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Hands-Free Wearable Crutch

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ENTITLED

HANDS-FREE WEARABLE CRUTCH

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HANDS-FREE WEARABLE CRUTCH

By

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Equal participants

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Department of Bioengineering
Santa Clara University
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ABSTRACT

Traditional crutches have long been the primary mobility aid for patients with a lower-leg injuries. However, forced to place most of their weight on their hands and underarms while balancing on only one leg, users find that such crutches present a physically demanding, uncomfortable, and inconvenient means of getting around. To combat these issues, we propose a hands-free crutch that will attach only to the injured leg, increasing maneuverability while preserving natural walking mechanics. Within the last decade, other hands-free crutch solutions have proven to increase user satisfaction by reducing fatigue, increasing safety and efficiency by allowing users to perform additional tasks with their hands, and allowing them to navigate more difficult obstacles. Our product aims to be more customizable, comfortable, and affordable than such hands-free solutions. This crutch is designed to give the user the opportunity to suspend their injured leg at a variety of angles to alleviate varying amounts of stress. In addition, a "stair mode" uses a hydraulic suspension to shorten the crutch and allow the user to more easily raise their leg up to the next step.

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We would also like to thank those at the Santa Clara University Maker Lab for providing us the space and tools to build our prototype. The supervision given by their employees positively assisted our efforts to create our model in a safe and efficient way.

Lastly, we thank the Santa Clara University School of Engineering for providing us with the funding and resources that made this project possible, as well as for giving us the opportunity to present our project at the 2018 Senior Design Conference.

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Chapter 1: Introduction

For centuries, orthotic aids such as wheelchairs, canes, and crutches have been widely used to enhance the mobility of people with lower body injuries and disabilities. Common use continues today as approximately 6.8 million Americans use these various devices every year (UC Disability Statistics Center 2015), and about 69% of all leg fractures and sprains occur at or below the knee (Lambers et. al 286). However, despite such prominent use, the general designs of these devices, namely crutches, have largely gone unchanged with only minor advancements in the materials used. This is surprising when considering that crutches have long been the subject of ridicule due to their structural and functional shortcomings. For example, it is well documented that traditional (axillary) crutch users experience both underarm and hand pain due to the stiffness of the cushioning material and the pressure applied at these sites. Instead of softening impact pressure and making use more comfortable, crutch padding causes notable discomfort as the crutch attempts to support a user's weight. This forces users to adapt to this poor design with homemade remedies such as wrapping towels around the underarm and hand supports.

Aside from comfort, ease of mobility is also an issue. Crutch users experience difficulty when performing everyday tasks, such as ascending/descending stairs, moving through narrow aisles, and moving laterally. This is in large part due to the elimination of the use of the injured leg as well as the arms and hands since they are occupied by the crutches. Therefore, only one leg can contribute to mobility and balance which greatly hinders physical ability and also poses a safety threat should the user fall.

Lastly, axillary crutch users easily succumb to fatigue. They are forced to utilize their entire body to move while also using core and leg strength to keep the injured leg or foot elevated. Crutches depend on the upper body, an area made up of smaller, non-specialized muscles in order to propel the user. This part of the body pales in comparison to the legs when it comes to successful locomotive ability. Despite such downfalls these traditional crutches are still widely accepted because of their minimal cost, usually ranging between $15 and $40.

Other current solutions attempt to address the shortcomings of axillary crutches, but all fall short in one way or another. For example, knee scooters have been accepted as a desirable solution to assist those with lower leg injuries. While they assist with minimizing the full-body fatigue associated with crutches by allowing the user to roll on wheels and rest their injured leg, this solution requires flat surfaces and thereby makes use up/down stairs and over other obstacles nearly impossible. Also, from a storage standpoint, knee scooters take up an inconveniently large amount of space. They may be good at moving longer distances in open space, but are impractical in a household setting. However, a plus side to a knee scooter is the elevation of the injured leg/foot which can be helpful in the healing process.

Over 7 million people use crutches worldwide every year (Vive Health 2017), but not all of these are axillary crutches. Forearm crutches have been developed that eliminate the connection to the underarm and distribute the weight purely across the user's hands and forearms. While this solution improves upon the comfort issue associated with crutches, the maneuverability complications associated with a crutch still remain, as well as the fatigue. Improved comfort on these devices is due to improved materials used on the forearm and hand sections; this comes with increased cost, as models can range from $25-160, reducing their feasibility for the average patient.

All of the solutions described above also require the use of at least one hand in order to move. This can be debilitating in everyday life. Most objects, food, and drink must be carried either in a backpack (in a completely sealed container, for spillage reasons), or in the case of a knee scooter, a basket. This lack of ability to use the hands can make tasks as simple as making and drinking a cup of morning coffee quite difficult. However, there are a few hands-free crutch solutions that attempt to address these issues. One such solution is the iWalk 2.0, generally priced around $150. This device mimics knee scooters by providing the user with a horizontal platform to rest their lower leg. A single support extends from below the knee, providing a single point of balance for the user. While the crutch is attached to the leg via adjustable belts, customers have complained about a lack of security which leads to discomfort and inconvenience. In addition, the elevated leg and single support causes an unnatural gait which places excess stress on the knee, adding further discomfort. A second potential hands-free crutch solution is the Freedom Leg by Forward Mobility. This device allows the user's leg to hang in a downward position, providing a far more natural gait. In addition, its construction consists of two supports, running along both sides of the leg, which curve with the patient's knee. The main attachment points are located at the mid-thigh and at the ankle by adjustable Velcro straps, which according to customers has provided greater security than the iWalk. Overall, in allowing users to keep their leg naturally slightly bent, the shape and slim profile of the Freedom leg is extremely adaptable as users can use the device while going up stairs, sitting at a desk, or even driving a car. However, the Freedom Leg's use is limited due to its price point of $500.

After assessing current solutions (see Appendix C), we look to develop a customizable, low-cost hands-free crutch that can be worn throughout the day without being removed. This originates from a concern with the unfeasibly high prices of the Freedom Leg, discomfort with the iWalk, and customer feedback regarding their lack of ability to be used in everyday activities. To address these concerns, we wish to make our product customizable, hence optimizing the user's gait and desires regarding leg support.

Figure 1: (Left) iWalk 2.0 (MaxiAids.com)
Figure 2: (Right) Freedom Leg by Forward Mobility (www.freedomlegbrace.com)

Chapter 2: System Level

2.1 Overview:

Our crutch system consists of a variety of components. These include the crutch/ground interface, the lower leg frame, upper leg frame, knee joints, and leg sling. The crutch/ground interface serves as the base of the crutch, touching the ground and attaching to the lower leg frame at two points, one on either side of the leg. The lower leg frame comes up either side of the lower leg and attaches to the knee joints. These knee joints serve as the sites that connect all other components. The upper leg frame binds to the superior side of the knee joints; this frame features large Velcro straps that secure the user to the crutch. The upper leg frame acts as the primary point of attachment to the body. The leg sling also attaches to the knee joint, lateral to the knee itself. The leg sling then protrudes back from the user at an angle specified by the physician; this angle can be altered by the user via adjustable pins that are inserted into the knee joints.

2.2 Requirements:

Our ultimate goal throughout the creation of this crutch was to address the shortcomings of traditional crutches while also trying to improve upon those of current hands-free solutions. Therefore, the system must satisfy the requirements detailed in the introduction and further in the design process section. Based off of complaints of traditional crutches, these basic requirements include being very comfortable, having a slim profile, and enhancing mobility in everyday situations. When examining issues related to competing products, our solution must preserve gait mechanics, feature a one-size-fits-most design, and exhibit cost efficiency. In an effort to provide maximum comfort, we also emphasize shock absorbance, inducing minimal fatigue, and allowing extended length of use.

2.3 Benchmarking Results:

There are currently a variety of products available for those with lower leg injuries who need to reduce weight to an injured area. These products mainly include traditional crutches, knee scooters, forearm crutches, and slight variations of each. Considering the scope of our project, we have focused our benchmark competition in the hands-free wearable crutch field. Our two major competitors are the iWalk 2.0 and the Freedom Leg. Both are wearable solutions with their own pros and cons. The iWalk 2.0 provides good lower leg support with a horizontal, padded platform. However, this structure greatly alters gait mechanics and its single support directly beneath the knee places much of the stress of walking on the kneecap, causing discomfort that worsens over time. The unnatural gait has been reported to cause fatigue and the thin belts on the thigh, knee, and ankle provide minimal security. The Freedom Leg by Forward

Mobility, conversely, uses thick Velcro straps on the thigh and ankle to provide increased security and greater ease when putting in on. Its nearly straight frame also allows users to keep their leg in a downward position which induces a natural gait, causing less fatigue and allowing the user to keep it on during a wider range of activities such as sitting in a desk or car. However, while functionally more sound, the Freedom Leg is priced at nearly $500, unreasonably high for the average lower-leg injury patient. Overall, both models lack adjustability in their structure; we aim to introduce adjustability as a way to bring the best of both models into one product.

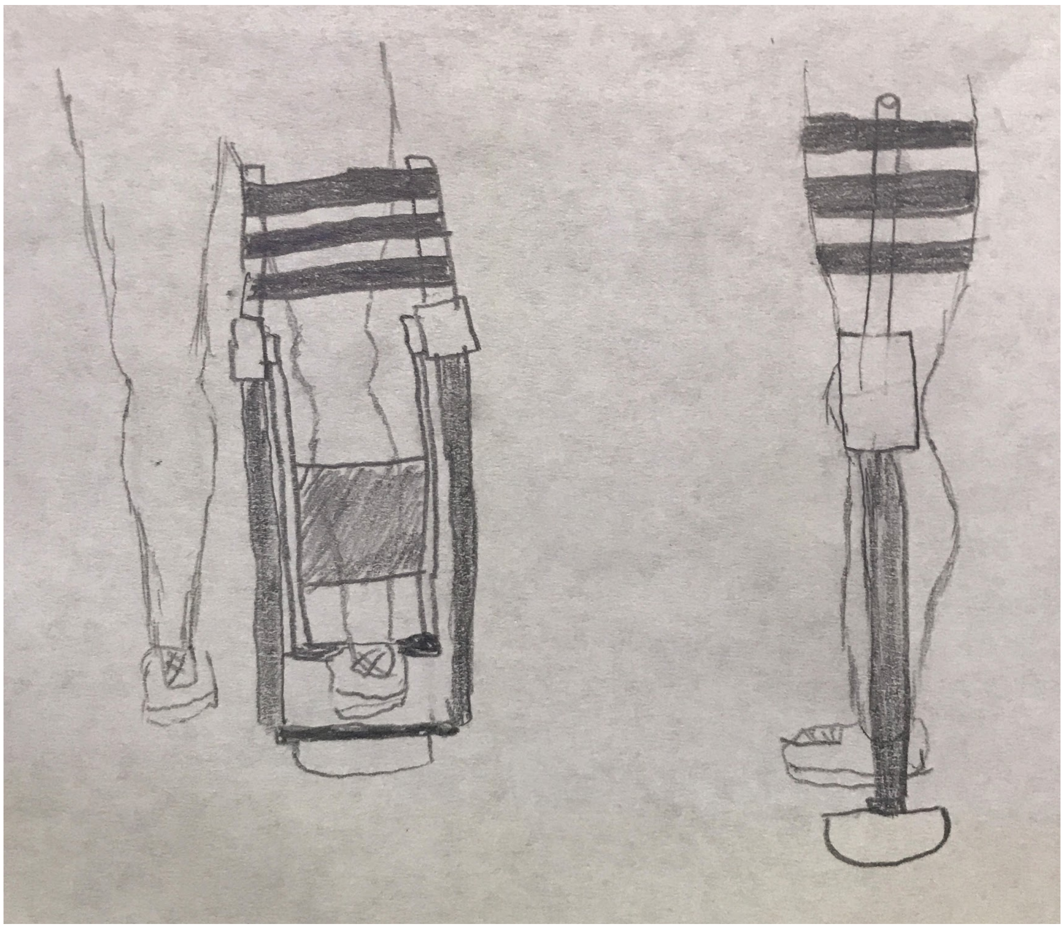


Figure 3: Sketch of hands-free crutch design

2.4 Functional Analysis:

As previously mentioned, our crutch design features 5 main subsystems: the crutch/ground interface, the lower leg frame, upper leg frame, knee joints, and leg sling. The ground interface is the single piece that makes contact with the floor; as such, it features a rubber-like material that creates traction on nearly all surfaces to give users a stable base throughout each step. The lower leg frame provides a rigid structure that supports the weight of the user and transfers it down to the ground interface; this rigidity is crucial as any warping or flexibility in this area would cause the foot to hit the floor beneath, causing it to bear weight and produce a clinically unacceptable outcome. The upper leg frame features Velcro straps that can be tightened or loosened for a comfortable yet secure fit. Security in this region is a primary concern as a lack of security will cause the device to slide during walking which could cause skin abrasions and also destabilize the injury, possibly inducing further injury. The knee joints lie at the heart of the crutch and are the main point of weight transfer from the attachment at the thigh to the lower leg frame and thus the floor. This calls for them to be strong enough to not fail under tensile stress while also having strong bonds to the upper and lower frames to prevent them from coming apart. The leg sling is meant to suspend the injured leg in a mesh-like material for added structural support. This is meant to prevent the user from feeling the need to hold up a portion of their leg's weight which would cause fatigue. With the sling the user can rest their leg's full weight on a comfortable, malleable material instead of a more rigid, uncomfortable one. The angle of the sling can be adjusted via pins in the knee joints. This gives the user the freedom to choose how much support they want for their injury, whether it be maximal in the horizontal position, minimal when the leg is in a natural, downward position, or somewhere in between.

2.5 System Level Issues/Decisions:

There are several key tradeoffs and device decisions made by the group in order to maximize efficiency, quality, and hands-free mobility. Significant design requirements needed for our device include: customizable leg posture, shock absorbance, preservation of gait mechanics, minimal fatigue, extended length of use, one-size-fits-most design, and cost efficiency. These device characteristics were based on numerous user interviews and suggestions (refer to Appendix B). However, while going through the prototyping phase, continuous design iterations added expenses and redirected key system level decisions toward comfort and quality over cost efficiency due to limited economic and manufacturing resources. While still keeping the competitive landscape in mind, system options leaned towards competing directly with the Freedom Leg brace (the more expensive product). Until a sophisticated manufacturing process was developed for the product, our device must value its effectiveness and our prototype must use high quality materials. Other tradeoffs related to efficiency include the shock absorbance versus preservation of gait mechanics. Adding a shock absorbance component to the device would add undesirable expenses to an already costly prototype. In order to avoid unnecessary expenditures, it was beneficial for the success of the device to focus on a clear cut path to helping preserve normal walking mechanics for the user. Moving forward, other design iterations may affect the primary goals of the end product, and force the team to make decisions to increase the success of the hands-free crutch.

2.6 Team & Project Management:

Throughout the ideation, designing, prototyping and testing phases of creating this crutch, all project challenges and constraints were discussed amongst the three group members until a consensus was made regarding a potential solution. This potential solution was then proposed to the faculty advisor for final approval. Beginning with a budget of $1500, the creation of prototypes proposed no financial threat, as most work was done by hand in the SCU Maker Lab and most materials were bought from Home Depot rather than being outsourced to industry partners. A full cost breakdown can be found in Appendix M2.

Regarding the project timeline, different phases occurred throughout each quarter and were extended as necessary. The first 3-4 weeks of the fall quarter consisted of generating a general direction for our project. Upon deciding that a hands-free crutch was a interesting concept, next came need identification, where we examined which shortcomings of traditional and hands-free crutches could and should be modified. This step lasted across the next 3 weeks as customer and literary research was conducted. The last weeks of the fall and a few weeks into the winter made up the design ideation stage, as we made drawings of potential prototype models and proposed special features. The majority of the winter consisted of prototyping, working in the Maker Lab to shape and assemble bulk materials. The final weeks of the winter will consist of testing the prototype for durability, comfort, and other parameters to see how a final prototype could be improved.

Risks during this project mainly pertain to the building of the prototype and testing the finished model. All group members renewed their safety training in the Maker Lab to be able to comfortably work with power tools, table saws, and other machinery. User testing after the prototype has been built will first be conducted by group members, and upon analyzing its safety and stability will be extended to peers. Testing will initially be only conducted on flat surfaces to maximize safety until confidence in the strength of the materials is confirmed. Names of test subjects will not be recorded for confidentiality reasons.

All group members contributed to the ideation, project design, material assembly, and testing phases in equal amounts. (Refer to Appendix D & E).

Chapter 3: Subsystems

3.1 Introduction of Roles/Requirements:

Our device consists of five key subsystem components. Each component serves a unique function in order to benefit the user and prevent abnormal gait mechanics.

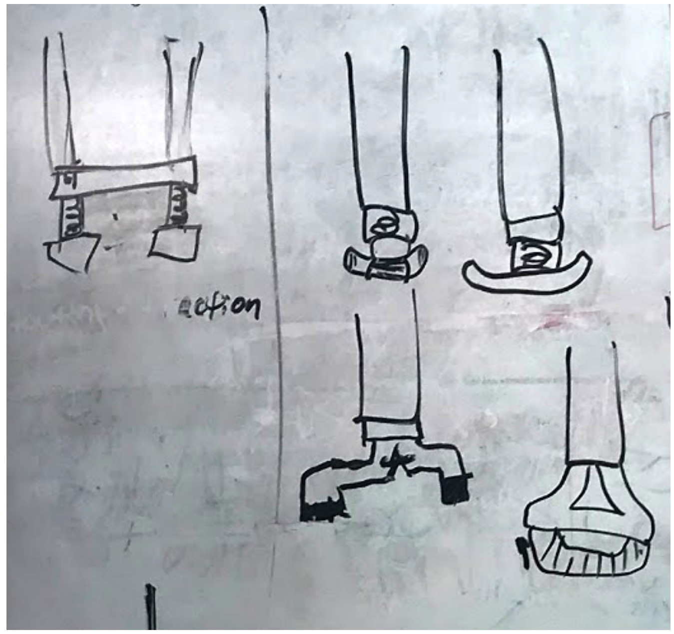


Figure 4: (Top) Preliminary drawings of ground interface ideation
Figure 5: (bottom) Ground interface padding in prototype

3.2 Crutch/Ground Interface:

The crutch/ground interface serves as a contact point between the lower leg frame and the ground. The purpose of this subsystem is to create a sturdy, slip-free attachment that emulates the way a foot naturally moves when healthy. In order to achieve this, we've implemented a rounded bottom with tread that can roll as the user rocks forward on the crutch during a step. Underneath the tread is a soft, woven fabric (Figure 4) used to provide extra cushion upon taking a step. Various approaches were considered (Figure 5), such as models with two points of contact and with varying shapes. For example, some solutions featured small, circular peg-like interfaces, as well as longer slimmer shapes resembling snow skis or flexible two-piece interfaces resembling the shape of shoes. When considering this interface we prioritized manufacturability and functionality. We felt that a rounded bottom for the shape, which would allow for a natural roll forward or backward, would prove more comfortable and stable during walking as solid contact could be initiated at a wide range of angles. For the same stability concern as well as for ease of construction, we went for a single horizontal bar or the interface instead of two, side-by-side pieces to have higher surface area in contact with the ground. Lastly, we simply did not have the machinery or materials to create intricate interfaces with complex structure and flexing mechanisms, thus we opted for a simpler option.

3.3 Lower Leg Frame:

The lower leg frame consists of two poles and serves two general purposes. Firstly, it attaches the crutch/ground interface to the knee joints and helps support the weight of the user. This is achieved using a simple metal bar attaching the distal ends of the right and left pole. The bar then attaches to the crutch/ground interface (Figure 7). The proximal ends of the poles are inserted into the knee joints and kept there via adhesives. Secondly, the lower leg frame is meant to shorten, for use when walking up stairs. This addition was made to prevent the user from having to swing their leg in a wide arc to clear the stair in front of them if the frame was too long. In our prototype, we achieved this by using mountain biking dropper posts (Figure 6). These use a hydraulic system in order to shorten when a trigger is pulled. While a simple wooden frame could have been used, we chose this more complex option for the initial prototype to test the necessity of this extra functionality.

Figure 6: (Left) Dropper Posts, pre-installation
Figure 7: (Right) Lower leg frame, post-assembly

3.4 Upper Leg Frame:

The upper leg frame serves as a connection to both the thigh and the knee joints. It consists of two steel poles taken from the iWalk. The distal end of the poles attaches to the knee joints via a pin-lock system. Directly above the joints, attached to each of the poles, is one trigger used to activate the dropper post lowering mechanisms. To allow these to fit, channels were carved into the wood to make room for the dropper post cables. The proximal ends of the poles have Velcro straps that attach to the thigh to facilitate a secure hold on the user. These straps are epoxied to the poles and then looped through plastic buckles which were also epoxied to the poles. We chose Velcro for the straps instead of, for example, belts because when analyzing customer feedback for the iWalk and Freedom Leg models, users complemented the Freedom Leg for its secure attachment using thick Velcro, while the belts used on the iWalk were less secure, causing the frame to move while walking. The belts would need to be tightened to a uncomfortable degree to create the same security, thus Velcro was the more desirable option.

Figure 8: Prototype upper leg frame - dropper post triggers, Velcro straps & buckles

3.5 Knee Joints:

The knee joints serve a variety of purposes. There are two knee joints, one on either side of the knee, that are a mirror image of each other. The superior side attaches to the upper leg frame via a pin lock system. The inferior side attaches to the lower leg frame via adhesives. The sides that are lateral to the knee attach to the leg sling and provide adjustability. This adjustability with the bars from the leg sling is accomplished via a pin system. The pin system consists of a rounded head with holes drilled at a variety of angles, in which the pin can be placed to lock the sling in position. Upon pulling the pin, the angle of the leg sling can be changed until the desired degree is obtained and the pin can be placed back in the correct hole. The use of a pin system was chosen to create a fast, easy method of adjusting the leg angle. It was also chosen for its simple manufacturability. In the sides of the wooden joints, channels were carved out to allow for a tight, slim fit for the dropper post cables.

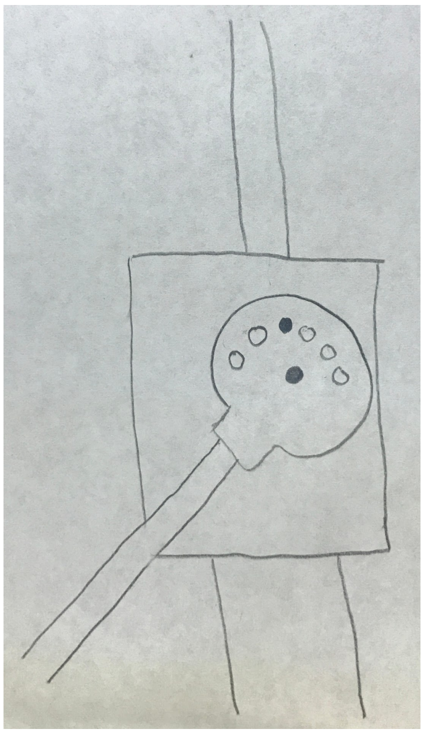
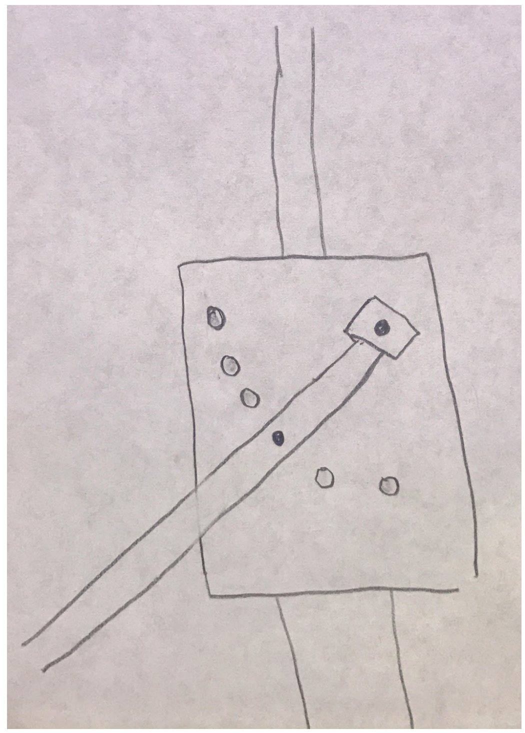
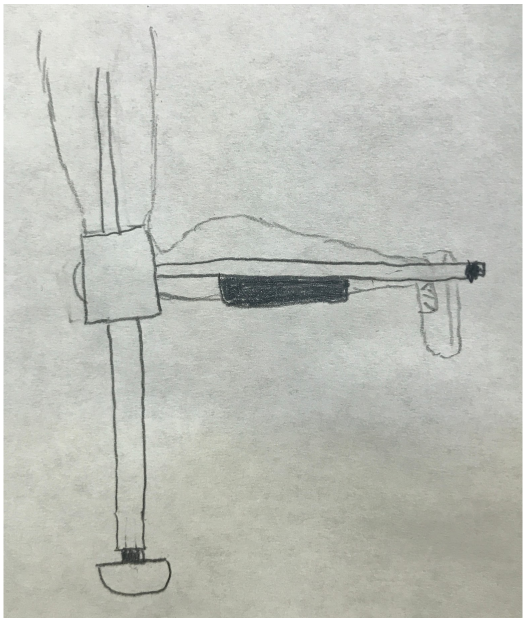



Figure 9: (Left) Alternate Knee joint design drawing
Figure 10: (Right) Final Knee joint design drawing

3.6 Leg Sling:

The leg sling serves to support the injured lower leg. There are two supporting beams on either side of the lower leg. A piece of durable fabric is connected to the supporting beams and is located on the inferior side to the knee and shin areas in order to support the leg in the vertical direction. The leg sling will provide more or less support dependent on the angle it is attached to the pin system on the knee joint. As the angle of the leg is lowered closer toward the ground, more weight will be placed on the injured lower leg. We look to use this mechanism as a means of accurately combating muscle atrophy, as over time the user can slowly start to put pressure on the injury to strengthen the surrounding tissue without the risk of placing too much or too little weight which could lead to reinjury. A Velcro strap will be harnessed around the leg to prevent movement and a connecting block will keep the support beams in place and stable. Other models such as the iWalk support the leg by having a padded horizontal platform (Figure 16), while the Freedom Leg stabilizes the leg with a strap that wraps around the ankle and pins it to a pad.

While the Freedom Leg's single strap method works well when the leg is angled downward, it would lack support when the leg angle is raised such as seen with the iWalk. Thus, our sling design was chosen to mimic the iWalk without having such a rigid, uncomfortable frame.



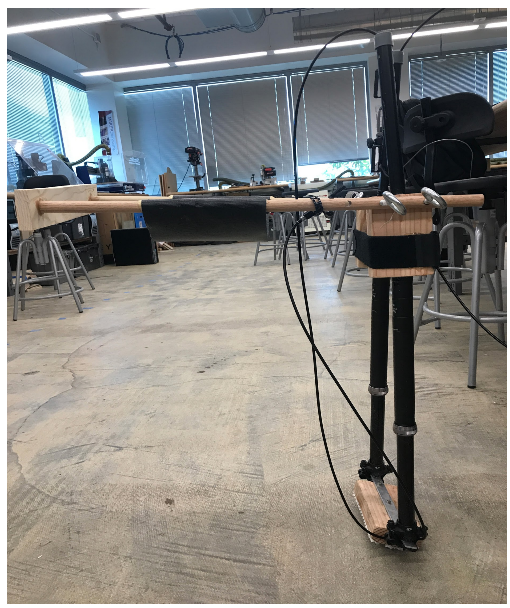


Figure 11: (Top Left) Preliminary side drawing of leg sling functionality
Figure 12: (Top Right) Unattached leg sling
Figure 13a: (Bottom Left) Crutch with leg sling at low angle
Figure 13b: (Bottom Right) Crutch with leg sling at 90 degree angle

3.7 Design Description:

The general design description includes a similar design to the Freedom Leg with a curved support that conforms to the natural bending of the leg. A pin-locking-rotating system is located at the knee joint and is incorporated to provide customizability and a mechanism to change weight distribution for walking/standing to increase both comfort, ease of use, and force distribution at various points of the leg to help expedite the healing process. The crutch/ground interface will include a rounded bottom with tread in order to provide a non-slip, durable stance to mimic foot-to-floor walking mechanics. The upper leg frame attachment includes wide Velcro straps to ensure secure fitting. These straps are positioned along the thigh at critical points to support center of gravity and other force components related to walking. The lower leg frame is connected from the knee joint mechanism to the crutch/ground interface. Finally the leg sling is meant to alleviate the injured lower leg from experience forces related to standing.

The design's purpose serves to create normal gait mechanics without distributing an uncomfortable amount of force to the upper thigh. The side beams form fit to the leg shape and size in order to prevent an unnecessary force exertion to the knee cap. This will help minimize fatigue and painful pressure when the user travels from point A to point B. As a way to increase the ease of normal gait movements when climbing stairs (one of the most problematic situations of crutches), the lower leg frame is equipped with two hydraulic systems. When a trigger is pressed, the hydraulic systems are activated and move upward simultaneously. This action creates an easier stair-walking motion for the user, as they will eliminate the need to "swing" their leg around the step in order to advance up the stairs. The leg sling will act as if it were a sling for broken arms. The injured lower leg is held in place with two supporting beams that are connected together via a connecting block. When the leg sling is parallel to the lower leg frame, it is entirely within the lower leg frame. The leg sling will be adjustable in order to allow for different weight distributions along various points of the leg in order to help the healing process (refer to appendix).

3.8 Prototyping Results:

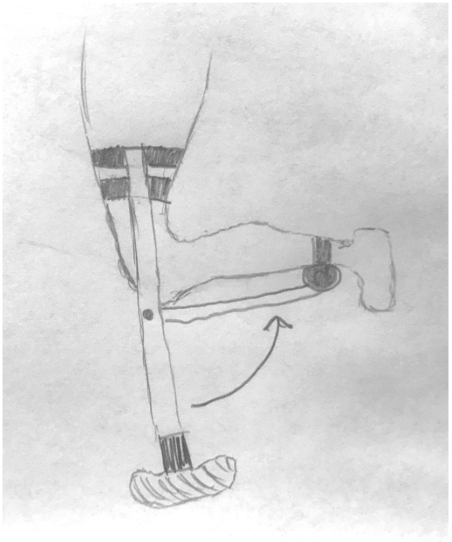
The initial prototype was able to successfully support the weight of the user. However, it did have various shortcomings. One area of failure was the upper leg frame. The Velcro straps, while adequately keeping the crutch attached to the leg, did not facilitate a tight enough connection to stabilize the leg and prevent it from moving during walking. This caused the knee to drift up and down, causing a lack of security which made going up or down stairs to be more difficult and gave the feeling of instability. Another issue with the upper leg frame was that the epoxy used to attach the plastic buckles and the Velcro straps was not strong enough to handle the weight of the users, causing a few straps and buckles to disconnect after only a few uses.

An area of success was the lower leg frame. When the dropper post triggers were depressed and weight was applied to the crutch, the dropper posts successfully compressed, moving the ground interface closer to the foot, shortening the crutch. Once shortened, the triggers were returned to the resting position to lock the posts in the "stair mode". Once stair mode was no longer needed, the triggers were depressed again with the crutch lifted off the ground, and the posts expanded. This "stair mode" may also be used to achieve user to user adjustability. Because the dropper post can be changed to a variety of heights, it is the perfect mechanism to allow for people of many heights and body types to use our product. We discovered that, upon activating the triggers for the dropper posts and leaving the triggers depressed, the posts remain unlocked. This allows for them to move freely, compressing when applying weight and quickly returning to the original height when the device moves off the ground. This functionality provides tremendous shock absorbance for the user; however, while a desirable quality, this functionality is not the primary focus of the dropper posts, so to minimize damage to the posts due to overuse, we will not be utilizing this ability.

The leg sling, while able to successfully lock into various positions in the knee joint to change the leg angle, felt unstable at higher angles once leg weight was applied. This is due to the fact that the pin that locks the sling into each position is located a very short distance (about 2-3 inches) from the axis of rotation. To provide adequate support (i.e. torque) at such a short distance, the adjustable pin and the wooden block must bear a tremendous amount of force. While they are able to do so, the rest of the sling's wooden frame consists mostly of thin dowels made of soft wood, so users reported feeling a slight bend in the dowels when the weight of the foot is rested in the sling. The ability to use stronger materials in the final design of the frame would eliminate this issue.


Figure 14a: (Left) Initial Prototype front view
Figure 14b: (Right) Initial Prototype side view

3.9 Sketches/Photos:



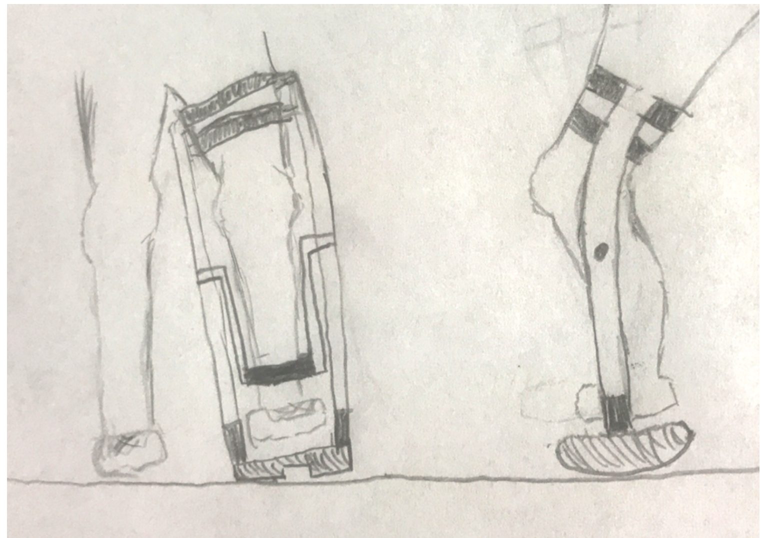


Figure 15a: (Top Left) Preliminary leg support concept at 90 degree angle
Figure 15b: (Top Right) Preliminary leg support concept at 0 degree angle
Figure 16: (Bottom Left) iWalk leg pad
Figure 17: (Bottom Middle) Dismantled pieces to iWalk, including posts used in Upper leg frame
Figure 18: (Bottom Right) Early Upper leg frame assembly

3.10 Verification Procedures:

In order to perform a detailed and thorough analysis of the prototype, we developed a testing protocol and post-test questionnaire to determine user interest in the hands-free crutch. Since the proposed invention does not place “human subjects at more than minimal risk and does not utilize systematic data gathering procedures with vulnerable populations,” the team did not need to apply for human subjects approval methods from Santa Clara University (2011). The next chapter fully describes the testing population, the testing protocols, and results of the user survey. It also details the team’s ambitions for future testing and prototype/CAD improvements.

Chapter 4: System Integrations and Testing

4.1 Prototype User Survey Data:

To test the success of our prototype, we asked a large group of Santa Clara University students to put our prototype on and rate their experience on a quantitative scale. The scale was arranged from 1 to 5, 1 being the lowest-ranking option, 5 being the highest-ranking. The users (portion seen in Appendix H) were asked to attach the hands-free crutch to their leg, and then walk for an extended period on a flat length of ground, such as a hallway or a sidewalk; this flat-ground test would last about 2 minutes on average. After finishing the test, a group member would immediately send a link for the online survey to the user. Stairs were excluded from our user prototype test to ensure safety of the users. The names of test subjects were not be obtained; while confidentiality was preserved, the users' heights and weights were recorded to ensure our prototype could withstand a wide range of body profiles. An excerpt of our survey data is shown below, and the full data sets can be found in Appendix G.

Table 1: Summary of user survey data

	Comfort	Ease of Use	Aesthetic	Performance
Percentage of Users submitting a score of 4 or 5	67.9	77.4	43.4	73.6

The users were asked to score the prototype within four main areas. The first parameter sought to find out how comfortable the materials were that were in contact with the body, as well as how this impacted the overall experience of use. The second area, ease of use, asked users to rate how much energy the user expended using the crutch and how convenient it was to attach/detach it from the leg. Regarding aesthetic, we realized our prototype materials were less than ideal, and thus wanted to gauge what users thought of the general structure of the crutch to see if it was attractive enough to make it appealing. Last, the performance metric described, on a basic level, how well the crutch worked; this includes how well it supports the user's weight, how secure the attachments to the leg were, and how well they felt it supported the injured lower leg. Our prototype performed delightfully well; in a survey of 53 users, the prototype was given a score of 4 or 5 by more than two-thirds of the population in 3 out of the 4 test areas. The success in these areas not only verified that our design could work well, but also that it could potentially address the main shortcomings of other hands-free models, namely comfort and performance. This data suggests that, with access to higher quality materials and more advanced fabrication methods, our design could compete in the crutch market, especially amongst other hands-free solutions.

4.2 Testing Design Feedback

Prototype testing and user input helped us to improve the hands-free wearable crutch over various testing prototype iterations. When walking with a crutch structure that is rigid and leg-length, walking up stairs required an unnaturally wide leg swing. Hence, early in the prototyping process we realized that the stair mode would be advantageous. One response given by users, discussed in section 3.8, was that their knees felt unsupported and insecure when walking, causing the rest of the leg to shift position when weight was applied. A Velcro strap was attached at the knee joints and went under the knee to support it, but this was merely a temporary fix and did not provide enough stability to be a viable option in a final model. In addition, we found that the straps used in the prototype were fairly thin and caused occasional discomfort as they would dig into the user's leg. Therefore, wider straps should be used to make a more comfortable, more secure attachment.

Another area of improvement that was identified during prototyping was the comfort of the knee joints. When a user would wear the crutch prototype, the inner surfaces of the knee joints would occasionally press inward onto the outer sides of the knee. Since the prototype joints are made of wood, this would cause discomfort after walking for an extended period of time. Thus, we took a foam padding and lined the inner surface of the joints, making this contact with the knee far more comfortable.

One last shortcoming encountered, involving the leg sling, was the lack of security of the foot. The foot was originally not bound to the sling and would, thus, move freely especially at lower leg angles. This was resolved by wrapping a Velcro strap around the sling at the ankle, pinning the foot to the sling.

4.3 CAD Model Details:

This is an exploded view image of our current device. It highlights the five main subsystems. Again, each serves a unique function allowing the user to efficiently walk. The next subsections look closely at each individual component of the device.

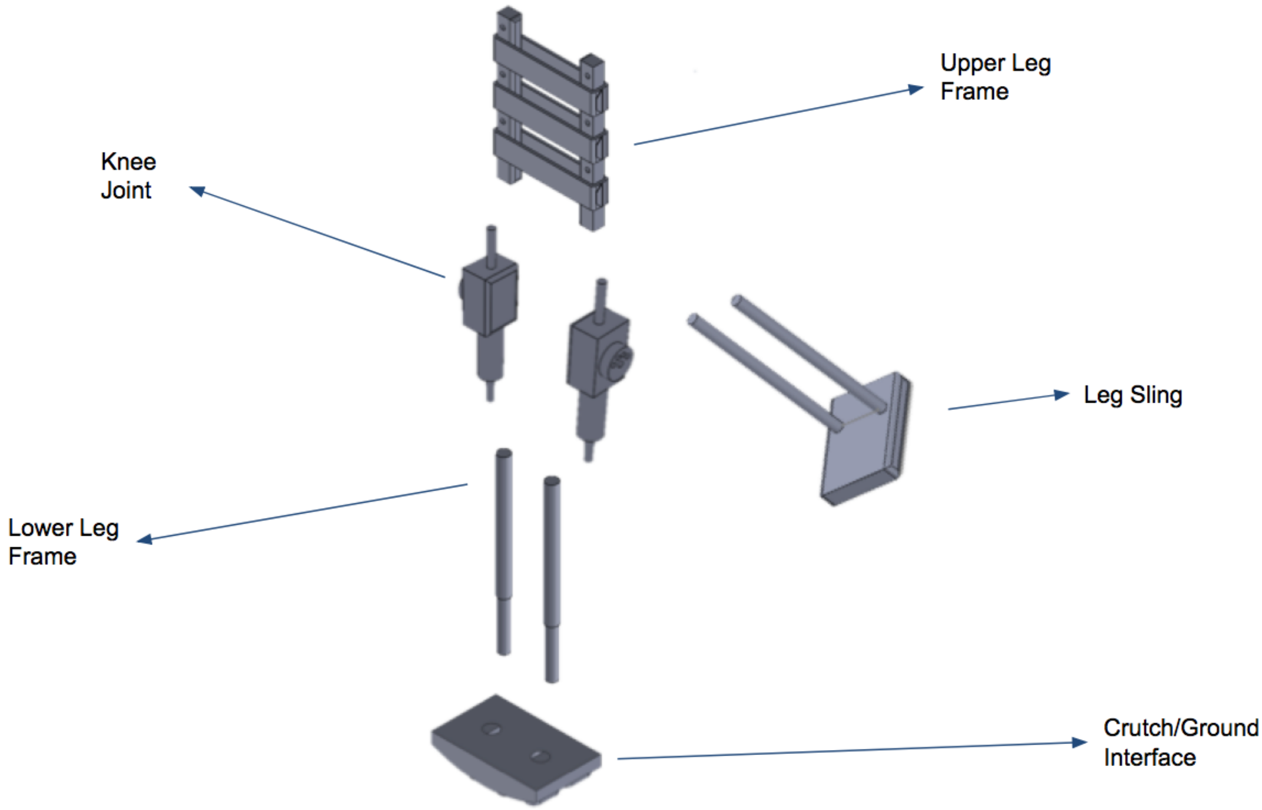


Figure 19: (Above) Exploded View of Current Model

4.3.1 Upper Leg Frame:

This is the upper leg frame. It serves as the main force-holding component and is strapped to the quadriceps. It has wide, cushy straps with a buckle system for security. It also has heavy padding along the upper poles to ensure comfort. There is also a pin-locking mechanism that provides customizability and can be moved up or down to provide for different user heights and body types.

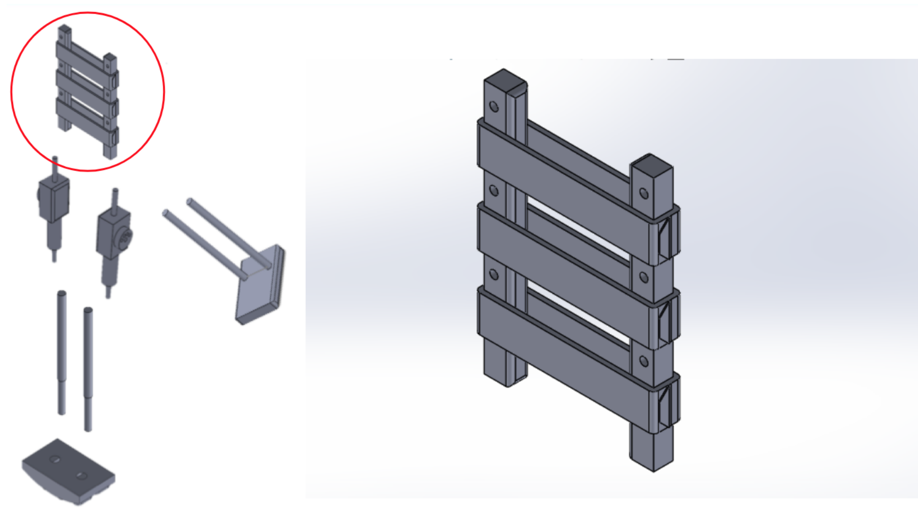


Figure 20: (Above) Upper Leg Frame Subsystem

4.3.2 Knee Joint:

The knee joint component is located on the right and left side of the knee cap of the injured leg. Arguably the most important subsystem of the device, the box-shaped component connects the upper leg frame, lower leg frame, and the leg sling into one central hub. On the outside of the box component is the rotating and pin-locking force-adjustability mechanism, that changes the angle of the leg sling, and thus alters the amount of load pressure experienced by the user on the injured lower leg. The bottom set of pictures shows the rotating fashion of the force-adjustability mechanism, having four different pin settings for 4 different leg angles. However, depending on further physician input, the rotating can have fewer or more stages (or pins).

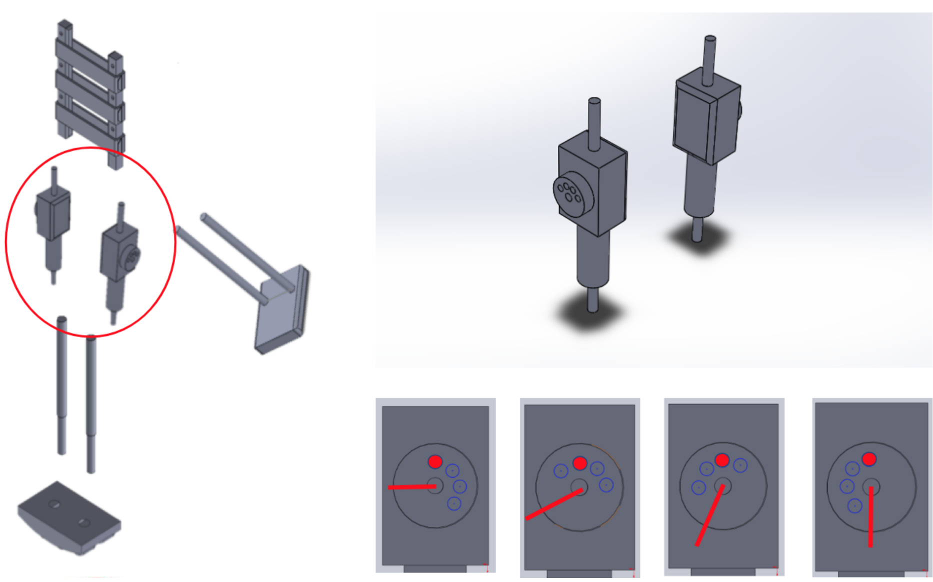


Figure 21: (Above) Knee Joint Subsystem

4.3.3 Lower Leg Frame:

This component is connected to the knee joint and crutch/ground interface. It replaces the function of the lower leg. On the lower portion, the "stair mode" can be activated by triggers to lift the bottom 7 inches upward (which is the average height of a single step). This allows the user to more easily walk up stairs instead of swinging the leg around.

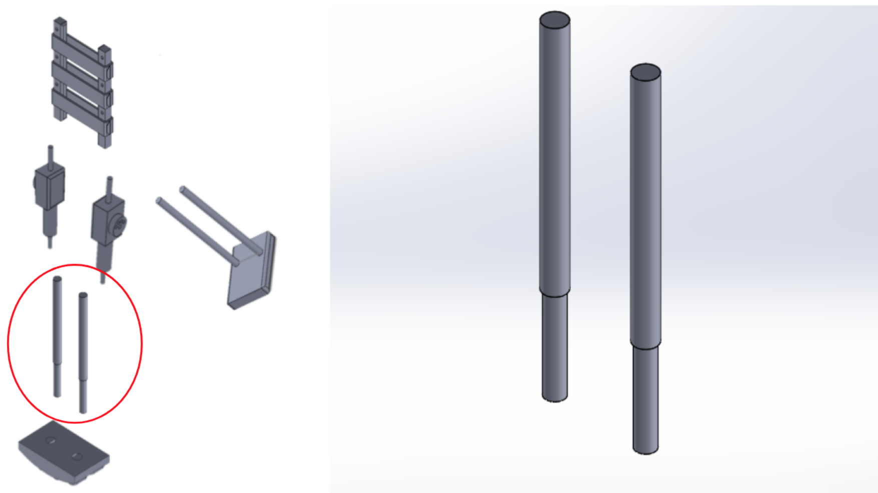


Figure 22: (Above) Lower Leg Frame Subsystem

4.3.4 Leg Sling:

The leg sling houses the injured lower-leg and has straps connected around the long poles to hold up the leg and around the foot base. This will securely hold the injured leg in place and make sure the foot is fully on the foot base to prevent further injury. The leg sling is rotated to different angles via the knee joint force-adjustability mechanism.

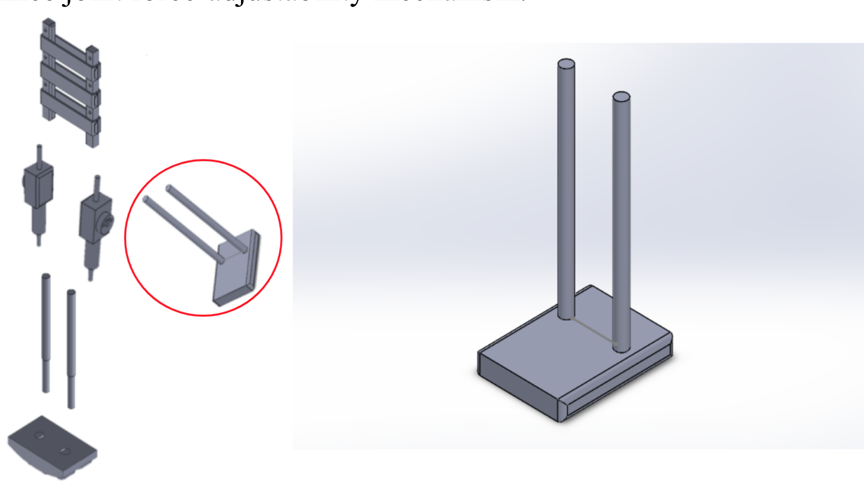


Figure 23: (Above) Leg Sling Subsystem

4.3.5 Crutch/Ground Interface:

Last but not least, here is the top and bottom viewpoints of the crutch/ground interface. The top view is securely connected to the lower leg frame. The bottom view has a curved surface to assist the user in making the heel-to-toe rocking motion with each step. It also has multiple protruding/cushioning grips to provide suspension and traction for nearly any terrain.

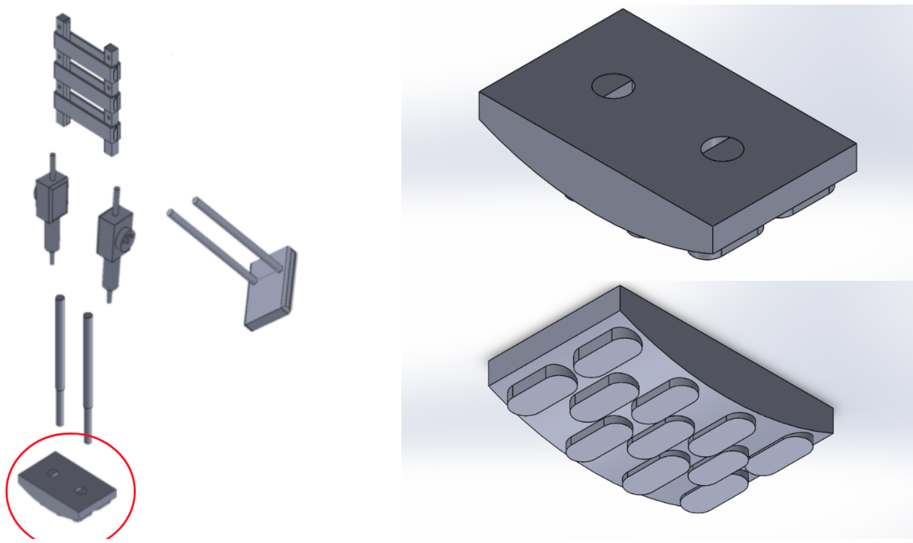


Figure 24: (Above) Crutch/Ground Interface Subsystem

4.4 Materials Selection:

If the CAD model were to be made into a market-ready product, of main concern would be the materials used to build the ideal hands-free wearable crutch. While our prototype was made from wood and salvaged plastic and metal, this combination would not be ideal. The main parameters considered when discussing the materials that would make a final model were the cost to buy the raw materials, the ease as well as cost of their manufacturing processes, their weight, and their durability. The weight of the materials were of interest because, if a user is to wear the hands-free wearable crutch around for an extended period of time, it cannot be too heavy and cause unwanted fatigue.

When looking at the different types of materials used by competing technologies, three main categories of materials emerged; the first is carbon fiber. Carbon fiber has excellent mechanical properties, being very lightweight with impressively high tensile and compressive strengths. However, carbon fiber, due to its structural complexity, is extremely expensive to manufacture. In addition, if a carbon fiber frame becomes damaged or broken, a manufacturer cannot just replace that small broken section; rather, the entire frame must be replaced. Therefore, the manufacturing cost for carbon fiber, whether it be for the initial model or during replacement, would be a deterrent too high to justify its use for our model.

The next class of material would be metals; specifically, we looked at a popular alloy on the market: 6061 T6 Aluminum. This aluminum alloy has great mechanical properties as well, having strength and compression moduli that, while less than those of carbon fiber, are still more than enough to support the weight of a user with ease. Also, this alloy has great corrosion resistance. Last, it is much easier to manufacture, making its use much more economically viable.

The last set of materials are engineering-grade plastics; these would likely be high-strength thermosets such as polyurethane. Plastics generally lack the mechanical properties and durability of metals, and can, depending on the size and thickness of the piece, be heavier than metal structures. However, plastics can be easily and cheaply manufactured.

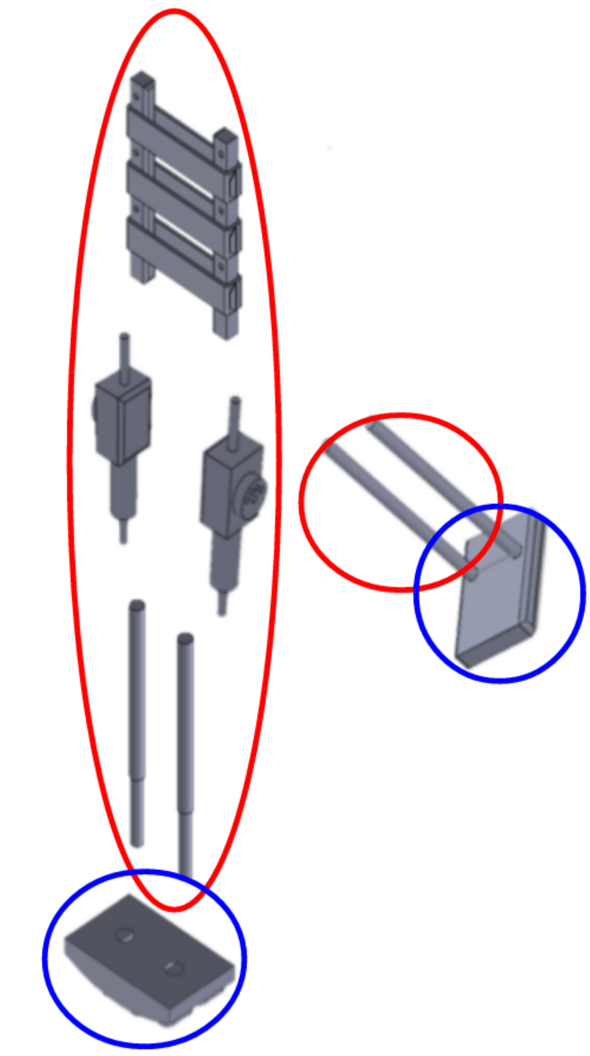


Figure 25: Expanded CAD model highlighting material choice

After considering the benefits and shortcomings of each of the three classes of materials, we decided to make the upper leg frame, lower leg frame, knee joints, and the upper portion of the leg sling out of 6061 T6 Aluminum, as highlighted in red in Figure 25. These sections of the crutch are all under constant torsional, bending or compressive loads. For this reason, the materials used would need to have great mechanical properties to withstand these forces over extended periods of time without showing fatigue. Thus, we believed the metallic option best fit these needs. Also, since the mechanical properties of the alloy are so good, the frames of these pieces can be thin, making the crutch much lighter while still preserving structural integrity. The portions in Figure 25 highlighted in blue, the lower portion of the leg sling and the crutch/ground interface, would both be made out of engineering-grade plastics. This decision was made because these areas will undergo the most wear and tear, since they are closest to the rough ground. Therefore, should these high-stress, high-wear parts need to be replaced, plastics would be easily and cheaply manufacturable. In addition, since these pieces may be touching the injured foot when walking, we wanted them to be made of a softer, less rigid material to provide a slightly more comfortable ride.

Chapter 5: Cost, Pricing and Reimbursement

5.1 Prototype Cost:

The cost of our prototype is broken down as follows:

Table 2: Itemized cost breakdown for prototype

Prototyping Material	**Cost**
Dropper Posts	$534.00
iWalk 2.0	$149.00
Wood	$16.73
Containers, Locks, Storage	$23.00
Pins, Screws, Sheet Metal	$16.40
Fabric, Velcro, Consumables	$44.85
Total	$783.98

We would expect that our costs, were we to move into production, would decrease drastically. For subsequent builds, we would not need containers, locks, storage, the iWalk 2.0, or nearly as much wood. If we went to large scale production, we would design our own dropper post mechanism, mold the knee joints from a plastic, and buy metal bars in bulk. This would bring down the expected manufacturing cost to about $52 ($5 for crutch/ground interface, $20 for dropper posts, $10 for knee joints, $2 for Velcro straps, $10 for metal poles, $8 for pins, $2 for sling material). The remaining budget ($716.02) will be used to create CAD drawings, incorporate final prototype iterations, and create models for IP strategy and commercialization.

5.2 Pricing and Reimbursement:

Establishing a viable price point and reimbursement strategy for the hands-free wearable crutch is crucial for its commercial success. The expected price of the hands-free wearable crutch would be in the $150 to $200 range. Comparable products cost between $150 and $500 and have significant disadvantages, as discussed above. These products are also covered by insurance under level II HCPCS codes E0118 and L2136. These insurance codes cover “crutch substitute, lower leg platform, with or without wheels” and “kafo, fracture orthosis, femoral cast orthosis, rigid, prefabricated, includes fitting and adjustment,” respectively. Considering both our product advantages and our competitive price point, we would expect to be fully or mostly covered by the insurance codes above. However, for those without insurance, or people with basic insurance plans, we find that $150 to $200 is an affordable price. This is made even more affordable because of the fact that the hands-free wearable crutch is both adjustable and reusable, driving the cost per use down. After identifying the manufacturing cost of competing technologies, we think we could make a commercially-available model of the hands-free wearable crutch for $40 to $80, depending on the volume of the order. Finally, based on the customer feedback survey, shown below (Figure 26), users claimed they were willing to pay well over $200 for this kind of technology; thus, our price point is significantly lower than the mean proposed price. All of these facts point towards a commercially viable product.

Figure 26: Hands-free crutch user survey data on acceptable market price for a final model

Chapter 6: Engineering Standards/Realistic Constraints

6.1 Economic:

Economic constraints play a large role in our product. Considering that traditional crutches cost a consumer a meager $20, we cannot make our product too expensive. Of course, our system, and other available systems, has advantages over traditional crutches. However, we must carefully consider the cost to advantage ratio in order to deliver a product that is economically feasible.

6.2 Health and Safety:

Health and safety is another extremely important standard that we must build our product to. Considering that our system is worn on the leg, for large portions of the day and by people who are injured means that health and safety cannot be overlooked. If our system were to break, it would expose the user to further injury or reinjury of the affected area. Of course, this would be both a liability and a health hazard. For this reason we have put forth an effort to make our product from quality materials, manufactured to high standards.

6.3 Sustainability:

Sustainability is an issue that we have not considered in the prototyping stage, but that will play a large role in the production phase. As we move from a testing prototype to a product, sourcing sustainable materials will be of great importance. We plan on achieving this by working with companies known for sustainable material sourcing and quality parts. Furthermore, the device is completely reusable which will significantly decrease our

6.4 Manufacturability:

Manufacturability will be a significant factor in the production phase of our project. By using a simple pin locking system we have greatly reduced the complexity of the system. Furthermore, by using metals and plastics that are easily cut and molded, we can make our manufacturing process simple and efficient. As we scale up our manufacturing process, we can also decrease cost and increase efficiency.

6.5 Social:

Finally, social constraints will thoroughly affect our product. Currently, most physicians suggest crutches to their patients, even though there are other options available with more advantages. Crutch alternatives are usually found by the patient after they see the shortcomings of crutches. This is one social hurdle that we might need to overcome in order to have a financially feasible product. If this can be overcome or if there is significant product use by individuals without physician suggestion, we can solve a variety of social issues. By giving injured people the freedom to use their hands and operate in a way that is extremely similar to a healthy individual, we can alleviate much of the social issues associated a lack of mobility.

Chapter 7: Conclusion

7.1 Summary:

Over the last few centuries, traditional crutches have structurally gone unchanged, relying on the injured user to place their weight on their underarms and hands. While materials used to make traditional crutches have evolved to include more comfortable options, the general structure of the crutch places an undesirable amount of stress on these upper body areas, and when considering the need to balance on one leg while also holding up the injured leg, the use of traditional crutches introduces unnecessary fatigue on the user. Coupled with this fatigue, standing on one leg requires the user to create a wide base with the crutches for stability, while also preventing them from traversing non-flat obstacles and making their gate profile significantly wider than that of a healthy person. Thus, use of traditional crutches on narrow or elevated surfaces. such as stairs, prove to be an issue. These concerns could be addressed with a device that utilizes a slimmer profile, allows the user to use both legs to move, and takes the weight off of the hands and upper body; we aimed to develop such a device with our hands-free wearable crutch. By freeing the hands to be used for other purposes, the user can move around safely by being able to hold onto handrails if necessary, while also being able to simultaneously perform other tasks such as driving, working at a desk, etc. Furthermore, by creating a system that focuses on the legs instead of the upper body, we can better preserve gait mechanics.

Hands-free solutions such as the iWalk and the Freedom Leg have already addressed such issues. In the creation of our own design, we analyzed where these models fell short in performance and wanted to improve upon those areas. We aimed to take the positives of the leg angles seen in both models, and made the angle of the leg on our model adjustable, providing varying amounts of support as the angle is changed. Also, to assist with traversing stairs, we introduced a "stair mode" using bicycle dropper posts to shorten the device so it can easily clear the space above the next stair. We built our prototype model using standard saws, glue, metal rods, screws, and wood. While the initial prototype was structurally sound and supported the weight of the user, we found that the upper leg frame did not facilitate a secure enough connection to the leg to prevent the foot and knee from moving. In addition, the buckles and straps on the frame could not withstand the weight of the user and became detached.

However, after testing the prototype on 53 SCU students, the results were resoundingly positive, as they rated our crutch very highly in comfort and performance. This verified that our prototype was not only highly functional but also had a structure that provided an enjoyable experience for users. In addition, the users priced our product at a range much higher than our desired commercial price point. Therefore, we believe we developed an economically and mechanically viable product that could successfully challenge other hands-free crutch options.

7.2 Future Work:

The final prototype is just the first step in our future process. Moving forward, we will continue to improve the CAD design so that our hands-free device can be commercialized and benefiting patients with lower leg injuries very soon. Associated with the CAD model, we will be looking to generate a bill of materials for our ideal end product. This will not only help us get a grasp on exactly what materials we would need, but also what manufacturing processes would be needed to shape those materials, and lastly, how much this entire process would cost. Each change to the CAD model or to the materials featured in the BOM would help us move closer to developing an industry-ready product. We will also need to design a hydraulic mechanism that can reflect the abilities of the dropper posts used for the lower leg frame. The combination of the hydraulic mechanism and the force-weight distribution leg sling will create a useful, non-obvious, and novel product ready to improve the mobility of users with lower leg injuries. However, an essential first step moving forward, before any of this is possible, is to secure funding for our project; this will be a key focus in the immediate future.

Another area of future interest is establishing intellectual property rights for our stair mode as well as the force-adjustability mechanism. We believe these capabilities are very valuable and would want to secure patents before putting out a final product. Preliminary paperwork has already been filed to determine if the stair mode and force-adjustability mechanism are patentable; we will closely monitor this process as the project progresses.

In order to market and commercialize our product, we will also explore the option of teaming up with MBA students in order to blueprint a structured business model. This will help plan out future strategies to market, implement, and sell the device to the interested users. Early ideation has allowed us to discuss two main marketing strategies we could employ; a business-to-business strategy and a business-to-consumer strategy. The business-to-business (B-to-B) strategy would focus on selling the crutch directly to businesses such as physical therapy offices or sports teams that would use the crutch as a rehabilitation tool for their clients with lower leg injuries; these types of businesses would want to help their users minimize muscle atrophy, and our adjustable weight mechanism would be a perfect match for this need. This strategy could be first tested on the Santa Clara University sports teams. The second strategy, business-to-consumer (B-to-C) marketing, would include having our crutch be easily purchasable at any local general store. Essentially, a consumer should be able to buy the crutch over the counter, put it on, and be able to walk next door to get a cup of coffee and drink it without having to worry about their hands being occupied by crutches. Our exact marketing strategy will be determined after more research amongst business students and advisors.

Once we have secured the funding, materials and business strategy to make a high-quality product, we would look forward to receiving FDA approval for the crutch. Due to its non-invasive, low-risk functionality, this would be filed as a Class I medical device. In addition, based on other comparable devices in this category, we believe we could be filed as a 510(k) exempt device, making the FDA approval process less extensive, and thus helping us get our product out to users faster.

Bibliography

Health, Vive. “Temporary Weight-Bearing Injuries and the Danger of Crutches.” Orthogate, 2 Sept. 2017, www.orthogate.org/news/viewpoints/temporary-weight-bearing-injuries-and-the-danger-of-crutches.

“IWALK.” MaxiAids.com, www.maxiaids.com/iwalk-20-hands-free-crutch-new-and-improved.

Lambers, Kaj, et al. “Incidence of Patients with Lower Extremity Injuries Presenting to US Emergency Departments by Anatomic Region, Disease Category, and Age.” Clinical Orthopaedics and Related Research, vol. 470, no. 1, 2011, pp. 284–290., doi:10.1007/s11999-011-1982-z.

“No Limitations.” Freedom Leg, www.freedomlegbrace.com/benefits/.

Santa Clara University. “Example: Biomedical Full/Expedited.” Santa Clara University, 3 Nov. 2011.

The University of California - Disability Statistics Center. “Mobility Device Statistics - United States.” Disabled World, Disabled World, 18 Mar. 2015, www.disabled-world.com/disability/statistics/mobility-stats.php.

Appendices:

Appendix A: 2015 Comparison between iWalk 2.0 & Freedom Leg by Forward Mobility

Citation:

“Customer Review.”*Amazon*, Amazon, www.amazon.com/gp/customer-reviews/R3NLBO2ODK7T4K/ref=cm_cr_dp_d_rvw_ttl?ie=UTF8&ASIN=B00092RB06

“I was misfortunate enough to be able to purchase and use both the iWalk 2.0 and the Freedom Leg. I compare both here. I preface this by stating it is my opinion *that either product requires the user to be somewhat physically fit and have decent balance.”*

FL= Freedom leg
iW= iWalk 2.0

Ease of assembly (5=best)
FL: 3 – a bit bulky, requires inserting bottom bracket into brace and this does not go together easily. Uses (steel?) screw and bolt to lock into softer milled aluminum bracket (the bolt recesses can get damaged because of the softness and I’d recommend them to use a harder grade). Numbered rules on both sides of the bracket for reference when adjusting are very helpful but can get worn off with use. Knee & shin pad and thigh straps already assembled.

iW:5 – compact, great packaging, very easy and intuitive to put together, uses spring loaded pins (like those on a regular crutch) for adjusting height, has lateral adjustment on thigh.

Quality of construction (5=best)
Appendix AFL: 3/4 – I already mentioned the bottom bracket but I have to mention that I had two failures that could have been catastrophic. The knee and shin pads are attached to the brace with a D-ring on either side. This D-ring is only @1/16 diameter and butt-welded closed. Both failures were on the knee pad at the butt weld joint. I may be unique that I liked a tight fit of this pad on my knee compared to others and FL was kind enough to replace them but this needs to be improved. Note that even if the pads fail, you are still locked in at the thigh and indeed the device could be used without the pads – however the failure during loaded use is enough to throw off your balance. I was going down the stairs and holding onto the handrail fortunately.
iW: 5 – no doubt about it – this company’s product is top notch.

Price (5=better price)
FL: 2 –this is over $500 – price gouging imo
iW: 4 – this is @$150 – quality product for a fair price

Ease to put on: (5=easiest)
FL: 4 – slides easily on, lock down the Velcro straps and done - fast
iW:3 – not as easy to put on and lock down the three straps and adjust.

Ease to take off: Same ratings

Ease to Fit and Adjustment – (5=easiest)
If you wear heeled shoes (even 0.5-1") but also go barefoot or slippers on your good leg, that difference in height may mean you want to adjust the device for a better experience.
FL: 3 – After initial assembly you have two adjustments to fit. A – the bottom bracket for macro-adjustment and B – the thigh straps for micro adjustment as well as knee and shin pads. FW should work on improving the ease to macro-fit (again the bracket). It is a big pain and the bracket wears with repeated adjustments.
iW: 4 – After initial assembly adjusting the fit is easy in theory. However the spring loaded pins are really really really hard to squeeze in. I wish they had used two threaded screws instead. That would still be very fast and two would protect against shear.

Stability: (5=best)
FL: 4 – with the thigh straps and knee & shin pads I felt securely locked in. The bottom bracket provides a non-slip 1" long x 5-6" wide bar of contact with the ground and the polymer compound has some 'stick' to it meaning it doesn't slip or slide easily. I always felt secure – walked in rain, snow, ice. This is a key advantage of FW.
iW: 2 – the bottom pad (actually two pads) where the device touches the ground is rounded front to back I suppose so that you can roll into and out of your gait. However the two pads are also offset in height. Therefore it is more of a point contact than I liked and I had many uneasy moments and slight slips. I hated that and wished they had used a bottom assembly more like the FL. Anyone who has researched hiking boots knows that different compounds can result in different stickiness in a variety of terrain. The pads on the iW should be stickier - they may wear faster but who is going to wear this thing out anyway - and since they are replaceable it's not a problem. Also, the unit anchors at the knee. The knee can move sideways to some degree and this can cause some instability at times although this can be adjusted with the thigh bracket to a degree.

Ease to Walk (5=easiest)
FL: 4 – FW was a clear winner here – more natural gait and spring
iW: 2 – I was much less secure in the iW and fatigued.

Fatigue to Use (5=less fatigue)
FL: 3 – took a longer time to fatigue – since the support is anchored at the thigh you engage the

glutes more and there is more ‘spring’ in your step. It actually felt like a decent workout if I used it for a long enough period. I'd feel fatigued in the hip due to the less than natural gait.
iW: 1 – very quick to fatigue. Constant landing on the knee and shin would hurt and fatigue my knee and hip pretty fast. Even though the iW is padded there is no spring in your step and landing feelings jarring.

Handling Stairs – (5=easiest)
I don’t think anyone should use either device without a handrail unless it’s a single step up or very gradual steps.
FL: 4 – it was pretty easy going up or down (got where I go up or down normally rather than the step (with good)-meet (with bad), step-meet process.
iW: 2 – not as stable going up and best to turn around to go down the stairs backwards as bad leg bottoms out on the stair behind it if going forward– can only do step-meet

Driving: (5=easiest)
FL: 4 – left it on while driving a minivan and also a sports sedan
iW: 0 – have to remove it

Riding in Car (5=easiest)
FL: 4 – left it on in a Range Rover, a Taxi, and a Honda Fit
iW: 1 – best to take it off

Sitting Down: (5=easiest)
FL: 5 – leave it on – stick your leg down or put it on a chair
iW: 2 – best to take it off

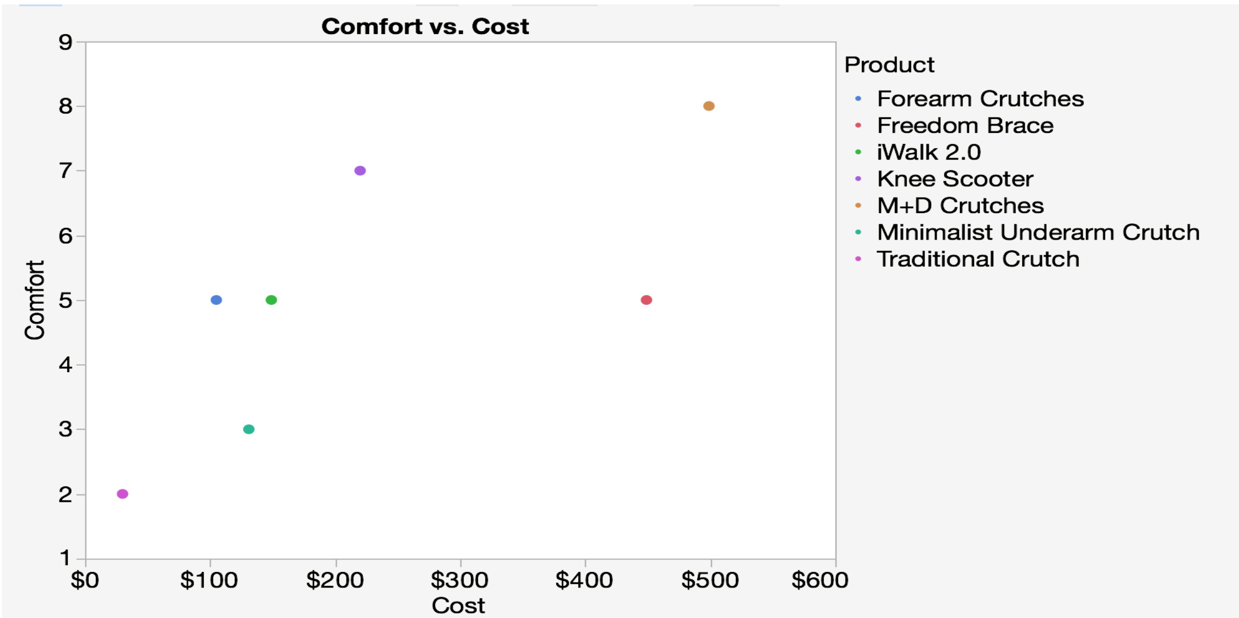
Summary:
FL: *Hated the price: concerned about quality*: customer support was good (although I have heard this is a problem for many), loved to use it.
iW: Okay with the price: quality is great: can’t comment on customer support, *didn’t enjoy using it*.

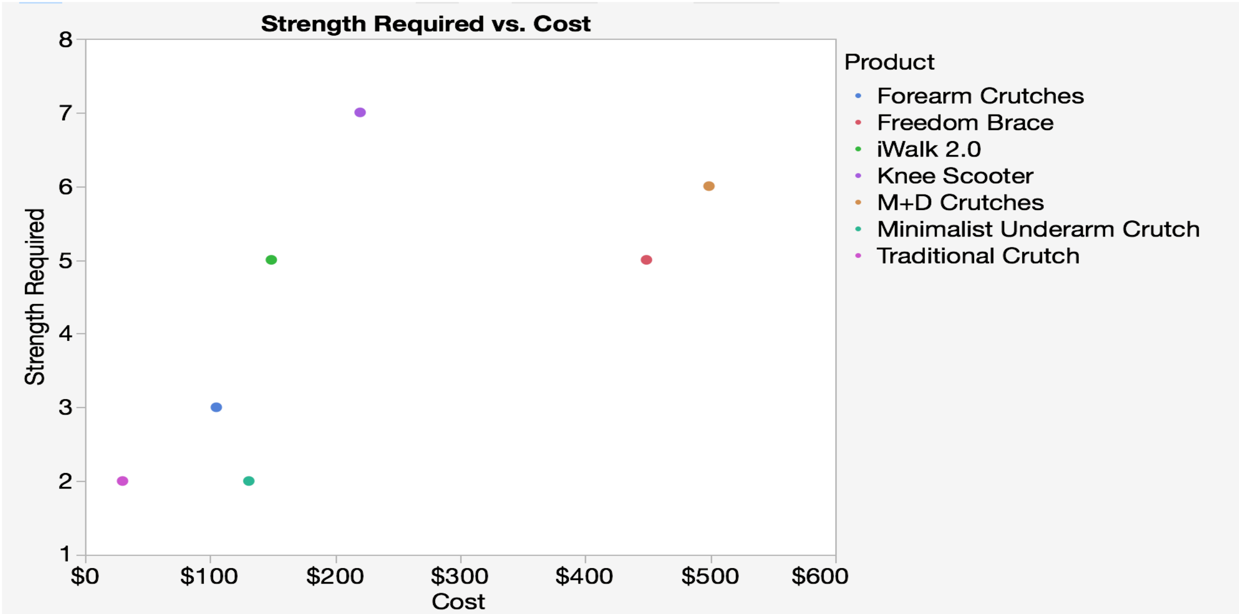
The one I would buy if money was no issue - FL
Good Value - iW but please see the negatives!

Appendix B: Customer interview results regarding the use of standard crutches

Injury	Solution Used	Time Using Solution	Pros	Pros (broken down)	Pros Impact (1-10)	Cons	Cons (broken down)	Con Impact (1-10)
distal fibula fracture	traditional crutches	5 weeks	could move	mobility	10	ran into things b/c crutches are so wide	wide profile	4
			didn't rebreak ankle	relieves weight	10	couldn't carry anything while walking	not hands free	8
						got fatigued easily	requires strength	5
						sweated anytime going long distances	smelled bad	2
						hurt underarms	pain	5
						didn't have anywhere to put crutches		3
						hard to get in/out of car		6
torn achilles tendon	crutches (webbed underarm)	3 weeks	could move	mobility	9	couldn't carry anything while walking	not hands free	7
			didn't retear tendon	relieves weight	10	got fatigued easily	requires strength	5
						hard to get up to get crutches	detached	6
broken calcaneus	leg scooter	2 weeks	could move	mobility	10	stairs		7
			no reinjury	relieves weight	10	bumps going through doorways		4
			basket on front	storage	4	wide, couldn't really use inside		9
			doubles as seat		2			

Appendix C: Graphical analyses of various qualities for competing technologies




Strength Required vs. Cost
Strength Required
8
7
6
5
4
3
2
1
$0
$100
$200
$300
$400
$500
$600
Cost
Product
Forearm Crutches
Freedom Brace
iWalk 2.0
Knee Scooter
M+D Crutches
Minimalist Underarm Crutch
Traditional Crutch

Appendix D: Fall Quarter Deliverables

Deliverable	Owner	Due Date	TK Contribution	Marcus Contribution	Cooper Contribution	Beers Owed?	Who's Buying?
Presentation	Team	Week 3	30%	40%	30%	No	n/a
Competitive Landscape Research	Team	Week 6	33%	33%	33%	No	n/a
Interviews	Team	Ongoing	33%	33%	33%	No	n/a
Funding Proposal	Team	Week 5	40%	20%	40%	No	n/a
First Chapter	Team	Week 10					
Team Building Module	Individual	Week 3	done	done	done	No	n/a
Customer Awareness Presentation	Team	Week 7	33%	33%	33%	No	n/a
Customer Awareness Report	Team	Week 8					
CDR	Team	Week 10					

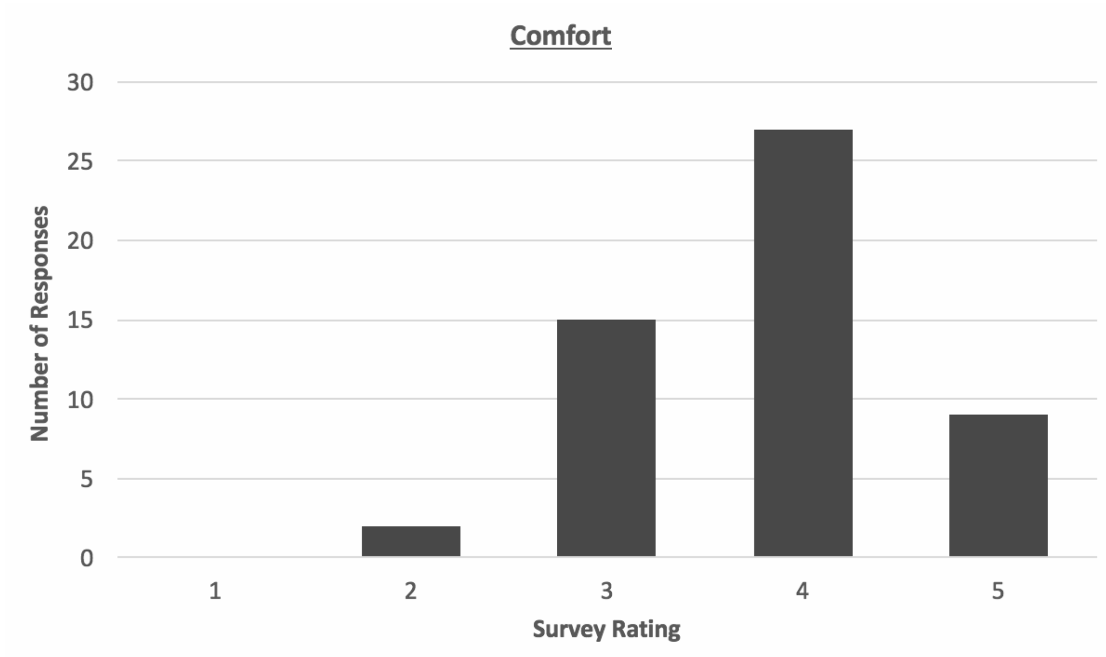
Appendix E: Winter Quarter Deliverables

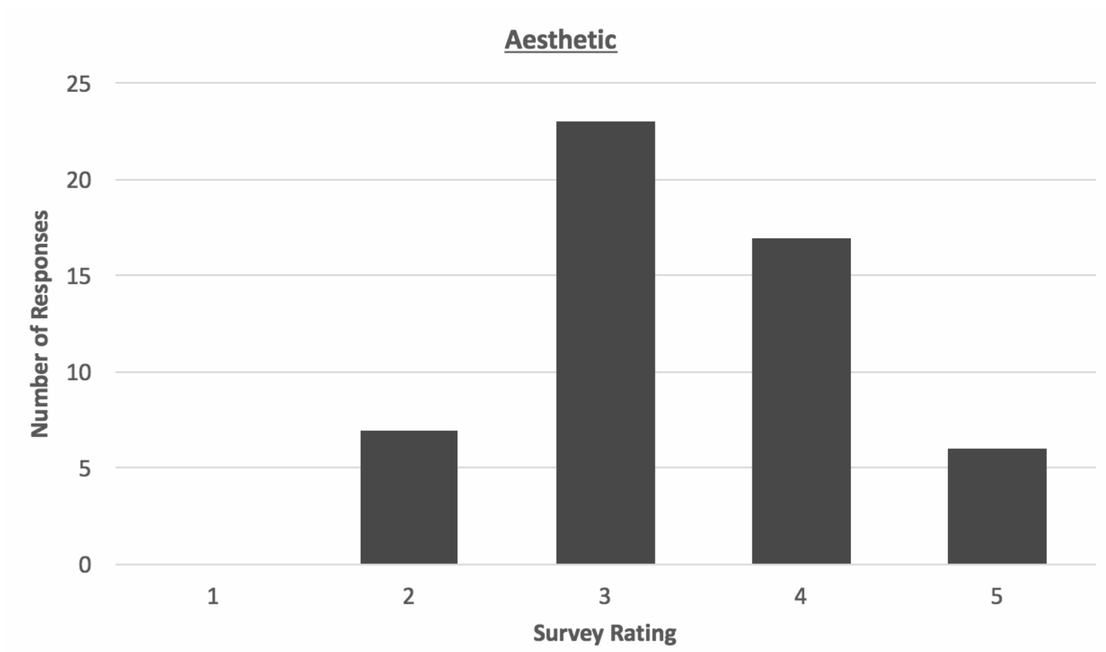
Deliverable	Due Date	TK Contribution	Marcus Contribution	Cooper Contribution	Beers Owed?	Who's Buying?
Progress Presentation One	02/16/2018	33%	33%	33%	N/A	N/A
Prototype	03/02/2018	40%	30%	30%	N/A	N/A
FDR Thesis (Initial)	02/23/2018	30%	40%	30%	N/A	N/A
FDR Thesis (FInal)	03/09/2018	N/A	N/A	N/A	N/A	N/A
Progress Presentation Two	03/16/2018	N/A	N/A	N/A	N/A	N/A

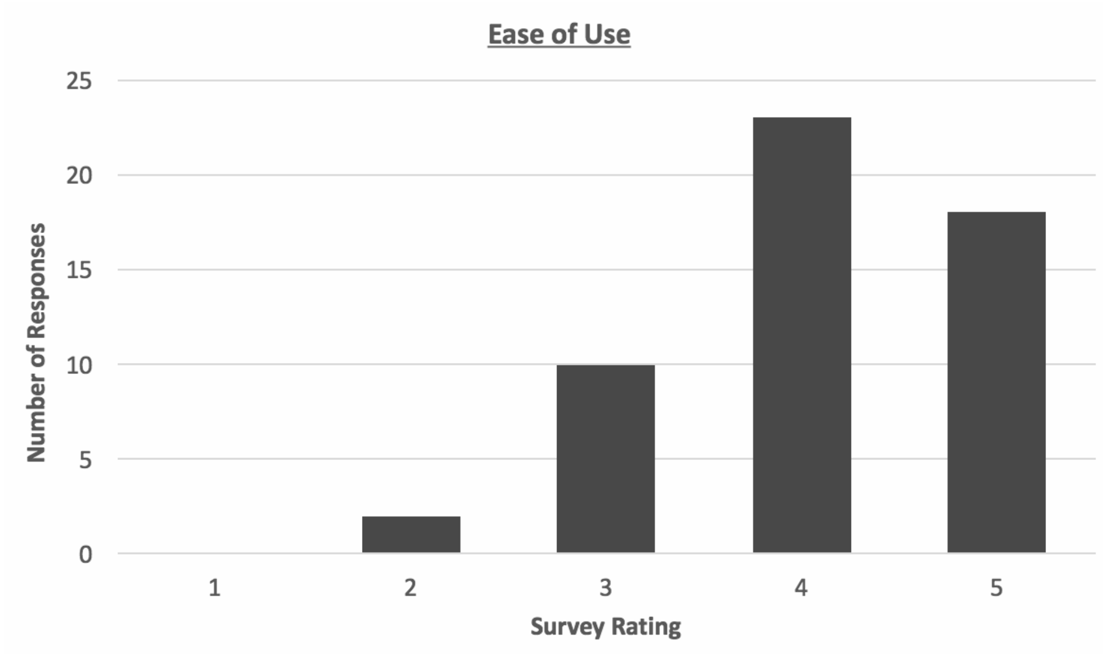
Appendix F: Project Grant Chart

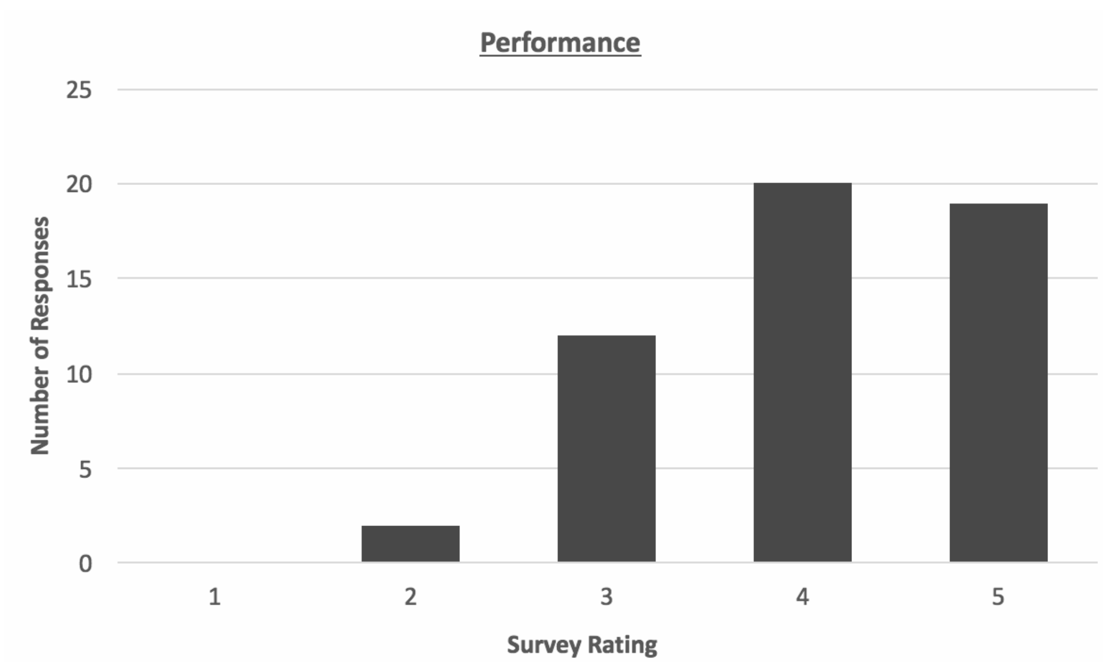
	Month										
Task	**September**	**October**	**November**	**December**	**January**	**February**	**March**	**April**	**May**	**June**	**2019**
Project Acceptance Criteria	■	■									
Market/Customer Research		■	■								
Problem Statement Generation			■								
Establish Budget			■								
Developing Preliminary Design			■	■	■						
Conceptual Design Review				■							
Prototype Production					■	■	■				
Prototype Testing							■				
Redesigning/Final Prototype Design							■	■			
Write Thesis							■	■	■		
Senior Design Conference									■		
Further Development/IP										■	■

Appendix G: Graphs of prototype user survey data






Ease of Use
Number of Responses
Survey Rating
25
20
15
10
5
0
1
2
3
4
5


Performance
Number of Responses
Survey Rating
25
20
15
10
5
0
1
2
3
4
5

Appendix H: Photos of prototype users

Appendix I: Photos of final prototype at each leg angle - side view

Appendix J: Photos of final prototype at each leg angle - front view

Appendix K: Competing Technology Patent Search

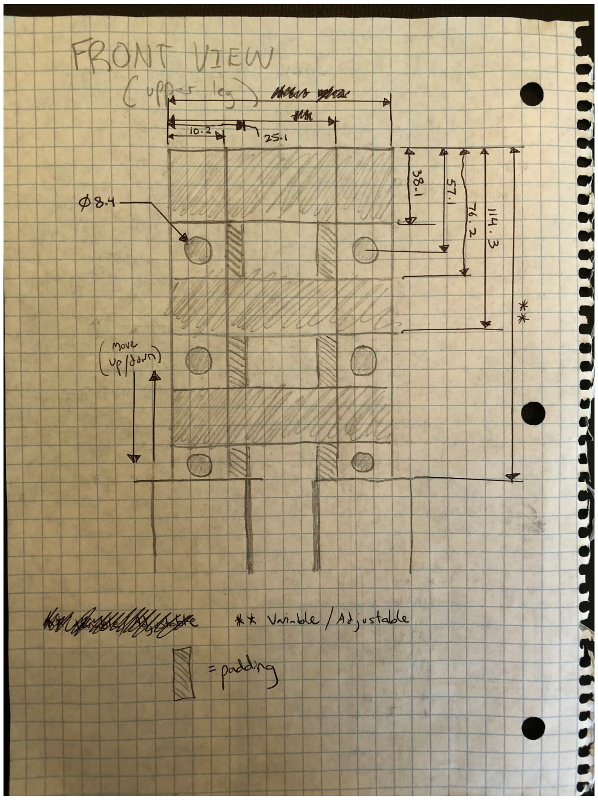
HANDS-FREE CRUTCH Patent No.: US 9.408,443 B2
CRUTCH DEVICE Patent No.: US 6,494,919 B1
LEG BRACE Patent No.: US 9,180,037 B1

The two main hands-free crutch solutions on the market today are the iWalk and the Freedom Leg by FwdMobiliy. While there are numerous patents outlining potential hands-free crutch devices, only these two were found *actually* in production after an extensive search. The iWalk reports two patents that contributed to its design: HANDS-FREE CRUTCH and CRUTCH DEVICE (seen above). The Freedom Leg has a single patent titled LEG BRACE. Issues with the iWalk include having a solid, horizontal platform that supports the weight of the user and the lower leg at all times. While keeping the injury elevated and protecting it from ground-level obstacles, users have reported that much of their weight is focused on their kneecaps which causes discomfort. The Freedom Leg's design, in contrast, causes the user's leg to remain pointed downward in a natural walking position. Both the iWalk and the Freedom Leg do not allow the angle of the lower leg to be altered. We feel our solution is better because we see the benefits in both models and look to give users the option to choose between natural walking mechanics and increased support by allowing them to change the angle of their lower leg via our adjustable leg sling. This also serves a more clinical purpose. Physicians may advise their patients after an injury to, over time, place increasingly more weight on the injury to strengthen the nearby bones. Our solution promotes this increase in load; the leg sling parallel to the ground with the lower leg at a 90 degree angle will provide optimal support and minimal load on the injury, while smaller angles will provide more load, ending with maximal load with the leg pointing straight down.

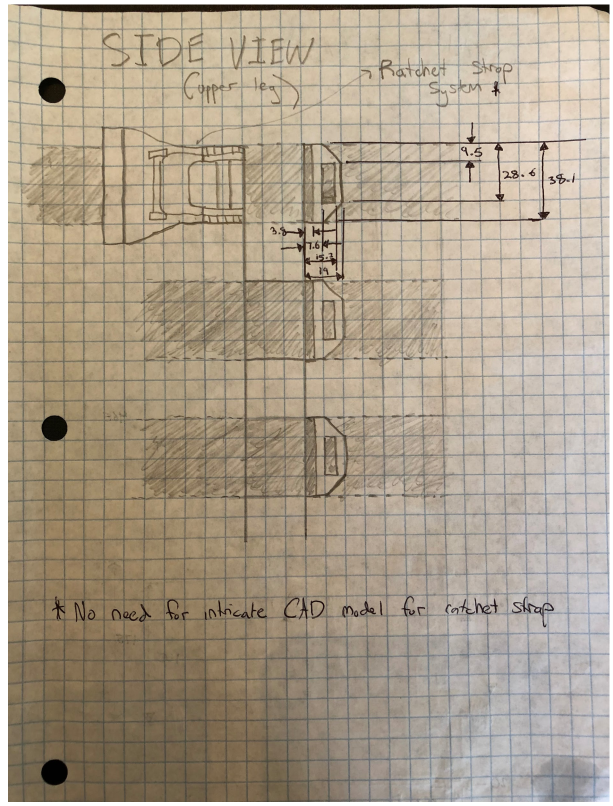
Appendix L: Mechanical Drawings for CAD Subsystems

UPPER LEG

Front View

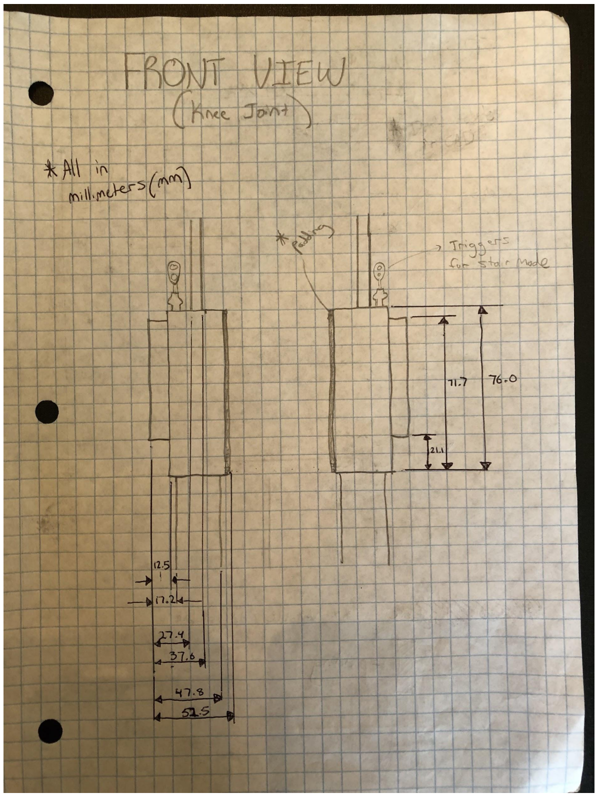


Side View

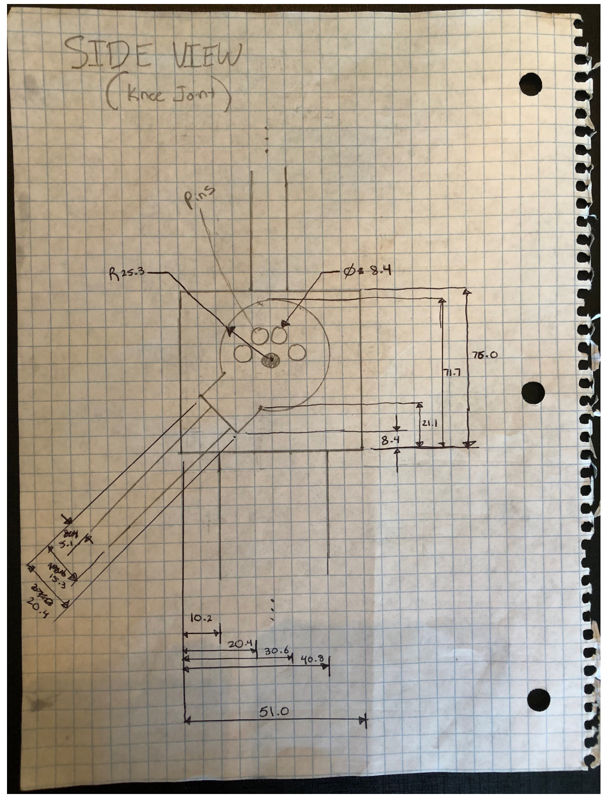


KNEE JOINT

Front View

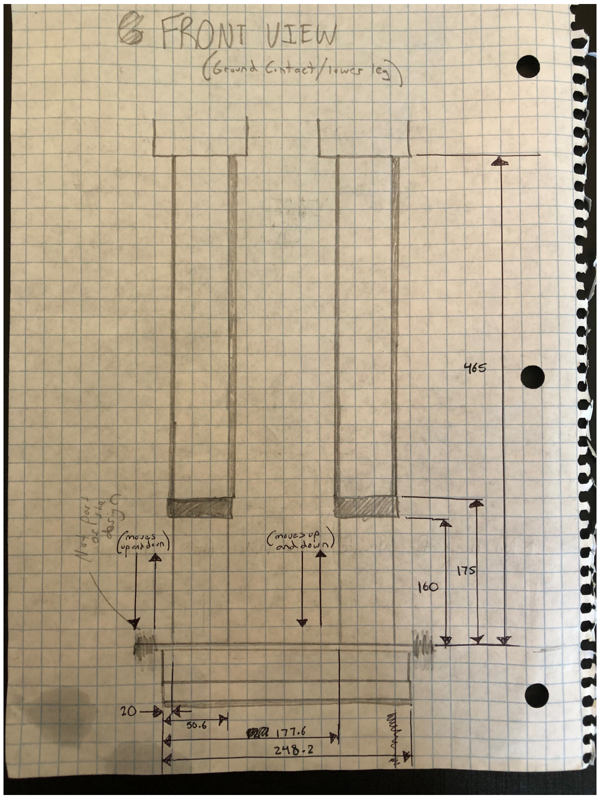


Side View

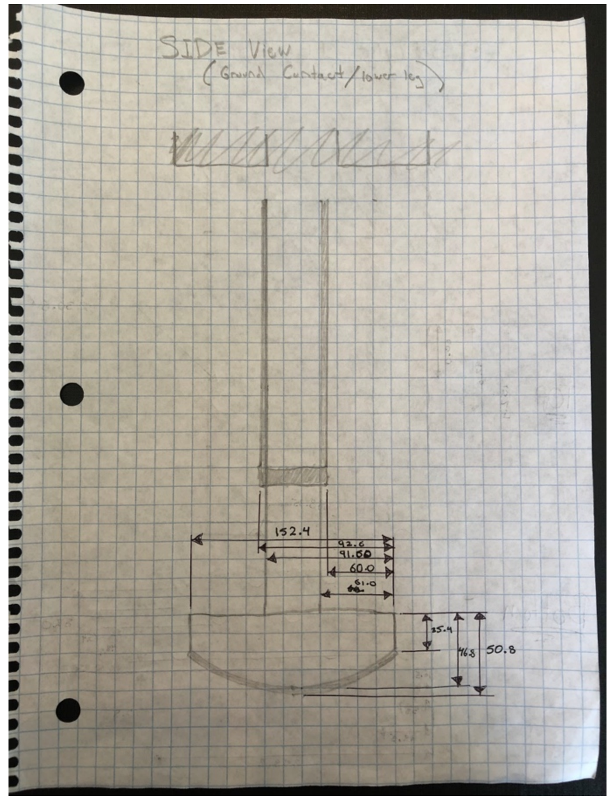


LOWER LEG

Front View

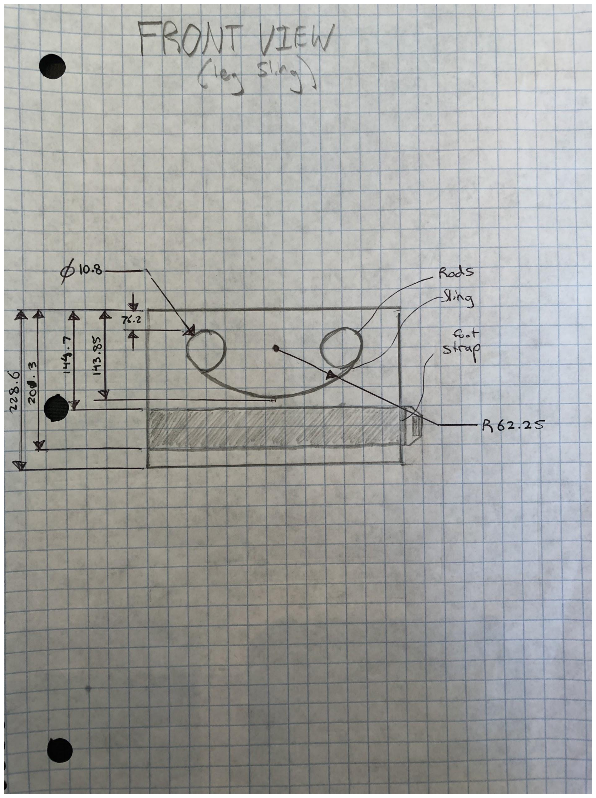


Side View

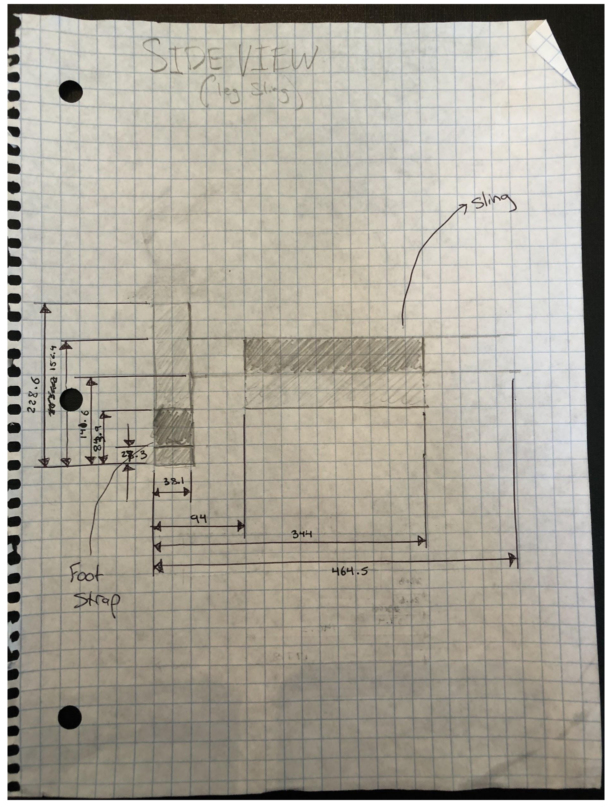


LEG SLING

Front View

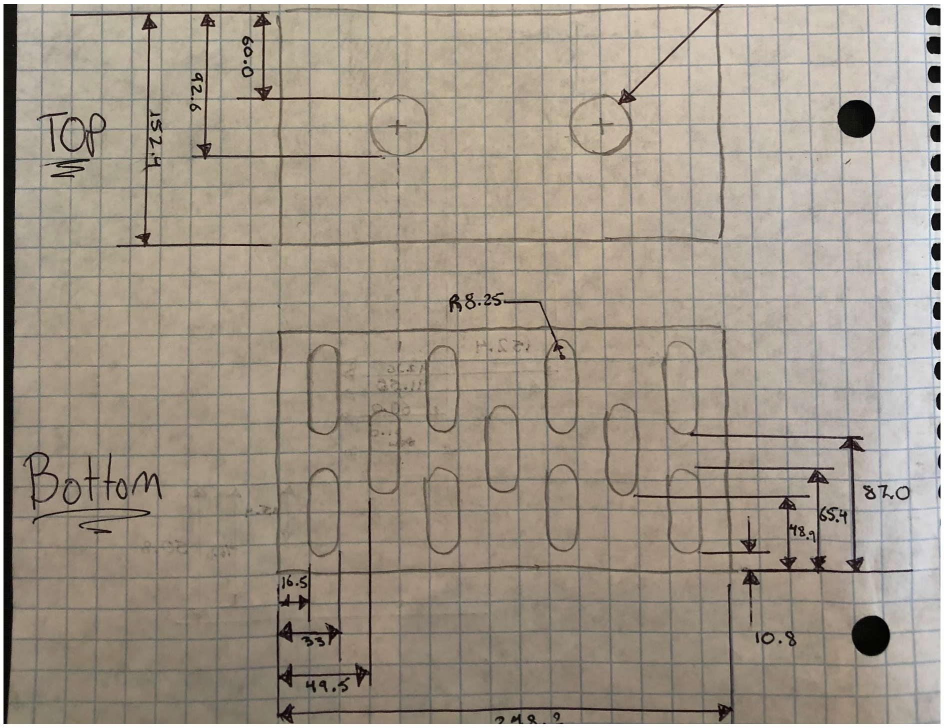


Side View



GROUND CONTACT/INTERFACE

Top/Bottom View



Appendix M: Prototype Bill of Materials

Appendix M1: Parts Material List

Item #	Name Of Part	Material	Quantity	Manufacturer	Manufacturer Part #
1	Crutch/Ground Interface	Douglas Fir Wood	1	SCU Team	SCU01
2	Flat Bar Aluminum 1” x ⅛” x 48”	Aluminum	1	Everbilt	SKU 482552
3	Multimaterial 8” x 1-½” construction screws	Yellow Zinc	3	SPAX	1000-021-904
4	Grip Premium Liner 20” x 4’ White	Thick Foam	1	Con-Tact	04F-C6O52-01
5	Grip Premium Liner 18” x 4’ Black	Thin Foam	1	Con-Tact	04F-C6U59-01
6	Highline Dropper Post	7075-T6 aluminum	2	CrankBrothers	
7	Dowels 0.75” x 0.75” x 48”	Hardwood	2	Home Depot	0000-659-601
8	Leg Sling Footrest	Wood	1	SCU Team	SCU02
9	Knee Joint	Douglas Fir Wood	2	SCU Team	SCU03
10	Eye Bolt with Nut ⅜” x 5”	Zinc	4	Home Depot	SKU 116220
11	Hex Bolt ¼” x 4”	Zinc	2	Home Depot	AOC 06956
12	Hex Nut ¼”	Zinc	2	Home Depot	AAB 06426
13	Knee Platform Padding	Foam	2	iWalk	IW00012
14	Upper Assembly Poles	Steel	2	iWalk	IW00005
15	All-Purpose Straps 36” x 2”, 2 Pack	Nylon	2	VELCRO	0000-245-578
16	T Lock Buckles	Plastic	4	iWalk	IW00011
17	Gloss Protective Enamel Black Paint	Paint	1	RUST-OLEUM	0000-480-169
18	Epoxy Glue 0.85 oz	Epoxy Resin	3	Gorilla Glue	0000-757-442

Appendix M2: Parts List - Costing

Item #	Name Of Part	Manufacturer Part #	Type	Method	Cost
1	Crutch/Ground Interface	SCU01	Custom	Machined	$11.65
2	Flat Bar Aluminum 1" x ⅛" x 48"	SKU 482552	Hardware	Purchased	$9.67
3	Multimaterial 8" x 1-½" construction screws	1000-021-904	Hardware	Purchased	$2.17/box
4	Grip Premium Liner 20" x 4' White	04F-C6O52-01	Fabric	Purchased	$6.27
5	Grip Premium Liner 18" x 4' Black	04F-C6U59-01	Fabric	Purchased	$6.27
6	Highline Dropper Post		Hardware	Purchased	$267.00/each
7	Dowels 0.75" x 0.75" x 48"	0000-659-601	Hardware	Purchased	$2.54/each
8	Leg Sling Footrest	SCU02	Custom	Machined	Donated
9	Knee Joint	SCU03	Custom	Machined	
10	Eye Bolt with Nut ⅜" x 5"	SKU 116220	Hardware	Purchased	$0.98/each
11	Hex Bolt ¼" x 4"	AOC 06956	Hardware	Purchased	$0.26/each
12	Hex Nut ¼"	AAB 06426	Hardware	Purchased	$0.06/each
13	Knee Platform Padding	IW00012	Fabric	Purchased	$149.00
14	Upper Assembly Poles	IW00005	Hardware	Purchased	
15	All-Purpose Straps 36" x 2", 2 Pack	0000-245-578	Fabric	Purchased	$5.96/each
16	T Lock Buckles	IW00011	Hardware	Purchased	
17	Gloss Protective Enamel Black Paint	0000-480-169	Decoration	Purchased	$3.98
18	Epoxy Glue 0.85 oz	0000-757-442	Adhesive	Purchased	$5.47/each
Total					**$760.98**

Appendix N: Force Calculations

Assumptions: - The upper leg is perpendicular to the ground at maximum impact.

- The load is calculated from the bottom of the foot.
- The foot is approximated as a point.
- Weight is evenly distributed between the two halves of the body.

Load in terms of % body weight = 50cos(Θ)

Angle (Θ, in degrees)	0	25	50	90
Load	50%	45%	32%	0%