Project Kutembea

December 17, 2016

EID-101-E

Professor Anita Raja

By Group 2 consisting of:

Mrigank Saksena, Changru Chen, Ivan Chowdhury, Naomi Javitt, Matthew Jumadiao, Felix Klein, Armaan Kohli, Alex Liu, Samuel Makarovskiy, Sally Na, Daniel Zabari, and Peter Zhao

Table Of Contents

Executive Summary

Project Kutembea is a project we are working on in order to make low-cost prosthetic limbs for children and adults in Soroti, Uganda who suffer from malnutrition diabetes. Soroti is an agrarian society where a majority of jobs are in farmlands. Because of this, it is important that workers are able to move about in order to farm and tend to their land. The issue that arises is that when the soon-to-be amputee loses his limb, he is unable to go back to work and therefore loses his source of income. Not only that, but it is extremely important that amputees are able to be reintegrated into society. Uganda is a developing nation; there is no easy access to natural resources and money is scarce. Children are already suffering from malnutrition and this is the cause of many complications such as diabetes leading to amputations. Without a prosthesis, the life expectancy of amputees in Soroti is significantly diminished. In order to help these people, the problem was analyzed and the exact criteria that had to be met were defined. We used various charts including a Gantt chart and a Why-Why diagram in order to analyze the situation and come up with solutions in a much more effective way. Once we analyzed the different solutions we realized that the best solution was to create a prosthetic limb. Some criteria included durability, cost, comfort, and aesthetics. We began brainstorming ideas for our prosthetic and began by figuring out what materials we were going to use. We did this by performing a cost-analysis of all materials we could use for the parts of the prosthetic limb. After finding the materials we began the modeling process. We made diagrams on SolidWorks and CAD and consulted experts for advice. We went to a specialist at the Hospital for Special Surgery who gave us an idea of how prosthetics work today and how we can build a low-cost prosthesis using similar techniques. We also talked with experts about our design, and they were able to give us valuable insights on the specifics of building the prosthesis. After adhering to their advice, we tweaked our design until it met all of our restrictions. Once we began building the design, we noted a lot of our flaws and were able to work on them by constantly improving our design. After we built the prototype we began the testing and evaluation process. In SolidWorks, we were able to perform multiple stress tests in order to see how the prosthesis would perform under varying circumstances. After this, we began testing the prosthetic in person by performing a drop test and stress test.

Design Problem & Objectives

The primary problem being addressed is the lack of an affordable prosthesis in Uganda. Many families in Soroti are unable to afford a prosthesis, let alone the maintenance costs that arise from wearing a prosthesis. That is why one of our group's objectives is to have the final prosthesis cost less than $40 to produce. Although the prosthesis must be affordable, it must also be sturdy enough to withstand the conditions of Uganda. Many of the jobs in the region are agriculture based, so the prosthesis must be able to endure the heat and rugged terrain. Because creating a custom prosthesis for the patient has a high price, our group decided to create a single model that is adjustable in height and size of the socket. This would allow the prosthesis to be easily mass produced. Another design goal was to create a model that has modular parts so that if a single piece breaks, the whole prosthesis does not have to be replaced. Comfort for the patient was also a goal, as the design planned on reducing stress on the bones of the stump. The final objective was aesthetic of the prosthesis. Many people who become amputees are outcasts of society, so our design attempted to replicate the appearance of a human leg to reduce stigma and help the patient reintegrate into society.

Detailed Design Documentation

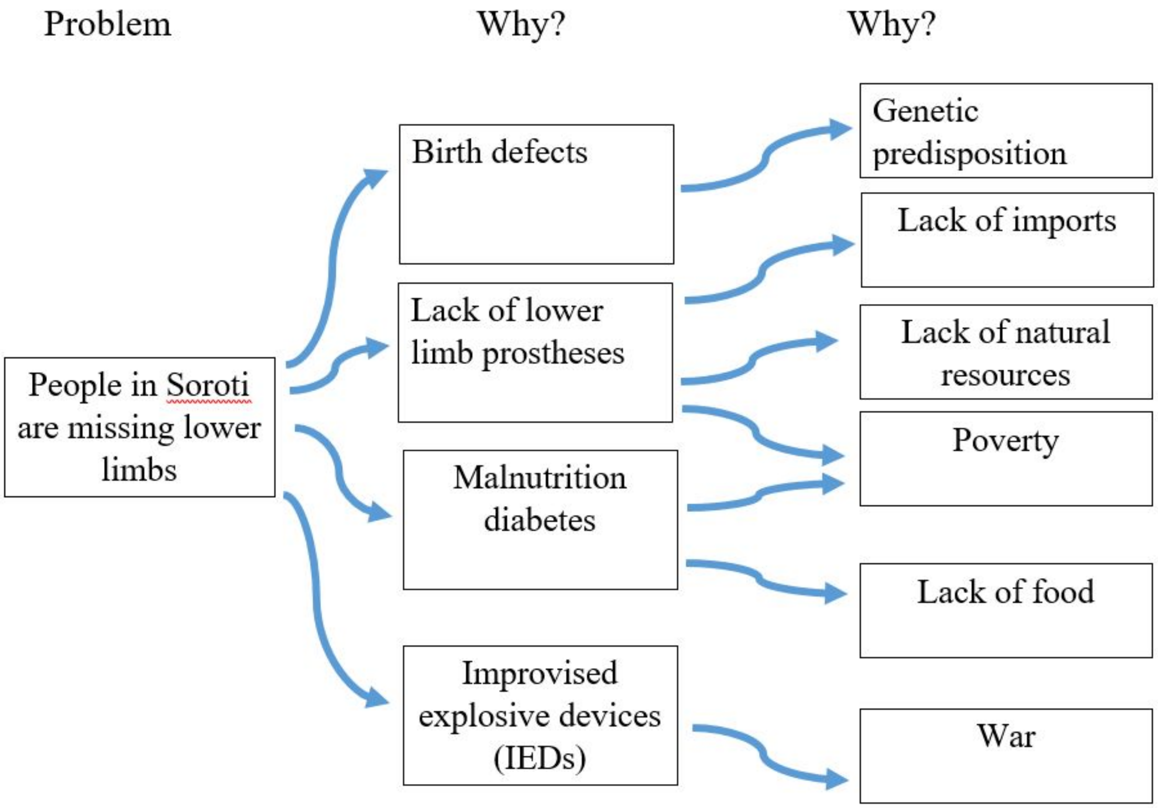
A.) Assumptions Made

We made several assumptions about the uses of the prosthetic limb, the type of people using the limb, and the time that the limb would be used. We assumed that the limb would be used by a working class Ugandan who farms for a living and who would be walking on uneven terrain and operating in a tropical climate. As such, we chose durable, weatherproof materials in PVC and rubber and opted for a limb with an ankle joint to allow the foot to adapt to uneven surfaces. In addition, our clients would most likely be of normal height and weight, which determined our estimates for the size of the socket, the length of the pylon, and the maximum load our limb could take.

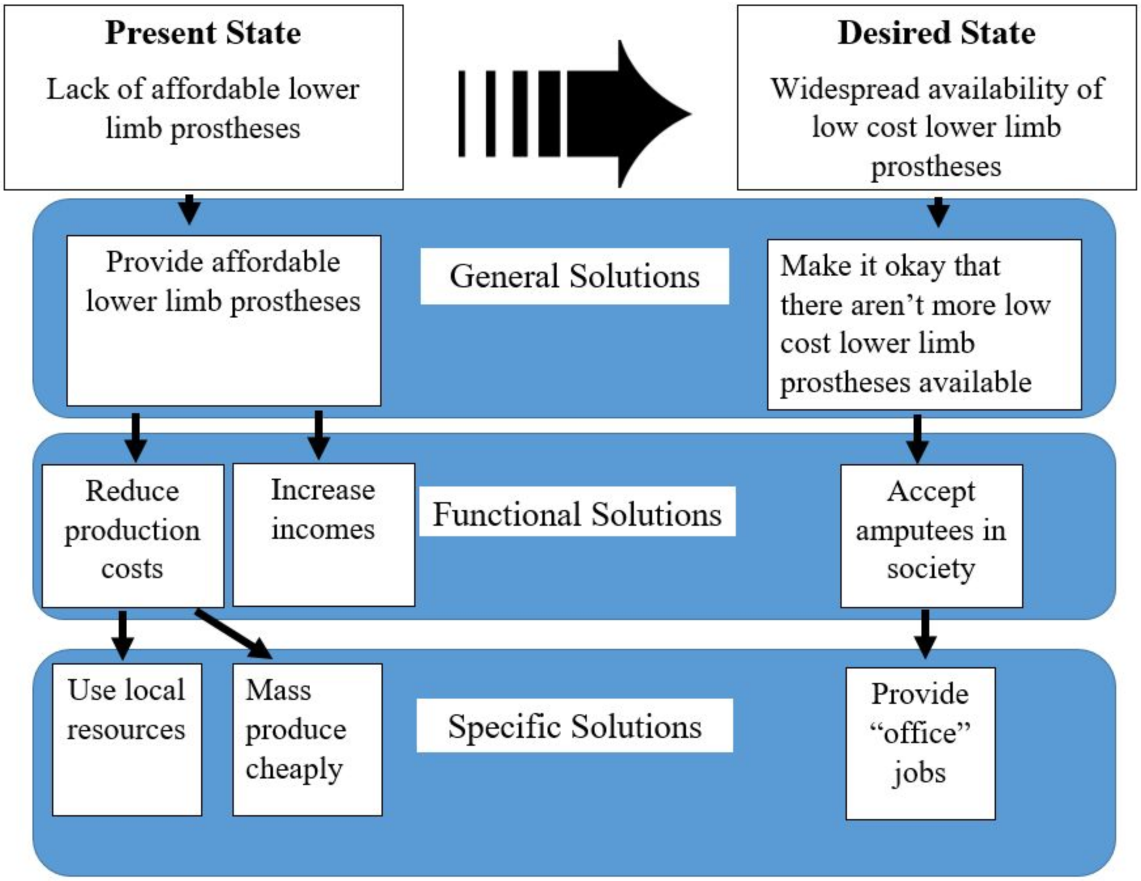
We also assumed that our clients' families would make around 650 dollars a year and that it would be a hassle for amputees to travel to the site where they would be fitted with their limbs, meaning that we had to reduce maintenance costs as much as possible and limit the need for repeated trips back to the clinic to maintain the prosthesis. As a result, we decided on having an adjustable socket and pylon as well as a modular design. An adjustable socket meant that our clients would not need to return to the clinic after a year to have their sockets remade due to their their stump getting smaller. This, along with an adjustable pylon would allow young amputees to constantly readjust their limb as they grow or for a deceased amputee to bequeath his or her limb to someone else. Plus, a modular design makes it possible to easily replace defective parts of the limb rather than spending the time and money to replace the entire thing. In summary, modularity and adjustability means that the entire process of fitting, making, and buying a prosthesis is convenient, efficient, and low cost.

B.) Why-Why Diagrams, Duncker Diagrams

The Why-Why Diagram is used to help determine the source of the problem we are trying to solve. From it, we determined that there were several reasons for lower limb loss in Soroti.



The purpose of the of the Dunker Diagram is to help us analyze potential solutions and their viability.



C.) Function of the System

The functional purpose of the system was to allow lower-limb amputees in Soroti, Uganda to reintegrate back into society and live normal lives. After evaluating the possible solutions, a prosthesis was determined to be the best method to help the amputees. The structure of prostheses typically consists of a socket, pylon and foot.

The socket is the part of the prosthesis that receives the amputee's stump and connects the stump to the pylon. The socket's chief purpose is to grasp onto the stump securely so that the prosthesis does not fall off during use and to make the prosthesis comfortable to wear for the user by conforming to the stump shape and distributing the weight of the user well.

To achieve both security and comfort, our socket design uses a standard sized hard outer shell that loosely fits the stump, with space left over. Inflatable rubber lines the inside of the shell, so that when pumped full of air, the rubber compartment will inflate to fill the space between the stump and the outer shell. A nozzle is accessible from the outside of the outer shell, channeling air into the inflatable rubber compartment.

Through this design, the socket will conform to the shape of the user's stump because the rubber inflates around it and is elastic enough to conform to it. In addition, the inflated rubber also acts as a shock absorber due to the rubber's elasticity, which also means that none of the surfaces in contact with the stump will be hard. As a result, the socket will not cause any pain to the user. Because of all these qualities, our socket will be quite comfortable for any amputee. At the same time, the rubber material is strong enough not to pop under pressure but rather keep the stump firmly in place. In addition to the rubber around the stump, we will use a harness that goes over the outer shell and attaches to the upper leg to further secure the stump. Thus, our socket will ensure that the stump does not move around in the socket and that the prosthesis does not fall off or shift during use.

The pylon acts as the shin of the apparatus. It connects the socket to the foot while being able to support the force of the weight transferred through the socket. It should be exceptionally effective in sustaining vertical loads and should deal with reasonable shear stress that may arise during walking. The size of a prosthesis is dependent on the height of the wearer and must be adjusted during the initial fitting accordingly. The pylon is generally where the height is most economically adjusted.

Our design for the foot addresses both the need for durability and the varying heights of potential users. For strength, we use two PVC pipes, one inside the other and held together with screws. There are holes along the length of the pylon so that the user can adjust the length of the pylon by taking out the screws, moving the inner cylinder, and rescrewing the two cylinders together. That way, we can make a mass produce a standard pylon, which is more efficient and cheaper.

The foot is meant to serve the function of a human foot. In that sense, it must be slightly flexible around the ankle to allow a ten to fifteen degree range of motion. This is especially necessary in the rough, hilly terrain in Soroti. The foot must also redistribute the load of the weight from above into the ground in order to reduce stress and the possibility of breakage points.

Our ankle design achieves the necessary range of movement without being too flexible by making use of a rubber tube that stretches to allow the foot to bend when enough pressure is applied. The foot itself is made of wood and wrapped in rubber for durability and grip on the ground.

Overall, the system must be affordable (less than 40 US Dollars), durable in that it will last over a year, and ideally locally produced.

D.) Ability to Meet Engineering Specifications

From a design perspective, only materials and expected connections could be analyzed before vigorous testing. The skeleton of the pylon and foot is schedule 40 PVC piping which can withstand loads upward of 800 pounds. Shear stresses are less predictable and could only be evaluated during the testing phase. The connection between the foot and the pylon in both foot designs (as will be elaborated in the following sections) are held by radially molded, 1" thick rubber. The major concern in regard to the rubber is its tendency to dry, crack and lose structural integrity after a few years. However, that timeframe is outside the desired life expectancy of the system, so it can be ignored but is worth noting. The two foot designs themselves are meant to allow for the range of motion in the ankle and toes through controlled flexion and elastic rebound of the rubber in those areas.

The two shaft system of the pylon is meant to allow for individualized adjustability, but it also creates two stress points along the lengths of the bolts connecting the two shafts. However, the compressive strength of PVC (50 MPa) and the tensile strength of steel bolts (400 MPa) are capable of sustaining loads far greater than those expected of humans.

The socket's cylindrical structure makes for great redistribution of force despite it being composed of relatively weak PLA from 3D printing. The inflatable rubber prevents the pressure points on the residual limb from translating to stress points along the socket. The rubber redistributes the force of the weight effectively and acts as a buffer between the limb and PLA. The inflatable rubber serves to connect the limb to the prosthesis via friction. The rubber itself can withstand forces upwards of 200 psi which is well beyond the means of the wearer.

The connection between the pylon and socket is fixed by two steel bolts which should be strong enough to sustain the forces of human body weights due to their material properties. The PLA will have a stress-point at the interface of the PVC pylon and the two bolt connections. The PLA is likely to deform at these locations due to wear, but further testing will clarify the actual outcome. Additionally, PLA is only used in the prototype, PVC is the desired socket material because it is more durable and should be locally available.

E.) Prototypes Developed, Their Testing and Results Relative to Engineering Specifications

Generally, a socket has a custom shape made by taking a mold of the stump. However, everyone's stump sizes and shapes are different and change over time due to muscle shrinkage. This means users of current prostheses need to make a new socket every so often, returning for a new mold every so often for a few years until the size of the stump is stabilized. Our solution is to have a one-size-fits-all PVC reducer socket, with an inside lining of inflatable rubber. This socket narrows down on the bottom to fit into the PVC pipes that make up the pylon. The inflatable rubber acts similar to the inner lining of a bicycle tire, getting inflated by pumping air into the nozzle that conveniently extends out of the socket. This rubber binds around the user's stump like a sphygmomanometer, the instrument used to measure blood pressure, and morph to any shape and size. This accounts for the various stump sizes which is the issue with currently used sockets. Not only does this socket design act as a holding mechanism to keep the prosthesis in place, but it also acts as a shock absorber that cushions the stump. This idea was carried on throughout our prototyping process. We used a rubber tire inner-tube and a 3D printed model of the socket for materials. We left a hole in the 3D printed socket model for the nozzle of the inner-tube and two holes in the narrow cylindrical portion of the socket for the bolt connection between the socket and the pylon. We tested the socket by inflating the rubber tire with a PVC pipe in the middle of it. The whole prosthesis was successfully lifted, and the PVC pipe was held in place by the inner-tube. Furthermore, there was very little movement of our testing stump within the socket, making our socket very stable. This verified that our inflatable rubber and socket idea worked.

For the pylon design, our group focused on length adjustability. We decided to have 2 PVC tubes with holes drilled on the sides. One is narrower than the other, so that it slides in and out to allow for the desired length adjustment. Two screws were used to hold the inner PVC tube in place. This design gives a level of tolerance to compensate for expansion as well. When we built the pylon following this design, it was sturdy and convenient. Although we previously had planned to add a skin layer to the pylon for aesthetic reasons and for protection from minimal injures or weather, we had to give up the idea to make the prosthesis lighter and more cost-effective.

For the ankle, we had two different designs: a ball joint model and a rubber cylinder design. Our objective was to have an ankle joint that allows for about 10 to 15 degrees of movement but is stable. We began by attempting the ball joint design in which the lower PVC pipe of the pylon is attached to a ball, which slides on a horizontal PVC pipe that acted as the tarsals and metatarsals of the foot. A rubber layer was supposed to wrap around the entirety of the foot and go up to the ankle to keep the ball from slipping out of place. As we were building this ankle design, there were many modifications, eventually leading us to attach the ball to the horizontal PVC pipe in the foot. Because of issues in making a proper mold, a cheap rain boot was used instead. We placed the ball, horizontal PVC pipe and lower pylon PVC pipe inside one boot and poured in rubber. However, this process did not go as planned because the rubber did not harden as we wanted, and the pylon was unable to slide on the ball. Hence, this ball joint design was discarded and we ultimately settled on a new ankle design, using a simple rubber cylinder.

The rubber cylinder foot design is a complete change from our initial idea. It consists of a solid wooden block, preferably hardwood, for the whole of the foot. The mobility in the ankle is a product of a flexible rubber cylinder acting as a tendon. This rubber is secured via wood screws through the rear of the foot such that the rubber is perpendicular to and extruding from the top of the foot. The extruding rubber above when connected to the lower pylon allows for flexion and extension like a human ankle. The range of motion of the rubber cylinder is constrained by a rubber washer roughly 3” in diameter that is inserted over the rubber cylinder. The lower PVC pipe of the pylon is fastened to the rubber washer and cylinder by 4 orthogonal wood screws.

We wanted to have a design similar to the normal human foot with toes, but doing so in wood was unreasonable so the front end of the block was carved to form a curve at the front that allows foot to roll with the ankle like the toes would. A flat sheet of rubber is glued to the bottom of the block to act as a sole for traction.

F.) Cost Analysis

The main objective of our design goal was to stay within budget. What makes our prosthetic limb unique is its low cost and feasibility. We made sure to keep the cost down in order to make it practical for amputees in Soroti to use our product. We were given $400 to design, build, and test our prototypes, and our final product had to be under $40, including the cost of labor. With high end prosthetic limbs costing thousands of dollars, we had to think more practically in terms of materials and parts. After researching materials that fit our needs, we found a few options that were durable, inexpensive, and easily accessible. The list included wood, PVC, and rubber. All three materials were fundamental in our building process. PVC, sold in cylindrical units of various radii, was ideal for our pylon design. After analyzing the plastic material, we concluded that it could hold the weight of an amputee with ease and withhold any climate change or rough terrain. We considered wood and rubber for the design of our foot and joint in our initial prototypes. A rubber mold would be relatively cheap, durable, flexible, and it would serve as shock absorption. A wooden foot would be ideal due to its ubiquity and ease of manipulation. For the socket, comfortability was key. We decided to line the interior with inflatable rubber because it is cheap, accessible, and allows for adjustability and comfort for the stump. Ultimately, our total bill fell short of $400 for prototyping, and the cost of making an individual unit of the prosthetic leg was under $40 (including the cost of labor, which is relatively negligible due to the cheapness of labor and ease of manufacturing.) The total cost of the raw materials used to create the prosthetic limb totaled to be under $30, and the cost of labor would be under $10. We built the durable prosthetic limb, keeping in mind the price of production throughout the entire process, and we successfully met the constraints.

G.) Manufacturing Processes Used

As mentioned in previous sections the prosthesis consists of the three parts socket, pylon and foot. These parts were designed in an integrated manner and manufactured separately.

Socket:

The main parts of the socket are an inflatable rubber tire inner-tube and the PVC cylinder shown in Figure 1. The rubber tire was ordered online and is commonly used on a large scale in different applications, such as cars. Therefore it is a cheap, easy accessible and a high quality product. We decided to buy this part online to lower our overall manufacturing costs and follow industry standards.

The cylinder is made of PVC and ordered from a manufacturer. It consists of a cylindrical part with a tapered dome bottom. For the prototype we decided to 3D print this part, but we ensured that this part is available on a larger scale from a manufacturer.

The assembling of the socket starts with drilling holes in the cylinder. The location of the holes is shown in Figure 1.

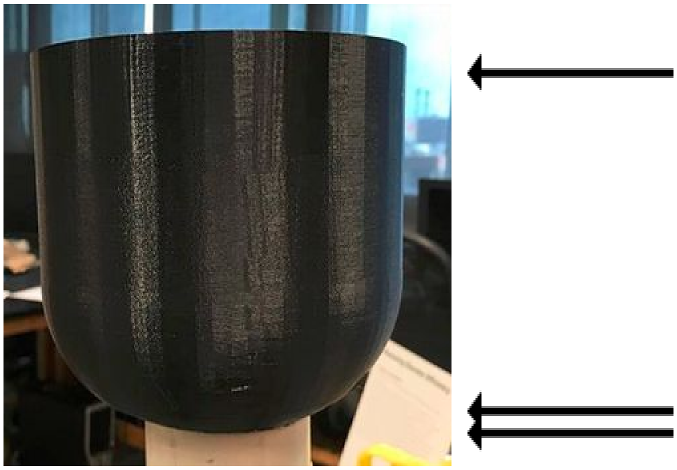


Figure 1

The hole on the top is for the nozzle of the tire. The tire can be easily inflated via this nozzle. The two holes below are provided for the bolt connection between the pylon and the socket.

The next step is to glue the tire into the funnel. The nozzle needs to be in line with the dedicated hole and the tire should not have any overlapping parts it is glued to the funnel.

Pylon:

The pylon consists of two different sized PVC pipes and two bolts. PVC is a widely used material and available in standard and customized shapes. It is cheap, meets the physical requirements, and is stainless. The bolts and nuts are made of stainless steel, because they need to hold the entire body weight of the person and are expected to endure rain, mud and other rough physical conditions. The assembly process starts with sawing the pipes into the appropriate size based on the average height of the targeted amputees. Afterwards the adjusting holes are drilled into the pipes. The distance of these holes also depends on the average height of the targeted amputees. The fewer the number of holes, the higher the durability of the pylon. In any case they need to line up, otherwise it is impossible to fit in the bolts to connect the pipes with each other. This process is time intensive, because the adjustment of the drilling machine takes time. If the setting is not correct, the holes will not line up, and the pylon must be scrapped.

Foot:

The foot is made of a wooden block and a thin rubber layer. This construct is attached to the pylon with a rubber disc and a cylindrical strip of rubber inside the smaller pipe of the pylon. This flexible joint allows some movement of the food and ensures good performance in uneven terrain. As mentioned, PVC and rubber are very common materials and can operate under rough environmental circumstances. We chose wood for the foot, because it is cheap and easily accessible. Furthermore it will not rot in our setup, because it is totally covered by paint.

The product of the following manufacturing process is shown in Figure 2.

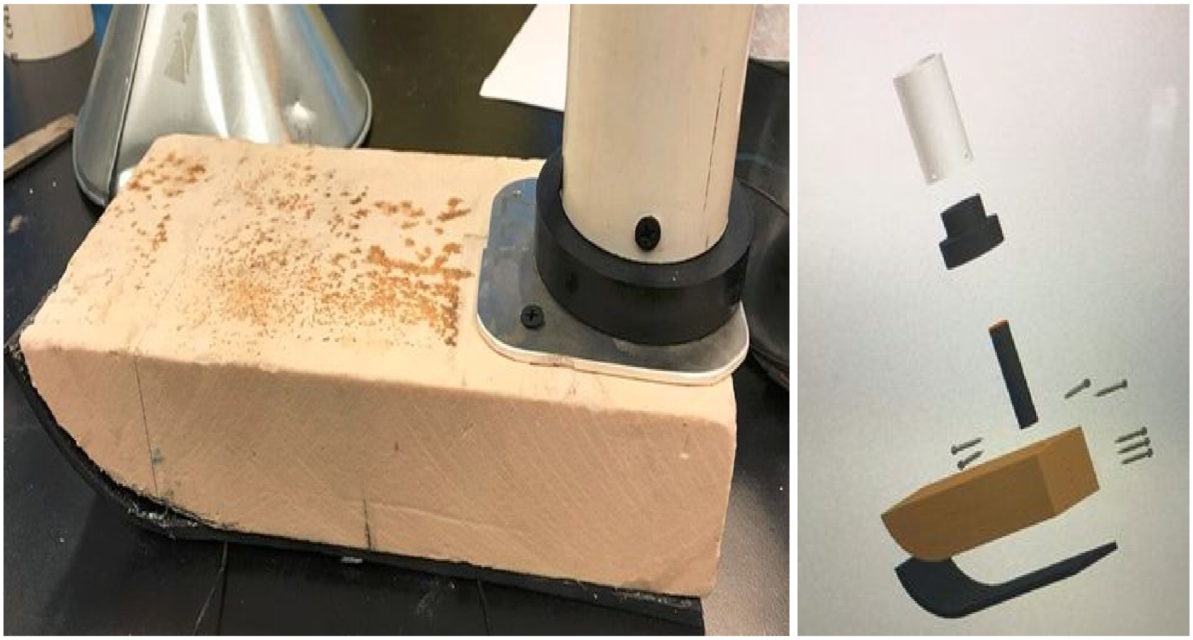


Figure 2

The first step to set up the foot is to shape the block of wood. It is curved at the front, and the thin layer of rubber is glued on the bottom.

The second step is to drill a center hole in the rubber disc and a hole in the foot at the position where the pylon is supposed to be mounted. Afterwards the rubber disc is assembled on the foot so that the two holes line up.

The last step is to attach the foot to the pylon. The rubber strip is inserted into the foot and rubber disc. It is then attached to the foot with screws. The smaller pipe of the pylon is assembled on this set up so that the rubber strip is in the middle of the pipe. In order to hold its position, the strip is fixed with screws inside the pylon.

Assembling of the prosthesis

After measurements are taken, the socket is simply connected to the pylon with two bolts.

H.) Kepner-Tregoe Decision Matrix and Evaluation Matrix of Adverse Consequences

NOTE: This decision was based on our original design plan of a ball joint for the ankle. We did not conduct another evaluation when we changed our design but we believe it has roughly the same functionality as the original idea. We were challenged with building a prosthetic limb for a developing nation. When we analyzed this problem we created a list of design objectives, and decided that the top 5 are durability, low cost, motion in the ankle, lightweight, and modularity. We then rated each of these objectives based on importance from a scale of 1-10. The results can be seen in the chart below. We came up with a few different design ideas, all of which satisfied the requirements. One of our design ideas was to create the socket out of wax or some other malleable material in order to customize the socket to each individual without being costly. Another idea we had was to create an ankle with too fix PVC pipes orthogonal to each other. This reduces cost and customization time and is a more simplistic design that requires less maintenance. Another design alternative was to integrate circuitry into the prosthetic leg to create a more precise leg. For example, we could use a waterproof solar panel to collect energy and use that energy to run a pressure sensor attached to the bottom of the toe. When the pressure sensor is activated, the foot rolls up using a small motor, and after the foot is lifted, the "ankle" rolls back down. We then used Kepler decision tree to determine which design satisfied our design objectives most.

Adverse effects

We identified adverse effects for each of our design objectives and then assigned a probability of impact for each one.

Current Design

	Probability	Impact	Weighted	Sum Score
Ankle doesn't move smoothly	0.5	8	4	**10**
Doesn't stay attached to the stump	0.4	8	3	
Inconvenient	0.4	7	3	

Wax Socket

	Probability	Impact	Weighted	Sum Score
Doesn't stay attached to stump	0.3	10	3	**11**
Not durable	0.5	9	4	
Inconvenience	0.5	9	4	

Fixed Ankle

	Probability	Impact	Weighted	Sum Score
Falling on uneven terrain	0.6	7	4	**12**
Damaging other leg	0.6	10	6	
Bruising stump due	0.3	7	2	

Circuit Design

	Probability	Impact	Weighted	Sum Score
Too costly	0.9	9	9	**21**
Not durable	0.8	9	7	
Not weather proof	0.7	8	5	

Based on these data points we came to a consensus on which design to build. Although our final design had the lowest adverse effect score we nevertheless had to be cautious when designing our project to try and minimize them.

I.) Human Factors Considered

One of our early concerns was the appearance of our prosthetic limb. Our clients live in a religious area in which there is a social stigma against amputees, so in turn our design ideally had to look like an actual human foot. However, we decided that for the amputees, being able to work and support their families was probably a priority. We decided aesthetics would be factored in last, and would only be considered if we had enough money left over out of the 40 dollars.

Our primary concern when designing the foot was enabling an amputee fitted with our prosthesis to walk normally with minimum change in gait. Through gait analysis, we looked at the movement of the foot. The heel comes down first, the weight of the body shifts onto the balls of the foot, which then push off the ground. From this, we knew that a stiff ankle would not work but rather a flexible ankle with frontal, backwards, and lateral movement would best mimic a natural ankle. Our design successfully achieves this range of movement and would thus allow the user to walk on even surfaces as well as traverse uneven and inclined surfaces.

Another facet of the amputees' lives includes recreational physical activities such as dancing and playing sports. While an artificial leg will always be much more stiff than a natural one, our ball and ankle design, which allows for ample movement of the foot in all directions, provides for the flexibility needed to dance and partake in other physical activities.

Comfort, as one of the most important human factors, is also difficult to achieve and test. Our team does not have trained prosthetists to help fit the leg, nor an actual amputee to test our prototype. Despite this, we are confident in the ability of our rubber socket design to cushion the stump and absorb shock. In addition, the average human lower foot weighs 3.36 kilograms, and our prototype is around the same weight, meaning that the prosthetic foot will feel natural when fitted.

Laboratory Test Plans and Results

The laboratory test aims at testing the strength of our design. The ISO International Standards are followed to ensure the product being tested is safe, reliable, and of good quality to use. The ISO 10328 standard gives the basis for testing a lower limb prosthesis. This standard requires the lower limb prosthesis to go through two strength tests: the static strength test and the cyclic strength test, which is also known as the fatigue test. The static strength test is used to measure the static load representing an occasional severe event that can be sustained by the prosthesis and still allow it to function as intended. It can be tested with the electromechanical universal testing machine, applying 2240N load to both the forefoot and the heel at an incline of twenty degrees and fifteen degrees, respectively. The cyclic strength test is to check for durability and for normal walking activities where loads occur regularly with each step. This can be tested through 2,000,000 cycles at a rate of 1 Hz with the fatigue tester.

Although there is a clear ISO standard given to follow, we could not specifically carry out such tests. Some previous research suggested that it is impossible to build a type of testing machine for the prosthesis. Limited time prohibited sending our design to any qualified testing center. However, since our prototype still needed to be tested in some way to prove its function, with the help of Raymond Pye, a prosthesis expert, we were able to perform an alternative test that is cheap, efficient, and generally accepted in the industry. After our design had passed the SolidWorks simulation, we carried out this simple laboratory testing, called the “drop test,” that enabled us to add pressure onto our prototype and safely drop it from a certain height. The method is shown by the diagram below (Figure 3) .

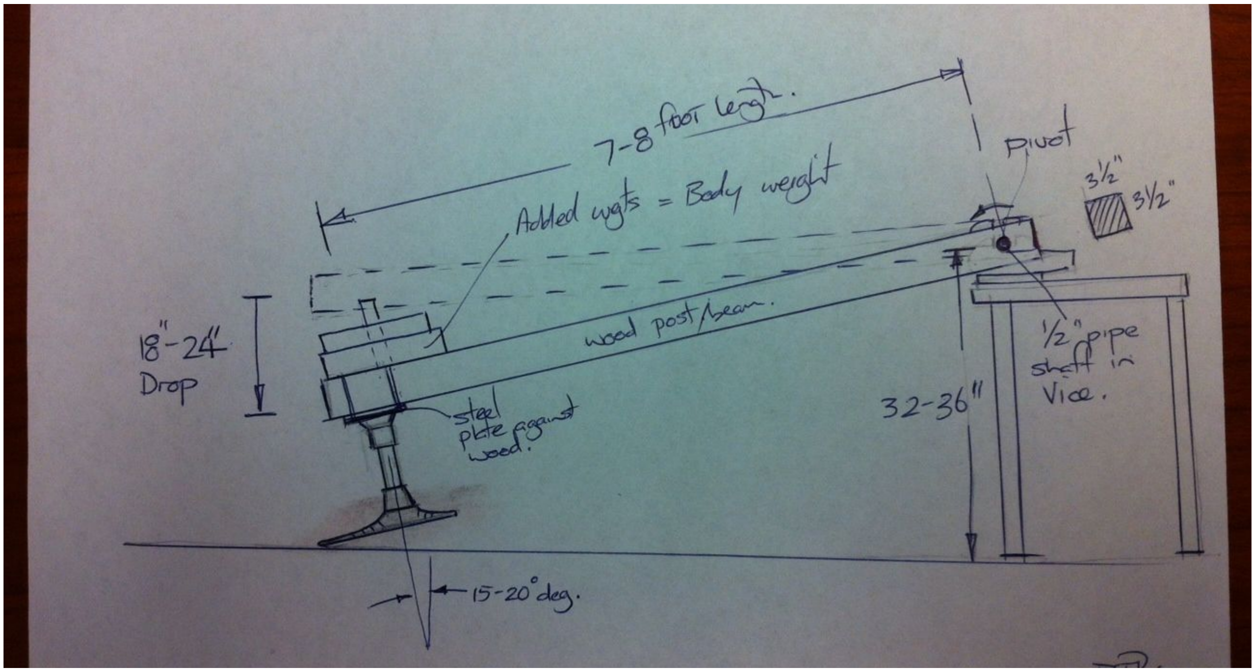


Figure 3

There would be one 7 to 8 feet long wooden beam, one side of which acts as a pivot on top of a table, and the other side of which is connected to the prototype. The side with the prototype attached will also have some weights attached, preferably similar to the average body weight of a human being, then dropped from above, making the drop about 18 to 24 inches. In our drop test, the long wood beam in the diagram was replaced by two PVC pipes connected together by bolts to reach the length of 7 to 8 feet. The prototype was fixed onto the PVC pipe by tying it with shoe laces and used two clamps as added weights, although it was not as heavy as the average human weight. We then performed the drop test, and confirmed our prototype passed the drop test because our prototype did not break.

To test whether the friction given by the inflatable rubber could sustain the weight of the prosthesis when users lift their feet up, we used a three-inch-diameter PVC pipe as the stump. The size is close to that of human stumps and the friction coefficient of the surface of the pipe is smaller than the liner, as is the case with a human leg. The frictional force successfully held the weight of the prosthesis. Since the surface of the liner can only provide greater friction, the prototype passed the test.

Bill of Materials

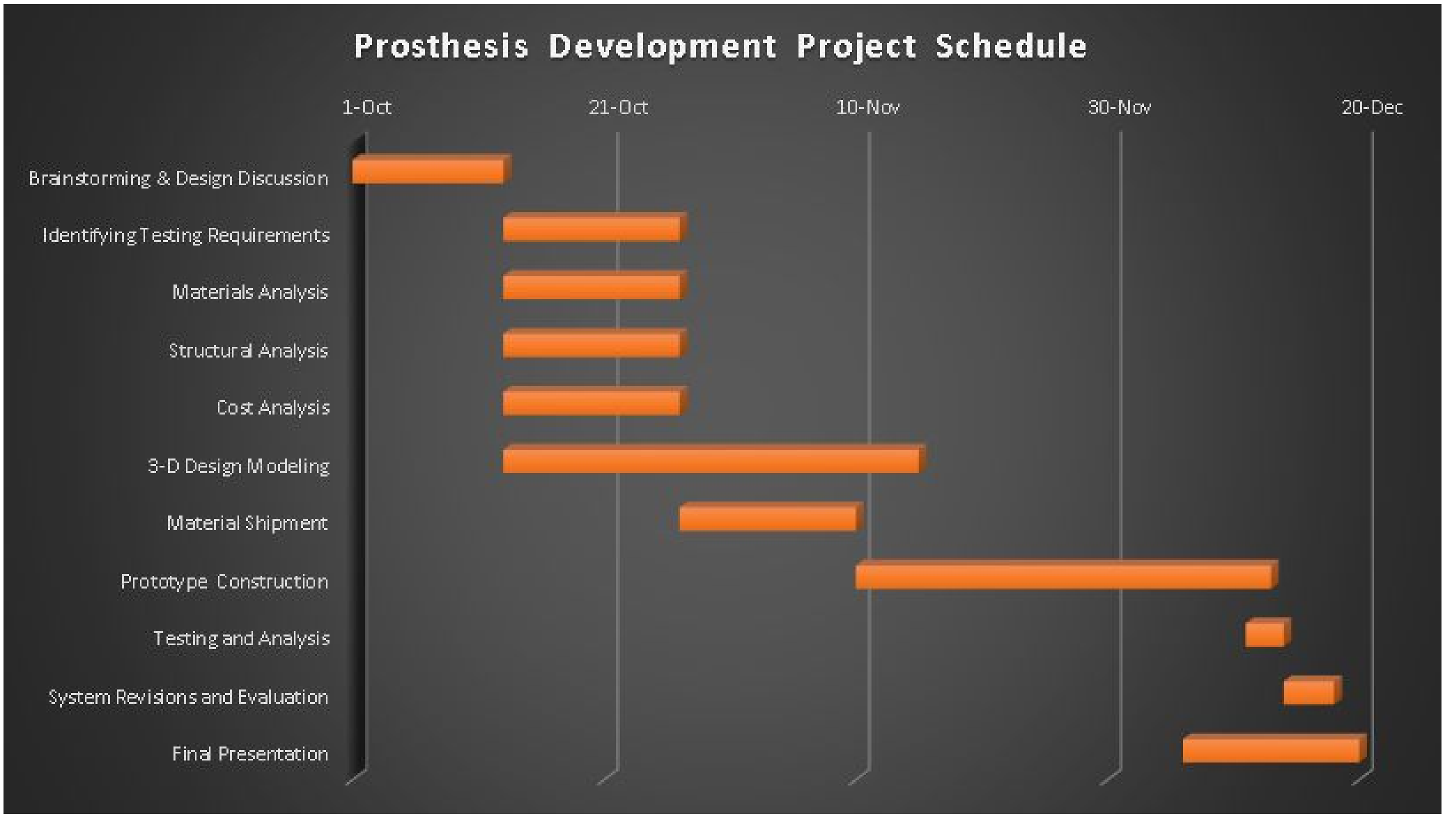
Bill of Materials

#	Material	Expected Units	Total Cost*	Source of purchase	Purchaser
1	2-1/2" Hardwood Ball (2-Pack)	1	$9.74	Amazon	Team
2	Inflatable rubber	1	$10.99	Amazon	Team
3	3.7 oz E-6000 Craft Adhesive	1	$7.78	Amazon	Team
4	Smoothon Mold Max® 40 Trial Unit 2.2lbs	1	$41.15	Smooth-on, Inc.	Team
5	EasyFlo 60 Liquid Plastic 3.8lbs.	1	$57.12	Polytek Development Corps	Team
6	Socket shell 2.25" inner radius	1	$92.56	Makerspace	Team
7	Metal screws	40	$0.00	Supplied by workshop	
8	1-1/4" Schedule 40 PVC Pipe - 5ft	1	$4.25	PVC Fittings Online	Team
9	1-1/2" Schedule 40 PVC Pipe - 5ft	1	$4.68	PVC Fittings Online	Team
10	2" Schedule 40 PVC Pipe - 5ft	2	$11.72	PVC Fittings Online	Team
11	2-1/2" Schedule 40 PVC Pipe - 5ft	2	$23.74	PVC Fittings Online	Team
12	1" Schedule 40 PVC Pipe - 5ft	1	$3.91	PVC Fittings Online	Team
13	Multi 30644 Willene Multi Boot	1	$29.99	Kmart	Team
14	Shipping and Handling (PVC Fittings)	--	$27.18	--	--
			$324.81		
			$315.88		

* Bottom sum represents total cost of all group 2 materials. Top sum includes the cost of materials purchased by group 2 that were used for group 1's prosthesis

** Full table can be found in the appendix

Gantt Chart/Project Schedule



Prosthesis Development Project Schedule

Task	Members Responsible	Start Date	End Date	Duration (days)
Brainstorming & Design Discussion	All members	1-Oct	13-Oct	12
Identifying Testing Requirements	All members	13-Oct	27-Oct	14
Materials Analysis	Naomi,Ivan, Matthew	13-Oct	27-Oct	14
Structural Analysis	Samuel,Changru, Alex	13-Oct	27-Oct	14
Cost Analysis	Ivan, Peter, Felix	13-Oct	27-Oct	14
3-D Design Modeling	Armaan, Changru	13-Oct	15-Nov	33
Material Shipment	Peter, Ivan	27-Oct	10-Nov	14
Prototype Construction	All members	10-Nov	13-Dec	33
Testing and Analysis	Sally, Alex	11-Dec	14-Dec	3
System Changes and Evaluation	All members	14-Dec	18-Dec	4
Final Presentation	All members	6-Dec	20-Dec	14

Ethical Considerations

As with any product associated with daily lifestyle changes in people, there are strict standards to which prostheses must adhere. As explained in section 4 (Laboratory Test Plans and Results), prostheses must be able to withstand instantaneous and continuous loads while maintaining a consistent level of comfort. Through a stress and drop test, we concluded that our prosthetic limb would withstand any wear and tear of daily use in Soroti, Uganda. Regardless of the weight of the user, roughness of the terrain, and extremity of climate, the design would not be susceptible to damage with practical use. As regards to comfort, our design for the socket would provide adjustability for virtually any stump shape. With the use of inflatable rubber, we achieved both comfort and adjustability. For additional comfort, padding can be added within the socket as a form of shock absorption for the user's leg. For example, cloth, cotton, or foam can be inserted into the socket.

According to the engineering code of ethics, engineers shall hold paramount the safety, health, and welfare of the public. Engineers shall approve only those engineering documents that are in conformity with applicable standards. For any potential hazards that we have not taken into account, we take full responsibility. If any part is defective, it will be modified as soon as possible if the design is used by the people of Uganda. Such problems should not come up, but must be dealt with responsibly in the event of failure. If the socket fails to adjust, a new design will be implemented. If the foot does not provide for stability or comfort, the part will be modified. If the pylon does not meet standards for adjustability, it will be changed.

Other ethical considerations include potential unethical behavior within our engineering group, including the disclosure of confidential information. According to the code of ethics for engineers, each team member is trusted with the technical processes and design information involved with Project Kutembea. Any violations might be dealt with in the future.

Ethical considerations involve both the prosthetic limb and the actions of the engineers that built it. We will function under the code of ethics for engineers.

Safety

The prototype has passed the SolidWorks simulation test and the drop test. Assuming these testing methods are trustworthy enough, the design is proved to be able to sustain the weight of the users. However, due to our limiting testing environment, the fatigue life, or the time it takes for the material of the prosthesis to weaken by repeated appliance of loads, of the prototype cannot be tested. Since the aim of this project is to design a low-cost prosthesis affordable for amputees in Soroti, the cost of maintenance has to be as low as possible. If the occurrence of failure is high, replacement will be too expensive for them to afford. They may continue using the broken component which will cause risks to hurt themselves.

Currently, few potential sources of danger of our prototype are identified:

1. The bolts used to fix different components will get looser and looser as time passes. The movement of components may reduce the efficiency of shock absorption and hurt the stump, the part that attaches to the socket of the prosthesis, of the users.
2. If the rubber cylinder used in the ankle part is rotted to a certain extent, it may suddenly break or snap when users lean in one direction too much. There are risks of falling down when users are unprepared. The rubber cylinder is put in as closed a space as possible to avoid its contact with outside. Users should be instructed to check the conditions of it frequently.
3. The nozzle may damage the liner and scratch the user's skin. To eliminate the risk, we made the nozzle point down. If the users keep the cap on all the time, the danger should be negligible.
4. Users should make sure the socket is tight enough to hold their stump in place, but not too tight as to squeeze their stump. If the socket is too loose, the users might get hurt when the prosthesis suddenly detaches from their stump.

The humid and warm climate in Soroti, Uganda tends to damage the materials used in our design, including rubber, wood, and steel. The strength and durability will not be as ideal as in the lab. Although we took the climate into consideration when we chose the materials, the durability and safety of the product are never definite without a long-term on-site testing process.

Another safety concern is that many of the users have diabetes, which may not only cause problems to their feet, but also to their eyesight. Also, since Uganda has a rugged terrain, the users of the prosthesis should be advised to pay extra attention to the conditions of the ground.

Conclusions

After going through the engineering design process we were able to experiment with various design proposals. We went through many AutoCAD and SolidWorks prototypes before settling on one final design.

The first part we decided to make was the pylon. We made the pylon by making two tubes, one inside of the other in order to take into account adjustability. We concluded that since the prosthesis needs to be used by people of all ages that the height should be adjustable. We also concluded that the pylon would have to be a certain material and be able to withstand a certain force. After doing a cost and material analysis we concluded that PVC (polyvinyl chloride) would be our best option.

After the pylon we made the socket. Our socket consists of two main parts. The first part is the outer shell which is a hard plastic alloy in order to fit the stump inside. We made the funnel shell tall so that more of the stumps' surface area is covered. Inside of the shell we decided to use an inflatable rubber tube. By using an inflatable rubber tube, we are making the prosthetic adjustable by the user themselves. We decided on using an inflatable rubber tube in order to hold the stump in place. When the user fills the stump in air, with something as common as a bicycle pump, the tube inflates and constricts the stump, fitting snugly around it.

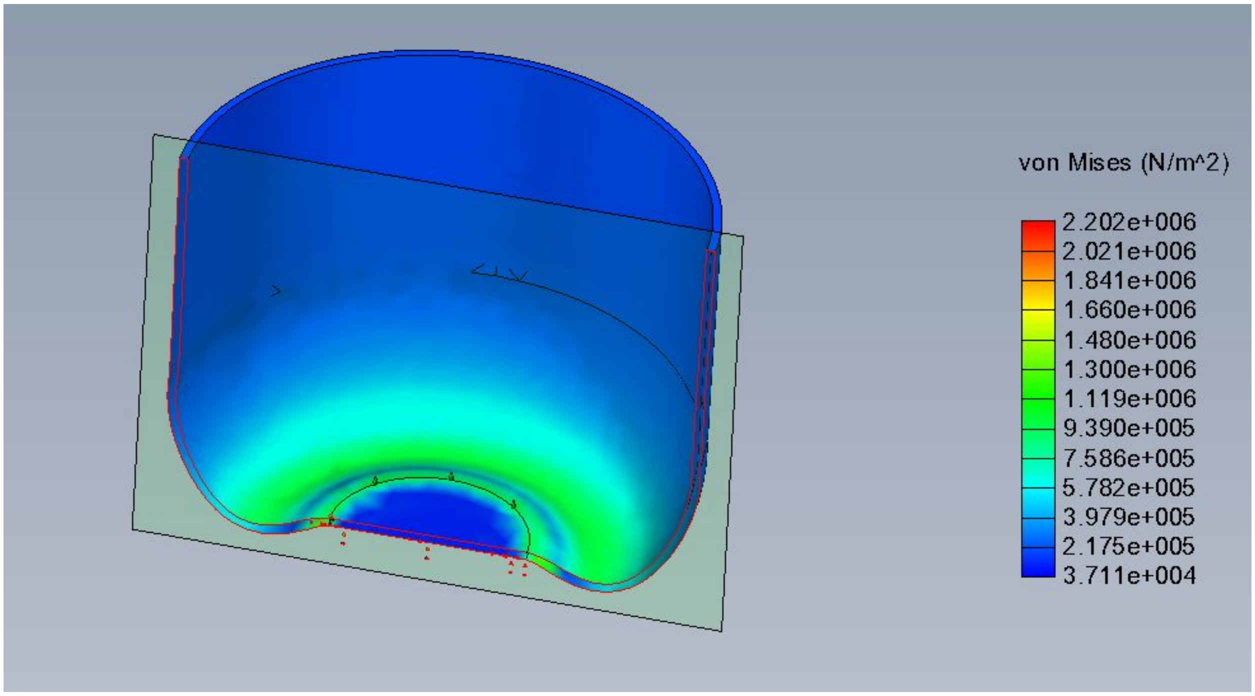
The final part of the prosthesis was the ankle and the foot. Although we had previous designs, such as the ball joint design for the ankle, we decided on the rubber cylinder for the ankle due to time limitations and too much difficulty in constructing our original design of the ankle. Similar to the ankle, the foot design was also changed due to time limitations. The foot design we used for our prototype was simply a block of wood that was curved at the end for the toes and a rubber bottom.

Appendices

Appendix I: Computations and Computer Generated Data

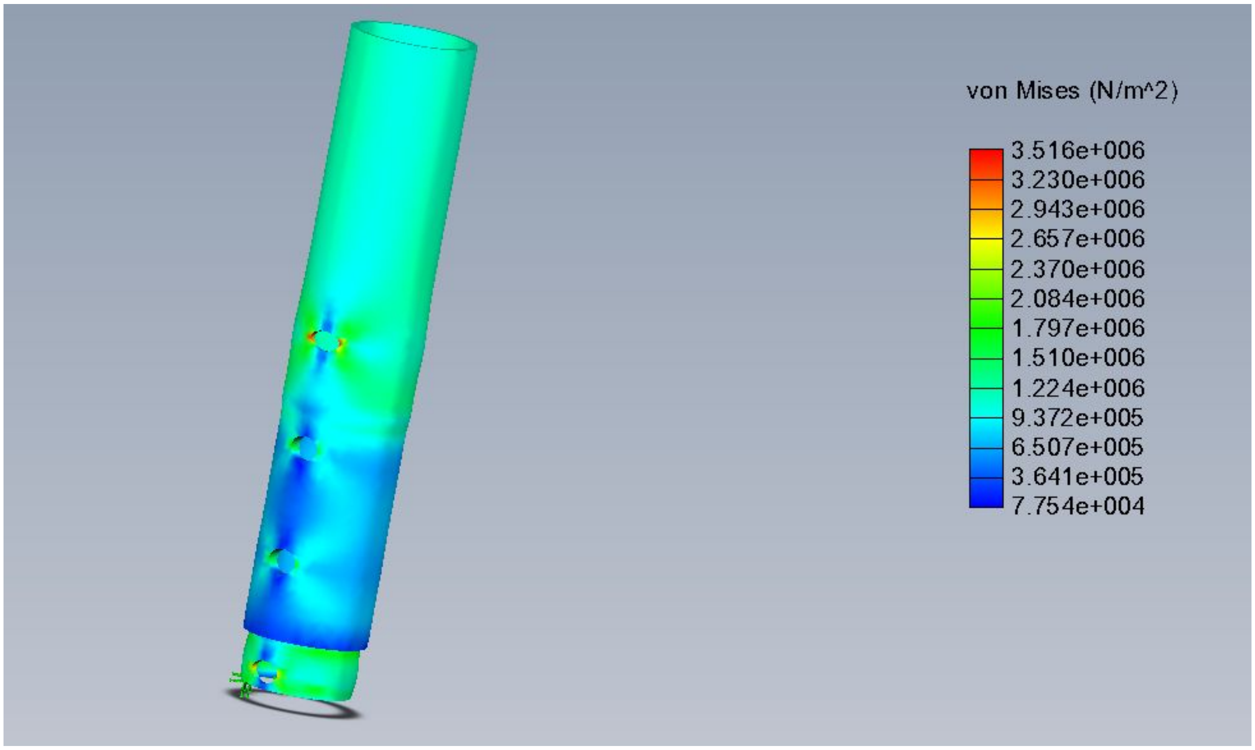
Finite Element Analysis is a method for testing how a product will react to the strains, pressures, tensions and vibrations that it will receive in application. Finite Element Analysis was conducted on all the component parts of the design, as well as the entire model. The results of the Finite Element Analysis are presented here:

Socket:



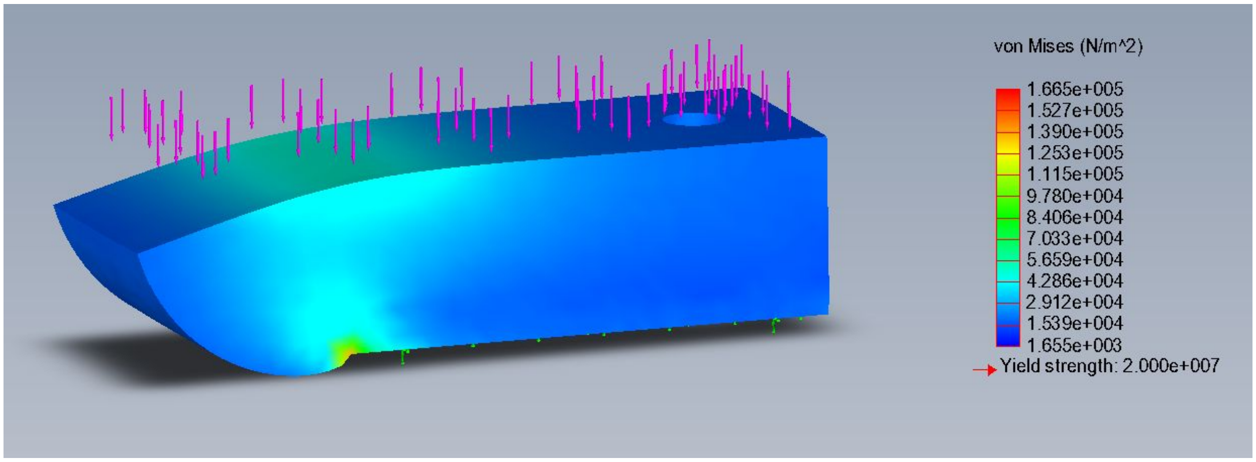
The above image is the a section view of the Solidworks model of of the socket designed to show how the model will deform when forces are applied to the bottom and sides of the socket pushing outward as a stump would. The deformation of the socket would only occur at the base of the socket, with almost no deformation occurring to the outer wall.

Pylon:



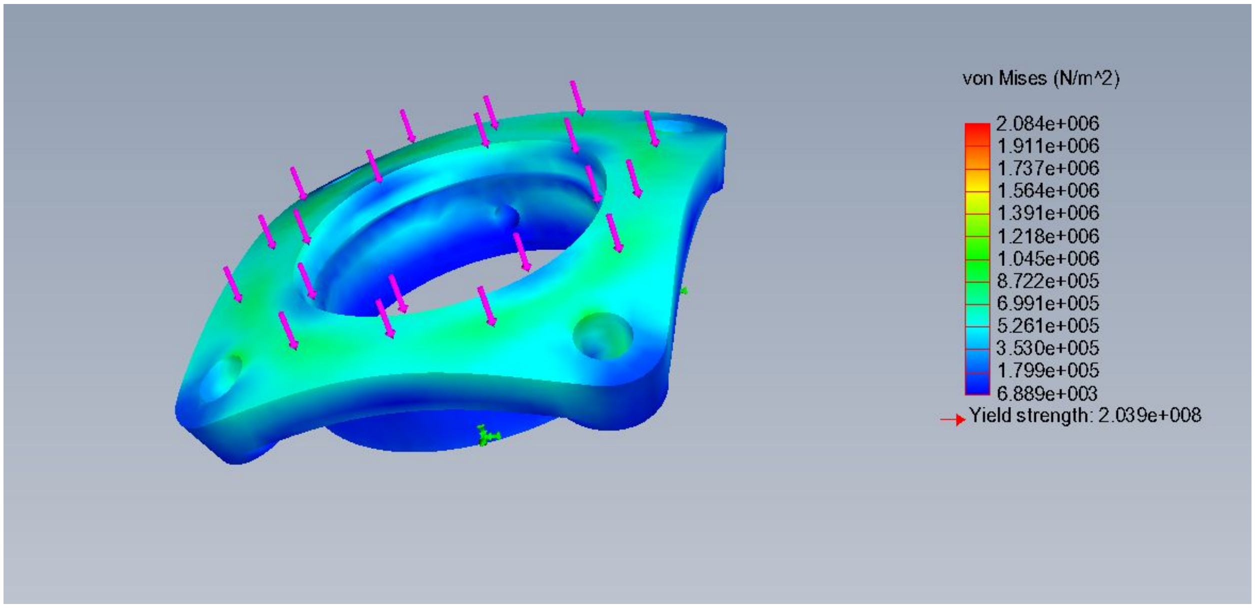
The above image is a view of the solidworks model of the pylon designed to show how it will deform when forces are applied directly on the top of the pylon rim downward, since the weight will be pushing directly onto the pylon. The deformation will most likely occur at the holes designed where the bolts go through the pylon for adjustability. Otherwise, the pylon does not deform much.

Foot:



The above image is the a section view of the Solidworks model of of the foot designed to show how the model will deform when forces are applied to directly on top of the foot. The deformation of the foot will only occur at the point where the sole begins to curve upward. Otherwise, deformation is minimal.

Universal Connector Joint:



The above image is a view of the solidworks model of the universal connector joint designed to show how it will deform when forces are applied directly on the top of the connector downward, since the weight will be pushing directly downward on the connector. The deformation will most likely occur at the holes designed where the bolts go through the pylon for adjustability and on the outer corners of the connector.

Appendix II: Properties of Materials

The load bearing parts of the prosthetic are made of polyvinyl chloride (PVC) and African pencil cedar (an indigenous wood) and galvanized steel. The following constants were used in the Finite Element Analysis to ensure that the materials would not break under a realistic load.

PVC Properties		
Property	**Value**	**Units**
Elastic Modulus	2410000000	N/m^2
Poisson's Ratio	0.3825	N/A
Shear Modulus	866700000	N/m^2
Mass Density	1300	kg/m^3
Tensile Strength	40700000	N/m^2

Galvanized Steel Properties		
Property	**Value**	**Units**
Elastic Modulus	2e+011	N/m^2
Poisson's Ratio	0.29	N/A
Yield Strength	203943242.6	N/m^2
Mass Density	7870	kg/m^3
Tensile Strength	356900674.5	N/m^2

Pine (Wood) Properties		
Property	**Value**	**Units**
Mass Density	470	kg/m^3

Acknowledgments

Throughout the semester, we received a plethora of help from various sources. Most importantly, our professor guided us through the course and helped us along the way in our building and prototyping process. Through rigorous assignments and a myriad of presentations, Professor Raja taught us the technical skills required to function within an engineering group, delegate and complete tasks, and follow the various rules accompanied by engineering design.

The Einstein team (Dr. Hawkins M.D and Anneka) helped us by offering constructive criticism and providing helpful information and first hand experience about the situation in Soroti. We were able to incorporate pathos in our presentation after presenting to the Einstein group.

Professor Alan Wolf also provided insightful comments about our presentation. Seemingly harsh, his criticism greatly improved our presentation and bolstered our presentation skills and formatting.

Ray Pye helped determine the feasibility of our design and brainstormed alternatives to impractical design proposals. We contacted him through Skype and he gave us very helpful advice.

Brian and Sanisa in the workshop helped us throughout the building process. From allowing us to use the workshop to build our prototypes, to suggesting different parts to use to improve the functionality of our design, the duo helped us tremendously.

Dr. Garrison from Hospital for Special Surgery in NYC offered helpful on the workings of the human leg. We incorporated his help into our design to make the prosthetic leg more comfortable for the user.

We ordered most of our materials from online manufacturers, and they streamlined the process of designing our prosthetic limb by shipping the materials in a reasonable amount of time and cooperating with our timetable. A big shoutout to “pvcfittingsonline” for cooperating with us when Peter Zhao accidentally ordered the shipment under the name “Oeter Zhao” and listening to our complaints when we thought the shipment was not on schedule. Additionally, Amazon Prime ensured we received our materials in the shortest amount of time possible.

References

[1] "PVC." *PVC Strength - PVC*. N.p., n.d. Web. 3 Dec. 2016. <http://www.pvc.org/en/p/pvc-strength>.

[2] VanBuskirk, W. C. and Ashman, R. B., The elastic moduli of bone, in *Mechanical Properties of Bone* , Joint ASME-ASCE Applied Mechanics, Fluids Engineering and Bioengineering Conference, Boulder, CO, 1981.

[3] "Can medical prostheses advance further, and what are their potential risks?" *MIT School of Engineering*. Massachusetts Institute of Technology, 16 Apr. 2013. Web. 17 Dec. 2016.

[4] "Low-Cost Adjustable Prosthetic Leg (Louisiana Tech University)." *RESNA Student Design Competition*. Rehabilitation Engineering and Assistive Technology Society of North America, 13 June 2012. Web. 17 Dec. 2016.

[5] "ISO 22675:2016 Prosthetics -- Testing of ankle-foot devices and foot units -- Requirements and test methods." *International Organization for Standardization* (2016): n. pag. Web. 17 Dec. 2016.