



**College of Engineering**  
UNIVERSITY OF WISCONSIN-MADISON

# **Creating distraction at the knee joint: a treatment option for osteoarthritis**

## **Mid-Semester Report**

October 26, 2011

### **Team Members**

Kelsi Bjorklund

Jacob Stangl

Taylor Lamberty

Amy Martin

Lindy Couwenhoven

### **Client**

Kim Skinner, P.T.

### **Advisor**

Tracy Puccinelli

## **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. Knee osteoarthritis is a painful and degenerative disease that is caused by the deterioration of the articular cartilage in the knee, causing a narrowed joint space [1]. Symptoms include pain, stiffness, limited range of motion, and localized swelling [1]. Currently, there is no treatment option to halt or reverse tissue damage. However, it has been 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 which may prolong, or even eliminate, the need for knee replacement surgery.

## Table of Contents

Abstract	2
Background	4
Client Description	4
Current Devices	4
Marketed Devices	4
Problem Motivation	5
Design Requirements	6
Design Alternatives	7
Weight Design	8
Band Design	9
Pump Design	10
Design Matrix	11
Effectiveness	12
Patient Comfort	12
Safety	12
Durability	13
Cost	13
Portability	14
Future Work	14
Testing	14
Projected Costs	15
Wrap Up	15
References	17
Appendix	18

## **Background**

### ***Client Description***

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

### **Current Devices**

#### ***Marketed Devices***

The current clinical knee traction treatment uses a traction unit designed for lumbar and cervical traction. During lumbar or cervical traction, patients are strapped onto a traction table that has two separable horizontal pieces (Figure 1). By gradually increasing the distance between the pieces, force is applied to the patient's joints and distraction occurs. Traction tables



Figure 1: A traction device currently used for cervical and lumbar traction 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 [3].

can be adjusted to perform knee traction as well, but although the device provides a constant force at the knee, it also produces undesirable separation at the hip and ankle joints. Because the clinic apparatus is not meant for knee traction, it is difficult and cumbersome to set up. Overall, the current method is in need of improvement.

The client occasionally performs her own at-home method of knee distraction using ankle weights. Wearing the weights, she positions herself on a staircase and hangs her leg over the stairs. Gravity then pulls the knee apart, providing the knee

distraction. However, the ankle weights are not heavy enough, and therefore do not apply enough force to create significant and long-term results.



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

Currently, there are no devices on the market specifically for knee traction. However, cervical and lumbar devices do exist in a variety of different forms including portable, at-home treatment units. The Saunders Cervical Neck Traction Device, for example, is a twelve pound portable unit that can apply up to fifty pounds of force to distract the vertebrae in the neck (Figure 2) [4]. Another example, the MSEC Lumbar Traction Unit, uses a similar principle to distract the lumbar region of the back (Figure 3) [5].

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, so the user has constant control of the force exerted by the device [5]. Ideally, this unique hand-held pump could be incorporated into a portable knee traction unit.



Figure 2: 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 traction force [5].

### **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 subsequent pain [6]. OA in the joints can affect the hands, feet, spine, hips, or knees, and currently there is no cure.

Factors contributing to this disease include being overweight, aging, joint injury, heredity, and muscle weakness [6]. Treatments include weight loss, acupuncture, nutritional supplements, and for severe cases, full joint replacement surgery [7]. However, these options are not always available or obtainable for people suffering from the disease.

Recent studies have shown that distraction of joints allows for the cartilage cushioning ~~in~~ between the joints to grow back and thicken [1]. Joint distraction is a procedure that gradually separates the two bony ends of a joint for a specified amount of time [1]. As stated earlier, cervical and lumbar traction units are currently available on the market however, no traction unit for the knee has been produced yet. The goal of this design is to provide a non-surgical device that can be used as a home-based intervention to create distraction in the knee. The theory is that when used regularly, the effects of osteoarthritis could be diminished and potentially reversed. A device to distract the knee would have great payoff for patients by prolonging the life of their knee and either delaying, or completely eliminating the need for total knee replacement surgery.

### **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, performance standards, and patient comfort.

Safety requirements are crucial to the design process because they 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 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 31.8 kg (70 pounds). Increments of force should be available and total force should range from zero to 31.8 kg (70 pounds). It was also requested that the knee would ideally be positioned in a 30° angle from the horizontal, often referred to as the “open pack” position because this angle allows for the most separation between the bony ends of the tibia and femur.

Due to the wide variety of body types and sizes, the device will need to be adjustable. The client would also like the product to be portable so that patients are able to use it in their homes in between doctor visits. 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 and people with osteoarthritis will need to be able to operate it with ease and without causing further pain to their affected joints. Even though the device will be used two or three times a day in 15-20 minute increments, it will ideally last a lifetime. The client has set this list of requirements that she would like the design to meet; therefore these requirements will play a great role in the final design of the knee distraction device.

Finally, patient comfort is very important to consider when designing the device. All of the components of the device that will be in contact with the skin need to be non-abrasive and adjustable. The materials used should also be easily sanitized and cleaned. In addition, as the patient should feel relaxed while using the device, the knee and leg should be supported however all other parts of the body should not feel restricted or tense.

A wide range of components go into the design requirements, and all are taken into account when deciding on design options.

### **Design Alternatives**

Prior to building and testing, three design alternatives were conceptualized and evaluated based on criteria set in the design matrix. All three designs were created for the patient to be lying on their back, and will keep the knee at a 30° angle from the horizontal in order to maintain an “open pack” position. The designs will maintain this 30° angle through the incorporation of a right triangular structure underneath the leg. This structure also provides support of the leg and keeps the quadriceps and hamstring muscles relaxed so that no unnecessary tension forces are acting upon the knee. Another component incorporated into the three designs is a foot cart in which the foot and leg will be placed allowing stability and movement of the leg downward during distraction due to the applied forces. An additional component utilized by all three designs is a Velcro strap around the leg directly below the knee and above the calf which is attached to the foot cart system.

## *Weight Design*

The free weight design, as seen in Figure 4, utilizes a two pulley system, an inextensible band, and a group of free weights. The inextensible band is attached to the strap beneath the knee and then wraps underneath a pulley near the ankle of the patient, attached to the triangular structure. The inextensible band then runs from beneath the first pulley, over the top of a second pulley located on a vertical stand. The end of the inextensible band is then attached to free weights. The free weights supply the force which is redirected by the pulleys in order to distract the knee. The use of free weights allows the patient to know the exact weight being used to distract their knee, and specific increments of weight are readily available.

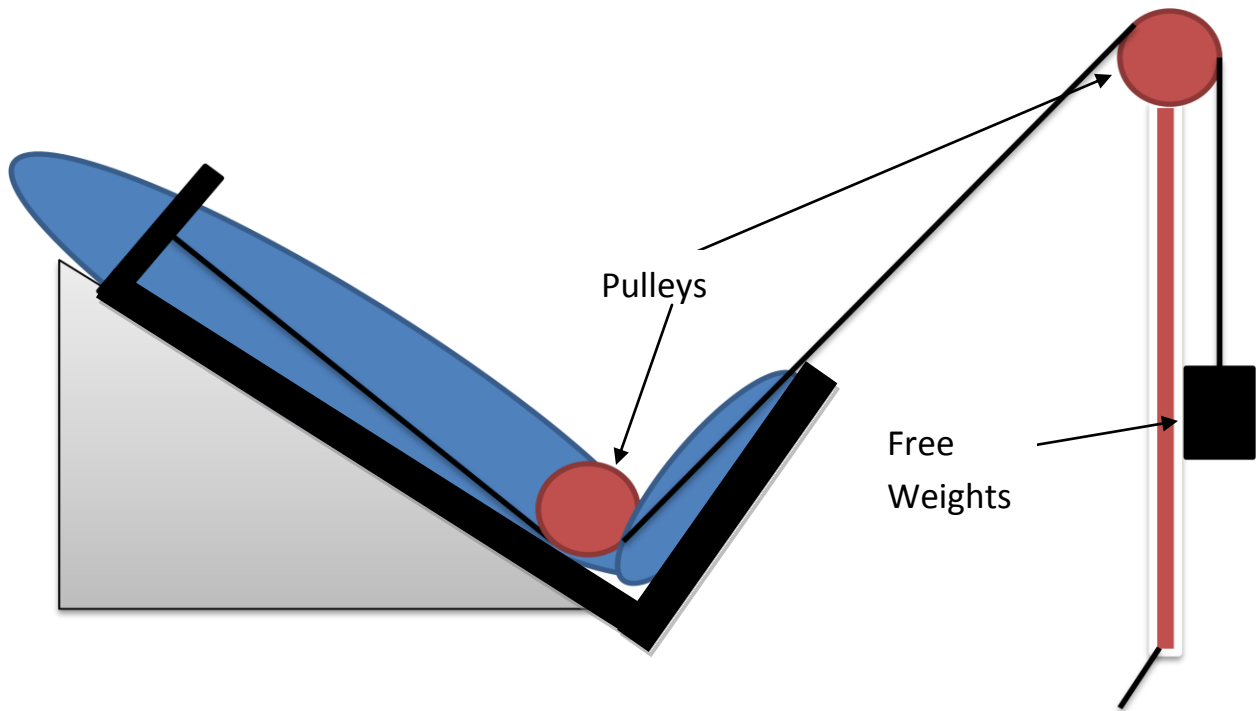


Figure 4: Free Weight Diagram

The free weight design utilizes a system of two pulleys, an inextensible band, a triangular structure, a foot cart, and free weights. The free weights supply the force in the system which is then redirected by the pulleys to distract the knee.



## ***Band Design***

The extensible band design, as seen in Figure 5, utilizes an extensible band, analogous to a Thera-Band or bungee cord, and a series of hooks. The band attached to the Velcro strap beneath the knee in this design is extensible and provides a tension force necessary for the distraction of the knee. The extensible band is wrapped around the top of a pulley near the patient's ankle which is attached to the triangular structure, and then comes back toward the triangular structure where it is attached to one of five different hooks.

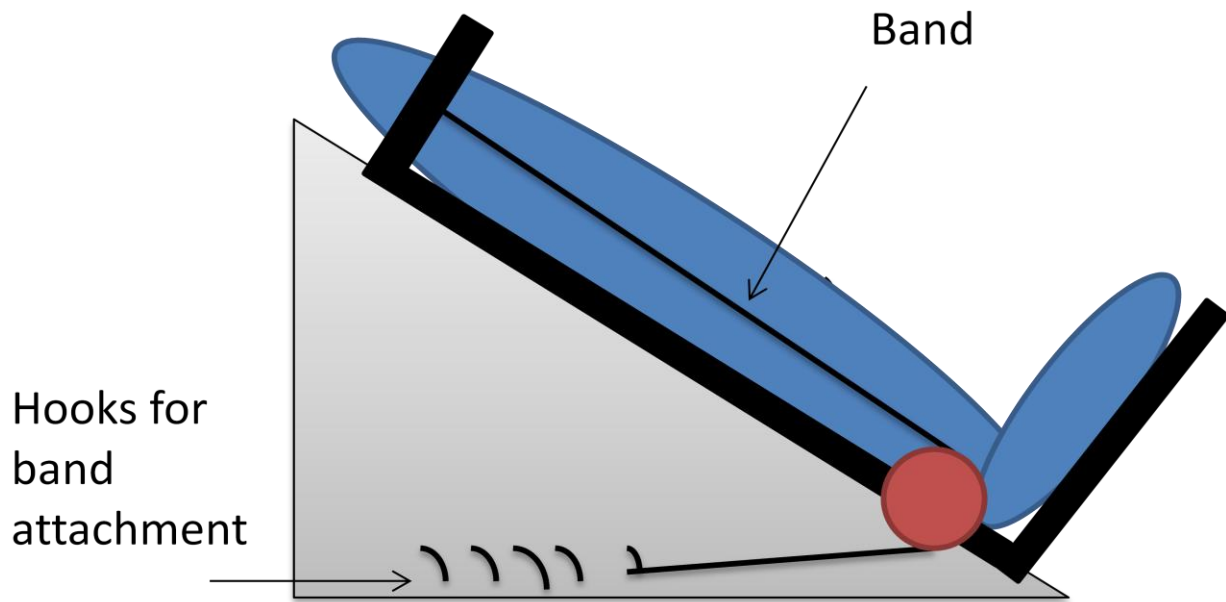


Figure 5: Extensible Band Diagram

The system consists of a foot cart, pulley, triangular support structure, Velcro strap, an extensible band, and a series of hooks. The extensible band provides the force to distract the knee through tension. The hooks provide varying levels of tension.

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. In addition to the different hook levels which will change the amount of force provided to the knee, different tension strengths of bands will be interchanged to provide varying levels of force.

## ***Pump Design***

The hydraulic pump design incorporates an air pressurized cylinder (much like the cervical and lumbar traction units currently on the market), an air hand pump with a gauge, a pulley, and an inextensible chord as seen in Figure 6. The inextensible cord is attached to the Velcro strap wraps around the top of a pulley near the ankle of the patient, and is angled around the pulley back towards the patient's body. The other end of the inextensible cord is attached to the piston of the air pressurized cylinder (also called an actuator). The actuator will be set in a position so that the piston is pushing in a negative -x direction back toward the patient, thus pulling the cord and distracting the knee. The actuator itself is attached to the inside of the triangular structure and incorporates a hand pump to apply pressure inside the cylinder, which causes the piston to supply force.

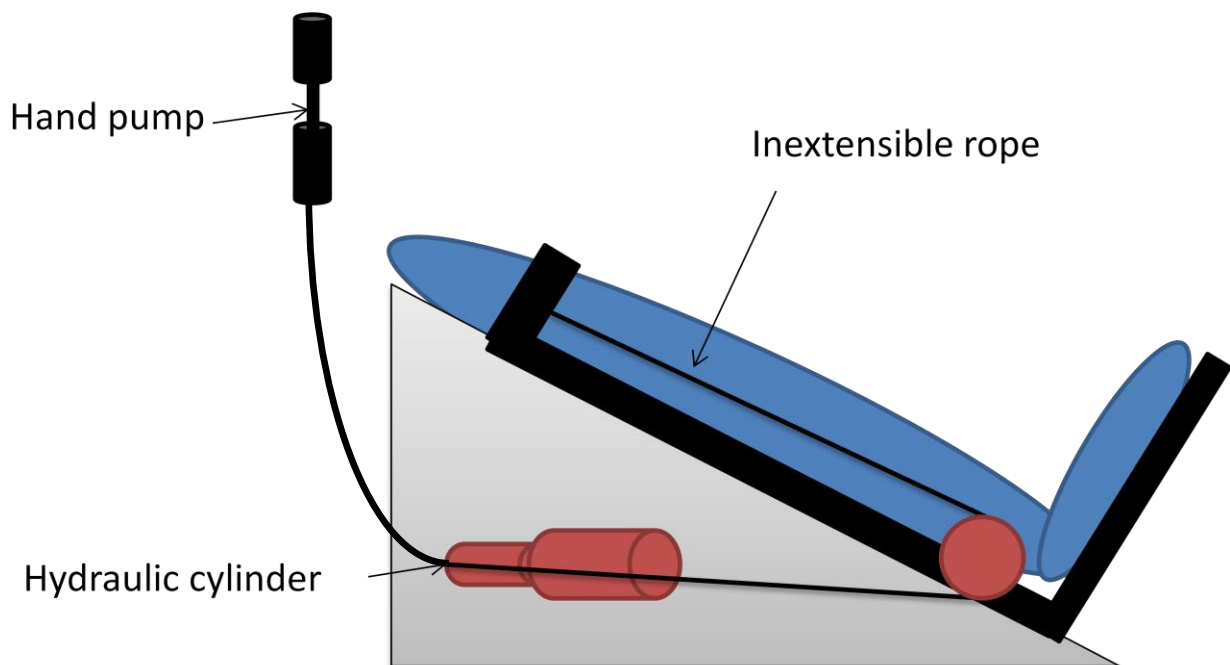


Figure 6: Hydraulic Pump Diagram

The hydraulic pump design utilizes a hydraulic cylinder actuator, an air hand pump, an inextensible rope, a pulley, a foot cart, 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 band. The inextensible band redirects the force to be parallel to the leg, therefore pulling the knee downward.

The hand pump will have a gauge to inform the patient of the amount of pressure that is in the actuator. 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 hydraulic 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 force values to apply to the knee.

**Design Matrix**

Each preliminary design had strengths and weaknesses in comparison to the others. To effectively evaluate the individual points of all three designs, a design matrix was constructed and used to analyze each.

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 weighed more heavily. The scores for each design in each category were 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 design we have chosen to pursue prototyping.

<b>Weight</b>	<b>Criteria</b>	<b>Pump Design</b>	<b>Band Design</b>	<b>Weight Design</b>
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
<b>100</b>	<b>Total</b>	<b>82</b>	<b>80</b>	<b>71</b>

Table 1: Design Matrix  
 The maximum point values are indicated in the left-most row.  
 The point allotment will be discussed in the proceeding analysis.

### ***Effectiveness***

If a product is not effective, it does not fulfill its purpose. 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 scored the highest, receiving 23 out of a possible 25 points. It was closely followed by the free weight system (21 points) and the band system (20 points). The pump system 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, no matter the frequency of use. The free weight device scored the second-highest because while it would be effective and use gravity to its advantage, the device might apply a greater instant force, rather than one that would be gradual and constant. The band system received the fewest points because even over a short time, the bands would lose elasticity and therefore, be less effective.

### ***Patient Comfort***

Patient comfort is a significant aspect of the design, and was also given 20 points in the design matrix. The comfort of patients while using this device is even more important than other devices because it will be used in the patient's home multiple times per day. If the patient is not comfortable while performing distraction, they will not use the product. Comfortable, yet durable fabrics will be used for the straps and padding of the device to constrain the knee but not irritate the patient's skin. 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 traction force will be applied gradually in both designs, patient comfort will be better optimized. The weight design received a slightly lower value of 18 points for patient comfort because the traction force will be immediate, and it also may be uncomfortable for a patient with knee osteoarthritis to lift a free weight onto the pulley system.

### ***Safety***

Safety was weighted at 20 points in the design matrix because our design will be used by individuals and should not cause any pain or harm. The traction force from the device should not

distract any joints other than the desired knee joint. Also, the fact that the device will be used in the home magnifies the need for a safe device. The pump design scored the highest in this category with 18 points because the distraction force would be applied gradually, and the design would provide the least amount of risk to the patient. The band design scored the next highest with 17 points, as the traction force would still be applied gradually, yet bands may snap causing possible injury to the patient. The 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 preferably a lifetime. Thus, 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 every component. Durability was given a maximum of ten points in the design matrix, because the patients will be using the device at home and therefore will be in charge of the maintenance of their own equipment. The pump design was given nine points as the only component that could weaken over time would be the pump system. Since the pump would not be applying an excessive amount of force, it was determined that the chance for failure was fairly low for this extended amount of time. Given the second greatest amount of points was the free weight design, which received six points. It was suspected that the pulleys used to reroute the inextensible rope may wear out over time, as may the rope itself. The band design was given three points, the least amount in this category because of the lack of necessary strength in the bands. They may stretch and break over time which would require the patient to purchase multiple bands, or replace them frequently.

### ***Cost***

In order for the device to be marketable, it must be cost effective. 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. Cost was given a value of 15 points in the design matrix. The band design was given the highest value of 13 points because these bands are readily available and

inexpensive. Ten points were given in the cost category to the weight design as weights would be more expensive than the bands, and the pulley design would cost more to manufacture. Finally the hand pump was given the lowest value of seven points in cost as hydraulic pumps 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 but would likely not 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 the category of portability. This design would be of the lightest weight and have the least amount of components. The pump design was given the next highest value of five points as it would involve a hydraulic cylinder that would add some weight to the device and hinder portability. Finally, as it would be quite difficult to transport free weights, the weight design was given the lowest value of three points.

### **Future Work**

#### ***Testing***

Preliminary testing has yet to be completed, as there are no current knee distraction devices on the market. However, the team has had the opportunity to observe lumbar and cervical traction devices used by our client. Both of these units are run using hydraulic pumps, which furthered thoughts that the pump design for knee distraction would be feasible.

Future testing on a prototype will include testing on team members and eventually physical therapy patients to determine its usability and effectiveness. The user will be instructed to use the device for a period of seven days. Joint distraction will be performed twice a day, for 20 minutes to ensure a consistent way to determine effectiveness. Patients will be given a journal to record their experience with the device every day, and asked to create a summary at the end of the week focusing on whether a noticeable improvement has been observed. If there is no change, adjustments will be made in order to increase its effectiveness in relieving the patients'

symptoms. 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. All of the team members are currently in the process of obtaining the human subjects training necessary for completing this testing.

***Projected Costs***

We are planning on creating and testing a pump device. As determined by our client, the final budget for the device is \$500. The major component of the final expense report will be the pump, as research by the group members has shown that the costs of such a part are high. However, as there are few parts needed to construct the device, the final prototype is expected to fall below this limit.

***Wrap Up***

Table 2 shows our timeline with goals outlined from the beginning of the semester until now. As you can see filled boxes are our projected timeline and the checks are the actual progression, with the team either completing or in the process of accomplishing these tasks. Up to this point in the semester, we had wished to have ordered parts to fabricate a prototype, and have started constructing it, but these have not yet become a reality. However, a list of necessary materials has been formed, and they are scheduled to be ordered this week. Overall, our team has stayed within our projected timeline thus far.

Tasks	September				October				November				December	
	9	16	23	30	7	14	21	28	4	11	18	25	2	9
<b>Meetings</b>														
Advisor	X	X	X	X	X	X	X							
Client	X					X								
Team	X	X	X	X	X	X	X							
<b>Product Development</b>														
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							
Order Materials														
Fabricate Prototype														

Testing															
<b>Deliverables</b>															
Progress Reports	X	X	X	X	X	X	X								
PDS		X	X												
Mid Semester PPT							X								
Mid Semester Report							X								
Final Report															
Final Poster															
<b>Website Updates</b>	X	X	X	X	X	X	X								

Filled boxes = projected timeline

X = task was worked on or completed

Table 2: Timeline  
 Projected timeline of work throughout the semester with checks upon tasks completed up to current date.



## **References**

- [1] Interna F., Van Roermund PM, Marijnissen ACA, et al. Tissue structure modification in knee osteoarthritis by use of joint distraction: an open 1-year pilot study. *Annals of the Rheumatic Diseases* (May, 2011).
- [2] Skinner, Kim. Interview by studiomelt.com. *studiomelt*. (2011). Retrieved 10/23, 2011, from <http://studiomelt.com/kim.html>
- [3] *Traction tables and units: tables and units*. (2011). Retrieved 10/23, 2011, from <http://www.keitzer.com/Qstore/Qstore.cgi?CMD=009&DEPT=1137884894&CAT=000054&BACK=A0007A1B01137884894B>
- [4] *Saunders Cervical Traction Device*. (2011). Retrieved 10/23, 2011, [http://www.empi.com/empi\\_products/detail.aspx?id=230](http://www.empi.com/empi_products/detail.aspx?id=230)
- [5] *Saunders Lumbar Traction Device*. (2011). Retrieved 10/23, 2011, from [http://www.empi.com/empi\\_products/detail.aspx?id=232](http://www.empi.com/empi_products/detail.aspx?id=232)
- [6] *Types of arthritis*. (2011). Retrieved 10/23, 2011, from <http://www.vimovo.com/types-of-arthritis.aspx>
- [7] *Diseases and conditions*. (2011). Retrieved 10/23, 2011, from <http://www.mayoclinic.com/health/osteoarthritis/>

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

### **Product Design Specifications**

10/24/2011

**Group Members:** Kelsi Bjorklund, Jacob Stangl, Taylor Lamberty, Amy Martin, Lindy Couwenhoven

**Advisor:** Tracy Stefonek Puccinelli

#### **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 a joint distraction to 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 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, the open pack position, to maintain largest 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 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 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 degrees 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 mattress or other flat surface where the user can stably lie on their back.

**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 as well as set up.

**G. Size:** The traction unit must be small enough to fit on a typical kitchen or desk chair.

**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 nonabrasive to the skin. Materials that will be 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 \$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 put off surgery 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 final product must meet any and all FDA requirements. It must not be harmful to the user in any way and be comfortable so as to not put the patient in any more discomfort.

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