ME 450 Final Written Report

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Team 13

Providing Preoperative Traction for Femur Fractures in Low-Resource Settings

Dr. Kathleen Sienko
Professor, Mechanical Engineering

Caroline Soyars
Sponsor and Program Manager of the Global Health Design Initiative

Forest Brown
Daniel Carty
Ian Hall
Evan Wang

Table of Contents

Executive Summary

Bone fractures can be difficult to treat in low-resource settings, leading to increased pain experienced by the patient, longer treatment times, and a higher mortality rate when compared to high resource settings. Among fractures, the femur creates a unique treatment challenge. Although the strongest bone in the body, the femur also represents one of the most commonly fractured bones in low resource countries due to the increased frequency of traffic accidents. In fact, over 90% of road incident morality comes from low resource countries [1].

At Komfo Anokye Teaching Hospital (K.A.T.H.) in Kumasi, Ghana, the Emergency Department is seeking a way to better treat patients with femur fractures. Challenges experienced at K.A.T.H. include delays of up to 12 hours for traction due to limited staff and evan up to a week delay for the surgical procedure. Even once the current treatment is administered, the patient may still experience extreme pain and discomfort. Current methods used at K.A.T.H. do not provide adequate pre-operative treatment for the patient [2]. There is a need for a system that can be rapidly applied to accommodate the hospital's high patient load that also relieves pain for the patient. The solution must be mobile, allow for easy patient transport, and improve the quality of pre-operative care. Most importantly, the solution must meet these criteria while being affordable to the average Ghanaian citizen.

When developing user requirements the solution must address, our design team used scholarly research, journal articles, and conducted stakeholder interviews. The requirements were sorted into high, medium, and low priority. The high priority category includes requirements such as “Durable”, “Returns leg to original length”, “Fixable by K.A.T.H. Staff”, and others. The user requirements form the base for developing a solution that solves K.A.T.H. staff’s needs. Multiple experiments, calculations, and qualitative reasoning were used to verify multiple requirements from our design. From these results our design was evaluated and recommendations for future progress on this problem were proposed.

Background

Problem Statement

At the Emergency Department of the Komfo Anokye Teaching Hospital in Kumasi, Ghana, treatment for femur fractures is limited by the availability of trained staff, method of treatment, and costs. There is a need for a system that can be rapidly and easily deployed, increase the mobility of the system, improve the traction applied, and is affordable to average Ghanaian citizens.

Health Technology in Low Resource Settings

According to The Lancet Commissions, "availability of health technology is inversely related to health needs" [3]. When thinking about medical technology it's important to acknowledge the context in which the technology exists. Outside the U.S. and other high-income countries (HIC), low and middle income countries (LMICs) struggle with the cost and availability of health technologies. Kumasi, Ghana is no exception. For example, the average Ghanian citizen makes just $5 a day [4], in comparison to the average U.S. citizen who makes $113 a day [5]. In LMICs there is also an increased need for health technology when compared to HICs. In LMICs, Road Traffic Incidents (RTIs) are the major cause of femur fracture, responsible for 90% of global road traffic incidents [1]. The Tanzanian femur fracture incidence rate is 15.7 - 45.5 per 100,000 traffic incidents (used as a proxy source for Ghana), compared to the US femoral fracture incidence rate of 10–18 per 100,000 traffic incidents annually [1].

What is a Femur Fracture?

The femur is the largest, strongest, and one of the most important bones in the body. The femur is surrounded by three major muscle groups, the quadriceps, hamstrings, and semimembranosus muscles along with other major bloodways and nerves that allow us to walk, run, and carry large masses [6]. The femur can be divided into three parts: the proximal femur (where the femur joins the hip joint), the distal femur (where the femur joins knee joint), and the femoral shaft (located throughout the thigh). A picture of the different femur parts are shown in Figure 1.

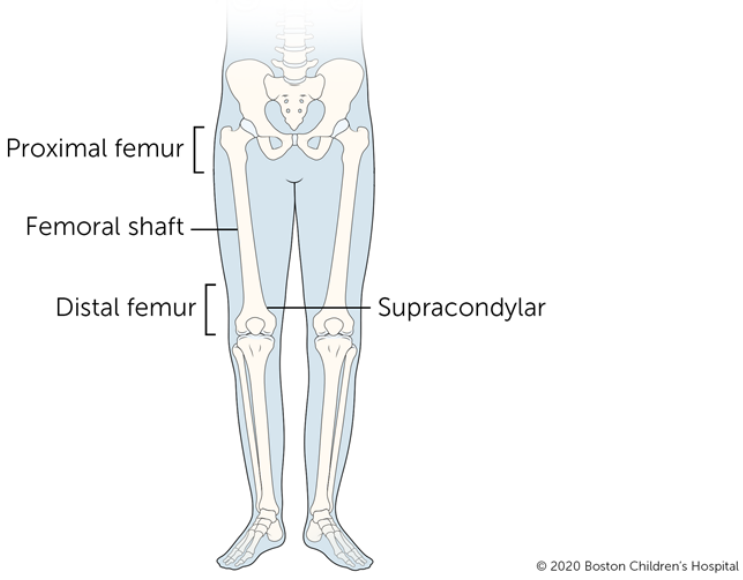


Figure 1: Parts of the Femur [7]

Fracture is the breaking or the partial breaking of bones in the body. The femur prevents the surrounding muscle groups from contracting. When a fracture occurs the leg contracts and the

bone fragments cause intense pain as they are moved inside the leg [8]. As the femur is also surrounded by important blood ways, femur fractures can lead to up to 30% blood loss and nerve damage [8]. There are many types of femur fractures, open vs. closed, transverse vs. linear vs. oblique, displaced vs. non-displaced, all of which and more can be seen in Figure 2.

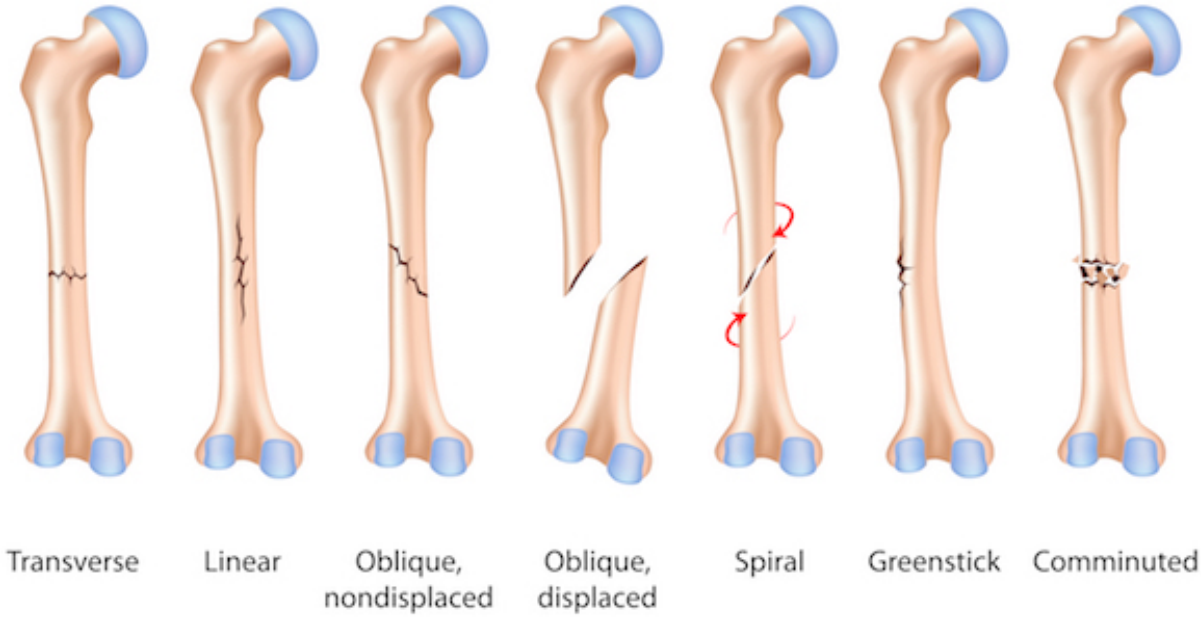


Figure 2: Types of Femur Fracture [9]

An open fracture means that the fracture has penetrated the skin, while a closed fracture means that the bone is still within the skin tissue. A transverse fracture is one that is perpendicular to the direction of the femoral shaft, while a linear fracture is one that is parallel to the direction of the femoral shaft. An oblique fracture is one that is neither perfectly perpendicular or parallel to the direction of the femoral shaft. A displaced fracture means that the bones are no longer in close proximity of each other, while non-displaced means they are in close proximity and are still touching. The focus of our project is closed, transverse, displaced, femoral shaft fractures.

Comparing and Contrasting Femur Fractures at K.A.T.H. and in HICs

The femur is the strongest bone in the body and takes incredible forces to break. The causes of these forces have changed throughout the years. In wartime, mines, factories, and railroads caused these forces. Now the major cause is road traffic incidents (RTIs) [10]. Femur fractures occur both in LMICs and HICs because of road traffic incidents. LMICs and HICs differ in terms of incident frequency, emergency management, and timing of surgical procedures.

LMICs are disproportionately impacted by femur fracture injuries. K.A.T.H. is the second largest hospital in Ghana only to Korle-Bu Teaching Hospital (K.B.T.H.) located in the capital, Accra [2]. As the economy and infrastructure continue to grow in LMICs, the incidence rate is expected

to grow as well. It is worth stating again that LMICs account for more than 90% of road traffic incident mortality [1].

A large hospital in a developing country comes with unique challenges. For example, in HIC's there are dedicated emergency management services (EMS) that apply traction (see the following section) immediately at the site of the accident [8]. For K.A.T.H., being a LMIC means a lack of a dedicated EMS. The hospital also lacks the amount of trained professionals to provide the application of emergency services around the clock. The team that applies Buck's Extension, the current solution, only works from 9am - 5pm [2]. If someone has an accident in the middle of the night they could wait several hours for treatment. A large amount of high trauma emergency procedures take place in this hospital [2]. Many in the country come to K.A.T.H. for the unique services they provide. This leads to a higher than normal congestion for the emergency department. Due to limited resources and the congestion of the emergency department, femur fracture treatment is delayed for many people, leading to higher pain and mortality rates.

The last difference between femur fractures in LMICs and HICs is the timing of surgical procedures. In a HIC there is a short lead time between traction application and when the intramedullary nailing (IMN) is applied. Intramedullary nailing is the normal surgery in which the femur bone is drilled and a large nail is placed through the hole in order to reconnect the femur bones [11]. In HICs normally patients only have to wait less than 48 hours. At K.A.T.H. the cost of the procedure is so expensive that many patients require time to procure funds from family members.

Traction

While the current surgical procedure works well, the emergency management procedures at K.A.T.H. are in need of improvement. The emergency management for femur fractures is the application of traction, a tensile force along the leg designed to counteract the contracting muscles. In doing so, the original length of the leg is achieved and pain reduction is typical [8].

Previous Semester Contributions

This design problem was previously addressed by a different student team in the fall of 2019. Our design team's efforts address the same problem, but the design process has been started from the beginning with new team members and research. For a further summary of project similarities and differences, see Appendix A.

Benchmarking of Current Solutions

The current method used at K.A.T.H. is Buck's Extension. Strips of foam are laid along the inside and outside of the patient's leg and around the foot. Strips of plaster are then applied to attach the foam strips to the leg. Weight is then connected to the foam at the base of the foot. The

weight applied axially along the leg provides traction [2, 8]. This method is limited by the skin traction that can be safely applied and requires trained hospital staff that are only available during working hours. The foam and plaster strips are disposed after use.

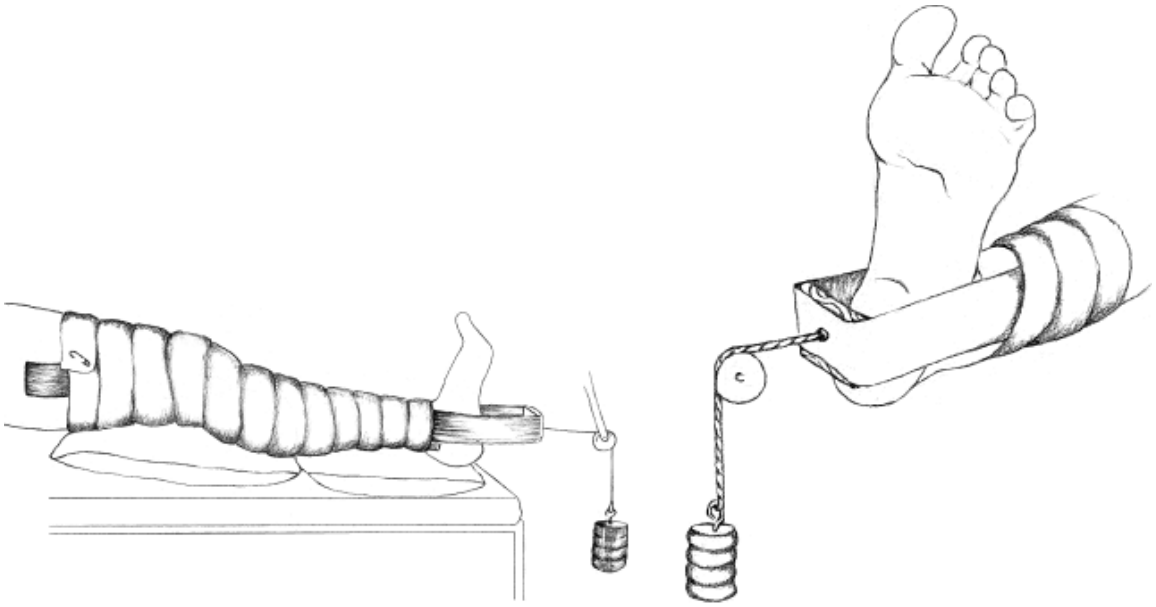


Figure 3: Buck's Extension [8]

Dyna Med Hare Traction Splint

The Dyna Med Hare Traction Splint is a common solution used in medical applications. The device features multiple leg straps which attach to the patient. A ratchet device connects to the system for applying traction axially along the leg [13]. This system provides higher traction forces and is reusable, advantages over Buck's Extension. Its downfall is its cost to the consumer and the fact that it cannot be repaired by K.A.T.H. staff.

Figure 4: Dyna Med Hare Traction Splint [13]

CT-6 Traction Splint

The CT-6 Traction Splint is a common solution used in military applications. Similar to the Hare Traction Splint, the device features multiple leg straps for connecting to the patient. This system differs with a single bar frame and uses elastic bands for applying traction [14]. It has similar advantages and disadvantages as the CT-6 with respect to Buck's Extension. This system is also the cheapest and least material intensive of the high resource setting solutions.

Figure 5: CT-6 Traction Splint [14]

Sager Splint

The Sager splint is most similar in design to the CT-6 splint.The Sager Splint offers the best performance with the ability to document exact force application [15]. It is also the most expensive of the high resource setting solutions. Similar to the other high resource setting solutions, the Sager Splint has poor repairability. The device is made of precision-made parts not repairable by the K.A.T.H. staff.

Figure 6: Sager Splint [15]

Summary of Benchmarking

The current method used at K.A.T.H. lacks in force application and requires trained hospital staff to be applied to the patient. The benchmarked high resource setting solutions treat femur fractures more adequately through increased force application. All benchmarked solutions lack in either their repairability or reusability. Our solution must combine the performance characteristics of the high resource setting solutions with low resource setting material and tool availability.

Table 1: Summary of Benchmarking

Device	**Price**	**Strengths**	**Limitations**
Buck's Extension	<$26	Applicable to LMICs	Limited by skin traction Complicated setup process Not reusable
Dyna Med Hare Traction Splint	$529.99	Increased force application Reusable	Cost Repairability
Sager Splint	$248.99	Increased force application Reusable	Cost Repairability
CT-6 Splint	$659.99	Increased force application Reusable Precise force measurement	Cost Repairability

Priority Stakeholder Engagement

The general stakeholders for this project consist of Ghanaian patients, doctors, manufacturers, procurement officers, biomedical technicians, emergency medical technicians, and some

individuals involved in the design process. Due to time constraints as well as limitations caused by COVID-19, not every possible stakeholder was contacted. Those who had a major involvement in the project as well as those who would potentially contribute the most were given priority and were contacted in the first weeks of the project. In Table 2, a list of the stakeholders contacted as well as their contributions to the project is presented.

Table 2: List of Stakeholders and Interactions

Stakeholder Name	**Stakeholder Role and Impact**
Kathleen Sienko	Mentor and professor at the University of Michigan. Provided project guidance and the bulk of our curriculum.
Caroline Soyars	Sponsor. Provided information on potential stakeholders as well as background information and directly put stakeholders in contact with the team.
Rockefeller Oteng	Lead Clinician at K.A.T.H. Emergency Medicine. Provided background information, technical information, and main needs for the project to fulfill.
Nana Sefa	Doctor at K.A.T.H. Emergency Medicine. Provided background information, technical information, and main needs for the project to fulfill.
KNUST Student Team	Collaborative Student Team. Provided background information and an exchange of ideas involving the creation of the requirements and specifications.

Requirements and Specifications

Shown below are three tables of the user requirements and engineering specifications for the design problem. The tables are separated by priority level: HIGH, MED, and LOW, and within each table they are ordered with the furthest developed specifications at the top and the least developed at the bottom. An overview of the coding is included below for reference.

Priority Level:
HIGH - Requirements which are fully necessary for a successful solution. Without these requirements, the solution would not work or could not be implemented.
MED - Requirements that are beneficial to the solution, but would still represent improvement over current solution if they were not met.
LOW - Requirements that would be beneficial to have included, but do not greatly alter success

or implementation of product.
Green - Specifications that are complete and verified.
Yellow - Nearly complete specifications or specifications that we are in the process of verifying and have identified a source to verify with.
Orange - Incomplete specifications or specifications with proxy resources in which we have not identified a source for verification.

Table 3: HIGH Priority Requirements and Specifications

Requirements	**Specifications**	**Info Sources**
Fits Ghanaian adults 18-59	Leg length 80.9 cm to 109.9 cm Knee height 38.9 cm to 52.8 cm Thigh length 42 cm to 57.1 cm Thigh circumference 52.7 cm to 72.3 cm	[2] [16] [17]
Relieves the pain of the patient	Using a Numerical Rating Scale (NRS) pain should reduce by 2.4 on a 10 scale within 12 hours.	[2] [18] [19]
Returns leg to original length	Within 2 cm of non-injured leg length Provides up to 142.29 N traction force	[12] [20] [23]
Durable	Provide 142.29 N of traction force a while maintaining functionality Withstands 30 uses while maintaining 142.29 N	[2] [8] [20]
Fixable by K.A.T.H. Staff	Device should be returned to working condition in 30 minutes or less if broken Able to be fixed by standard tools, power drills, welding, saw, hammer, screwdriver.	[21]
Does not damage skin	Should not exceed 20 MPa tensile stress to skin on leg	[2] [25] [26]
Does not cause pressure related damage to the patient	Should not apply a pressure of more than 100 mmHg	[2] [28]
Cleanable	Device should allow for cleaning by 10% bleach in water solution, soap and water, or spirit solution and pass ASTM standard E1766 – 15	[32] [43] [44]

Table 4: MED Priority Requirements and Specifications

Requirements	Specifications	Info Sources
Easy to apply	Should be applied in less than 15 minutes Should require no more than 2 staff members to apply Should require less than 15 steps to apply	[2] [19]
Low cost	The cost per use for the consumer must not exceed 58.30 Cedi The cost per use for the consumer should not exceed 42.30 Cedi The cost to the hospital should be less than 52.5 Cedi per use	[2] [4] [5]
Sourceable	Made of easily accessible materials E.g. Hospital bed parts, wood, used car parts	[21] [24]
Easy to transport patient	Must fit within dimensions of a hospital bed (36” x 80”) Patient can be transported while in traction	[2] [21] [22]

Table 5: LOW Priority Requirements and Specifications

Requirements	Specifications	Info Sources
Follows codes/regulations	Follows ISO 10993-10 standard in testing for irritation and skin sensitization and U.S. Food and Drug Administration (FDA) regulations for medical devices	[29][45]

Fits Ghanaian adults 18-59

The target group for the device are Ghanaian adults. Through speaking with Doctors Oteng and Sefa, femur injuries are most commonly seen in working age adults. To quantify the size ranges necessary, our group used anthropometric data from Ghanaian public workers published by the International Journal of Innovative Research in Science, Engineering, and Technology and used a range of sizes spanning from the 5th percentile female to the 95th percentile male.

A 5th to 95th percentile range was used to provide treatment to the greatest number of patients while reducing outliers. Measurements defined are leg length, knee height, thigh length, and thigh circumference. Of these measurements, all were taken from Ghanaian workers age 24-59 except thigh circumference which had to be taken from the United States Military. The relevant Ghanaian data were all taken while sitting down. Because the United States Military is likely not

an accurate representation of Ghanaian workers, the thigh circumference measure was expanded to the 1st to 99th percentile to ensure the Ghanaian population is within the range.

Leg length is measured as the combined value of the distance between the floor and the popliteal and the length of the popliteal to the buttocks. The popliteal is the area behind one's knee joint. To support the Ghanaian working population, the device must fit leg lengths spanning from 80.9 cm to 109.9 cm [16].

Knee height is defined as the distance from the popliteal to the floor when seated in a chair with feet flat on the floor. The range of knee heights the device must support is 38.9 cm to 52.8 cm [16].

Thigh length is the distance between the buttocks and the popliteal when standing. The device must fit patients with thigh lengths between 42 cm to 57.1 cm [16].

Thigh circumference is measured directly below the buttocks. Using United States Military Data, the device must fit thigh circumference measurements between 49.5 cm and 77.4 cm. This range spans from the 1st percentile female to the 99th percentile male. All measurements are shown below for reference:

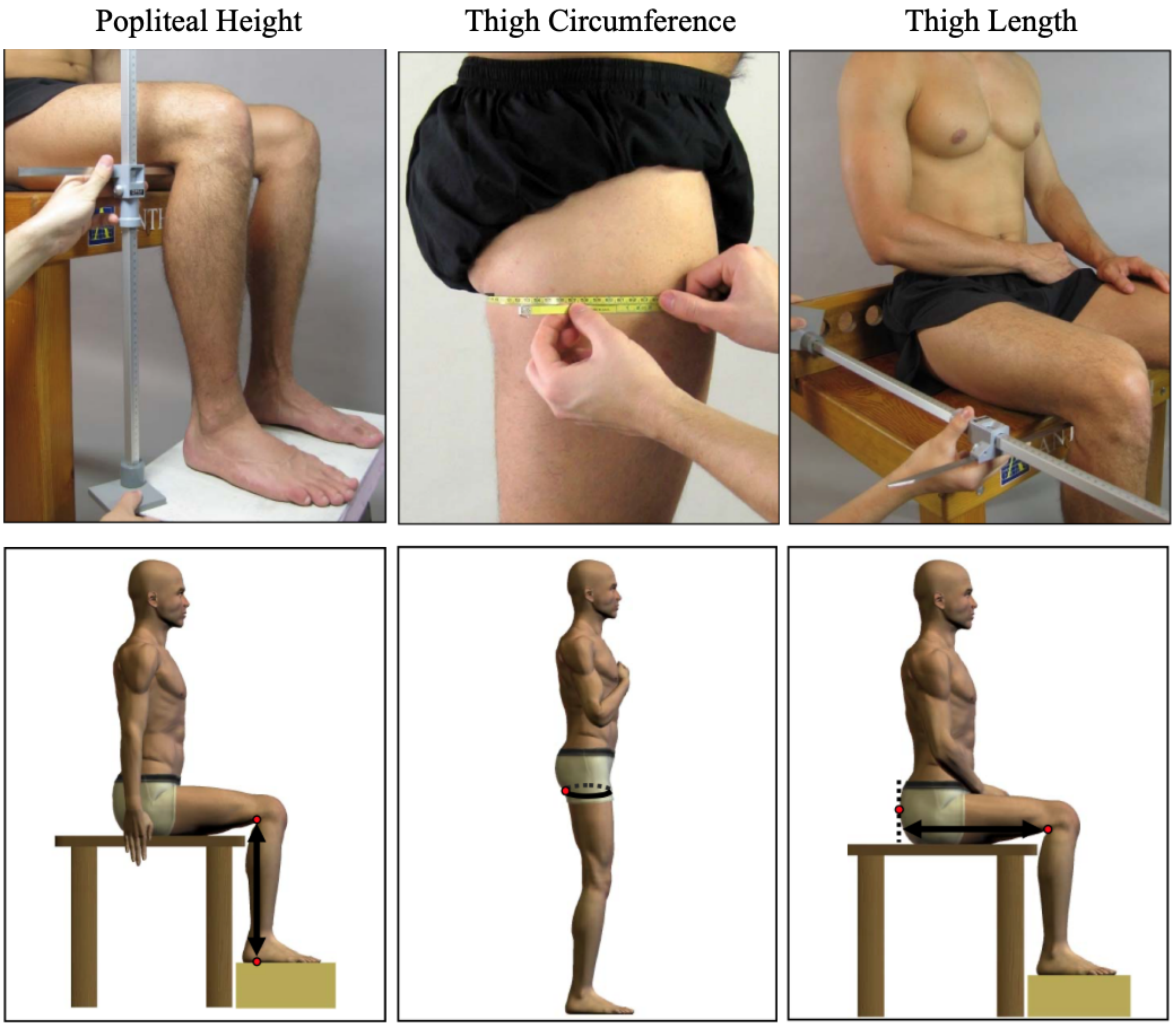


Figure 7: Measurement Locations [17]

Relieves the pain of the patient

Pre-operative femur fracture care has two main benefits: aligning bones in preparation for surgery, and relieving pain the patient is experiencing. By providing traction and aligning bones, there is better blood flow through the leg promoting healing and decreasing pain for the patient. The current benchmark provided in research shows that using a traction splint reduces pain by 2.4 on a 10 degree scale [18]. Research also suggests that the best pain scale is the Numerical Rating Scale (NRS). Therefore the solution will aim for the current benchmark of decreasing pain by 2.4 on a 10 point scale.

Returns leg to original length

Due to the strong muscles of the thigh, following a femur fracture, the fractured portions are pulled past each other, shortening the leg. This process causes additional pain to the patient and restricts proper blood flow through the leg [2]. The solution must return the leg to its original

length. In doing so, it is necessary for the device to supply a maximum traction force between 10 and 15% of the patient's body weight [20]. Using the maximum percentage with the maximum projected size patient using anthropometric data from Ghanaian public workers, the maximum traction force required was calculated as 142.29 N [16].

Durable

Through speaking with Dr. Oteng and Dr. Sefa, it became apparent that a solution should be durable, lasting multiple uses. Current traction kits are single use, driving up cost for patients and the hospital. The target number of uses is 30 while maintaining functionality. Functionality is defined as no loss in traction ability and no additional risk of injury for the patient. One use is defined as the maximum time the maximum sized patient would use the solution for. For this, the 95th percentile male was used as an estimate as previously stated and the corresponding force is 142.29 N [12].

Fixable by K.A.T.H. staff

Maintenance of femur fracture equipment is an additional obstacle faced by K.A.T.H. Medical equipment often includes complex mechanisms that require maintenance if broken [2]. In a low resource setting, hiring maintenance technicians with knowledge of specific systems is costly, timely, and often not feasible. Scott Vanden Heuvel outlined some of the capabilities and struggles K.A.T.H. maintenance personnel have. Most important was Scott's explanation of the broken equipment where equipment went when it was not fixable or took too long to fix [21].

The first specification developed was that any solution should be maintainable by K.A.T.H. maintenance staff using the tools they already have such as welding tools, power drills, and saws. Secondly, the solution should require maintenance no longer than 30 minutes. Scott defined this is the approximate time limit for maintenance where broken devices would be thrown out rather than serviced if the time was surpassed [21].

Does not damage skin

One concern mentioned by Dr. Oteng and Dr. Sefa was the possibility of tearing skin when providing traction to the patient. The current method to treat femur fractures involves using plaster to create a boot around the patients lower leg. The plaster adheres to the skin and when traction is applied, it can create discomfort or even damage the patient's skin.

To avoid any damage to the skin, the solution should put a maximum of 20 MPa of stress on the patient's skin. 20 MPa is an estimate of the stress required to tear skin based on two research studies that quantified this stress between 20 and 24 MPa. Skin tested in these experiments was from the back and abdomen, so further research is needed to verify that 20 MPa is an acceptable estimate for skin on the leg as well. [26, 27]

Patient comfort is also a large concern for the solution and future research must be conducted to quantify the amount of stress to the skin to cause abrasions or discomfort.

Does not cause pressure related damage to the patient

A third patient health concern is restricted blood flow. Compression is often needed to apply traction or stabilize the leg during treatment, but too much compression can restrict blood flow. A study focused on tourniquets quantifies the amount of pressure applied that restricts blood flow as 100 mmHg [28]. Our specification follows this study and states the maximum pressure the device should apply to the patient is 100 mmHg.

Furthermore, following design feedback from Dr. Sefa, pressure sores became a concern as well [32]. Pressure sores are caused by constant pressures over or near 100mmHg applied to the skin over prolonged periods of time [36]. Furthermore, pressure sores are common near bony areas such as the ankle where pressure concentrations can develop [36]. Prevention of pressure sores can be achieved in several ways: decrease the time the pressure is applied on the skin or decrease the pressure applied to the skin, or pad the area where the pressure is applied [37]. Both pressure sores and blood flow are pressure related damages to the body, so the requirement was rewritten to accomodate for both injury possibilities. While our target is for our device to apply less than 100mmHg to the patient, pressure sores may still develop even at lower pressures during serious sustained traction and should be researched.

Cleanable

Because the device is planned to be reusable, it must be cleaned between uses. The solution should allow for easy disinfection of all materials by K.A.T.H. staff [32]. Following additional research into cleaning methods used at K.A.T.H., we were informed three methods are currently used: A 10% bleach solution in water, soap and water, and spirit, an 83% ethanol solution [43]. Currently, the specification states our device should be cleanable by any of these methods. Using ASTM standard E1766 – 15, a standard for judging the effectiveness of sterilization, we can determine the effectiveness of these methods as well as the best method. Plans would also need to be made to learn the hospital's cleaning preferences such as frequency, bacteria content, or device function and its relationship to cleaning.

Easy to apply

One of the major challenges with the current solution is the availability of trained staff to treat patients. The plaster group that applies treatment currently is not available during nights leaving some patients waiting hours to receive treatment. An easy to apply solution could provide patients with significantly faster care and less pain.

The first two specifications, “should take less than 15 minutes to apply” and “should require no more than 2 staff members to apply,” were developed after speaking with Dr. Oteng and Dr. Sefa. They mentioned K.A.T.H. is a very busy hospital and staff availability is limited. As specified by the doctors, in an ideal situation, a maximum of two staff members would move from one patient to the next in 15 minutes.

The third specification, “requires less than 15 steps to apply” was developed using the Buck’s Traction Splint setup in the United States as a proxy source. It is the most similar setup to the current solution in Ghana, and it currently requires 15 steps to apply [19]. To facilitate an easier setup, this is the number of steps the solution should improve upon.

Low cost

K.A.T.H. is located in a low resource setting and therefore the device must be produced to a low cost to patients. Our design team estimates the optimal cost per use for a patient at K.A.T.H. for a solution is 42.30 GHS. In order to quantify the optimal cost per use for patients, the average annual income per capita in the United States was compared to Accra, Ghana, a similar sized city to Kumasi. The average annual income per capita in and Accra, Ghana is $950 according to a 2012 study [4]. In the United States, average income for a single homeowner is $39279 according to the 2016 census [5]. In addition, the price for a new Hare Traction Splint is $300 accounting for 0.76% of the income of an average American. Assuming citizens in Ghana are able to spend the same percentage of their annual income on a femur fracture solution, an optimal cost to the patient would be no more than $7.25 or 42.30 GHS when converted.

Furthermore, Dr. Oteng provided the current cost per use to the hospital and to the patient. K.A.T.H currently spends 52.50 GHS for a single use skin traction kit and patients are charged 58 GHS [31]. Also discussed with Dr. Oteng was the priority difference between performance and cost. While cost is important, if the solution increased performance, the hospital would be able to spend more on the solution. For this reason we consider Low Cost a MED priority. Using these prices along with the data found by our design team, we define 42.30 GHS as the optimal price per use for patients and 58 GHS as the acceptable price per use for patients. Our design team is undergoing further research to find the maximum cost that K.A.T.H. would be willing to spend on an improved solution as an upper bound for solution development.

Sourceable

In a low resource setting, the cost to manufacture and distribute can become too costly for hospitals [2]. In an effort to keep costs low and solutions attainable, this solution must be sourceable for K.A.T.H. Using materials or manufacturing available in Ghana will dramatically reduce manufacturing costs and allow more patients to receive treatment. The specification states the solution must be made of only products found in Ghana such as wood, aluminum, used car

parts, and old hospital device parts [23, 24]. Additionally, Ghana has a large fabric industry that could be used to make custom components as well. These materials have been identified through speaking with Scott, Randy Schwemmin, and the KNUST group. Following further research and contact with KNUST, we have identified aluminum and certain plastics as sourceable materials [30]. K.A.T.H., as stated before, has most standard tools, so manufacturing at K.A.T.H. as well as outside manufacturers within Ghana may be feasible solutions.

Easy to transport patient

A current challenge expressed by both Dr. Oteng and Dr. Sefa was their current struggle to transport patients between rooms. In the emergency department of K.A.T.H, there are separate sections where patients are sent to depending on their condition. As patients heal or as new patients come in, their location may change within the hospital [21]. The current solution is not able to maintain traction on the patient's leg when they are moved and traction must be reapplied after the patient is relocated. This creates added discomfort for the patient and requires more time and effort from hospital staff [2].

The engineering specifications developed for ease of transport were developed around hospital spacing. In order to ease the process of transportation, specifications state that one, the patient should be able to be transported without traction being removed. Second, the device should fit within the dimensions of a standard hospital bed 36 in width x 80 in length [22]

Follows Codes and Regulations

ISO 10993-10 is a testing protocol that assesses chemicals released from medical devices and their impact on skin irritation [29]. In an effort to maximize patient comfort, the solution should pass standards outlined in this code. FDA regulations were chosen as a substitute for Ghanaian regulations, with the functional areas of the regulations being the key areas of focus.

Other Design Considerations

Table 6: Other Design Considerations

Patient Comfort	Patients should have maximum allowable movement with exception of leg. Device should perform beyond only avoiding damage
Aesthetics	Device should not look intimidating to patient or staff
Hospital Training	Training should be as short as possible and no license should be required for set up.
Immobilize Knee	Knee movement should be restricted to within patient comfort

Patient comfort
While device effectiveness takes slight precedence over patient comfort, the patient's experience should also influence the final design. Although it may not be directly quantifiable, the solution should allow maximum movement for the patient with the exception of their leg. Furthermore, as addressed in the skin damage and ankle damage specifications, our solution should go beyond just preventing damage; it should relieve pain or discomfort for the patient.

Aesthetics
Visual aesthetics should also play a role in the development of solutions. A device that looks intimidating may increase stress for a patient who is already in pain and discomfort. Furthermore, the device should not appear complex to staff with minimal experience with the product. An emergency department is a highly stressful work environment and a non-intuitive product setup could cause stress for staff.

Hospital training
Hospital training was removed from our requirements and specifications after our initial conversation with Dr. Oteng and Dr. Sefa. In the interview they stated that the ability to train staff is not a concern, and that if an improved solution is implemented, it would be a priority for staff to receive training. While training may not be an immediate concern, the K.A.T.H Emergency Department is highly busy, so any solution should not take an excessive amount of training time.

Immobilizes the knee
During conversations with Dr. Oteng and Dr. Sefa, they expressed immobilization is not a priority concern. Immobilizing the hip is not feasible and immobilizing the knee comes as a result of adequate traction [31, 32]. While not a high priority, knee immobilization may improve patient comfort. As knee immobilization is a product of traction, verification of knee immobilization will be through the verification of traction application.

Concept Exploration

Concept Generation
The first step within the concept exploration phase was concept generation which consisted of multiple stages of ideation. As a design team, we decided to begin our ideation with brainstorming because it was a method that we were all familiar with and let us transition smoothly into idea generation. The purpose of the brainstorming was to extract as many diverse

ideas as possible while not restricting any ideas or imposing any limitations. During brainstorming, the team began ideating individually before expanding out to a team exercise. In doing so, each team member was allowed to generate their own ideas before being influenced by others' thoughts. Drawings were heavily implemented, with each idea having some sort of visual representation. The goal for this session was to create 50 ideas, which was achieved.

The second stage of concept generation utilized morphological analysis: creating a chart organizing sub-functions, ideas, and solutions. This method was less familiar to us than brainstorming, but after generating a foundation of ideas, using a new framework allowed us to think in ways that we were not used to, generating more diverse ideas. First, the team discussed and created a list of sub-functions based on functional decomposition to use with morphological analysis. This was done using the different basic functions of typical medical devices for femur fractures. In Figure 8 below, the functional decomposition resulting from the discussion is shown.

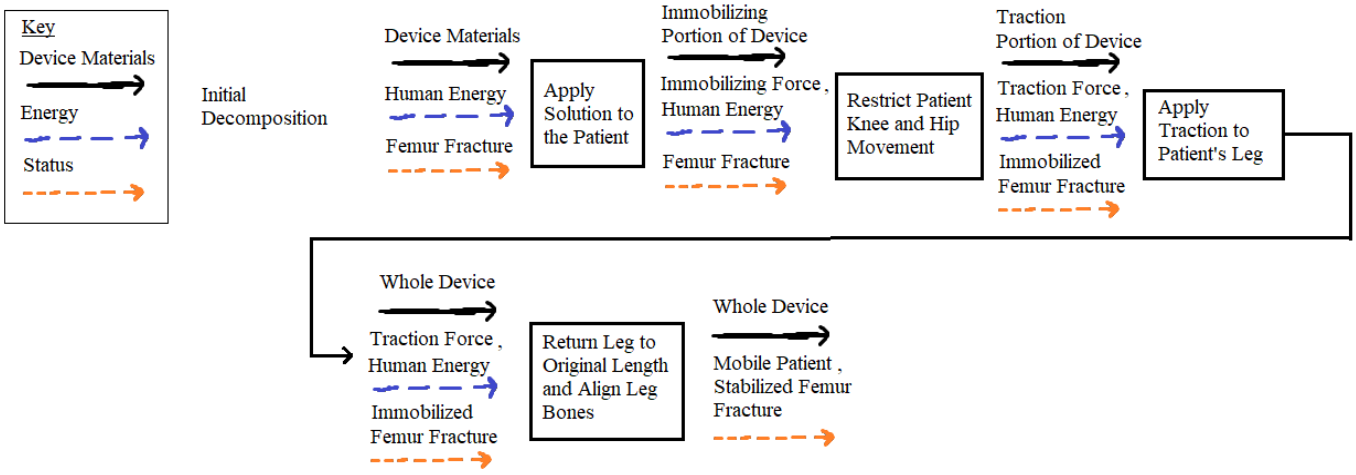


Figure 8: Functional decomposition of a typical medical device for femur fractures

The list produced from the functional decomposition was put into the morphological chart as subfunctions. Then each team member independently created solutions as well as five ideas using their individual matrix. These solutions also provide some insight on the diversity of our ideas overall including the brainstorming session. Shown in Table 7 is the first iteration of the morphological analysis.

Table 7. First Iteration of the Morphological Chart

Function	Immobilize Hip		Immobilize knee		Apply Traction			Align Femur Portions
Subfunctions	Secures Leg	Attaches to Patient	Secures Leg	Attaches to Patient	Secure Traction Force to Patient	Human Input to Traction Force	Traction provider	
Solutions	Dye Cast	Straps	Dye Cast	Straps	Hook and Hole	Crank	Weight	Metal Frames
	Metal Bar	Adhesive	Metal Bar	Adhesive	Pulley	Hook/ Platform	Pulley/ Mech. Adv.	Cloth Compression
	Clamps	Cloth Sleeve	Clamps	Cloth Sleeve	Velcro	Handle	Cable	Clamps
	Pins	Pins	Pins	Pins	Adhesive	Button	Elastic/ Surgical Tubing	Metal Frames
					Wraps		Hydraulics	
					Clamps		Magnetic	

The design team came together after to share and discuss the ideas. This discussion led to a change in the morphological analysis as some functions were shifted or changed to better categorize the subfunctions for ideation. The second iteration of the morphological chart is shown below in Table 8.

Table 8. Second Iteration of Morphological Chart

Function	Immobilization			Apply Traction		Align Femur Portions
Subfunctions	Restricts Hip Movement	Restricts Knee Movement	Patient - Immobilization Interface	Patient-Traction Interface	Force Generator	
Solutions	Bars	Bars	Straps	Ankle	Weights	Compression
	Mold	Mold	String/rope	Skin	Pull	Air pressure
	2x4	2x4	Elastic	Super skin	Crank	Manual - by nurse/doctor
	Compression wrap	Knee brace	Plaster	Boot	Magnet	Alignment rods
	Clamps	Compression wrap	Fabric/Padding	Adhesive	Body weight	
		Cloth and Pads	Brace		Pulley/Mechanical Advantage	
					Cables	
					Pins/Dowels	
					Turnbuckle	
					Locking system	

This process was then repeated with everyone using an expanded matrix composed of each individual's original matrix until more ideas were formulated for each team member. Using this method, 30 more ideas were generated, for a total of 80 ideas generated for the concept generation phase.

Concept Development

The second step of concept exploration was concept development. The two main development tools that were used were SCAMPER and design heuristics. The concept development consisted of two stages. The team split into two pairs with one pair utilizing SCAMPER and the other pair using design heuristics. The SCAMPER pair generated 15 ideas using the table presented in Figure 9.

Proposed Change	Description
Substitute	What if used in a different material,process, person, power source, place, or approach?
Combine	Could I combine units, purposes or ideas?
Adapt	What else is like this? What other idea does it suggest? Does the past offer a parallel? What can I copy?
Modify, magnify, minify	Could I add a new twist? Could I change the meaning, color, motion, form, or shape? Could I add something? Make stronger, higher, longer, thicker? Could I subtract something?
Put to other uses	Are there new ways to use this as is? If I modify it, does it have other uses?
Eliminate	Can I remove a part, function, person without affecting outcome?
Rearrange, reverse	Could I interchange components? Could I use a different layout or sequence? What if i transpose cause and effect? Could I transpose positive and negative? What if I turn it backward, upside down or inside out?

Figure 9: SCAMPER Acronym Expanded [34]

The design heuristics pair chose from the design heuristics cards from Figure 10 and generated 15 ideas from their selection.

1. Add features from nature
2. Add gradations
3. Add motion
4. Add to existing product
5. Adjust function through movement
6. Adjust functions for specific users
7. Align components around center
8. Allow user to assemble
9. Allow user to customize
10. Allow user to reconfigure
11. Animate
12. Apply existing mechanism in new way
13. Attach independent functional components
14. Attach product to user
15. Bend
16. Build user community
17. Change contact surface
18. Change direction of access
19. Change flexibility
20. Change geometry
21. Compartmentalize
22. Convert 2-D to 3-D
23. Convert for second function
24. Cover or remove joints
25. Cover or wrap
26. Create system
27. Distinguish functions visually
28. Divide continuous surface
29. Elevate or lower
30. Expand or collapse
31. Expose interior
32. Extend surface
33. Extrude
34. Flatten
35. Fold
36. Hollow out
37. Impose hierarchy on functions
38. Incorporate environment
39. Incorporate user input
40. Layer
41. Make component multifunctional
42. Make components attachable or detachable
43. Make product resuable or recyclable
44. Merge functions with same energy source
45. Merge surfaces
46. Mirror or array
47. Nest
48. Offer optional components
49. Provide sensory feedback
50. Reconfigure
51. Recycle to manufacturer
52. Reduce material
53. Reorient
54. Repeat
55. Repurpose packaging
56. Reverse direction or change angle
57. Roll
58. Rotate
59. Scale up or down
60. Separate parts
61. Slide components
62. Stack
63. Substitute
64. Synthesize functions
65. Telescope
66. Texturize
67. Twist
68. Unify
69. Use alternative energy source
70. Use common base to hold components
71. Use continuous material
72. Use human-generated power
73. Use multiple components for one function
74. Use packaging as functional component
75. Use recycled or recyclable materials
76. Utilize inner space
77. Utilize opposite surface

Figure 10: Descriptive titles for the 77 design heuristics [33]

After 30 ideas were formulated between the two groups, we switched methods and generated another 20 ideas, with the design heuristics group utilizing unused heuristics. In total, the plan was to develop 50 ideas, which was achieved with 14 different design heuristic cards being used. After development, the goal was to reach a minimum of 100 ideas. This goal was surpassed, resulting in a total of 130 ideas. For the full list of ideas, various sketches, as well as the specific design heuristic cards used, see Appendix C.

Below are three diverse examples of concepts generated that will be discussed to show the breadth of the ideas generated. While other concepts were also discussed, these concepts were discussed slightly more in depth with other more promising concepts analyzed later in concept evaluation. The first concept was the magnetic traction concept, which was chosen for its unique approach. A magnetic wall would pull on a magnetic boot that the patient would be wearing, thus providing the necessary traction for pulling the fracture apart. The pros to this would be that this method could be utilized by multiple patients as well as the effectiveness of utilizing magnetic force. However, the cons to this are evident as implementing such a solution would not be feasible due to complexity, cost, bulkiness, and its effect on any electronics. Below, the concept is presented in Figure 11.

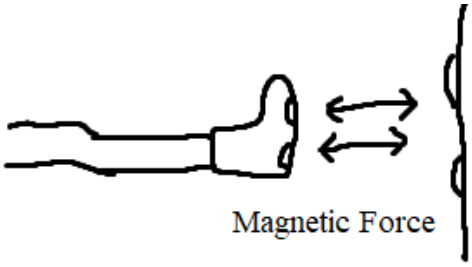


Figure 11: Magnetic Traction Concept Sketch

The next concept we discussed was the cable reel concept. This had a more realistic premise than the magnetic traction concept and had the pros of being able to provide sufficient traction accurately while being sturdy. However, this concept also had major drawbacks as it would be expensive, bulky, and could possibly greatly injure the patient if not properly operated. Below, the concept is given in Figure 12.

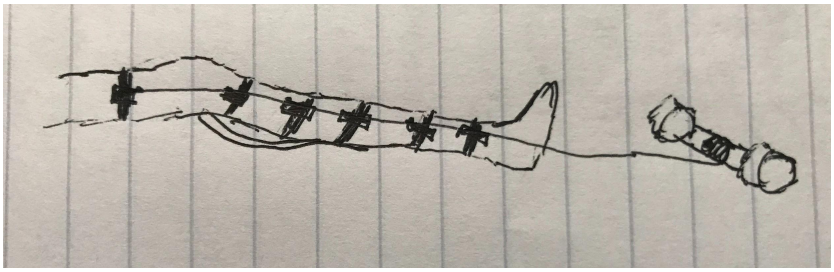


Figure 12: Cable Reel Concept Sketch

The last concept we discussed was the padded wooden brace concept. This concept was discussed for its similarities and improvements to the currently implemented device at K.A.T.H. Although this concept has its pros in its improvement upon the current device, it was still lacking in too many areas to be properly considered as things like pressure sores and ineffective traction would still be issues. Below, the concept is shown in Figure 13.

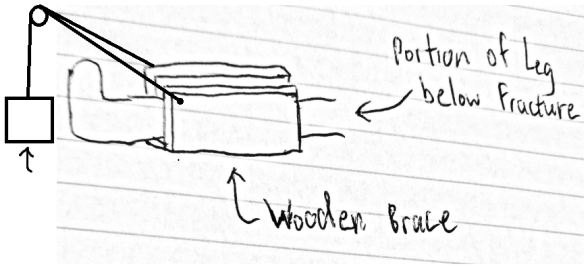


Figure 13: Padded Wooden Brace Concept Sketch

Concept Evaluation

Following concept generation, our design team had a total of 130 concepts. To best analyze quality and limit bias, our design team underwent multiple stages of evaluation with gut checks mixed in to reflect on our progress. In total, we underwent three general evaluation stages: Idea Component Table, General Category Rating, Requirements and Specifications Rating.

Idea Component Table

Our team developed an idea component table as an effort to break down concepts to their base parts and evaluate those individual components. In doing so, the table could function both as an evaluation technique as well as further idea development. When creating the table, our design team refined the categories from our morphological chart and listed all components present in our 130 ideas in one of five categories. This table is shown below.

Table 9: Idea Component Table

	Immobilization		**Traction Method**		**Align Femur Portions**
	Device Infrastructure	Patient - infrastructure interface	Point of Traction on patient	Force Generator	
Component	Bars	Straps	Ankle	weights	Compression
	Shell	string/rope	skin	pull	Air pressure
	2x4	elastic	Super skin	crank	Manual - by nurse/doctor
	Compression wrap	plaster	boot	magnet	Alignment rods
	Clamps	fabric/padding	adhesive	Body weight	
	Compression wrap	brace	Thigh/Mid-Thigh	Pulley/Mechanical Advantage	
	Cloth and Pads		Upper Body	Cables	
			Knee	pins/dowels	

			Multiple Points	turnbuckle	
				Locking system	
				Linear Slide	
				Springs	
				Extendable Pole	

As shown above, the table was broken into three general categories: Immobilization, Traction Method, and Align Femur Portions. In this table, immobilization does not refer to limited mobility in any individual part of the leg, but rather securing the patient's leg to the device. Immobilization was further separated into device infrastructure and patient-infrastructure interface. Device infrastructure represents the base material or structure the device is made of. The patient-infrastructure interface was defined by our design team as the connection between the patient and the device infrastructure.

Likewise, the traction method was divided into a force generator and the point of traction on the patient. The force generator subcategory contains components that create the traction force for the device while the point of traction on the patient indicates where the traction is applied on the device or patient.

Align femur portions was not divided into any subcategories. After generating this table, our design team noted that all fully developed ideas should have components from the other four subcategories, but it does not necessarily need an individual component dedicated to align femur portions. When combining traction and the device infrastructure, alignment is maintained in most of the solutions generated, so there is no need for the alignment component as it would not add any functionality to the device. The category was left in the table, however, to account for solutions that did not use an interface traction combination that aligned femur portions.

Following the creation of our idea component table, our design team planned to rate the best components in each category to either validate our best designs or to generate new ideas composed of the highest scoring components. In practice, however, we discovered that rating the components was difficult as they were dependent on many factors. For example, bars may be a stronger infrastructure than cloth but it is also likely more expensive making rating the two relative to each other difficult. Without a clear, unbiased ranking method, our design team decided to pause this evaluation method. Later, we found it a useful tool to iterate upon and use as an evaluation technique.

General Category Rating

As our design team moved forward to our next step, we conducted a gut check to narrow down ideas. Our criteria for the gut check was any idea that was completely unfeasible would be deleted from consideration. For the purpose of this gut check, we defined an unfeasible idea as an idea that was not technologically possible or that would not be implementable with cost or resource requirements. The gut check was conducted as a quick decision, and any ideas that were in question were advanced to the next stage of evaluation. One concern of our team during this phase was having a full understanding of every idea. Because we had limited interaction with each other and could not directly interact with others drawings, we feared it limited our ability to recall some of the intricacies of many of the ideas. To combat this challenge, we decided to gut check our own ideas as we each had the greatest understanding of our own concepts. In doing so, we understood possible bias may be introduced, so in order to limit that bias, we met as a group to review our gut check results. For each eliminated idea, the person who eliminated it briefly explained the idea and why it was deleted. Any disagreement from the team put the idea back into the next round of evaluation.

Following the gut check, we had filtered our ideas down from 130 to 80 ideas. To further converge, we decided on a general category rating system. This system was used because doing a full requirements and specifications rating would be too time consuming with so many ideas, and differentiating between ideas would be difficult. For the general category rating systems, four categories were used: performance, usability, perceived fixability, and durability.

Usability takes into account factors such as ease of use and the amount of time and effort required by staff to apply the solution. Performance refers to overall performance including fit and traction generation. Fixability ranks the perceived ability of K.A.T.H. to fix the device assuming that a break occurs. Durability rankings represent the anticipated lifetime of the device under conditions they will experience at K.A.T.H.

Each idea was rated 1-5 in each category and each rating was discussed and agreed upon by our entire team. After rating, the total score was summed together and compared. After review, ratings spanned from 7 to 15 with an average score of 11. For comparison, we rated the current solution which scored a 10. Concepts that received scores of 12 and above moved on to the next stage of idea evaluation. This number was picked as the cutoff based on its improvement upon the current solution. Because ratings can be fairly subjective even when discussed as a team, a one point margin may not mark a true improvement over the current solution. To validate our ranking strategy, all concepts that scored 11 were reviewed, and any concepts that our design team felt were deserving of further consideration were moved into the next phase of evaluation. During the general category rating, our design team converged from 80 to 18 ideas. An excerpt

of our general category rating table is shown below with ideas scoring 12 and above coded in yellow, ideas scoring 11 in blue, and all else not highlighted. The full table can be found in Appendix D.

Table 10: General Category Rating

Design Name	Usability	Performance	Perceived Fixability	Durability	SUM
The Clamp Device	4	1	3	3	11
A Telescoping Single Pole	4	3	2	3	12
Replace Plaster and Cloth	5	2	4	1	12
Ankle and Skin Traction	2	4	3	2	11
Pin and Board	2	3	1	3	9
Plaster the Whole Leg	3	3	4	2	12
Cable Extension	2	4	2	3	11
Tube filled with air designed to increase axial pressure	4	2	2	2	10
Hole in Bed with Patient Applying the Weight	4	2	1	5	12

Requirements and Specifications Rating

The final step in our concept evaluation was requirements and specifications rating in which we rated each of the 18 remaining concepts against our requirements and specifications. While attempting to rate ideas, our design team noticed a flaw in our system. Many of our 18 ideas were only partial solutions. Because different ideas addressed different aspects of the design problem, it was not possible to rate them against each other using specific criteria from our requirements and specifications. To combat this challenge, we drew inspiration from our idea component table and realized that our ideas fell into two categories: Interfaces and Force Generators. For this portion of concept evaluation, we defined an interface as how the traction was attached to the patient and the base structure or material of the device. Force Generators were the components or methods that created the traction force on the patient. Several ideas were considered both interfaces and force generators and were scored in both categories.

Interfaces

Following the separation of idea categories, our design team chose which requirements were relevant for which category. For interfaces, the requirements chosen to rate ideas were: fits ghanaian adults, durable, fixable by K.A.T.H. staff, does not damage skin, does not restrict blood

flow, easy to apply, and low cost per use. Requirements that were omitted from rating this section were: relieves pain, returns leg to original length, easy to transport patient while in traction, and follows codes. Returns leg to original length and easy to transport patient while in traction were left out because they were dependent on the traction force generator and instead were used in the force generator category rankings. Pain relief and follows codes were not included because our design team had no way of differentiating between ideas using these categories. ISO-10993 analyzes chemicals released from the device and is out of the scope of the problem for the given stage. Pain relief is difficult to anticipate, however, our research shows pain relief comes as a function of traction, so this requirement should be being addressed by traction requirement under the force generator category. A table of the interface rating scores is shown below

Table 11: Interface Rating Table

Interfaces	Fits Ghanaian adults 18-59 years	Durable	Fixable by K.A.T.H. Staff	Sourceable	Does not damage skin	Does not restrict blood flow	Easy to apply	Low cost/use	Sum
Replace Plaster with Cloth/Strong Material	5	1	5	3	2	4	3	2	25
Plaster the Whole Leg	5	1	5	2	2	4	3	2	24
Ankle brace	**4**	**3**	**3**	**2**	**3**	**4**	**5**	**3**	**27**
Combine Boot Clamp	3	3	3	3	3	3	3	3	24
Tape front and back of leg	4	1	5	2	2	4	3	2	23
Modified Crutch Extender	3	4	2	3	3	3	3	3	24
Speaker Stand	**4**	**4**	**3**	**3**	**3**	**3**	**3**	**4**	**27**
Telescoping L bar with boot	4	3	2	2	3	3	3	3	23

As shown above, the highest scoring concepts were the Speaker Stand design and the Ankle Brace at 27 points. Again, as with the general category rating, we consider a two point margin significant and these two ideas have a two point margin on the rest of the concepts. Results were also gut checked and ratings were compared against each other for individual requirements to ensure ratings were accurate relative to each other.

Force Generators

To rate the force generator ideas, the requirements used were: returns leg to original length, durable, fixable by K.A.T.H. staff, sourceable, easy to apply, easy to transport patient while in traction, and low cost per use. Requirements omitted from this ranking system were: fits Ghanaian adults, relieves pain of patients, does not damage skin, does not restrict blood flow, and follows codes. Fits Ghanaian adults, does not damage skin, and does not restrict blood flow were all left out because they were not relevant to the force generator. They were included in the interface scoring table. The requirements for pain relief and code/regulations were left out of this section for the same reasons they were not included in the interface table. ISO-10993 analyzes chemicals released from the device and is out of the scope of the problem for the given stage. As stated before, pain relief is difficult to anticipate, however pain relief is experienced as a result of traction, so we anticipate designs that score well in returns leg to original length will also provide pain relief. The force generator chart is shown below.

Table 12: Force Generator Rating Table

Force Generators	Returns leg to original length	Durable	Fixable by K.A.T.H. Staff	Sourceable	Easy to apply	Easy to transport patient while in traction	Low cost/use	Sum
Pulley System	5	3	2	3	2	2	3	20
Multi-Turn Buckle	4	4	2	2	3	4	2	21
Surgical Tubing Pulley	3	3	2	3	2	2	3	18
Linear slide	3	3	2	2	4	4	2	20
Detachable Ratchet	**5**	**4**	**1**	**2**	**4**	**4**	**2**	**22**
Winch	5	4	1	2	4	2	2	20
Telescoping Single Pole (w/human force)	**4**	**4**	**2**	**3**	**3**	**3**	**3**	**22**
Speaker Stand (w/human force)	**5**	**4**	**3**	**3**	**3**	**3**	**4**	**25**
Modified crutch (w/human force)	**4**	**4**	**2**	**3**	**3**	**3**	**3**	**22**
Human Force	**3**	**4**	**3**	**5**	**2**	**4**	**4**	**25**

The results of the Force Generator had slightly more difficult to interpret results. Speaker Stand and Human Force were the highest scorers at 25. Importantly, Human Force must also be combined with a locking mechanism as it is unfeasible for a human to be constantly applying traction. Our design team defines a locking mechanism as a structure that can lock at a given length to hold traction on a patient. Furthermore, Speaker Stand, Modified Crutch, and Telescoping Pole all hold traction force but require an input force. During ranking, human force was assumed to be the input force. Through analyzing the results, our design team interpreted that locking mechanisms scored the highest and should be an initial focus in solution development. Furthermore a speaker stand was the highest scoring locking mechanism with a telescoping pole and modified crutch tied for second best locking mechanism. A detachable ratchet was included as the highest scoring true force generator outside of human force.

Following the rankings, our design team created new concepts using these highest scoring force generators and interfaces. These concepts included a speaker stand idea with a detachable ratchet, and a locking telescoping pole using human force for traction. To verify that these ideas do not experience a drop in performance when paired together, we conducted one final rating with these new concepts compared with other fully developed solutions from our ideation as well as the current solution. During this rating, all requirements were used as criteria with the exception of pain relief and codes/regulations for the reasons listed previously. This table is shown below.

Table 13: Full Concept Ranking

	Returns leg to original length	Durable	Fixable by K.A.T.H. Staff	Sourceable	Easy to apply	Easy to transport patient while in traction	Low cost/use	Fits Ghanaian adults 18-59 years	Does not damage skin	Does not restrict blood flow	Sum
Speaker stand w brace and ratchet	**5**	**4**	**2**	**2**	**4**	**4**	**3**	**4**	**3**	**3**	**34**
Telescoping pole w ankle brace	**4**	**3**	**3**	**3**	**3**	**4**	**3**	**4**	**3**	**3**	**33**
Crutch extender	4	3	3	3	3	4	3	3	3	3	32
Improved Material	3	1	5	2	2	2	2	4	2	4	27
Multi-Turnbuckle idea	4	4	2	2	3	4	2	4	3	3	31
Current Solution	2	1	5	2	2	2	3	4	2	4	27

As shown in the table, the speaker stand and telescoping pole were the highest scoring ideas still and show a sizable improvement over the current solution. We also noted that the crutch idea performed well. While it may not be the first option tested, our design team is considering it as a possible research area during solution development. As a design team, we are moving forward cautiously with these two solutions. In the rating system, locking mechanisms performed very well leading to similar selected concepts. As a design team we feel optimistic that locking mechanisms, if implemented, would address needs well. If during solution development locking mechanisms prove unfeasible, we feel we have a diverse enough list that we could develop other methods to address the design problem.

Selected Concepts

Following our concept evaluation, we were able to narrow our solution down to two possible designs to develop further. They are similar in their application of traction but different in subtle ways. First is a manual (or human applied) traction with a locking mechanism. Second, is a ratchet applied traction with a locking mechanism. This locking mechanism can be easily understood when compared to external skeletal fixation, as shown below.

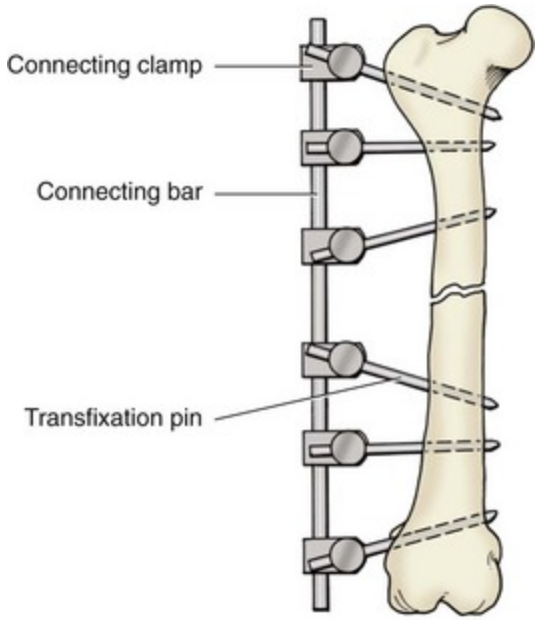


Figure 14: External Skeletal Fixation [35]

External skeletal fixation is a way to hold the fractured femur in its original position by nailing a metal bar and rigidly attaching it to the femur. The rigid bar provides the traction force that keeps the two femoral fractures from misaligning. This solution restores the leg to its original position and therefore should eliminate the pain associated with this injury.

Concept 1: Telescoping Pole

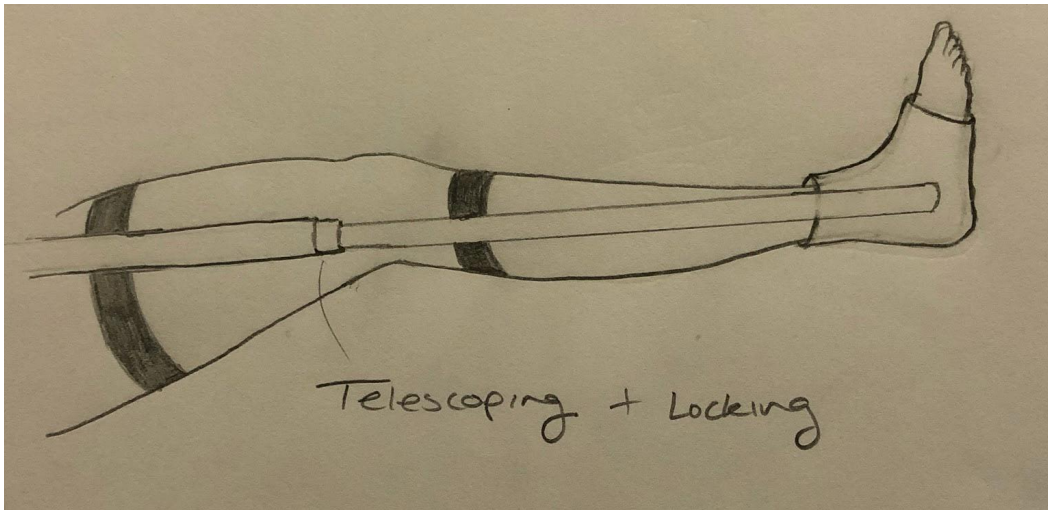


Figure 15: Telescoping Pole Design

The telescoping pole utilizes a locking mechanism and manual traction to relieve the patient of pain. The pole is composed of two or more circular rods, one being larger in diameter than the other. The larger rod is hollow, allowing for the inner rod to slide within it. Whenever the rods are at the correct position the inner rod is twisted and locks into the larger rod, making one rigid rod.

The image above shows how the device attaches to the patient. Two people are required in order to apply this device. The proximal femur portion is attached to the larger rod at the hip and above the fracture site. The distal femur position is attached to the smaller rod below the fracture site and to the ankle using an ankle brace. The hip and ankle provide anchor points for force to be applied, while the extra straps around the fracture site help to minimize stress on the skin. After the device is attached to the patient using the straps and ankle brace, manual traction is applied to the patient by K.A.T.H. staff until the leg is returned to its original length, which can be seen by comparing the fractured leg to the unfractured leg. As manual traction is applied the inner rod extends out of the outer rod moving with the distal femur portion. Once manual traction has been applied, and the leg has been aligned, then the telescoping pole is locked into place by a second employee. The locked pole now acts as a rigid bar holding the leg in its original position.

There are many strengths about this design, it's portable, durable, lightweight and has a low cost per use. The design is portable in the sense that it is small and attaches only to the leg of the patient. It does not extrude out of the bed, nor does it need to be removed in order for a patient to be transported. The design is durable since it can be used by multiple patients. The different components of this design are multi-use and can be reused unlike the current solution. The design is lightweight because the rods are hollowed out and not one large piece of heavy metal.

Lastly, along with being durable this design has a low cost per use since it can be used multiple times and can be charged at a lower cost than a one use device.

The design also has several weaknesses, as it uses manual traction, has a high initial cost, could be harder to fix than other designs, and requires multiple people to apply traction. This device uses manual traction, which could be considered not to be accurate and may not generate enough force in order to return the leg to its original position. Manual traction also means that this design is limited by the user, if the user can't apply enough force to return the leg to its original position then this design does not work. The design also has a higher initial cost than the current design due to its materials, and durability. As with any long-term solution this design is an investment, but if the K.A.T.H. hospital can't afford the initial cost of this device, then the design becomes infeasible. The design could also be infeasible if it is not easily fixable by the K.A.T.H. staff. Depending on the nature of the twisting locking mechanism it could be impossible for the staff to be able to fix this design. Fixablity is not only a matter of if the device is fixable or not, but also a matter of how quickly this device can be fixed. Things that take longer than 30 minutes to fix normally end being thrown out [21], if the device is not easily fixable then there is a high chance that the device will not get fixed. Lastly the device requires multiple people to apply this solution. K.A.T.H. is the second largest hospital in Kumasi, Ghana, the requirement of additional people needed in order to provide traction limits the hospital's ability to function as efficiently as possible. The hospital must also have enough people to apply this solution, which means that patients could be denied the treatment until enough staff is available to apply the device.

Concept 2: Speaker Stand Pole with Detachable Ratchet Traction

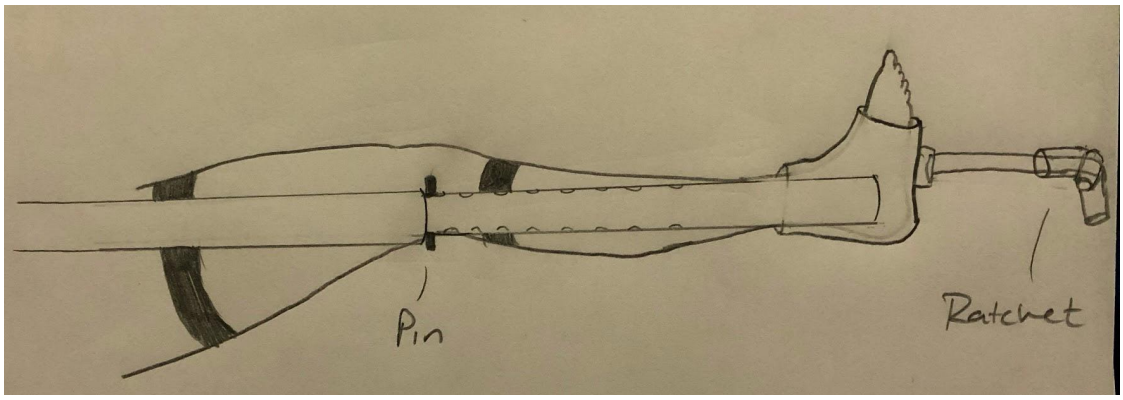


Figure 16: Speaker Stand Design

The speaker stand design uses a pin locking mechanism and ratchet traction in order to relieve the pain of the patient. Like the telescoping pole, the device is composed of two circular rods, one being larger in diameter than the other. The larger rod is hollowed out, allowing for the inner rod to slide within it. The inner rod has holes drilled through the rod in the radial direction. The holes are spread out at various lengths in the axial direction. Whenever the rods are at the correct

position a pin is placed within the inner rod, which prevents the inner rod from sliding inside of the hollowed out larger rod. The muscle will attempt to contract but the pin prevents the rod from moving, the pinned device acts as one rod applying traction to the entire leg.

The image above shows how the device attaches to the patient. This device can be applied by one person. The proximal femur portion is attached to the larger rod at the hip and above the fracture site. The distal femur position is attached to the smaller rod below the fracture site and to the ankle using an ankle brace. The hip and ankle provide great anchor points for force to be applied, while the extra straps around the fracture site help to minimize stress on the skin. After the device is attached to the patient using the straps and ankle brace, ratchet traction is applied to the patient by the K.A.T.H. staff by using the hoop at the bottom of the ankle brace, and an external fixed anchor point. The employee ratchets the leg until it is returned to its original length, which can be seen by comparing the fractured leg to the unfractured leg. As traction is applied the inner rod extends out of the outer rod moving with the distal femur portion. Once traction has been applied, and the leg has been aligned, then the rod is locked into place by placing the pin inside of the nearest inner rod hole. The ratchet traction device is now removed and the pinned pole acts as a rigid bar holding the leg in its original position.

Similarly to the strengths of the telescoping design this device is portable, durable, lightweight, and has a low cost per use. It is also more easily fixed when compared to the telescoping design, since the locking mechanism is simply inserting a solid pin inside the hole. If a hole is enlarged due to wear and tear, then another hole can be drilled in that same location in a different radial orientation. If the pin fails, then a new pin can be ordered, or simply made, or even substituted if something similar in size to that hole diameter is accessible. The flexibility of this design makes it incredibly advantageous to address the high needs of the K.A.T.H. staff. It's also worth noting that this solution can be applied by one person, no other assistants are needed, meaning that there is an increase in patient treatment. The last benefit of this design is the detachable ratchet traction. In the past, ratchet solutions have been thought of as infeasible, but this was because the ratchet traction that was proposed was a continually ratchet traction. Continual ratchet traction leads to a shorter life span of the ratchet, leading to large amounts of ratchets needing to be purchased. Furthermore, because it was continual ratchet traction, a ratchet was needed for each solution.This design combines with a locking mechanism so that it is easy to apply traction without any of the weaknesses of continual ratchet traction, such as failing ratchets, and a large amount of ratchets.

Conversely this design has a few weaknesses which include: a high initial cost and a high set up time. Like the telescoping pole this design has a low cost per usen since it is reusable by multiple patients. However, it has a high initial cost due to the nature of the materials used in order to make the device multi-use. Although this device can be set up by one staff member, it has a

longer set up time. This is because of the extra steps like finding fixed anchor points to ratchet from, and applying the solution without any assistance.

Backup Concept: Crutch Extension

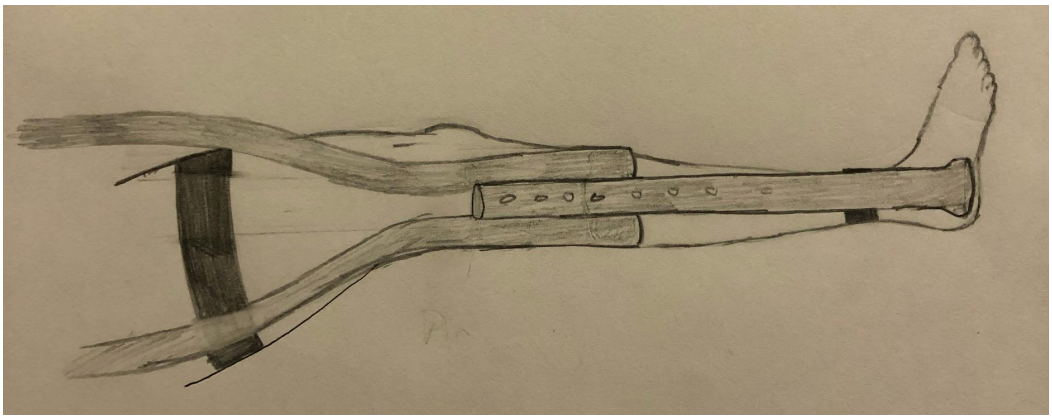


Figure 17: Crutch Extension Design

Something that is very important to consider is the possibility that during testing these concepts will fail. In the event that we need to switch to a new design we have many designs that were rated slightly below our selected concepts that we could return to and develop more. The first backup concept that we would consider is the Crutch Extension concept. This design uses a crutch's adjustable height peg as a locking mechanism to apply traction. This design is very similar to the concept 1 and 2 with a few differences. There is no ankle brace as the size of the crutch makes it hard to apply the traction force from the crutch onto an ankle brace. Instead of a twisting or a locking mechanism the device uses a spring loaded pin to lock itself in place. The crutch extension has the same strengths and weaknesses as the telescoping pole design with the added strength that this is a modification to an existing device that K.A.T.H. is likely to have. This means that the device is cheaper to procure, and easier to apply across the whole hospital. One major flaw of this design, not found in other designs, is that the size of the crutch might not be compatible with the different sizes of the various legs. There may be difficulty developing a one size fits all type of device.

Engineering Analysis

Our design team entered the engineering analysis stage with the speaker stand as our base design and aimed to further develop intricacies of the design. We started this process with the development of a journey map per the recommendation of Jeff Plott. In our journey map, we attempt to outline every step in the process that our product will have to undergo. Our team's current version of our journey map is shown below in Figure 18.

Figure 18: Journey Map

The journey map proved useful for thinking through the order of events the device must go through and helped our team design the straps, ankle brace, and traction application accordingly. This allowed us to further develop the journey map after engineering analysis as a more complete journey map was created involving every aspect of the design. In the left column are the steps to implement the device. In the right column are questions or design aspects that needed further attention that our design team noticed as we created the map. In addition, through the use

of design drivers, our team investigated possible problems and solutions of the design. In general, our research and analysis was conducted in five areas: general structure, traction method, straps, ankle brace, and connection method. Our progress can be seen in those sections below. Other design drivers focused on testing plans and future analysis. A table of our team's design drivers is shown below as reference. The table also provides the section where the design driver is explained in depth with any research and analysis conducted when working with the design driver. The table is also color coated with green indicating research has been finished, yellow meaning research is currently in progress, and orange indicating research will be done in the future.

Table 14: Design Drivers

Design Driver	Section
Is manual traction an option?	Traction Method
How do we apply traction?	Traction Method
Can skin support shear stress required for traction?	Straps
Will the required pressure for traction restrict blood flow?	Straps
How can pressure sores be prevented?	Straps
Should the ankle brace be custom made or bought and modified?	Ankle Brace
What materials are available for the ankle brace?	Ankle Brace
How do the ankle brace and straps connect to the bar?	Connection Method
Will a one bar design bend the leg?	One Bar Design Evaluation
What size should the pin be to avoid shear?	One Bar Design Evaluation
What is the relevancy and implementation of a cleaning method?	Cleaning Methods
Should FEA be used to evaluate our design?	Test Plans
How can we ensure proper tightness of the straps?	Straps/Test Plans
How can we ensure the proper traction is being applied?	Feedback Mechanisms

Traction Method

The current solution implemented at K.A.T.H. uses weights in order to provide the traction needed to pull apart the femur fracture. The weights are also tied on in such a way that the force is aligned with the axis of the leg. This allows for the leg to align and be pulled in the proper

direct, although not accurately or effectively. We looked into methods of manual traction as well as traction applied through mechanical leverage. Specifically, we sought to investigate two design drivers: Is manual traction feasible? If not, how is traction best applied?

Is manual traction feasible?

In applications of some devices like the Hare Traction Splint, manual traction is utilized for periods of time before the actual traction is applied for leg alignment and positioning [13]. However, further research and input from Dr. Sefa showed manual traction to not be viable as it would potentially cause issues in positioning and may require multiple people depending on the force needed [32]. Specifically, it could be limited by the strength of staff members and can be difficult to hold the patient's leg at a constant length causing them possible discomfort and pain. Knowing manual traction was not feasible, our group went back to our concept exploration data where we had previously prepared alternative traction methods in preparation for this case.

How is traction applied?

Turning to methods of mechanical advantage, we decided to implement ratchets as they are readily available and fairly compact compared to other methods like pulley systems. We included mounting points for the ratchet and an outer detachable bar. The outer detachable bar was added in order to provide a mounting point for the ratchet itself as well as to fix the upper bar, guaranteeing relative motion between the upper and lower bars when pulling the lower bar with the ratchet. These additions were positioned so that they could be implemented on both legs with no issues as well as be detached easily after the patient's leg is locked at the desired length.

Straps

Our strap design solution development was heavily influenced by patient safety and comfort and two initial design drivers: Can the skin support the shear stress required for traction? Will the required pressure of the straps restrict blood flow?

Can skin support shear stress required for traction?

To investigate skin's ability to withstand the shear stress required for traction, we used information from our requirements and specifications and performed basic calculations. Using anthropometric data from Ghanaian public workers, the traction required for the 95th percentile male was used as the extreme scenario for the device. We then assumed a worst case scenario that the entire traction force would be applied at one strap. With the strength of skin listed in our requirements and specifications, we calculated the minimum surface area that the strap should have to ensure traction application without the skin tearing to be .0711 cm^2. This value is very small and therefore skin tearing does not appear to be likely with this device as the proposed strap and ankle brace sizes are significantly larger than the minimum size limit. This analysis is limited as it assumes a constant pressure distribution. Our research on pressure sores and

pressure concentrations lead us to believe that some form of skin damage could be possible, specifically near the groin or ankle. These areas would need to be monitored during testing of the device.

Will the required pressure for traction restrict blood flow?
We presented the speaker stand base design to Dr. Sefa and while he liked many components, he outlined that pressures will be a limiting factor [32]. Previously, our design team was operating under the assumption that the limiting factors were skin shear strength and occlusion. This new insight prompted further research into pressure sores and how they are caused. As a result, this design driver evolved into: How can pressure sores be prevented?

How can pressure sores be prevented?
We learned that pressure sores are caused by constant pressure applied to the skin over prolonged periods of time [36]. Furthermore, pressure sores are most common around bony areas such as the ankle as there can be significant pressure concentrations around these locations [36]. Prevention of pressure sores can be achieved in several ways: decrease the time the pressure is applied on the skin, decrease the pressure applied to the skin, or pad the area where the pressure is applied [37].

As a result of pressure sore research, we altered the strap design to allow for adjustability in tightness as well as making the straps on the leg “functional straps”, which we define as straps that aid in the application of traction to the leg. To do so, each strap will be pinned to the bar and strapped to the leg prior to traction being applied. Then when traction is applied to the pole, the straps will pull on the leg, extending it to length. Current models such as the CT6, Sager, and Hare Traction Splint apply all traction at the ankle, however those models are not commonly used for long periods of time and therefore do not present a large risk for pressure sores. Implementing functional straps in our design will help distribute force limiting the risk of pressure sores at the ankle. Drawings of the strap design can be seen below in figure 19.

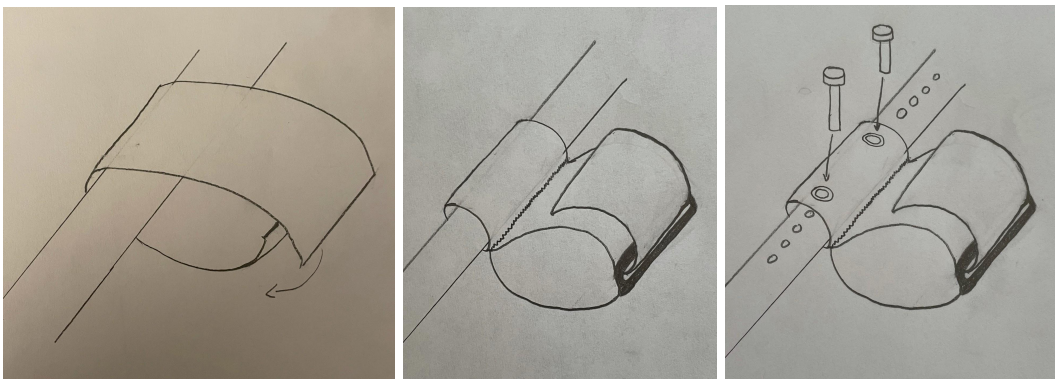


Figure 19: Strap Design Evolution

As seen in the figure above, the initial strap design (left) was a singular basic velcro strap that wrapped around the patient's leg and pole. As our design team gathered feedback and continued ideation for the straps, patient comfort led us to add a sewed piece around the bar to keep the patient's leg from constantly pushing directly on the bar. Furthermore, to add to adjustability and to allow for tighter straps, a clip was added for the velcro to loop around and tighten with (middle). Finally, resulting from the feedback received from Dr. Sefa and pressure sore research, pins were added as a connection point to make the straps functional. Straps and connection points were often developed in parallel, but connection methods will be highlighted later in the report as well.

Future strap design work includes testing various strap tightnesses to develop instructions for use. Specifically, our design team is seeking a way to inform the person administering the device that the straps are the correct tightness. Our current test plan uses a force sensitive resistor to measure pressure applied to a leg and the use of shims to measure the small spacing between the strap and leg when at the correct pressure. Using this test data, our design team could develop instructions that prioritize patient safety and help avoid occlusion or pressure sores. This device would also begin to determine how much stress the straps can redirect from the ankle brace.

Ankle Brace

Similar to the strap design, much of the development of the ankle braces was driven by patient comfort and safety. As mentioned previously, the ankle brace will be assisted by the straps during traction. The main design drivers for the ankle brace were the acceptable materials and whether the brace should be custom made or bought and modified.

Custom Brace vs Modified Off the Shelf Brace

Our design team initially assumed an off the shelf ankle brace would work best for our proposed solution. The initial design is shown below in figure 20.

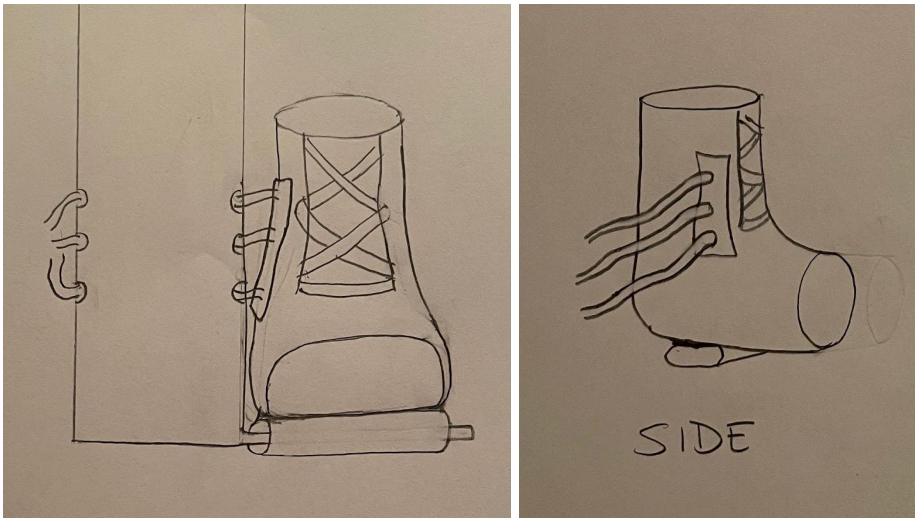


Figure 20: Initial Ankle Brace Design

One of the functions of an ankle brace is to distribute forces evenly, which would be useful in our design. Through minor modifications, a loop could be attached to the bottom, and some strings attached to the side, the brace could be used with our device.

After presenting the ankle brace and receiving presentation feedback, we realized patient comfort and safety may be limited through the use of most braces. Ankle braces often use compression around the foot and putting a tight ankle brace on a patient with a femur fracture could be challenging and painful to the patient. Furthermore, sourcing an acceptable model of the ankle brace, getting it to a seamstress or tailor for modifications, and then to the hospital would likely be a timely and difficult process. Due to these limitations with the off the shelf ankle brace, our design team updated the design to a custom made brace. Importantly, we also learned Ghana has a large population of seamstresses and tailors and that multiple sizes could be made. The custom ankle brace design and a mock up are shown below.

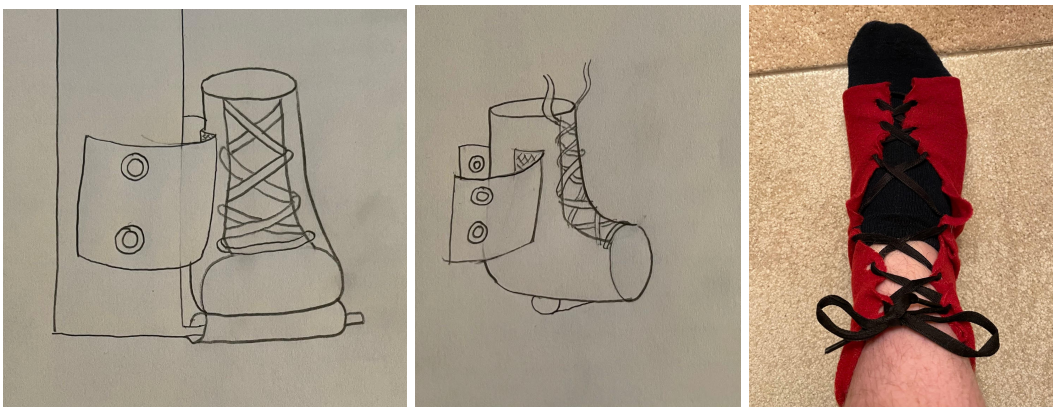


Figure 21: Custom Ankle Brace Design

The custom ankle brace is far more friendly to the patient during application. The laces were altered from the initial design so they go down the full length of the brace. They then are able to be loosened or completely removed so the fabric can lay down flat and be put under the patient's heel. The brace can then be wrapped around the foot and re-laced to secure the foot. Another change with this design iteration is the pins and fabric on the side of the brace to connect the brace to the pole. This connection method will be analyzed in depth in the connection method section.

Future work involving the ankle brace will be focused around force distribution and material selection. Our team plans to bring a mock up or drawing to a professional seamstress to get recommendations on materials, designs, and to have one made. Further research is also planned on materials to determine relative strength, comfort, and friction coefficients with the skin.

Connection Method

While one of the smallest physical pieces of our design, the ankle brace-bar and strap-bar connection method proved to be one of the most challenging and important aspects of our product. Our design team had only one design driver for this section: How do the straps and ankle brace connect to the bar?

Ankle Brace-bar and Strap-bar Connection

Following Design Review 2, our design team had not identified a connection method for the straps and ankle brace to the bar. Through speaking with Jeff Plott, we learned how important it was to have this method thought out before testing because many other subsystems were reliant on the connection. Following his advice, we took a step back and held a brainstorming session for the connection method. Many ideas were generated, and as a team we briefly developed them and attempted to incorporate them into our design. Following the brainstorming session, we came to consensus on using the pin design shown below.

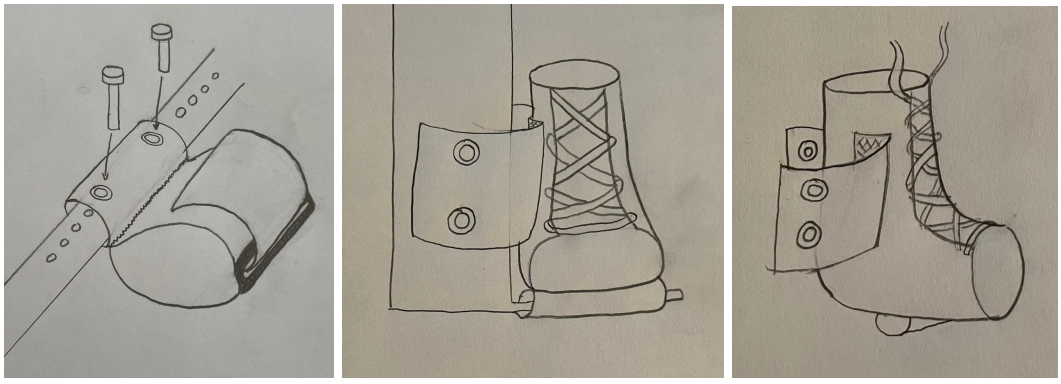


Figure 22: Ankle brace connection method

Benefits of this design is that it uses a removable pin to lock the straps and brace in place. This allows the straps to be moved to account for patients of all sizes within our specifications. Each pin will also be locked with a cotter pin to ensure it will not come loose. To strengthen the pin-fabric connection, grommets will be placed in the fabric and create the hole for the pin. Most importantly, the pin connection method allows for functional straps taking stress off of the ankle. The strap can be pinned in and strapped on to the lower leg prior to traction being applied. When traction is applied after, the device will be using both the ankle brace and strap to apply traction. Finally, the removable straps allow for easy cleaning of all components.

As our team continues on with this design, our focus shifts to storage and integration. While using pins works well functionally, it creates a large number of parts. We plan to research methods to connect the pins to the device or straps and ankle brace to aid with ease of storage and use.

One Bar Design Evaluation

Perhaps the largest concern with our design is the use of unilateral design instead of a bilateral design. There are many benefits with a unilateral design including less material which leads to a lower cost making it more feasible for Ghanaian citizens. However many questions arise when considering a one bar design. Will the design be able to support the uniaxial load of 142.29 N? Will the pin be able to withstand the shear forces as they lock the telescoping bar in place? Will the bending of the bar cause a moment on the leg that misaligned the femur? The goal of this evaluation was to find which of these questions limited the design the most. This was then identified as the most prominent one bar design driver.

The first assessment of the one bar design would be able to support the uniaxial load of 142.29 N. In order to answer this question a simple uniaxial stress calculation was performed. Using the initial relationship as shown below [38].

$$\sigma = \frac{P}{A}$$

Knowing that the stress of Aluminum 6061 is 276 MPa and the maximum force is 142.29 N the minimum area was found to be 0.51 mm^2 [39].This is an extremely small area and designs for multiple thicknesses were calculated. The smallest area that could be found was calculated from an aluminum pipe of 1.72 mm thickness and a nominal size of 3.175 mm, this resulted in the minimal stock area of 46.5 mm^2 [40]. From these calculations it was found that no stock pieces of aluminum had an area less than the minimal area. Knowing this it was found that this initial question would not limit the one bar design.

The second assessment of the one bar design was to determine if the locking pins would be able to withstand the maximum shear force. The equation and diagram for the pin shearing is shown below [41].

$$\tau \geq \frac{4F}{\pi d^2}$$

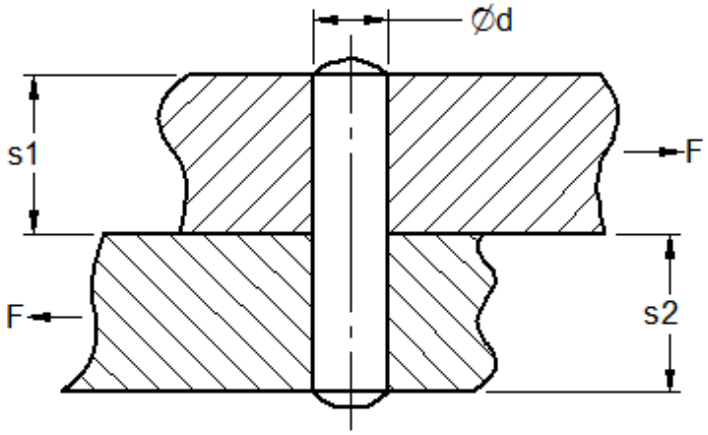


Figure 23: Pin Shear Diagram [41]

Where τis the shear strength of the material, F is the shear force, and d is the diameter of the locking pin. Rearranging this equation the diameter was found and shown below [41].

$$d \geq \sqrt{\frac{4F}{\pi\tau}}$$

The shear force is the maximum traction force of 142.29 N while the shear strength of aluminum is 207 MPA [39]. The minimum diameter was found to be 0.94 mm. As with the uniaxial design driver, this calculation showed that the minimum diameter needed for the locking pins is smaller than the smallest stock pin. This proved that the pin diameter was not something that would limit our design. This assessment is not without its limitations. The main flaw is that the pin does not only go through two layers of metal being pulled in opposite directions but it also goes through another two layers, and between these sets of layers there is a space between these layers. This would make the pin almost behave as a beam with two fixed components. However since the area is small this is a good initial approximation.

The last assessment that was made on the one bar design was the bending moment on the leg. In order to better understand this system we conducted a meeting with Professor Perkins [42]. From

this meeting a simple free body diagram was made with assuming no straps except for the hip and ankle anchor points. The first iteration of the free body diagram is shown below.

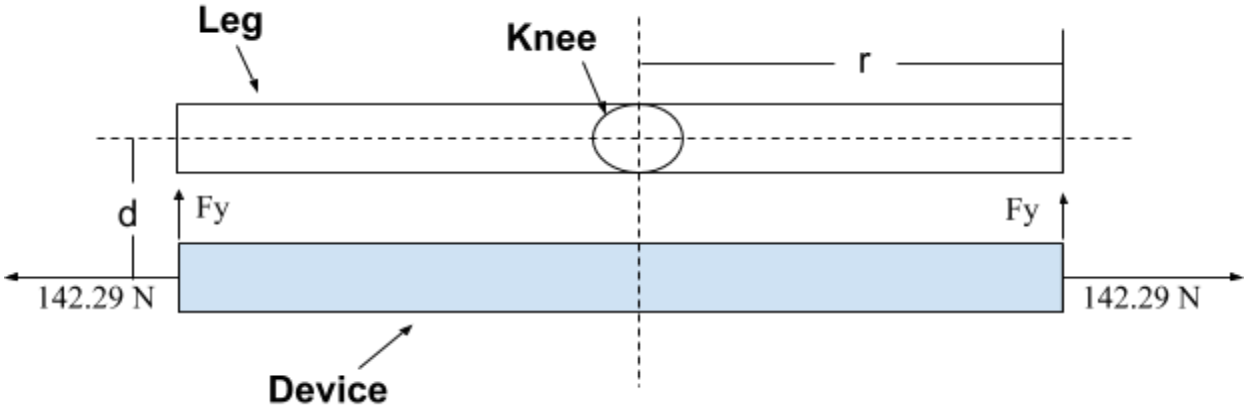


Figure 24: Bending Moment Free Body Diagram 1

It was found that the upward force (F_y) was zero due to the system being in equilibrium, while the total moment was found on the leg was found to be 142.29 N * d. As a preliminary model this gave us a good idea of the maximum bending moment without using straps. There were many possible solutions to this bending moment, making a bilateral design, attaching a rigid element to the opposite side of the leg, or even having one long sleeve that the leg went through which can be seen in the brief sketches below.

A. B. C.

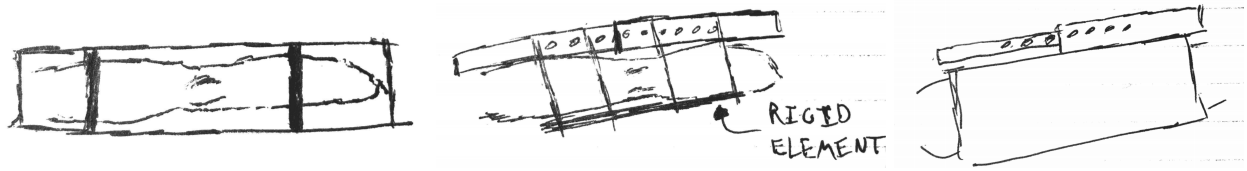


Figure 25: A) Bilateral Sketch B) Rigid Element Sketch C) Sleeve Sketch

However knowing we would be using functional straps on our design to mitigate pressure sores, we knew that some of the bending moment would be restricted from these straps. Therefore we developed a free body diagram that took into the straps in consideration. It's important to note

that the bending moment depends largely on the location and quantity of the straps. This can be understood conceptually. Imagine if straps were along the entire device such that it almost acted as a sleeve. The sleeve would prevent the bar from bending and eliminate the bending moment on the leg. As the straps begin to be taken away a bending moment would begin to form. As you added straps back the bending moment would be eliminated. So as more straps are added, the bending moment is reduced. The following free body diagram assumes using three straps, one around the upper thigh, one directly above the knee, and one directly below the knee. Three straps were used as a baseline since most existing unilateral solutions (CT-6, Sager) use 3 straps. This free body diagram is shown below.

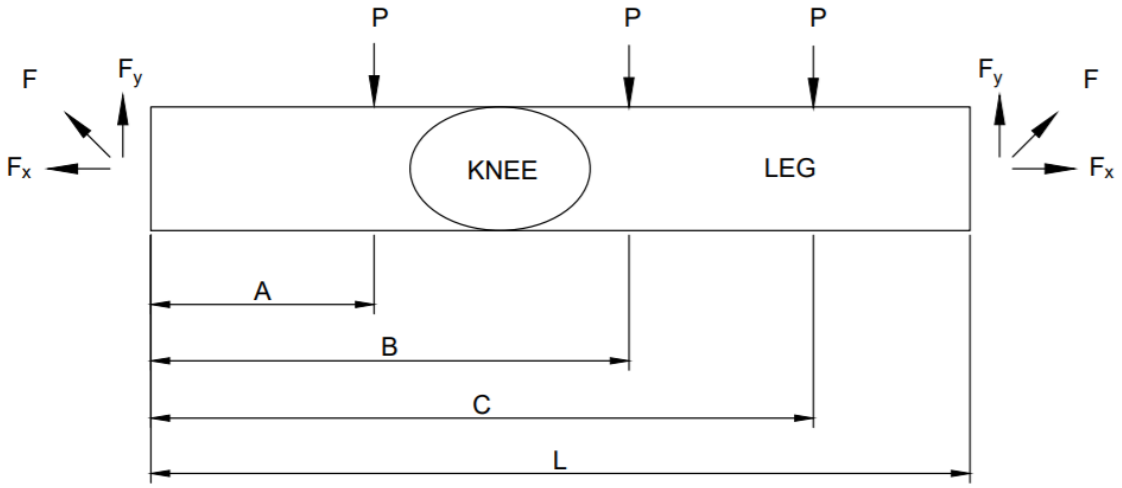


Figure 26: Bending Moment Free Body Diagram 2

Since the free body diagram depends on the location of the straps, variables A, B, and C were used to represent respective strap locations. L represents the total length of the leg from the hip to the foot. The forces are represented by arrows. The device force, F, represents the force from the device on the leg, while F_x and F_y are the respective components of the force on the leg. F_x can be thought of the necessary traction force of 142.29 N. P represents the force from the straps on the legs holding it in place. Many assumptions were made in the calculation of this model such as the leg being one rigid bar, the device force F was also assumed to have some angle Θ from the x-axis. Knowing this angle and $F_{x,}$ F_y can be defined as

$$F_y = F_x tan\Theta$$

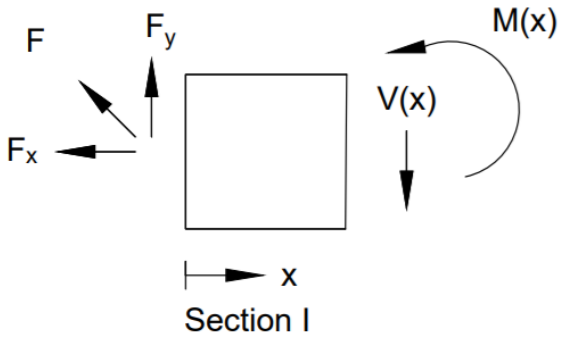
P can also be found by assuming the device is in equilibrium.

$$\Sigma F_y = 0 = 2F_y - 3P \rightarrow P = \frac{2F_y}{3}$$

From this it can be seen that the strap force is directly related to the number of straps used. P can therefore be represented as:

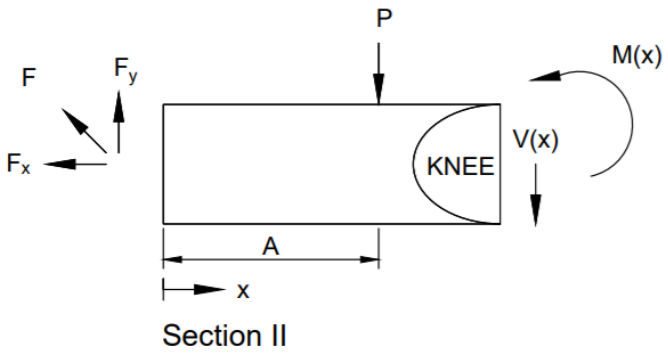
$$P = \frac{2F_y}{N}$$

Where N is the number of straps. This equation can also later be used to reduce pressure and therefore reduce pressure sores, as it can judge the number of straps required to increase pressure distribution. From this free body diagram section views were made in order to find the maximum moment on the leg. From these views the shear force and moment equations were found as seen in the figures below



Section I: $0 < x \leq A$

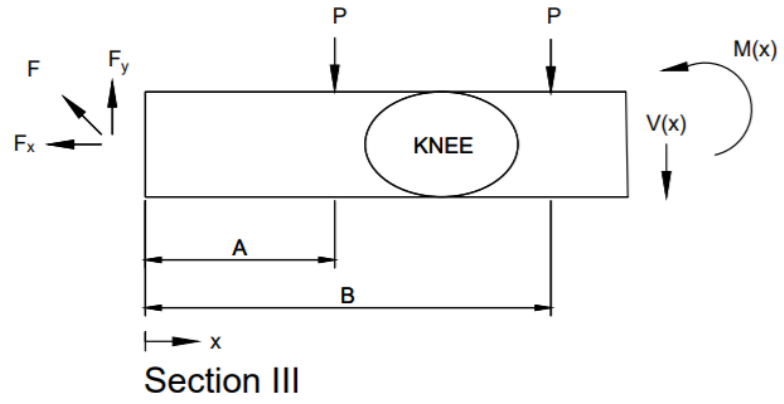
$$V(X) = F_y$$
$$M(X) = F_y x$$



Section II: $A < x \leq B$

$$V(X) = F_y - P$$
$$M(X) = \frac{F_y x}{3} - \frac{2F_y AL}{3}$$

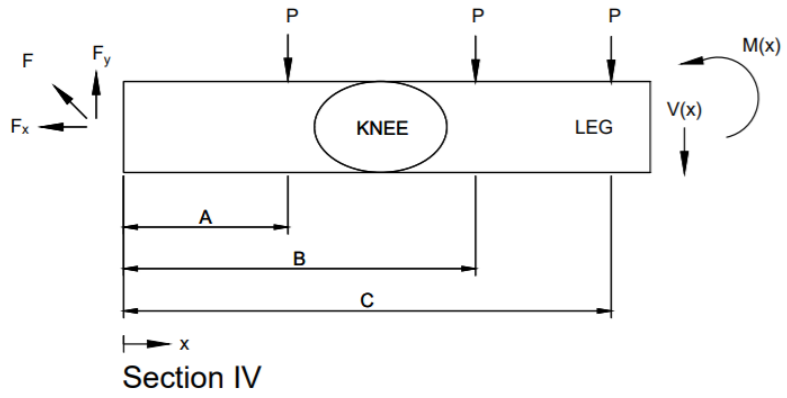
Figure 27: Bending Moment Section Views 1



Section III: $B < x \leq C$

$$V(X) = F_y - 2P$$

$$M(X) = \frac{-F_y x}{3} - \frac{2F_y L(A+$$



Section IV: $B < x \leq C$

$$V(X) = F_y - 2P$$

$$M(X) = -F_y x - \frac{2F_y L(A+B+$$

Figure 28: Bending Moment Section Views 2

Using these shear force and moment equations, a shear force and moment graph were made which allows us to see that the maximum bending moment.

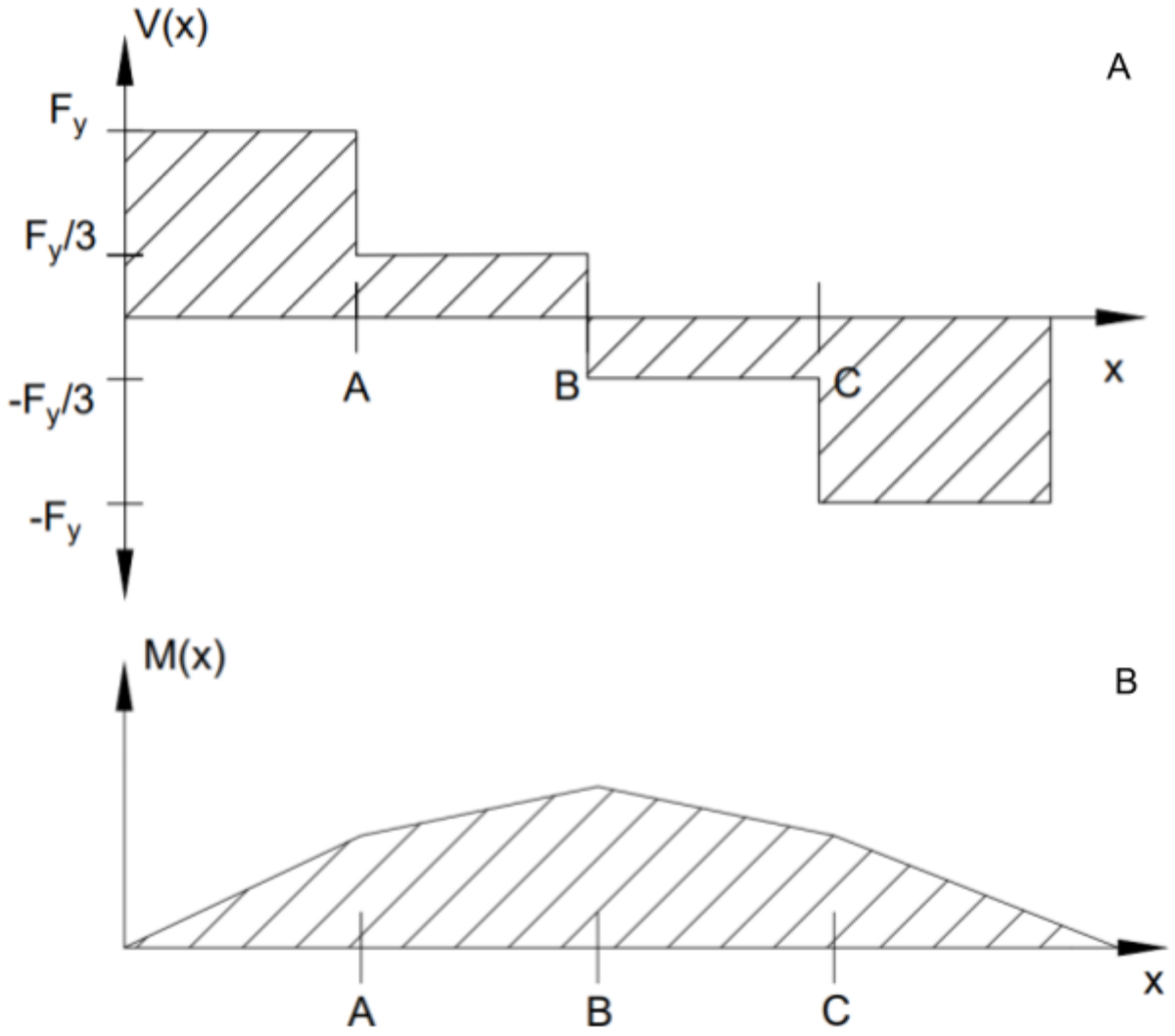


Figure 29: Shear and Bending Moment Graphs

The shear force is defined below [39].

$$V(x) = \frac{dM(x)}{dx}$$

There is a maximum where the shear force transitions from positive to negative. Using the moment equation from the Bending Moment Section II view. Using the differential equation of the deflection curve we can find an equation for the displacement [39].

$$EI\frac{d^2y}{dx^2} = M(x) = \frac{F_y x}{3} - \frac{2F_y AL}{3}$$

$$EIy(x) = \frac{F_y x^3}{3} - \frac{2F_y ALx^2}{3} + c_1 x + c_2$$

Where E is the young's modulus material in Pa, I is the moment of inertia in m^4, and y is the maximum displacement of the beam in m. It was then assumed that the deflection at the foot anchor point, y(0), and hip anchor point, y(L), were both zero. From these boundary equations the final equation was found.

$$EIy(x) = \frac{F_y x^3}{3} - \frac{2F_y ALx^2}{3} + \frac{F_y L^2(2A-1)x}{3}$$

This equation serves two purposes, the first purpose is as a design driver. I, the moment of inertia, can be used to find the diameter of the cross-sectional area assuming we know the maximum displacement of the leg. The equation can also be used as a computational model to find the maximum displacement based on the placement of the straps. This is a second iteration of the free body diagram, and while it does take into account the straps, it does not take into account the "functional straps" which further changes the moment equations. This free body diagram will need another iteration in order to account for the functional straps and give the most accurate result of the moment. Since this is a theoretical model, this model will need to be verified in order to use it as either a design driver or a theoretical model. The strain gauge test will be used to verify this equation, and based on this verification this equation will be used as a design driver and computational model. The maximum displacement of the fractured leg is also another section that is still undergoing research. We plan to talk to our stakeholders to find this maximum acceptable displacement and connect to access our academic sources. There are limitations to this model as it treats the leg as a rigid bar when really it is made up of joints and muscles and has internal weak points. Further research is needed to model this accurately.

Feedback Mechanisms

In order to determine if the device works, a proper method of determining the effectiveness must be implemented. One of the main issues with the current solution at K.A.T.H. is that there are no hard confirmations that the proper traction is applied. Instead, less reliable methods are used, such as visual inspection and patient feedback. Other methods that we have looked at use measurement tools such as force indicators or in process measurements like using adjustability as a way to indicate that proper lengths have been reached. After considering these methods as well as getting feedback from stakeholders, we have decided to go with a simpler route of directly comparing leg lengths during traction. This would be done with a rigid rectangular piece spanning 46.3 cm, the length of a 99th percentile male's biacromial breadth, which is essentially the shoulder length [17]. This piece can be made of various materials, such as aluminum or rigid plastics, as long as the material is rigid and straight. The piece would be put against the ankle brace attachment and extend to the other foot checking for equal length. This method was chosen for its ease of use, low cost, and modularity.

Cleaning Methods

For a reusable medical device, a proper cleaning method is essential to keep the device operational and safe for patient use. Simple cleaning methods that would typically be used and are convenient for use include cleaning the device with solutions consisting of bleach mixture or a solution consisting of ethanol spirit [23, 43]. Considering that the device could possibly be used for up to a week, a proper cleaning method would be conducted at certain lengths of times of use as well as after the device is used. A key factor in choosing the proper materials for the device is also the cleaning method as the device would need to be able to endure the cleaning method and the available cleaning solution without degrading and being properly cleansed. Our decision to make the device more modular in terms of components such as the straps or ankle brace was also given more weight due to the difficulty of cleaning. This allowed for the device to easily be separated and prepped for cleaning where the metal portions can be wiped down and the fabric portions can be soaked or wiped down. In general, this methodology would be followed throughout the device use and afterwards as it is essential to keep the patient safe from skin issues due to the device getting dirty as well as any other health issues such as infections.

Prototyping

Our team created a low fidelity prototype to better visualize our design. PVC pipe was the main structural component and velcro was the primary strap and "sewing" method. An off-the-shelf ratchet was used for the force application as it uses mechanical advantage to increase its pulling force. The prototype was purely for form and testing attachment mechanisms and not for validating performance. It can be seen in Figures 30 and 31. A bill of materials purchased can be found in Appendix F.

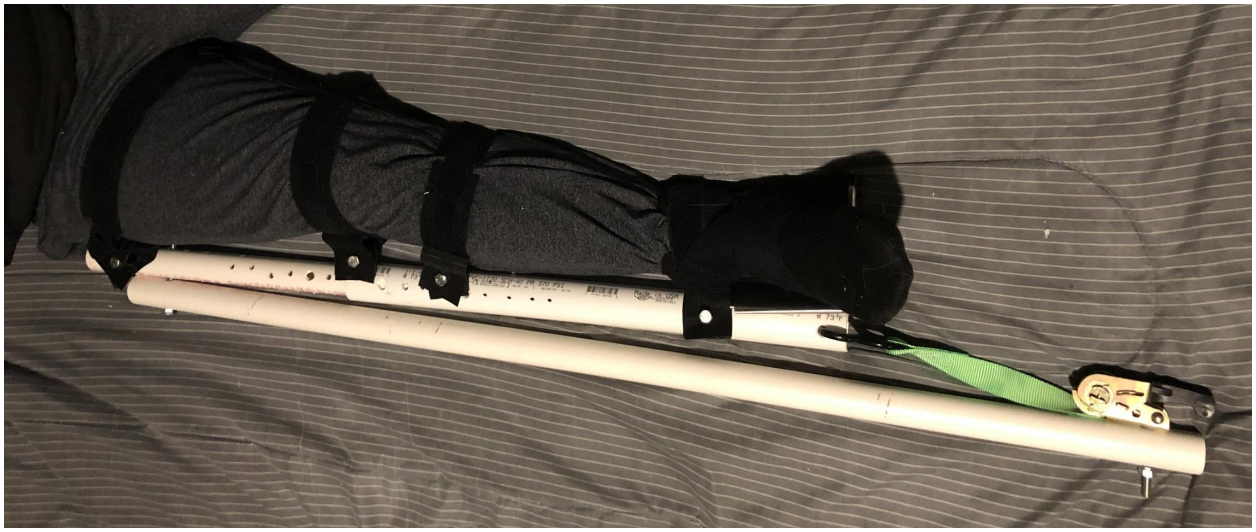


Figure 30: Traction being applied to the system

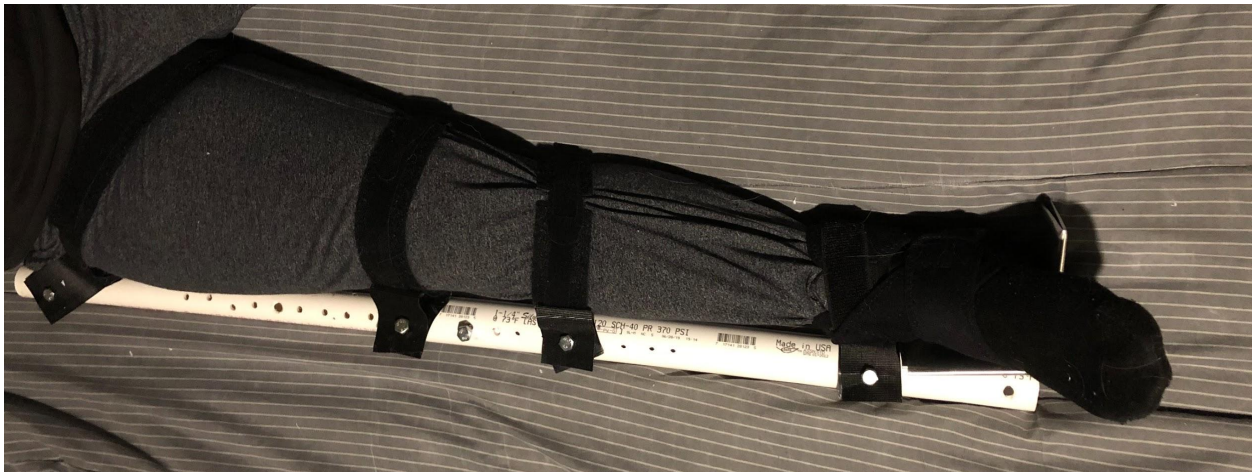


Figure 31: A locked mechanism after traction has been applied

Risk Analysis

In order to better guide our engineering analysis and any future design decisions, we have decided to perform two methods of risk analysis to ensure the safety and wellbeing of patients which is essential for medical devices, while also determining the strengths and weaknesses of our designs. The first risk analysis we have considered and have finished was Failure Modes and Effects Analysis (FMEA), which we felt was especially relevant due to how FMEA breaks down the device into components and functions, which suits our needs since each component has functions that are essential to the overall device. We are still in the process of considering a second risk analysis and have decided to implement it after solidifying some main design choices such as padding considerations. This would allow us to address any risk concerns more effectively down the line as we can reevaluate our design and change things accordingly.

FMEA

The FMEA performed broke down our device into seven main components with each having multiple functions. The components were then assessed for potential modes of failure and then the failures were judged based on their impact on device functionality as well as patient safety. A final look at the complete FMEA shows that the components that needed the most focus for development were the parts of the device in direct contact with the patient. This included areas such as the straps and the ankle brace. A further look into this analysis indicated that this was due to the potential harm that these components could cause to patients which was regarded more heavily than potential device failures that would likely not affect the patient. In Table 15 below, the full FMEA is presented with each potential effect of failure having its own rating.

Table 15. Full FMEA Chart

Component and Function	Potential Failure Modes	Potential Effects of Failure	Severity Rating	Potential Root Causes	Occurrence Rating	Current Process Controls	Detection Rating	RPN	Criticality	Recommended Actions
Telescoping Rod: Main part of device that carries the traction force and telescopes for adjustability.	Rod breaks; Damage to any portion of rod prevents sliding; Long term use deforms rod	Device is unusable and needs repair	8	Repeated misuse; Bad manufacturing process or materials used; Long term use	3	Structure and material decided through max limit calculations, rod can easily be inspected for damage and disassembled to ensure safety	1	24	24	Testing on chosen structure and material to ensure that device meets durability specifications
Straps: Device interface between patient legs and rod support that acts to stabilize the leg and carry the traction force from the rod to the leg.	Straps break; Strap to rod portion breaks; Straps are worn out or damaged and cannot tighten; Straps are too tight and causes patient damage	Straps need to be replaced; Patient has damage to skin or has circulatory issues and requires medical assistance	5; 8	Repeated misuse; Bad manufacturing process or materials used; Long term use; Many repeated applications in short amount of time	6; 5	Structure and material decided through max limit calculations, straps can easily be inspected for damage and disassembled to ensure safety, padding prevents strap tightness	3; 5	90; 200	30; 40	Testing on material and padding method to ensure patient safety as well as strap durability
Ankle Brace: Acts as an anchor point on the leg as one of the main traction areas while being attached to the lower portion of the support rod.	Ankle brace breaks; Ankle brace attachment to rod breaks; Ankle brace wears out and cannot tighten; Ankle brace is too tight and causes patient damage	Ankle brace need to be replaced; Patient has damage to skin or has circulatory issues and requires medical assistance	6; 9	Repeated misuse; Bad manufacturing process or materials used; Long term use; Many repeated applications in short amount of time	6; 5	Structure and material decided through max limit calculations, brace can easily be inspected for damage and disassembled to ensure safety, padding prevents brace	2; 5	72; 225	36; 45	Testing on material and padding method to ensure patient safety as well as brace durability

						tightness				
Hip Strap: Acts as an anchor point on the leg as one of the main traction areas while being attached to the upper portion of the support rod.	Hip strap breaks; Hip strap to rod portion breaks; Hip strap wears out or is damaged and cannot tighten; Hip strap is too tight and causes patient damage	Hip strap need to be replaced; Patient has minor damage on hip area and requires medical assistance	5; 7	Repeated misuse; Bad manufacturing process or materials used; Long term use; Many repeated applications in short amount of time	6; 5	Structure and material decided through max limit calculations, strap can easily be inspected for damage and disassembled to ensure safety, padding prevents strap tightness	3; 5	90; 175	30; 40	Testing on material and padding method to ensure patient safety as well as strap durability
Pin Locking Mechanism: Incremental locking system on the lower portion of the support rod that uses a pin to prevent sliding between the portions of the rod.	Pin breaks; Locking system on rod is damaged; Long term use breaks pin or damages locking system on rod; Pin wears away locking portion of rod	Device is unusable and needs repair; Locking system breaks while in traction	6; 10	Repeated misuse; Bad manufacturing process or materials used; Long term use	2; 2	Structure and material decided through max limit calculations, locking system can be inspected, pins should be replaced after certain duration of use based on calculations	2; 7	24; 140	12; 20	Testing on chosen structure and material to ensure that device meets durability specifications
Ratchet: Initial traction force provider that attaches to the lower portion of the main device and pulls for traction and detaches afterward.	Ratchet breaks; Traction force medium breaks; Connection points between main device and ratchet break; Ratchet wears from long term use	Ratchet needs to be replaced; Force medium needs to be replaced	3; 3	Repeated misuse; Bad manufacturing process or materials used; Long term use; Many repeated applications in short amount of time	6; 6	Force medium and ratchet can be inspected, replace the rachet when application becomes difficult	2; 2	36; 36	18; 18	Testing on best ratchet for force application as well as durability

Padding: Interface between patient and device that provides comfort and distributes pressure	Insufficient padding; Padding is not cleaned enough; Padding is not placed properly	Patient is uncomfortable; Patient needs medical assistance	6; 9	Misapplication of padding; Padding is not cleaned properly	4; 4	Padding method and cleaning process should be followed with extra padding being better than less	6; 6	144; 216	24; 36	Testing on cleaning methods as well as types of padding

Using the RPN as a guide, it was highlighted that the patient to device interfaces were the most concerning areas of the device as these areas would impact the patients the most if not properly considered. The other components that also need focus were the main functional areas of the device, such as the pin locking mechanism. However, these areas seemed to be more robust from preliminary calculations and less of a threat to patient safety than the areas previously mentioned. Since the interfaces are the concerning areas, one major change in the designs has been increasingly larger straps since they can distribute more force and are less harmful to the patient. Padding tests have also become more key mainly to determine pressure distribution. Other areas will generally stay the same with calculations being the controlling factor.

Current Design and Dimensions

Shown on the following page is the current design and dimensions for the device. Drawings may not be to scale.

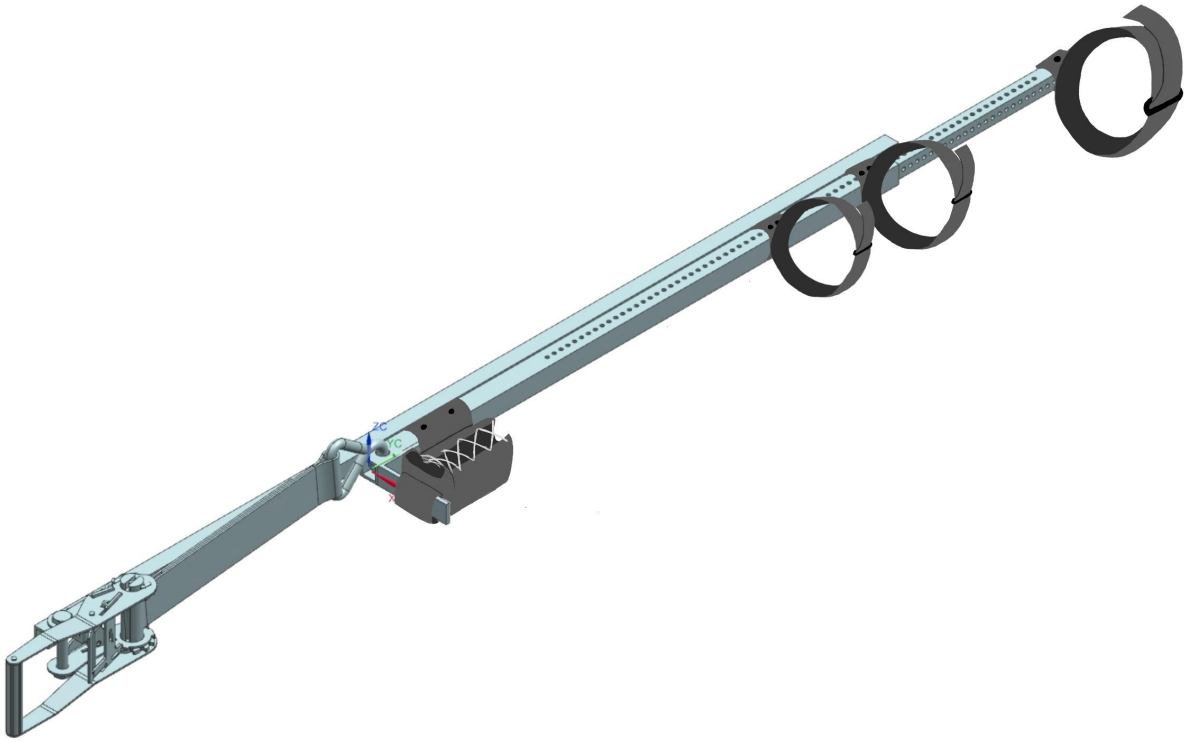


Figure 32: Full model

As mentioned previously, the design has three bars with square cross sections. The lower leg bar can slide into the upper leg bar to accommodate for patients of various sizes. The ratchet bar was added and pins to the upper leg bar to provide a structure to apply traction from. The ratchet hooks to the bottom of the lower leg bar and can be cranked to apply traction. All connection methods make use of pins to lock motion. Each pin is 5 mm in diameter and 38.1 mm in length.

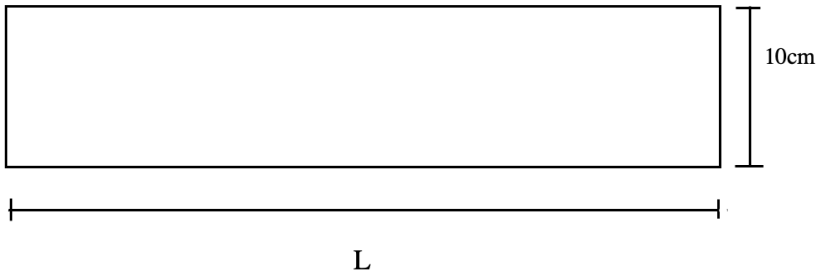


Figure 33: Strap Dimensions

The strap dimensions are shown above. The above knee and below knee straps have a width of 10 cm and an unwrapped length of 125 cm, which accommodates for a lower thigh

circumference of 46.3 cm and a calf circumference of 44.3 cm with both corresponding to a 95th percentile male [17]. The holes in the middle straps would be placed on the sides of the centerline of the strap according to the spacing of 1 cm matching the bar's spacing and placed 2.5 cm away from the sewing line allowing it to be pinned to the bar. The hip strap would have a width of 10 cm and an unwrapped length of 175 cm, which corresponds to a thigh circumference of 72.3 cm as previously mentioned in the specifications. The holes would be similarly placed as on the middle straps.

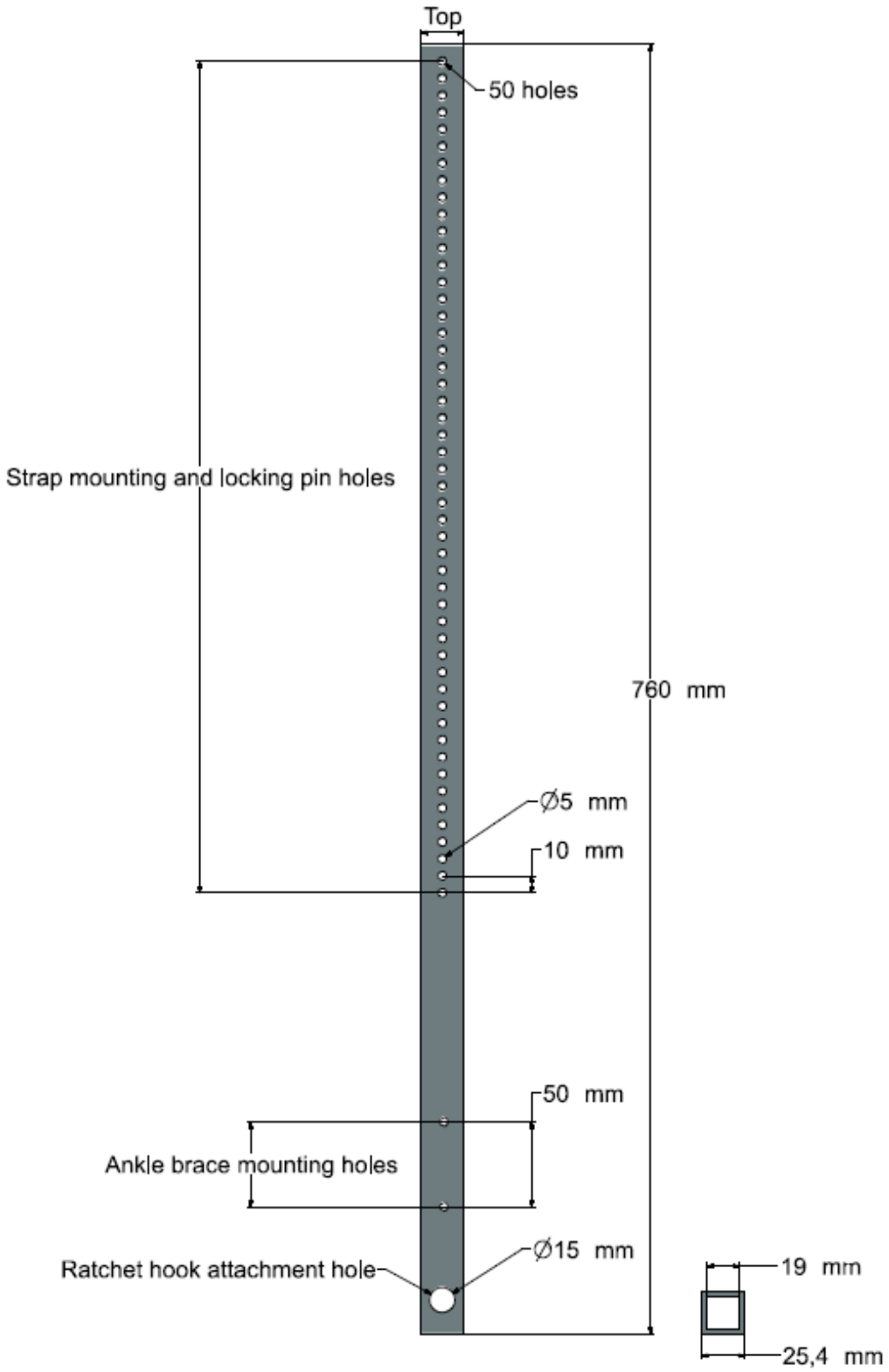


Figure 34: The lower bar of the device with relevant dimensions

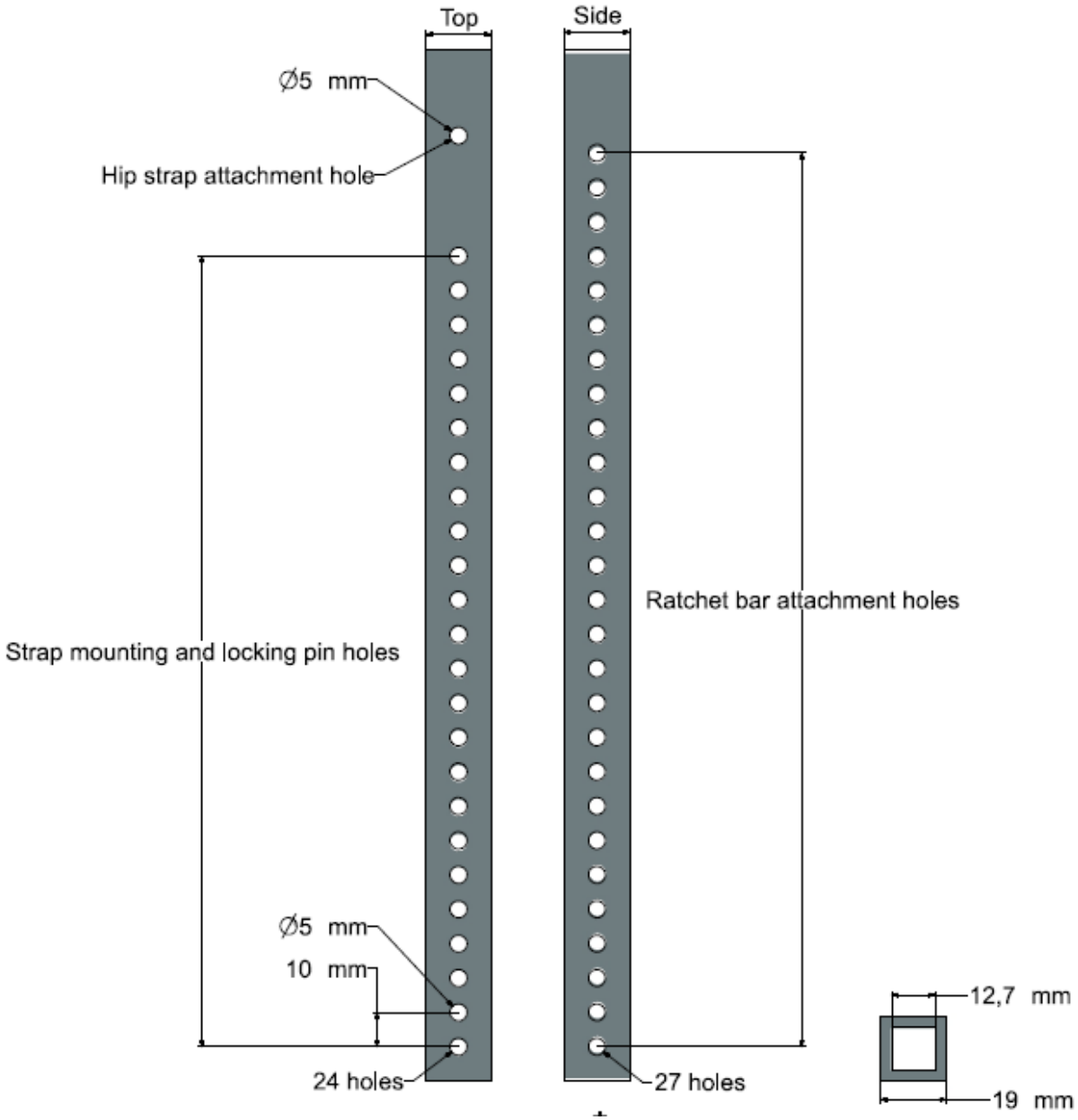


Figure 35: The upper bar of the device with relevant dimensions

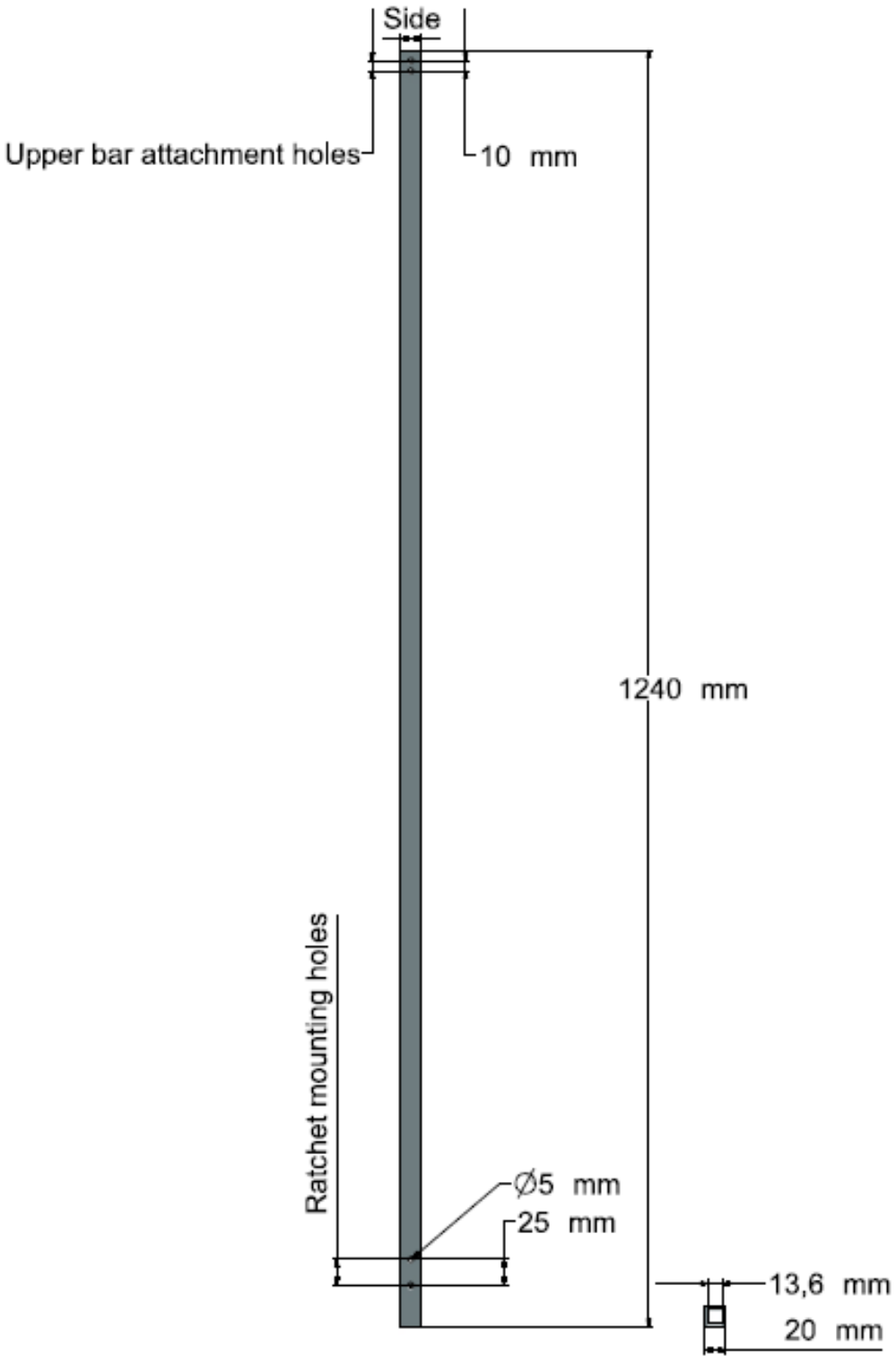


Figure 36: The ratchet bar of the device with relevant dimensions

Instructions for Use

Our device relies on a specific set of steps to properly apply traction. These steps are outlined below. A figure showing major steps: step one, two and seven is included below the process outline.

Step One (Left): Align upper and lower bar along leg. The lower bar is the longer bar with the L piece attached to the bottom. The metal L should contact the bottom of the foot. The upper bar should slide inside the lower bar.

Step Two (Middle): Attach straps and ankle brace. The hip strap should be attached at the top of the upper bar. The above and below knee straps should be attached to the lower bar. The straps should be pinned to the device and carefully wrapped around the patient's leg. The straps should be looped through the clip, tightened and velcroed to secure the hip. The ankle brace should be laid flat beneath the patient's heel with no laces and the loop on the bottom around the metal L . Then the brace should be wrapped around the foot and laces added and tied to secure the foot.

Step Three: Attach the ratchet bar by pinning it to the upper bar.

Step Four: Use the ratchet to apply traction. Extend the leg to its original length using the patient's good leg as a guide.

Step 6: Lock the device by inserting a pin through the lower and upper bar overlapping segment.

Step 7 : Disconnect the ratchet and remove the ratchet bar. The leg is now held in traction.

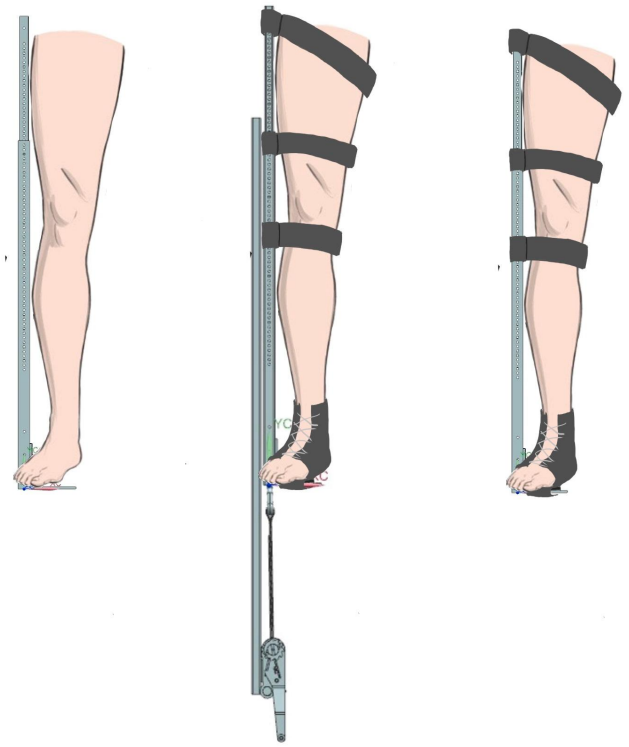


Figure 37 : Instructions for Use

Verification

To begin the verification process, our design team revisited our requirements and specifications. To verify our proposed design, we conducted verification methods in one of three ways: quantitative analysis, physical testing, and qualitative analysis. When possible, multiple methods were combined to allow the highest confidence verification. Due to the Coronavirus pandemic, our team worked remotely and were limited in the amount of physical testing we were able to conduct. For physical testing, we conducted experiments to the best of our ability but acknowledged the limitations of our methods. To fully verify the device, more testing must be done. To aid in this process, our design team has proposed next steps and additional verification strategies to be conducted beyond the scope of this class. Below is a table of our requirements and specifications along with their verification status.

Fits Ghanaian Adults 18-59

Our solution was designed with the 5th percentile female and 95th percentile male in mind. Our solution's frame is telescoping and can be adjusted to fit all leg lengths, including groin heights from 71.2 mm to 92.5 mm. Our straps are long enough to account for the widest thigh circumference. The above knee and below knee straps have a width of 10 cm and an unwrapped length of 125 cm, which accommodates for a lower thigh circumference of 46.3 cm and a calf

circumference of 44.3 cm with both corresponding to a 95th percentile male [17]. Three sizes of custom made ankle braces are recommended in order to fit all patients.

Returns leg to original length

Following the mathematical model, the worst case scenario was observed in which the full moment (equal to 142.29 N * 0.1278 m = 18.179 N-m) was applied to the bar. Using the equation below the displacement on was calculated [38].

$$v_{max} = \frac{-M_0 L^2}{\sqrt{243} EI}$$

v_{max} is the maximum displacement $(m\ )$, M_0 is the moment $(N\ -\ m)$, L is the length of the bar (m), E is Young's Modulus (Pa), and I is the moment of inertia (m^4). In this worst case scenario it was assumed that the ankle and hip anchors were fixed. From this the displacement was found to be 14.2 mm.

When it comes to verifying if our device can return the leg to its original length two things need to be considered. The first is to see if the device can apply the maximum traction force. The second is to see if the device can apply this force without bending and deforming the leg. Both of these considerations can be verified in one experiment. In order to verify these specifications, a leg model must be made and a high fidelity functional prototype must be made. The leg model would be made of two large wooden dowels that would have an extension spring running between them which would be attached using a mounting piece. One example of a mounting piece is shown below.

Figure 38: Potential Mount for Spring Test [46]

As the device is applied the spring would stretch and the displacement would be measured in order to calculate how much force has been applied. A strain gauge would also be placed on the high fidelity prototype in order to measure the displacement caused by the bending of the bar. This would verify the mathematical model since it would allow the mathematical model to be compared to actual results. This mathematical model could then be used to make sure that no matter the patient size, the device would still be able to provide traction without bending. As it stands the mathematical model of our device with straps is calculating displacement to be around - 4 mm. This means that the model is saying that the displacement is negligible with the straps. This would need to be verified with the spring experiment but this makes sense seeing as the worst case situation results in a deflection of only 14.2 mm. Besides the spring experiment the mathematical model would also benefit by having the derivation of the model looked over by a professor or someone who is proficient in analysis beams.

Relieves the pain of the patient

As stated previously, our design team was unable to make a functional model of the product and was therefore unable to verify pain relief for the patient. Our team's proposed testing plan was to develop a leg model simulating a fractured femur and apply the device to the model. Because pain relief is a function of proper traction, if the device could properly apply and hold traction, pain relief can be assumed. As the device gets closer to full verification, a clinical trial could possibly be conducted as long as the device passes all necessary conditions for the trial. Patients could use the device and rate their pain reduction on a Likert scale. As stated in the specifications, pain reduction of 2.4 points over 12 hours on a 10 point scale represents adequate pain reduction.

Durable

To determine the durability of the device that would fulfill the specifications of providing 142.29 N of traction force while maintaining functionality for 30 uses, tests with a final prototype would be required. The first test would consist of an application test using the final prototype on a model leg with a force gauge to ensure that the force can be properly applied without loss of functionality. The test would follow application instructions and then pull the ratchet to 142.29 N as read by the model leg. If this force can be locked and maintained with no issues for different five trials, then the available traction force can be confirmed. The second test would be a fatigue failure test, cyclically loading the device with 142.29 N parallel to the bar pointed towards the center of bar at the top strap and the ankle brace areas. This would be done 60 times with a cyclic load test machine or a manual setup, using force providers such as ratchets, repeated for three trials with the device being inspected for cracks or failure during each trial. Although it is better to empirically determine the lifetime cycles of the device, it may be also possible to estimate the lifetime through Basquin's Law or through software simulating the use of the device.

Fixable by K.A.T.H. Staff

In addition to Risk Analysis, our team conducted a break analysis in an attempt to predict most commonly broken parts of the device, the effect on performance, and the ability to replace or fix these components. Due to the lack of a high fidelity model, our design team chose this as the verification method for a fixable device. Our break analysis table is shown below.

Table 16: Break Analysis

Break	Likelihood	Result	Fix	Next Actions
Pin	Low	Device cannot lock/ strap insecure	Weld back together, use replacement	Extra pins may be used. Other device that functions as pin may be used instead
Hip Strap b	Med	Device will not work	Sew back together	New brace needs to be made. Likely multiple days to get new one. If other devices not in use, one can be substituted in
Leg Strap B	Med	Device may work, could be unsafe for patient	Sew back together	New brace needs to be made. Likely multiple days to get new one. If other devices not in use, one can be substituted in
Ankle Brace	High	Device will not work	Sew back together	New brace needs to be made. Likely multiple days to get new one. If other devices not in use, one can be substituted in
Thigh bar breaks/bends	Low	Device may work, could be unsafe for patient	Unable to fix	New bar must be made/ordered. Could be a week or longer until new bar is made. If other devices not in use, one can be substituted.
Lower Leg bar breaks/bends	Low	Device may work, could be unsafe for patient	Unable to fix	New bar must be made/ordered. Could be a week or longer until new bar is made. If other devices not in use, one can be substituted.
Ratchet bar breaks/bends	Very Low	Other ratchet bar can be used until replaced	Unable to fix	New bar must be made/ordered. Could be a week or longer until new bar is made. If other devices not in use, one can be substituted.
Ratchet	Low	Other ratchet used until ratchet is fixed/replaced	use other ratchet bar until replacement arrives	New ratchet must be ordered. Could be a week or longer until new bar is made. If other devices not in use, one can be substituted.

As shown in the break analysis table, the component at the highest risk of breaking is the ankle brace. This was due to the fact that it has multiple connection points, one below the foot and one on the side of the ankle. As a fabric material, the ankle brace has the ability to be easily sewn

back together for minor rips or tears. For irreparable damage, a new brace will have to be made. In this instance, local artisans would be able to fabricate a replacement likely within a couple days. Furthermore, if there are other devices not in use at the time, the ankle brace of that device could be used in place of the broken component.

Medium break risk components include the straps. Like the ankle brace, the straps could be sewn back together for minor damage or replaced within a couple days for extensive damage. Likewise, due to the modular design, each device could make use of straps from other devices not in use.

Low break risk components are the lower leg bar, upper leg bar, pin, and ratchet. Ratchet damage is difficult to predict as fixability is dependent on the type of failure experienced by the ratchet. A benefit of the locking mechanism is seen in this scenario though as the ratchet and ratchet bar are removable and not in use most of the time. This allows a separate ratchet and bar to be used in place of the broken one until a new one can be ordered. Depending on the failure, it is possible to order only a new ratchet or ratchet strap as well keeping the cost of replacement low. The pin is also a low risk break component based on pin thickness calculations outlined earlier in the report. As a low cost component, it is recommended extra are kept in storage though in the case of pin breaks. The lower and upper bar both would need to be replaced if broken as well. Based on calculations using aluminum material strength, this is considered unlikely. As with all other components, the bars from other devices could be used if not in use.

Finally, the ratchet bar is considered a very low break risk as it is used only briefly in the process. In the rare case of a broken ratchet bar, another ratchet bar could be used until a new bar can be obtained.

Following the completion of the break analysis, the straps and ankle brace were deemed to be the most concerning pieces as they are critical to device functionality and carry the highest probability of breaking. Though the modular design is beneficial, for the case when all devices are in use, it is recommended extra straps and braces are kept in storage for emergency use.

We consider this requirement verified based on the developed specifications: device should be returned to working condition in 30 minutes or less and device should be fixable using basic tools on hand at K.A.T.H. Strap damage can be sewn and the modular design allows most breaks to be replaced immediately. Highest risk components can be sourced within days. Without a built model of the device, our verification is limited, however. There may be unplanned breaks or assumptions on risk of break may not be fully correct. As a result, our design team proposes that further testing be done on specific components of the design or on an actual model. Lifetimes

could be generated for materials, common break areas or components could be noted and better planned for.

Does not damage skin

This requirement specifically refers to skin tearing by having a shear stress of over 20 MPa. Shear stress is one of the primary causes of pressure ulcers [47]. So this requirement is one of high importance. Unfortunately when it comes to verifying the shear stress and shear force, there are very few ways to actually do this. The first way to verify something like this is to use a shear force resistor to measure the shear force and use that value to calculate the shear pressure. The problem is that most of these devices are too big and thick to be used in the application of our device [47]. Some devices are being developed to be the same size and thickness as the normal force sensitive resistor, but this type of device is still being developed and tested [47]. Because of the lack of technology to measure shear force, it is suggested that an in-depth free body diagram is made to find the frictional force of each strap, and divide that by the straps area in order to find the shear stress. One additional recommendation to protect the skin from pressure ulcers is to implement strap rotation. Strap rotation is a method in which the straps are removed from the areas where they are applying pressure and moved to an area where pressure isn't being applied. This rotation relieves the pressure and prevents pressure ulcers from occurring. With our modular design there are many locations for straps to be moved to, and since these straps are functional the ankle brace could also be removed. This is also helpful if the device is applied for a long time and strap or brace needs to be cleaned during the device application period.

Does not cause pressure related damage to the patient

To verify this requirement a force resistor test was conducted. The purpose of force sensitive resistor test was to see how pressure is affected when a tongue depressor is inserted under a strap during its application. The hope of this experiment was to come up with a procedural step during the application of the traction device in order to prevent occlusion. The experiment also explored the effects of padding on pressure. If padding decreases the maximum pressure we could decrease the rate at which pressure ulcers appear. Right away it should be explained that the limitations of a home set-up lead to many complications with the experiment but many suggestions can be made from the results that were obtained. A future form of this experiment will also be suggested.

Many types of materials and tools were used in this experiment. Two times of foam were observed, NU foam which is used in cushions, and high density foam which is used in cushions and mattresses. The NU foam had a thickness of 1" while the high density foam was observed in both ½" and 1" thickness. 3 Medline 6" tongue depressors were used during the experiment. A guitar strap functioned as the strap used to observe pressure. Three leg models were used, being made out latex balloons and kinetic sand. The models varied in diameter, one 8", another 9.5",

and the last 10.5”. The 10.5” had few trials due to the breaking of that model after a few tests. To observe the pressure, an Arduino Uno was programmed to interpret the inputs from a Pololu 0.5” Force Sensing Resistor (FSR). Jumper wires and a 5.08mm Pitch 2p pluggable terminal block was used to connect the FSR to the breadboard.

The device used a code and circuit were adapted from a FSR Tutorial [48]. The code was edited (Appendix W) to take ten samples and also changed to incorporate values from the FSR calibration curve shown below [49].

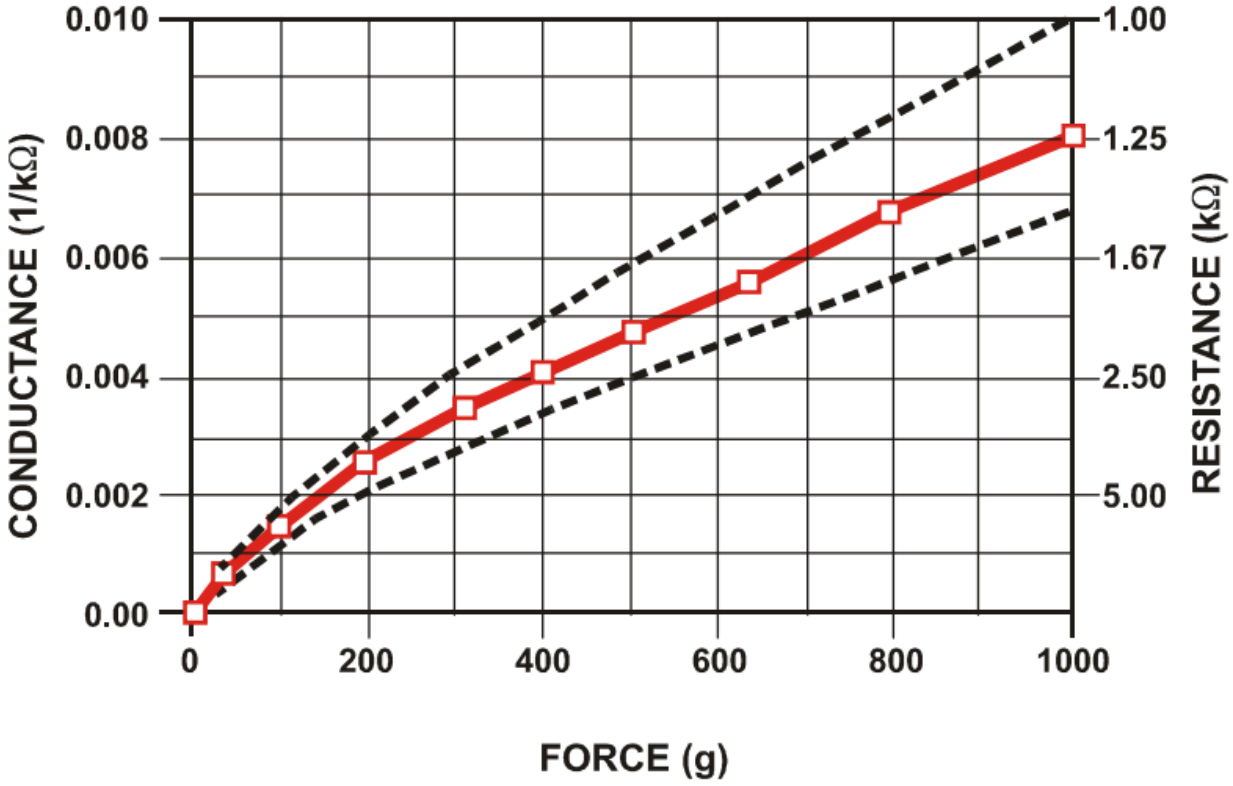
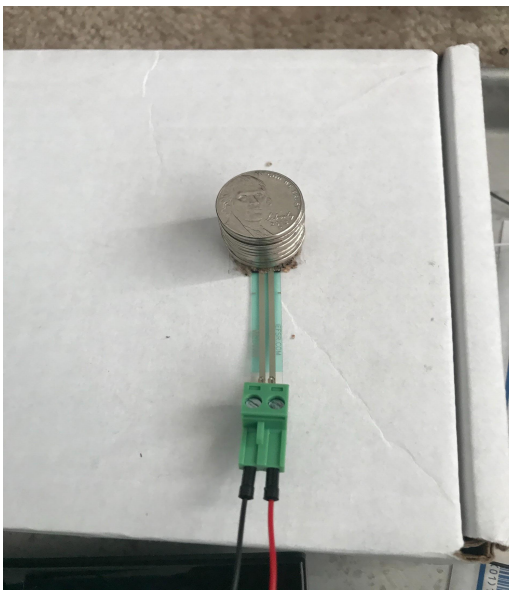


Figure 39: Calibration curve [49]

Once the device was hooked up calibration measurements were taken in order to see the device's ability to measure known weights shown below.

Table 17: Calibration Measurements



Mass (g)		Pressure (KPa)	
Actual	Measured	Actual	Measured
25	5.49	1.937	0.425
50	69.87	3.874	5.414
100	164.23	7.748	12.7

Nickels were used as masses, in the future it is suggested that multiple weights ranging from 0 to 1000 graphs be used and measured so that a calibration curve that is unique to this FSR can be used. In general this data provides us a look into the error that is associated with these measurements. It's important to know that this error was not only from the natural error associated with an electrical component but also from a set up issue associated with the FSR. The FSR has a lip that encircles the active measuring part of the FSR. This caused anything that is bigger than the active area not to be measured since the lip prevents it from touching this active area. In order to solve this problem a small amount of kinetic sand was placed on the active area of the FSR so the force would be applied to the active area of the sensor. This could be an additional source of error, since the sand could have been unevenly applying pressure and sand could have slipped out during the wide variety of trials.

After the calibration a FSR rig was made in order to prevent bending of the sensor when it was under the strap shown below.

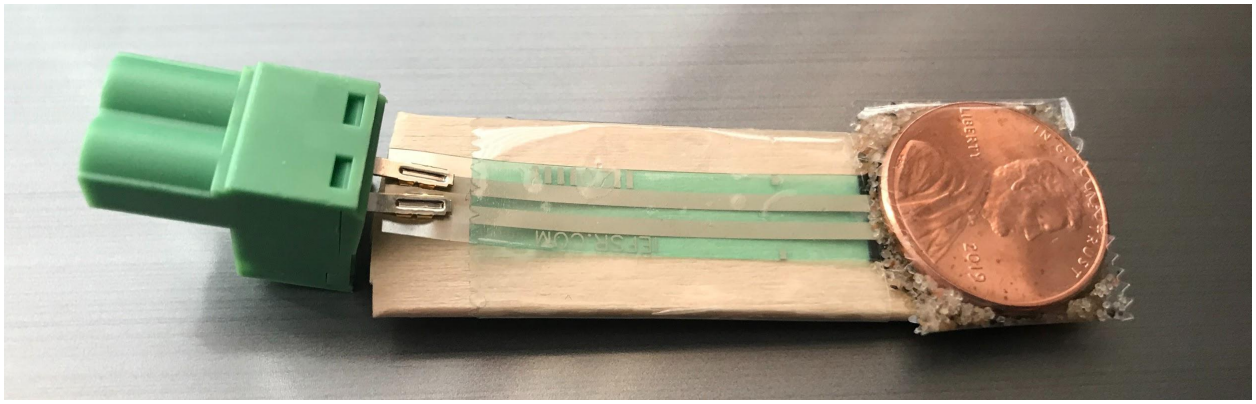


Figure 40: FSR Rig

The general procedure is as follows

1. Reset the sensor
2. Lay the sensor against the model
3. Add layer of foam (if applicable)
4. Loosely tighten the strap
5. Insert tongue depressor in stacked or parallel orientation
6. Tighten strap as much as possible
7. Record pressure

A note should be made ideally in an experiment like this the procedure would also include a step that would remove the tongue depressor before recording the pressure. However, for the smaller 8” and 9.5” models the small sized models and the large strap lead to some challenges when removing the tongue depressor such as values not being recorded. The depressors (1-3) where inserted into the model either stacked or parallel, the parallel example is shown below.

Figure 41: FSR Rig

For the larger 10.5” the tongue depressor was removed and those values were recorded. For the full recorded values see Appendix I. For our purposes we will make a few observations. First, we will look at the effects of removing stacked tongue depressors on the 10.5” model shown in the figure below.

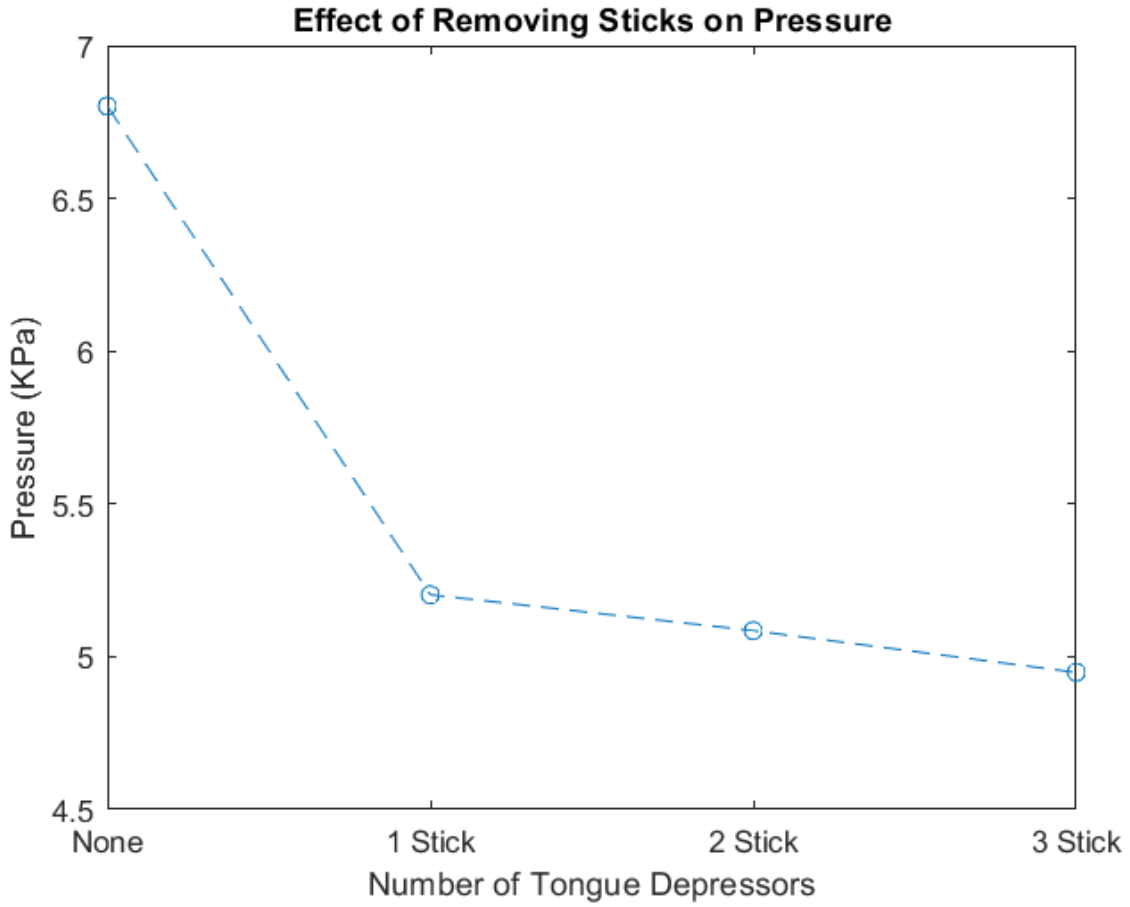


Figure 42: Removing Tongue Depressors leads to a decrease in pressure

The 10.5” model measurements were the most accurate and the most similar to how a procedural step would actually be applied. As we can the first stick removed reduces the pressure significantly, and from there it is a gradual decline. This tells us that inserting a tongue depressor may be a good way to ensure that the pressure doesn’t go beyond occlusion pressure. The 8” model also shows a similar trend. Similarly we can also look at the stacked method vs the parallel method.

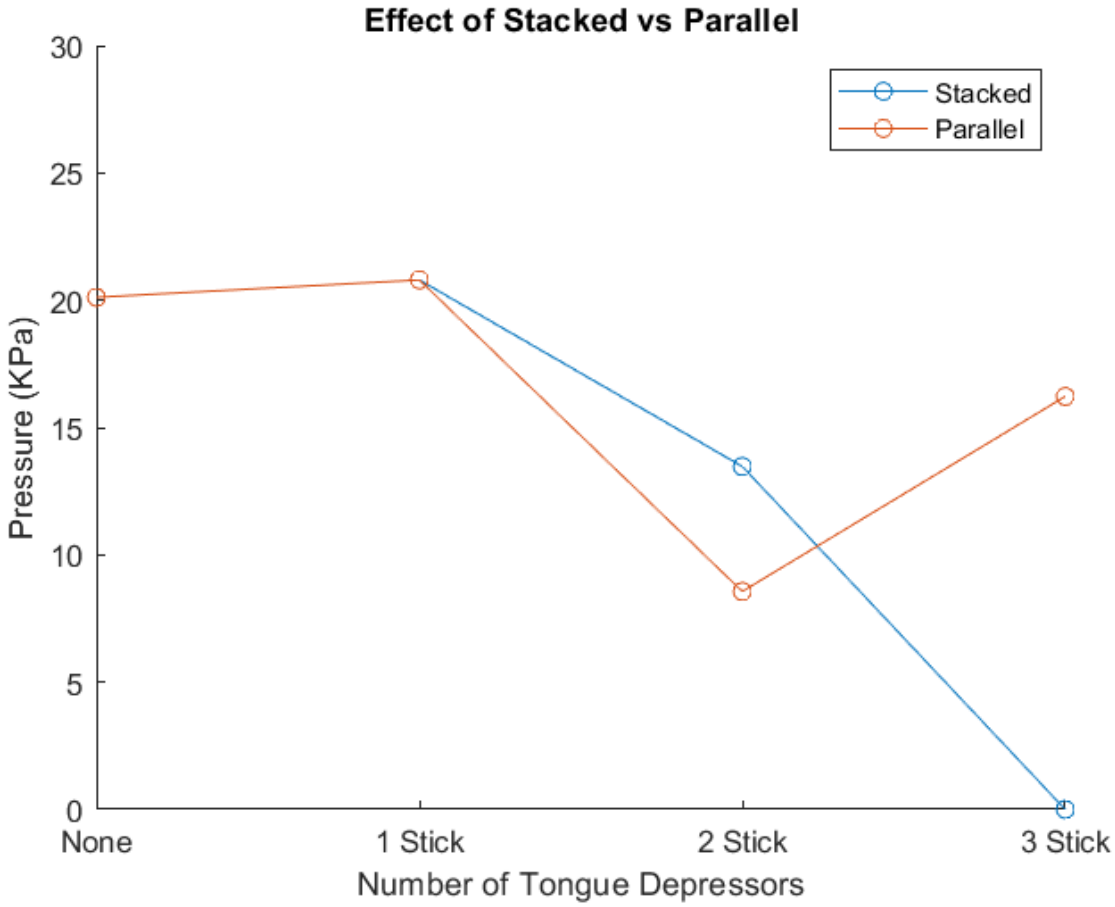


Figure 43: Inconclusive results on stacked vs parallel method

From this graph we see that over all the stacked and parallel methods follow a similar pattern. The last data point of the seems to be an outlier. This is the trend of most of the data making it hard to conclude if one method was much better than another. The third data point of the stacked also seems to be an outlier since it drops completely to zero, which indicates that there was a problem with retrieving the measurement of that data point. Lastly, we observe the effects of the different paddings on the pressure.

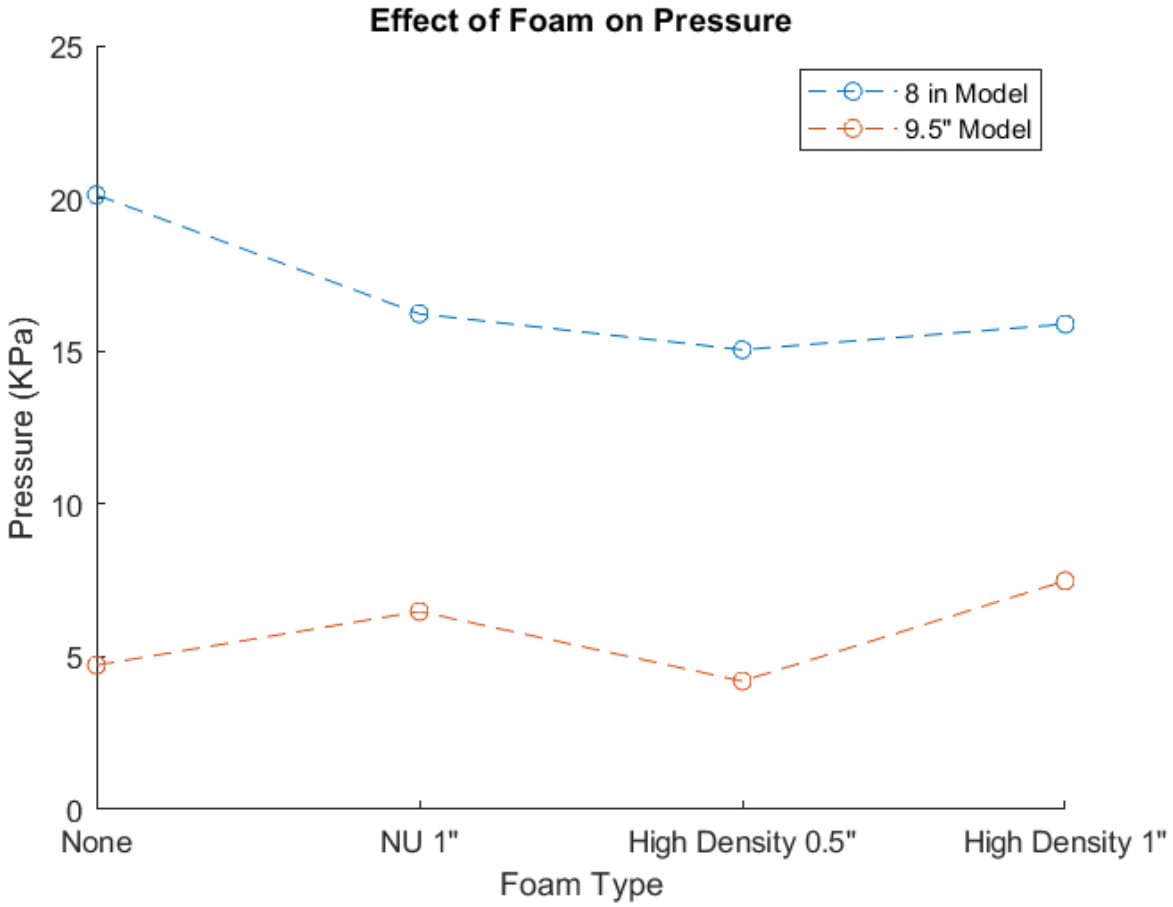


Figure 44: 0.5” High Density Foam has the lowest pressure

From the graph it's clear to see that high density foam results in lower pressures. This makes sense when considering the normal application of these different foams. While NU foams are used in seating high density foams are normally used in sofas and high quality mattresses. These mattresses or sofas are meant to last around 10 years so this type of foam is made to last long, and to absorb force well, while also providing comfort to the user. In regards to the thickness of the foam, it seems like thinner high density foam performed better. This is strange but one effect that thicker foam might have is encouraging the staff member to tighten the strap more than they normally would. The staff member may think that more foam leads to more of a license to tighten the strap. This is simply a hypothesis and if time permitted we would suggest running more experiments on the effect of thickness on pressure.

From these experiments a few general suggestions can be made. The first is that a step should be added to the procedure of the device that instructs the staff member to insert a tongue depressor into straps to prevent occlusion pressure. More tests should be performed to see the exact effects the type of insertion (staked or parallel) has on the pressure but in general, one tongue depressor

should be inserted. One tongue depressors allows for the biggest decrease in pressure, also we don't want to lose all pressure in the straps since they are still trying to assist in applying traction. The second suggestion would be that the padding that this device uses should be one of a higher density both for comfort and because of it's pressure reducing effects. By reducing the high pressure we decrease the rate at which pressure ulcers appear. However, more experiments would need to be carried out in order to find out the thickness of the foam.

Due to the nuance of this set-up these results are very much preliminary and secondary experiment is encouraged. If a secondary experiment was to be performed a few changes could be made. The first would be to make a more accurate leg model. Kinetic sand was great for these experiments but is much more pliable than actual skin. One solution would be to use something less pliable than sand, such as beans. It also might be helpful to put something in the model that resembles a bone such as a piece of wood or metal. The second recommendation would be to run this experiment on larger models. The preliminary experiment was obviously limited by resources and materials but the closer the model is to a human leg the better. This could mean instead of a latex balloon representing the skin a soft silicon leg model represents the skin instead. There are custom made silicone covers for leg prosthesis that would work great as a leg model if it were filled with beans. The third recommendation would be to have a special piece that fits on the active area of the FSR so that the error associated with the kinetic sand solution would be eliminated. The fourth recommendation would be to make a calibration curve specifically for the FSR that is being used. The final recommendation would be to add the procedural step of removing the tongue depressors before recording the results assuming that the resistor is tight enough to measure results.

Cleanable

For cleaning purposes, the device has been separated into two portions, the main device consisting of the bars and ratchet and the detachable parts consisting of the straps and ankle brace. These two portions must be cleaned separately as the detachable parts can be cleaned more easily by wiping or soaking each piece in the cleaning solution, while the main portion can only be wiped or sprayed down with the cleaning solution. Currently, there are three cleaning solutions that are being considered, a 10% bleach solution in water, soap and water, and spirit, an 83% ethanol solution. In order to verify the effectiveness of these solutions as well as the cleaning methods, ASTM standard E1766 - 15 will be used. E1766 - 15 is a standard that determines the effectiveness of sterilization processes for reusable medical devices and confirms effectiveness by showing a lack of recoverable microorganisms when five or more consecutive tests are conducted using the methods [45]. As there is a lack of equipment and the ability to perform tests according to the standard for us, we recommend following the standard with varying amounts of each cleaning solution to determine the best solution as well as the effectiveness of the methods.

Easy to apply

A usability test was conducted with several of a team member's roommates who were not familiar with the project. The team member played an injured Ghanain and the roommate played a doctor applying the prototype and administering traction. The scope of the testing was to improve the instruction set associated with applying the prototype. Physical actions required for assembling the prototype were screwing on bolts and ratcheting. Ratcheting was made easy by an off-the-shelf ratchet that uses mechanical advantage to increase its pulling force. Corrections were made during the application of the prototype after major deviations. Major deviations are defined as actions separate from the intended instructions that would destroy the functionality of the device and were counted. Minor deviations are defined as initial misinterpretation of instructions with eventual self correction and no input required and were not counted. Between each test subject, feedback was gathered on how to improve the instruction set. The improved instruction set was then used for the next subject.

The first subject was given written instructions and no demonstrations with the device. Three major deviations were recorded. The second subject was first demonstrated how to apply the device and then given improved written instructions. One major deviation was recorded. The third subject was given picture instructions and no demonstrations with the device. Two major deviations were recorded. The final two subjects were given improved picture, word, and demonstration instructions. Zero major deviations were recorded.

All participants completed the exercise individually and in under 15 minutes despite mistakes and backtracking. The final instruction set is less than 11 steps and satisfies the last specification of this requirement.

Low cost

Our design team has created a table with the projected cost analysis. Prices for strap, ankle brace material, and velcro was provided by Kwadwo Opoku, a member of the KNUST Student Project Team. He retrieved pricing by asking a tailor in the region for costs associated with the production of the straps and brace. Remaining prices were taken from Ghanaian websites and using Cambridge Engineering Selector (CES) when data was not available. The table is shown below

Table 18: Cost Analysis

Quantity	Component	Cost (Cedi/USD)
1	Aluminum Upper Leg Bar	103 Cedi (17.58 USD)
1	Aluminum Lower Leg Bar	109 Cedi (18.61 USD)
1/4	Ratchet Bar	55 Cedi (9.39 USD)
1/4	Ratchet	11 Cedi (1.88 USD)
3	Velcro Straps (9cm x 36cm)	25 Cedi (4.25 USD)
1	Fabric for Straps and Ankle Brace (91cm x 208cm)	25 Cedi (4.25 USD)
15	Pins	37 Cedi (6.32 USD)
1	Manufacturing of Straps/Brace	20 Cedi (3.40 USD)
	Total	**385 Cedi (62 USD)**

Our cost estimate totals 385 Ghanaian Cedi per device, however that price includes only a quarter of a ratchet and ratchet bar. This is a result of the locking mechanism. The ratchet and ratchet bar are removable and could be used for multiple patients. For the purpose of this cost analysis, our design team assumed the ratchet and ratchet bar would be used for four devices. Using our specification for durability of 30 uses per device, the device comes to 12.80 Cedi for the hospital. This is well under the accepted price of 52.5 Cedi per use for the hospital with room for them to charge the consumer the same markup they currently charge of 6 Cedi. Aluminum and ratchet prices are still estimates at this point in time, however they were taken from Ghanaian websites. In addition, they were compared with CES pricing, and were higher than CES. To assume a worst case price scenario, our design team chose the higher price. To verify specifications for pricing for the patients, a 6 Cedi markup was used in line with the markup of the current solution. The price to the consumer becomes about 19 Cedi. Because this price is still significantly cheaper than the ideal and maximum allowed prices of 42 and 58 Cedi, we consider the specification for low cost verified. Future research would involve identifying supply chains for the remaining components, quantifying manufacturing and assembly costs associated with the device, and finalizing the price estimate

Sourceable

Our device has many components that can be separated into four different categories: metal, straps/braces, padding, and ratchet. When we talk about something being sourable we are talking both about the materials being available and the materials being machined or constructed in that

area. Aluminum is a metal that is widely available in Kumasi, Ghana. This can be seen through the large car industry, and also its availability on local ghana sites [50]. Furthermore, our initial meeting with our stakeholders revealed that Kumasi, Ghana is capable of welding and basic operations such as drilling, screwing, and cutting. Since our device stocks aluminum bars with holes in them and some light welding, the machining of this device is sourceable. Kumasi, Ghana is also home to many fabrics, textiles , and seamstresses. Velcro is a widely used fabric in Ghana, and the type of sewing that is needed to make these fabrics into our device can be done by the local seamstresses in Ghana according to Kwadwo from the KNUST team. Padding is another material that is readily available to ghana. From the force sensitive resistor test (see does not apply pressure related damage to the leg requirement) it was shown that high density foam worked well as padding to reduce the pressure on the leg. This padding is also used in furniture and sofa, so it is a material that's predicted to be extremely comfortable to the patient. This type of foam and many others are available on ghanian shopping sites [50]. Lastly, the ratchet is an off the shelf device that although it is not available locally in Ghana, Ghana does already have a supply chain connection to gain access to this component. The ratchet is also not actively applying traction, so if the ratchet does break another ratchet pole could be used in its place while the ratchet is being replaced. Since there is less dependence on the ratchet to be actively applying the solution there is less concern that it's not locally from Ghana.

Easy to transport patient

To verify the ease of patient transportation within the hospital, our team used qualitative reasoning and product dimensions. Difficulties with previous products during patient transportation involved the hanging weight off the bed. To safely move the patient, traction had to be removed. Our design improves these areas of concern as the locking system ensures no hanging pieces and constant traction. In addition, the device takes up minimal space as it sits close to the leg, extending only a few centimeters to the outside of the leg and bottom of foot, fitting within the standard dimensions of a hospital bed. Finally, the device is relatively lightweight and provides better lateral stability than the previous solution.

Using these dimensions, we were able to verify the requirement: Easy to transport patient. Specifications state the device must fit within the dimensions of a hospital bed. Additional work would include putting the device on a model patient and attempting to move them to new locations or on to different hospital beds to gain clinical opinions and feedback on the ability to move patients.

Follows codes/regulations

Design choices were made with both ISO 10993-10 and FDA regulations in mind. ISO 10993-10 was used in choosing the materials to prevent skin irritation as well using no chemicals in the creation of the device, which lessens the chance of any skin irritation. Using FDA guidelines, the

device classifies as a Class I with exemptions, meaning that the device is subject to general FDA controls [51]. FDA regulations were not strictly followed as nonfunctional factors such as labels were not implemented, but other factors, like making sure the design was not adulterated, were checked during final design choices. Other functional FDA regulations that were not yet reached, such as performance as advertised, will be confirmed during other verification tests.

Verification of Other Design Considerations

As stated previously, there are other design considerations relevant to the success of the device despite not being as heavily weighted as the requirements and specifications. Among these are hospital staff training, device aesthetics, knee immobilization, and patient comfort. Each of these was addressed during design evolution and is discussed below.

Hospital staff training was considered during the development of the instructions for use and during the usability testing previously discussed. Through stakeholder engagement, we understand the time to train staff is not a driving concern, however we strived to create a design that is easy to apply having a limited number of steps. As a result, the training time required is likely relatively short. As said before, initial usability testing showed quick and consistent training possible with our suggested methods.

Device aesthetics was also considered. Our design team's goal was to create a device that was not intimidating to the patient or hospital staff. To do so, we modified the design during concept development changing the base structure from a circular cross section to a square. This allows easier manufacturing and lets the device sit flat on the bed creating a more stable application environment, keeping both the patient and staff calm and reassured. Furthermore, the use of a ratchet as the traction provider is an easy, intuitive process for the staff member applying the device.

Knee immobilization is addressed by this device as well. Immobilization in this sense refers to the lateral motion of the knee rather than extension and flexion. Straps were placed just above and below the knee aiding in traction application and keeping the leg aligned along the bar. This increases patient comfort and the general stability of the leg.

Finally, patient comfort was considered when developing the design as well. While no patient with a femur fracture will be fully comfortable, the device should not cause additional pain or discomfort. The use of a ratchet to apply traction is one major way this was addressed. Manual traction scored higher during concept exploration based on functionality, however through concept development, manual traction was considered not feasible due to its possible impacts on patient comfort. In addition, the straps material was chosen with guidance from ISO 10993-10

standard for skin sensitivity and padding is suggested beneath the straps to allow for maximum patient comfort during traction application.

Discussion and Recommendations

Many of the current solutions we benchmarked could be grouped into two families: those that anchored on the groin/hip and those that anchored on the gluteal fold. We wanted our solution to be as simple as possible to facilitate its introduction into LRS. As such, we chose the groin as our anchor point because it allowed us to create a single frame pole design. All other systems we saw included a non-removable, integrated traction provider. Our solution is unique because it has built in functionality for locking the traction in place. This allowed for a design that was more compact, portable, and cheaper than other designs. This came from using the single pole design utilizing a detachable portable ratchet rather than a two pole frame design utilizing multiple pulleys. These design choices also provided for a modular design, allowing for benefits such as easier repairs or replacements as well as smaller size when unassembled.

Another benefit of our device as compared to others are the use of functional straps. Although not fully verified, our device spreads out traction application between the ankle brace and two other straps around the knee. This differs from alternative solutions where traction is traditionally applied only to the ankle. The need for this change comes from the duration this device is used for and the possibility of developing pressure sores. It also allows for the possibility of strap rotation. We recommend future testing to verify the ability for a single strap to hold traction, and the amount of time it can safely hold traction for. This would provide verification for the ability to rotate straps and could add a procedural step to increase patient safety.

As with any product, our device does have weaknesses as well. Our design team was unable to fully verify the device due to a number of limitations, but we attempted to propose additional testing as well as consider possible design changes as a result of future testing as well. Possible weaknesses of each component are outlined below with recommendations for future testing.

Aluminum Bars

Calculations were run on aluminum bar sizing to test its ability to apply traction forces without deforming. In addition to these calculations, we proposed cyclical loading calculations and in depth testing on the aluminum strength. If testing comes back showing aluminum is deforming, our design is accommodating of new cross sectional areas or wall thicknesses for the aluminum bars. This would provide a simple fix that does not alter the overall design of the product.

Another weakness of our design is the weakness of our calculations. One calculation that needs revision is the pin shear calculation. The pin shear equation shown in the engineering analysis section relates the materials shear stress limit to the shear stress being applied. From this

calculation it was concluded that this pin was able to withstand the load. This calculation is a good first approximation but is not the most accurate representation of the pins forces. The pin is inserted through four layers of metal and between the middle layer is the internal thickness of the lower pole. This makes the pin force more like a beam bending with fixed points instead of a strictly pin shear equation.

Our design team also recommends future testing to verify the ability to apply traction and extend the leg. This testing method is outlined in the verification section under "Returns leg to original length." Verifying traction capability will also aid in verification of pain relief.

Straps

Two other weaknesses of the design that currently exist that go together are the straps and the padding. The straps need to be further tested and iterated in order to get straps that can distribute the pressure properly while maintaining the traction of the device. The purpose of padding is to reinforce the straps by distributing pressure further and providing more comfort for patients. However, only foam was tested and although high density foam had promising results, further testing and research is needed to improve the validity of the current design. As mentioned previously, testing for strap rotation is strongly recommended as well.

Our FSR experiment also failed to give us adequate data. The test was able to give us general trends but the issues with the setup such as issues with the active area being directly applied, the leg models breaking during the experiment, and not being able to remove the tongue depressor during the test led to weak results. It is suggested that this test is run again with five recommendations, first that models use a material that is less pliable than kinetic sand, such as beans. Second, the models are larger. Third, that a better method is developed to interact with the active area of the FSR. Fourth, that a calibration curve is made exclusively for the FSR that is being used. Lastly the tests should be run with the procedural step of refusing the tongue depressor before recording the pressure. However, based on our initial data we suggest that a procedural step is added where a tongue depressor is inserted under the strap during it being tightened and then is removed in order to regulate the amount of pressure that is being applied.

Ankle Brace

One remaining design portion of our design is the ankle brace. The ankle brace design admittedly is more of a concept than a full fleshed out idea and the portion of the design that needs the most work. The general concept for the ankle brace is that it essentially forms alongside the sides of the ankle and is then tied with laces to tight around the ankle. Currently, no dimensions are provided, though the hope is that it would come into three sizes small, medium and large to account for various patient sizes. Furthermore, the pressure distribution of an ankle brace of this

design would need to be observed either FEA or a model with multiple pressure sensors to verify the brace is safe for use.

Other Recommendations

Our design team recommends the expansion of our usability test. Giving instructions for use to clinicians or other staff for trial and feedback will help improve procedures and fully verify ease of use.

Finally, if implemented, our design team recommends the purchase of extra straps and pins in the case of any unexpected breaks. This will account for the rare occurrence when all devices are in use and one device experiences a failure or loss of a strap or pin. This ensures that even in the case of broken components, the device will still be fixable, and patients can still be treated.

Although our device needs to be developed further to encompass the major weaknesses, we believe that if these remaining factors can be resolved that the device will be extremely effective in solving the problems that K.A.T.H. has. Much of the tests and research that needs to be conducted have also been delayed due to lack of equipment as well the lack of a proper team working environment for conducting experiments. If these issues are solved, then these recommendations can be performed much more easily and further develop the device.

Conclusion

At the Emergency Department of K.A.T.H, treatment for femur fractures is limited by the availability of trained staff, method of treatment, and costs. Femur fractures are an important injury to address especially in LMICs like Ghana in which K.A.T.H. is located. This is due to the high incidence of traffic accidents that cause femur fractures and the accompanying high mortality rate. The current method used by the hospital in Kumasi is a form of Buck's Extension. This method is limited by the skin traction that can be safely applied and requires trained hospital staff that are only available during standard working hours.

Through engaging with key stakeholders, such as Doctor Oteng and Doctor Sefa, and conducting research pertaining to femur fractures and medical devices, the team isolated various aspects that should be targeted for improvement. Looking at current widespread solutions, such as the Hare traction splint, the main issues that K.A.T.H. faced with these devices were price, availability, and traction capability. Combining the issues caused by the current solution at K.A.T.H. and the issues presented by current widespread solutions, it was decided that the goal was to create a solution to address the majority of these issues. This meant designing a solution that would be rapidly and easily deployed with increased mobility and traction compared to the solution at K.A.T.H, while still being affordable to the average Ghanaian citizen.

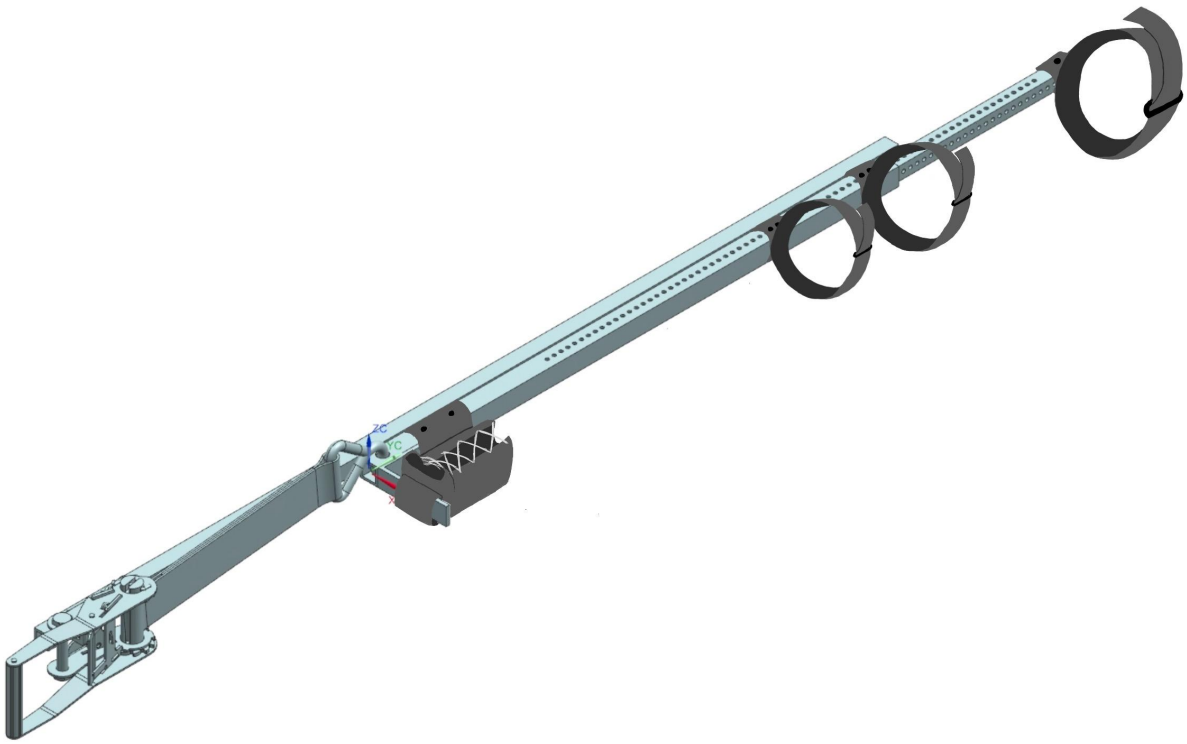


Figure 45: Full model

Our solution features a two-bar, telescoping frame that runs along the leg. Through careful strap placement, traction isolated on the fracture site can be achieved. The ratchet pulls the lower bar, and the ratchet bar is mounted to the upper bar and holds it at bay. These design choices allowed for a design that was more compact, portable, and cheaper than other designs. One reason for this was from the single pole design utilizing a detachable portable ratchet rather than a two pole frame design utilizing multiple pulleys. This also provided for a modular design, allowing for things like easier repairs or replacements as well as a smaller size when unassembled.

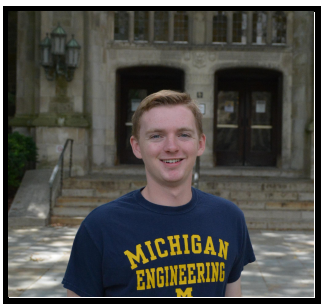
Requirements that could be tested were tested. Due to the remote nature of our semester, we were unable to verify several requirements. We suggest testing that could be conducted during a regular semester or by a team with access to different resources. Key design components that need to be better developed include the straps and padding. Data specifically on pressure sores on groins and ankles or research in that area would be required to ensure our solution does not cause any unintentional damage to the patient. More comprehensive calculations and tests have to be performed in order to fully develop the device as idealized in the recommendations section.

AUTHORS

Forest Brown

Forest is a senior studying mechanical engineering at the University of Michigan. Growing up in Tampa, FL he studied civil, aerospace, mechanical, and robotics engineering through a magnet program at his high school. After deciding to pursue a degree in mechanical engineering he found himself at U of M. Following graduation he hopes to move back to his hometown and find a job that combines mechanical engineering, design, and consulting. Since he is interested in many industries he does not know where his career will take him but excited for the future opportunities.

Daniel Carty



Daniel is a graduating senior studying mechanical engineering at the University of Michigan. He grew up in Farmington Hills, Michigan and participates in MRover, the American Institute for Aeronautics and Astronautics, as well as playing for the Club Baseball team at the University. Following graduation, he plans to work in the product development field before attending graduate school.

Ian Hall

Ian is a graduating senior studying mechanical engineering at the University of Michigan. He grew up in Marysville, Michigan and transferred in his junior year from Lawrence Technological University. Ian has been skydiving for 3 years, a coach for 1, and is training to become an instructor.

Evan Wang

Evan is a senior born and raised in New York City. Intrigued by technology, he has invested much of his time in learning about simple mechanical and electrical systems and ended up at the University of Michigan. Evan is interested in working as mechanical engineer, but keeps an open mind about every industry. In his free time, he enjoys traveling long distances to experience new types of food.

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ME 450 Section 005

and all others

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Appendix A

Similarities and Differences From Fall 2019 Project Iteration

As stated in the Executive Summary, a past iteration of this design problem exists. Our design team used the previous project as background information, but information included in this report is based on our own research. Our team is focused on creating a new solution rather than using the previous team's end result as a starting point.

While we strive to go through our design process independently, the previous design team was contacted due to their extensive background knowledge of the problem. Scott Vanden Heuvel, the former student project lead, spent several weeks in Kumasi, Ghana observing and researching this design problem. Due to the COVID-19 pandemic, our design team was unable to have the same experience. As a result, our design team contacted Scott in order to increase our background knowledge of K.A.T.H. as well as Kumasi. Scott and the previous design team played no role in developing our solution outside of the information he shared during our meeting, and other background information from their report.

Appendix B

Table B.1 Full Benchmarking Table

	Buck's Extension	**Hare Traction Splint**	**Sager Traction Splint**	**CT6**
Low cost	Traction Boot and Pulley System: $26.04 + $753.40	Dyna med brand $529.99 SPLINT, QD-4 TRACTION LEG MOOREM $298.82	Sager® S301 Form III $390.16	CT-6 Traction Splints $167.99 - $248.99
Causes no additional harm to patient	Possible with extended use	Possible with extended use	Possible with extended use	Possible with extended use
Immobilizes the hip joint	N	N	N	N
Immobilizes the knee joint	Y	Y	Y	Y
Returns leg to original length	Possible	Y	Y	Y
Follows codes/regulations	Unknown	Y	Y	Y
Durable	Y	Y	Y	Y
Fixable by K.A.T.H. Staff	Y	N	N	N
Easy to apply	N	Y	Y	Y
Sourceable	Y	N	N	N
Easy to transport patient while in traction	N	Y	Y	Y
Fits Ghanaian adults 24-59	Y	Y	Y	Y
Relieves the Pain of Patient	Possible	Y	Y	Y

Table B.2 Full Requirements and Specifications Table

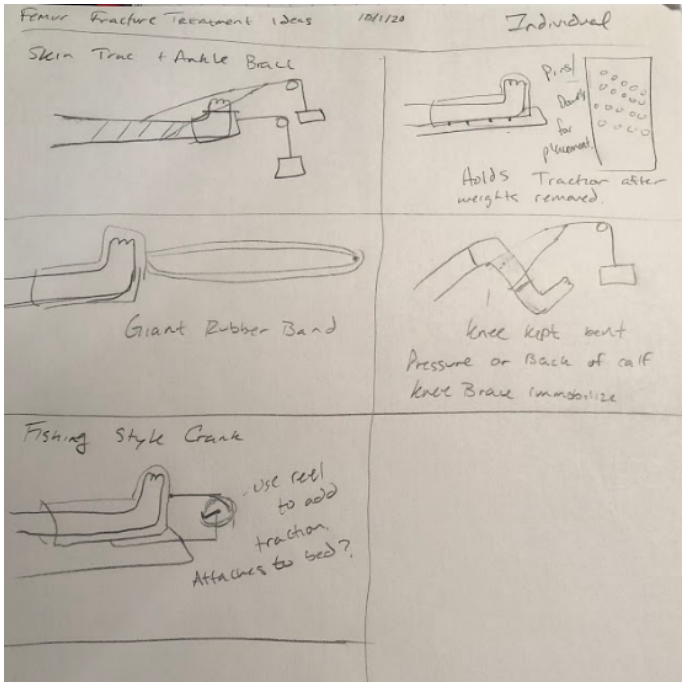
Requirements	Specifications	Info Sources
Fits Ghanaian adults 24-59 **HIGH**	Leg length 80.9 cm to 109.9 cm Knee height 38.9 cm to 52.8 cm Thigh length 42 cm to 57.1 cm Thigh circumference 52.7 cm to 72.3 cm	[2] [16] [17]
Relieves the Pain of Patient **HIGH**	Using a Numerical Rating Scale (NRS) pain should reduce by 2.4 on a 10 scale within 12 hours.	[2] [18][19]
Returns leg to original length **HIGH**	Within 2 cm of non-injured leg length Provides up to 142.29 N traction force	[20] [12][23]
Durable **HIGH**	Provide 142.29 N of traction force a while maintaining functionality Withstands 30 uses while maintaining 142.29 N	[20] [12] [2]
Fixable by K.A.T.H. Staff **HIGH**	Device should be returned to working condition in 30 minutes or less if broken Able to be fixed by standard tools, power drills, welding, saw, hammer, screwdriver.	[21]
Does not damage skin **HIGH**	Should not exceed 20 MPa tensile stress to skin on leg	[2] [25] [26]
Does not cause pressure related damage **HIGH**	Should not apply a pressure of more than 100 mmHg	[2] [28]
Easy to apply **MED**	Should be applied in less than 15 minutes Should require no more than 2 staff members to apply Should require less than 11 steps to apply	[19] [2]
Low cost **MED**	The cost per use for the consumer must not exceed 58.30 Cedi The cost per use for the consumer should not exceed 42.30 Cedi The cost to the hospital should be less than 52.5 Cedi per use	[2] [5] [4]
Sourceable **MED**	Made of easily accessible materials E.g. Hospital bed parts, wood, used car parts	[21] [24]
Easy to transport patient while in traction **MED**	Must fit within dimensions of a hospital bed (36” x 80”) Patient can be transported while in traction	[2] [21] [22]
Follows codes/regulations **LOW**	Follows ISO 10993-10 standard in testing for irritation and skin sensitization	[29]

Appendix C

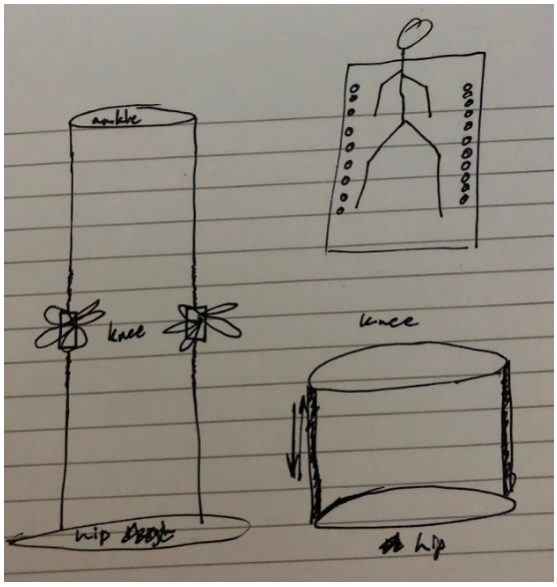
Full Concept List

Concept: Timestamp for Brainstorming

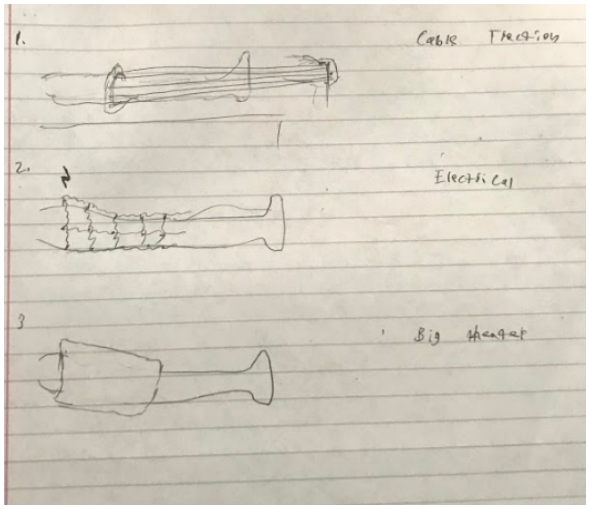
1. The Clamp Device: 1:16 - Evan
2. A Telescoping Single Pole: 1:45 - Evan
3. Replace Plaster with Cloth: 2:25 - Evan
4. String with a Crank: 2:45 - Evan
5. Car Jack: Applying That: 3:45 - Evan
6. Clamp with Air Pump: 3:55 - Evan
7. Ankle and Skin Hook: 7:40 - Daniel
8. Pin and Dowel Traction: 7:55 - Daniel
9. Giant Rubber Band: 8:40 - Daniel
10. Pull on knee: 8:55 -Daniel
11. Fishing Reel: 9:05 - Daniel



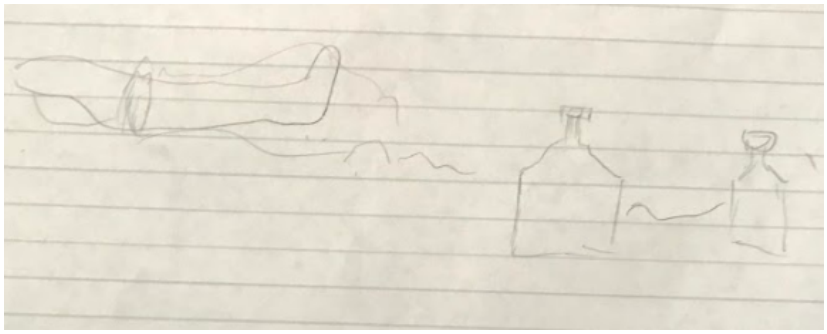
12. Knob Device 11:20 - Ian
13. Pin and Board: 12:10 - Ian



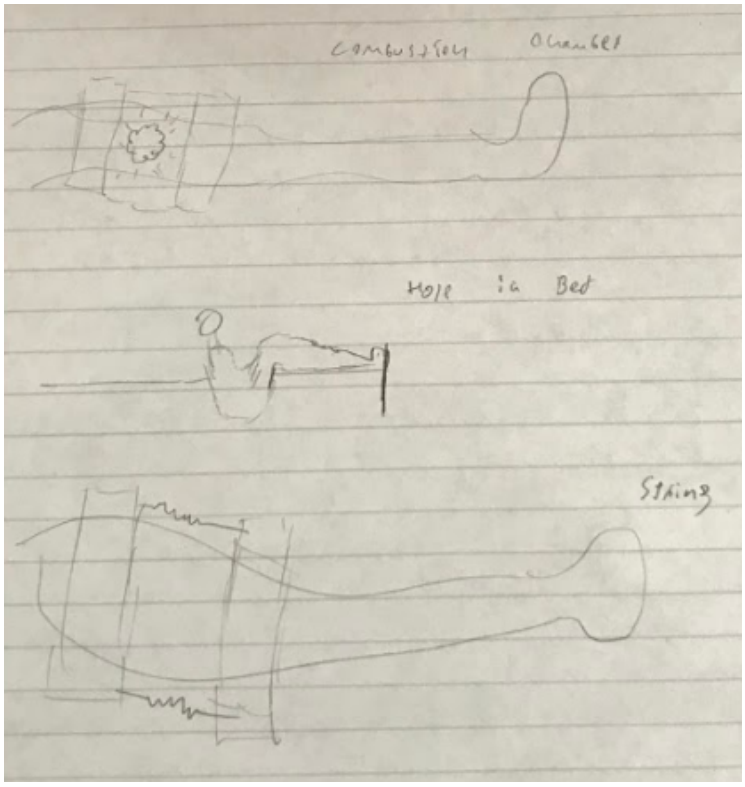
14. Fracture extension Glider: 12:20 - Ian
15. Plaster the Whole Leg: 12:50 - Ian
16. Cable Extension: 16:30 - Forest
17. Electrical: 16:45 - Forest - too expensive
18. Big Heater: 17:10 - Forest-too expensive



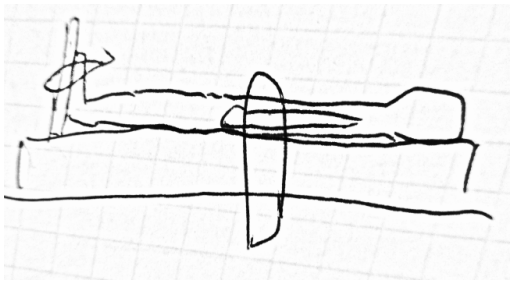
19. Botox: 17:45 - Daniel
20. Inverse Chair: 18:28 - Evan
21. Hang someone upside down from the ankle: 19:10 - Daniel
22. Tube filled with air designed to increase pressure axial: 20:30 - Ian
23. Water Pressure with different fluids: 21 - Forest -too expensive
24. Pistons to amply Force: 22 - Forest-too expensive



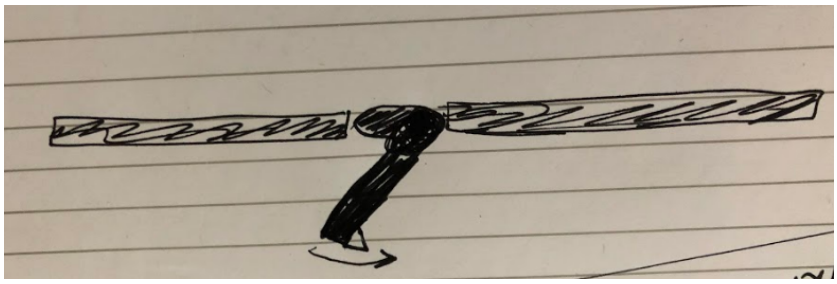
25. Mutual Traction: Two Femur Fractions Patients Tied together: 25 -Daniel
26. Magnetic Force Boot: 26 - Forest
27. Treadmill with Cow on it with Rope tied: 27- Evan
28. Air Chamber: 28 - Daniel
29. Combustion Chamber: 32 - Forest
30. Quads and Ham Extension Surgery: 33 - Daniel
31. Leg and Weight in Hole: 34:30 - Evan
32. Hole in Bed with Patient Applying the Weight: 35:30 - Forest



33. Reverse Slide: 36:30 - Daniel
34. Radiation Decay Femur Fracture: 39 - All
35. Manual Traction: 40:45 - Forest
36. Tie them to the bed: 41:30 - Daniel



37. Pulley System with Mechanical Advantage: 42:30 - Daniel
38. Rail System: 43 - Forest
39. Peg Board Boot: 45 - Daniel
40. Watermill Weight System: 48 - Evan
41. Super Compression Pants: 50 - Evan
42. The Lever: 51 - Ian

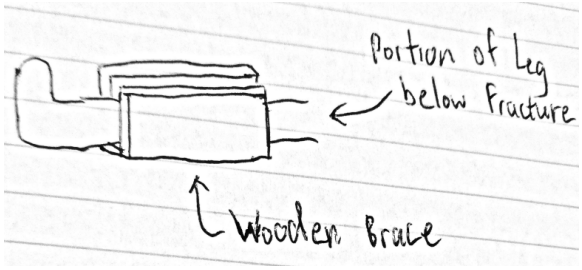


43. Bike applied traction: 52 - Evan
44. Knee Brace: 55 Daniel
45. Compression Springs: 55 - Forest
46. Sticky Compression: 57:30 - Daniel
47. Cement: 58 - Evan
48. Super Skin: 59 - Daniel (Layers of plaster)
49. Multi-Belt Idea: 1:00:00 - Evan
50. Multi-Turn Buckle: 1:01:00 - Daniel

Morphological Chart

51. Diecast Traction Clamp - Forest
52. CT6 w/ Surgical Tubing - Forest
53. Circular Clamps with Metal Cables - Forest
54. Straps plaster weight - Evan
55. Compression straps to immobilize, weight for traction - Evan
56. Two metal rods strapped on lower leg and weight applied - Evan
57. Full leg cast, hook on foot, weight hung off bed - Ian
58. Brace bar into hip, rod along length, pulley applied at foot - Ian
59. Compression wrap glued in place, elastic bands pulling for traction - Ian

60. Super Skin that attaches to patient with a rope which has force provided by a one directional crank, Hips and Knee are secured with metal bars - Forest
61. Full Leg Compression wrap that is pull the leg using attachment to cables - Forest
62. Super Skin/ Ankle Anchors with mechanical advantage w/ compression wrap - Forest
63. Ankle hitch linear slide - Forest
64. Knee Sleeve (i.e. 61 but just the knee) - Forest
65. Compression wrap around joints, plaster along leg, boot with pulley - Ian
66. Cast for hip and knee (may be separate), elastic cables applied for traction - Ian
67. 2x4s along leg for alignment and wraps for securing the system, dowels and mechanical advantage for force application - Ian
68. Rod along a leg, multiple attachment straps, linear clamp attached to clamp - Ian
69. Magnetic repulsion between knee and thigh - Daniel
70. 2x4 with elastic and boot - Daniel
71. Boot locking system - Daniel
72. Clamp and pin - Daniel
73. Temperature extension bars - Daniel
74. Skeletal super skin traction - Daniel
75. wooden braces to restrict movement with cloth, weight applied traction - Evan



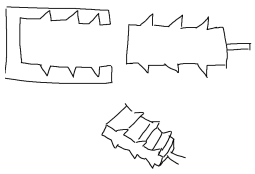
76. pin dowels crank with cables on knee brace - Evan
77. Double clamp with cable and turnbuckle on hip and knee - Evan
78. Extendable pins attached to bars attached to weights - Evan
79. Extendable weights attached to knee - Evan

Design Heuristics used - 1, 2, 9, 19, 31, 42, 47, 55, 63, 65, 71, 74, 76, 78

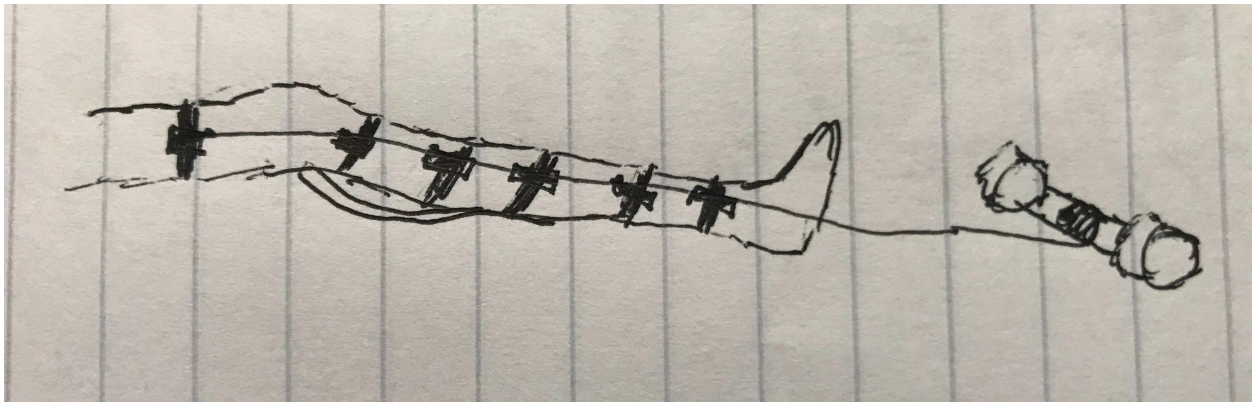
Tuesday SCAMPER/Design Heuristics

80. wooden braces idea but with leather or cloth instead of wood - Evan
81. pins and dowels but instead of a board, it's on two poles - Evan
82. current solution, but with a metal chain as weight and a crank on the chain for weight adjustment - Evan
83. knee brace that extends to lower leg with attachment for weight at foot and stiff sides - Evan
84. current solution, but knee brace under plaster instead - Evan

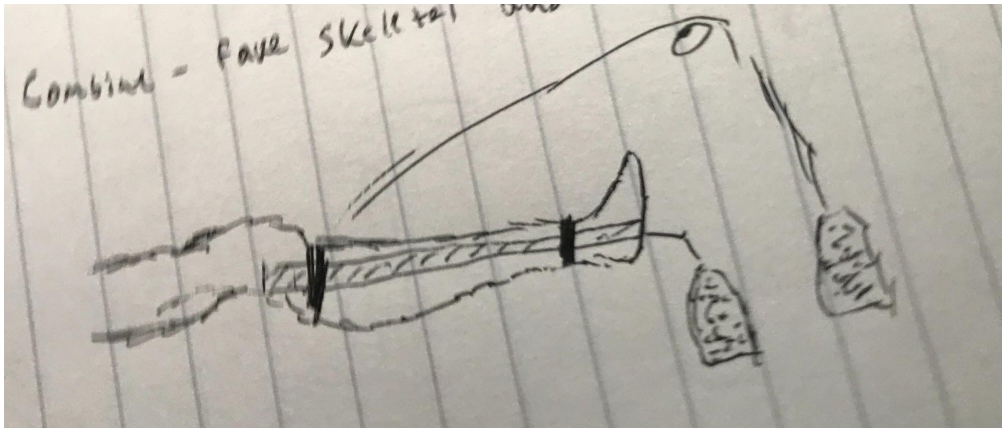
85. current solution, but the weight is placed on a pedal system with increments - Evan
86. knee brace but rigid and tough for a bent knee at 90 degrees and attached to some weight system - Evan
87. current solution except toothed slot with open side and a buckle with two teeth attached to foot for traction, the slot has no give - Evan



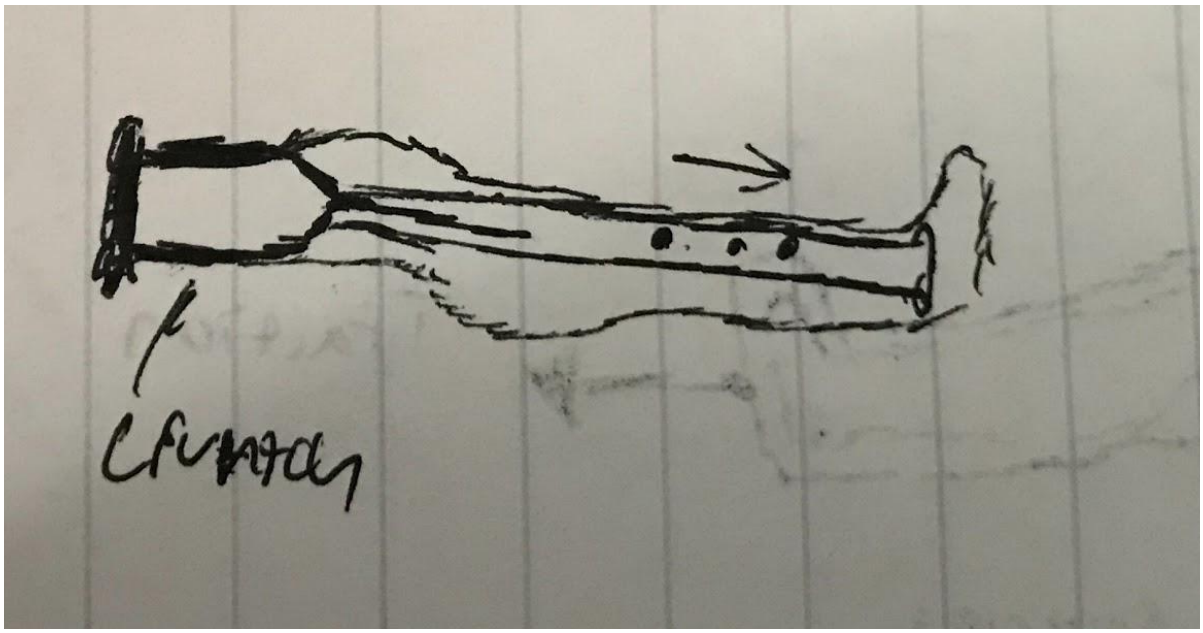
88. same mechanic with toothed slot except like a hares traction - Evan
89. current solution but big screw that goes into a slot with a latch - Evan
90. Brace that uses the other leg for mounting/traction - Ian 76
91. Apply the force at several bands going up the leg - Ian 47
92. Insertable wedges for increasing traction, like suspension adjustment on cars - Ian
93. Use pulleys so force can be applied along different axis, good packaging - Ian 55
94. Turning knob for applying force, continuously increasable with patient comfort - Ian
95. Sphygmomanometer and cuff for measuring pressure applied (doctor stuff) - Ian
96. Make traction application system removable (locking system needed) so it can be used on other patients - Ian
97. U-bar front of the leg and back of leg - Forest - 76
98. Pin and Dowel with Sheet Metal - Forest - 74
99. 1,000 kids hold on it - Forest - 71
100. Pull on the torso and keep still the knee - Forest - 78
101. Crutch turn buckle system - Forest - 65
102. Speaker Stand Turn buckle system (more on next page)
103. Cable Reel



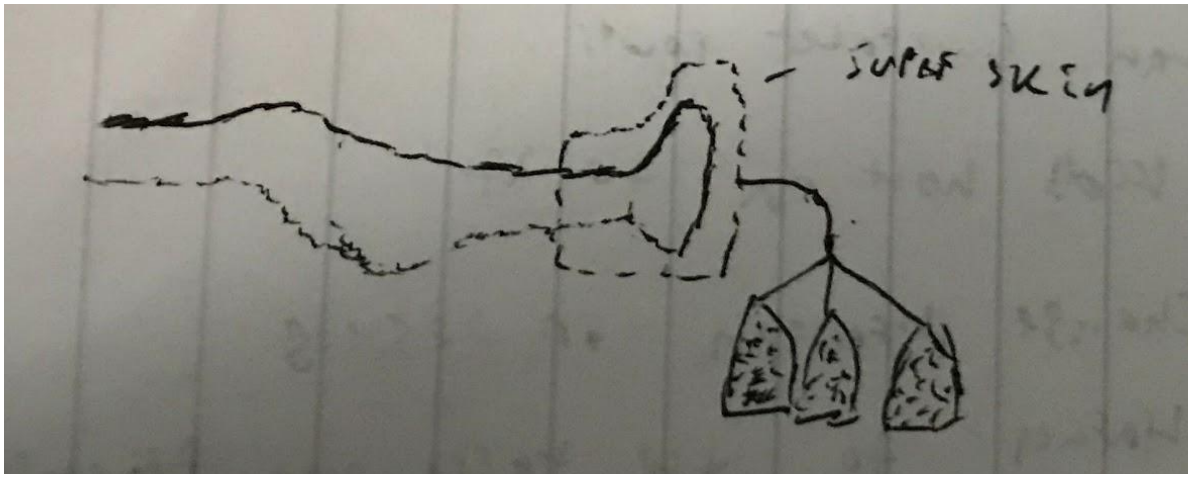
104. Fake Skeletal Traction + Current Solution



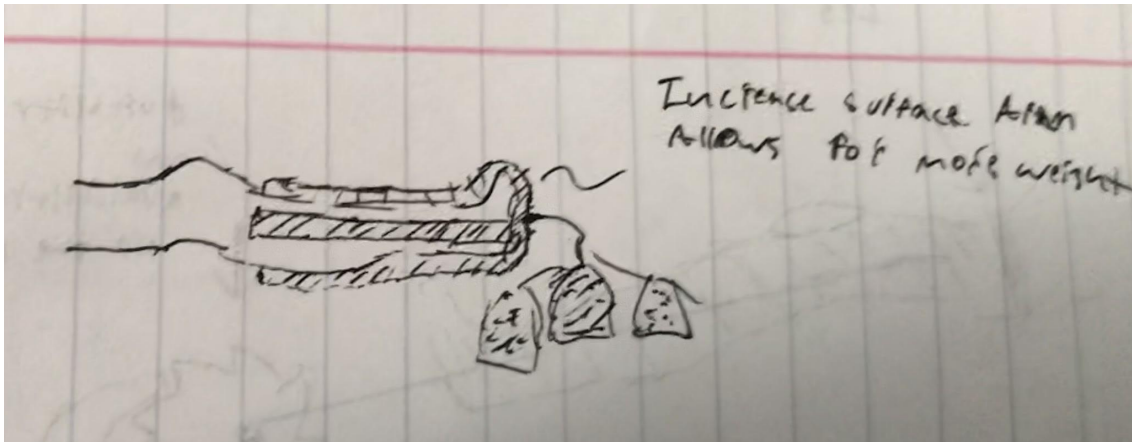
105. Modified Crutch Extender



106. Super-Skin + Current Solution + More weight



107. Increased Surface Area + more weight



108. Modified Clamp - Daniel
109. Turnbuckle locking knee brace - Daniel
110. Telescoping with straps - Daniel
111. Telescoping L bar with boot - Daniel
112. Spring with straps - Daniel
113. Combine boot - clamp idea - Daniel
114. Modified locking with straps - Danie
115. Telescoping 2 bar turnbuckle with straps - Daniel

SCAMPER/Design Heuristics 2

116. Foldable with straps - Daniel 2
117. Multiple boot pins - Daniel 1
118. Ultra comfort - Daniel 9
119. Leg cover - Daniel 9
120. Detachable pieces - Daniel 42
121. Detachable crank - Daniel 42
122. Wrapping technique for making boot and plaster one combined unit - Ian
123. Inflatable leg tube for most consistent pressure allowing max - Ian
124. Somehow have force application internally as part of wrap/setup - cleans design - Ian
125. Elastic band wrapped around foot and tether - compressive force applying tensile force - Ian
126. Something pulling on upper body hinged on completely separate surface area along with bottom of foot pull force - Ian
127. Pulley and the patient pulls the rope themself - Evan 71
128. Elastic plaster and the weight is directly applied to plaster - Evan 19
129. Patient lies in hammock and is pulled up while leg is fixed in place - Evan 31

130. Instead of a weight on rope, use a fixed telescope rod to provide tension force for traction instead - Evan 63

Appendix D

Idea Component Table

	Immobilization		**Traction Method**		**Align Femur Portions**
	Device Infrastructure	Patient - infrastructure interface	Point of Traction on patient	Force Generator	
Component	Bars	Straps	Ankle	weights	Compression
	Shell	string/rope	skin	pull	Air pressure
	2x4	elastic	Super skin	crank	Manual - by nurse/doctor
	Compression wrap	plaster	boot	magnet	Alignment rods
	Clamps	fabric/padding	adhesive	Body weight	
	Compression wrap	brace	Thigh/Mid-Thigh	Pulley/Mechanical Advantage	
	Cloth and Pads		Upper Body	Cables	
			Knee	pins/dowels	
			Multiple Points	turnbuckle	
				Locking system	
				Linear Slide	
				Springs	
				Extendable Pole	

General Category Ranking Table

Design Name	Usability	Performance	Perceived Fixability	Durability	SUM
The Clamp Device	4	1	3	3	11
A Telescoping Single Pole	4	3	2	3	12
Replace Plaster and Cloth	5	2	4	1	12
Ankle and Skin Traction	2	4	3	2	11
Pin and Board	2	3	1	3	9
Plaster the Whole Leg	3	3	4	2	12
Cable Extension	2	4	2	3	11
Tube filled with air designed to increase axial pressure	4	2	2	2	10
Hole in Bed with Patient Applying the Weight	4	2	1	5	12
Reverse Slide	4	3	1	4	12
Pulley System with Mechanical Advantage	2	5	2	3	12
Rail System	3	3	2	3	11
Peg Board Boot	2	3	1	3	9
Knee Brace	3	3	2	3	11
Multi-Turn Buckle	4	4	2	4	14
Diecast Traction Clamp	2	3	1	5	11
CT6 w/ Surgical Tubing	3	4	3	3	13
Circular Clamps with Metal Cables	1	3	2	3	9
Full leg cast, hook on foot, weight hung off bed	3	3	3	2	11
Brace bar into hip, rod along length, pulley applied at foot	2	4	2	3	11

Super Skin that attaches to patient with a rope which has force provided by a one directional crank, Hips and Knee are secured with metal bars	2	4	1	3	10
Full Leg Compression wrap that is pull the leg using attachment to cables	3	3	2	2	10
Super Skin/ Ankle Anchors with mechanical advantage w/ compression wrap	1	5	1	3	10
Ankle hitch linear slide	3	4	2	3	12
Knee Sleeve (i.e. 61 but just the knee)	3	3	2	2	10
Compression wrap around joints, plaster along leg, boot with pulley	2	3	2	2	9
Cast for hip and knee (may be separate), elastic cables applied for traction	3	4	2	2	11
Rod along a leg, multiple attachment straps, linear clamp attached to boot	2	4	2	3	11
2x4 with elastic and boot	3	2	2	3	10
Clamp and pin	3	3	3	4	13
wooden braces to restrict movement with cloth, weight applied traction	2	2	3	3	10
wooden braces idea but with leather or cloth instead of wood	1	2	3	2	8
pins and dowels but instead of a board, it's on two poles	2	3	2	4	11
knee brace that extends to lower leg with attachment for weight at foot and stiff sides	2	3	3	3	11
Brace that uses the other leg for mounting/traction	3	2	3	3	11
Apply the force at several bands going up the leg	3	3	2	3	11
Insertable wedges for increasing traction, like suspension adjustment on cars	2	2	4	3	11
Turning knob for applying force,	5	4	2	3	14

continuously increasable with patient comfort					
U-bar front of the leg and back of leg	4	3	4	2	13
Pin and Dowel with Sheet Metal	2	3	2	4	11
Speaker Stand Turn buckle system (more on next page)	3	4	4	4	15
Cable Reel	2	4	2	4	12
Fake Skeletal Traction + Current Solution	2	3	2	2	9
Modified Crutch Extender	4	3	2	4	13
Super-Skin + Current Solution + More weight	2	3	3	3	11
Increased Surface Area + more weight	3	3	3	2	11
Modified Clamp	2	1	2	2	7
Turnbuckle locking knee brace	2	4	1	4	11
Telescoping with straps	3	4	2	3	12
Telescoping L bar with boot	2	4	2	4	12
Combine boot - clamp idea	3	3	3	4	13
Modified locking with straps	2	3	2	3	10
Telescoping 2 bar turnbuckle with straps	2	4	2	3	11
Foldable with straps	2	3	2	3	10
Multiple boot pins	2	3	1	3	9
Detachable crank	2	4	2	4	12
Wrapping technique for making boot and plaster one combined unit	2	3	3	2	10
Inflatable leg tube for most consistent pressure allowing max	4	2	1	2	9
Elastic band wrapped around foot and tether - compressive force applying tensile force - Ian	4	2	3	2	11

Interfaces Ranking Table

Interfaces	Fits Ghanaian adults 18-59 years	Durable	Fixable by K.A.T.H. Staff	Sourceable	Does not damage skin	Does not restrict blood flow	Easy to apply	Low cost/use	Sum
Replace Plaster with Cloth/Strong Material	5	1	5	3	2	4	3	2	25
Plaster the Whole Leg	5	1	5	2	2	4	3	2	24
Ankle brace	**4**	**3**	**3**	**2**	**3**	**4**	**5**	**3**	**27**
Combine Boot Clamp	3	3	3	3	3	3	3	3	24
Tape front and back of leg	4	1	5	2	2	4	3	2	23
Modified Crutch Extender	3	4	2	3	3	3	3	3	24
Speaker Stand	**4**	**4**	**3**	**3**	**3**	**3**	**3**	**4**	**27**
Telescoping L bar with boot	4	3	2	2	3	3	3	3	23

Force Generators Ranking Table

Force Generators	Returns leg to original length	Durable	Fixable by K.A.T.H. Staff	Sourceable	Easy to apply	Easy to transport patient while in traction	Low cost/use	Sum
Pulley System	5	3	2	3	2	2	3	20
Multi-Turn Buckle	4	4	2	2	3	4	2	21
Surgical Tubing Pulley	3	3	2	3	2	2	3	18
Linear slide	3	3	2	2	4	4	2	20
Detachable Ratchet	**5**	**4**	**1**	**2**	**4**	**4**	**2**	**22**
Winch	5	4	1	2	4	2	2	20

Telescoping Single Pole (w/human force)	**4**	**4**	**2**	**3**	**3**	**3**	**3**	**22**
Speaker Stand (w/human force)	**5**	**4**	**3**	**3**	**3**	**3**	**4**	**25**
Modified crutch (w/human force)	**4**	**4**	**2**	**3**	**3**	**3**	**3**	**22**
Human Force	**3**	**4**	**3**	**5**	**2**	**4**	**4**	**25**

Full Requirements and Specifications Ranking Table

	Returns leg to original length	Durable	Fixable by K.A.T.H. Staff	Sourceable	Easy to apply	Easy to transport patient while in traction	Low cost/use	Fits Ghanaian adults 18-59 years	Does not damage skin	Does not restrict blood flow	Sum
Speaker stand w brace and ratchet	**5**	**4**	**2**	**2**	**4**	**4**	**3**	**4**	**3**	**3**	**34**
Telescoping pole w ankle brace	**4**	**3**	**3**	**3**	**3**	**4**	**3**	**4**	**3**	**3**	**33**
Crutch extender	4	3	3	3	3	4	3	3	3	3	32
Improved Material	3	1	5	2	2	2	2	4	2	4	27
Multi-Turnbuckle idea	4	4	2	2	3	4	2	4	3	3	31
Current Solution	2	1	5	2	2	2	3	4	2	4	27

Appendix E

Design Drivers

- Patient-Device Interface
    - Can we apply enough force to the skin to realign the femur
    - Will we damage the skin with how much force we need
    - How much do we need to disperse the force on the leg
- What will the infrastructure-strap/ankle brace look like?
    - How are they connected?
- Can locking mechanisms bear enough weight?
    - Golf ball retriever design
- What is the lifetime of the locking mechanisms?
- What materials are sourceable?
- Is manual traction feasible?
- How much force can an ankle brace hold before slipping or breaking?
- Can we make our device sturdy enough
    - One bar v two bar?
- What materials to make straps and bars out of?
- Is there a way to implement a way to measure if the proper traction is being applied?
    - Length vs force measurement?
- How can we ensure that the leg is aligned?

Appendix F

Item	Price
6 in x 18 in aluminum sheet	9.98
1-1/4 in x 2 ft PVC pipe	5.2
1 in x 5 ft PVC pipe	6.08
2 in x 15 ft velcro	29.98
7/8 in x 23 in velcro straps	4.28
10 ft pad ratchet 4 pack	14.98
Med ankle brace	11.79
Force Sensitive Resistor, 0.5"	11.48

Table F.1: Bill of materials for prototyping as of 12/8/2020

Appendix G

FSR Code

```
/* FSR testing sketch.

Connect one end of FSR to power, the other end to Analog 0.
Then connect one end of a 10K resistor from Analog 0 to ground

For more information see www.ladyada.net/learn/sensors/fsr.html */ (original source)
const int button = 8;
int fsrPin = A0;     // the FSR and 10K pulldown are connected to a0
int fsrReading;     // the analog reading from the FSR resistor divider
float fsrVoltage;     // the analog reading converted to voltage
float fsrResistance;
float fsrConductance;
float fsrForce;       // Finally, the resistance converted to force

void setup(void) {
  Serial.begin(9600);   // We'll send debugging information via the Serial monitor
}

void loop(void) {
 if (digitalRead(button) == LOW){ //the original code was edited to take 10 readings when the
button was pressed
 for (int i = 0; i <= 10; i++){
  fsrReading = analogRead(fsrPin);
  Serial.print("Analog reading:");
  Serial.print("\t");
  Serial.print(fsrReading);
  Serial.print("\t");

  // analog voltage reading ranges from about 0 to 1023 which maps to 0V to 5V (= 5000mV)
  fsrVoltage = map(fsrReading, 0, 1023, 0, 5000);
  Serial.print("Volt(mV):");
  Serial.print("\t");
  Serial.print(fsrVoltage);
  Serial.print("\t");
  if (fsrVoltage == 0) {
    Serial.print("Force(N):");
```

```
    Serial.print("\t");
    Serial.print("0");
    Serial.print("\t");
    Serial.print("Mass(g):");
    Serial.print("\t");
    Serial.print("0");
    Serial.print("\t");
    Serial.print("Pressure(Pa):");
    Serial.print("\t");
    Serial.print("0");
    Serial.print("\t");
    Serial.print("Conductance(microMhos):");
    Serial.print("\t");
    Serial.print("0");
    Serial.print("\t");
    Serial.print("FSR resistance (Ohms): ");
    Serial.print("\t");
    Serial.println("0");

  } else {
    // The voltage = Vcc * R / (R + FSR) where R = 10K and Vcc = 5V
    // so FSR = ((Vcc - V) * R) / V
    fsrResistance = 5000 - fsrVoltage;     // fsrVoltage is in millivolts so 5V = 5000mV
    fsrResistance *= 10000;                // 10K resistor
    fsrResistance /= fsrVoltage;


    fsrConductance = 1000000;           // we measure in micromhos
    fsrConductance /= fsrResistance;


    // Use the two FSR guide graphs to approximate the force
    if (fsrConductance <= 1000) {
      fsrForce = fsrConductance / 145;  //145 comes from calculating the slope of the calibration
curve which relates conductance and force linearly
      Serial.print("Force(N):");
      Serial.print("\t");
      Serial.print(fsrForce);
      Serial.print("\t");
```

```
    Serial.print("Mass(g):");
    Serial.print("\t");
    Serial.print(fsrForce*1000/9.81);
    Serial.print("\t");
    Serial.print("Pressure(Pa):");
    Serial.print("\t");
    Serial.print(fsrForce*1000000 / 126.6);
    Serial.print("\t");
    Serial.print("Conductance(microMhos):");
    Serial.print("\t");
    Serial.print(fsrConductance);
    Serial.print("\t");
    Serial.print("FSR resistance (Ohms): ");
    Serial.print("\t");
    Serial.println(fsrResistance);
  } else {
    fsrForce = fsrConductance - 1000;
    fsrForce /= 60;
    Serial.print("Force(N):");
    Serial.print("\t");
    Serial.print(fsrForce);
    Serial.print("\t");
    Serial.print("Mass(g):");
    Serial.print("\t");
    Serial.print(fsrForce*1000/9.81);
    Serial.print("\t");
    Serial.print("Pressure(Pa):");
    Serial.print("\t");
    Serial.print(fsrForce*1000000 / 126.6); //126.6 is the area of the resistor in mm^2
    Serial.print("\t");
    Serial.print("Conductance(microMhos):");
    Serial.print("\t");
    Serial.print(fsrConductance);
    Serial.print("\t");
    Serial.print("FSR resistance (Ohms): ");
    Serial.print("\t");
    Serial.println(fsrResistance);
  }
fsrConductance = 0;
```

```
  fsrForce = 0;
  fsrVoltage = 0;
  fsrReading = 0;
  delay(500);
  }
  }
 }
}
```

Appendix H

FSR Test Results

8" Model Stacked (KPa)				
	None	1	2	3
No Foam	20.115	20.795	13.471	0
NU 1"	16.221	13.829	13.364	11.425
High Density 0.5"	15.046	15.725	15.591	16.42
High Density 1"	15.883	17.764	18.991	15.643

8" Model Parallel (KPa)				
	None	1	2	3
No Foam	20.115	20.795	8.562	16.221
NU 1"	16.221	13.829	10.484	8.801
High Density 0.5"	15.046	15.725	14.716	14.83
High Density 1"	15.883	17.764	15.223	15.004

9.5" Model Stacked (KPa)				
	None	1	2	3
No Foam	4.721	10.21	6.851	10.425
NU 1"	6.481	7.052	3.964	5.891
High Density 0.5"	4.202	5.718	4.955	4.868
High Density 1"	7.483	8.456	9.346	10.129

9.5" Model Parallel (KPa)				
	None	1	2	3
No Foam	4.721	10.21	9.05	9.859
NU 1"	16.221	13.829	10.484	8.801
High Density 0.5"	4.202	5.718	5.194	6.908
High Density 1"	7.483	8.456	5.091	2.586

10.5" Model Stacked (KPa)				
	None	1	2	3
No Foam	6.802	5.202	5.085	4.949