The Ergonomics and Functionality of Orthopedic Shoes: A Research Study to Develop a Better Orthopedic Shoe for People with Diabetes

by
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ABSTRACT

According to the American Diabetes Association, over 37 million adults in America have diabetes. Diabetes comes with many side effects and can severely impact foot health. Symptoms such as neuropathy, ulcers and Charcot foot are regularly seen in patients with diabetes. People with diabetes-related foot conditions are often recommended to wear orthopedic shoes. Features, such as a wide toe box, extra cushioning, and soft, stretchy fabrics are incorporated into orthopedic shoes to accommodate for affected feet and help prevent ulcers and other damage. The study shows that most orthopedic shoes do not meet patients' comprehensive needs including a perfect fit, discomfort due to not enough cushion or the cushion wearing out quickly, difficulties in putting on, and appropriate visual appeals. Findings from an online survey and in-person interviews confirmed that most people with diabetes are not satisfied with the current orthopedic shoes and would like to see improvements in functionality and aesthetics. This project uncovers specific unmet needs in the orthopedic shoes and aims to design an orthopedic shoe with improved support, conformity, accessibility, and aesthetics. A functioning prototype was developed and tested by the researcher. Participants reviewed the prototype by viewing videos and touching and looking at the shoes. Design modifications were made based on the feedback. An improved prototype was validated through a second round of assessment. Through a user-centered design approach, a better alternative to current orthopedic shoes was developed to make the lives of those who have diabetes-related foot conditions easier and healthier.

Keywords: Orthopedic shoes, Ergonomics, Functionality, Design, Accessibility

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CHAPTER 1: INTRODUCTION

1.1 BACKGROUND

People with diabetes face many kinds of health problems. One of them is often problems with their feet, primarily including swelling, neuropathy, and Charcot foot, which can lead to ulcers and infections (Charcot Foot). Doctors often recommend people with diabetes who have foot problems to buy orthopedic shoes to prevent ulcers (Charcot Foot). Most medical professionals tell their patients that very specific orthopedic tennis shoes are what they will have to wear either most of the time or for the rest of their lives. That can cause some people to become disheartened and possibly lose a part of their identity, especially for those who like nice-looking and/or formal dress shoes (Swinnen, 2015). While there are a lot of existing orthopedic shoes that are modified tennis-shoes, there are some orthopedic dress shoes, as well as some sandals. But, according to customer reviews, existing orthopedic shoes tend to be limited in functionality, ergonomics, comfort, and aesthetic quality.

1.2 SIGNIFICANCE OF RESEARCH

This research would be important to the diabetic community as well as the medical community. Many people with diabetes either buy the wrong size of shoes and have to return them, or are generally unhappy with the orthopedic shoes, which causes them to not wear the shoes and become more at risk for developing ulcers. Ulcers can be difficult to heal due to the patient's daily activity and complications of diabetes, such as poor circulation in the feet (*Charcot Foot*). If an ulcer does not heal, it can result in the loss of the foot or leg (Charcot Foot). Designing a more functional and ergonomic orthopedic shoe can save limbs and lives.

Other foot deformities or problems that can be managed by wearing orthopedic shoes are bunions, plantar fasciitis, arthritis, etc. Designing a more ergonomic and comfortable orthopedic shoe for foot problems related to diabetes can also be beneficial for other foot complications.

CHAPTER 2: LITERATURE REVIEW

Orthopedic shoes are recommended for many types of foot problems, including problems related to diabetes. While orthopedic shoes provide good features for people, there are still some unmet needs.

2.1 FOOT CONDITIONS

Diabetic neuropathy (DN) is nerve damage in the feet and/or lower legs caused by high blood sugar (Albers, Pop-Busui, 2014). The result is a loss of sensation in the extremities (Feldman, et.al., 2019). It can impact nerve perfusion and calcium balance, and can cause low-grade inflammation (Albers, Pop-Busui, 2014). When paired with peripheral artery disease and infection, it can contribute to diabetic foot syndrome and cause potentially limb-threatening foot ulcers (Papatheodorou, et.al, 2018). Treatments include diet and lifestyle modifications, the improvement of glycemic control, and disease-modifying therapies (Albers, Pop-Busui, 2014; Feldman, et.al., 2019). Orthotic footwear is often recommended to prevent ulcers from forming due to constant rubbing or injury that is not felt because of neuropathy (Volmer-Thole, Lobmann, 2016).

Charcot foot affects the bones, joints, and soft tissues of the foot or ankle (*Charcot Foot*). The bones and joints within the foot break and collapse (*Charcot Foot*). This often happens in the middle of the foot, resulting in a "rocker bottom" deformity as shown in Fig. 1 (*Charcot Foot*). There is no known single cause of Charcot foot, but it often happens in patients with DN (*Charcot Foot*). Without sensation, a person could perform activities that harm the foot without knowing it, potentially causing an ulcer or wound to form (*Charcot Foot*). In severe cases, the wound can cause the patient to lose their foot or their leg (*Charcot Foot*). Treatments include offloading or taking weight off of the foot by casting the foot and using crutches, a knee scooter, or a wheelchair, followed by prescription use of orthotic footwear *(Charcot Foot*). Surgery is performed in severe cases (*Charcot Foot*).

Fig. 1: Charcot Foot
Image Credit: https://www.babureddymd.com/charcot-foot-deformity-foot-ankle-surgeon-dallas-plano-garland-tx.html

2.2 ORTHOTIC FOOTWEAR

Orthopedic shoes often have a wide toe box to accommodate for swelling, arch support, lots of cushion in the sole, and removable insole components (*The Orthofeet Advantage*). Laces or straps are best to make the fit adjustable each time so that the shoe isn't putting too much pressure on certain parts of the foot when swelling occurs (*The Orthofeet Advantage*). Flexible materials, such as leather and soft foam, are often used to reduce pressure points (*The Orthofeet Advantage*). Fig. 2 shows the technological features of an orthopedic shoe as established by The Orthofeet Advantage company.

Fig. 2: Orthopedic Shoe Technological Features
Image Credit: *The Orthofeet Advantage*

Although orthopedic shoes are made with the patient's needs in mind, studies have shown that a large amount of people are not satisfied with their shoes. Many patients do not continue to wear their orthopedic shoes due to pain, discomfort, or limited quality in aesthetics (Swinnen, 2015). Some patients, often women, are initially distressed about or reject the use of orthopedic shoes because of the limited aesthetic qualities (Jarl, et.al., 2019; Paton, et.al., 2014; Swinnen, 2015). Orthopedic shoes have been found to benefit those with more severe foot conditions, such as previous ulcer locations and Charcot foot, but do not adequately accommodate for less severe foot conditions, such as forefoot and metatarsal region deformities (Arts, et.al., 2012). But shoes with a rocker profile, as shown in Fig. 3, can improve gait stability and reduce peak pressure under the forefoot (Ahmed, et.al., 2020; Ghomian, et.al., 2019; Zwaferink, et.al., 2019). Results of two studies conducted concluded that the sooner the patient sees or feels outcomes, the more likely they are to continue to wear the orthopedic shoes and have a more positive opinion regarding the usability of the shoes (Van Netten, et.al., 2010 (2)).

Fig. 3: Shoe with rocker bottom profile
Image Credit: *healthyfeetstore.com*

There have been algorithms developed to aid in recommending specific orthopedic shoes or the need for custom-made shoes based on the measurements of the patient's feet (Davia, et.al., 2011; Ermakova, et.al., 2022). While this would help in choosing the right shoe size and its orthotic qualities, it still does not guarantee that the shoe will fit correctly. Custom-made orthopedic shoes do usually provide an overall better fit specific to the patient because they are designed based on the patient's foot measurements taken with technology and a mold of the foot (Yick & Tse, 2021; Zwaferink, et.al., 2019). But the customization and manual labor of hand-making the shoes make them more expensive (Yick & Tse, 2021).

2.3 SOCIOECONOMIC STATUS

Treatment of diabetes complications can be costly (Zhuo, et.al., 2013). Studies have shown that there is a correlation between socioeconomic status (SES) and diabetes complications management and mortality (Bird, et.al., 2015; Fulton, et.al., 2021; Lee, et.al., 2011; Nelson, et.al., 2019; Osborn, et.al., 2013; Saydah, et.al., 2013; Sharifirad, et.al., 2013; Tatulashvili, et.al., 2020). It has been found that the lower the educational level and income of a patient, as well as other SES factors, the more likely the patient will develop diabetic complications that will progressively get worse (Bird, et.al., 2015; Lee, et.al., 2011; Osborn, et.al., 2013; Saydah, et.al., 2013; Sharifirad, et.al., 2013; Tatulashvili, et.al., 2020). Not having access to proper healthcare, affordable and comfortable shoes, and/or safe places to walk and get exercise can severely impact the health of people with diabetes and low SES. Proper resources, strategies and policies would need to be implemented and provided to aid people with low SES in managing their diabetes complications (Fulton, et.al., 2021; Nelson, et.al., 2019; Osborn, et.al., 2013; Sharifirad, et.al., 2013; Tatulashvili, et.al., 2020). Providing a more affordable, functional, and formal shoe would be a way to help people with low SES in managing their diabetes-related foot conditions. Being able to walk in a shoe that is stylish, yet functional and affordable will not only prevent their foot conditions from getting worse, but also improve their overall health.

2.4 ORTHOPEDIC SHOE DESIGN ANALYSIS

Many kinds of orthopedic shoes exist. Tables 1-3 show evaluations of some existing orthopedic shoes from online stores. According to customer reviews, they can be uncomfortable, and are often unattractive or cumbersome. There are options for orthopedic dress shoes and sandals for both men and women, but most of the best orthopedic shoes are tennis-shoes or “running” shoes, which, according to reviews, are often considered cumbersome. The dress shoes and sandals that are more attractive tend to be less comfortable. Note that most people removed the insoles and put in their own orthotic inserts, especially in tennis shoes. Some people took out the insoles to accommodate for their ankle-foot orthosis.

Orthopedic Tennis Shoes					
	Shoe	**Price**	**Customer Ratings**	**Pros**	**Cons**
Breathable Casual Air Cushion Slip On Orthopedic Diabetic Walking Shoes - Amazon		$25.99	2 stars (1 review)	No comment on review	No comment on review
Women's Air Cushion Slip-On Orthopedic Diabetic Walking Shoes – Amazon		$25.99	3 stars (6 reviews)	No positive comments	Shoe runs large. Threading is bad. Arch support is hard
Women's Lace Walking Shoe - Apex		$147.95	4.5 stars (93 reviews)	Comfortable Wide toe box Good for plantar fasciitis No-slip bottoms. Good for diabetes Good arch support	Size runs big. Heel too high Need more cushion. Starts to break down after a while. Heavy Expensive Not breathable
Women's Boss Runner Active Shoe - X-Last - Apex		$147.95	4 stars (120 reviews)	Comfortable Large toe box Good arch support Good for neuropathy Good for plantar fasciitis, Morton's neuroma and diabetes	Sometimes run small. Too big/bulky Sometimes not wide enough Heel area too big Stiff Poor fit
Francis No-Tie – Ortho Feet		$112.95 (Discounted)	5 stars (171 reviews)	Good arch support Lightweight Wide toe box Slip-on/No-tie Good for neuropathy	Too big around the ankle (Many 1-star reviews were positive)
Women's Trail Runner Active Shoe – Apex		$147.95	4 stars (91 reviews)	Wide toe box Non-slip soles Sturdy Comfortable Good for diabetes Good support	Size runs big. Bulky/Heavy Hard soles Need more cushion. Stiff Expensive

Table 1: Orthopedic Tennis Shoes

Orthopedic Dress Shoes					
	Shoe	**Price**	**Customer Ratings**	**Pros**	**Cons**
Emma – Ortho Feet		$109.95 (Discounted)	5 star (187 reviews)	Attractive Comfortable Some people thought arch support was good. Good for plantar fasciitis, diabetes, and neuropathy	Odd fit around ankles Not available in extra wide Need more arch support. Not very comfortable
Celina – Ortho Feet		$82.95 (Discounted)	5 star (328 reviews)	Comfortable Good support Good for plantar fasciitis Attractive Good for neuropathy Good for diabetes	Need more arch support. Too wide in the heel
Dr. Comfort Cindee Women's Classic Heels – Orthotic Shop		$139.00 (Discounted)	5 star (3 reviews)	Attractive Good support Comfortable Good for plantar fasciitis Good arch support	Size runs large. Adjustable dial protrudes. One customer did not find this shoe attractive
Drew Summer- Women's Dress Shoe – Healthy Feet Store		$179.95 (Discounted)	4.5 stars (3 reviews)	Comfortable Wide toe box Heel not too high Adjustable	Outside material comes off after a while

Table 2: Orthopedic Dress Shoes

Orthopedic Sandals/Flip-Flops/Slip-On					
	Shoe	**Price**	**Customer Ratings**	**Pros**	**Cons**
Women's Diabetic Edema Shoes – Amazon		$49.90	4 stars (150 reviews)	Soft Non-slip bottom Adjustable Good for edema Comfortable Firm sole (can be negative)	Too big around ankle Boxy Runs large. Not attractive
Drew Andi – Women's Wedge Sandals – Orthotic Shop		$134.95	5 star (1 review)	Comfortable/does not cause heel pain. Attractive Well made	Expensive (customer says it's worth it)
Drew Bon Voyage - Women's Sandal – Healthy Feet Store		$169.95 (Discounted)	4.5 stars (5 reviews)	Attractive Adjustable Good cushion Decent arch support (but not great)	Runs wide (can be positive)
Vionic Amber – Women's Sandals – Healthy Feet Store		$89.95 (Discounted)	4.5 stars (22 reviews)	Attractive Adjustable Good arch support (can be too high) Wide toe box Good for plantar fasciitis	Material is stiff
Softwalk Bolivia - Women's Sandal – Healthy Feet Store		$109.95 (Discounted)	4.5 stars (17 reviews)	Soft Good for neuropathy Good for plantar fasciitis Come in different widths	Not good for Charcot foot Back strap not adjustable

Table 3: Orthopedic Sandals/Flip-Flops/Slip-Ons

Fig. 4 shows common qualities of orthopedic shoes based on the literature, customer reviews of shoes and design strategies of companies. Red circles indicate research focus areas.

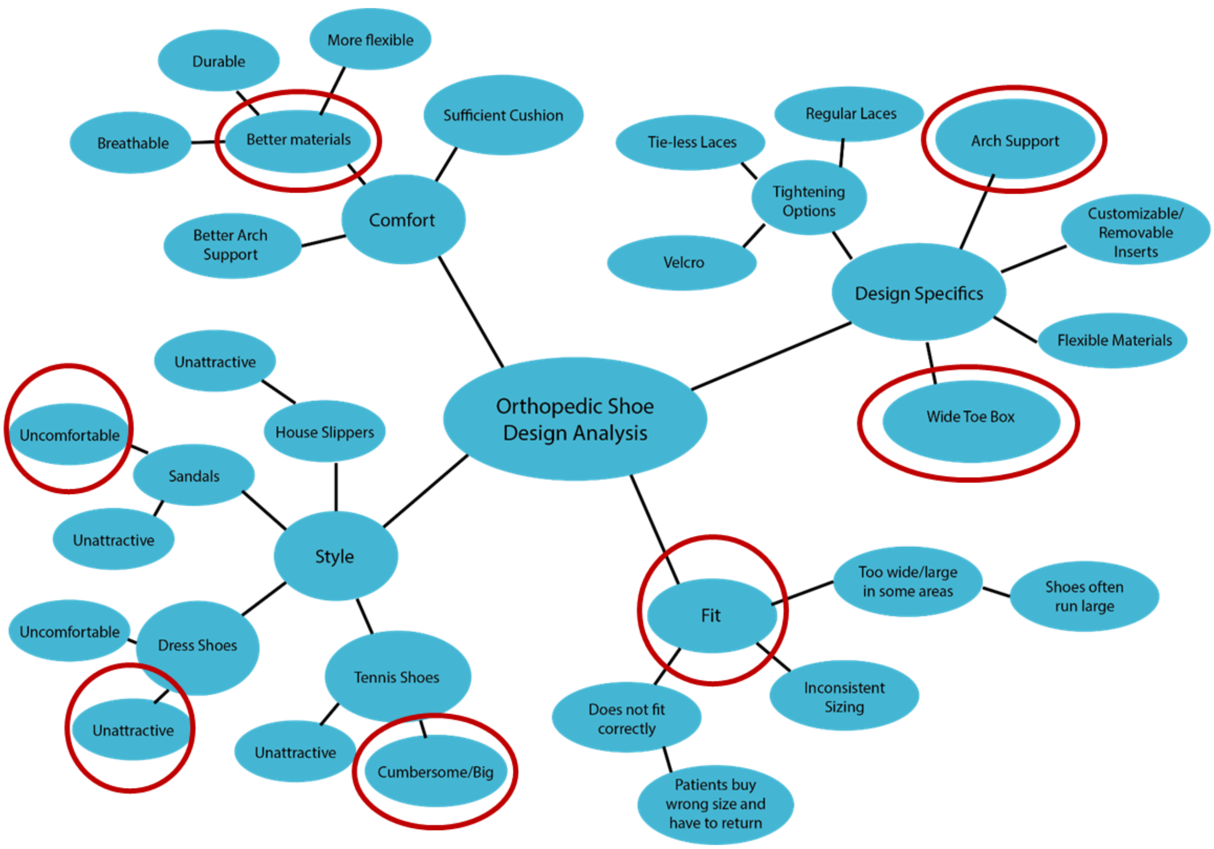


Fig 4: Common Qualities Map

CHAPTER 3: METHODS

A literature review has been conducted to review facts and critical issues to identify specific problems with orthopedic shoes for people with diabetes. About thirty-five pieces of literature published between 2010 and 2022 were reviewed.

A survey was developed that focused on what diabetes-related foot conditions the participant had, how they managed their symptoms, if they wear orthopedic shoes, and what they liked or disliked about their orthopedic shoes. Anyone who was 45 years of age or older and has diabetes and diabetes-related foot conditions qualified to take the survey. The survey was posted to specific diabetes sites and support groups. Sixteen responses were recorded.

User interviews were conducted to determine what they would want in an orthopedic shoe. The population of interest was people 45 years of age or older that have diabetes-related foot conditions and wear or are recommended to wear orthopedic shoes. Four participants were interviewed. The interview consisted of questions on what types of conditions they had, what they like or dislike about their current orthopedic shoes, and what they value in a shoe.

Local podiatrists and orthotists were interviewed to gain insights into what the medical personnel see and what they think could be improved. The interviews consisted of questions that pertained to types of treatment, types of shoes, and what could be improved in orthopedic shoes.

With the information from the literature review, survey, and interviews, the concept generation of a prototype was formed through sketching and evaluations. One concept was chosen to develop a prototype. The prototype was then tested by the researcher by wearing it and walking around. A video was taken of the researcher walking in the shoe. Interviews with the participants followed for them to indirectly review the shoe by watching the video and touching and looking at the shoe. An improved prototype was developed with modifications from the participants' interviews. It was then tested in the same way by the researcher. Participant interviews followed.

CHAPTER 4: RESEARCH

4.1 IRB PROCESS

All research procedures, surveys, and questionnaires were submitted and approved by the university IRB system. The guidelines on doing proper and ethical investigative research were followed. Fig. 5 – Fig. 9 show the online survey questions, participant interview questions – both for the initial interview and prototype testing interview, and flyers with information about the online survey and participating in the study that were posted to diabetes-related online sites and clinics that treat patients with diabetes, respectively.

Online Questionnaire

Title of research study: The Ergonomics and Functionality of Orthopedic Shoes: A Research Study to Develop a Better Orthopedic Shoe for People with Diabetes
Primary Investigator: Erika Lopez

(This questionnaire will be formatted into a secured online survey. A flyer about the survey and study, along with the primary investigator's contact information, will be posted on social media groups for people with diabetes. A QR code to a screening questionnaire will be on the flyer. Should someone interested in participating contact the primary investigator instead of scanning the QR code, a link to the screening questionnaire will be provided. Participants will be given a secured link to this online survey after they complete the screening process.)

Hello,

I am an Industrial Design graduate student at the University of Houston studying the ergonomics and design characteristics of orthopedic shoes. Most people who have diabetes-related foot conditions that require orthotics encounter functionality and comfortability issues with their orthopedic shoes, which can potentially cause their conditions to worsen. This is a study to investigate and uncover specific issues and unmet needs in orthopedic shoes with an aim to develop an orthopedic shoe with an improved ergonomic and functional design. Thank you for your contribution to this study.

1. What age group are you in?
   - 45-55
   - 56-65
   - 66-75
   - 76-85
   - 86 +
2. Do you have type 1 or type 2 diabetes?
   - Type 1
   - Type 2
3. What specific foot conditions do you have? (Select all that apply)
   - Swelling
   - Diabetic foot syndrome
   - Ulcers
   - Neuropathy
   - Charcot foot
   - Other (please explain)
4. What are your current solutions to manage your foot condition(s) other than medicine or physician help? (Select all that apply)
   - Orthopedic shoes
   - Orthotic inserts
   - Other (please explain)
5. If you wear orthopedic shoes and/or inserts, do you experience any issues with them? (Select all that apply)
   - I do not experience issues with them
   - Too little or too much arch support
   - Too little or too much heel support
   - Not wide enough or too wide in any area of the shoe
   - Difficult to put on and take off
   - I do not wear orthopedic shoes and/or inserts
   - Other (please explain)
6. Additional comments on your feet and shoe related issues.

Fig 5: Online survey document submitted and approved by the University of Houston IRB

In-person Interview Questionnaire

Title of research study: The Ergonomics and Functionality of Orthopedic Shoes: A Research Study to Develop a Better Orthopedic Shoe for People with Diabetes
Primary Investigator: Erika Lopez

(These questions will be asked during an in-person audio recorded interview. Family members or caretakers of the participant are welcome to be present during the interview. They will also sign a consent form should they choose to be present for the interview.)

I am an Industrial Design graduate student at the University of Houston studying the ergonomics and design characteristics of orthopedic shoes. Most people who have foot conditions that require orthotics encounter functionality and comfortability issues with their orthopedic shoes, which can potentially cause their conditions to worsen. This is a study to investigate and uncover specific issues and unmet needs in orthopedic shoes with an aim to develop an orthopedic shoe with an improved ergonomic and functional design. Thank you for your contribution to this study.

1. What is your age?
2. Do you have type 1 or type 2 diabetes?
3. What kind of foot conditions do you have?
    a. Are there any specific reasons why you have these foot conditions? (work, lifestyle, general side-effects from diabetes/neuropathy)
4. What are your current solutions to manage your foot condition(s) other than medicine or physician help?
    a. Do you wear orthopedic shoes?
5. (If they say they wear orthopedic footwear) Do you experience any issues with your orthopedic footwear?
    a. If no, what do you like about the shoes?
    b. If yes, what do you not like about them?
    c. How often do you wear orthopedic footwear?
6. What do you like or dislike about putting on or taking off your shoes?
7. What qualities of a shoe are important to you?
    a. What kind of aesthetics do you like in shoes.
8. Is there anything else you would like to mention?

Fig 6: In-person interview questionnaire document submitted and approved by the University of Houston IRB

In-person Interview Questionnaire – Prototype Testing

Title of research study: The Ergonomics and Functionality of Orthopedic Shoes: A Research Study to Develop a Better Orthopedic Shoe for People with Diabetes
Primary Investigator: Erika Lopez

These questions will be asked during an in-person audio recorded interview after the participant indirectly evaluated prototype.

This questionnaire contains questions regarding your thoughts on the shoe prototype. Thank you for your contribution to this study.

1. What are your initial thoughts on the video you watched of the investigator testing the prototype?
2. Do you think there is enough support provided in the prototype?
3. How do you feel about the materials of the prototype? Do you think they will be comfortable, or do you think some materials may cause rubbing to occur?
4. What do you think about the breathability of the upper part of the shoe?
5. Do you think the materials of the upper part of the shoe are stretchy enough?
6. What do you think about the process of putting the prototype on and taking it off? Do you think it will be easy or hard?
7. What do you like about the prototype?
8. What do you dislike about the prototype?
9. On a scale of 1 to 10, with 1 being the very poor and 10 being excellent, how would you rate the shoe prototype?
10. Is there anything else you would like to mention?

Fig 7: In-person interview questionnaire for prototype testing document submitted and approved by the University of Houston IRB

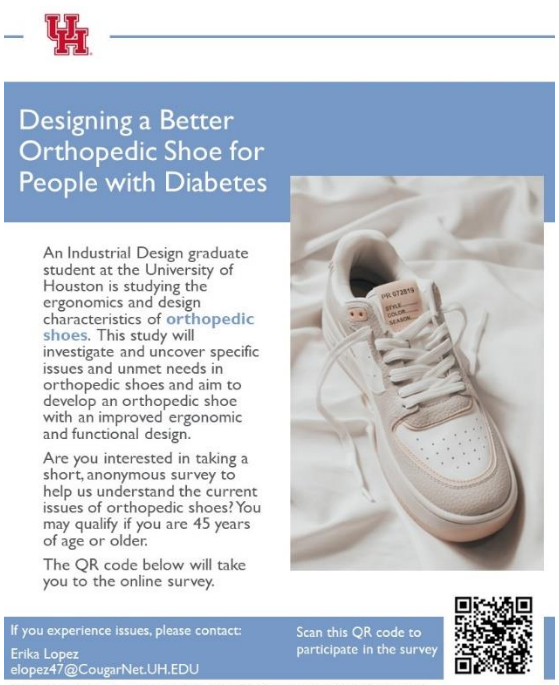


Fig 8: Online survey flyer submitted and approved by the University of Houston IRB

Fig 9: Study participant flyer submitted and approved by the University of Houston IRB

4.2 SURVEY RESULTS

The survey developed to obtain data on the opinions of orthopedic shoes was posted to multiple specific diabetes sites and support groups. Sixteen responses were recorded. The results of the survey are shown below (Fig. 10 – Fig. 15).

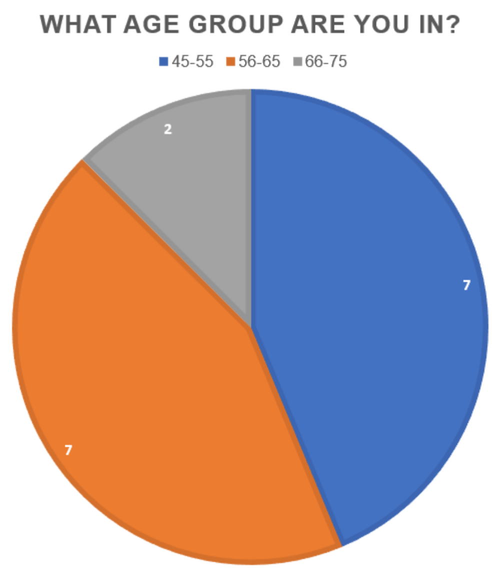


Fig 10: Survey results

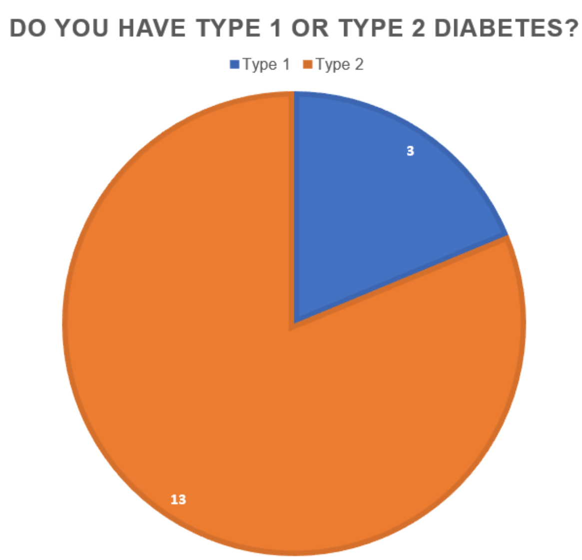


Fig 11: Survey results

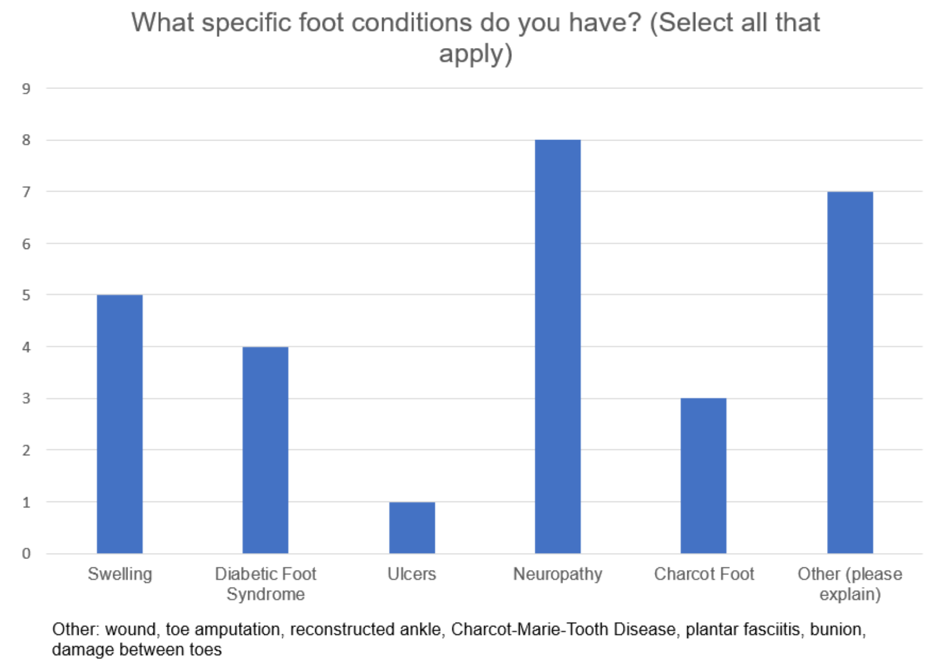


Fig 12: Survey results

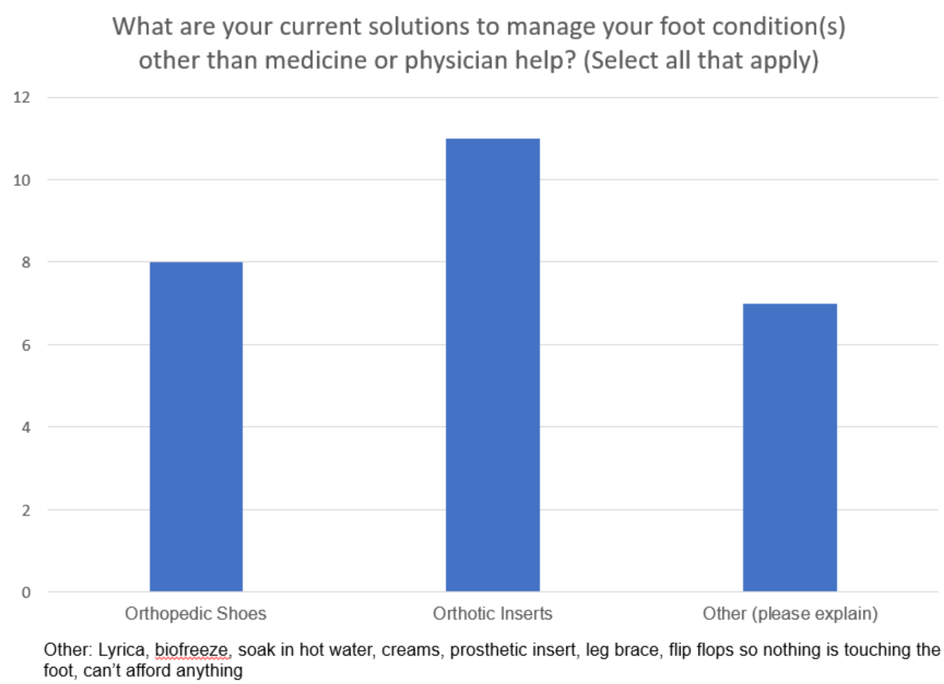
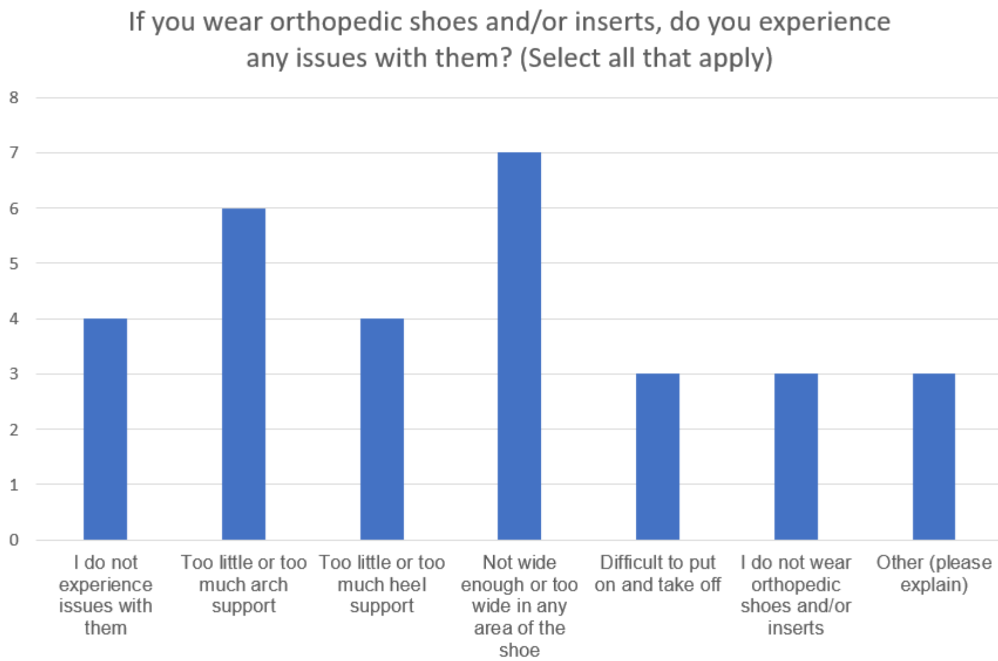


Fig 13: Survey results



Other: not fashionable, not enough ankle support, inserts won't work in many shoes

Fig 14: Survey results

Additional comments on your feet and shoe related issues.
Insurance only pays for one pair a year. Try wearing the same pair for a year.
I don't know what shoes I should use. both feet now numb but still burns, shocking, electrical like pain in both.
I need more cushion in the insole of the shoe and high enough in toe area because the neuropathy has caused my toes to be permanently curled
Supination is a problem as the orthotic does not provide proper support to resolve the issue of my foot rolling outward when walking.
Have had a number of ulcers resulting from movement in shoes in spite of orthotics
Never enough selection to choose from
Closed shoes/tennis shoe type shoes make my toes go numb and my feet swell. They don't offer a good enough cushion and are usually pretty heavy which causes my already awkward gait to be even more dangerous
I pronate
Feet feel too tired too fast
It has to be affordable

Fig 15: Survey results

The survey results show that current orthopedic shoes generally do not accommodate the needs of users. They do not have the correct amount of arch support, heel support, width, weight, or ease of ingress and egress, and are lacking in aesthetic quality.

4.3 RECRUITMENT PROCESS

Flyers about participating in the study (Fig. 9) were posted in local podiatry, wound care, and diabetic care clinics, as well as one wound care clinic in the Dallas metroplex. Three patients from the Dallas wound care clinic agreed to participate in the study.

A local diabetes awareness walk was attended to recruit participants. Opportunities did not arise there, so a local volunteering opportunity for a food distribution center was attended to potentially recruit participants. The fourth participant was recruited at the center.

4.4 USER INTERVIEWS

Four people who were over the age of 45, had diabetes or were pre-diabetic, had diabetes-related foot conditions, and wore or were recommended to wear orthopedic shoes were interviewed (Fig. 16). The participants were asked questions on what types of conditions they had, what they like or dislike about their current orthopedic shoes, and what they value in a shoe. The consensus was that they wanted a shoe that was wide enough in certain areas, like the toe, but snug enough in other areas, such as the heel, to stabilize the foot while not causing discomfort or rubbing. They also expressed the need for lightweight shoes that can aid in their walking gait instead of hindering it like their current orthopedic shoes. They all wanted a shoe with sufficient cushion, that is big enough to fit their custom orthotic inserts, easy to put on and take off, soft and seamless inside, and nice enough to wear to a variety of occasions, even to more formal events such as weddings and work meetings.

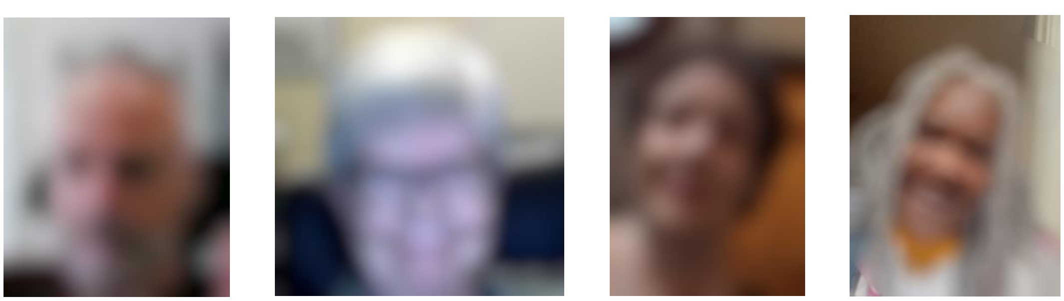


Fig 16: Four participants that were interviewed.

4.5 PROFESSIONAL INSIGHTS

A local orthotics store was visited to discover how they recommend certain orthotics to people with diabetes-related foot problems. The store manager explained that they need to know the customer's shoe size and take the imprint of their feet before giving a recommendation of a shoe and/or insole with supports that flex and give with weight.

Local podiatrists who have expertise in diabetic foot care were contacted, and one such podiatrist was eager to answer questions and give his professional insight. This board-certified podiatrist has years of experience and is trained in diabetic limb salvage, bunion repair, rearfoot and ankle trauma, arthroscopic repair of the ankle, sports medicine, and reconstructive rearfoot and ankle surgery. If a patient needs orthotics, the clinic will send them to orthotists who can recommend an orthopedic shoe or make inserts for them. Orthotics should ultimately relieve pressure points, and the clinic recommends patients to get orthotics that are as custom as possible because the best shoe is based on the patient's foot anatomy. While the podiatrist thinks highly of custom orthopedic shoes, they think that there is room for improvement in off-the-shelf orthopedic shoes. The podiatrist would like to see better support in the medial side of the shoe, or the inner arch area. This would provide more support for the arch and rear foot joints.

An orthotist company was contacted to learn about their process of making customized orthotics. Through emailing the manager, it was pointed out that they primarily make braces and prosthetics now, and not so much custom orthopedic shoes. Competition and the need to greatly reduce prices due to low reimbursement from Medicare/Medicaid forced the majority of custom orthopedic shoe manufacturers to move overseas. So, now there are very few custom orthopedic shoe companies in the United States. One of the orthotists mentioned that orthopedic shoes have specific qualities to make the user comfortable, such as seamless lining, and padded collar and tongue. Orthopedic shoes are often made of leather, which is better for durability. Neoprene is sometimes used as it doesn't take as long to break in. Even though orthopedic shoes have these qualities to be user-friendly, the manager sees a need for better formal shoes, especially for women. The catalog that the clinic gives to customers does not have much of a selection of orthopedic shoes. In terms of putting on the shoe and securing it, the manager said Velcro is one of the most common options but can wear out quickly. A slip-on shoe with a mechanism similar to the Kizik's "pop-up" heel could be implemented (Fig. 25).

One of the things that the podiatrist and the manager at the orthotics store mentioned would be beneficial in orthopedic shoes is carbon fiber. Carbon fiber doesn't allow for a lot of twisting or flexibility and stabilizes the area of the foot with which it interacts. As of now, most carbon fiber is either in the inserts of running/walking shoes, or the toe caps of work shoes and boots. The inserts keep the midsole more stable and less flexible, which can be good for some injuries from running (Hata, et.al., 2022) (Fig. 17). Runners like carbon fiber inserts because it puts more "spring" in their step and helps them push off, especially when they get tired (Hata, et.al., 2022) (Fig. 18). The carbon fiber toe caps in safety boots and shoes protect against impact, compression, punctures, and electrical hazards (*Work Gearz)* (Fig. 19). They are lighter than steel-toed boots while offering the same protection (*Work Gearz)*. Carbon fiber would be useful in the toe box of orthopedic shoes. This could make the upper surface rigid enough to keep away from the forefoot and prevent rubbing and areas of pressure.

Fig. 17: HOKA shoe with carbon fiber for smooth transition through gate cycle
Image Credit: hoka.com

Fig. 18: Work boot with carbon fiber for protection
Image Credit: wolverine.com

Fig. 19: Nike ZoomX Vaporfly Next% with carbon fiber for ease of stride
Image Credit: trackstaa.com

4.6 ORTHOPEDIC SHOES VS RUNNING SHOES

To learn about the different layers and materials of a shoe, an old HOKA shoe was cut in half to examine. This HOKA Bondi 7 pictured in Fig. 20 is one of the HOKA running shoes with the most cushion. The features of this specific shoe are breathable mesh uppers; EVA foam midsole with TPU overlays to provide cushion and midfoot support respectively; a rubber outsole to reduce weight and increase durability; memory foam at the back to “cradle” and provide comfort for the ankle and Achilles; a beveled heel for durability and smooth transitions; an internal heel counter to provide support for the heel; and Meta-Rocker technology for a smooth and easy stride.

Fig. 20: HOKA Women’s Bondi 7 Shoe Study

Orthopedic shoes often have a deep toe box, width options, soft or conforming material in the toe band, a soft composite insole, Vibram or EVA foam midsole, and a thin rubber outsole (Fig. 2). Sometimes neoprene will be in the toe band for especially bad structural problems. EVA foam typically forms the midsole and provides good cushioning and shock absorption. Fabric throughout the shoe is typically soft and padded to prevent rubbing. A firm heel counter provides support and rigidity for the back of the heel and Achilles tendon. Some offer a deep heel cup that stabilizes the heel. Most orthopedic shoes, and some running shoes, have rocker-bottom design, which softens impact and helps with the natural movement of walking. Levels of arch support can vary, but some do offer additional arch support that can be added to the insole.

Throughout the research, it was observed that most orthopedic shoes are essentially exaggerated running shoes. According to the Pedorthic Association of Canada, orthopedic shoes are "…shoes that are specifically designed to support or accommodate the mechanics and structure of the foot, ankle and leg and [have] a number of medically beneficial features and functions that separate them from everyday footwear" (Claire, 2013). Running shoes are generally referred to as lightweight shoes that are designed to be used by runners (Merriam-Webster Dictionary, 2020). There are different types of running shoes for different disciplines, so the shape and technology of running shoes vary. Fig. 21 shows a comparison between running and orthopedic shoes.

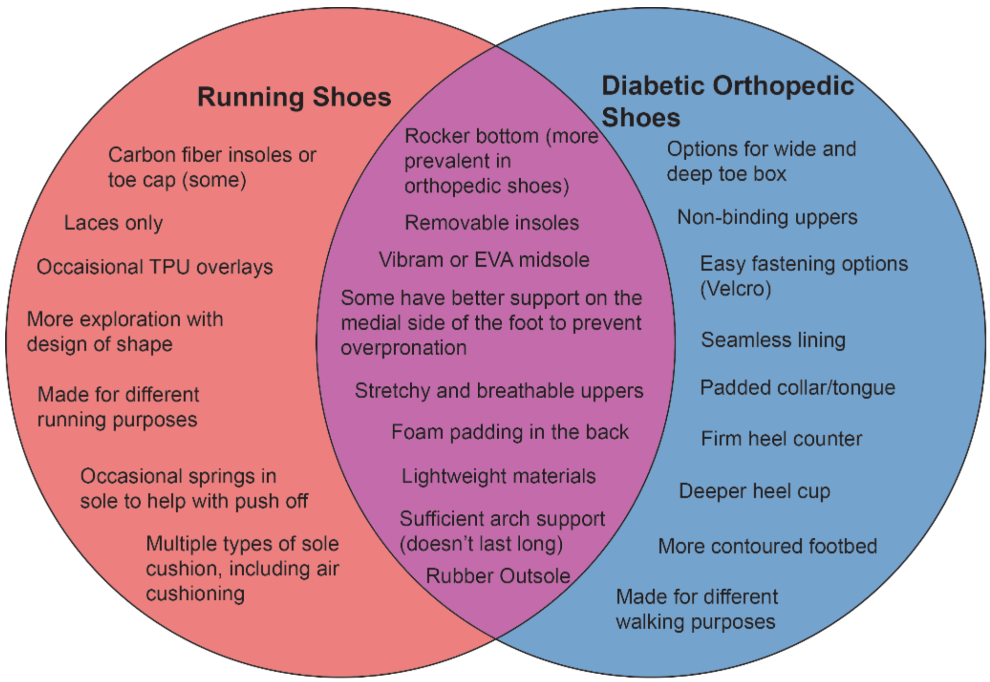


Fig. 21: Running shoes and orthopedic shoes comparison. Materials and features can vary for both types of shoes.

4.7 INGRESS AND EGRESS

Current orthopedic shoes are secured either with laces, Velcro, or a combination of both, as seen in Fig. 22, 23 and 24. This is to provide a customized fit for each wear. The swelling of a patient's foot may increase or decrease over time and need a different shoe fit to accommodate for the amount of swelling. But some patients may not be able to reach the laces or Velcro to fasten the shoes. Designing an alternate way to put on and take off shoes without having to bend down or adjust the tightness of the shoe would make a positive change to orthopedic shoes.

Fig. 22: Two-Way Strap System with Velcro
Image Credit: *The Orthofeet Advantage*

Fig. 23: Tie-Less Lace System
Image Credit: *The Orthofeet Advantage*

Fig. 24: Traditional Lace System
Image Credit: *The Orthofeet Advantage*

Kizik shoes have External Cage technology that does not require the user to touch the shoes or tighten them (Fig. 25). The heel is crushed when the user puts their foot in, but it springs right back once their foot is in the shoe. Designing a hands-free way to take shoes on and off that is suited for orthotics and conforms to the patient's foot or ankle would contribute to orthopedic shoe design and make the process of wearing orthopedic shoes easier for patients.

Fig. 25: Kizik shoe with External Cage technology
Image Credit: kizik.com

The Nike Go FlyEase is a shoe with easy on-and-off technology (Fig. 26). The heel and the sole hinges and stay open until the user puts their foot in and steps down, closing the shoe. Nike advertises the shoe to be great for people who are on the move or people with limited mobility. Technology similar to this could be a part of the prototype to make putting the shoe on and taking it off easy. The easiness of it would also make the user want to wear it more often.

Fig. 26: Nike Go FlyEase
Image Credit: nike.com

4.8 AESTHETIC QUALITY

While the local podiatrist who was interviewed does believe that orthopedic shoes are generally lacking in aesthetic quality, the podiatrist did tell of the companies Bionica, Taryn Rose, The Walking Company, Dansko, and Clarks that make orthopedic or orthopedic friendly formal shoes for women (Table 4). When looking at the shoe selection, the brands offer aesthetically pleasing shoes, but reviews for some of the shoes were concerning and some of the brands did not offer many orthopedic qualities. For example, the Dansko dress shoes do not offer a roomy toe box. While Bionica shoes seem to have good arch support, they are marketed to people who hike or like to be outdoors, so they only offer boots, walking shoes, and casual sandals. The shoe features don't have much of the qualities that an orthopedic shoe for someone with diabetes should have. Some reviewers from Dansko, Clarks, Taryn Rose and The Walking Company complained that the particular shoes were uncomfortable or didn't fit correctly. The materials of Clarks shoes don't seem to be the same as shoes for people with diabetes. There were also several reviewers from The Walking Company that complained that the shoes were made from poor materials that easily scuffed and left marks and began to break down fairly soon after purchase. This seemed to be a case where the higher priced shoe did not mean that it was a better product. Most of the shoes from these companies appear to be beneficial for those who may have foot problems, though not severe. People who have more severe diabetes-related foot conditions would probably not be able to wear a large portion of the shoes. Designing an aesthetically pleasing shoe that is functional and comfortable for people with diabetes-related foot conditions would stop the exclusion of the group from shoe fashion.

Table 4: Fashionable Orthopedic-Like Shoes

Bionica	
Clarks	
Dansko	
Taryn Rose	
The Walking Company	

To get an idea of the aesthetics of the shoes to be developed, research was conducted on current fashion trends in women's shoes, particularly for women 45 years of age and up. Most of the shoes are not flashy and bold, but rather classy and sheik. This gives a sense of maturity and wisdom while still being fashionable. Women's shoes are often boots, sandals, fashionable sneakers, heels (mostly chunky), wedges, flats and loafers. From my observations, it seems that shoes with solid soles or that have a larger contact area with the ground are easier to balance and walk in. Women's shoes sometimes offer different colors and patterns but are not outlandish. Fig. 27 shows design inspiration in women's shoes.

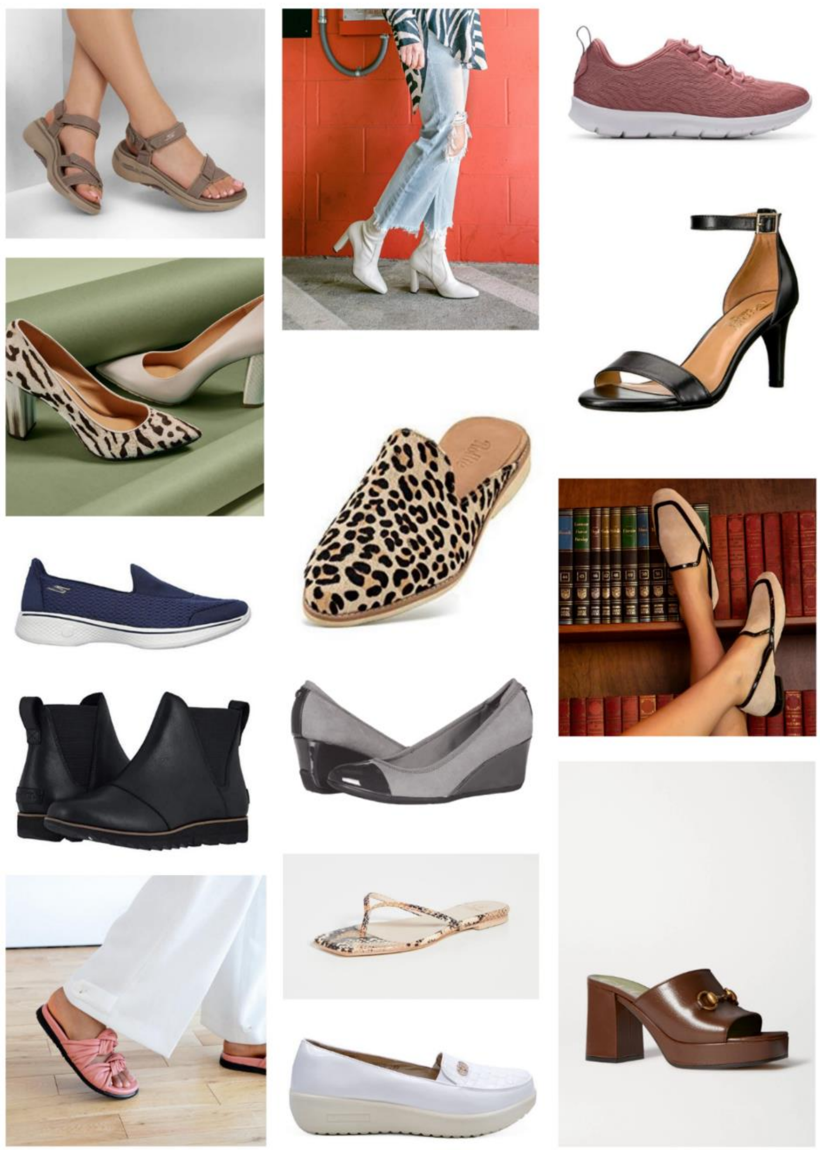


Fig. 27: Women's Shoe Fashion

4.9 ARCH SUPPORT

One of the things mentioned by the professionals, surveyors, and participants was the want for better arch support. Shoes made for the gym and weightlifting are an example of added arch support to stabilize the user when doing intense workouts. This Nike Metcon 7, shown in Fig. 28, has rubber tread arch support to add more traction and grip, and to secure the foot during training. A feature in orthopedic shoes similar to this could provide sufficient arch support and stabilize the foot more.

Fig. 28: Nike Metcon 7
Image Credit: roadrunnersports.com

4.10 THESIS STATEMENT

Evidenced by research and interviews, critical needs of universal conformity, sufficient and lasting materials, ample and consistent support, accessibility in slipping on and off, and functional aesthetic quality are not being met in orthopedic shoes for people with diabetes-related foot problems. Through a user-centered research and design process, a more ergonomic shoe with improved materials, support, conformity, and accessibility can be developed as a better alternative.

CHAPTER 5: DESIGN DEVELOPMENT

5.1 SHOE MAKING PRACTICE

Learning how and practicing making shoes needed to be done before actually constructing the prototype to be tested. Viewing videos on YouTube and following instructional websites helped in learning how to make shoes. A pair of lasts that matched the researcher's foot size was bought to make the patterns of the upper materials of the shoe (Fig. 29). Masking tape was tightly wrapped around the last (Fig. 30). Then a pattern was drawn on the masking tape. The pattern was then cut out with an exacto knife and placed flat on thin poster board. An outline of ½" to 1" was drawn around each pattern piece to leave room for stitching and gluing (Fig. 31). Little cut-outs at the edge of the original outline were made to accurately put pieces together (Fig. 31). Those were then cut out to use as stencils to cut out the fabric (Fig. 31). Random cloth and upholstery found around the studio were used for practice. Each piece was outlined and cut for assembling. Both shoe glue and sewing were utilized to attach each piece together (Fig. 32). A thin piece of EVA foam was cut to the size of the shoe last and used as an insole to which the upper materials would be attached (Fig. 33). The sole for the first practice shoe was made of foam board (Fig. 34). For the second practice shoe made (Fig. 35), a shoe sole made of TPU was constructed by 3D modeling with dimensions from the shoe last and then 3D-printed.

Fig. 29: Shoe last

Fig. 30: Shoe last wrapped with masking tape

Fig. 31: Masking tape on poster board cut out to use as stencils to cut out fabric

Fig. 32: Fabric cut out and halfway assembled with thread

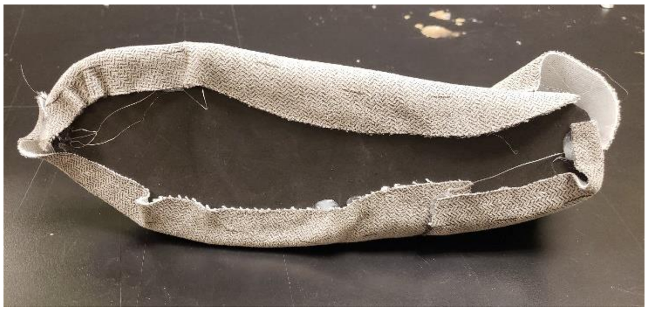


Fig. 33: Upper materials attached to EVA foam insole

Fig. 34: First fully assembled practice shoe with foam board sole

Fig. 35: Second fully assembled practice shoe with 3D-printed TPU sole

5.2 CONCEPT GENERATION

Concept generation began with sketch ideation. Multiple rounds of sketches were compiled and reviewed. Sketch experimentation consisted of combining different materials and features from research findings to come up with the best solution to develop further. The key aspects of cushion, weight, support, hinge mechanism, and aesthetics were addressed in the sketches. Fig. 36 shows the initial concept generation sketches.

Fig. 36: Initial concept sketches

Features from different sketches were chosen to form three potential prototypes (Fig. 37 – Fig. 39). Design aspects from Fig. 31 and Fig. 32, such as the hinge mechanism, rocker bottom profile, and material configurations, were chosen to develop further and become the first workable prototype.

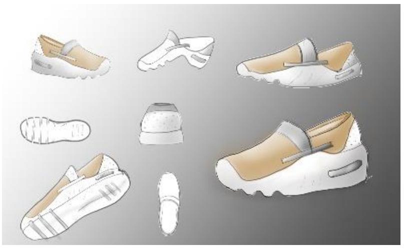


Fig. 37: A concept in refined ideation sketch.

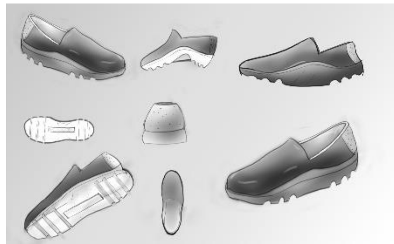


Fig. 38: Features such as the bending mechanism and the rocker bottom profile were chosen to develop further.

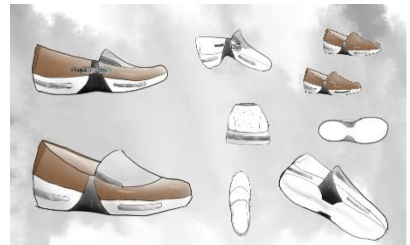


Fig. 39: Features such as different material configurations were chosen to develop further.

5.3 MATERIALS

Material selection was determined by what is generally required in orthopedic shoes, with the additions of professional recommendations, user insights, and literature research. Leather was chosen because it is often used in orthopedic shoes for its durability and ability to flex and conform to the user's feet. Nylon mesh fabric was used to add some breathability for more comfort. Elastic belting was used in the uppers where the two halves of the shoe meet for ease of stretching while the sole is bending for the user to put on the shoe. Spandex and suede materials were used interchangeably in the first and second prototype for its softness and stretchiness. A general, breathable, and cushioned insert was cut to fit the shoe sole and used as the main insole. Memory foam was cut and placed in strategic places within the upper materials of the shoe for comfort. TPU was used for the construction of the sole because of its cushion and flexibility. All materials used, except for the memory foam, insole, and first sole, were black to give a uniform look and be able to match any outfit.

When designing the first prototype, slits in the 3D-printed sole were made to slide in carbon fiber plates. But when the fully 3D-printed sole was being inspected, the TPU was flexible, yet rigid enough that the carbon fiber wasn't necessary. Carbon fiber plates in the toe cap was ruled to be too hard, so a 3D-printed TPU toe cap and heel piece were made to give the shoe shape, keep the materials away from the toe to prevent rubbing, and support the back of the heel.

For the bending mechanism, different materials were used for different types of mechanisms, as explained in section 5.4 and 5.6. A metal slap-wrist bracelet was used in the first prototype. Strong, rare-earth magnets were used for both the second prototype and the final design. Experimentation with magnet sizes was done to determine what size would hold the shoe open for the user to put the shoe on completely hands-free.

5.4 FIRST PROTOTYPE DEVELOPMENT

The shoe sole was the first part of the shoe to be developed. The researcher took measurements from a tennis shoe of theirs and brought that into SOLIDWORKS. The toe box of the shoe was made to be wider at the big toe to give more room for the toes and allow them to spread out naturally. The cut-out in the middle of the arch allowed for easy bending. The contour of the arch would also give added support to the arch of the foot. Other cut-outs in the sole made it lighter in weight. The sole has a rocker bottom profile to aid in push-off and walking. Fig. 40 shows the 3D CAD model of the sole.

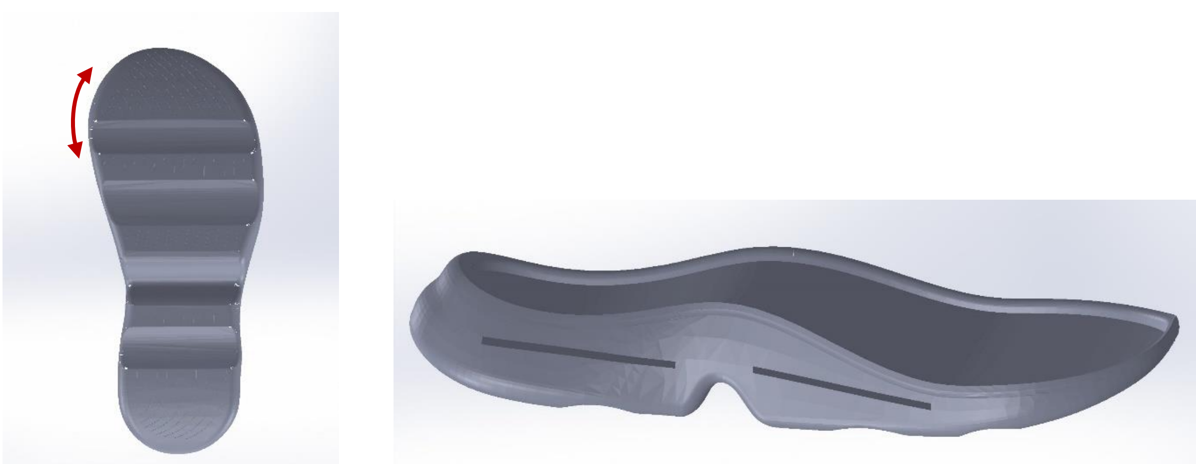


Fig. 40: A 3D SOLIDWORKS model of the sole of the first prototype.
The wider toe box will make the user more comfortable.

A study model made of EVA foam was made to understand the form and make sure it would work before making the functional prototype (Fig. 41).

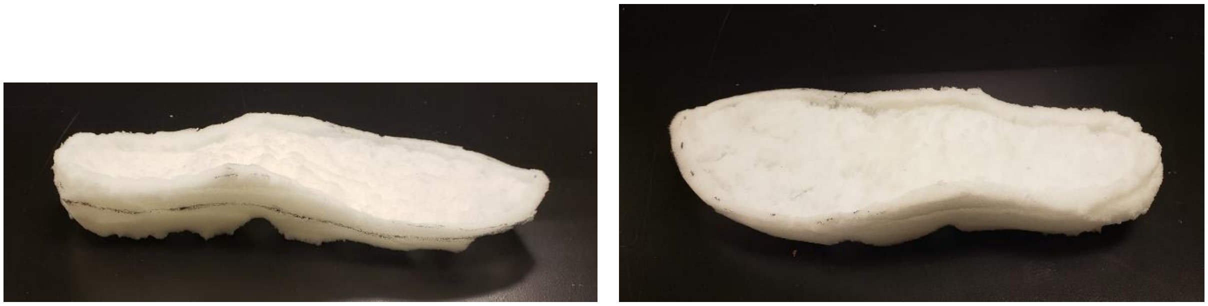


Fig. 41: Foam study model of the first prototype sole.

After confirming that the sole would be functional, it was 3D-printed with white TPU. Black would have been preferred, but white was the fastest available material. Small grooves on the bottom were added to provide more traction to prevent slipping. After it was printed, it was discovered that the cut-out in the middle of the arch didn't allow for appropriate bending, so it was further cut to make a bigger cut-out. Fig. 42 shows the 3D-printed sole before the cut-out in the middle was cut more.

Fig. 42: 3D-printed first prototype sole. The grooves for traction are pointed out in the picture on the right.

Since the shape of the sole was different than the shoe last, the stencils for the upper materials were made in SOLIDWORKS from the researcher's tennis shoe dimensions and an orthographic sketch of the patterns. Flattened surfaces from the SOLIDWORKS file were printed out and placed on poster board. Once those were cut out, they were used to cut out the fabric for the upper part of the shoe. Shoe GOO was used to glue most of the fabric together to achieve a seamless interior, which prevents rubbing from happening. The fabric was sewn together at the elastic belting and the edge of top of the heel. A 3D-printed TPU toe cap and heel cup were inserted between pieces of fabric to keep the fabric away from the foot to prevent rubbing and support the back of the heel. Memory foam was inserted at the top of the shoe, in the toe box, and in the heel. Fig. 43 shows the assembled upper materials of the first prototype.

Fig. 43: Glued and sewn upper materials of the first prototype.

The upper materials were glued to the insole. The insole with the attached uppers were then glued to the sole. Fig. 44 – Fig. 46 show the assembled first working prototype.

Fig. 44: First working prototype.

Fig. 45: The stretchable materials of the upper part of the first prototype. This will accommodate for swelling.

Fig. 46: The bending mechanism of the first prototype.

5.5 FIRST PROTOTYPE TESTING

During the first round of testing, the researcher tested the shoe by wearing it and walking around. The shoe itself was mostly comfortable, but the toe cap did not allow for sufficient toe room inside the shoe. The interior seam of the toe area felt like it could possibly rub the top of the foot. The heel slipped when walking which made it difficult to have a consistent walking stride. The full bending mechanism hadn't been fully developed yet, so the shoe still had to be put on the foot with the use of two hands. Fig. 47 shows the researcher testing the first prototype.

Fig. 47: The researcher testing the first prototype.

The prototype was then tested with the four participants by having them look at the video of the researcher wearing the shoe and looking at and touching the shoe. The prototype testing questionnaire shown in Fig. 7 was used to record the reviews from the participants. The following are lists of what the participants liked and disliked about the prototype.

Participant Likes (Fig. 48):

1. Aesthetics and feel of the leather.
2. The amount of arch support
3. The soft and stretchy materials on the top of the foot
4. The weight of the shoe itself
5. Likes the concept of the slip-on mechanism.

Participant dislikes (Fig. 49 – Fig. 54):

1. The color of the sole (they wanted it to be black)
2. The materials are not very breathable.
3. The heel base of the sole was not wide enough.
4. The sole didn’t cup the foot very well for support.
5. The interior seam at the middle of the toes could rub.
6. The ridges on the bottom are too small.
7. The slip-on mechanism didn’t work.
8. A better piece of the elastic belting needs to be used.

Fig. 48: Participant likes #1-3

Fig. 49: Participant dislikes #1-2.

Fig. 50: Participant dislikes #3.

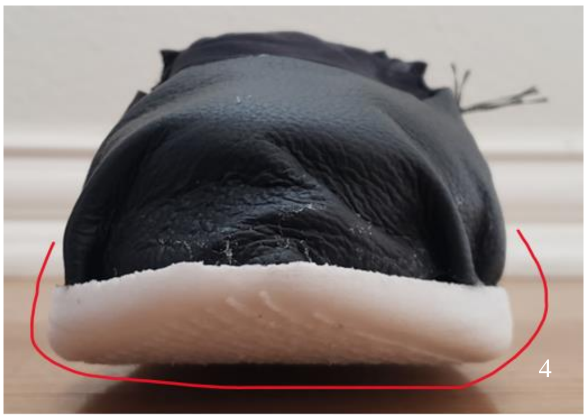


Fig. 51: Participant dislikes #4.

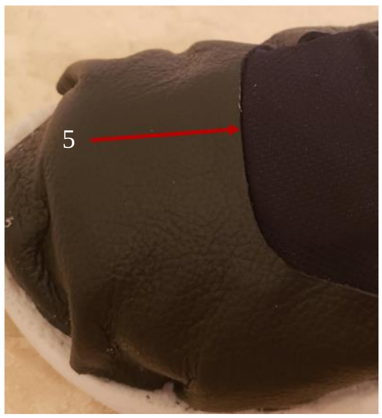


Fig. 52: Participant dislikes #5.

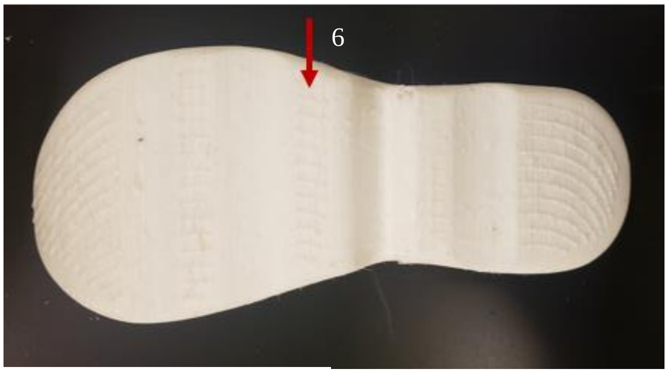


Fig. 53: Participant dislikes #6.

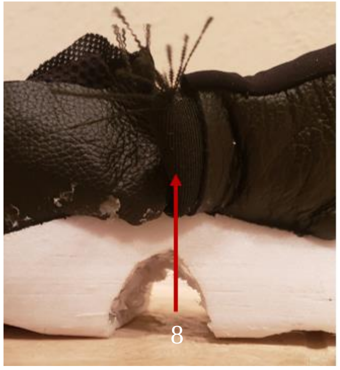


Fig. 54: Participant dislikes #8.

One participant advocated for laces or a Velcro strap to provide a more custom fit. Since the other participants and findings from the research disagreed, it was determined to not add those features. A compromise would be to make multiple versions of the shoes for the users to choose which one to buy. For the sake of time, the simple slip-on concept was chosen to continue developing.

One participant expressed the want for a type of heel strap, something like the Nike Air Huarache (Fig. 55). A heel strap could take the place of the heel cup and provide shape and support for the ankle.

Fig. 55: Nike Air Huarache
Image Credit: nike.com

After the first round of testing was done, a slap-wrist bracelet was added to the bottom of the shoe to experiment with the bending mechanism. The system did not work, so a new method had to be established. Fig. 56 shows the first prototype with the slap-wrist bracelet as the bending mechanism.

Fig. 56: First prototype with slap-wrist bracelet bending mechanism.

5.6 SECOND PROTOTYPE DEVELOPMENT

The development of the second prototype again started with a 3D model in SOLIDWORKS. The model of the first prototype was used as a reference. The cut-out in the middle of the arch was made to be more subtle and higher to allow for adequate bending. The heel was widened and the indention where the insert would be attached was deepened to cradle the foot more. The grooves on the bottom of the sole were deepened for more traction. A heel strap was added to be able to attach to the sole and support the heel. Fig. 57 and Fig. 58 show the 3D CAD model of the sole.

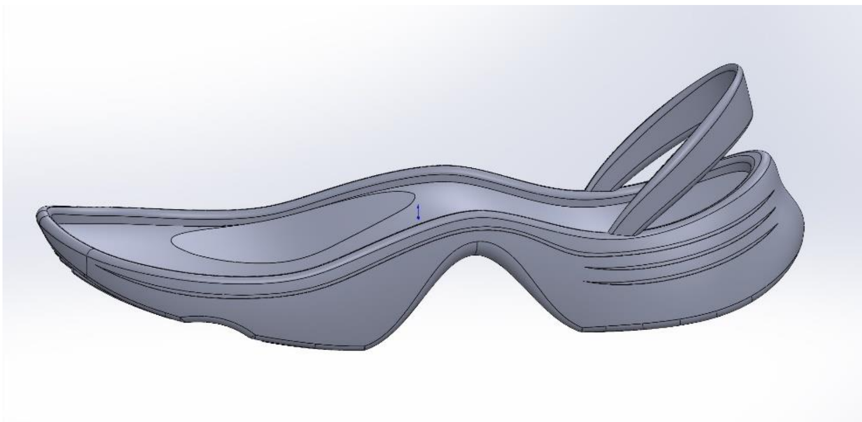


Fig. 57: 3D CAD model of the second prototype.

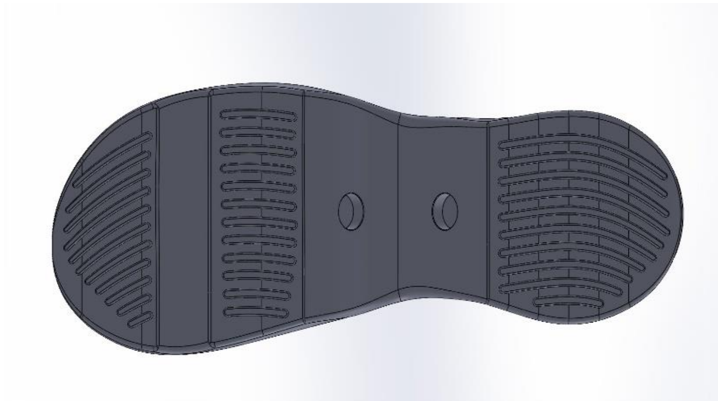


Fig. 58: Bottom of the 3D CAD model of the second prototype.

The slip-on concept was a magnet mechanism for the second prototype. Strong rare-earth magnets were imbedded in the cut-out in the middle of the arch in the sole. The idea was that the user would bend the shoe and the magnets would connect to hold the shoe open until the user put their foot down to snap it back in place.

The sole was made of black 3D-printed TPU. Fig. 59 – Fig. 61 show the sole of the second prototype without the heel strap attached.

Fig. 59: 3D-printed sole of the second prototype.

Fig. 60: Sole of the second prototype with a wider heel.

Fig. 61: Sole of the second prototype with deeper grooves for traction.

For the upper materials, a 3D scan of the researcher's foot was made and brought into SOLIDWORKS. This way, the fabric would be more accurately fitted to the researcher's foot. Flattened surfaces from the SOLIDWORKS file were printed and put on poster board. They were outlined and cut to make stencils for cutting the fabric. Softer and more durable materials were used for the uppers. A better elastic belting was placed in the point of the arch to allow for bending. Cut-outs in the leather were made to add more breathable fabrics throughout the shoe. Shoe GOO was used to attach most of the fabric. Stitching attached the elastic belting to the rest of the fabric and the exterior and interior fabrics at the heel. Fig. 62 – Fig. 63 show the materials before complete assembly.

Fig. 62: Top part of the upper materials of the second prototype.

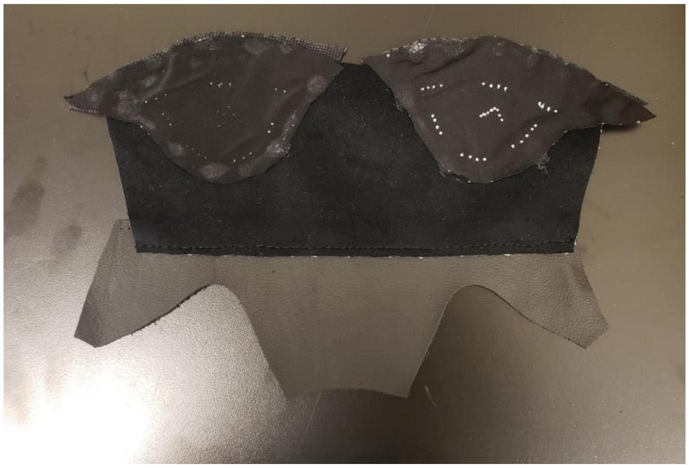


Fig. 63: Heel part of the upper materials of the second prototype.

Memory foam was placed in between the exterior leather at the heel and the interior fabric. It was determined that a toe cap was not necessary and could cause the toe box to become too ridged, so no toe cap was inserted between fabrics. The upper fabrics were then glued to the insole that was fitted for the sole (Fig. 64).

Fig. 64: The upper materials of the second prototype attached to the insole.

The insole with the uppers was then glued to the sole. The heel strap was inserted into the sole. Fig. 65 – Fig. 68 show the fully assembled second working prototype.

Fig. 65: The second working prototype.

Fig. 66: The second working prototype.

Fig. 67: The second working prototype.

Fig. 68: The second working prototype. Magnets within the sole serve as the bending mechanism.

5.7 SECOND PROTOTYPE TESTING

During the second round of testing, the researcher tested the shoe in the same way by wearing it and walking around. The researcher found that the arch pressed too much into the foot and made it a little uncomfortable to wear. There was not enough material in the toe to allow for the whole foot to fit in the shoe correctly. Cutting out more materials would provide sufficient room in the toe box. The rest of the materials also did not fully fit the researcher's foot and were too big, so the heel still slipped. The magnets proved to be not strong enough to hold the shoe in the bent position for an easy slip-on. The heel strap did stabilize the shape of the heel but did not help with the slipping of the heel. Fig. 69 shows the researcher testing the second prototype.

Fig. 69: The researcher testing the second prototype.

The prototype was then tested with the four participants in the same way by having them look at the video of the researcher wearing the shoe and looking at and touching the shoe. The prototype testing questionnaire shown in Fig. 7 was used again to record the reviews from the participants. The following are lists of what the participants liked and disliked about the prototype.

Participant likes (Fig. 70 – Fig. 72):

1. The material at the top of the foot is breathable.
2. The sole looks better.
3. The heel is now wide enough.
4. There is sufficient cushioning.
5. Like the weight of the shoe.
6. Likes the concept of the slip-on mechanism with the magnets.

Fig. 70: Participant likes #1, 2, and 4

Fig. 71: Participant likes #3

Fig. 72: Participant likes #6

Participant dislikes (Fig. 73 – Fig. 74):

1. Aesthetics at the top of the foot could be improved by attaching the leather pieces.
2. The fabric was not stiff enough.
3. The interior fabric of the heel could get too hot.
4. The slip-on mechanism was not functional.

Fig. 73: Participant dislikes #1and 2

Fig. 74: Participant dislikes #3

Overall, the participants thought the second prototype was a significant improvement from the first prototype. One participant suggested changing the direction of some of the grooves on the bottom to avoid the shoe being pulled in one direction when walking on certain surfaces. Another participant suggested making the heel strap adjustable to give a more custom fit for the user.

5.8 FINAL DESIGN

The development of the final design began with modifications to the CAD model. The height of the arch was slightly reduced to relieve pressure on the arch of the foot. A smaller arch was placed in the middle of the bottom cut out to aid in bending and to avoid a crease from forming down the middle. Fig. 75 shows the arch of the CAD model. The direction of one section of the grooves on the bottom of the sole was changed to prevent the shoe from being pulled in one direction (Fig. 76). Magnet holders were added to the bottom of the sole for the bending mechanism (Fig. 77). The upper materials were made in the CAD program with the same method as the second prototype and the same 3D scan of the researcher's foot. Parameters were adjusted to make them better conform to the foot. Fig. 78 shows the full design in SOLIDWORKS.

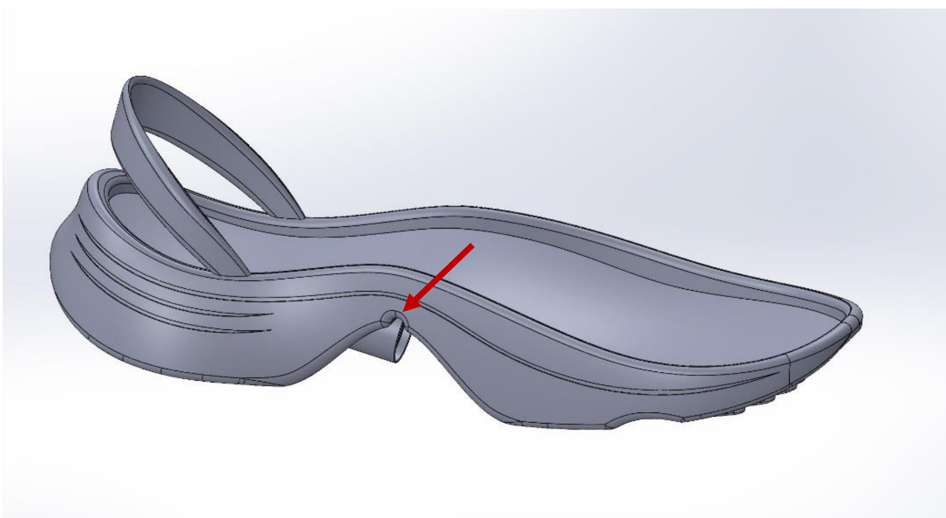


Fig. 75: 3D CAD model of the sole of the final design. The arrow points to the small arch that aids in the bending mechanism.

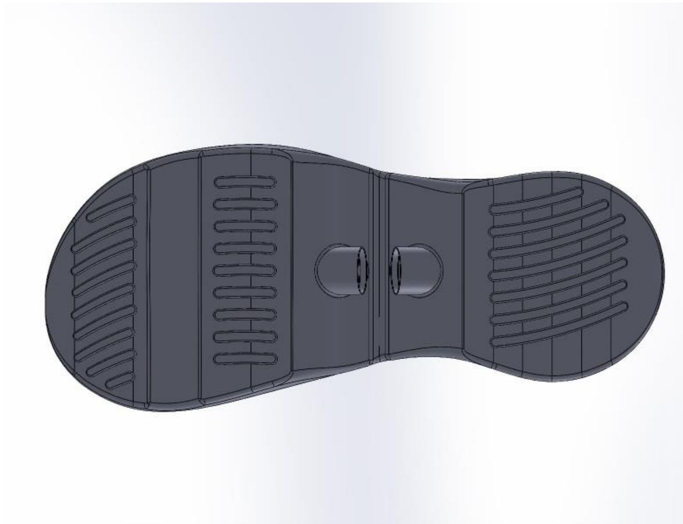


Fig. 76: 3D CAD model of the sole of the final design. Grooves on the bottom are in different directions to add traction.

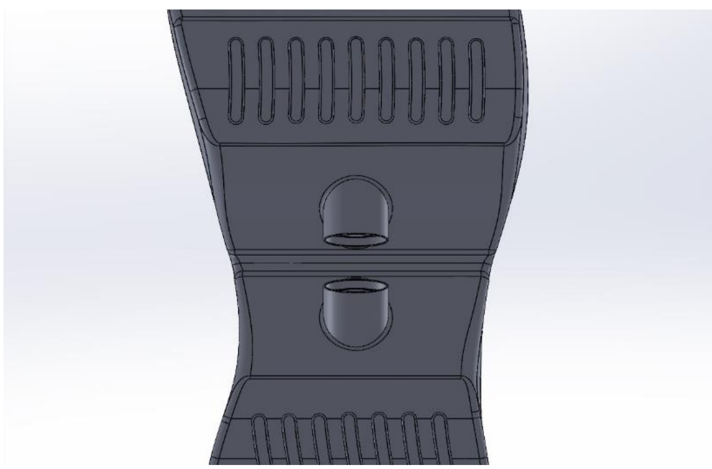


Fig. 77: 3D CAD model of the sole of the final design. Magnet holders were added to the bottom for the bending mechanism.

Fig. 78: 3D CAD model of the final design.

The fabric for the uppers was cut out in the same way as the second prototype using stencils from the CAD model. Breathable mesh material was used throughout the inner lining. Holes were strategically and fashionably punched in the outer leather to add to the breathability without losing aesthetic quality (Fig. 79).

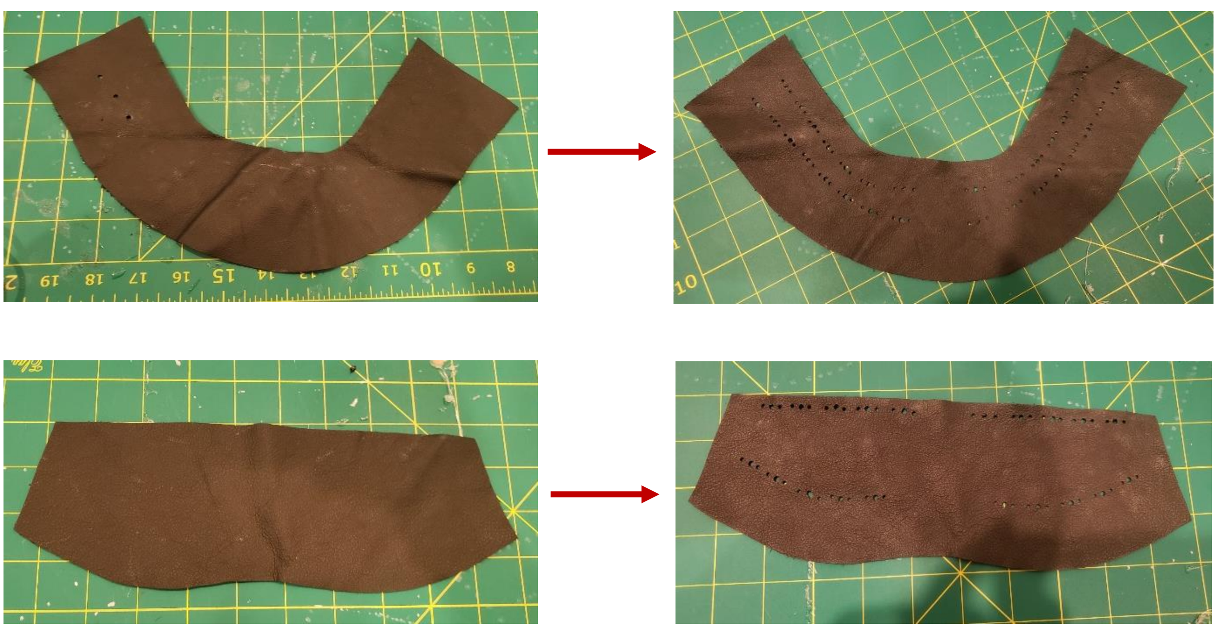


Fig. 79: Punched holes in the leather for breathability

The same insole and heel strap design were used for the final design. Memory foam was embedded in the top rim of the heel and the edge of the top of the shoe. Fabric stiffener was lightly sprayed on the shoe to make the upper materials stiffer and have more of a traditional shoe shape. Fig. 80 – Fig. 84 show the fully assembled final design. Stronger magnets were placed in the magnet holders to keep the shoe bent during the slip-on process (Fig. 82). The original magnet holders that printed with the sole were too long, so the magnets were stuck together all the time and didn't allow the shoe to go back to its natural state. A new set of holders that are shorter were 3D printed and attached to the sole (Fig. 82). The shorter holders plus the stronger magnets made the sole stay bent so the user can put their foot in easily. Fig. 85 shows the working bending mechanism for the slip-on method.

Fig. 80: Fully assembled final design.

Fig. 81: Fully assembled final design. Fabric stiffener made the upper materials stay up and be able to conform to the foot better.

Fig. 82: Bottom sole of the final design.

Fig. 83: Back heel of the final design. The 3D-printed heel strap helps keep the materials upright.

Fig. 84: Close-up of punched holes in the leather for added breathability.

Fig. 85: Successful slip-on method with strong magnets that allow the shoe to stay bent.

The 3D model shown in Fig. 78 was brought into KeyShot where realistic images were rendered. Fig. 86 – Fig. 88 show the realistic rendered images of the final design.

Fig. 86: Realistic rendered image of the final design pair.

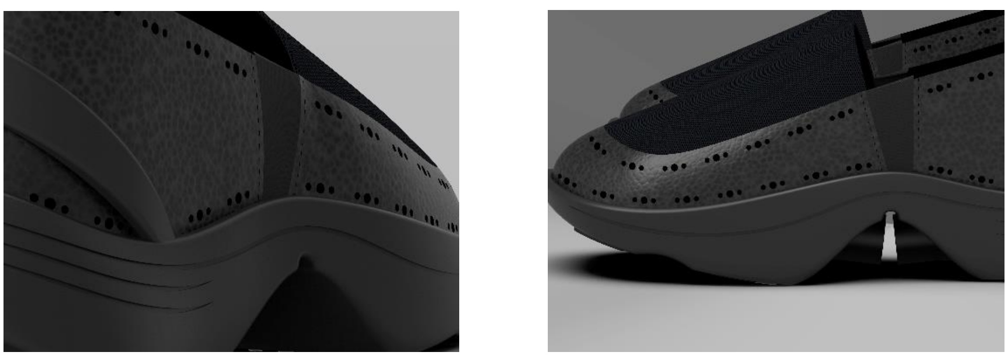


Fig. 87: Detail renders of the final design.

Fig. 88: In-context render of the final design.

CHAPTER 6: DISCUSSION

6.1 DATA ANALYSIS

In the first and second rounds of testing, question #10 on the prototype testing interview questionnaire asked the participants to rate the orthopedic shoe prototype from 1 to 10, with 1 being the worst and 10 being the best. Since the ratings within the participants and each testing round can vary, a Friedman’s ANOVA was performed on the rating scale data. The resulting p-value was 0.3173. This indicates that there were no significant differences within the ratings that each participant gave in the first and second testing stages. Fig. 89 shows the box plot of the Friedman’s ANOVA results.

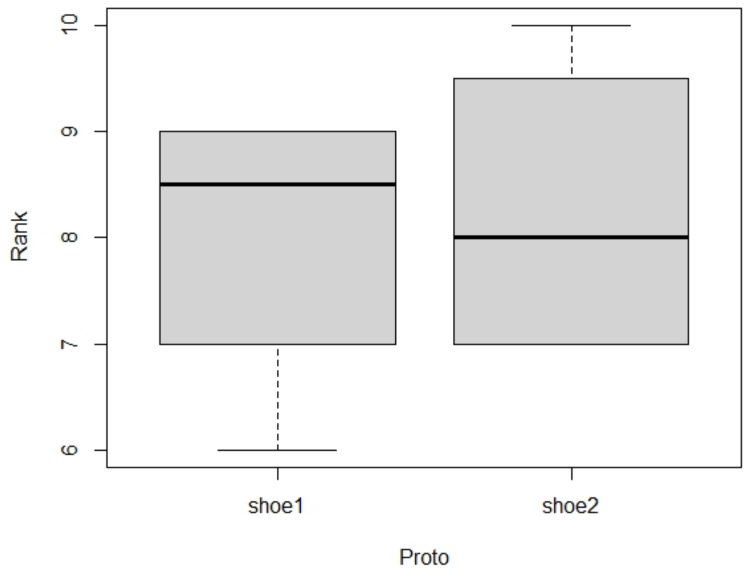


Fig. 89: Box plot of Friedman’s ANOVA test for question #10 in the testing questionnaires.

Though this data shows that the participants didn’t see much difference in quality between the first and second prototype, the three participants that rated highest based their ratings on the quality of the prototype at the specific prototyping stage, not on what they would expect from a shoe that is ready to be sold on the market. The participant likes and dislikes mentioned in sections 5.5 and 5.7 show that the participants did see a significant improvement from the first prototype to the second prototype.

6.2 COST ESTIMATE

As mentioned in section 2.3, there are many people who have diabetes that have low SES and cannot afford to buy orthopedic shoes. This causes their diabetes-related foot conditions to worsen and can threaten the loss of their limb or their life. One of the aims of this study was to design an aesthetically pleasing and functional orthopedic shoe that could be affordable for all. Table 5 shows the cost of the materials of the final design.

BILL OF MATERIALS		
Material	**Quantity**	**Cost**
Leather	1 12"x24" Square	$17.99
Mesh Fabric	1 Yard	$10.99
Elastic Belting	1/2 Yard	$4.00
Memory Foam	1/4 of 20"x16" Sheet	$6.86
Insole	1 Pair	$16.00
Black TPU Filament	1/2 Spool	$14.00
1/8" Thick, 3/4" OD Neodymium Magnet	2 Magnets	$7.14
Heavy Duty Thread	1/8 Spool	$1.25
		Total: $78.23

Table 5: Bill of Materials

The price of the $78.23 is significantly better compared to the ~$150 - $200 cost of current orthopedic shoes from reputable companies. One purchase of an affordable pair will ensure the user has a comfortable and attractive shoe that will last for a few years. This will not only boost the confidence of the user, but also save their feet and their quality of life.

6.3 DISCUSSION

This study utilized a user-centered design approach of literature review, survey, user interview, and user testing to uncover and resolve specific unmet needs in the ergonomics and functionality of orthopedic shoes for people with diabetes. Evidence uncovered by the study confirms the complex functional needs among people who have a variety of diabetes-related foot conditions. Understanding what people with these foot conditions needed in a shoe leads to the development of innovative features in the final design solution as presented in this paper.

Current orthopedic shoes are lacking in adequate support, breathability, easy ingress and egress, and aesthetic quality. Additional support throughout the shoe will prevent injuries and help with walking. A breathable shoe will make the user more comfortable when wearing the shoe and be more of an incentive to wear it. Some people who have diabetes might not be able to bend down to put their shoes on, so providing a simple slip-on shoe would give the user independence and self-confidence. The aesthetic quality of the shoe is very important. Orthopedic shoes currently on the market are limited in the appropriate styles. Offering a shoe that appeals to the user will make them want to wear the shoes more and become confident in how they dress. The study addressed all these significant unmet needs to provide an orthopedic shoe that is comfortable, easy to use, and of quality style. Overall, this project was a step in the right direction in finding a better solution in orthopedic shoes for people with diabetes.

6.4 LIMITATIONS

Limitations in this study include timing, resources, and the number of participants. More time with the project would result in a better final product validated through more testing. Some resources were difficult to come by and pushed back progress. Ultimately, the sole of the shoe would be made with a different kind of foam-like material so it could be pressed the way normal shoe soles are made. One would either need to reinforce EVA foam to not wear out so quickly or find a different kind of foam that provides enough cushion and doesn't wear out. Carbon fiber could then be embedded into the sole to add more rigidity. Sending the design of the uppers to a professional cobbler would guarantee they would fit the user's foot. The process used in this study is not used by cobblers. Using a shoe last that is essentially a mold of the user's foot and that will fit the contour of the sole would be best to develop the upper materials. The small number of participants is also a limitation of this study. The validity of the design would be more substantial with a greater number of participants.

CHAPTER 7: CONCLUSION

In conclusion, the issues of conformity, sufficient and lasting materials, support, accessibility in ingress and egress, and functional aesthetic quality were addressed to develop a better alternative to current orthopedic shoes for people with diabetes and diabetes-related foot conditions. Through a user-centered research and design approach, the developed prototypes were partially validated by user testing. The shoe design with a wider toe box to allow the toes to spread out will evenly distribute weight across the ball of the foot and toes, which will result in a better walking gait. Leather uppers appeal to users with the look of a high-quality shoe. The cut-out in the middle of the sole serves two purposes – allowing for bending for the slip-on mechanism and reducing the amount of material printed to make it lightweight and of better aesthetic quality. The cut-out makes it look more like a high-heel shoe and less like a large and heavy orthopedic shoe, while providing the support and cushion of an orthopedic shoe. Offering an orthopedic shoe with more support, breathable materials, and a style that is discreet yet pleasing to the eye will make the user more confident when wearing the shoes because they are stable, comfortable, and fashionable all at the same time. The innovations of this design, especially the sole and the slip-on mechanism, could not only be implemented in orthopedic shoe design but also the design of ordinary shoes, making the lives of those with and without foot conditions easier and healthier.

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APPENDIX A: ONLINE SURVEY DOCUMENT

Hello,
I am an Industrial Design graduate student at the University of Houston studying the ergonomics and design characteristics of orthopedic shoes. Most people who have diabetes-related foot conditions that require orthotics encounter functionality and comfortability issues with their orthopedic shoes, which can potentially cause their conditions to worsen. This is a study to investigate and uncover specific issues and unmet needs in orthopedic shoes with an aim to develop an orthopedic shoe with an improved ergonomic and functional design. Thank you for your contribution to this study.

1. What age group are you in?

   ○ 45-55 ○ 56-65 ○ 66-75 ○ 76-85 ○ 86 +

2. Do you have type 1 or type 2 diabetes?

   ○ Type 1 ○ Type 2

3. What specific foot conditions do you have? (Select all that apply)

   ○ Swelling ○ Diabetic foot syndrome ○ Ulcers ○ Neuropathy ○ Charcot foot ○ Other (please explain)

4. What are your current solutions to manage your foot condition(s) other than medicine or physician help? (Select all that apply)

   ○ Orthopedic shoes ○ Orthotic inserts ○ Other (please explain)

5. If you wear orthopedic shoes and/or inserts, do you experience any issues with them? (Select all that apply)

   ○ I do not experience issues with them ○ Too little or too much arch support ○ Too little or too much heel support ○ Not wide enough or too wide in any area of the shoe ○ Difficult to put on and take off ○ I do not wear orthopedic shoes and/or inserts ○ Other (please explain)

6. Additional comments on your feet and shoe related issues.

APPENDIX B: ONLINE SURVEY FLYER

Designing a Better Orthopedic Shoe for People with Diabetes

An Industrial Design graduate student at the University of Houston is studying the ergonomics and design characteristics of **orthopedic shoes**. This study will investigate and uncover specific issues and unmet needs in orthopedic shoes and aim to develop an orthopedic shoe with an improved ergonomic and functional design.

Are you interested in taking a short, anonymous survey to help us understand the current issues of orthopedic shoes? You may qualify if you are 45 years of age or older.

The QR code below will take you to the online survey.

If you experience issues, please contact:

Erika Lopez
elopez47@CougarNet.UH.EDU

Scan this QR code to participate in the survey

This research study has been reviewed by the University of Houston Institutional Review Board

APPENDIX C: IN-PERSON INTERVIEW QUESTIONNAIRE

I am an Industrial Design graduate student at the University of Houston studying the ergonomics and design characteristics of orthopedic shoes. Most people who have foot conditions that require orthotics encounter functionality and comfortability issues with their orthopedic shoes, which can potentially cause their conditions to worsen. This is a study to investigate and uncover specific issues and unmet needs in orthopedic shoes with an aim to develop an orthopedic shoe with an improved ergonomic and functional design. Thank you for your contribution to this study.

1. What is your age?
2. Do you have type 1 or type 2 diabetes?
3. What kind of foot conditions do you have?
    a. Are there any specific reasons why you have these foot conditions? (work, lifestyle, general side-effects from diabetes/neuropathy)
4. What are your current solutions to manage your foot condition(s) other than medicine or physician help?
    a. Do you wear orthopedic shoes?
5. (If they say they wear orthopedic footwear) Do you experience any issues with your orthopedic footwear?
    a. If not, what do you like about the shoes?
    b. If yes, what do you not like about them?
    c. How often do you wear orthopedic footwear?
6. What do you like or dislike about putting on or taking off your shoes?
7. What qualities of a shoe are important to you?
    a. What kind of aesthetics do you like in shoes.
8. Is there anything else you would like to mention?

APPENDIX D: STUDY PARTICIPANT FLYER

Designing a Better Orthopedic Shoe for People with Diabetes

An Industrial Design graduate student at the University of Houston is studying the ergonomics and design characteristics of **orthopedic shoes**. This study will investigate and uncover specific issues and unmet needs in orthopedic shoes and aim to develop an orthopedic shoe with an improved ergonomic and functional design.

Are you interested in helping us understand the current issues of orthopedic shoes? You may qualify if you are 45 years of age or older.

To participate, please contact:

Erika Lopez
elopez47@CougarNet.UH.EDU

Or scan this QR code

This research study has been reviewed by the University of Houston Institutional Review Board

APPENDIX E: IN-PERSON INTERVIEW QUESTIONNAIRE FOR PROTOTYPE TESTING

This questionnaire contains questions regarding your thoughts on the shoe prototype. Thank you for your contribution to this study.

1. What are your initial thoughts on the video you watched of the investigator testing the prototype?

2. Do you think there is enough support provided in the prototype?

3. How do you feel about the materials of the prototype? Do you think they will be comfortable, or do you think some materials may cause rubbing to occur?

4. What do you think about the breathability of the upper part of the shoe?

5. Do you think the materials of the upper part of the shoe are stretchy enough?

6. What do you think about the process of putting the prototype on and taking it off? Do you think it will be easy or hard?

7. What do you like about the prototype?

8. What do you dislike about the prototype?

9. On a scale of 1 to 10, with 1 being the very poor and 10 being excellent, how would you rate the shoe prototype?

10. Is there anything else you would like to mention?