Foot’s Ease:
An integrated smart shoe and paired activity tracker that improves mobility for foot drop patients

ESE Senior Design 2017-2018

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I. Executive Summary

As an interdisciplinary team of electrical and mechanical engineers, we started with the idea of designing a physical device that solved a problem and we were all drawn to medical devices, particularly leg-focused ones, because of our own personal and familial encounters with leg and knee injuries. We looked around for different issues to solve, but we were really intrigued by the issue of foot drop and the fact that there wasn’t a good solution available in the market. When we were looking at different issues with the leg, knee, and foot, we became aware of the fact that most issues in this area have a number of causes, so it is very difficult to make a universal fix. This is also the problem with some devices for foot drop, since they don't help patients with physical injury. This is what inspired us to make an electromechanical work around to aid foot drop. Since it is caused by musculoskeletal or nerve damage of foot causing gait imbalances, patients have difficulty in walking and could potentially experience secondary skeletal disorders which make the problem much worse.

After interviewing Penn Med Surgeons we came up to a conclusion that patients need a support device that is more flexible, less painful, more aesthetic and less limiting with a reasonable price. Another point that was common across our meetings was the ability to identify patient conditions overtime in an accurate way. Because many orthopedics related problems are still majorly diagnosed from patient's personal perspective, it does not let doctors to see the process information, in other words continuous data sample which could show better insight on patients daily activity levels. Thinking on how to address those pain points we designed an electro mechanical shoe that would allow patients better mobility, comfortable use and simultaneous data output mechanism.

This semester we were able to design the final prototype of our idea, Foot’s Ease that can improve the daily life and solve the mobility issues encountered by foot drop patients. We were able to increase the mobility, provide data visualization and customization in design at a reasonable price point. We proposed to offer in 2 product lines: Foot’s Ease Basic and Foot’s Ease Couture to be able to address the needs of our target patient groups. When designing the final product we also made sure that we abide by the industry rules and standards to ensure user safety and avoid potential ethical concerns.

II. Overview of Project

Foot drop is a general term for difficulty with ankle dorsiflexion (lifting the front part of the foot), and is a symptom from a multitude of diseases, such as multiple sclerosis, cerebral palsy, and diabetes as well as injuries, such as traumatic brain injuries, spinal cord injuries, stroke, and physical injuries to the lower leg. This results in a variety of unique conditions for patients. Left untreated, foot drop causes overcompensation in gait and increases risk for further injury.

Currently, those affected by foot drop are prescribed one of two options- a cheap, passive, bulky plastic ankle-foot orthosis (AFO) or an expensive, gait predictive functional electrical stimulator (FES) ankle cuff. Robotic systems for foot drop have remained within research labs and at the tens of thousands of dollars price point, and not commercialized.
Our proposed product, Foot’s Ease, will be an FDA Class I smart shoe medical device to assist ankle dorsiflexion in foot drop patients and provide real time gait data and fall detection, while integrating into the user’s daily life to improve the ease of adoption for the user at a reasonable cost to all stakeholders. This will provide a fashionable option for foot drop patients that could be used as a long-term solution without the social stigma of the current market solutions. Foot’s Ease can provide walking stability to anyone affected by drop foot since it relies on a mechanical solution.

III. Method of Solution

A. Specification and requirements

Foot’s Ease uses distance sensors and an accelerometer to sense the location of the foot, and the current stage of the gait cycle. There will be two distance located on the bottom of the shoe that measure the distance from the ground. The accelerometer senses the acceleration of the foot as it moves in the air and also gauges the angle of the foot. With this sensor data, our code sends a signal to our H bridge motor driver which then powers the motor to either lift or drop the foot. For specifications, we need the distance sensors to be able to measure from about 6 inches off the ground, the accelerometer needs to be able to measure angles from about 15 degrees to -35 degrees, and the motor speed to enable walking at 3 miles per hour. The motor speed and torque specifications match the dynamic analysis for walking speed requirements and the static analysis for total weight of the foot and shoe that informs the torque requirements. We will be designing the shoe to meet the requirement of a standard size 10 men’s shoe and 220 lb user weight.

To design a new type of powered prosthetic, we utilized recent technological developments such as the Internet of Medical Things (IoMT) and design for 3D printing. Gait data from the accelerometer can be sent to the cloud, as a way to quantitatively track patient recovery. Design for 3D printing allows the shoe to be parametrically fit to different standard shoe sizes.

B. Classes and Knowledge That the Project Depend On

The Foot’s Ease project of designing a smart shoe medical device splits into a few categories of knowledge: technical (EE, MEAM), medical, and business. Between the four members of our team, we have covered a wide breadth and depth of courses that provide a baseline knowledge set to build upon while developing our project.

Julia has drawn heavily on prototyping and lab classes to design, build, and test mechanical systems to accomplish a set task like MEAM 101 (Mech Design), MEAM 201 (Mfg), MEAM 247 (Soph Lab), MEAM 347 (Jun Lab), and IPD 501 (Advanced Mfg). The mechanical design skills are complemented with electromechanical integration skills and PCB design through MEAM 510 (Mechatronics) and ESE 292 (PCBs). Julia learned the complexities of medical device design in IPD 504 (Rehab Robotics).
Cody has worked on the mechanical design of Foot’s Ease by developing physics models and free-body diagrams (FBDs) based off classes like MEAM 210 (Statics), MEAM 211 (Dynamics), and MEAM 520 (Robotics). These models also allow parametric equations that allow us to scale and modify the design based off different variables.

Kelly has designed the electrical control systems with circuit design skills based off ESE 350 (Microcontrollers), ESE 505 (Controls), ESE 224 (Signals), and ESE 292 (PCBs). Once the breadboarded circuit design was tested and debugged, it was converted into a custom PCB design that fits into the midsole of the shoe. The coding knowledge came from a combination of classes, such as CIS 120 and knowledge of Arduino from ESE 111.

Ece has been developing wireless data processing using skills from ESE 350 (Microcontrollers), ESE 292 (PCBs), ESE 224 (Signals), and BE 470 (Medical Devices). In addition, she brings the business and revenue model design aspect to the product through classes like MGMT 235 (Tech Innovation & Entrepreneurship) and MGMT 237 (Mgmt of Technology).

IV. Self-learning.

Julia:
I researched different materials and processes in order to choose the materials and manufacturing method that satisfied the engineering and cost requirements for Foot’s Ease. The loading analyses were simulated with Finite Element Analysis for the design, and then tested in real life by putting weight on the shoe.

Cody: This project required me to design a free body diagrams and do analysis of an undesigned system. I needed to adjust the design to fit specific requirements of the shoe that we had to determine ourselves. This was the first project in which I needed to design the specifications for a mechanism from the ground up.

Kelly: This project required a lot of skills from classes I had taken with some additional learning to build on that. For the PCB design, I built on my knowledge from ESE 292, but had to do some more complex board design which I had to look up separately. I also had to do some more circuit design for the H-bridge, which I hadn’t done before.

Ece: This project gave me the opportunity to use and further develop my electrical engineering and data processing skills using sensors designing a web app as well as my Wharton degree background when we worked on the business plan and the revenue model creation for the M&T integration Lab. It was a great way to combine my interdisciplinary knowledge under a product design process with the Senior Design Class.
V. Design and Iteration

Foot’s Ease was designed with the user, stakeholders, and functional expectations in mind. These user and stakeholder needs were found through over 20 conversations with clinicians, gait researchers, and our medical advisor. These conversations guided our priorities during the design of Foot’s Ease. For example, we were told by a gait researcher that the potential real environment gait data tracking functionality was a key differentiator for our product between consumer and research devices. A prosthetist and orthotist specialist informed us that we had invented a novel type of orthosis, in a traditionally under innovated space of orthotics. As a medical device, Foot’s Ease required adherence to regulatory standards such as the safe packaging of the battery and electronics. To be useful, the design had to be well-engineered to satisfy the technical specifications.

As with the design of many orthotics and prosthetics, we started with the gait cycle, which breaks a single step into stages. The toe-off stage has the highest pressure, where the user’s weight is on the small toe area. Using a standard Men’s Size 10 shoe and 220 lb loading weight, the toe structure was designed to have a 2.5 safety factor during maximum loading conditions during the gait cycle. The free body diagram of a 1 DOF system of the system helped us determine our motor specifications.

The mechanism started with a lace lift that pulled the shoe from above over a cuff on the ankle. With the user safety in mind, we didn’t want to put any pressure on the user’s ankle, especially side loads that could injure the user. In addition, aligning the pulley and cable were key for reducing friction, as well as eliminating the binding that we saw in our fall prototype. The design became a push against the back of the ankle to lift the foot, rather than push on any part of the ankle. Instead of lifting from above by the laces, the mechanism lifts from pulling the midsole up.

Foot’s Ease was developed through a very iterative product development process, which allowed us to keep our mechanical and electrical subteams informed, and receive better feedback from our advisor. Please see the below Diagram 1 for the visual details of the iterative process.
We followed certain industry standards during our final prototype process which will be addressed in more detail in the following sections of the report. (XI. Standards and Compliance) As shown in the Diagram 2 on the previous page, we designed the mechanical and electrical components of the project by following the American National Standards, FDA rules, IEEE standards as well as HIPAA to ensure the user safety and device durability in our product design.
As of now our project falls under FDA Class 1 Medical device category with its design. It mostly satisfies the standards that we covered, for the internet of things and data category in order to satisfy the patient data safety in a more meticulous way we will be working with an external data encryption service provider companies such as Thingworx. As of now it is patient motion data is outputted to a private Thingspeak channel which can be visible only if you have the data key. Nevertheless, because it is a medical personal data we looked at the encryption platforms to make sure even further to keep the patient data completely secured.

![Foot's Ease](image)

Diagram 3: Annotated Exploded View of the Final Prototype

VI. Societal, global and/or economic impact.

A. Relate the global, economic and/or societal context of the project.

As listed in the Overview of the Project, Foot’s Ease targets patients with foot drop, which is a symptom of a wide range of common afflictions like MS and diabetes. Globally, there are many people affected by foot drop, and the global orthopedic braces and supports market will reach $5.8 billion by 2025. Societally, Foot’s Ease will improve the long-term rehabilitation plan for many patients, improve their gait abilities, and facilitate reintegration into society without the social stigma associated with medical-looking orthotics or functional electrical stimulator (FES) devices. Our smart shoe design follows the macro trend of wearables and personalized medical devices and data feedback to improve rehabilitation outcomes.

B. Potential Ethical Issues and Ways to Address Them

Ethical concerns that we might face is that we need to put human life and user safety above any value when designing our product. There is an ethical requirement to identify and set the minimum product requirements for user safety. In medical device design and manufacturing, process control and documentation are crucial to create accountability for consistent quality. If user gait data is stored and shared with clinicians, patient privacy and anonymity will follow HIPAA standards. That is why before releasing the product to market we will be working with an external encryption service provider.

Moreover human testing on the device would also require additional permits from the hospitals and research institutes. Hence in order to avoid any test related ethical concerns we would work with Penn Med Gait research lab if we continue with human testing with the device.

VII. Summary of Meetings

To summarize our meetings, in the first semester, we focused on meeting with as many different people as possible for our need finding. This included doctors such as gait specialists and podiatrists to people who have had leg and foot injuries to see the market size, feasibility of design, and pain points to fix. The second semester was focused on moving from our fall MVP design to an integrated, wearable product.

Table 1: Team and Interview Meeting Notes

<table>
<thead>
<tr>
<th>Dates</th>
<th>Advisor/Consultant</th>
<th>Title</th>
<th>Meeting Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sept 15</td>
<td>Dr. Ari Brooks (medical</td>
<td>UPHS Surgical Oncology</td>
<td>Starting to narrow the project focus from powered leg exoskeleton to a foot drop</td>
</tr>
<tr>
<td></td>
<td>advisor)</td>
<td></td>
<td>device</td>
</tr>
<tr>
<td>Sept 20</td>
<td>Dr. Michelle Johnson</td>
<td>Assistant Professor of Physical Medicine and Rehabilitation</td>
<td>Consulted on approaching a rehabilitation robotics project, arranged a tour of</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>her PM&amp;R lab</td>
</tr>
<tr>
<td>Sept 20</td>
<td>V. Zhang</td>
<td>Friend with leg injury</td>
<td>Ruptured Achilles tendon, walked through her physical rehabilitation process</td>
</tr>
<tr>
<td>Sept 20</td>
<td>D. Mason</td>
<td>Friend with foot injury</td>
<td>Multiple metatarsal fractures, walked through her physical rehabilitation and</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>PT process</td>
</tr>
<tr>
<td>Sept 23</td>
<td>R. Shinkle</td>
<td>Friend with leg injury</td>
<td>ACL/ MCL tear, walked through her physical rehabilitation and PT process</td>
</tr>
<tr>
<td>Date</td>
<td>Name</td>
<td>Organization / Position</td>
<td>Description</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------</td>
<td>----------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Sept 26</td>
<td>Dr. Michael Hast and Dr. Josh Baxter</td>
<td>Penn Motion Lab</td>
<td>Advised on previous Penn Engineering senior design projects, and talked from a research perspective</td>
</tr>
<tr>
<td>Sept 28</td>
<td>Ryan Cummings, PT, MS, OC</td>
<td>Penn Sports Med PT</td>
<td>Observed a physical therapy session, asked about current technologies in use</td>
</tr>
<tr>
<td>Sept 28</td>
<td>Dr. Ari Brooks (medical advisor)</td>
<td>UPHS Surgical Oncology</td>
<td>More discussion on current project focus, connected us to more people to talk to</td>
</tr>
<tr>
<td>Oct 2</td>
<td>Eric Sugalski</td>
<td>Smithwise CEO</td>
<td>Learned about phase 2 of the FDA approval of medical devices</td>
</tr>
<tr>
<td>Oct 7</td>
<td>Dr. Samir Mehta</td>
<td>Trauma and Fracture Services - Orthopaedic Surgery</td>
<td>Almost pivoted to an implanted orthopedic surgery device</td>
</tr>
<tr>
<td>Oct 13</td>
<td>Dr. Andres Deik</td>
<td>Trauma and Fracture Services - Orthopaedic Surgery</td>
<td>Physician perspective on our project, more cons of the current AFO solution for foot drop</td>
</tr>
<tr>
<td>Oct 20</td>
<td>Dr. Wen Chao</td>
<td>Penn Med Orthopedic Surgeries (Foot and Ankle Services)</td>
<td>Learned about gait cycles and shortcomings of current solutions</td>
</tr>
<tr>
<td>Nov 22</td>
<td>Dr. Samuel Pierce</td>
<td>Widener University Associate Professor, Institute for PT Education</td>
<td>Advised on current prototype and potential user testing pending IRB approval</td>
</tr>
<tr>
<td>Dec 13</td>
<td>Team meeting</td>
<td>-</td>
<td>Summary of semester and scheduling the next semester</td>
</tr>
<tr>
<td>Jan 16</td>
<td>Team meeting</td>
<td>-</td>
<td>Check in and division of tasks</td>
</tr>
<tr>
<td>Jan 26</td>
<td>Team meeting</td>
<td>-</td>
<td>Working on individual tasks together</td>
</tr>
<tr>
<td>Feb 8</td>
<td>Team meeting</td>
<td>-</td>
<td>Check in on tasks and updating timeline</td>
</tr>
<tr>
<td>Feb 16</td>
<td>Team meeting</td>
<td>-</td>
<td>Group work on project</td>
</tr>
<tr>
<td>Feb 18</td>
<td>Team meeting</td>
<td>-</td>
<td>Group work on project</td>
</tr>
</tbody>
</table>
Feb 26 | Team meeting | Group check-in and division of more tasks before spring break
---|---|---
Mar 14 | Team meeting | Check in on progress
Mar 22 | Team meeting | Group work together
Mar 24 | Presentation | M&T Summit-practice for presentation
April 3 | Team meeting | Check in and group work
April 6 | Team meeting | Group work and integration
April 7 | Team meeting | Integration of product and debugging
April 8 | Team meeting | Integration of product and debugging
April 16 | Team meeting | Review of demo day and plans for SEAS competition
April 21 | Team meeting | Planning for SEAS competition
April 22 | Leroy Sibanda, Senior design TA | Practice and comments on SEAS-wide presentation

### VIII. Final schedule with milestones

#### Table 2: Team Spring Semester Milestones

<table>
<thead>
<tr>
<th>Date</th>
<th>Julia</th>
<th>Ece</th>
<th>Cody</th>
<th>Kelly</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/24</td>
<td>Final Model CAD</td>
<td>Standards Research</td>
<td>Order Battery</td>
<td>Order Sensors</td>
</tr>
<tr>
<td>1/31</td>
<td>3D Printed Parts</td>
<td>WIFI Data Transfer options research</td>
<td>Motor Requirements</td>
<td></td>
</tr>
<tr>
<td>2/7</td>
<td>Nylon Material Research</td>
<td>Cost Analysis</td>
<td>Battery Compartment</td>
<td>Soldering Electrical Components</td>
</tr>
<tr>
<td>2/14</td>
<td>Assembly</td>
<td>WIFI Data Transfer</td>
<td>Assembly</td>
<td>Sensors Working</td>
</tr>
<tr>
<td>2/21</td>
<td>Mid-semester Demo</td>
<td>Mid-semester Demo</td>
<td>Mid-semester Demo</td>
<td>Mid-semester Demo</td>
</tr>
<tr>
<td>2/28</td>
<td>Strength Testing</td>
<td>WIFI Data Transfer</td>
<td>Battery Integration</td>
<td>Custom PCB</td>
</tr>
</tbody>
</table>
IX. Discussion of teamwork.

A. Overall Teamwork Task Allocation:

Before the final integration of the project, we used our team meetings primarily to check in on our progress and divide more tasks for moving forward. Our communication was very effective, as was our group message via Facebook, meaning we didn’t have to work all at once as frequently just for accountability.

This semester was focused more on the mechanical and electrical integration of the product, so we did meet as a group more frequently to work together. We would divide up work on presentations and the product so that we were all working effectively during our time together. Towards the end, we created a final list of tasks to accomplish before demo day and divided them amongst the team as people finished other tasks. This helped us get everything prepped and ready for demo day to be as successful as possible.

B. Individual Member Contributions:

Julia: I worked on mechanical design from selection of materials and manufacturing through electromechanical integration. The mechanical design required iterative prototyping to accommodate electronics packaging and different user requirements as well. Once the CAD and design were finalized, explode views and renders were created to explain the concept better.

Cody: I worked on the analysis and justifications of the mechanical design. The motor and pulley system required FBD, static, and kinematic analysis to carry the correct load and
move at the correct speed. The shoe also needed to be designed to withstand the force of an adult, while protecting the PCB, battery, motor.

Kelly: I worked on the majority of the electrical components for the project. In the fall semester, this meant designing the circuit for the sensors, the voltage regulation for the board with the motor and components, and the H-bridge to act as the motor driver as well as the selection of these electrical components. I also wrote the code for the MKR1000 to know when to lift and drop the foot. The second semester involved moving this circuit design to a custom PCB that fit in the toe of the shoe. We were fortunate that we only had to do two iterations of the PCB in order to have our final design. We had some adjustments to the code to fine-tune it to the final shoe design and some adjustments to the H-bridge design.

Ece: I worked on the data transfer and display parts of the project. This is a crucial differentiating element of our product from the other alternative products in the market. There is no other product that allows real-time data output and display of gait cycle of a user. I was able to design that by collecting the accelerometer data in x, y, z axes as well as the step count data to graph the motion information of patients on Thingspeak IoT platform using the data output by the MKR 1000 WiFi connection. I also worked on the market research, business and revenue models to show the viability and feasibility of our project in the overall orthopedic devices market. When making the pricing decisions I made sure to update the pricing data for every iteration by keeping in mind that we need to have a certain margin of sales to be able make a profitable and scalable business. She also looked at the industry related standards that needs to be addressed when designing the product.

Since the Fall Semester Prototype, we integrated the idea into the form factor of a shoe. This required over a dozen iterations of CAD, four 3D printed prototypes, and two iterations of custom PCB to get to the Spring Semester Demo Prototype. At the start of that design process, we created static and dynamic analyses for Foot’s Ease for a typical (using Cody for shoe size and weight) user, and defined engineering specifications. That lead to the motor and battery selection, which were the main design components that the rest of the CAD were built around. In addition, the entire mechanism of the shoe underwent significant change since the last semester, as explained in Section VI. Once the product was more defined, we established its competitive positioning, materials and manufacturing costs, pricing strategy, and potential market for Foot’s Ease.

X. **Budget and Justification:**

We divided our cost breakdown as hardware and the mechanical manufacturing cost. As of now the total cost is $373.64 per shoe. More detailed cost breakdown could be seen below in the Table 3 as shown below.
### Table 3: Cost Breakdown of the Foot’s Ease Basic Product

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Part No.</th>
<th>Unit Price ($)</th>
<th>Qty.</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shoes (for teardown)</td>
<td>Amazon XIANV</td>
<td>$23.99</td>
<td>1</td>
<td>$23.99</td>
</tr>
<tr>
<td>12V Li-Ion Battery</td>
<td>MG Electronics LBP-124500</td>
<td>$61.94</td>
<td>1</td>
<td>$61.94</td>
</tr>
<tr>
<td>Arduino MKR1000 Wifi</td>
<td>Arduino MKR1000</td>
<td>$34.99</td>
<td>1</td>
<td>$34.99</td>
</tr>
<tr>
<td>Triple Axis Accelerometer Breakout</td>
<td>Sparkfun ADXL335</td>
<td>$14.95</td>
<td>1</td>
<td>$14.95</td>
</tr>
<tr>
<td>IR Distance Sensors (10cm-80cm)</td>
<td>Adafruit ADA164</td>
<td>$14.95</td>
<td>2</td>
<td>$29.90</td>
</tr>
<tr>
<td>30RPM DC High Torque Motor</td>
<td>Amazon uccell</td>
<td>$15.99</td>
<td>1</td>
<td>$15.99</td>
</tr>
<tr>
<td>Weather-Resistant Steel Cable</td>
<td>McMaster 8912T125</td>
<td>$7.75</td>
<td>1</td>
<td>$7.75</td>
</tr>
<tr>
<td>Shielded Ball Bearing</td>
<td>McMaster 60355K41</td>
<td>$6.56</td>
<td>2</td>
<td>$13.12</td>
</tr>
<tr>
<td><strong>Hardware Total Cost</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>$183.64</strong></td>
</tr>
<tr>
<td>PCB Production</td>
<td>PCB Way</td>
<td>$5.00</td>
<td>1</td>
<td>$5.00</td>
</tr>
<tr>
<td>CFF GRF 3D Printing</td>
<td>3D Hubs</td>
<td>$185.00</td>
<td>1</td>
<td>$185.00</td>
</tr>
<tr>
<td><strong>Manufacturing Total Cost</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>$190.00</strong></td>
</tr>
<tr>
<td><strong>TOTAL COST</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>$373.64</strong></td>
</tr>
</tbody>
</table>

![Diagram 4: Value Based Pricing Model for Foot’s Ease Products and the Market Alternatives](image)

Diagram 4: Value Based Pricing Model for Foot’s Ease Products and the Market Alternatives
We offer 2 Foot’s Ease product types: Foot’s Ease Basic and Foot’s Ease Couture
Foot’s Ease Basic respond needs of patients that prefer fast and affordable shoe option at $1000. Foot’s Ease Couture serves the needs of patients with more complex preferences and personalized design with a slightly more price, $1500 and slower delivery as a result of complex personal design and manufacturing process. The difference between $375 and $1000 will cover the labor, overhead costs and profit margin. The increase to $1500 reflects the personalized mapping and R&D costs. When compared to other available options such as FES at $4500 and Powered Exoskeleton at $10000, our product price looks strikingly reasonable for the value it offers. This makes Foot’s Ease a great opportunity for the orthopedic support devices market.

XI. Revenue Model and Market Landscape:

After an extensive market research we found out that the orthopedic support systems market is to grow as large as 5.8 Billion by 2025. ² The current big players in the market are the major biomedical companies such as Medtronics, Abbott, General Electric and Johnson & Johnson.

Current solutions are:
1- Functional Electrical Stimulator (FES) : electrical device that sends electrical stimulation to muscles, not comfortable to wear and does not provide any mobility or real time motion data.
2- Ankle Foot Orthosis (AFO) : passive brace that keeps the leg and ankle at a stable angle, not providing any mobility or data, often times it is uncomfortable to wear due to its rigid structure.
3- Powered Exoskeleton: Electro mechanical wearable device that is very complex and only available to use at lab settings not in real life, also very costly.

Below on Diagram 5 the images of the current solutions and the Foot’s Ease shoe are demonstrated.

Diagram 5: Current Market Solutions and Foot’s Ease

Foot's Ease is providing increased mobility and real time and real environment data monitoring features which did not exist before in the previous solutions. We are offering those crucial benefits to drop foot patients at a very reasonable price range as well. Thus this makes Foot’s Ease the most attractive potential solution in the market.

Below Diagram 6 shows where all 4 products stay on the competitive matrix on cost and mobility attributes.

Diagram 6: The Cost Matrix on Mobility Attribute Foot’s Ease vs Current Market Alternatives

Our product will be purchased after doctor patient talk and understand the needs of the patient. If patient prefers a faster and non customized option he/she will order the Foot’s Ease Basic on our website. We will be using third party payment services such as PayPal. If the patient needs a custom design his/her feet will be mapped and custom design process will follow for him/her. This will be a more expensive and time taking process, but it will allow personalized design flexibility. Finally order will be delivered to patients as ready to use right after the delivery.

Diagram 7 displays the process as follows:

Diagram 7 : Revenue Model for Foot’s Ease Products
XII. Standards and compliance:

Because we are designing a complex electromechanical biomedical device we wanted to make sure that we abide by certain healthcare, electrical engineering, mechanical engineering and informatics sectors standards. We made a comprehensive research on the American National Standards (ANSI), Food and Drug Administration (FDA), Institute of Electrical and Electronics Engineers Standards (IEEE) and Health Insurance Portability and Accountability Act (HIPAA) when we were designing the final prototype of the project. As of now our product falls under FDA Class 1 medical device category. Please see the below chart for the detailed outline of all crucial standards we followed when designing the final iteration.

Table 4: Detailed Outline of the Standards and Foot's Ease Design Connection

<table>
<thead>
<tr>
<th>STANDARD</th>
<th>CODE</th>
<th>TITLE</th>
<th>Foot's Ease Connection</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANSI</td>
<td>ASTM F1541-17</td>
<td>Standard Specification and Test Methods for External Skeletal Fixation Devices</td>
<td>Testing and mechanical design requirements of Foot's Ease measurement and fixation related testings abides by this standard</td>
</tr>
<tr>
<td></td>
<td>ASTM F565-04(2013)</td>
<td>Standard Practice for Care and Handling of Orthopedic Implants and Instruments</td>
<td>This standard relates to Foot's Ease handling Standards as a medical device.</td>
</tr>
<tr>
<td></td>
<td>ASTM F1839-08(2016)</td>
<td>Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments</td>
<td>Materials used in the design of the medical device, external material and the internal component materials such as the PCB</td>
</tr>
<tr>
<td>IEEE</td>
<td>IEEE 802.11</td>
<td>Wireless Local Area Networks</td>
<td>Wifi enabled medical wearable device.</td>
</tr>
<tr>
<td>CFR</td>
<td>45 CFR 46</td>
<td>Protection of Human Subjects</td>
<td>Wearable device with human users, physical safety requirements</td>
</tr>
<tr>
<td></td>
<td>21 CFR 890 sub clause:</td>
<td>890.348 Physical Medical Devices</td>
<td>Foot's Ease is a Class 1 Medical device.</td>
</tr>
<tr>
<td>HIPAA</td>
<td>Patient Data Privacy Rule</td>
<td></td>
<td>Battery safety and handling.</td>
</tr>
</tbody>
</table>

XIV. Conclusion

Overall, we are very pleased with the product we were able to create. After getting feedback from our advisors and clinicians, as well as the judges, we believe that this is a very viable product for market. We did a number of designs for the electrical and mechanical sides of the product during the fall semester and were pleased with the success of our fall MVP. We made some adjustments to it during the spring, but we focused primarily on integrating the electrical and mechanical designs into a more compact, sleek structure.
We were very pleased with our model for demo day and our 3-D model in CAD that can be used to create a Foot's Ease shoe for any US size shoe. We are talking about how we would like to continue with Foot's Ease in the future and are looking into patents at the moment. We all learned a lot about teamwork and product design through this project. This was different than other classes we have taken in that it provided a more realistic timeline for the development for a final product.

We had to deal with constraints due to time and ordering parts, as well as budgeting to be competitive in the market. We had to divide tasks and hold each other accountable for deadlines since they affected the whole team. We learned a lot during this past year and came together as a team to create something that we're all very proud of.
XV. Appendices

![Diagram of sensor system with stages:
- Sensor
- Custom PCB
- Motor
- Pulley
- Lift Shoe & Clear Ground
- User App
- Improved Treatment
- Gait Data
- Medical Log
- Encrypt & Transmit
- Improved Gait Assistance]