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Hands Free Fitted Shoe

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PodAl Sole Lifter: A Hands-Free Fitted Shoe

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BME Senior Design Honors Project: Hands-Free Fitted Shoe

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Abstract

The ability to don and doff fitted shoes can be a challenge for many people including those diagnosed with diabetes, obesity, limb loss, pregnancy[29], Parkinson's disease[35], arthritis[31], surgical complications, and aging[25]. Though these actions may seem trivial, the ability to independently put on shoes is necessary because it can significantly impact one's capacity to complete everyday tasks, hold relationships, and maintain mental health. Current competitors in the market are excessively expensive, not completely hands-free, or not fully enclosed shoes, so a new design for an accessible and affordable hands-free fitted shoe could be of great benefit to the general population. In this biomedical engineering senior design project, the team, PodAl, found a way to increase the user- friendliness of fitted shoes for those with mobility issues, deformities, or other maladies to increase independence, safety, comfort, and functionality of fitted shoes for targeted populations. This design has undergone verification and validation testing and was proven to meet customer and engineering requirements.

Keywords—accessible, fitted, foot, hands-free, shoe

I. Introduction

Motivations for the project include helping those who would be able to gain more independence or confidence from an accessible shoe. PodAl has created two prototypes of a fitted shoe with the hands-free mechanism: an alpha prototype to represent mechanism function, and a beta prototype to represent the final product. These prototypes allow users to accomplish everyday activities that normal active shoes allow with the benefit of not having to bend over to put the shoes on. This product is different from slip-on shoe styles like Crocs™ [20], house slippers, loafers, clogs, or slides, because it is an enclosed, fitted shoe with a back support. Products from current competitors in the market are expensive, not completely hands-free, or only partially enclosed, so a new design for an accessible and affordable hands-free fitted shoe could be of great benefit to many people.

II. User Needs

User needs were identified based on five interviews with stakeholders for the project during the User Needs stage. Identified stakeholders included potential future users of the product, podiatric medical professionals, and biomechanics experts. Interviews were conducted with people within each of these categories, including an elderly person, a care giver, a pregnant woman, a Veteran's Affairs (VA) employee, and a biomechanics engineer. The following user needs for the product were devised from the stakeholder interviews: ease of foot insertion, ease of foot removal, flexibility, non-slip properties, antibacterial and antimicrobial properties, water resistance, cost effectiveness, breathability, comfort, arch support, strength, durability, aesthetic appeal, and product availability. Additionally, user needs were defined to include the ability of the shoes to self-tighten and user ability to detect and remove foreign objects. These requirements can be found in *Table A.*

Patent and competitor searches were also completed during the User Needs stage. The following results were revealed: Kizik Shoe patent[1], Nike Air Mag patent[3], Bimodal Heel Rapid Entry System patent[4], Bimodal Heel Counter patent[5], Actuator Arm Rapid Entry System patent[8], Lattice Structure Rapid Entry System patent[10], Compressed Medium Pocket Rapid-Entry Footwear patent[9], and the Nike Go-Fly Ease patent pending[23]. The patent and competitor search proved that PodAl was not the first team to attempt to solve the problems with fitted shoes, thus validating that this issue is a significant problem. The patent search also allowed PodAl to ensure that there were no legal issues with potential design ideas. This design differs from the existing patents for hands-free shoes in the main aspect that the mechanism that closes the shoe involves making the tongue and insole one piece, the insole and tongue is what moves within the shoe for entry, and the outer shell of the shoe is immobile.

III. Design Inputs

The initial Quality Function Deployment (QFD) was completed during the Design Inputs stage and will be referred to as phase one QFD. Engineering requirements, shown in Table *A*, were derived from user requirements, and then evaluated and ranked in phase one QFD, shown in *Figure A*. The most important user requirements were the time of insertion and removal, hands-free insertion and removal, tensile strength of material, size of the shoe opening, and cost. *Figure B* was also completed in this stage, which allowed for the ranking of competitors against the engineering requirements. Phase one QFD allowed the engineers to find relationships between the user requirements and the engineering requirements to create an optimized design.

Further within the Design Inputs stage, the preliminary risk assessment was performed and compiled into a condensed form, shown below in *Table 1*. There are few risks associated with a shoe design aside from those associated with falling, which have the highest Risk Priority Number (RPN) as shown in *Table 1*. The entire Failure Modes and Effects Analysis (FMEA) that the condensed version is made from is shown in *Table F* of the Appendix. *Table 1* below is a summary of the FMEA during the Design Inputs stage all potential failure modes were nonhazardous.

Table 1: FMEA from Design Inputs stage.

Potential Failure Mode	Potential Effects of Failure	SEV	OCC	DET	RPN
Unable to quickly put on or take off; mechanism breaks upon insertion or removal	Time is wasted	1	2	1	2
	Falling while putting on shoes	5	1	1	5
	Falling while taking off shoes	5	1	1	5
Degredation of material	Falling from slipping	4	1	3	12
Unable to accommodate environmental changes	Falling from slipping	4	3	2	24
	Rolling ankle	2	2	1	4
Elastic material becomes stiff	Foot loses circulation	2	1	2	4
	Blisters	2	2	2	8
Material becomes too loose	Foot is not secured causing tripping	3	2	2	12
	Rolled ankle	2	2	1	4
Material rips or tears	Destruction of the shoe leading to tripping or falling	3	1	2	6
	Foreign objects enter shoe	2	3	3	18
	Rain enters shoe	1	3	3	9
	Abrasion of foot due to foreign objects	3	1	2	6
Mechanism fails to tighten on its	Hands are required to put on shoes	1	1	1	1
Mechanism fails to loosen on its	Hands are required to take off shoes	1	1	1	1
Shoe breaks down from extended use	Customer is left with blisters	2	1	2	4
	Customer discomfort	1	1	3	3
Material rips or tears	Foreign objects enter shoe	2	2	3	12
	Abrasion of foot	3	1	2	6
	Rain enters shoe	1	3	3	9
Upper material gets covered	Excessive heat from blocked upper material may cause blisters	2	1	4	8
	Athletes foot	2	1	3	6

IV. Design Process

The final design was chosen by creating a second QFD, phase two QFD, which included an evaluation matrix to compare all potential designs. To brainstorm concepts, the 6-3-5 method was used where individuals generated three ideas and exchanged them among each group member to evaluate, combine, refine, or eliminate. Improvements, questions, and idea additions were written down during the brainstorming session and discussed afterwards, resulting in four final design concept candidates. The four design concepts were then analyzed using down-selection charts. In phase one of down-selection, all four design ideas were compared against user needs, also called design demands, shown in *Table D*. The two highest ranked ideas were then compared in phase two, which included making a list of pros and cons, shown in *Table H* for the highest-ranked design, the Sole Lifter. Strong was determined by the shoe's ability to withstand a normal shoe lifetime of seven years. Tight was determined by the ability of the shoe to stay secure on the foot during walking and other active movements.

In Phase Two QFD, relative scoring was used to evaluate all four design concepts against engineering and user requirements, as shown in *Figure C*. Each input in the QFD was assigned a relative weight and importance which resulted in a final score for each design concept. In order from lowest to highest score, the design concepts were Ratchet Shoe, Flayed Shoe, Lever Slide, and Sole Lifter. Based on design, the Sole Lifter was expected to meet the greatest number of user and engineering requirements with the highest scores associated with that design. In addition to its high score, the Sole Lifter was selected to undergo the rest of the design process due to its feasibility and simplicity. The Sole Lifter connects the insole to the tongue, so the insole lifts when taking the shoe off and the insole is secured to the bottom when putting the shoe on, resulting in a hands-free fitted shoe. This design concept is like a slipper fitting inside an athletic shoe because it provides comfort and stability.

Preliminary design specifications were developed based on background research. The most important specifications included: a long-lasting hook and loop lifetime[56], all the aspects of the design to be water resistant[51], and a mechanism which could be adjusted to fit all common shoe sizes.

Risk Assessment was completed in the format of a Design Failure Modes Effects Analysis (dFMEA), as can be seen in *Table C*. The Sole Lifter Design concept was assessed for satisfying user and engineering requirements, component functionality and total mechanism functionality. Each function was assigned a risk severity, class, and occurrence, resulting in a final Risk Priority Number (RPN) to determine the designs' functions that needed addressed to minimize risk. Risks ranged from the shoe taking a large amount of time to put on or take off to causing long term failure of knee or ankle due to harsh impact on ground. These risks were addressed in the design to make all RPNs fall under the low-risk category.

An alpha prototype was created during this stage to provide proof of concept. Photos of the prototype can be seen in *Figure D*. Simple materials were used including a worn tennis shoe, scissors, Gorilla Super Glue[61], Velcro, Dritz ½ inch braided elastic bands, a shoelace, and a needle and thread[60]. Minor changes were required after the design concept was proved. These changes were addressed during the Design Outputs stage using the proper materials and adjusting the appropriate attachments to the tongue and insole. Preliminary testing results of the alpha prototype can be seen in *Table G*.

V. Design Outputs

The deliverables for the Design Outputs stage include design specifications, assembly device drawings, bill of materials, and analytical modeling. Device specifications from Design Process stage were expanded upon to increase detail.

For example, quantitative values were added based on background research and analytical modeling. Verification testing was also completed during this stage to ensure that the design outputs met the design inputs. For example, the PodAl Sole Lifter was tested to determine the time required to don and doff the shoe. The results were as follows: 3.05 seconds to don the shoes and 2.70 seconds to doff the shoes.

The beta prototype was made to optimize comfort and ease of use. Down-selection was performed to ensure that the appropriate materials were purchased so the design specifications were met. These decision matrices consisted of a list of design demands, and at least three brands for each part selected, as can be seen in *Table H.* The parts that were purchased include Dritz 3" Knit elastic bands[58], fabric thread[60], insoles[59], a pair of shoes[65 66], Velcro[56], super glue[61], waterproofing spray[62], and microfiber antimicrobial fabric[63]. The brand options were first weighed and scored to validate their purchase. Then, the winners of the down-selections were compiled into the bill of materials, which can be seen in *Table I*. These materials were then ordered via a purchase request. The bill of materials showed that one pair of PodAl Sole Lifter's would cost less than fifty dollars to produce not including manufacturing or labor costs. This meets our low-cost design requirement when compared to other competitive brands such as Nike[41 19 13] and Kizik[14].

Once the materials arrived, the beta prototype was created. Three-Dimensional device drawings of components and assembly of parts were modeled in SolidWorks and shown in *Figure E*. The models provided visualization of the final design and allowed for revisions to be made prior to construction of the beta prototype to improve efficiency and minimize unnecessary expenditures. The device drawings in SolidWorks also ensured that all components would fit and perform together as expected. Analytical modeling was completed at this time to show what the maximum force that each material needed to be able to withstand in the design. The analytical model showed that the device and each material used in it must withstand a maximum force of 37.50 N. This force value was used during verification testing as the passing criteria for the minimum tensile strength that each material needed to withstand.

After obtaining the selected materials, the beta prototype was fabricated. This prototype can be seen in *Figure F*. This beta prototype was used for verification testing.

VI. Design Verification

Design verification testing was used to ensure that the design outputs met the criteria of the design inputs. This was completed by testing the beta prototype against the engineering requirements. Design verification was completed as part of the Design Outputs stage.

As can be seen in *Table 2* below and *Table J* of the appendix, the beta prototype passed all the verification tests that were performed. Notably, from these results, the beta prototype can be considered easily usable, lightweight, tightly fitting, comfortable, supportive, and durable.

Table 2. Condensed design verification test names & results.

Test Name	Engineering Requirement Tested	Result
Insertion & Removal Time	Easy Application & Removal	Pass
Weight	Lightweight	Pass
Heel & Shoe Sole Distance	Tight Fit	Pass
Insole Fit	Comfortable	Pass
Insole Support	Supportive	Pass
Sole Visibility	Easy Detection of Foreign Objects	Pass
Tensile Strength	Durable	Pass
Fatigue	Durable	Pass

The insertion and removal time test was based on a test performed using human subjects. A statistical summary of these test results can be seen in *Table K*. The weight test utilized a scale. The heel and shoe sole distance test, insole fit test, insole support test, and sole visibility test were based on measurements of various dimensions of the shoe. Finally, the tensile strength test and fatigue test were based on stress-strain curves. The tests were completed using an Instron universal testing machine set to the tensile setting or fatigue setting, respectively. Samples were placed in between clamps on the Instron in a taut position and the machine was zeroed. Then, for tensile testing, the samples were pulled until breaking occurred. For fatigue testing, the sample was stretched to 200% elongation for ten thousand cycles. Each of these tests was repeated three times for each material. Hysteresis testing data can be seen in *Figure G* and tensile testing data can be seen in *Figure H*.

VII. Medical Device

The final stage of the FDA design process was focused on validating that the PodAl Sole Lifer mechanism met the users' needs. Another task of this stage was to implement any modifications that result from the verification stage. The major design change needed was to ensure that our device was water-resistant. It was determined that this would be rectified by coating the hands-free shoe with a waterproofing spray that would protect the shoe as well as keep the users' feet dry, blister-free, and warm. This ensured that the device resists water and fully performs to the users' demands. Finally, in this stage, two pairs of prototypes were created in various shoe sizes and brands to prove the versatility of the Sole Lifter mechanism. The construction of four prototypes in different sizes also allowed for more practical and efficient validation testing to occur. Images related to the final medical device design and links to a demonstration video regarding the performance of the shoe can be found in *Figure J*.

VIII. Validation Testing

To validate the functionality of the PodAl Sole Lifter, tests were performed using the final prototypes created during the Medical Device stage. Utilizing six detailed tests as well as a general customer satisfaction survey, the device was validated against user needs. The on/off test showed the ease of insertion and removal of the shoe for a person. The running test guaranteed that the shoe was usable for activities such as running and validated that the shoe was self-tightening, flexible, comfortable, and breathable. The jumping test validated that the shoe was self-tightening, flexible, and comfortability. The trip test confirmed that the sole lifter was self-tightening. The rip test validated the strength and durability of the shoe. The inspection test involved asking participants to look carefully at the shoe in different scenarios and then answer questions about aspects of the shoe such as aesthetic appeal and how easy it was to detect foreign objects within the shoe.

Table 3: Condensed design validation test names & results.

Test Name	User Requirement Tested	Result
On/Off	Easy foot insertion & removal, cost effective	Pass
Running	Self-tightening, flexible, comfortable, breathable, cost effective	Pass
Jumping	Self-tightening, flexible, comfortable, cost effective	Pass
Tripping	Self-tightening	Pass
Rip Test	Strong & durable	Pass
Inspection	Aesthetically appealing, easy to detect & remove foreign objects	Pass

There were six tests that were conducted to validate the shoes to show the feasibility of placing them on the market. The first test conducted was the on/off test which is meant to show how easy it is to put on the shoe and take off the shoe. This test was completed by five test subjects and only passed if all five subjects passed the test. The running, jumping, and tripping test were conducted to show how during exercise the PodAl Sole Lifter is comfortable and tight fitting, making them ideal for exercise. These tests were completed by five test subjects and only passed if all five subjects passed the test. The rip test was used to check if the materials were strong, durable, and able to withstand daily use. This test was also completed by five test subjects, and all the beta prototypes passed the qualifications of the test. The last validation test conducted was the inspection test, which allowed for gauging of the aesthetic appeal of the shoe and determining if foreign objects inside of the shoe were able to be detected. Five subjects completed this test to complete the validation testing. All the validation tests passed, which shows that the PodAl Sole Lifter is a validated design that meets user needs. These results were expected, as the design was simple and does not have major failure points that are likely to cause validation failure to occur.

IX. Risk Mitigation Process

Potential hazards needed to be analyzed to create a low-risk final design. Risks were mitigated using a design Failure Modes Effects Analysis (dFMEA). This document helped to identify, understand, control, and prevent potential failures within the device design. Specifically, all risks associated with the gait cycle while wearing the PodAl Sole Lifter were analyzed. Risks that were identified while using the risk mitigation process include hindered ability to easily put on and take off the shoes, inability to accommodate environmental changes, decreased security of shoes, and tear of materials. A risk summary table can be seen in *Table M*.

The inability to quickly don and doff shoes was mitigated by using durable and appropriate materials which work well together. Durable materials were obtained, and verification was completed to mitigate the inability of the shoe to accommodate weather changes. Materials were selected to resist water, allow airflow, resist tears, and encourage flexibility. Security of the shoes was increased using thread material that has a tensile strength over 14 MPa. Additionally, the elastic was wrapped completely around the tongue of the shoe to allow for maximum security around the foot and reduce ankle instability. The tear of materials was reduced by purchasing durable, Dritz 3" Knit elastic bands that withstood well over 14 MPa of tensile strength, which was verified through mechanical testing. The microfiber fabric was attached at the soles and elastic to increase the stability of the shoe. Lastly the self-tightening mechanism failure was mitigated using durable materials.

All the risks listed above were mitigated and ranked in accordance with the severity of the risk, the likelihood of occurrence of the risk, and the ease of detection of the risk. A rank of one was given for low severity, low occurrence, and high detection ratings while a rank of five was attributed to high-risk severity, high level of occurrence, and a low possibility of the risk being detected. These scores were added to create a risk priority number (RPN) for each risk item. All risks received RPNs less than twenty-four after mitigation, which is considered low risk. Overall, the final product is considered to have a low-risk design. Most of the remaining risks are associated with long-term use, which can be avoided by replacing the shoes after the expected seven years of normal use. The benefits of the shoe such as efficiency, hands-free use, and cost effectiveness greatly outweigh the low-level risks associated with the design.

X. Marketing & Manufacturing Considerations

The PodAl Sole Lifter will be marketed to target those with mobility or dexterity complications, which include millions of Americans. Some of the targeted populations consist of those with obesity, which affects 139 million people[43]; the elderly (Americans over the age of 65)[43], which consists of 45 million people; and those with diabetes, which affects 34.2 million Americans[33].

The footwear market in The United States is worth over $90 billion dollars. The diabetic shoe market is expected to have a compound annual gross rate of almost 7% by 2026[49]. This is due to increasing awareness of more comfortable footwear that can minimize injuries. Medicaid pays for two pairs of diabetic shoes and three pairs of inserts per year[49]. Based on these statistics, there is potential of selling over 68.4 million pairs of hands-free fitted shoes.

Various competitors hands-free fitted shoes and prices for each pair are listed below:

- Nike's Go GlyEase- $200-$800[23]
- Nike Air Mag- $25,000-$80,000[41]
- Kizik Shoes- $99-$129[24]

The Bill of Materials (*Table I)* shows the cost of materials to build one pair of shoes is $43.93 based on the beta prototype. Considering that materials will be significantly cheaper when purchased in higher quantities for manufacturing, a pair of Sole Lifters will be able to be produced and sold for less money. Assuming a 40% price reduction from buying in bulk for each individual material needed to make the Sole Lifter, the cost of materials will be $26.36 per pair. When considering the estimated labor cost of assembly, the cost of material will be doubled to $52.72 for a pair of shoes. Company overhead would double the cost, and a 60% margin will result in the shoe being sold at a price of $168.70.

Due to a relatively higher price than anticipated, it is considered a possibility to outsource the manufacturing to China, like the other footwear competitors in The United States, which can reduce the manufacturing costs by up to 80%. This would result in the Sole Lifter being sold for significantly below $100. However, the PodAl team would like to avoid outsourcing to prevent moral issues. It is anticipated that Medicaid will cover the cost of this medical footwear for insurance carriers. This will result in the hands-free fitted shoe being competitive in the market with lower costs than leading footwear companies.

XI. Summary Feasibility Discussion

This innovated product addressed the clinical need for improving the user-friendliness of fitted shoes for those with mobility issues, deformities, or other maladies. The proposed Sole Lifter design has the potential to achieve easy insertion and removal of a fitted shoe for the users while providing comfort and durability. The importance of a high-performing mechanism for a hand-free shoe that is cost-effective was achieved through the design of connecting the insole of the shoe with the tongue of the shoe. The mechanism is feasible because when the shoe is in the open position, insertion of the foot will result in pushing the sole and therefore tongue down in the closed position. When in the closed position, removal of the foot will result in pushing on the tongue of the shoe and therefore pulling the sole upward as well as returning to the open position. This design can be modified onto any fitted shoe.

The team was able to demonstrate fully functioning prototypes scaled to real-life that met the engineering and customer requirements throughout the duration of the project. Regarding large-scale manufacturing, purchasing the materials in bulk will allow the shoe to be sold for less than the competitors.

XII. Conclusion

This project allowed the PodAl team to learn many lessons. Firstly, extra meetings outside of regularly scheduled meetings were often held online to allow for scheduling flexibility. Secondly, another lesson learned was how to incorporate multiple people's ideas into one final product. While a majority of the team is made up of relatively strongly opinionated people, PodAl was able to use contributions from each member to make the final Sole Lifter design. While this resulted in members having to compromise on their ideas, it is firmly believed that contributions from all members led to the unique final product. Overall, the team worked efficiently and collaboratively to create a new solution to a common problem.

XIII. Future Work

The most significant task moving forward for the Sole Lifter is implementation of a whole shoe design rather than the mechanism only. This would be done by increasing the research and development of the design of the entire shoe. This is expected to greatly increase the satisfaction of the customer, as they can buy an entire shoe that already has the Sole Lifter mechanism built in. Improving the manufacturing process is also a potential future focus, as that would greatly increase shoe production capabilities and even open the possibility of mass production. Alternatively, intellectual property could potentially be sold to a shoe manufacturer so they can produce the Sole Lifter at a larger scale.

XIV. Individual Roles & Responsibilities

There are five members of PodAl: Maddison Schutt, Nicole Rizkala, Elizabeth Scheatzle, Alexander Hershey, and Austin Fowkes. Each member was assigned a title and a set of responsibilities associated with said title. These are only some of the contributions that each team member made

Maddison Schutt was the team leader. She was responsible for meeting agendas, setting deadlines, and ensuring that all work was divided evenly amongst members. Maddison also helped in creating the QFD, creating drop down selection sheets, and helped make the engineering requirements from the user needs.

Nicole Rizkala was the technical writer. She was responsible for ensuring that all written documents are coherent, concise, and technically sound. She was also the main contributor in making the presentations for every gate, analyzing the potential future market, and interviewed some of our stakeholders to create the user needs.

Elizabeth Scheatzle was the coordinator. She was responsible for proofreading all documentation, organizing the design history file (DHF), and ensuring that assignments were turned in on time. Additionally, most risk mitigations and analysis such as the FMEA were done by Elizabeth. She was also the primary member responsible for creating the Sole Lifter design prototypes.

Alexander Hershey was the designer. He was responsible for finalizing all designs and creating the SolidWorks model. He helped create the QFD, made the drawings for the design, and contributed to creating the down-selection for the alpha prototype.

Austin Fowkes was the designer. He was responsible for compiling all background research into a usable format for future reference as well as ensuring that future designs corresponded with the initial research for the project. Austin did most of the research, aided in creating the FMEA, and assisted with creating the design drawings.

XV. Professional & Ethical Responsibilities

When producing this medical device, environmental, economic, and societal impacts were taken into consideration. Environmentally, the Sole Lifter should have minimal impact as it will only replace shoes currently on the market and does not use any materials or manufacturing processes known to be harmful to the environment. It will also be economically beneficial, as it will be less expensive for consumers compared to current competitors. There would be little societal impact, as all people will continue to buy shoes at a relatively steady rate and wearing fitted shoes will continue to be a normal part of daily life. If anything, the Sole Lifter could potentially help to increase targeted populations' involvement in activities requiring fitted shoes. If the Sole Lifter can reach a global market, these impacts are expected to be similar on a global scale.

XVI. Aknowledgments

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XVII. References

1. M. Pratt. “Rapid entry shoe.” Google Patents. https://patents.google.com/patent/US20120317839A1/en https://patents.justia.com/assignee/kizik-design-llc (accessed Sept. 9, 2021)

2. M. Pratt. “Rapid entry shoe.” Google Patents. https://patents.google.com/patent/US10813405B2/en?q=A43B21%2f42(accessed Sept. 9, 2021)

3. T. A. Beers, M. R. Friton, and T. L. Hatfield. “Automatic lacing system.” Google Patents. https://patents.google.com/patent/US8769844B2/en (accessed Sept. 9, 2021)

4. K. Kentigern. “Shoe with bimodal heel counter and activation elements for rapid entry and release.” United States Patent and Trademark Office. https://pdfaiw.uspto.gov/.aiw?Docid=20210204644&homeurl=http%3A%2F%2Fappft.uspto.gov%2Fnetacgi%2Fnph-Parser%3FSect1%3DPTO2%2526Sect2%3DHITOFF%2526p%3D1%2526u%3D%25252Fnetahtml%25252FPTO%25252Fsearch-bool.html%2526r%3D2%2526f%3DG%2526l%3D50%2526co1%3DAND%2526d%3DPG01%2526s1%3Dshoe%2526s2%3D%252522rapid%252Bentry%252522%2526OS%3Dshoe%252BAND%252B%252522rapid%252Bentry%252522%2526RS%3Dshoe%252BAND%252B%252522rapid%252Bentry%252522&PageNum=&Rtype=&SectionNum=&idkey=FC520F43FB7D(accessed Sept. 9, 2021)

5. K. Kentigern. “Shoe device with bimodal structures for rapid entry and release.” United States Patent and Trademark Office. https://pdfaiw.uspto.gov/.aiw?Docid=20210204643&homeurl=http%3A%2F%2Fappft.uspto.gov%2Fnetacgi%2Fnph-Parser%3FSect1%3DPTO2%2526Sect2%3DHITOFF%2526p%3D1%2526u%3D%25252Fnetahtml%25252FPTO%25252Fsearch-bool.html%2526r%3D3%2526f%3DG%2526l%3D50%2526co1%3DAND%2526d%3DPG01%2526s1%3Dshoe%2526s2%3D%252522rapid%252Bentry%252522%2526OS%3Dshoe%252BAND%252B%252522rapid%252Bentry%252522%2526RS%3Dshoe%252BAND%252B%252522rapid%252Bentry%252522&PageNum=&Rtype=&SectionNum=&idkey=7D740F43AD66(accessed Sept. 9, 2021)

6. K. Kentigern. “Bimodal heel counter and dependent fastening elements for rapid entry and release footwear devices.” United States Patent and Trademark Office. https://pdfaiw.uspto.gov/.aiw?Docid=20210145114&homeurl=http%3A%2F%2Fappft.uspto.gov%2Fnetacgi%2Fnph-Parser%3FSect1%3DPTO2%2526Sect2%3DHITOFF%2526p%3D1%2526u%3D%25252Fnetahtml%25252FPTO%25252Fsearch-bool.html%2526r%3D4%2526f%3DG%2526l%3D50%2526co1%3DAND%2526d%3DPG01%2526s1%3Dshoe%2526s2%3D%252522rapid%252Bentry%252522%2526OS%3Dshoe%252BAND%252B%252522rapid%252Bentry%252522%2526RS%3Dshoe%252BAND%252B%252522rapid%252Bentry%252522&PageNum=&Rtype=&SectionNum=&idkey=089496970615(accessed Sept. 9, 2021)

7. Fast IP, LLC. “Rapid-entry footwear comprised of a unified material.” United States Patent and Trademark Office. https://pdfaiw.uspto.gov/.aiw?Docid=20210112914&homeurl=http%3A%2F%2Fappft.uspto.gov%2Fnetacgi%2Fnph-Parser%3FSect1%3DPTO2%2526Sect2%3DHITOFF%2526p%3D1%2526u%3D%25252Fnetahtml%25252FPTO%25252Fsearch-bool.html%2526r%3D5%2526f%3DG%2526l%3D50%2526co1%3DAND%2526d%3DPG01%2526s1%3Dshoe%2526s2%3D%252522rapid%252Bentry%252522%2526OS%3Dshoe%252BAND%252B%252522rapid%252Bentry%252522%2526RS%3Dshoe%252BAND%252B%252522rapid%252Bentry%252522&PageNum=&Rtype=&SectionNum=&idkey=5F4D8D9F3D59(accessed Sept. 9, 2021)

8. Fast IP, LLC. “Rapid-entry footwear having an actuator arm. United States Patent and Trademark Office. https://pdfaiw.uspto.gov/.aiw?Docid=20210112911&homeurl=http%3A%2F%2Fappft.uspto.gov%2Fnetacgi%2Fnph-Parser%3FSect1%3DPTO2%2526Sect2%3DHITOFF%2526p%3D1%2526u%3D%25252Fnetahtml%25252FPTO%25252Fsearch-bool.html%2526r%3D6%2526f%3DG%2526l%3D50%2526co1%3DAND%2526d%3DPG01%2526s1%3Dshoe%2526s2%3D%252522rapid%252Bentry%252522%2526OS%3Dshoe%252BAND%252B%252522rapid%252Bentry%25252

2%2526RS%3Dshoe%252BAND%252B%252522rapid%252Bentry%252522&PageNum=&Rtype=&SectionNum=&idkey=FB428A98D61A(accessed Sept. 9, 2021)

9. Fast IP, LLC. “Rapid-entry footwear having a pocket for a compressed medium.” United States Patent and Trademark Office. https://pdfaiw.uspto.gov/.aiw?Docid=20210106094&homeurl=http%3A%2F%2Fappft.uspto.gov%2Fnetacgi%2Fnph-Parser%3FSect1%3DPTO2%2526Sect2%3DHITOFF%2526p%3D1%2526u%3D%25252Fnetahtml%25252FPTO%25252Fsearch-bool.html%2526r%3D7%2526f%3DG%2526l%3D50%2526co1%3DAND%2526d%3DPG01%2526s1%3Dshoe%2526s2%3D%252522rapid%252Bentry%252522%2526OS%3Dshoe%252BAND%252B%252522rapid%252Bentry%252522%2526RS%3Dshoe%252BAND%252B%252522rapid%252Bentry%252522&PageNum=&Rtype=&SectionNum=&idkey=A11AAE359ECF(accessed Sept. 9, 2021)

10. Fast IP, LLC. “Rapid-entry footwear having a compressible lattice structure.” United States Patent and Trademark Office. https://pdfaiw.uspto.gov/.aiw?Docid=20200367607&homeurl=http%3A%2F%2Fappft.uspto.gov%2Fnetacgi%2Fnph-Parser%3FSect1%3DPTO2%2526Sect2%3DHITOFF%2526p%3D1%2526u%3D%25252Fnetahtml%25252FPTO%25252Fsearch-bool.html%2526r%3D12%2526f%3DG%2526l%3D50%2526co1%3DAND%2526d%3DPG01%2526s1%3Dshoe%2526s2%3D%252522rapid%252Bentry%252522%2526OS%3Dshoe%252BAND%252B%252522rapid%252Bentry%252522%2526RS%3Dshoe%252BAND%252B%252522rapid%252Bentry%252522&PageNum=&Rtype=&SectionNum=&idkey=EDCEEF1F505F(accessed Sept. 9, 2021)

11. N/A. “How To Treat A Bunion Before It Gets Worse.” MVS Podiatry Associates. https://podiatryassociates.org/how-to-treat-a-bunion-before-it-gets-worse/ (accessed Sept. 9, 2021)go fly

12. D. McLoughlin. “Nike Go FlyEase.” RunRepeat. https://runrepeat.com/nike-go-flyease (accessed Sept. 9, 2021)

13. D. McLoughlin. “Nike Air Mag.” RunRepeat. https://runrepeat.com/nike-air-mag (accessed Sept. 9, 2021)

14. N/A. “Kizik Men’s Signature Collection Madrid Slip-on Sneaker.” Amazon. https://www.amazon.com/product-reviews/B08MWTX11D (accessed Sept. 9, 2021)

15. N/A. “Zeba Shoes Reviews.” Reviewopedia. https://www.reviewopedia.com/zeba-shoes-reviews (accessed Sept. 9, 2021)

16. E. Manning. “These Accessible Shoes for Kids with Special Needs are Genius!” My Kids Time. https://www.mykidstime.com/lifestyle/genius-accessible-shoes-for-kids-with-special-needs/ (accessed Sept. 9, 2021)

17. M. Hoffman. “Picture of the Feet.” WebMD. https://www.webmd.com/pain-management/picture-of-the-feet (accessed Sept. 9, 2021)

18. E. Quinn. “The Anatomy of the Foot and Common Foot Problems.” Verywell health. https://www.verywellhealth.com/foot-anatomy-and-physiology-3119204 (accessed Sept. 9, 2021)

19. N/A. “Adapt BB 2.0 ‘Nike Mag’.” Goat. https://www.goat.com/sneakers/adapt-bb-2-0-nike-mag-bq5397-003?utm_source=google_int&utm_medium=google_shopping_int&utm_campaign=11548457463_113867805298&utm_content=477267975289_&utm_term=194494412071&gclid=CjwKCAjwj8eJBhA5EiwAg3z0m2fQLPRgnqZlxZAv-1T5KZdLLCCXE7uIXGsv4GhmzOjQE5w56NFoyRoCj8QQAvD_BwE (accessed Sept. 9, 2021)

20. N/A. “Classic Lined Clog.” Crocs. https://www.crocs.com/p/classic-lined-clog/203591.html?cgid=men-footwear&cid=060#start=32 (accessed Sept. 9, 2021)

21. A. Tarlton. “People love to hate crocs.” Reviewed. https://www.reviewed.com/style/features/crocs-shoes-review-are-clogs-worth-buying (accessed Sept. 9, 2021)

22. N/A. “Winner X.” Dr. Comfort. https://www.drcomfort.com/winner-x (accessed Sept. 9, 2021)

23. N/A. “Go FlyEase.” Nike. https://www.nike.com/flyease/go-flyease (accessed Sept. 9, 2021)

24. N/A. “Kizik.” Kizik. https://kizik.com/?utm_source=paid_search&utm_medium=search&utm_campaign=prospecting&gclid=Cj0KCQjw-NaJBhDsARIsAAja6dNYjym0vjeALrYCwwMLBe_fmkPMZf6m7vFtFYp2fR6abCjGiP7_ntIaAoTLEALw_wcB (accessed Sept. 9, 2021)

25. Iezzoni, L. I., McCarthy, E. P., Davis, R. B., & Siebens, H. “Mobility difficulties are not only a problem of old age.” Journal of general internal medicine. *16*(4), 235–243. https://doi.org/10.1046/j.1525-1497.2001.016004235.x (accessed Sept. 9, 2021)

26. N/A. “Arthritis.” National Center for Chronic Disease Prevention and Health Promotion. https://www.cdc.gov/chronicdisease/resources/publications/factsheets/arthritis.htm#:~:text=In%20the%20United%20States%2C%2023,arthritis%20report%20severe%20joint%20pain (accessed Sept. 9, 2021)

27. N/A. “15 Limb Loss Statistics that May Surprise You.” Access Prosthetics. https://accessprosthetics.com/15-limb-loss-statistics-may-surprise/#:~:text=There%20are%202.1%20million%20people,2 (accessed Sept. 9, 2021)

28. N/A. “Births and Natality.” National Center for Health Statistics. https://www.cdc.gov/nchs/fastats/births.htm (accessed Sept. 9, 2021)

29. KGUN9. “Can’t put my shoes on due to pregnancy swelling, Help!” Youtube. https://www.youtube.com/watch?v=3V71AHupZsc (accessed Sept. 9, 2021)

30. N/A. “Can’t put my shoes on!!!” Patient. https://patient.info/forums/discuss/can-t-put-my-shoe-on--529774 (accessed Sept. 9, 2021)

31. C. Centeno. “Can’t Put on Socks? Why This Could Be a Bad Sign.” Regenexx. https://regenexx.com/blog/can-t-put-on-socks/#gref (accessed Sept. 9, 2021)

32. N/A. “Limb Loss Stats.” One Handy Barrow. https://u.osu.edu/wheelbarrows/upper-limb-injury-statistics/ (accessed Sept. 9, 2021)

33. N/A. “The Facts, Stats, and Impacts of Diabetes.” Centers for Disease Control and Prevention. https://www.cdc.gov/diabetes/library/spotlights/diabetes-facts-stats.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fdiabetes%2Flibrary%2Ffeatures%2Fdiabetes-stat-report.html (accessed Sept. 9, 2021)

34. N/A. “Parkinson’s disease.” Mayo Clinic. https://www.mayoclinic.org/diseases-conditions/parkinsons-disease/symptoms-causes/syc-20376055 (accessed Sept. 9, 2021)

35. M. Trudeau. “Involuntary Shaking Can Be Caused By Essential Tremors.” North Country Public Radio. https://www.northcountrypublicradio.org/news/npr/298361607/involuntary-shaking-can-be-caused-by-essential-tremors (accessed Sept. 9, 2021)

36. P. Smith. “U.S. footwear market-statistics & facts.” Statista. https://www.statista.com/topics/4704/us-footwear-market/ (accessed Sept. 9, 2021)

37. L. Robinson, M. Smith, and J. Segal. “Depression in Older Adults: Signs, Symptoms, Treatment.” Help Guide. https://www.helpguide.org/articles/depression/depression-in-older-adults.htm (accessed Sept. 9, 2021)

38. N/A. “Registry Plastic Shoe Horn, Black.” American Hotel Register. https://www.americanhotel.com/registry-plastic-shoe-horn-black/p/1057662 (accessed Sept. 9, 2021)

39. R. Carhart. “Amazon Shoppers Say These $24 Memory Foam Slippers Are So Comfortable It Feels Like They’re ‘Walking on Clouds’.” People. https://people.com/style/coface-plush-memory-foam-slippers-amazon/ (accessed Sept. 9, 2021)

40. N/A. “Go Tour Men’s Penny Loafers Moccasin Driving Shoes Slip On Flats Boat Shoes.” Amazon Fashion. https://www.amazon.com/Go-Tour-Loafers-Moccasin-Driving/dp/B079Q86X2B (accessed Sept. 9, 2021)

41. N/A. “Nike Mag Back to the Future (2016).” StockX. https://stockx.com/nike-air-mag-back-to-the-future-bttf-2016 (accessed Sept. 9, 2021)

42. N/A. “Diabetic Foot Care.” Peninsula Podiatry. https://peninsulapod.com/diabetic-foot-care/ (accessed Sept. 9, 2021)

43. N/A. “Obesity is a common, serious, and costly disease.” Overweight and Obesity Adult Obesity Facts. https://www.cdc.gov/obesity/data/adult.html (accessed Sept. 9, 2021)

44. S. Colby, and J. Ortman. “ Demographic Changes and an Aging Population.” Rural Health Information Hub. https://www.ruralhealthinfo.org/toolkits/aging/1/demographics (accessed Sept. 9, 2021)

45. N/A. “Statistics Who Has Parkinson’s?” Parkinson’s Foundation. https://www.parkinson.org/Understanding-Parkinsons/Statistics (accessed Sept. 9, 2021)

46. N/A. “How to Tell if Shoes are Non-Slip.” Shoerazzi. https://shoerazzi.com/how-to-tell-if-shoes-are-non-slip/ (accessed Oct. 15, 2021)

47. T. Jones, A. Iraqi, and K. Beschorner. “Coefficient of friction of footwear with and without “slip-resistant” labels.” Human Movement and Balance Lab, Department of Bioengineering, University of Pittsburgh, Pittsburgh, PA. COEFFICIENT OF FRICTION OF FOOTWEAR WITH AND WITHOUT “SLIP-RESISTANT” LABELS (accessed Oct. 15, 2021)

48. N/A. “what is the coefficient of evaporative resistance?” Quechua. https://www.quechua.com/how-do-you-measure-the-breathability-r-e-t-of-a-material (accessed Oct. 15, 2021)

49. N/A. “Diabetic Footwear Market-Growth, Trends, COVID-19 Impact, and Forecasts (2022-2027).” Mordor Intelligence. https://www.mordorintelligence.com/industry-reports/diabetic-footwear-market (accessed Oct. 15, 2021)

50. N/A. “Understanding Foam Firmness and Compression Strength and Applying The Values to Your Needs.” Foam Factory. https://www.foambymail.com/blog/understanding-foam-firmness-and-compression-strength-and-applying-the-values-to-your-needs/ (accessed Oct. 15, 2021)

51. N/A. “Ingress Protection-Dripping Water Tests(IPX1 and IPX2).” Keystone Compliance. https://keystonecompliance.com/ipx1-ipx2-dripping-water/ (accessed Oct. 15, 2021)

52. N/A. “Weight of Sheos.” What Things Weigh. https://whatthingsweigh.com/how-much-do-shoes-weigh/ (accessed Oct. 15, 2021)

53. H. Menz, M. Fotoohabadi , E. Wee, M Spink. “Visual categorisation of the arch index: a simplified measure of foot posture in older people.” Journal of Foot and Ankle Research. 2012;5(1):10. Published 2012 Jul 3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3388464/ (accessed Oct. 15, 2021)

54. N/A. “Body Segment Data.” ExRx. https://exrx.net/Kinesiology/Segments (accessed Oct. 15, 2021)

55. N/A. “Footwear size chart.” Armstreet. https://armstreet.com/footwear-size-chart.html (accessed Oct. 15, 2021)

56. S. Ira. “How Long Will It Stick? Understanding the Lifespan of Hook and Loop.” Hooke and Loop. https://www.hookandloop.com/blog/how-long-will-it-stick-understanding-the-lifespan-of-hook-and-loop (accessed Nov. 18, 2021)

57. N/A. “What is Cyanoacrylate (Super Glue) and How Does It Work?” MT Copeland. https://mtcopeland.com/blog/what-is-cyanoacrylate-super-glue-and-how-does-it-work/ (accessed Nov. 18, 2021)

58. N/A. “Dritz 3” Knit Elastic, Black, 2 yd.” Joann. https://www.joann.com/black-knit-elastic/11384385.html (accessed Jan. 23, 2022)

59. N/A. “Dr. Foot's Shoe Insoles, Foam Insoles for Shock Absorption and Relief from Plantar Fasciitis, Metatarsal and Heel Pain, Diabetic Foot Pain (Medium(Women's 6-10/ Men's 5-8)).” Amazon. https://www.amazon.com/Insoles-Absorption-Fasciitis-Metatarsal-Diabetic/dp/B08V5CY6HT/ref=sr_1_27?keywords=diabetic%2Binsoles%2Bwomens%2B9&qid=1642466024&refinements=p_36%3A-1500&rnid=386636011&s=hpc&sr=1-27&th=1 (accessed Jan. 23, 2022)

60. N/A. “Coats & Clark Extra Strong & Upholstery Thread 150 yd.” Joann. https://www.joann.com/coats-andamp-clark-extra-strong-andamp-upholstery-thread-150-yd/2430643.html (accessed Jan. 23, 2022)

61. N/A. “Gorilla Clear Glue, 1.75 Ounce Bottle, Clear, (Pack of 1).” Amazon. https://www.amazon.com/dp/B06WD6R96X/ref=redir_mobile_desktop?_encoding=UTF8&aaxitk=56759a7ccb42e0a0738bfc9e4d94aiezzdc6&hsa_cr_id=6813483780101&pd_rd_plhdr=t&pd_rd_r=3321f4da-0d4f-4896-8449-4a87ce1c95a2&pd_rd_w=zSAqu&pd_rd_wg=OoUNt&ref_=sbx_be_s_sparkle_mcd_asin_0_img&th=1 (accessed Jan. 23, 2022)

62. N/A. “Kiwi Unisex-Adult Shoe Waterproofer.” Amazon. https://www.amazon.com/KIWI-Waterproofer-Repellent-Hunting-Outdoor/dp/B01LXP7UTU/ref=sr_1_2?keywords=kiwi+boot+waterproofer&qid=1642527255&sr=8-2 (accessed Jan. 23, 2022)

63. N/A. “CleanAide Silver Embedded Cleaning Microfiber Towels Ultra Cut 12 X 12 Inches 25 Pack.” Amazon. https://www.amazon.com/Udderly-Clean-Antimicrobial-Silver-Microfiber/dp/B01E0PWNVO/ref=sr_1_5?crid=RWJAABDBTR24&keywords=antimicrobial+fabric&qid=1642543323&sprefix=antimicrobial+fabric%2Caps%2C97&sr=8-5 (accessed Jan. 23, 2022)

64. C. Yates. “The maths behind the fastest person on Earth (and no it’s not Usain Bolt).” The Conversation. https://theconversation.com/the-maths-behind-the-fastest-person-on-earth-and-no-its-not-usain-bolt-63732#:~:text=Despite%20this%2C%20the%20fastest%20human,Bolt%20%E2%80%93%20at%20least%20for%20now (accessed Jan. 23, 2022)

XVIII. Appendix

Requirements	Pregnancy	Engineer	Elderly	Prostheist	Caregiver
Donning	✓	✓	✓	✓	✓
Doffing	✓	✓	✓	✓	✓
Flexible	✓		✓	✓	✓
Self-Tightening		✓			
Non-Slip			✓	✓	✓
Water Resistant				✓	
Cost Effective	✓	✓	✓		
Breathable				✓	
Easily Visible			✓	✓	✓
Comfortable, Arch Support	✓		✓		✓
Strong, Durable			✓		✓
Aesthetically Appealing				✓	
Antibacterial, Antimicrobial				✓	
Detect and Remove Foreign Objects				✓	

Table A: Customer Requirements- Gate 1 Stakeholder Interviews

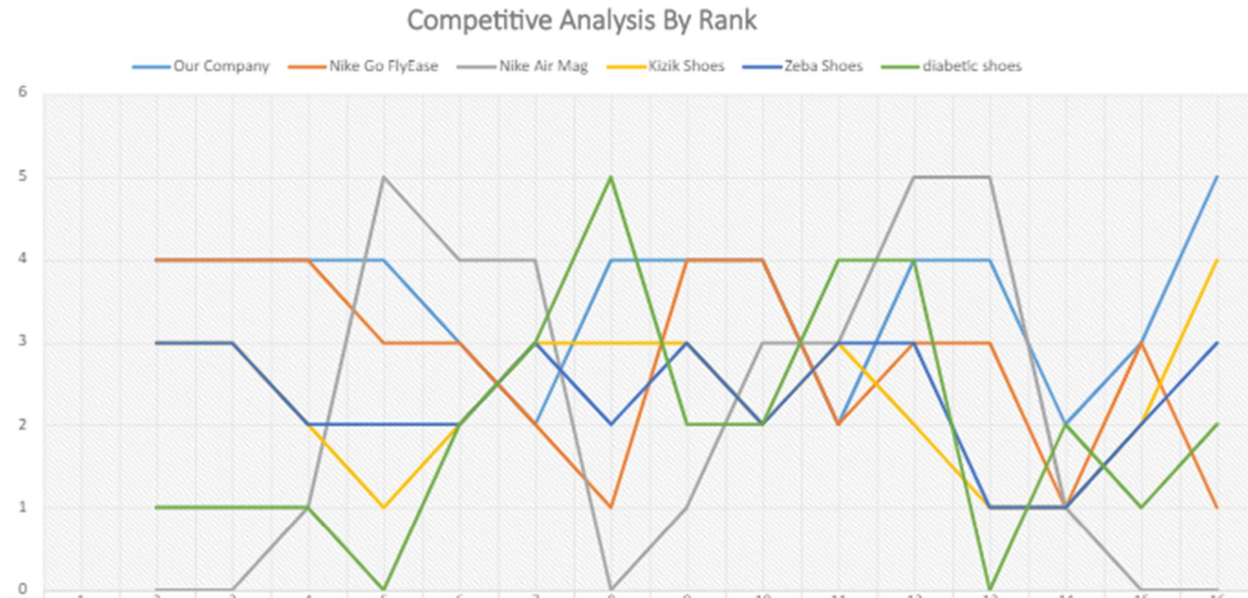
Row #	Max Relationship Value in Row	Relative Weight	Weight / Importance	Quality Characteristics (a.k.a. "Functional Requirements" or "Hows") Demanded Quality (a.k.a. "Customer Requirements" or "Whats")	Tensile strength of material	Cost	Time of insertion	Time of removal	Hands free insertion	Hands free removal	Distance between heel and shoe sole mid step	Coefficient of friction of tread material	Depth of tread	IPX-1 [43]	Thermal evaporative resistance coefficient [41]	ILD of sole material [42]	Arch Height Index falls within the range of a medium arch	Weight	Antimicrobial & antibacterial mechanisms are present	Percentage of shoe sole visible without foot inserted	Size of Shoe Opening
1	9	12.5	15.0	Ease of insertion	▲	▲	Θ	▲	Θ	▲	▲	▲	▲	▲	▲	O	O	O	▲	▲	Θ
2	9	11.7	14.0	Ease of removal	▲	▲	▲	Θ	▲	Θ	▲	▲	▲	▲	▲	▲	O	O	▲	▲	Θ
3	9	8.3	10.0	Flexible	Θ	▲	▲	▲	▲	▲	O	▲	▲	▲	▲	O	▲	▲	▲	▲	▲
4	9	10.8	13.0	Self tigthening	▲	▲	Θ	Θ	Θ	Θ	Θ	▲	▲	▲	▲	▲	▲	▲	▲	▲	O
5	9	6.7	8.0	Non-slip	▲	▲	▲	▲	▲	▲	▲	Θ	Θ	▲	▲	▲	▲	▲	▲	▲	▲
6	9	1.7	2.0	Water resistant	▲	▲	▲	▲	▲	▲	▲	▲	▲	Θ	O	▲	▲	▲	▲	▲	▲
7	9	5.0	6.0	Cost effective	▲	Θ	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲
8	9	3.3	4.0	Breathable	▲	▲	▲	▲	▲	▲	▲	▲	▲	O	Θ	▲	▲	▲	▲	▲	▲
9	9	10.0	12.0	Comfort	▲	▲	▲	▲	O	O	O	▲	O	Θ	O	Θ	Θ	Θ	▲	▲	Θ
10	9	5.8	7.0	Arch support	O	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	O	Θ	▲	▲	▲	▲
11	9	9.2	11.0	Strong & durable	Θ	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	O	▲	▲	▲	▲	▲
12	3	0.8	1.0	Aesthtically appealing	▲	O	▲	▲	▲	▲	▲	▲	O	▲	▲	▲	▲	▲	▲	O	O
13	9	2.5	3.0	Antibacterial & antimicrobial	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	O	▲	▲	▲	Θ	▲	▲
14	9	4.2	5.0	Ability of patient to detect and remove foreign objects	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	Θ	Θ
15	9	7.5	9.0	Availability of product	▲	Θ	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲

Figure A: Phase 1 QFD from the Design Inputs Stage

Engineering Requirement	Target Values
Tensile strength of material	≥ 37.5 N
Cost	≤ $100
Time of application	≤ 30 seconds
Time of removal	≤ 30 seconds
Hands free application	Possible
Hands free removal	Possible
Distance between heel and shoe sole mid step	≤ 2 cm
Coefficient of friction of tread material	≥ 0.16 [40]
Depth of tread	≥ 3 mm [39]
IPX-1* [43]	> 10 min [43]
Thermal evaporative resistance coefficient [41]	≤ 12 [41]
ILD** of sole material [42]	40 ≤ ILD ≤ 60 [42]
Height of arch	0.21 ≤ Arch Index ≤ 0.28 [45]
Weight	≤ 1.3 kg [44]
Antibacterial & antimicorbial mechanisms are present	Possible
Percentage of shoe sole visible without foot inserted	> 60%
Size of opening of shoe	1 ≤ Ratio of Length to Instep ≤ 1.1 [46]

*Ability to resist 1mm of rainfall per minute for a certain amount of time
** Indentation Load Deflection, which measures force necessary to compress a material by 75%

Table B: Engineering Requirements from the Design Inputs stage



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Our Company		4	4	4	4	3	2	4	4	4	2	4	4	2	3	5
Nike Go FlyEase		4	4	4	3	3	2	1	4	4	2	3	3	1	3	1
Nike Air Mag		0	0	1	5	4	4	0	1	3	3	5	5	1	0	0
Kizik Shoes		3	3	2	1	2	3	3	3	2	3	2	1	1	2	4
Zeba Shoes		3	3	2	2	2	3	2	3	2	3	3	1	1	2	3
diabetic shoes		1	1	1	0	2	3	5	2	2	4	4	0	2	1	2

Figure B: Analysis of Competitor Products Against Engineering Requirements

No	Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) Mechanism(s) of Failure	OCC
1	Rapid entry, hands free mechanism that allows the user to quickly insert and remove feet from the shoe	Unable to quickly put on or take off shoes; mechanism breaks upon insertion; mechanism breaks upon removal	Time is wasted	1	Environment breaks the mechanism, user misuse, degradation of materials	2
			Falling while putting on shoes	5		1
			Falling while taking off shoes	5		1
2	Sole that maximizes traction using a pattern of rubber	Degredation of material	Falling from slipping	4	Adverse weather conditions	1
		Unable to accommodate environmental changes	Falling from slipping	4		3
			Rolling ankle	2		2

No	CLASS	Suggested Mitigations	Verification	DET	Recommended Actions	Acting results SEV	OCC	DET	CLASS
1	B	Buy new batteries, buy new shoes	Ensure tensile strength of material ≥ 14MPa; time of application ≤ 30 seconds	1	Use durable materials and stress test mechanism	1	2	1	B
	A	Buy new batteries, buy new shoes	Ensure tensile strength of material ≥ 14MPa; time of application ≤ 30 seconds	1	Use durable materials and stress test mechanism	5	1	1	A
	A	Buy new batteries, buy new shoes	Ensure tensile strength of material ≥ 14MPa; time of application ≤ 30 seconds	1	Use durable materials and stress test mechanism	5	1	1	A
2	D	Buy new shoes, wear non-running shoes	Ensure tensile strength of material ≥ 14MPa; time of application ≤ 30 seconds	3	Use sustainable/long lasting materials	4	1	3	D
	C	Use materials that have traction	Device has high coefficient of friction and medium length of depth of tread (≥ 3mm)	2	Use materials that have traction	4	3	2	C
	C	Use sturdy materials	Ensure tensile strength of material ≥ 14MPa	1	Use sturdy materials	2	2	1	C

Table C: Preliminary risk analysis via the FMEA used in the Design Input stage

Symbol	Value	Description
+	1	Will meet specified engineering requirement
?	0	Uncertain if it will meet specified engineering requirement
-	-1	Will not meet specified engineering requirement

Design Demands	Design Candidates			
	Lever Slide	Flayed Shoe	Ratchet Shoe	Sole Lifter
Complete hands-free application and removal	+	+	+	+
Tight fit	+	+	+	+
Tightness Adjustment	-	-	+	-
Flexibility	?	-	?	+
Comfortable	+	+	-	+
Strong and durable	+	-	+	+
Cost effective	+	+	+	+
Feasible to create within time duration	+	?	+	+
Ability for patients to detect and remove foreign objects	+	+	-	+
Safe/low risk	+	+	+	+
Overall Score	+7	+3	+5	+8

Table D: Phase One Down Selection: Ranking of Four Design Ideas Against User Needs

Conceptual Design	Design Candidates	
	Pros	Cons
Sole Lifter	Simple in components design	Firm insole. May lose comfortability
	Stability within the heel	Lock wears down overtime: Latch may eventually not catch insole inside
	Useability. Simple in putting on and taking off shoes	Latch may be difficult to fit correctly in mechanism
	Complete hands free insertion and removal	Latch may cause discomfort upon heal strike
	Easy to detect and remove foreign objects	No adjustability in tightness
	Do not lose strength and durability of shoe	No antimicrobial or antibacterial material designated yet
	Cost effective	
	Feasible within time frame	
	Safe and low risk	
Overall Score	9	6

Table E: Phase Two Down Selection: Pros and Cons List of Highest Ranked Preliminary Designs

Legend		
Θ	Strong Relationship	9
O	Moderate Relationship	3
▲	Weak Relationship	1
++	Strong Positive Correlation	
+	Positive Correlation	
−	Negative Correlation	
▼	Strong Negative Correlation	
▼	Objective Is To Minimize	
▲	Objective Is To Maximize	
x	Objective Is To Hit Target	

Row #	Max Relationship Value in Row	Relative Weight	Weight / Importance	Demanded Quality (a.k.a. "Customer Requirements" or "Whats") / Quality Characteristics (a.k.a. "Functional Requirements" or "Hows")	Tensile strength of material	Cost	Time of insertion	Time of removal	Hands free insertion	Hands free removal	Distance between heel and shoe sole mid step	Coefficient of friction of tread material	Depth of tread	IPX-1 [43]	Thermal evaporative resistance coefficient [41]	ILD of sole material [42]	Arch Height Index falls within the range of a medium arch	Weight	Antimicrobial & antibacterial mechanisms are present	Percentage of shoe sole visible without foot inserted	Size of Shoe Opening	Our Company	Nike Go FlyEase	Nike Air Mag	Kizik Shoes	Zeba Shoes
1	9	12.5	15.0	Ease of insertion	▲	▲	Θ	▲	Θ	▲	▲	▲	▲	▲	▲	O	O	O	▲	▲	Θ	4	4	0	3	3
2	9	11.7	14.0	Ease of removal	▲	▲	▲	Θ	▲	Θ	▲	▲	▲	▲	▲	▲	O	O	▲	▲	Θ	4	4	0	3	3
3	9	8.3	10.0	Flexible	Θ	▲	▲	▲	▲	▲	O	▲	▲	▲	▲	O	▲	▲	▲	▲	▲	4	4	1	2	2
4	9	10.8	13.0	Self tigthening	▲	▲	Θ	Θ	Θ	Θ	Θ	▲	▲	▲	▲	▲	▲	▲	▲	▲	O	4	3	5	1	2
5	9	6.7	8.0	Non-slip	▲	▲	▲	▲	▲	▲	▲	Θ	Θ	▲	▲	▲	▲	▲	▲	▲	▲	3	3	4	2	2
6	9	1.7	2.0	Water resistant	▲	▲	▲	▲	▲	▲	▲	▲	▲	Θ	O	▲	▲	▲	▲	▲	▲	2	2	4	3	3
7	9	5.0	6.0	Cost effective	▲	Θ	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	4	1	0	3	2
8	9	3.3	4.0	Breathable	▲	▲	▲	▲	▲	▲	▲	▲	▲	O	Θ	▲	▲	▲	▲	▲	▲	4	4	1	3	3
9	9	10.0	12.0	Comfort	▲	▲	▲	▲	O	O	O	▲	O	Θ	O	Θ	Θ	Θ	▲	▲	Θ	4	4	3	2	2
10	9	5.8	7.0	Arch support	O	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	O	Θ	▲	▲	▲	▲	2	2	3	3	3
11	9	9.2	11.0	Strong & durable	Θ	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	O	▲	▲	▲	▲	▲	4	3	5	2	3
12	3	0.8	1.0	Aesthtically appealing	▲	O	▲	▲	▲	▲	▲	▲	O	▲	▲	▲	▲	▲	▲	O	O	4	3	5	1	1
13	9	2.5	3.0	Antibacterial & antimicrobial	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	O	▲	▲	▲	Θ	▲	▲	2	1	1	1	1
14	9	4.2	5.0	Ability of patient to detect and remove foreign objects	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	Θ	Θ	3	3	0	2	2
15	9	7.5	9.0	Availability of product	▲	Θ	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	5	1	0	4	3
16																										
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24																										
25																										

Figure C: Snippet of Phase Two QFD Used in the Design Inputs Stage

Potential Failure Mode	Potential Effects of Failure	SEV	OCC	DET	RPN
Unable to quickly put on shoes	Time is wasted	1	2	1	2
Mechanism (elastic or hook and loop) breaks upon insertion	No longer a tight fitted shoe; must choose another shoe to wear	2	2	2	8
Unable to quickly take off shoes	Time is wasted	1	2	1	2
Mechanism (elastic or hook and loop) breaks upon removal	No longer a tight fitted shoe; must choose another shoe to wear	2	2	2	8
Traction wears down material overtime	Slip is increased; therefore, probability of falling is increased	5	1	4	20
Outsole is damaged	Penetration of outsole damages shoe	5	3	1	15
Outsole does not absorb impact	Long term failure of ankle or knee due to harsh impact upon heel strike	5	3	3	45
Midsole does not provide cushioning with the hook and loop mechanism	User will feel uncomfortable	2	5	1	10
Insole does not maximize comfort	User is uncomfortable when wearing shoe	1	5	1	5

Table F: Condensed dFMEA For Risk Management of the Sole Lifter Design Idea

Figure D: Alpha Prototype Design: isotropic view on the left, interior view in the center, and sole attachment view on the right.

Symbol	Description
✓	Meets engineering requirement
?	Uncertain if it will meet engineering requirement or needs improvement
✗	Does not meet engineering requirement

Engineering Requirements	Sole Lifter Preliminary Prototype
Complete hands-free application and removal	✓
Comfortable	✓
User-friendly	✓
Secure fixture	✗
Flexibility	✓
Strong and durable	✓
Feasible to create within time duration	✓
Tight fit	✗
Arch support	✗
Water resistant	✗
Aesthetically appealing	?
Ability of patient to detect and remove foreign objects	✓

Table G: Preliminary Testing Results of the Alpha Prototype Against Engineering Requirements

			Shoe				
Relative Weight	Importance	Design Demands	Nike Revolution 5	Avia Titan 2.0	Brooks Anthem 4		
0.182	8	Hands Free Foot Insertion	○	○	○	●	Meets = 1
0.182	8	Hands Free Foot Removal	○	○	○	○	Does Not Meet = 0
0.159	7	User Friendly	○	○	○		
0.091	4	Tight Fit	●	●	●		
0.114	5	Flexibility	●	●	●		
0.045	2	Comfortable	●	●	●		
0.068	3	Strong & Durable	○	●	●		
0.023	1	Cost Effective	○	●	○		
0.136	6	Lead Time	○	●	○		
			0.250	0.477	0.318		

Table H: Weighted Down Selection of Parts: Shoe Chosen for Base of Design. Weighting was decided based off background research, customer reviews, and observations.

Item No.	Part No.	Item/Material	Quantity/Unit	Description	Unit Cost	Manufacturer/ Supplier
1.	Style #: 1072A055.001 UPC #: 193604964929	Athletic Shoe	1 pair	Men's Size 12 Avia Titan 2.0 Cross Training Shoe	$29.97	Avia
2.	ASIN: B0010HADEA	Hook & Loop	2 sets of pack of 4 sets	Industrial Strength	$2.97	Velcro Brand/ Amazon
3.	Item#: 11384385	Knit Elastic	16in of the 72in in a pack of elastic	3" Wide x 2yds Long	$0.46	Dritz/Joann Fabric and Craft Store
4.	ASIN: B08WD6R96X	Gorilla Super Glue	1/20th of a bottle	1.75 oz bottle, clear	$0.29	Gorilla Store/Amazon
5.	Item#: 2430643	Fabric String	1/2 Spool	Extra Strong Black 150 Yard Upholstery thread	$1.33	Coats & Clark/Joann Fabric and Craft Store
6.	ASIN : B01LXP7UTU	Waterproofing Spray	2oz	KIWI Boot Waterproofer | Water Repellent for Hunting, Hiking and Outdoor Boots | Spray Bottle, 10.5oz	$1.32	KIWI store/ Amazon
7.	ASIN : B08V5CY6HT	Shoe Insoles	2 Insoles	Memory Foam Insoles, Women's 6-10 Dr. Foot's Shoe Insoles, Foam Insoles for Shock Absorption and Relief from Plantar Fasciitis, Metatarsal and Heel Pain, Diabetic Foot Pain (Medium(Women's 6-10/ Men's 5-8))	$5.99	Dr. Foot/Amazon
8.	ASIN : B01E0PWNVO	Microfiber Towel	2 Towels	Silver Embedded Ultra Cut	$1.60	Eurow & O'Reilly Corp./Amazon
Total Cost:					$43.93	

Table I: Bill of Materials for Beta Prototype

Figure E: SolidWorks 3D Models of Sole Lifter Design to verify feasibility; Outsole on left, Insole mechanism in center, combined SolidWorks models on right

Figure F: Beta prototype shown in various orientations. The beta prototype was made with Dritz 3" Knit elastic bands[58], fabric thread[60], insoles[59], a pair of shoes[65 66], Velcro[56], super glue[61], waterproofing spray[62], and microfiber antimicrobial fabric[63].

Test Number	Test Name	Engineering Requirement Tested	Criteria	Result
1	Insertion & Removal Time	Easy Application & Removal	Foot insertion & removal time ≤ 30 seconds	Pass
2	Weight	Lightweight	Weight ≤ 0.65 kg	Pass
3	Heel & Shoe Sole Distance	Tight Fit	≤ 2 cm of space between heel & shoe sole mid-step	Pass
4	Insole Fit	Comfortable	Same dimensions as original shoe insole (10 7/16" long)	Pass
5	Insole Support	Supportive	0.21 ≤ Arch index ≤ 0.28	Pass
6	Sole Visibility	Easy Detection of Foreign Objects	Percentage of shoe sole visible without foot inserted ≥ 40%,	Pass
7	Tensile Strength	Durable	Ultimate strength ≥ 37.50 N	Pass
8	Fatigue	Durable	Can withstand 10,000 tensile cycles	Pass

Table J: Detailed verification testing table showing how the beta prototype performed during verification tests during the Design Outputs stage

Summary statistics:

Column	Mode	n	Mean	Std. dev.	Range	Min	Max	Median	IQR	Q1	Q3
Time Insertion	2.11	30	2.697	0.64271059	2.42	1.72	4.14	2.5	1.02	2.16	3.18
Time Removal	Multiple modes	30	3.0513333	0.5144983	2.28	1.81	4.09	2.955	0.5	2.83	3.33
Total Time (Seconds)	5.18	30	5.7566667	0.71547589	3.39	4.3	7.69	5.62	1.09	5.18	6.27

Table K: Verification testing results for putting the shoe on and taking the shoe off. The values above were obtained from StatCrunch program based on input numbers from time verification results. IQR represents variation from Q1 and Q3. Q1 represents the expectation for the fastest times to don and doff shoes, and Q3 represents the expectations for the slowest times. It is expected that the average population will take anywhere from 1.09 to 6.27 seconds to don and doff the PodAl Sole Lifter.

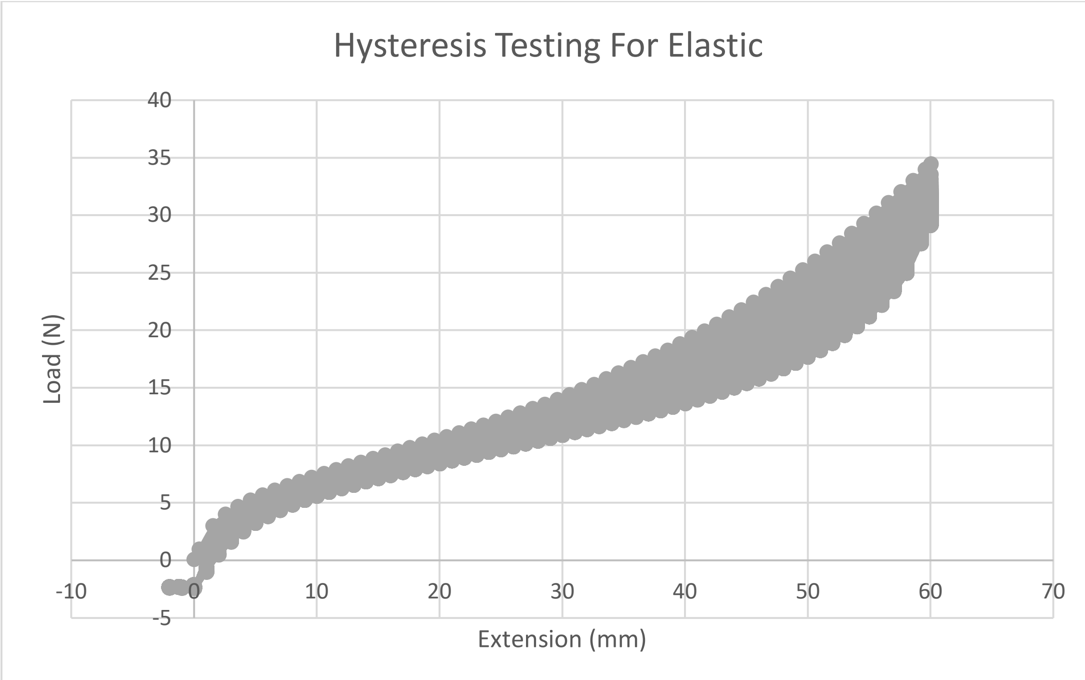

Figure G: Verification testing results for hysteresis testing for elastic bands

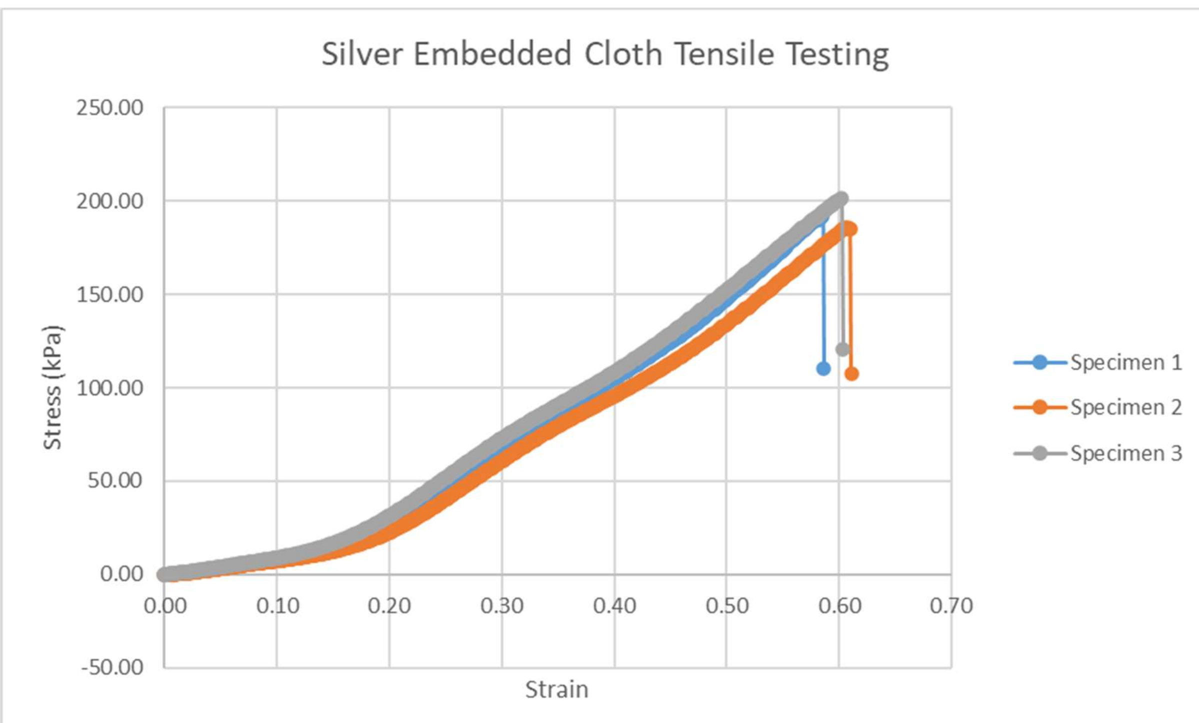

Figure H: Verification testing results for tensile testing of the silver embedded cloth

Customer Requirement Number	Customer Requirement	Validaton Method	Validation Name	Validation Procedure Number	Passed/Failed	Comments
1	Ease of foot insertion & removal, cost effective	Test	On/Off	1		
2	Self tightening, flexible, comfortable, breathable, cost effective	Demonstration	Running	2		
3	Self tightening, flexible, comfortable, cost effective	Demonstration	Jumping	3		
4	Self tightening	Demonstration	Tripping	4		
5	Strength & durability	Test	Rip Test	5		
6	Aesthetic appeal, easily detect & remove foreign objects	Inspection	Inspection	6		

Table L: Detailed validation testing table showing how the beta prototype performed during validation tests during the Medical Device stage

RPN	Name of Risk	Summary of Risk	Risk Level	How Risk was Mitigated
2	Time	Users could have difficulty putting the shoe on and taking the shoe off quickly	Low	Shoe was tested for ease of don and doff and passed all criteria
8	Break	The elastic or hook and loop mechanism breaks upon putting the shoe on or taking the shoe off	Low	Materials were selected through down selecteion to buy the best materials by strength and durability. Materials were verified and validated for strength and durability
20	Traction	The traction of the insole and mechanism wears down material overtime	Low	Materials were tested by hysterisis to verify that they will last the expected seven years of normal use
15	Outsole	The environment causes damage to the outsole of the shoe such as puncture	Low	Shoe was selected through down selection to purchase durable shoes with maximum protection
45	Impact	The outsole does not absorb the impact of the ground causing long term angle or knee failure	Medium	Shoe was selected through down selection to purchase durable shoes with maximum protection
10	Midsole Comfort	Midsole does not provide cushioning with the hook and loop mechanism causing the user to feel uncomfortable	Low	Microfiber antimicrobial fabric was used to reinforce the mechanism boosting comfortability
5	Insole Comfort	Insole does not maximize comfort	Low	Insole was selected via down selection to reinforce it to combat the stress put on the insole

Table M: Risk Summary Table

PodAl Gantt Chart

Maddison Schutt, Nicole Rizkala, Elizabeth Scheatzle, Alex Hershey, Austin Fowkes

Period Highlight: 1 | Plan Duration | Actual Start | % Complete | Actual (beyond plan) | % Complete (beyond plan)

ACTIVITY	PLAN START	PLAN DURATION	ACTUAL START	ACTUAL DURATION	PERCENT COMPLETE
Team Formation	1	1	1	1	100%
Need Statement	1	2	1	2	100%
Background Research	2	4	2	4	100%
Competitor Analysis	3	6	3	6	100%
Patent Search	2	4	2	4	100%
Stakehold Interviews	4	3	4	4	100%
Customer Requirements	6	2	6	2	100%
Engineering Requirements	7	2	7	2	100%
QFD	7	2	7	2	100%
Risk Assesment	7	3	7	3	100%
Brainstorming	11	2	11	2	100%
Down-Select Design Analysis	11	2	12	2	100%
Preliminary Modeling	12	2	12	2	100%
Preliminary Tests	12	2	12	2	100%
Alpha Prototype Creation	13	2	13	2	100%
Design QFD	13	2	12	3	100%
Desgin FMEA	13	2	12	3	100%
Alpha Prototype Test	14	1	14	1	100%
Revise Customer Specifications	15	1	15	1	100%
Winter Break	16	4	16	4	100%
Device Specifications	20	1	20	1	100%
Device Drawings	20	1	20	2	100%
Bill of Materials	20	1	21	1	100%
SolidWorks	20	2	21	2	100%
Analytical Modeling and Calculations	22	1	22	1	100%
Verification	22	1	21	1	100%
Report of Verification Results	23	2	21	2	100%
Spreadsheet Creation of Eng. Reqs, test method, date, tester name	24	1	24	2	100%
Risk Assesment dFMEA	24	1	23	1	100%
Validation Plans and Procedures	24	2	24	2	100%
Gate 4 Presentation	25	1	25	1	100%
Honors Report First Draft	26	2	26	2	100%
Honors Final Draft	30	4	30	3	100%
Video Script	26	5	26	1	100%
Video Filming	30	2	30	2	0%
NEOvations poster	29	3	28	1	25%
DHF	33	1	33	1	50%
Captsone Poster	29	3	29	4	0%
Capstone Script	33	1	33	1	0%
Capstone Brochure/Flyer	32	2	32	2	0%
Risk Mitigation	27	2	27	3	100%
Business Analysis	28	3	28	2	100%
Validation Testing	27	3	27	2	0%
Final Prototype	29	4	30	2	75%
Gate 5 Presentation	33	1	33	1	25%

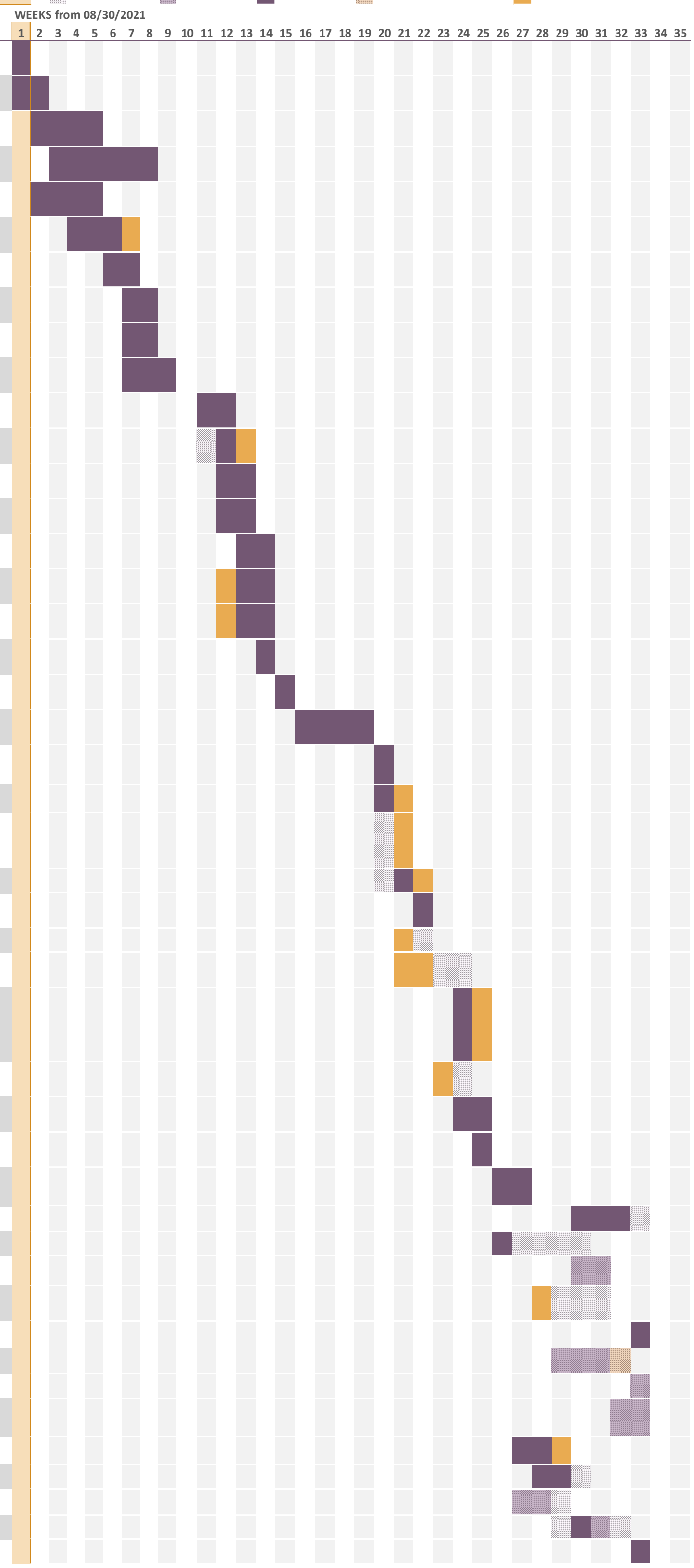

Figure I: Gantt Chart

Vendor	Item	Quantity	Cost
Amazon	Size 12 Avia TItan 2.0 Men's Cross Training Shoes - Lightweight Mesh Sneakers for Men - ASIN : B09819KZ7X	1 pair	$29.97
Amazon	Size 7 FLARUT Running Shoes Womens Lightweight Fashion Sport Sneakers Casual Walking Athletic Non Slip - ASIN : B07J5CPW33	1 pair	$29.99
Amazon	Waterproofing Spray: KIWI Boot Waterproofer | Water Repellent for Hunting, Hiking and Outdoor Boots | Spray Bottle, 10.5oz - ASIN : B01LXP7UTU	1 bottle	$6.94
Amazon	Sole Insoles: Memory Foam Insoles, Women's 6-10; Dr. Foot's Shoe Insoles, Foam Insoles for Shock Absorption and Relief from Plantar Fasciitis, Metatarsal and Heel Pain, Diabetic Foot Pain (Medium(Women's 6-10/ Men's 5-8)) - ASIN: B08V5CY6HT	5 packages	$29.95
Amazon	VELCRO: Brand Heavy-Duty Fasteners | 4x2 Inch Strips 4 Sets | Holds 10 lbs | Stick-On Adhesive Backed | Black Industrial Strength | For Indoor or Outdoor Use, 90209 - ASIN: B0010HADEA	1 package	$10.78
Amazon	Gorilla Clear Glue, 1.75 Ounce Bottle, Clear, (Pack of 1) - ASIN: B06WD6R96X	1 bottle	$5.87
Amazon	Microfiber Fabric: Silver Embedded Ultra Cut - ASIN: B01E0PWNVO	1 package of 20	$19.95
Joann Fabrics	Knit Elastic: Dritz 3" Knit Elastic, Black, 2 yd - Item # 11384385	2 packs	$13.98
Joann Fabrics	Fabric String: Coats & Clark Extra Strong & Upholstery Thread 150 yd	1 spindle	$2.44
		Total	$149.87

Table N: Project Expense Chart

Prototype Demonstrations:
https://docs.google.com/document/d/1W0UsRH9_5GCi2tFZTpUBUNyhPl1rH66GXTxdQQS75aI/edit
https://drive.google.com/drive/u/0/folders/1l9MJS1RYDU-wDLnJwbi1mWO4ZxCU_96O

Figure J: Links for videos of beta prototype demonstrations