since Dan lacks flexibility, he must use both hands to put on the shoe. Ideally, in the final design, only one hand is needed.

Figure 41: Dan Uses the Drawstring to Pull the Shoe into his Foot. This was not the intention of the of the original design, though it is a neat feature that helps the user stabilize the shoe during the donning process.

Figure 42: Dan Pulls the Drawstring Closed. The flap closes effectively considering that the shoe is two sizes too small. Note that Dan had to use both hands to complete this motion. In our final design, only one hand should be needed.

Interview

At the beginning, he showed us the new size 12 shoes he had bought to put on over his AFO. According to him, not only has the AFO made his feet bigger, but his feet themselves have swollen, too, making it necessary to size up in shoes. He talked vaguely of his service during the Vietnam War, emphasizing the terrible side effects of the war on his health and the extensive treatment he's been going through. Despite this, he was very lively and agreeable. His wife told us that usually she puts his shoe over his AFO for him. She told us that it works best when his leg is outstretched and she pushes the shoe on. After the user test, Ms. Henderson added that most patients are able to enter the cross-legged position after therapy.

Analysis and Implications for the Design

The major implication of this user testing was that the Flappy Shoe has been selected as the design that will be prototyped. Additional implications include:

Table 15: Analysis and Implications for the Design by Device

Design	Analysis and Implications
Flappy Shoe	• The user was immediately very enthused by the velcro mechanism. • Despite being a size smaller than the user's current shoe size, he was able

	to fit his foot inside of the flappy shoe. ● The size of the shoe and flap made it difficult for the user to secure the velcro flap, especially since he was unable to bend over or sit in the cross leg position.
Burritoe	● The process of donning the shoe is too complicated for the user to remember and operate. ● The user can not close the cord lock with one hand. ● The user could not bend over in order to access the mechanism well enough for use.

- The user prefers the shoe that has a simple process to put on instead of having several steps, thus the simplicity of the Flappy Shoe was appealing.
- The Flappy Shoe is the design that will be prototyped due to its ease of use, appealing design, and the user's clear preference for that mock-up.
- The shoe size needs to be customized to the user in order to ensure appropriate fit, but the flap must also be expanded in addition to this in order to secure the gap.
- The difficulty reaching the flap could be remedied with a reacher and loops on the flap for the user to hook and pull tight. This would afford the user ease of use with the shoe even when out of reach.

Appendix L: Proxy Testing

Date: 11/22/19-11/24/19
Location: Northwestern University

Objectives:

- Test for shoe durability
- Determine if shoe is comfortable
- Identify any unforeseen problems

Conditions of Test

For two days, Andy wore the CroBro and performed his usual activities such as walking, jogging, and playing ping-pong. In addition to observing the CroBro during these activities, he also took notes while donning and taking off the shoe.

User Information

Name: Andy
Shoe size: 11.5
Mobility: Both legs, both legs
Age: 19

Table 16 : Performance Testing Activities with CroBro

Activity	Duration/ distance of Activity	Comments/Observations
Walk from Sargent to Seagle along the Lakefront and back	1.4 miles	The shoe was very comfortable for walking.
Jog along lakefront	15 minutes	“The flap held very well, and I even forgot I was wearing a modified shoe.”
Walked downtown and back	2.4 miles	“I walked downtown with 6 other friends, and not one of them noticed the flap.”
Played ping-pong	20 minutes	“I won all three rounds of ping-pong.”

Other Observations

- Very easy to take off

- Can be put on and taken off one-handed within one minute
- Encountered some problems when putting on
    - It is still possible for the foot to get stuck on the shoe tongue, since it droops and is only attached to the shoe at the base
    - The velcro flap on top sometimes gets stuck to the user's sock

Conclusions

- Shoe is both comfortable and durable
- Modificaiton on the shoe is unobtrusive
- Should consider swapping hook and loop velcro positions
- Should look for a way to not let tongue get in the way
    - Consider sewing the tongue to the shoe

Appendix M: Vogue Fabrics Expert Interview

Date: 11/11/2019
Time: 3:30 - 4:00
Location: Vogue Fabrics, Evanston, IL
Team members in attendance: Hannah Huang, Katrina Baniak
Expert + other key attendees: Carol (Vogue Fabric)

Expert name, qualifications, and affiliation

Carol is an employee at Vogue Fabric, a fabric business with a warehouse in Evanston, IL, and as a part of her work responsibilities frequently advises customers on fabric choices for their projects. Due to the team's decision to proceed with shoe modification as our prototype, an interview with an expert in fabrics was necessary to make decisions in regards to the materials that should be used in the prototype. The object of this interview was to learn what type of fabric would best suit the flap we needed to create as well as rationale and how we could go about sewing the modifications.

Background on Velcro Burritoe (CroBro)

CroBro, formerly known as "Flappy Shoe", was unanimously chosen as our rough prototype design after the second round of user testing. CroBro is a modified running shoe that is cut along its inward facing side to create a larger opening for the user's foot. A large vinyl patch was sewn to the upper flap and velcro was attached underneath to close the open flap. This system was proven to be effective and intuitive during user testing.

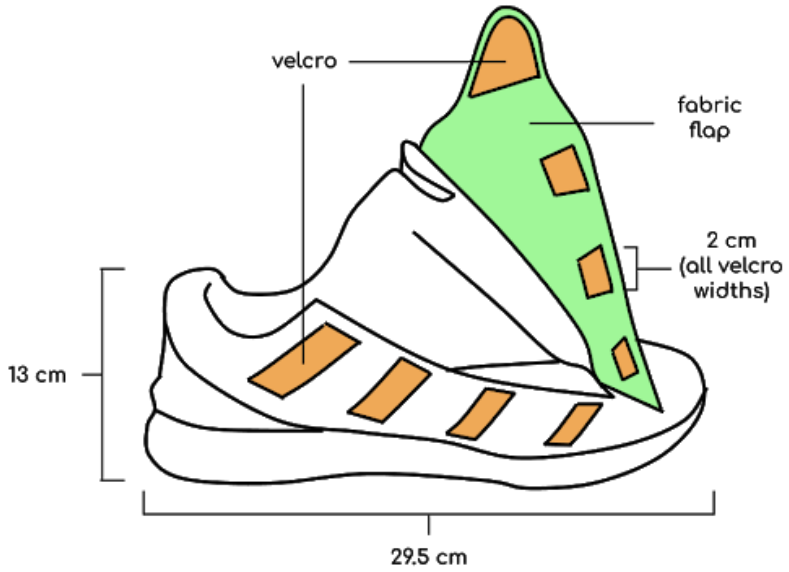


Figure 43: CroBro Mockup Design. The mockup design used strips of velcro to close the open flap of the shoe and a thin black piece of leather-like fabric for the patch. Drawing by Hannah Huang.

Fabric Recommendation - Marine Vinyl

When asked about fabrics to use for shoe modification, Carol initially suggested upholstery fabrics due to its thickness and sturdiness, both needed for a shoe. When she was presented with the mock-up and additional elaboration on the design, she instead recommended vinyl (specifically marine vinyl) be used as the material for the flap due to its:

- Outdoor use
- Resistance to mildew and rust
- Sturdiness
- Very slight stretch

In order to make use of what stretch marine vinyl has, Carol emphasized the need to cut along what is called 'the bias.' This is when the fabric is cut at a forty-five degree angle to its seams, resulting in a fabric that stretches and gives more.

Figure 44: Upholstery Fabric. Initially Carol showed us this fabric because the thickness gave it the ability to stand up.

Figure 45: A Roll of Marine Vinyl Fabric. It is visibly sturdy and thick. Notice that the fabric appears double layered, with a fibrous inside and waterproof outside.

Sewing Methods Recommendations

Carol recommended both sewing and gluing the velcro to the shoe and flap due to two concerns:

- Heavy use of shoe might weaken glue alone
- Moisture might make the glue come undone
- Thread rottens out over time

When used in conjunction, glue and sewing will make the velcro mechanism stronger overall. The velcro should also be sewn as close to its edge as possible, for aesthetics and best attachment. In regards to the actual sewing of the vinyl, whether to attach velcro or to attach the flap to the shoe, she recommended the following supplies:

- A thick needle (Size 18)
- Upholstery Thread

She also noted that vinyl, like leather, has a tendency to shift while sewing. In order to prevent this shifting, vinyl should be glued first, left to dry, and then sewn.

Figure 46: Different Types of Velcro. Carol showed us the different options of velcro we could use, including velcro strips and velcro dots. All the velcro shown in the picture has a built in sticky back.

Conclusions and Next Steps

The fabric that best suits our needs is marine vinyl, according to the interviewed expert, and we have numerous recommendations for the sewing process going forward should we decide to do the work ourselves rather than outsourcing. Our next steps should include:

- Speaking with shoe repair shop owners
- Deciding whether to have a business do the modifications or to do them ourselves
- Order materials from McMaster Carr or a fabric business

Appendix N: Shoe Repair Expert Interviews

Date: 11/12/2019
Time: 12:45 pm - 1:45 pm
Location 1: Lou's Shoe and Luggage Service in Skokie, IL
Location 2: National Shoe Services in Cook County, IL
Team members in attendance: Andy Xu, Sam Huang
Expert: Eric (Lou's) and Chris (National)

Expert Name, Qualifications, and Affiliation

Eric
Eric has been working at Lou's Shoe and Luggage Service for several years and seems to have thorough knowledge of shoe modifications from our brief conversation. Eric is the sole repairman at Lou's.

Chris
Chris has been working at Nation Shoe Service for over 50 years and has experience with modifying shoes for medical purposes. Chris is the sole repairman at National's.

Our goals for the interview were to learn the:

- Best method of communication of modification to shoe repairman
- Duration of repair job
- Total cost estimate
- Recommendations for our design
- Manufacturing methods

Background on Velcro Burritoe (CroBro)

CroBro, formerly known as "Flappy Shoe," was unanimously chosen as our rough prototype design after the second round of user testing. CroBro is a modified running shoe that is cut along its inward facing side to create a larger opening for the user's foot. A large vinyl patch was sewn to the upper flap and velcro was attached underneath to close the open flap. This system was proven to be both effective and intuitive for the user during user testing.

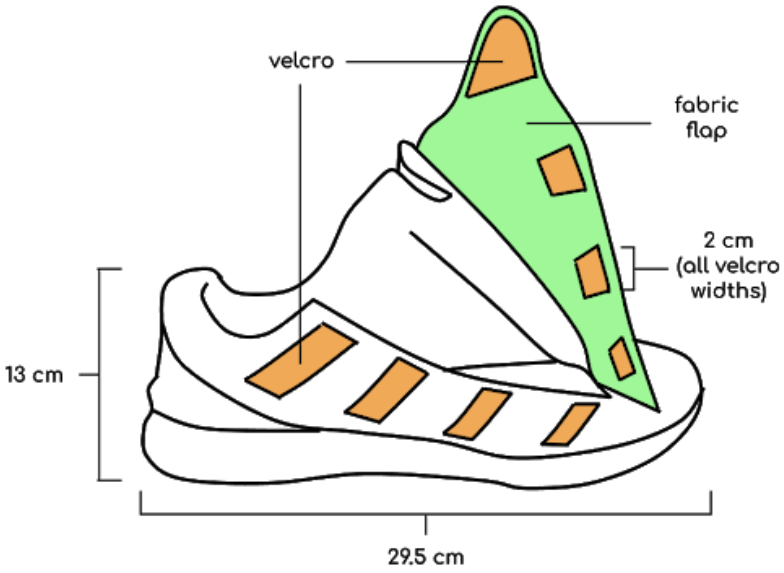


Figure 47: CroBro Mockup Design. The mockup design used strips of velcro to close the open flap of the shoe and a thin black piece of leather-like fabric for the patch. Drawing by Hannah Huang.

Recommendations

Eric and Chris both had similar recommendations for our design.

Table 17: Expert Recommendations

Recommendation	Rationale	Eric or Chris?
Add lining to edges	Some runnings shoes are composed of multiple layers of fabric. Lining the open edges will connect these exposed layers and reinforce the shoe in general.	Both
Replace vinyl with leather	Leather is a stronger material and is better suited to handle harsh Chicago winters.	Both
Large velcro patch instead of strips	A large patch allows for more velcro points of contact and will hold the flap in place more	Both

	effectively. Also, the strips are more difficult to line up and require more effort to produce.	
Flip velcro sides	The flap is easier to open if the side with bristles is on the top flap and the fuzzy side is on the bottom.	Chris

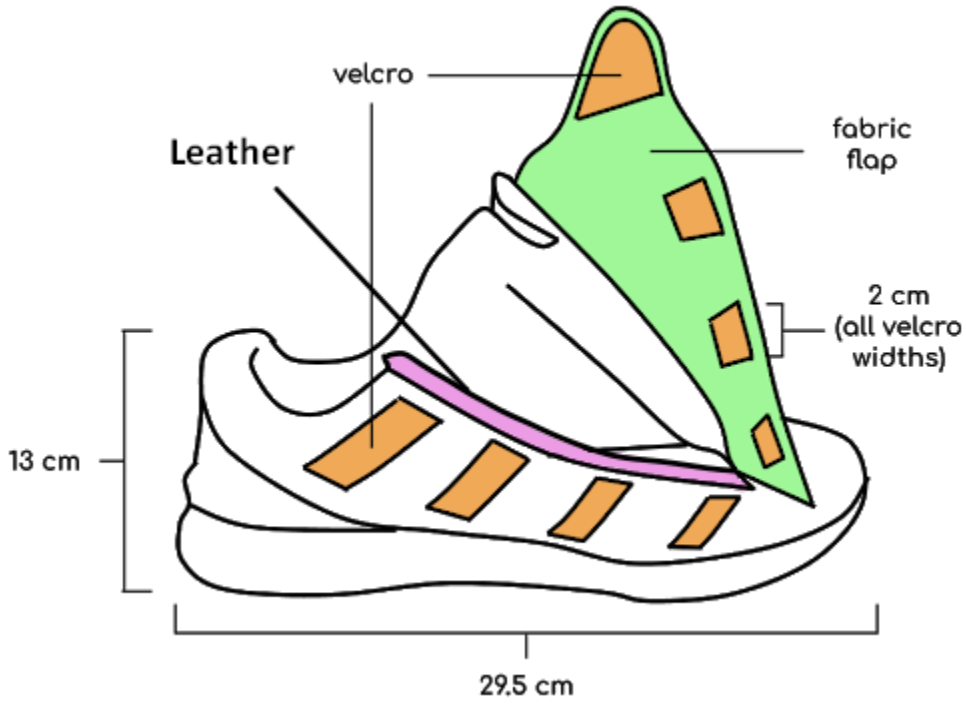


Figure 48: Leather Lining. The leather lining closes off the exposed fabric and gives the shoe a neater finish. Drawing by Katrina Baniak and Hannah Huang.

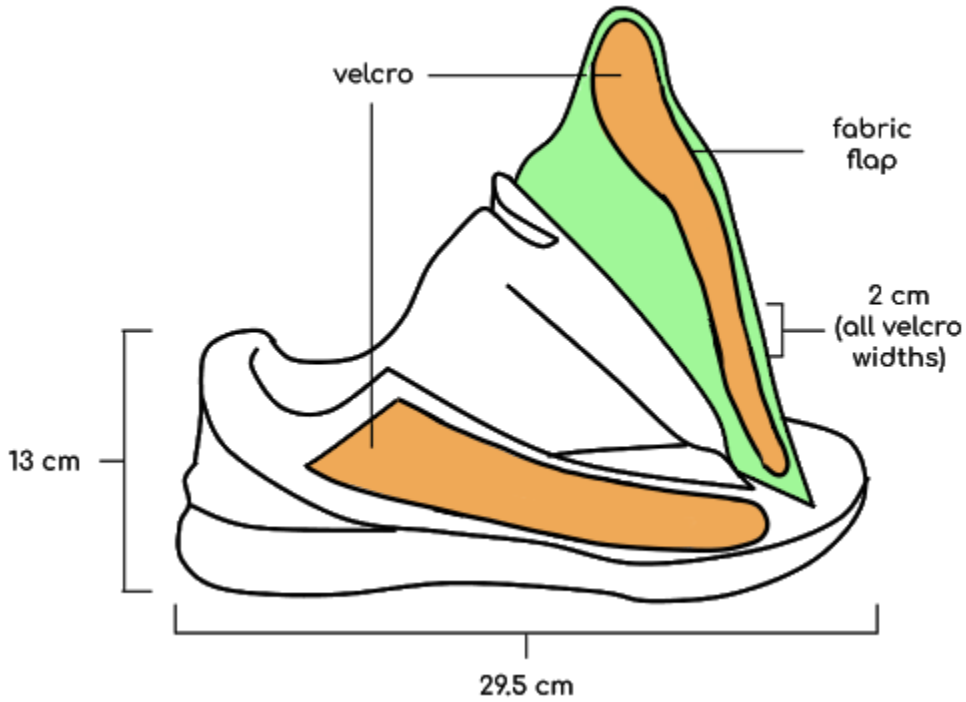


Figure 49: Velcro Patch. The large velcro patches serve to increase the amount of overlapping area between the flaps and strengthens the connection between the flaps.. Drawing by Katrina Baniak.

Pricing, Delivery Timeline, and Location

There was great variability between the two shoe repair shops we visited.

Table 18: Pricing, Delivery Timeline, and Location Information

Shop	Pricing	Duration to Complete Modification	Distance from Shirley Ryan Ability Lab
Lou's	$100	1 - 2 weeks	13.4 miles (33 minute drive)
National's	around $50	2 days	10.3 miles (23 minute drive)

Process

How to Communicate Instructions to Shop

- Give repairman sketch of dimensions from relevant angles to reduce ambiguity
- Complex designs may need to be conveyed in-person to go over specific details
- Once instructions are conveyed once, the shop can reuse the same instructions for other shoes that need to be modified in the same manner

Delivering Instructions

- Contact repairman by email, phone, or in-person
- Deliver the shoe in-person to the shop

Methods of Construction

- Cut shoe to create flap
- Using specialized patching machine to stitch on vinyl/leather patch and lining
- Cut velcro to size and attach to open sides

Conclusions and Next Steps

Conclusions

- Shoe modifications are not cheap and we only have the budget for a single modification
- There exists great variability between stores
    - The only way to find out the information is to talk directly to the shop owner over the phone or in store since no websites exist for the shops
- Shoe repair shops can help tremendously to make the shoe look aesthetically pleasing
    - Both repairmen commented on the "messiness" of our modification

Next Steps

- Finalize design and draw out dimensions for shops to use
- Order materials from McMaster-Carr and/or amazon.com for use
- Check out more shops to get a better idea of pricing and other information
- Draft final report

Appendix O: Bill of Materials

Below are the materials needed and services used for building Team 11.1's CroBro prototype. Note that although the total cost was $108, the actual modification cost was only $68.

Table 19: Bill of Materials for CroBro

Item	Qty	Unit Price ($)	Purchase Website
Plain Backing Weather-Resistant Hook and Loop (2'' x 5'')	1	$ 16.76	https://www.mcmaster.com/hook-and-loop
New Balance Men's 009 V1 Running Shoe	1	$ 40	https://www.amazon.com/gp/product/B07BQTVNBK/ref=ppx_yo_dt_b_asin_title_o01_s00?ie=UTF8&psc=1
Shoe Modification Contract	1	$ 50	https://www.yelp.com/biz/national-shoe-service-chicago
MODIFICATION COST:	**$ 56.76**		
TOTAL COST:	**$ 106.76**		

Appendix P: Methods of Construction

Overview of the CroBro

The CroBro is a modified athletic shoe. Modifications consist of cutting a slit in the side of the shoe, affixing a flap above the slit, and attaching velcro to the flap and on the shoe below the slit. This results in a final shoe with a velcro-secured flap that entirely covers the added slit.

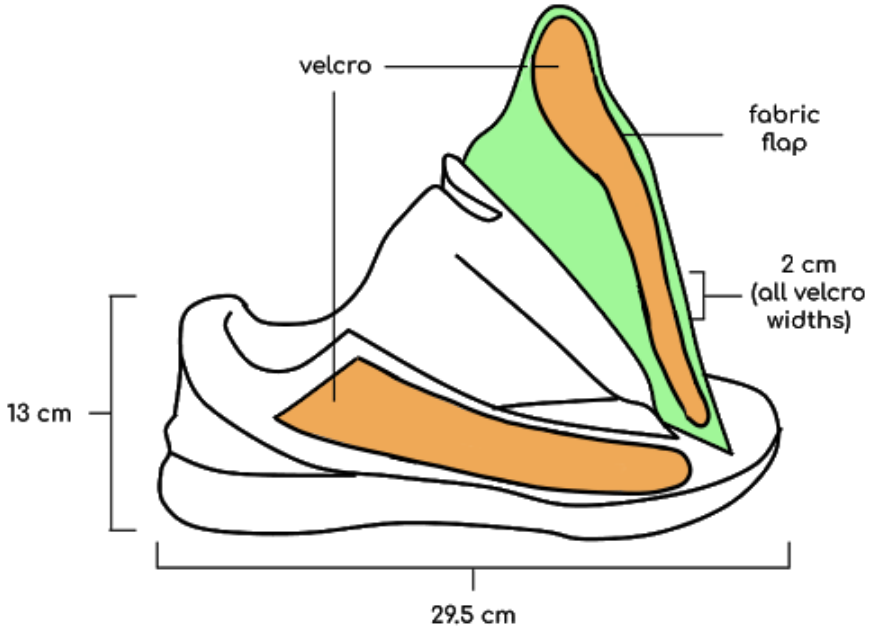


Figure 50: Diagram of the CroBro

Table 20: Materials used for Construction

Item(s)	Specifications*	Qty
NewBalance Men's Shoes 009V1	Size 12 Extra Wide	1 Pair
Weather Resistant Velcro	2 in wide, hook and loop	5 ft

*All additional materials were provided by shoe repair shop, team is not responsible for ordering them.

Step-by-Step Instructions

1. Locate a nearby shoe repair shop that agrees to create necessary modifications. (National Shoe Services was used for the prototype specifically)
2. Discuss modifications with employee and give them instruction sheets (attached on following page).
    a. Be careful to specify that the slit should not be cut too far. Otherwise, a gap may become apparent in the shoe where the flap does not cover the slit.
3. Pick up newly modified CroBro.

Appendix Q: Handbook

CroBro Modification Guide for Running Shoe: Script

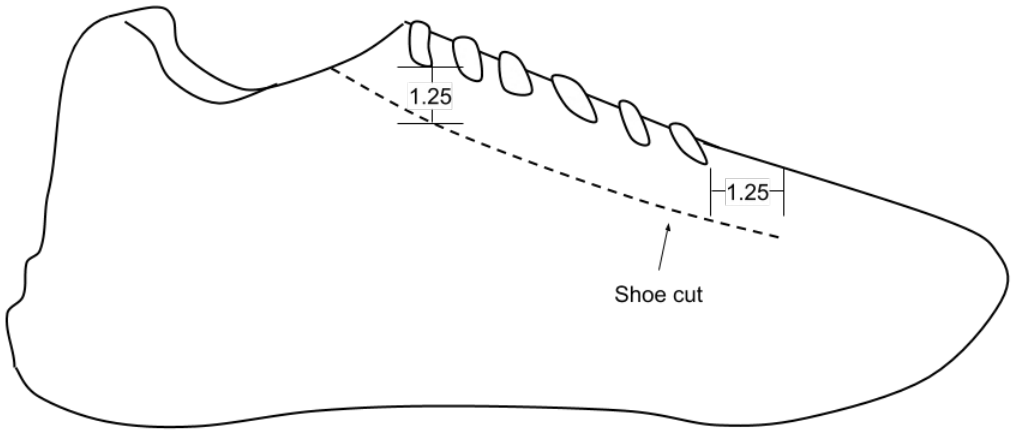
Ordering Process:

1. Find shoe repair shop on Google Maps
2. Call shop in advance or look on website for availability
3. **Materials to purchase**:
    a. Weather-resistant hook-and-loop velcro from Amazon
        i. "XFasten Adhesive Hook and Loop, Black, 2-Inch x 10-Foot Water-Resistant, Sewing Compatible and Wear and Tear Resistant"
    b. Athletic shoe of your choice sized up by one (leaving space for the AFO)
4. After velcro is ordered go to shop in-person with velcro and desired shoe for modifications.
5. Explain the general purpose of the modification
    a. (ie. "We hope to cut open the side of the shoe and place a flap along the incision to help make it easier to put the shoe on.")
6. Give the shop-person:
    a. CroBro modification instructions
    b. Photos of prototype
    c. Shoe to be modified
    d. Weather-resistant velcro
7. Give brief description of design
    a. (ie. "All the dimensions and methods of construction are detailed in this document. [hand over instructions] Here's what the completed modification should look like. [hand over photos] We've also provided you with the weather-resistant velcro needed for the job. [hand over velcro]")
8. Ask repairman to describe to the modification back to you to check mutual understanding
    a. (ie. "Would you mind reiterating the design back to me so that I know we are on the same page?")
9. Request price estimate along with expected completion time
10. Order modification
11. Go back to shop-person after completion to get final product

GIVE TO SHOE REPAIR SHOP

Cutting the Shoe:

1. On the **inner** facing side of the shoe, measure 1.25 inches below the laces, and mark this line on the shoe. The line should extend only 1.25 inches past the laces. Refer to the diagram below:



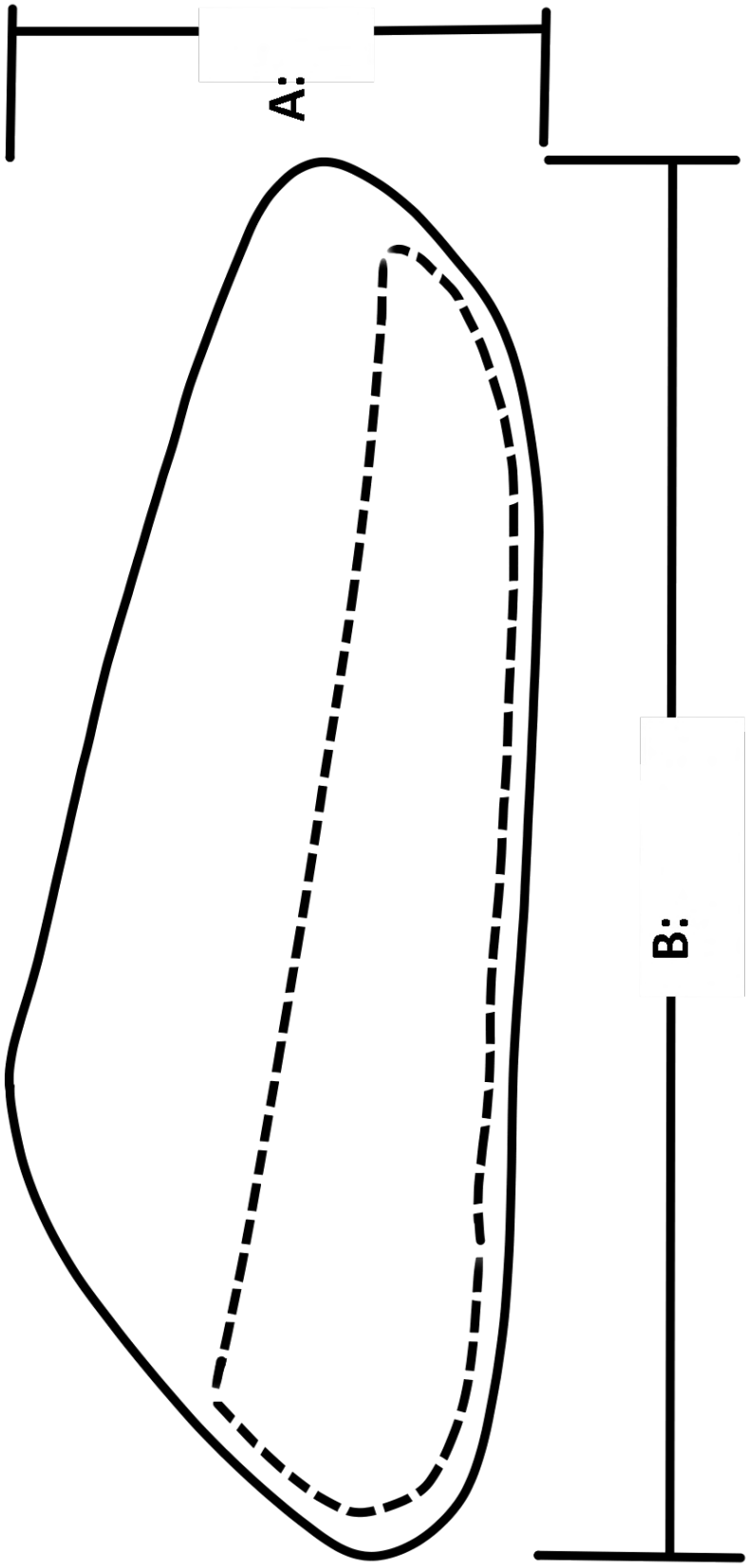
2. Cut along the marked line

Measurement Process (MEASURE IN INCHES):

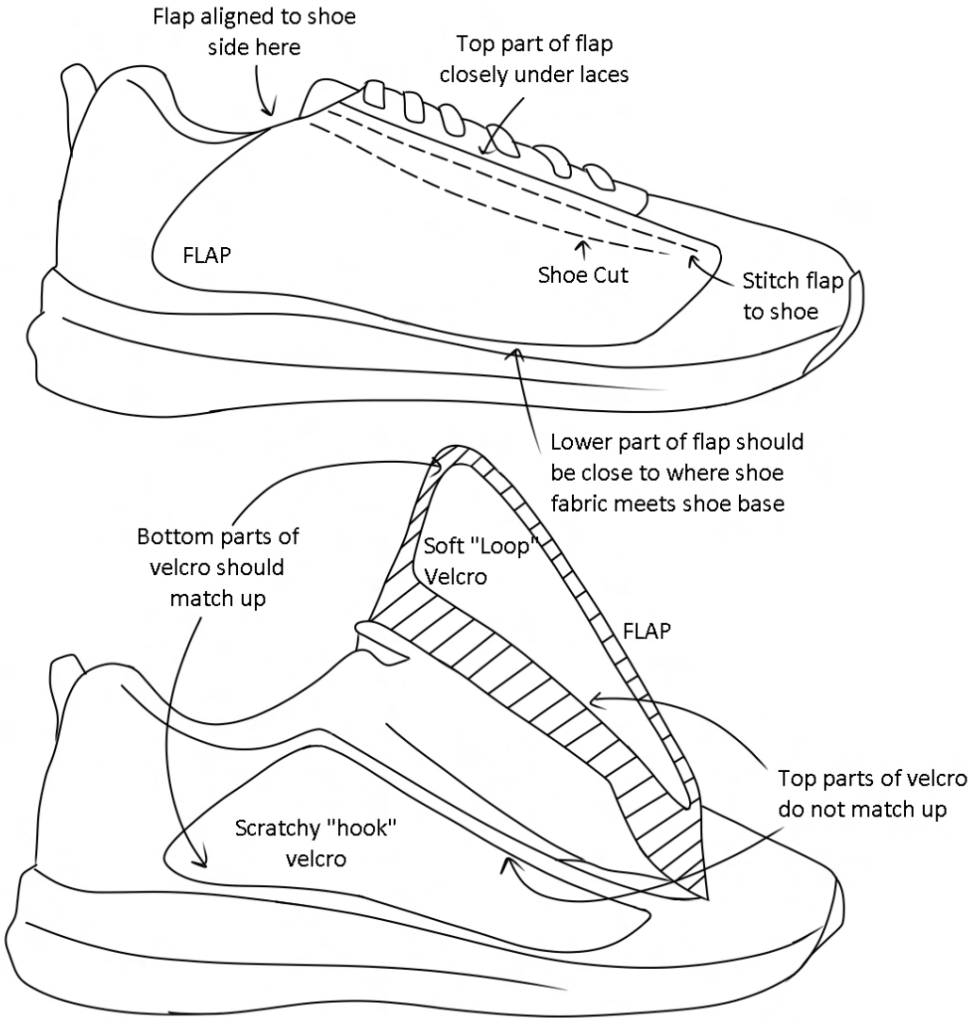
1. Measure from the highest point of the shoe straight down to the rubber sole. Place this measurement in the space labeled **A**.
2. Measure from heel to toe of the shoe. Multiply this number by ¾ and place this measurement in the space labeled **B**.
3. Rescale the pattern accordingly

GIVE TO SHOE REPAIR SHOP

Image of the Leather Flap (Measurements in INCHES)



GIVE TO SHOE REPAIR SHOP



Example Photograph of a CroBro: