



College of Engineering
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Creating distraction at the knee joint: a treatment option for osteoarthritis

Final Report

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Table of Contents

Abstract	4
Background	5
Client Description	5
Current Devices	5
Marketed Devices	5
Problem Motivation	7
Design Requirements	8
Prior Work	9
Design Alternatives	10
Free Weight Design	10
Band Design	11
Pump Design	12
Design Matrix	13
Effectiveness	14
Patient Comfort	14
Safety	15
Durability	15
Cost	16
Portability	16
Testing and Results	16
Testing	16
Discussion	17
Future Work	19
Cost	20
Timeline	21
References	22

Abstract

Our client, Kim Skinner, is a practicing physical therapist at Group Health Cooperative of South Central Wisconsin. She treats many patients who suffer from knee osteoarthritis and also suffers from symptoms herself. It is a painful and degenerative disease that is caused by the deterioration of the articulate cartilage in the knee, causing a narrowed joint space [1]. Recent studies have shown that joint distraction (the forced separation of the two bony ends of a joint) increases cartilage thickness, decreases denuded bone area, decreases pain, and improves functional ability [1]. Mrs. Skinner has asked our group to create an at-home system for joint distraction on the knee in hopes of prolonging, or even eliminating, the need for knee replacement surgery. Our team has designed a device which utilizes the natural force of gravity, as well as an air pump system to distract the knee joint, relieving pressure and stress on the joint. Initial testing of this device has proven successful in applying a distraction force significant enough to separate the joints in the knee. With further work, we are hopeful that this product will be made available to all those who suffer from knee osteoarthritis.

Background

Client Description

Kim Skinner is a physical therapist at Group Health Cooperative in Madison. She works with a variety of patients who require physical therapy for a multitude of reasons, but over the years has noticed the prevalence of knee osteoarthritis. Kim would like our group to design a portable knee traction unit for home use to help slow the progression of knee osteoarthritis in her patients. Her clinic currently provides portable cervical and lumbar traction devices, and she would like to offer a similar option for clients that suffer from knee osteoarthritis. By using a knee traction device regularly, it is hopeful that patients will be able to slow the progression of their osteoarthritis, further eliminating the need for knee replacement surgery or other invasive treatments [1].

Current Devices

Marketed Devices

Currently, there are no devices on the market specifically for knee traction. There are, however, clinical devices that perform cervical and lumbar distraction, and these devices can also be utilized for knee distraction. Lumbar distraction in a clinical setting is performed while patients are strapped onto a traction table that has two separable horizontal components (Figure 1). By gradually increasing the distance between these components, force is applied to the patient's joints and distraction occurs. These traction tables can be adjusted to perform knee traction as well. Although the device performs the intended distraction at the knee, it also causes undesirable distraction at the hip and ankle. Due to the fact that this clinical apparatus is not meant for knee distraction, it is difficult and cumbersome to set up, and is also dangerous to the patient.



Figure 1: A traction device currently used for cervical and lumbar distraction in a clinical setting. The patient is strapped onto a two-piece table that separates, applying a specific and controlled distraction force to the vertebrae [2].

In addition to clinical practices, the client occasionally performs her own at-home method of knee distraction using ankle weights. While wearing the weights, she positions herself on a staircase and hangs her leg over the stairs. Gravity pulls the knee apart, providing the desired knee distraction. However, the dilemma with this method is that the ankle weights are not heavy enough and therefore do not apply enough force to create significant and long-term results.

In addition to the previously stated clinical devices, portable cervical and lumbar units for at-home treatment exist in a variety of different forms. The Saunders Cervical Neck Traction Device is a twelve pound portable unit that can apply up to 50 pounds of force to distract the vertebrae in the neck (Figure 2) [3]. The Saunders Lumbar Traction Unit uses a similar principle to distract the lumbar region of the back (Figure 3) [4]. There are also different variations of these models available to encompass a



Figure 2: The Saunders Cervical Neck Traction Device is currently available on the market for patients to provide at home distraction therapy similar to what they might experience in a clinical setting [3].

wide range of osteoarthritis severities.

Although neither of these units can be used to distract the knee, several aspects of their design can be applied to a portable knee traction device.

Both the cervical and lumbar units are light weight and easily portable, making it convenient for the patient to use on a regular basis.

Additionally, both of these devices utilize a hand-held pump with a pressure release valve,

which enables the user to have constant control of the force exerted by the device [4]. Ideally, this hand-held pump mechanism could be incorporated into a portable knee traction unit.



Figure 3: The Saunders Lumbar Traction Unit functions similarly to the cervical traction device. Both the cervical and lumbar units utilize a hand held pump with a gauge and lock-release mechanism to provide and maintain the distraction force [4].

Problem Motivation

Osteoarthritis (OA) is a painful, degenerative disease that affects millions of people around the world. Often referred to as “wear-and-tear” arthritis, OA is the breaking down of the cartilage that cushions the joints, which causes the bones to rub together and leads to subsequent pain [5].

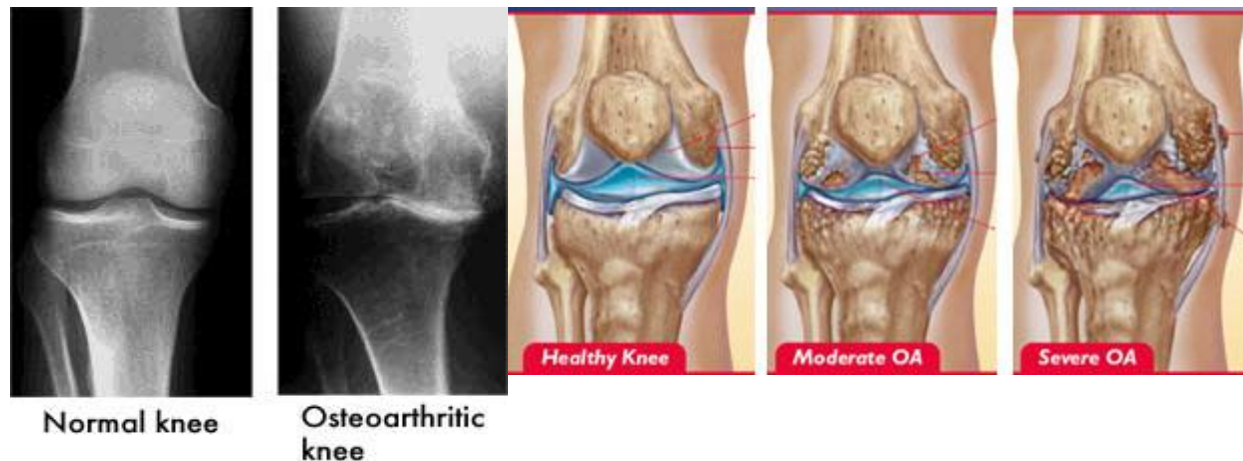


Figure 4: A comparison of a healthy knee and a knee with osteoarthritis. The left picture shows an x-ray image and the right illustrates a diagram of the progression of osteoarthritis [6]. The cartilage cushioning is clearly present in a healthy knee, while there is a lack of cartilage between the bones in an osteoarthritic knee [7].

Joint distraction is a procedure that gradually separates the two bony ends of a joint for a specified amount of time [1] [8]. Recent studies have shown that distraction of joints allows the cartilage between the joints to grow back and thicken [1]. Invasive arthroscopic surgical procedures have been performed, supplying a distraction to the knee. These experiments have shown to be effective in delaying the, often requisite, total knee replacement surgery as this procedure promotes cartilage re-growth [9]. However, a surgical procedure is required and a device implanted in the body must be worn for a period of eight to 12 weeks, limiting the patient’s lifestyle and comfort [9]. Therefore, a noninvasive device that replicates this treatment for knee osteoarthritis without the need for surgery is preferred [10]. As previously mentioned, cervical and lumbar traction units are currently available on the market; however, a traction unit for the knee has not yet been produced. The goal of this design project is to provide a non-

surgical device that can be used as a home-based treatment method by creating distraction in the knee. When used regularly, the effects of osteoarthritis could be diminished and potentially reversed. A device to distract the knee would be greatly advantageous for patients by prolonging the life of their knee and either delaying, or completely eliminating, the need for total knee replacement surgery [11].

Design Requirements

The design requirements outlined in the Product Design Specifications in the Appendix are explained in detail here. Requirements for this design revolve around three main focuses: safety requirements, client requirements, and patient comfort.

Safety requirements are crucial to the design process and must be met in order for the device to be usable and effective. The knee distraction device must not cause pain or further damage to any part of the body. Therefore, it must not distract either the hip or the ankle joints. The device must also meet all the requirements for class one medical devices established by the FDA.

In addition to the safety requirements, the design must also meet the requirements set forth by the client. The client has specified that the distraction force should be constant, and not vary over the time it is used. It is estimated that the applied force should be about half of the weight of the leg, with a maximum force of 311.4 N (70 pounds). Increments of force should be available, and total force should range from zero to 311.4 N. The client would also like the product to be portable so that patients are able to use it in their homes between doctor visits. Furthermore, the knee will have to be positioned in a 30° angle from the horizontal, often referred to as the “open pack” position. This angle of the knee allows for the most separation between the bony ends of the tibia and femur. Due to the wide variety of body types and sizes, all components of the device will need to be adjustable, especially the strap that fastens around the upper calf. Additionally, since the patient will be using it at home without the aid of a physical therapist, usability is important. The device will need to be user-friendly so that people with knee osteoarthritis are able to operate it with ease and without causing further pain to their affected joints. The device should have the durability to last a lifetime because the patient will use it two to three times a day in 15-20 minute increments [12]. These requirements that have

been set forth by the client will play a significant role in the final design of the knee traction device.

Finally, patient comfort is very important to consider when designing the device. All of the components of the device in contact with the skin need to be non-abrasive and adjustable so that the patient feels relaxed and comfortable while using it. The materials used should also be easily sanitized and cleaned. The knee and leg should be supported, while assuring that all other parts of the body are not restricted. A wide range of components go into the design requirements including safety requirements, client requirements, and patient comfort. All are important to the success of our design, and all are taken into account when developing and deciding design options.

Prior Work

Free Body Diagram

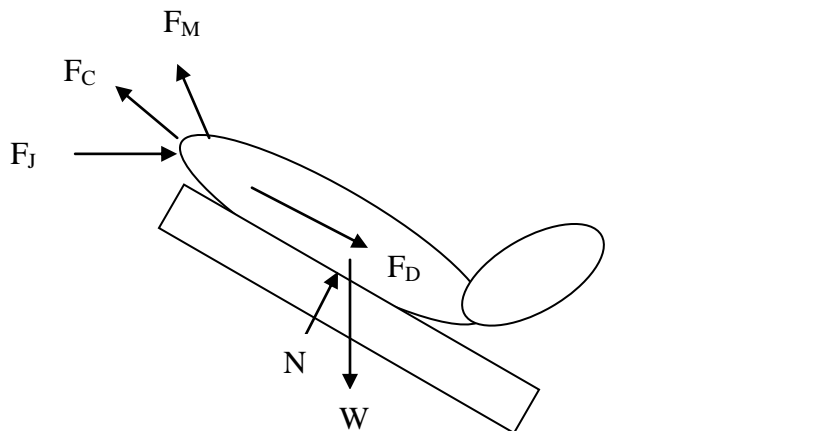


Figure 5: A free body diagram of the lower leg and our device. F_C is the tensile force from ligaments in the knee. F_M is the tensile force of the quadriceps muscle. F_J is the joint force. F_D is the distraction force from the device. W is the weight force of the lower leg. N is the normal force exerted on the leg from the device.

For our calculations, we modeled F_C , F_J , F_M as zero, as we want to minimize these forces in order to have optimal distraction between the joints. We can model F_M as zero because the quadriceps muscle will be relaxed, and therefore, will not be applying any force to the knee. F_J can be modeled as zero because if distraction is being performed, the joints will not be touching and will not supply a force against each other. The tensile force from ligaments (F_C) can never

truly be zero, but we will model it as such because when the knee is in the “open-pack” position, the tensile force is minimized. We modeled F_D as 70 pounds (311.4 N) because it is the maximum traction force that our device will supply. Variable “W” depends on the weight of the individual. By equating the forces in the horizontal and vertical directions, all unknown forces were found. These equations were:

$$\sum Y = -F_D \sin 30 + N \sin 60 - W = 0 \quad (1)$$

$$\sum X = F_D \cos 30 + N \cos 60 = 0 \quad (2)$$

By evaluating equations 1 and 2 all unknowns were found and incorporated into fabrication of the design. [13][14][15].

Design Alternatives

Prior to building and testing, three design alternatives were conceptualized and evaluated based on criteria set in the design matrix shown below (See Table 1). All designs were created for the patient to be seated in a standard kitchen chair, 0.4826 m (19 inches) tall, and will keep the knee at a 30° angle from the horizontal in order to maintain an “open pack” position. All three designs will maintain this 30° angle through the incorporation of a triangular structure underneath the leg. This will function to support the leg, as well as keep the quadriceps and hamstring muscles relaxed so that no unnecessary tension forces act upon the knee. No support will be given to the foot and it will be suspended with the heel resting on the top of the device. An additional component utilized by all three designs is a strap around the leg directly below the knee.

Free Weight Design

The free weight design, as seen in Figure 6, utilizes a two pulley system, a steel cable, and a set of free weights. Along with the triangular structure and strap stated above, this design also incorporates a vertical stand with a pulley on top of it that is separate from the base. The steel cable is attached to the strap and then wraps underneath a pulley mounted on the triangular structure near the ankle of the patient. The steel cable runs from beneath the first pulley, and over the top of a second pulley located on the vertical stand. The steel cable is then attached to various free weights. The free weights supply a force downward which is then redirected by the

pulleys to distract the knee in a direction parallel to the incline of the triangular structure. The use of free weights allows the patient to know the exact force being applied to distract their knee, and specific increments of weight are readily available.

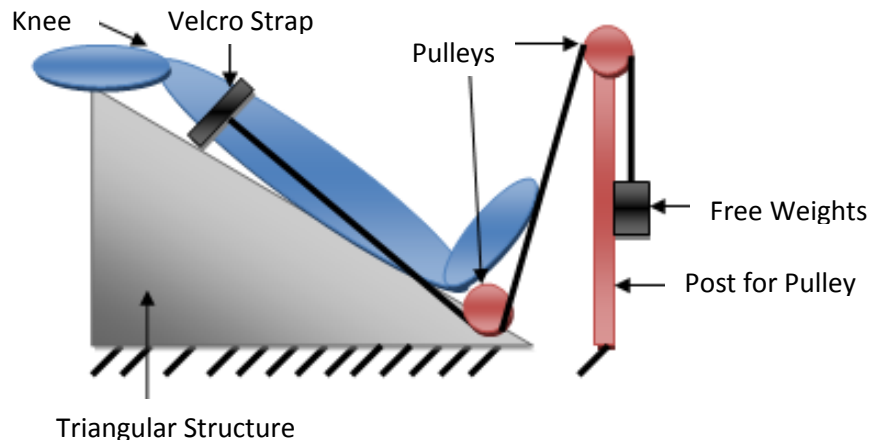


Figure 6: Free Weight Diagram

The free weight design utilizes a system of two pulleys, an inextensible cord, a triangular structure, and free weights. The free weights supply the force in the system which is then redirected by the pulleys to distract the knee. The blue ovals represent the foot and leg of the patient.

Band Design

The band design, as seen in Figure 7, utilizes an extensible band and a series of hooks. The extensible band, which is analogous to a bungee cord or exercise band, provides the tension force necessary to distract the knee. It wraps around the top of the pulley near the patient's ankle, and then goes back toward the body, where it is attached to one of five different hooks. The hooks are placed at different distances from the pulley in order to provide varying levels of tension in the band to distract the knee. The hooks furthest away from the pulley provide the most force, while the hooks closest to the pulley provide the least. In addition to these hooks, bands of different tension strengths can be interchanged to provide varying levels of force.

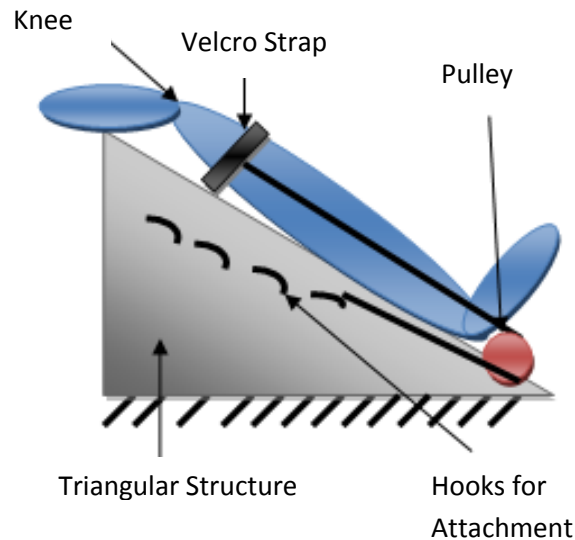


Figure 7: Extensible Band Diagram

The system consists of a pulley, a triangular support structure, a strap, an extensible band, and a series of hooks. The extensible band provides the tensile force to distract the knee. The hooks provide varying levels of tension. The blue ovals represent the foot and leg of the patient.

Pump Design

The pump design incorporates an air pressurized cylinder (much like the cervical and lumbar traction units currently on the market) and hand pump along with the triangular structure, a steel cable, and strap. As seen in Figure 8, the cable is attached to the strap, wraps around the top of the pulley, and is angled around the pulley back towards the patient's body. The other end of the cable is attached to the piston of the air pressurized cylinder (also called an actuator). The actuator itself is mounted on the inside of the triangular structure, and is positioned so that the piston is extended back toward the patient when the hand pump is compressed. The applied pressure inside the cylinder will extend the piston out of the actuator and supply a force pulling the cable, and therefore, distracting the knee joint. The hand pump will be equipped with a gauge to inform the patient of the amount of pressure being supplied. This translates to an amount of force in pounds that is applied to the knee. The hand pump will have a normal setting in which the patient will pump the pressure into the air cylinder, a locked setting in which the amount of force in pounds will be kept at a steady amount, and a release setting to relieve the

pressure from the actuator. These settings will allow the patient ease of use and a very wide range of magnitudes of force to distract the knee.

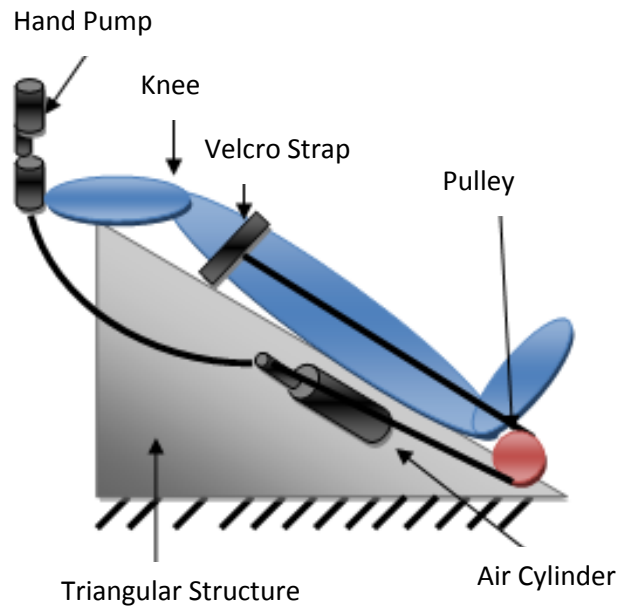


Figure 8: Pump Diagram

The pump design utilizes an air cylinder (actuator), a hand pump, a steel cable, a pulley, a Velcro strap, and a triangular structure. The hand pump provides the pressure force into the actuator which provides the pulling force onto the inextensible cable. The inextensible cable redirects the force to be parallel to the leg, therefore pulling the knee downward. The blue ovals are again the foot and leg of the patient.

Design Matrix

To effectively evaluate the individual components of all three designs, a design matrix was constructed and used to analyze each design alternative. The three knee traction systems were rated on several different design criteria. These aspects included effectiveness, patient comfort, safety, durability, cost, and portability. It was determined that effectiveness and patient comfort were more significant than the others based on the product design specifications, and therefore were weighted more heavily. The scores for each design in each category were then summed to give a total score out of 100, as shown in Table 1. Based on the point breakdown shown below, the pump system received the largest allotment of points, and therefore, is the final design we chose to pursue in prototyping.

Weight	Criteria	Pump Design	Band Design	Weight Design
25	Effectiveness	23	20	21
20	Patient Comfort	19	19	18
15	Safety	12	13	8
15	Durability	14	10	11
15	Cost	7	13	10
10	Portability	7	5	3
100	Total	82	80	71

Table 1: Design Matrix

This design matrix breaks down each design based on certain criteria that we believe are important for our design. The maximum point values are indicated in the left-most row, and the total points allotted out of 100 are specified in the bottom row.

Effectiveness

The purpose of our design is to apply a force to the lower leg to distract the knee joint for 15-20 minutes, multiple times per day. As the most important category, effectiveness was given a weight of 25 points in the design matrix because it determines the ultimate performance of the device. The pump design scored the highest, receiving 23 out of a possible 25 points. It was closely followed by the free weight design (21 points) and the band design (20 points). The pump design scored the highest because it would be the most effective in supplying a constant force on the knee, and could uphold that force for an extended period of time. The free weight design scored the second-highest in this category because while it would be effective and use gravity to its advantage, the device might apply a greater instant force immediately after weights are added, rather than one that would be gradual and constant. The band design received the fewest points because over time, the bands would lose elasticity and therefore, be less effective.

Patient Comfort

Patient comfort is a significant aspect of the design, and was given 20 points in the design matrix. The comfort of patients while using this device is important because it will be used in the

patient's home multiple times per day, and if the patient is not comfortable while performing distraction, they likely will not use the product. The pump and band designs were both given 19 points in the area of patient comfort. Both designs will provide comfortable padding for the knee, and because the distraction force will be applied gradually in both designs, patient comfort will be optimized. The free weight design received a slightly lower value of 18 points for patient comfort because it may be uncomfortable for a patient with knee osteoarthritis to lift a free weight onto the pulley system.

Safety

Safety was also weighted at 20 points in the design matrix because our design will be used by individuals as a form of therapy, and should not cause any pain or harm. The force supplied by the device should not distract any joints other than the desired knee joint. The pump design scored the highest in this category with 18 points because the distraction force would be applied gradually, and the actuator would be unlikely to cause physical harm to the patient while in use. The band design scored the next highest with 17 points because the distraction force would still be applied gradually, but bands may snap causing possible injury to the patient. The free weight design received eight points and would be the least safe due to the fact that the traction force would be instantly applied, and that weights can be dropped on the hands or feet.

Durability

As requested by our client, the device must be usable for a minimum of 15 years, and ideally a lifetime. Therefore durability must be included in the design matrix. The use of any machine over an extended period of time causes expected wear on individual parts, but the chosen device must minimize wear to each component. Durability was given a maximum of ten points in the design matrix because the patients will be using the device at home and will be in charge of the maintenance of their own equipment. The pump design was given nine points because it was determined that the chance of failure was rather low since the pump would not be applying an excessive amount of force. Scoring the next lowest was the free weight design, which received six points. It was suspected that the rope may wear out over time since it must hold a large amount of weight in the air. The band design was given three points, the least amount in this

category because the bands may stretch and break over time which would require the patient to either purchase multiple bands or replace them frequently.

Cost

In order for the device to be marketable, it must be cost effective. Furthermore, to make the purchase of this device a better option than having knee replacement surgery, it should be low in cost while still using durable materials. Thus, cost was given a value of 15 points in the design matrix. The band design was given the highest value of 13 points because elastic bands are readily available and inexpensive. Ten points were given to the free weight design because weights would be more expensive than the bands, and the pulley design would cost more to manufacture. Finally the pump design was given only seven points, the lowest value attained, because the air cylinder, gauge, and hosing components are significantly more expensive than the bands or free weights.

Portability

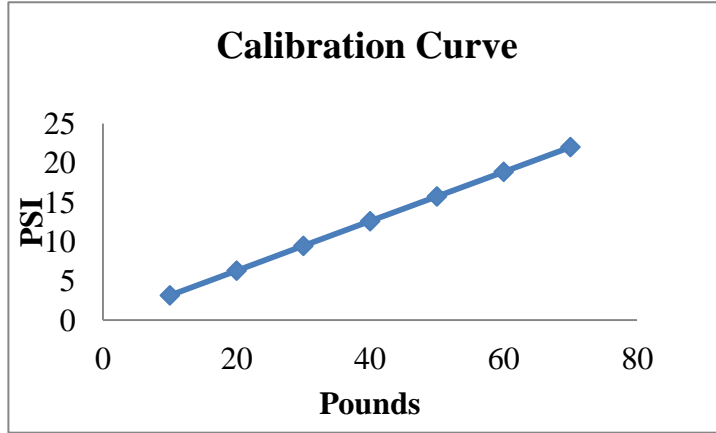
Portability was seen as a less important aspect of our design and was thus given only ten points in the design matrix. The device will need to be used in the patient's home, and would not likely need to be transported from place to place. It should be fairly lightweight so that the patient may easily lift the device. The device should also be easily stored so that it is out of the patient's way when not in use. The band design was given the highest value of seven points in this category because it would be the most lightweight and have the least amount of components. The pump design was given the next highest value of five points because although it is still relatively light weight, it includes the loose cable, Velcro strap, and hand pump components that would hinder portability. Finally, as it would be quite difficult to transport free weights, the weight design was given the lowest value of three points.

Testing and Results

Testing

Initial qualitative testing on the design prototype was conducted by team members on Wednesday, December 7, 2011. Overall, 16 subjects participated in the study, and all were

students of the University of Wisconsin-Madison. These participants varied in age from 18 to 22, in height from 5'4" to 6'2", and in weight from 120 lbs to 210 lbs. Each subject used the device for five minutes, and performed distraction with an average force of 63.7 pounds.



This average force corresponds to a PSI of 20, as can be seen in Figure 9.

The test subjects were then asked to complete an evaluation form containing questions about their experience with the device (see Appendix). Each question included a rating scale of one to five, where a one signified a negative response while a five represented an exceptional

Figure 9: Calibration curve between PSI and pounds of force.

Ratings	Average	Std. Dev.
Overall	4.25	0.5774
Comfort	4.4375	0.6292
Usability	4.125	0.7188

experience (see Appendix). Comfort, usability, and overall effectiveness ratings were collected from each patient, averaged, and then analyzed to determine where future adjustments should be made. The results of these tests are displayed in Table 3.

Table 2: Testing Results

Qualitative values averaged from 16 test subjects. Rating scale is from one to five with one corresponding to a low rating, and five as the highest.

Discussion

As seen in Table 2, positive feedback and high scores were observed for each category. The highest scoring category in our testing was patient comfort with a score of 4.4375. It was indicated that the padding and vinyl fabric cover were pleasing to the subjects, which led to this high rating. The overall effectiveness rating scored in the middle with an average of 4.25. During testing, we received many comments indicating that the device is successful in separating the joints in the knee. However, none of the test subjects reported having knee osteoarthritis, so

they were not able to compare joint pain before and after the joint distraction. The lowest scoring category included in our survey was usability. Judging from observations and the comments received, this lower score could be attributed to a variety of different problems that arose with the prototype. First, the majority of the test subjects experienced difficulty when putting on and fastening the leg strap, requiring another person's assistance. Additionally, the cables frequently slipped out of the pulley tracks, also requiring another person to adjust the apparatus before distraction could take place. A slight leak in the connection between the hand pump and air hose also hindered usability because it was difficult to maintain a constant distraction force on the knee. By applying this feedback, changes can be made to improve the functionality and usability of the knee traction device.

In the future, a similar evaluation will be given to physical therapy patients suffering from knee osteoarthritis when using our device for distraction therapy. The patient will be instructed to use the device for a period of seven days, and joint distraction will be performed twice a day for 20 minutes. Patients will fill out the evaluation every day, rating their experience with the device from one to five, similar to the procedure our test subjects followed. Comfort, usability, and overall effectiveness ratings will be collected from each patient, averaged and analyzed. If there is no change in comfort or pain, adjustments will be made in order to increase the effectiveness of the device in these areas. Tests will be run on a multitude of users ranging in height, weight and age to ensure that the device can safely be used by all patients.

Although these patient evaluation forms provide feedback and qualitative data, in the future, quantitative analysis will be completed as well. Our team plans to

compare an x-ray of the patient's knee with the device to an x-ray of the patient's knee without using the device, an example of which is seen in Figure 10. An image of the distracted knee would enable us to see the physical distance between the bony ends of the tibia and femur when a distraction force is applied and compare it to the natural space between the joints without application of this force [9]. After consulting our client and experts in the field of physical therapy and orthopedics, we can determine the distance between the bones that will optimize distraction treatment. Using this joint space data, a



Figure10: An x-ray of a distracted knee from invasive knee osteoarthritis treatment [8].

calibration curve can be constructed relating a person's weight to the force required to reach this joint space. Ultimately categorizing this data according to height and weight will allow necessary adjustments to be made to the device to allow a comfortable and effective experience for a multitude of users.

Future Work

There are many items that still need to be addressed before our device fully meets the established product design specifications. First, our current device is fabricated out of wood, and although it is stable and durable, the device is far too heavy. To make it more convenient for the patient to transport, in a future design the device should be constructed from lightweight plastics or metal. Ideally, the device will also be collapsible for easy storage in the home. Second, it will be necessary to develop a strap and cable system that is adjustable to accommodate patients varying in height and weight. The current strap is permanently fixed to the cables, causing the wire rope to often run down the back or front of the leg when being used by patients with smaller or larger legs. Also, a barrier to keep the cables in their respective pulley tracks during patient setup and throughout the time the device is in use should be an addition to the device. However, the component that requires the most revision in future prototypes is the hand pump and its respective connections. The hand pump used with the current device is normally used for bicycles, and the threads are not compatible with the rest of the hosing system. In the future, it will be necessary to either fabricate a custom adapter to attach the pump to the gauge, or find a hand pump with pipe threads to make the connection airtight, more durable, functional, and visually appealing. Additionally, the hand pump should have a release mechanism to allow the air cylinder to retreat to its original position after distraction. Currently, to release the air from the cylinder, it is necessary to unscrew one of the hose connections from the adaptor. Therefore, to improve the safety and usability of the device, a release valve is imperative in future prototypes. In all, there are various improvements that can be made to the device in the future, and with these modifications, it could soon be a marketable device.

Cost

The fabrication of our device was based on a hand pump design with an air cylinder. As determined by our client, the final budget for the device is \$500. The costs in building our prototype include:

Item	Purchased from	Item #	Price	Quantity
Cast wire rope clips	McMaster-Carr	31985T71	\$1.41	2
Gauge adaptor	McMaster-Carr	50785K226	\$4.68	1
Accuracy gauge	McMaster-Carr	4026K26	\$55.54	1
Air Cylinder	McMaster-Carr	6498K954	\$35.86	1
Pulley	McMaster-Carr	9466T75	\$5.85	2
Coated Cable	McMaster-Carr	8923T511	\$0.92/ft	10 ft
Foot Brackets	McMaster-Carr	6498K34	\$3.95	2
Hose	McMaster-Carr	5304K388	\$13.19	5 ft
Thread size adaptor	McMaster-Carr	48805K252	\$11.22	1
Pulley	McMaster-Carr	9466T73	\$8.35	2
Adaptor	McMaster-Carr	97088A205	\$2.45	1
Rod End	Grainger	6G173	\$10.26	1
Mueller ltb strap	Amazon		\$9.81	1
High density pads	JoAnn Fabric		\$13.99	1 yd x 1 yd
MedBlue Marine Vinyl	JoAnn Fabric		\$16.99	1 yd x 1 yd
2x4x6 SPF Construct	Menards		\$1.39	5
3/4" min 7.9 S	Menards		\$9.59	1
8 oz. tightbond II Wood	Menards		\$2.98	1
Multi-mate 10x2-1/2 ph	Menards		\$5.99	1
1/2" Chisel point staples	Menards		\$2.29	1
Adjustable knee brace	Dick's Sporting Goods		\$12.99	1
Avenir air pump	Dick's Sporting Goods		\$14.99	1

Final Total = \$298.42

Table 3: Contains prices of materials for construction of our device.

Timeline

Tasks	September				October				November				December	
	9	16	23	30	7	14	21	28	4	11	18	25	2	9
Meetings														
Advisor	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Client	X					X		X						X
Team	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Product Development														
Research	X	X	X	X	X	X	X							
Brainstorming		X	X	X	X	X	X							
Design Matrix				X	X	X	X							
Design Prototype						X	X	X						
Order Materials									X	X	X	X		
Fabricate Prototype										X	X	X	X	X
Testing														X
Deliverables														
Progress Reports	X	X	X	X	X	X	X	X	X	X	X	X	X	X
PDS		X	X											
Mid Semester PPT							X							
Mid Semester Report							X							
Final Report														X
Final Poster														X
Website Updates	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Table 4: Timeline

Projected timeline of work throughout the semester with checks upon tasks completed up to current date.

Table 4 shows our timeline with goals outlined from this semester. As you can see, filled boxes are our projected timeline and the checks are the actual progression. Overall, our team stayed within our projected timeline.

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Appendix

Creating distraction at the knee joint: a treatment option for osteoarthritis (Knee Traction)

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Advisor: Tracy Puccinelli, Ph.D.

Function:

Knee osteoarthritis affects millions of Americans and people around the world. It is a painful, degenerative disease for which there is no cure. Thus far, no treatment option has been shown to halt or reverse tissue damage. However, joint distraction has been shown to increase cartilage thickness, decrease denuded bone area, decrease pain and improve functional ability. It is a procedure that gradually separates the two bony ends of a joint for a specified period of time. This principal can be applied to the knee joint. We will be creating a non-surgical device that can be used as a home-based intervention to create joint distraction in the knee. No such device currently exists. The theory is that when used regularly, someone could potentially delay or eliminate the need for a knee replacement.

Client Requirements:

- A device that will distract the knee in order to stop or slow the progression of osteoarthritis.
- A device simple enough to be used at home by patients who may have limited mobility.
- Reach a maximum of 311.4 N (70 pounds) of pressure to distract the knee joint apart.
- Fit a wide range of patients in weight and size.
- Provide a constant force to maintain distraction for 20 minutes.
- Keep knee at a 30° angle from the horizontal, or the “open pack” position, to optimize separation of the knee joint.
- Take caution to not distract the ankle and hip joints.

1. Physical and Operational Characteristics

A. Performance Requirements: The device must be able to keep a patient’s knee distracted for a period of 20 minutes. The device must also reach a maximum pull of 311.4 N (70 pounds) and be easily stored in the home. It must be functional for a wide range of patients regarding size and dexterity.

B. Safety: The device must provide enough pressure to distract the knee but not cause injury to the joint or distract the hip or ankle. It also must be stable so that when force is applied, there is no extra movement that would put the user at risk.

C. Accuracy and Reliability: The device must be able to maintain a constant pressure up to 311.4 N (70 pounds) for a period of 20 minutes, multiple times a day. The force used to distract the knee joint will be easily adjusted by a patient based on their needs. The knee must also be kept at an angle of 30 ° to maintain an “open pack” position.

D. Life in Service: The device should maintain function for a minimum of 15 years. Ideally, the product should last a lifetime.

E. Operating Environment: The finished device will be used in the home on a firm, flat surface, and the user should be seated in a firm chair that is 0.5 meters (19 inches tall).

F. Ergonomics: As this device will be used by a range of patients at varying heights and weights, ergonomics is extremely important. The device must be functional for anyone weighing from 100 to 400 pounds. The prototype must also be adjustable, user friendly, and easily transported.

G. Size: The traction unit must be shorter in length than one meter, 0.5 meters tall, and wide enough to accommodate a wide range of leg sizes.

H. Weight: The traction unit must be lightweight so that it can be lifted by a patient who suffers from osteoarthritis in the knee. However, it should not be so lightweight that it impedes functionality or usability.

I. Materials: The materials used should be strong and durable for the device to last many years, as well as be nonabrasive to the skin. Materials used are nylon coated cables, wood covered in foam padding with a layer of vinyl fabric, pulleys, cotton straps, Velcro straps, cylinder mounting clips, and an air cylinder with a hand pump and gauge.

J. Aesthetics, Appearance and Finish: Since this device will be used in homes, it must be aesthetically pleasing and have a smooth, streamline design.

2. Production Characteristics

A. Quantity: We will be constructing one device.

B. Target Product cost: The target product cost will be at or below \$500.

3. Miscellaneous

A. Standards and Specifications: If marketed, the product will require approval from the FDA.

B. Customer: The intended customer for this device is anyone who may suffer from knee osteoarthritis that would prefer a way to ease their pain and prolong the amount of time before knee replacement surgery is needed by using an at home system. The patients will be of varying height, weight and ability level, therefore the product must be compatible to many different body types. All of these requirements must be considered in designing a final product.

C. Patient-related Concerns: The device must not be harmful to the user in any way and be comfortable so as to not put the patient in any more discomfort than already caused by their knee osteoarthritis.

D. Competition: Currently, there is no competition as there is no at home product for distracting the knee available on the market. Knee distraction is only done in a clinical setting and even then is very cumbersome to execute.

Knee Traction Unit 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?

Additional comments:

After using this device I feel (Please Circle):

1 2 3 4 5

Same or worse

No pain, 100% better

Please rate the comfort of the device (Please Circle):

1 2 3 4 5

Awkward, leg was strained during use

My leg did not feel strained

Please rate the 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

Note:

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: Kelsi Bjorklund, Lindy Couwenhoven, Taylor Lamberty, Amy Martin, Jacob Stangl, and the University of Wisconsin-Madison.

Signature:

Date: