

Knee Traction Device

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Abstract

Osteoarthritis is a rapidly growing problem in the United States. Unfortunately, current treatments for the disease do little to slow the progressive joint degradation that ensues. The knee is particularly troublesome as it is the largest load-bearing articulating joint in the body. A total knee replacement may eliminate the damaged cartilage and bone, but the procedure is highly invasive, risky, and often requiring repeated surgeries. Joint distraction is a potential alternative treatment for osteoarthritis. Devices already exist on the market today to provide distraction to the lumbar and cervical vertebrae and have shown promising results in alleviating pain. However, no such device is currently available to provide distraction at the knee. As such, our client has requested the development of a knee traction device. Continuing where the previous design team left off, the goal is to improve upon the prior device by making it adjustable, portable, and simple to operate. Three different designs were ultimately considered, each varying substantially in adjustability and ease of use. Using a design matrix, a Pivoting Platform design was chosen and is described within. The device was fabricated primarily out of aluminum and steel to provide suitable strength and aesthetics. Telescoping aluminum and steel tubes allow for easy adjustment of height and/or angle. The added modifications allow the user to utilize any convenient chair size and to transport the device with ease. Improvements to the force application system resulted in a reliable, constant load to the knee joint necessary for optimal distraction. A pneumatic cylinder, attached via cables to a leg strap, is actuated by an integrated hand pump that the user holds in their lap. While the device works well, further modifications are necessary to make the device more user friendly and fully marketable.

Background

Osteoarthritis (OA) is a progressively degenerative joint disease that is characterized by the loss of cartilage and/or increased bone formation at articulating joints (those designed for movement) of the body [3]. Joint cartilage provides both a cushion to absorb impact and an extremely low coefficient of friction, allowing bones to easily bear weight and glide across each other [9]. This tissue does not regenerate well, causing cartilage to break down over time as a result of age or simply by wear and tear at the joint from everyday activities or athletics [9]. Loss of cartilage allows bones to rub against each other, leading to a great deal of pain and stiffness – the primary symptoms of the disease [5]. In addition, bone-on-bone contact initiates a positive feedback loop, whereby the body senses a problem at the joint and begins stimulating bone growth at the affected areas and causing painful bone spurs [5]. Increased bone growth to “correct” the problem has the added disadvantage of stressing the surrounding ligaments and tendons. This weakens the joint, thus making it progressively less stable and more susceptible to further articular cartilage damage [5].

X-rays of afflicted joints reveal a dramatic decrease in the joint space between bones, as seen in Figure 1, indicative of a loss of articular cartilage [9]. This knee X-ray illustrates the damaging physiologic impact of OA. Because of the large size of the knee joint and the constant normal and shear stress applied to it, the knee is particularly susceptible to cartilage damage or degradation. In fact, it has been reported that the average individual has a 50% chance of developing symptomatic knee OA by age 85 [8]. This is largely due to knee kinetics. Forces in the knee can easily reach 3.5 to 8 times body weight during normal daily activities such as walking up a flight of stairs or walking downhill [12]. Such high forces accelerate cartilage degradation and ultimately contribute to the onset of OA.

When OA has progressed to the point where it is no longer manageable, joint replacement surgery is typically performed. This procedure is extremely invasive and involves shaving off of the ends of the articulating bones, then applying a metal covering to each bone between which a plastic plate is affixed [11]. An illustration of the final product can be seen in Figure 2. One can generally expect the implant to last only about 10 years [3], after which they must be replaced by another artificial joint, again with a limited lifespan. The inherent problem with joint replacement is that it does not really treat the disease; rather, it removes the immediate problem and creates another ten years in the future. Moreover, a 2010 paper by Waller et al. asserts that the sheer dearth of effective treatment is the direct result of misguided approaches to solving the problem. “Instead, we propose that research and development efforts be aimed at addressing the aberrant biomechanics that are the primary driver in progression of knee OA” [10]. Simply put, abnormal



Figure 1: X-ray of an osteoarthritic knee noting the decreased joint space caused by loss of cartilage. [11]

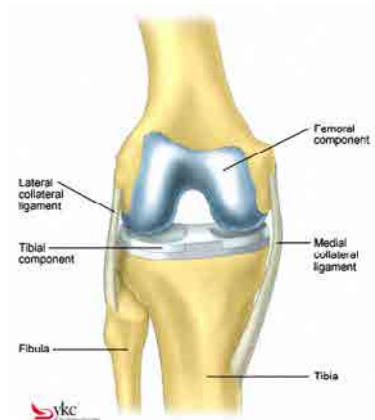


Figure 2: Illustration of total knee replacement wherein a metal form is fitted to the ends of each bone with a plastic plate in between. [11]

weight bearing and loading of the knee are directly related to cartilage degradation and OA. As such, it would follow that unloading the joint could prove to be a beneficial treatment.

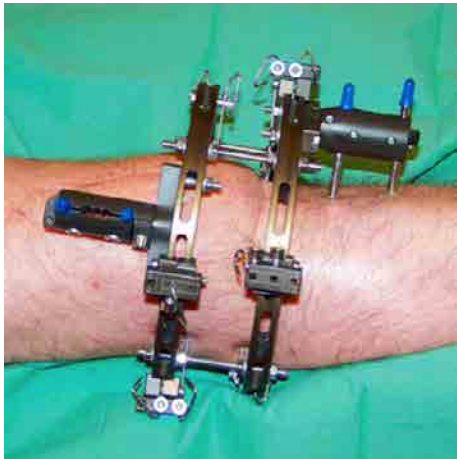


Figure 3: Example of an Ilizarov distraction apparatus used to mechanically unload a knee. [10]

One such method aiming to unload joints is a technique called joint distraction. The method involves gently separating the bones of a joint to slightly increase the internal space, therein lessening the load bearing within the joint itself [3]. Typically, distraction is achieved via installation of an external Ilizarov apparatus (Figure 3). The device is surgically affixed to the patient by inserting pins into the bones of the joint, then connecting the pins to the external frame, which can then be set to the desired separation. A patient wears the apparatus for a set number of months (determined by the individual study) after which it is removed [2][3][4]. The procedure shows immense promise in both alleviating pain from degenerative joint disorders such as OA and potentially contributing to reversal of damage [2][10]. In a study presented in a February, 1996 article from *The Lancet*, all eleven patients of the trial treated with joint distraction reported less pain, and five of them none whatsoever [2]. Moreover, a study conducted by Deie et al., published in 2007, showed that successful distraction procedure increased the knee-joint space by 1.5 mm that remained at final patient follow-up over an average 2.5 years later [4]. This evidence, along with radiographic imaging such as MRI or X-ray, suggests that distraction promotes healing and growth of new cartilage [10].

Problem Motivation

Joint distraction is the separation of the bony ends of a joint. This concept has been proven through experimental procedures such as Ilizarov distraction – a risky surgery where a device is surgically attached to each bone of the joint to provide a traction force [4]. However, surgery is not the ideal solution to osteoarthritis in the knee as it is invasive, expensive, and inconvenient. Non-surgical joint distraction of other major weight bearing joints, such as the spine and hip, has proven to be an effective way to reduce joint pain [13][14]. Applying the same concept to the knee joint will potentially provide similar results, prolonging or even eliminating the need for knee replacement surgery.

A prototype is currently in place that utilizes non-surgical joint traction to reverse the effects of osteoarthritis in the knee. This prototype was designed and developed by a previous (Fall 2011) BME design team. It is an effective design; however, it lacks the necessary characteristics of a marketable, personal-use device. The current device is heavy, bulky, and is not adjustable in height or knee flexion angle. The goal of this project is to modify and improve the current prototype to create an inexpensive, home-use device that is adjustable, easy to use, and easily transportable.

Analogous and Current Technology

Currently there are no devices that are marketed for knee traction. There is however, analogous technology that provides distraction for other joints of the body. A great example of this is a cervical traction device. As shown in Figure 4, the top of the device hooks to the backside of a door. After the bag is filled with an appropriate amount of water, the user places the harness around their head in the configuration shown. The water bag attached to the pulley system creates the upward distraction force at the cervical vertebra [15]. This method is very easy to use and can be done safely in the users own home.



Figure 4: A cervical traction device manufactured by Isokinetics that can be used in the patient's home. [15]

Another analogue of this device causes lumbar distraction. Machines like the one shown in Figure 5 perform this type of distraction in a clinical setting. Patients lie on their back and raise their feet into the air. The table is separable, and when the cables are tensed, a traction force is applied. This method has been used to apply distraction to several joints.

An in-home lumbar traction device has also been created. The Saunders lumbar traction unit, as seen in Figure 6, is a simplistic and comfortable way to receive treatment in the comfort of the patient's home, capable of delivering up to 90.72 N (200 lbs.) of force [17]. The patient lies on their back and straps the device across their lower back. The user then uses a hand held pump to create the traction force. The force is measured with a built in pressure gauge. For a constant force, the device also employs a lock-release mechanism. Once the proper pressure is found, the user locks the pump. After their distraction session is complete, the user releases the pressure from the pump to exit the device. There are different models that provide distraction for other joints in the body and many can be quite expensive.



Figure 5: This clinical traction device is used for lumbar distraction. The patient is strapped onto the separable platform and distraction is applied where needed. [16]



Figure 6: The Saunders Lumbar traction device is easy to set up and can be done in the user's home. [17]

Although none of these devices provide direct distraction of the knee, many aspects of their designs can be applied to the design of a knee traction device. The previous BME design team created the first prototype of this project (Figure 7). To use the device, the user selects a chair of appropriate height, about 48.26 cm (19 inches), and lays one leg down the padded inclined slope. The angle of the slope is at a fixed 30 degrees from the horizontal. This creates a position of the knee known as the "open-pack" position. In this position, the anatomical separation between the tibia and the femur is maximized, which is important in aiding distraction of the knee. After the leg is placed on the device, the leg strap is attached directly above the calf. This placement will ensure the strap will not slip when a force is applied. Two cables attached to

the strap run to the underside of the device where a pneumatic cylinder is located. The cylinder is attached to a hand pump with a pressure gauge that the user can comfortably pump while sitting. The device has proven effective and is very simple to use; however, it is heavy, bulky, and the height and angle are non-adjustable.

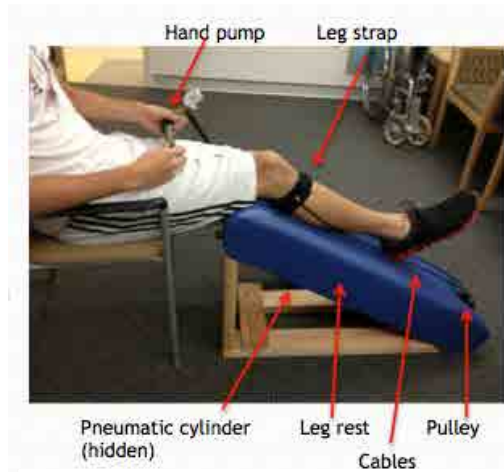


Figure 7: The previous knee traction prototype. The device is crafted from a wooden frame wrapped in vinyl. The device is currently inoperable due to a faulty air pump connection.

Design Requirements

An excellent proof of concept prototype from the previous design team has been presented. However, several improvements and modifications can and must be made. The new design must meet all requirements put in place by the client. The new design should maintain a similar style and force applicator of the current prototype. The previous design was very bulky and challenging for the user to transport, meaning necessary modifications must be made to make the design lightweight and portable. Introducing a collapsing mechanism to the design will allow the user to essentially pack up the device and roll it to their intended location. The device is planned for home use, so a collapsibility mechanism will also allow the user to stow it in an inconspicuous manner. Additionally, the device should be user-friendly since the user will be in the confines of their home without the aid of a registered therapist. The current prototype is at a fixed height that works with a specific chair height. The client has required the new design to be adjustable in height such that it can be deployed with a wide range of chair heights the user may have in their home. Adding an adjustability mechanism will increase sophistication, therefore creating a design that minimizes complexity is essential. The adjustability will allow the device to accommodate a wide range of individuals who seek knee distraction. The client would like the device to maintain an angle around 30 degrees from the horizontal. This would produce maximal distraction to the “open-packed” tibiofemoral knee joint, as described previously.

A budget of \$400 was provided by the client, and must be taken into consideration. The device must produce a reliable and adjustable force, up to 311.4 N (70 lb.), at the angle of inclination in a safe and effective manner. The measureable force must be constant and only provide distraction at the knee joint. Safety of the device is important, as this device will be used by patients on a daily basis. The device must not produce discomfort or pain in any part of the body, and should only distract the knee joint in a safe and pain-relieving manner. Furthermore, the device will be in direct contact with the patient’s leg, thus a soft, non-irritable, and easily sanitized padding is required. The client would like for this design to be marketable, consequently proper FDA approval for a class one device, such as this, is required.

Force Analysis

To further understand the mechanics occurring at the leg, a free body diagram was created and can be seen in Figure 8. We modeled the leg at the angle of inclination of the device, as that is the position the leg will be in when traction force is applied. F_T is the actual traction force the device is applying to the leg, and is modeled at the maximum desired force of 311.4 N (70 lbs.) From an anthropometry chart, the average leg length from the femoral condyles, in the knee, to the foot is 0.061 times the total body weight [20]. That being established, the average weight of a human is roughly 70 kg (154.32 lbs), so when computing the total weight of the lower leg, $W = 4.27$ N (9.41 lbs.). One can sum forces in both the x and y-coordinates to determine the values for all variables, as shown below.

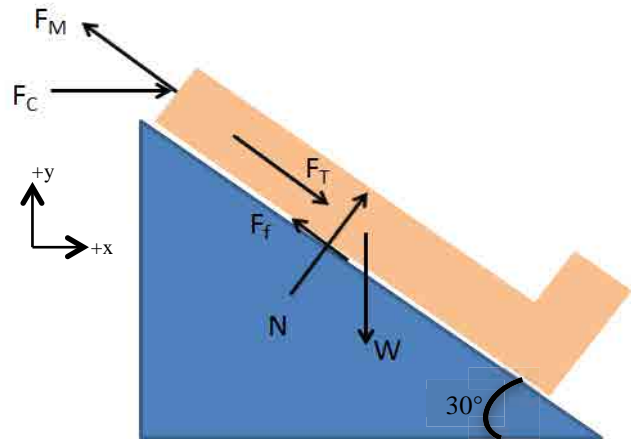


Figure 8: A free body diagram of the respective forces applied to the leg while operating the device. F_T = Force of traction; F_M = Force of tendons, muscles, and ligaments in knee; F_C = Internal joint contact force; F_f = Friction force; N = Normal force; W = Weight of leg

$$\sum F_x = F_T \sin 30^\circ + F_C - N \cos 30^\circ - F_M \cos 30^\circ - F_f \cos 30^\circ = 0$$

$$\sum F_y = -F_T \cos 30^\circ - W - N \sin 30^\circ + F_M \sin 30^\circ + F_f \sin 30^\circ = 0$$

F_C is modeled as the force of contact at the tibiofemoral joint, however, when traction is applied, that force would ideally go to zero, leaving you with the following equation for the forces in the x-direction. F_M is described to be the force applied by the muscles, tendons, and ligaments in the leg at the knee. Since the leg is resting in the “open-packed” position and is intended to be relaxed, the force F_M can also go to zero. This simplifies the equations to the following.

$$\sum F_x = F_T \sin 30^\circ - N \cos 30^\circ - F_f \cos 30^\circ = 0$$

$$\sum F_y = -F_T \cos 30^\circ - W - N \sin 30^\circ + F_f \sin 30^\circ = 0$$

Once all forces are known, the device can be fabricated while keeping the forces in mind. The length of the leg rest (hypotenuse) must accommodate the average leg length of a human. Based on an anthropometry chart, the length from the knee to the bottom of the foot is 0.285 times the total body height [20]. Assuming the average human is roughly 1.72 m ($\approx 5'8''$) tall, the length of the device must accommodate for a leg length of 0.4902 m (≈ 19.3 in). Knowing the length and forces, a design with correct dimensions and strengths can be produced.

Design Process

Validation of Previous Design

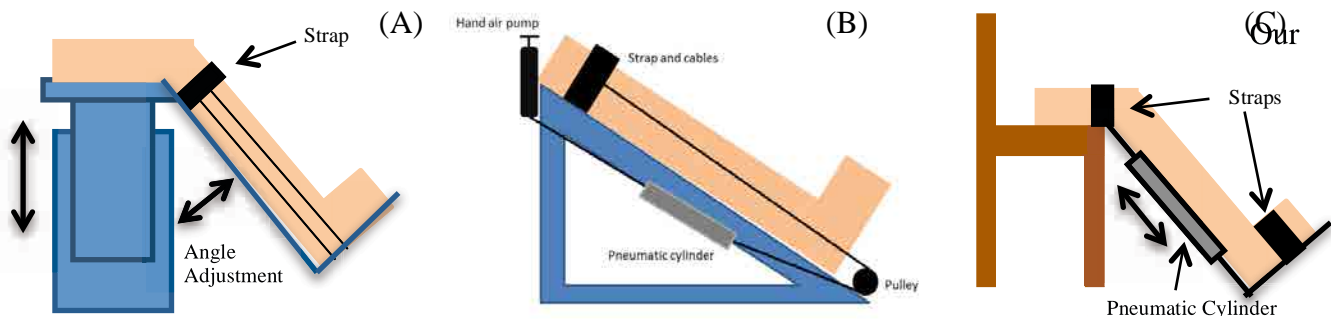


Figure 9: Original design concepts: (A) The rising pedestal design; (B) Current device's overall form with modifications; (C) Minimalist design

first design (Figure 9A) was created as a totally different approach to the product. The device would be a self-contained pedestal. The user would pick a chair and sit with their knee over the end of the pedestal. The user would attach the leg strap directly above their calf and place their foot on the platform. The pedestal would then rise to create an upward force on the distal end of the tibia. As the pedestal is rising, the foot platform is moving outward to create the desired knee flexion angle.

The current device inspired our second design, as depicted by Figure 9B. It was originally proposed that the wood would be replaced by aluminum and the device would be adjustable with a walker/crutch mechanism. This would also be accompanied with a sliding mechanism on the hypotenuse so that many different heights and angles can be accommodated for. The advantage of this overall design form is that it has already been proven to apply the correct traction force to the leg. However, it is bulky and non-adjustable. The main purpose of this design is to make the device lighter, collapsible, and more easily transportable.

The third design, seen in Figure 9C, was a minimalist design that was created using the least amount of parts. The design was similar, in concept, to the pedestal design, but with the pedestal removed. The user would first select any chair size that they would like to use. They would then lengthen the device until the top end was in contact with the hamstring muscle and the lower end reached the ground. Next, the user would attach the leg strap directly above the calf. The user would now make sure that their knee is at a 30-degree flexion angle. The sliding mechanism is attached to a pneumatic cylinder and incorporates a manual hand pump. The pneumatic cylinder spreads the device apart creating a force pushing up on the hamstring muscles and down on the floor. This force would cause distraction about the knee.

After evaluating the three designs and meeting with the client, it was determined that the second design was the best way to create distraction at the tibiofemoral joint. The other two designs were omitted due to an accompanying shear component. The large shear force is undesirable, as it does not create the traction force required to promote cartilage repair.

Validation of Previous Force Applicator

Criteria	Weight	Hydraulics	Winch	Water Bag	Hand Pump	Foot Pump
Ease of Force Application	30	20	30	10	23	15
Necessary Modification	20	10	12	20	15	18
Cost	15	0	12	15	11	11
Weight	15	0	12	5	13	11
Ease of Measurement	10	10	4	10	10	10
Safety	10	10	5	5	10	10
TOTAL	100	50	75	65	82	75

Table 1: Design matrix used to revalidate the use of the hand pump as the force applicator.

There are several different types of force applicators that could be utilized in creation of the device. A proposed mechanism was a hydraulic cylinder. Hydraulic cylinders apply the force with minimal user input. However, they are usually built for very large force applications, are very expensive, and also considerably heavy.

Another proposed mechanism was a winch, an example of which can be seen in Figure 10. This device would remove the need for the pneumatic cylinder and would apply the force by turning the crank. It is quite inexpensive and would be extremely reliable. However, measuring the force would be difficult with this particular design.



Figure 10: A winch mechanism similar to the one that would be used on the device.

A water bag could also be utilized to create traction force. As illustrated in Figure 11, the bag would be mounted underneath where the pneumatic cylinder originally was. The weight would be highly adjustable, meaning it could be tailored to many different users. This would also make the device very light, because the water can easily

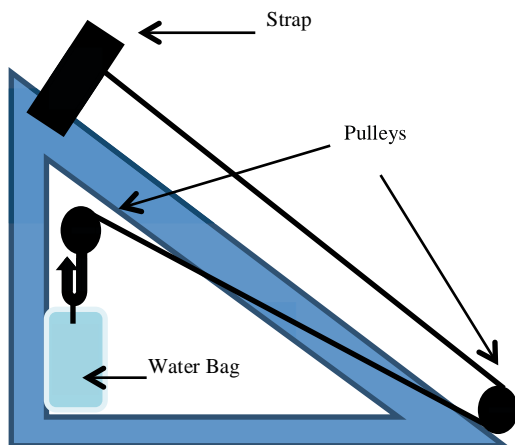


Figure 11: Schematic of water bag hanging-weight mechanism.

be drained for easy transportation.

The last two designs correspond to a hand and foot pump mechanism, respectively. The hand pump is implemented on the current prototype. It is very easy to use and the force can be applied and measured with ease. A foot pump mechanism could also be used in place of the hand pump. Since the user only has one leg on the device, the other could be used to apply the force. This has the same advantages as the hand pump, but may be cumbersome to users.

After critiquing all of the different force mechanisms using the matrix seen in Table 1, it was clear that using a pneumatic cylinder with a hand pump was the easiest and most cost effective way of applying the distraction force; therefore, the previous design was revalidated.

Overall Design Concept

After extensive evaluation of the previous design team's prototype, it became clear that their overall design and force application system was, in fact, the best method of providing distraction at the knee. With this knowledge, we decided to implement several of their ideas into our own design. The design concepts in this section will be reflected in all of our design alternatives.

As shown in Figure 12, the right-triangular shape will remain intact, and will be redesigned for use with a separate chair provided by the user. The same force application system will also be implemented in each of our design alternatives, meaning the traction force will be applied to the knee via a pneumatic cylinder and pulley system. Similar to the original prototype, the user would lay his leg over the device and attach the strap to his leg between his knee and upper calf. This strap would be connected to two cables that run around a pulley to the pneumatic cylinder on the underside of the leg rest. Actuating the pneumatic cylinder will be a hand pump that can comfortably be pumped in the user's lap. Attached to the hand pump will be a force gauge to allow the user to have a visible display of the force being applied.

We plan to modify the design in a way to make it more user-friendly. Although effective, having fixed height and angles is not convenient for the wide variety of patients that will be using the device. Instead, the new designs will consider adjustability in height and angle, as well as collapsibility.

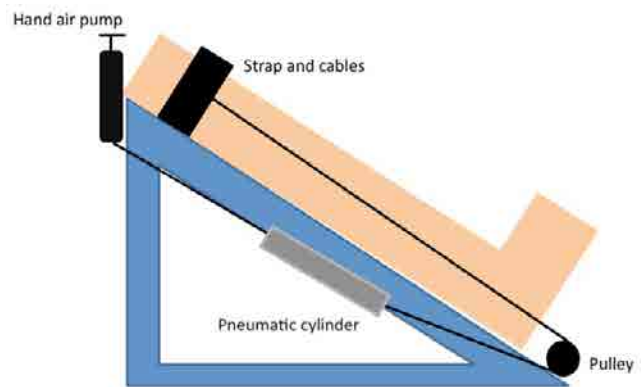


Figure 12: The overall design concept of the knee traction device.

Design Alternatives

Three-Sided Adjustment

The Three-Sided Adjustment design was put into place solely for the purpose of accommodating many chair heights and knee flexion angles. This design, in retrospect, is ideal for all scenarios, however, does have some flaws. This design, depicted in Figure 13, would incorporate a walker/crutch pin adjustment mechanism to adjust the length and height. The device would have each increment numbered such that the user could select the number on the vertical and correspond that to the number on the horizontal to acquire the desired angle. The device would come with a numbered chart attached to the side that described the angle and number adjustments in a logical manner. The

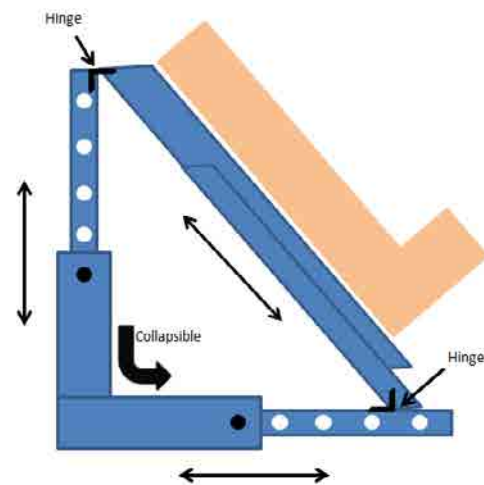


Figure 13: The Three-Sided Adjustment design incorporates a walker/crutch mechanism to adjust both the vertical and horizontal components. In response to such adjustment, the hypotenuse is designed to slide on itself to increase and decrease in length.

leg rest would be designed to have two sliding pads that would slide in the grooves of one another as the height and length of the device are adjusted.

As a design requirement, the device would be collapsible. The vertical component would pivot on the upper hinge and fold inward toward the leg rest, and subsequently the leg rest would fold down on top of the already collapsed vertical component. This would make the device relatively flat and provide an efficient means of portability. The drawback to this device is the complexity to adjust all three lengths. The user, with an already weak knee, would have to bend down and adjust the components to the desired height and angle until the optimal position is achieved. Fabricating the device such that all lengths match perfectly would be difficult. If the lengths do not match up, unwanted stress will be applied to areas of the device that are not accounted for. This device is an excellent representation of total adjustment. However, ease of use and fabrication has influenced the need for additional design alternatives.

Fixed Platform

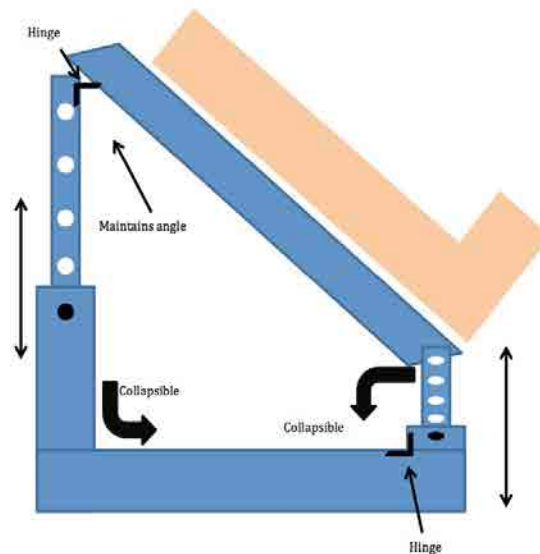


Figure 14: Both ends of the device are free to move vertically proportional to each other. The angle of inclination is a fixed 30 degrees.

In this design iteration, as seen in Figure 14, the angle of inclination is fixed at a desirable 30 degrees. Both ends of the device are vertically adjustable to accommodate many chair heights. This design requires that both ends of the device move in unison, as the leg rest is a fixed length. This adjustment would be difficult to accomplish on one's own. A complex folding mechanism adds another difficulty for the user. The back vertical adjustment support lifts out of the base and folds under the leg rest. The front support then folds down, flattening the device.

Pivoting Platform

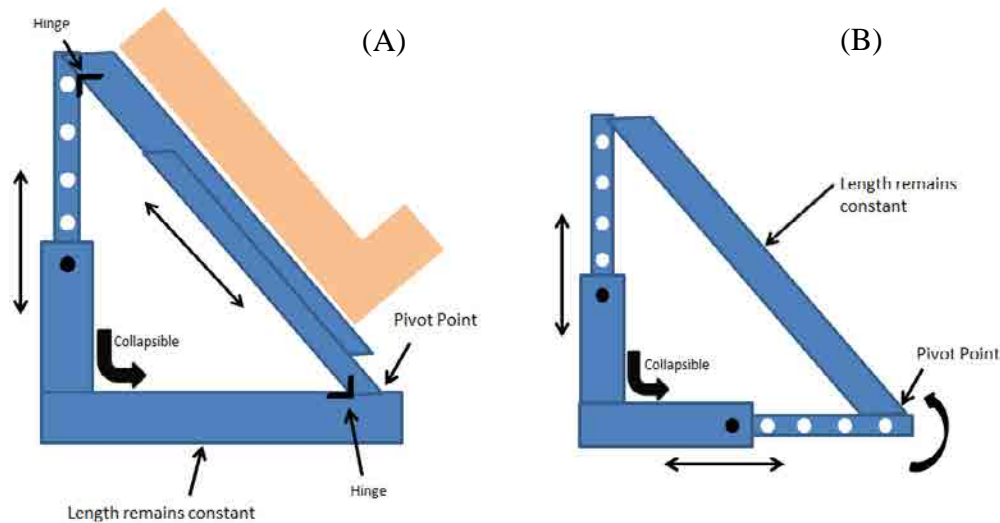


Figure 15: Two variations of the Pivoting Platform device. Device A is designed with the idea of home use, whereas Device B is intended for clinical use.

This design will provide mediation between adjustable height and angle. The idea behind this design is to fix one dimension of the triangular base, and allow the other two sides to be adjustable in a coupled system. Ideally, the height would be fully adjustable, and one of the other two lengths would remain fixed.

If the length of the device (bottom side) were to remain fixed, as seen in Figure 15A, the length of the leg rest would need to be adjustable to compensate for change in height. Implementing a sliding joint at the leg rest and a hinge at the rear-upper and front ends would help the user to easily adjust the height of the device while allowing the leg rest to adjust freely to the change in height. This design would make it very simple for the user to adjust and is ideal for in-home use.

A second option to achieve the same result is to fix the length of the leg rest, as seen in Figure 15B. Fixing the length of the leg rest would require the length of the device to be adjustable. To allow for adjustability, hinges would be installed at the rear-upper and front ends of the device. A design in this way, however, would add complexity as the user would have to adjust both the height and length of the device simultaneously, making this iteration better suited to a clinical setting.

In both instances, this design provides an opportunity for both height and angle adjustability; however, the height and angle are coupled together. An increase in height corresponds to an angle increase and vice versa. This allows the user to prioritize the adjustments they need. The user can choose a chair they would like to use the device with, set the device to the appropriate height, and use the device at the corresponding angle. Alternatively, the user could set the angle, and find a chair that works with the corresponding height. For the first device, a ± 4 inch vertical adjustment corresponds to a $\pm 5^\circ$ angle, whereas on the second, the same height variation corresponds to a $\pm 7^\circ$ angle.

Both ways of implementing this design have benefits. Keeping the length of the device fixed makes adjustments much easier, making it ideal for home use. Fixing the length of the leg rest makes it more difficult to adjust, but, by geometry, adds a wider range of angles to the same range of heights.

Collapsibility would be achieved in both options by putting a detachable joint at the rear-lower end of the device. Given that hinges already exist at the other corners, the device would simply fold in.

Final Design Matrix

Criteria	Weight	Three-Sided Adjustment	Fixed Platform	Pivoting Platform
Height Adjustability	30	30	30	25
Ease of Use	25	10	20	25
Portability	20	15	10	15
Ease of Fabrication	15	0	5	10
Angle Adjustability	10	10	0	5
TOTAL	100	65	65	80

Table 2: A design matrix orchestrating the different design alternatives to provide adjustability to the current knee traction prototype. The Pivoting Platform design scored highest and will be the design to move forward with.

A design matrix was constructed to analyze each of our design alternatives based on a set of criteria. The criteria chosen included height adjustability, ease of use, collapsibility, ease of fabrication, and angle adjustability. Each category was weighted based on the product design specifications and requirements of the client. The weights of each category were summed to 100 points. As seen in Table 2, the pivoting platform received the highest score, and is the design to move forward with.

Height adjustability

Each of the design alternatives was designed for use with a chair that is provided by the user. Since chairs come in a wide variety of heights, it is crucial that the device be able to adjust. This would allow for maximum effectiveness and comfort for the user. Height adjustability was weighted the highest, with a maximum of 30 points. Both the total adjustment and fixed platform designs received maximum points for this category because of their total independent height adjustment. The pivoting platform received a slightly lower score of 25 because the height adjustability is not completely independent. Although the height is adjustable, the user may need to use the device at a specified angle, thus limiting the height adjustability.

Ease of Use

With the amount of adjustability and collapsibility incorporated into the designs, a patient may find it too complex and overwhelming. This is why ease of use received a weight of 25. The total adjustment design has the most adjustment and would require the most user interface to adjust. The user would have to manually adjust both the height and length of the device, while being aware of the adjustment chart, thus scored only 10 points. The fixed platform would also require the user to manually adjust the height at both ends of the device. Because the user is only adjusting the height, it is a slightly easier concept, but still would have a bit of difficulty as each end would need to be adjusted at the same time. The fixed platform received a score of 20 in this category. Finally, the pivoting platform requires the user to only adjust the height manually at the back end of the device, giving it the full 25 points.

Portability

The current prototype is heavy, bulky, and cumbersome to move around. Although this is inconvenient, when the device is set up in a user's home, it is unlikely that it would be necessary to move it often. For these reasons, portability received a weight of 20. All three of the designs will be fully collapsible, but how they collapse will determine their transportability. Both the total adjustment and pivoting platform will collapse in the same way, giving them equal scores of 15. Both of these designs will allow for the rear vertical supports to detach, and have hinges that are already in place to account for adjustability. The fixed platform design received only 10 points because it adds difficulty to collapse. It deviates from the simple triangular base, thus requires that another connection be pinned, making it slightly more difficult to collapse.

Ease of Fabrication

Being able to easily fabricate this device is a priority since synchronized moving parts are difficult to accurately assemble. As a result, ease of fabrication received a weighting of 15 points. The total adjustment would require the most pieces and moving parts, thus making it most difficult to fabricate and earning zero points. The fixed platform would also be difficult to fabricate because of the added collapsible component. However, fixing the base would make it slightly easier and consequently the fixed platform earned 5 points. The pivoting platform would be the easiest to fabricate. It includes the simplest collapsibility mechanism and only one side of adjustability, scoring it 10 points.

Angle Adjustability

Although adjustability of the device is a priority, angle adjustability is the least important given that the ideal angle for knee distraction is 30 degrees, or the "open-packed" position. Understanding that everyone is different and different angles might work better for some patients, the angle would not need to deviate too far. Knowing this, the angle adjustability is less of a concern and received a weight of only 10 points. The total adjustment design received the full 10 points because the angle is fully adjustable. The fixed platform design received 0 points as its angle is fixed. The pivoting platform design received 5 points because, although the angle is adjustable, it is dependent on the height of the device.

Final Design

The final design of the knee traction device closely portrays the Pivoting Platform prototype drawings as presented above. Most of the items on the preliminary material list were indeed purchased; however, many items were added as unexpected scenarios developed.

The bottom frame was constructed from aluminum tubing cut to size and welded together by Schlieckau Welding, a local company. Aluminum was a major improvement over the wood found in the previous design due to its smaller form factor and weight saving properties. It also provides a sturdier platform for the entire design, while maintaining durability and increasing aesthetics. Two telescoping aluminum tubes allow the leg rest to accommodate vertical height adjustments and hold the pulley bar and nylon material which creates

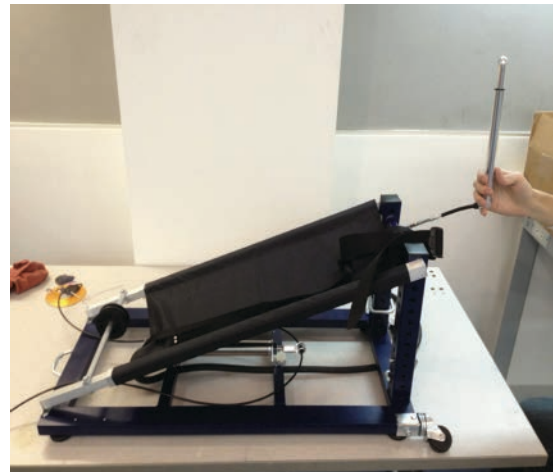


Figure 16: Depiction of the black nylon for the leg support. The pulley bar is mounted below the nylon material.

the leg rest for the device. The ends of the aluminum pulley bar were machined into half circles, similar to the previous prototype. This was proven to be the most effective design, as it provides strength, stability, and a simple way of attaching. Nylon material provides a comfortable platform for the leg to rest on, while being extremely lightweight, easily sanitized, and machine washable. Shown in Figure 16, a large nylon sheet was cut and stitched to size to fit around the square tubing with little slack. This material is held in place by hook and loop fasteners that are glued to the aluminum tubes.

Two vertical steel tubes in the back of the device also telescope to accommodate multiple chair heights. This square tubing was cut to size and a round handle was welded between them by the COE Instrument shop. The bar was welded close to the top to allow for complete telescoping motion while also functioning as a handle. Plumbing insulation was wrapped around the handle to provide a cushioned surface for the thigh to rest on.

Height of Vertical Adjustments (in)	Angle of Knee Flexion (deg)
15.0	24.5
16.0	25.9
17.0	27.3
18.0	28.7
19.0	30.0
20.0	31.3
21.0	32.5
22.0	33.8
23.0	34.9

Table 3: Reference chart indicating the correlation between height and knee flexion angle

Two adjusting sides correlate to a varying angle as the height changes. As displayed in Table 3, the device has a height range of 15 to 23 inches, which all correspond to different angles. At the lowest and highest height, the device has a knee flexion angle of 24.5° and 34.9° respectively. This is a second added advantage over the first prototype, due to the fact that the user can either select a chair and match the device to that height, or select the angle that they need and adjust a chair to that specific height.



Figure 17: The Lezyne Micro HP pump was used on the device. Equipped with inline pressure gauge and air-bleed button

The pump required a complete redesign from the previous prototype. The old design did not hold pressure, so a new pump was purchased. This pump, as seen in Figure 17, had threads that could be attached to the previously used pneumatic cylinder via a custom brass coupling. One unexpected cost was the purchase of a specialized tap to create the custom coupling required for a proper, air-tight seal. Additionally the pump included a built-in bleeder valve and inline pressure gauge.

Another part to receive a complete redesign was the leg cuff. The modified cuff is more comfortable and easier to adjust around the calf to suit a wide range of users. This is a large improvement over the old prototype, which used a neoprene strap that had raw bolt connections that dug into the user's leg. Since the new cuff has vertical strap adjustments, the device can now properly distract legs of all lengths, which was previously not the case. These straps were then attached to the cable ties that were taken off of the old prototype. This redesign moves the raw bolt connections lower on the device so it does not interact with the user's leg. This is an optimal fix and is required for FDA clearance.

Having the device collapsible not only makes it less bulky, but also makes it far more transportable than the previous prototype. As seen in Figure 18, swiveling casters were attached to the end of the device so it can be pulled behind the user which allows for easy movement. Pipe straps were added to the underside of the frame to guide the hoses such that they do not drag while the device is being moved. The hand pump included a mounting bracket that was attached to the device for easy storage. The previous prototype had a similar style bracket that has been relocated to the bottom frame. Square tubing caps were added to most of the open ends for safety and aesthetics. Finally, hook and loop was also added to the bottom frame and the vertical supports to ensure the telescoping mechanism would not slide during transport.



Figure 18: Depiction of the collapsed device as it is being transported

Testing

Thirteen students at the University of Wisconsin-Madison volunteered to test the device and provide feedback. Both male and female subjects were asked to set up, use, and collapse the device before filling out a questionnaire. Each question was based on a scale from one to five, where five was a positive response and one was negative response. The volunteers were instructed to pump the pressure to around 30 psi and apply said pressure for roughly five minutes. Figure 19 shows the conversion from psi in the pneumatic cylinder to tensile load on the knee, with an average force of roughly 36.8 pounds experienced by the test subjects. Many aspects of comfort and usability were assessed as seen in the Appendix. The scores for overall comfort and usability were $4.15 (\pm 0.66)$ and $4.42 (\pm 0.47)$ respectively. In summary, the device provided adequate distraction at the knee joint with little discomfort. Specific user comments dealt with issues that are described below in Future Works.

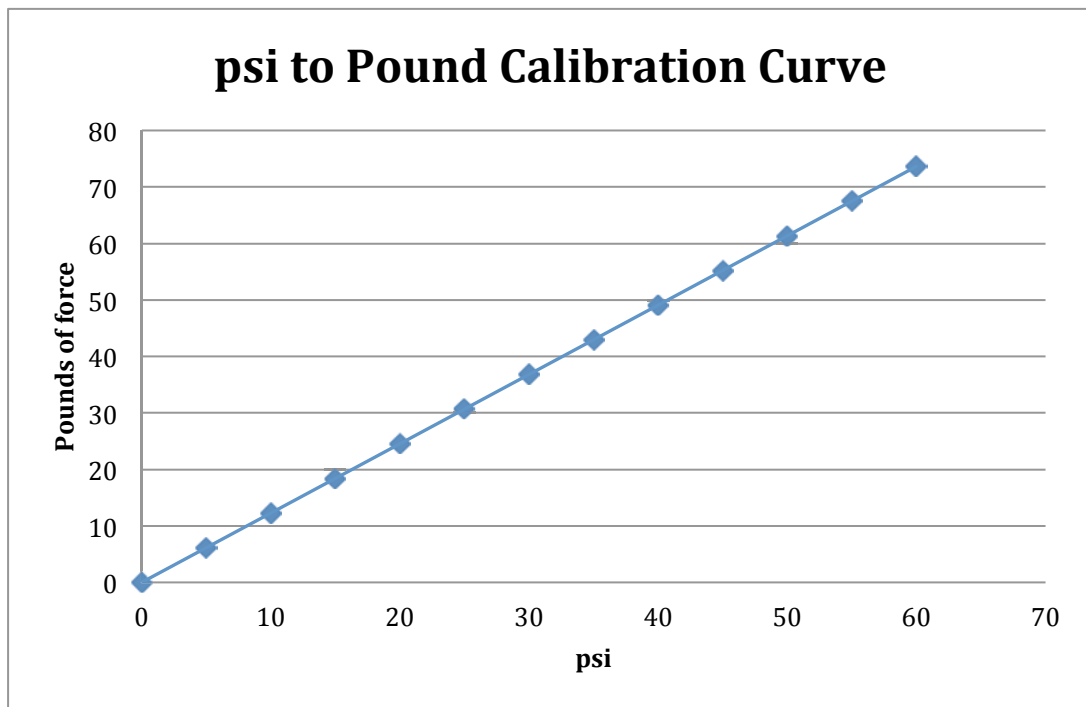


Figure 19: A graph displaying the conversion from psi in the pneumatic cylinder to the tensile load applied.

Cost Evaluation

The overall cost of the prototype was \$398.78, which was very close to the client’s allowable budget of \$400. A majority of the total cost came from the tubing that made up the frame of the device. Many items on the list were bought in higher quantity because they were only sold in such a way; therefore, those materials can be reused without additional costs in the future. Several materials were recycled from the previous group, which kept the total cost below budget. The client wishes the device to be reproducible, so buying all items in bulk will essentially reduce the overall cost. The cost of every individual part can be seen in Table 4.

Item	Retailor	Item #	Price/Unit	Qty.	Cost
1.75"x1.75" perforated steel tubing	McMaster-Carr	4931T124	\$20.15	4 ft	20.15
1.5"x1.5" perforated steel tubing	McMaster-Carr	4931T123	\$18.95	4 ft	18.95
Locking Pins	McMaster-Carr	4931T109	\$5.78	2	\$11.56
1"x2" aluminum tubing	Granger	6ALV3	\$29.45	6 ft	\$29.45
1"x2" aluminum tubing	Grainger	6ALV4	\$13.27	3 ft	\$13.27
Nylon fabric	JoAnn Fabric		\$6.32	1 yard	\$6.32
25 mm aluminum tubing	McMaster-Carr	1471T74	\$39.76	8 ft	\$39.76
20 mm aluminum tubing	McMaster-Carr	1471T73	\$15.75	4 ft	\$15.75
Hinges	McMaster-Carr	1530A310	\$1.22	2	\$2.44
Wheels	McMaster-Carr	2399T500	\$14.12	2	\$28.24
Handle	McMaster-Carr	14895A420	\$2.05	1	\$2.05
Leveling mounts	McMaster-Carr	21015T21	\$3.29	4	\$13.16
Hand pump	Amazon		\$55.44	1	\$55.44
1.75" tube caps	Fastenal	11131250	\$0.76	2	\$1.53
1" tube caps	Fastenal	11131240	\$0.32	2	\$0.64
.75" tube caps	Fastenal	11131236	\$0.25	2	\$0.50
Velcro	McMaster-Carr	94985K811	\$8.41	1	\$8.41
Plug tap	McMaster-Carr	2595A228	\$30.28	1	\$30.28
Teflon tape	McMaster-Carr	4591K11	\$1.86	1	\$1.86
Nuts/Bolts	Student Shop		≈\$5.00		\$5.00
Metal stock	Student Shop		≈\$7.50		\$7.50
Leg cuff	Amazon		\$19.89	1	\$19.89
Nylon webbing	Amazon		\$12.94	1	\$12.94
Strap adjustments	JoAnn Fabric		\$1.26	1	\$1.26
Paint/Primer	Menards		\$4.67	1	\$4.67
Welding	Instrument Shop		\$35.00	1	\$35.00
Pipe straps	Menards		\$1.99	1	\$1.99
Lacquer	Menards		\$4.68	1	\$4.68
Pipe insulation	Menards		\$6.09	1	\$6.09
TOTAL					\$398.78

Table 4: Itemized list of all materials purchased for the development and production of the device.

Future Work

The previous iteration of the knee traction device was made of wood and weighed approximately 30 lbs. That, coupled with the fixed shape of the frame, resulted in a heavy, bulky, and generally awkward device. With those issues in mind, the main goals of this second prototype were to create a lighter, collapsible, more user-friendly device. While those goals were met, there is certainly room for improvement.

Lighter Materials

At 27 lbs., the new prototype only resulted in a decrease of 3 lbs. from the previous device. While that may not seem like a significant reduction, it should be noted that more than a third of the overall weight is attributed to the steel tubing used for the posterior vertical adjustment. The vast majority of the prototype is already constructed from rectangular aluminum tubing, however, the perforated, telescoping tubing required for the functionality of the device was only available in steel. Switching the steel for aluminum would allow for sufficient strength while also providing a dramatic decrease in overall weight. This could be accomplished by simply purchasing aluminum telescoping tubing and utilizing a CNC mill to precisely drill the perforations necessary for adjusting the height of the device.

New psi Gauge

The client requested that the new prototype incorporate a gauge with a greater range than the previous maximum of 30 psi. While the hand pump used in this prototype includes a built-in gauge with a maximum reading of 120 psi, the gauge itself has very few graduations, drastically decreasing the precision of measurement while simultaneously eliminating any possibility of finely tuned psi adjustment. In addition, the overly compact size of the gauge makes the graduations extremely hard to read. Given that a large majority of potential users for the device are likely elderly, a gauge that is difficult to read is not ideal. Finely graduated rotary gauges are easily found on McMaster-Carr or Grainger and would greatly increase the usability of the pneumatic system. With a proper coupling, such a gauge could be integrated into the next prototype.

Mounted Hand Pump & Handle

While the current method of holding the hand pump in one hand whilst pumping with the other works, it is not particularly ergonomic. To improve on this system, the pump could be mounted to the frame of the device. This configuration would allow the user to apply an axial force to the plunger while the pump is fixed in place, potentially requiring less physical exertion on the part of the user. Furthermore, the mounted pump could double as a handle by which the user could push against to reposition his or her body relative to the device, should it be necessary. An inherent drawback to the device is that during initial pumping of the device, a user may be pulled forward in his or her seat due to limited friction between the seat and the user. Integrating a handle into the device would provide the user with a fixed member to push against such that proper tension in the knee, and therefore traction, could be achieved.

Cable Management/Covered Pulley

One especially frustrating problem with the former prototype, and the current one to a lesser extent, is that of cable management. When the device is not in use, the steel cable traversing the pulleys as well as the hoses of the pneumatic system are not sufficiently secured, resulting in a tangled mess. The current prototype alleviated some of this issue by affixing pipe straps to the underside of the frame, which serves to hold a portion of the pneumatic hose in place. That said, further modification is required to prevent the cables and hoses from dragging on the floor during transportation of the device.

Additionally, a better method of securing the cables to the pulley mechanism would be a welcome improvement. The current fix employs inserting zip-ties into holes drilled through the pulley that then wrap around the pulley and secure the cables in the track, as seen in Figure 20. Ideally, a covered pulley could be used to provide a more polished look to the device.

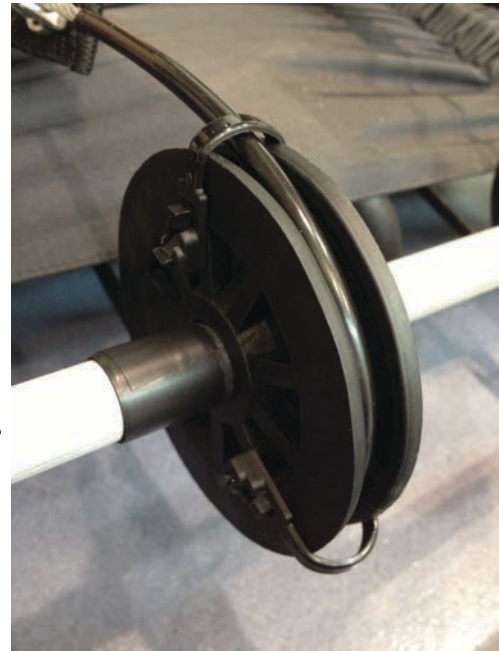


Figure 20: Picture of the current use of zip-ties to maintain cable placement within the track of the pulley.

Better Adjustment Pins

The adjustment pins used in the current prototype have a few disadvantages. First and foremost, they are not well suited to use when the device is folded and collapsed. Because of how closely the hypotenuse bars and the vertical adjustment bars must nest together when folded, the pins must be inserted in one particular orientation such that they do not interfere with the collapsed orientation. A depiction of this can be seen below in Figure 21. Furthermore, these pins can only be purchased bent in one direction, meaning that while the right pin easily remains in place while the device is folded, the left pin has a tendency to rotate and fall out. Simply purchasing different locking pins that do not need to wrap around the bar should help solve both of these problems.



Figure 21: Illustration of how locking pin orientation affects collapsibility – (A) Pins inserted from the side of the tubing prohibits the device from folding; (B) Pins inserted from the front or back allow for collapsibility, but are susceptible to falling out when the device is folded.

Rubber-bottomed Leveling Mounts

Addition of leveling mounts to the base of the device allowed for both clearance between the device and the floor as well as for fine adjustment of the overall height. The current leveling mounts are made of plastic and therefore have a tendency to slide on smooth floors when the device is in use. Replacing the plastic mounts with rubber-bottomed mounts would increase the friction between the device and the floor, therein preventing sliding during use.

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- Kim Skinner for sewing the fabric, straps, and leg cuff, as well as for continuous support and expertise
- Mitch Tyler for his unwavering guidance and assistance
- Schlieckau Welding, Painting & Sandblasting for welding the base of the frame
- The University of Wisconsin – Madison College of Engineering Instrument Shop for welding the vertical adjustment bars and posterior handle
- The University of Wisconsin – Madison College of Engineering Student Shop for all of their advice, tips, and assistance in the fabrication of the device
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Appendix

Product Design Specifications

Knee Traction Device

Product Design Specifications

Date: December 11, 2012

Team: Alex LaVanway, Mike Schmidt, Ryan Keuler, Ryan Reynebeau

Advisor: Mitch Tyler

Client: Kim Skinner

Problem Statement:

With the growing need for knee replacement surgery, finding methods to stave off risky operations is becoming increasingly important. Knee replacement surgery, in particular, is rarely a one-shot deal, often requiring multiple replacements, physical therapy, and frequent doctors appointments throughout the life of the patient. Mechanical traction is used as a treatment intervention for degenerative joint disease, particularly in the knee. Our goal is to create a device to offer rehabilitative joint distraction for those with chronic knee problems while aiming for simplicity, portability, and affordability.

Function: The device will provide mechanical distraction to the knee joint by gently separating the upper and lower portions of the leg.

Client requirements:

- The device must be affordable, i.e. within a \$400 project budget.
- The device must be easy to transport, i.e. lightweight and compact.
- The device must be aesthetically pleasing.
- The height of the device must be adjustable.
- The angle must be adjustable around 30°.
- The force applied to separate the joint should be adjustable up to 311.4 N (70 lbs).
- The device should be comfortable to use.
- The device should be simple to operate and suitable for home-use.
- The device should be designed with marketability in mind.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements:* The device is intended for daily use, at approximately 20 minutes per application. It should be able to provide a constant, consistent force to separate the joint, up

to approximately 311.4 N (70 lbs). It must also be comfortably usable by a wide range of patient sizes and weights.

b. *Safety*: The device will provide mechanical distraction at the knee joint, and as such, care must be taken that any potential failure will not harm the user. Padding will be used where necessary, and no sharp edges/points will come in contact with the user. In addition, care must be taken to not inadvertently distract the hip or ankle joints.

c. *Accuracy and Reliability*: The device will include a gauge to measure the applied force, and must be designed to administer up to 311.4 N (70 lbs) of force consistently for around 20 minutes, several times a day.

d. *Life in Service*: The device should be able to reliably operate for at least ten years under daily usage with the possibility of minimal maintenance.

e. *Shelf Life*: Provided the device is stored under reasonably temperate conditions (i.e., within the home), one should expect it to last indefinitely when not in use.

f. *Operating Environment*: The device is intended for home or clinical use, by anyone from patients to licensed physical therapists.

g. *Ergonomics*: The device is intended for use on a human leg only. The height, knee angle, and applied force will be adjustable to suit most, ideally all, patients. The design of this prototype will be based off of an anthropometrically idealized human 1.72 m tall and 70 kg in mass.

h. *Size*: The device should be compact, collapsible, and designed in such a manner that it may be unobtrusively stowed. It will be designed to be adjustable around an average chair height of 48.26 cm (19 in).

i. *Weight*: The device should be designed with elderly patients in mind, therefore it should be as lightweight as possible. However, durability will not be sacrificed in pursuit of lower weight.

j. *Materials*: Materials must be lightweight, yet durable. They must also be non-irritable since the device will be in contact with bare skin.

k. *Aesthetics, Appearance, and Finish*: Given that potential marketability is a goal, the device must appear polished and aesthetically pleasing.

2. Production Characteristics

a. *Quantity*: One prototype, with reproducibility in mind

b. *Target Product Cost*: \$400 or less

3. Miscellaneous

a. *Standards and Specifications:*

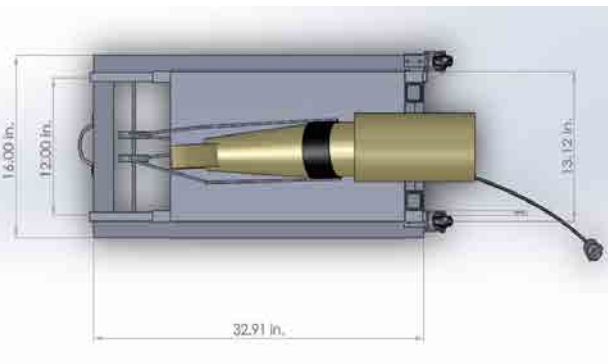
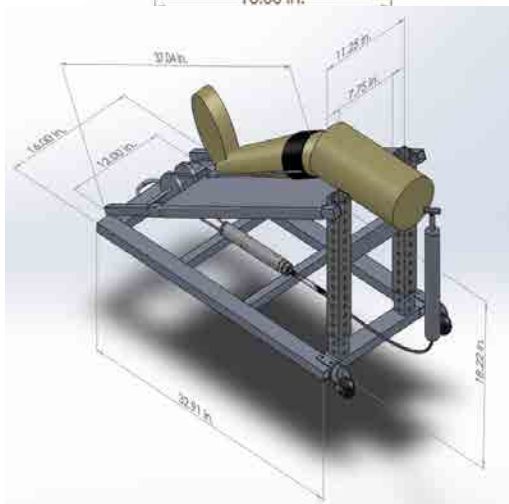
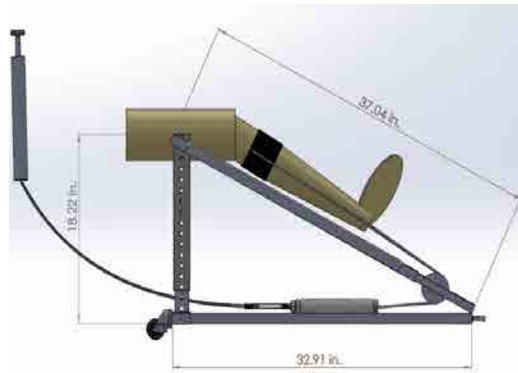
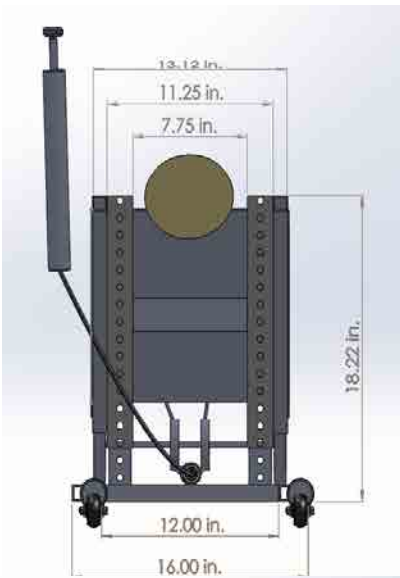
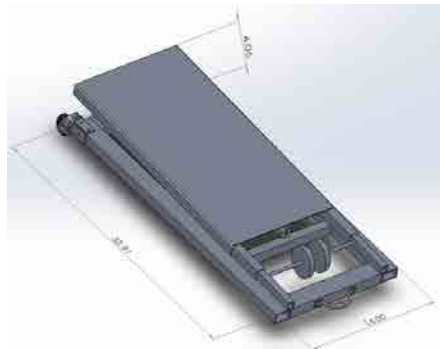
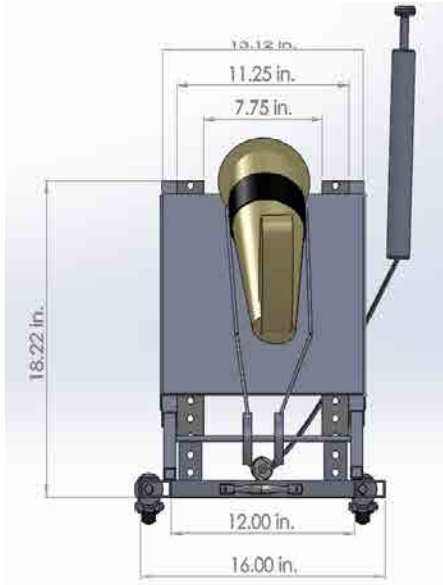
- FDA approval
- Possible IRB approval for human testing

b. *Customer:* The device is intended for patients suffering from osteoarthritis in the knee. No two patients have the same body size or type, and thus the device must be usable by a range of customers.

c. *Patient-related concerns:* The device must be both simple to operate and comfortable to use frequently so that the patient is not under any additional discomfort than they already are with osteoarthritis.

d. *Competition:* Similar products exist for other joints of the body, and surgical knee distraction devices as well. However, no home or clinical use devices are on the market.

SolidWorks Images of Final Design



Subject Testing Questionnaire

Knee Traction Device, v2 – Subject Evaluation Form

Age:

Weight:

Height:

Sex:

How long did you use the device for? (minutes):

What was the PSI reading when you used the device?:

COMFORT

How comfortable was the leg rest? (Please Circle):

1 2 3 4 5

Very uncomfortable

Very comfortable

Specific comments:

How comfortable was the leg strap? (Please Circle):

1 2 3 4 5

Very uncomfortable

Very comfortable

Specific comments:

Please rate the overall comfort when using the device (Please Circle):

1 2 3 4 5

Awkward, leg was
strained during use

My leg did not feel strained

Specific comments:

USABILITY

Did the weight of the device affect its usability? (Please Circle):

1 2 3 4 5

The device was much too heavy and cumbersome

The weight of the device had no impact on its usability

Specific comments:

How easy was the device to unfold and set up? (Please Circle):

1 2 3 4 5

Would not be able to use the device without assistance

Device was extremely user friendly

Specific comments:

How easy was the device to adjust? (Please Circle):

1 2 3 4 5

Would not be able to use the device without assistance

Device was extremely user friendly

Specific comments:

How easy was the device to fold/collapse? (Please Circle):

1 2 3 4 5

Would not be able to use the device without assistance

Device was extremely user friendly

Specific comments:

How easy was the device to pump? (Please Circle):

1 2 3 4 5

Very difficult

Very easy

Specific comments:

How user-friendly was the gauge? (Please Circle):

1 2 3 4 5

Extremely difficult to
read/understand

Clear and easy to
understand

Specific comments:

Please rate the overall usability of this device (Please Circle):

1 2 3 4 5

Would not be able to use
the device without assistance

Device was extremely
user friendly

Specific comments:

Additional comments not covered above:

By signing this form I acknowledge that I am aware that my name and information stated on this page will not be used in any form of publication or presentation. I also release the following parties from liability resulting from my participation in this study: Alex LaVanway, Michael Schmidt, Ryan Keuler, Ryan Reynebeau, Kim Skinner, Mitch Tyler, and the University of Wisconsin-Madison.

Signature:

Date: