CT Foot Loader

Midsemester Report

March 14, 2007

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Abstract

A CT scan can be used to find anatomic subtleties in the feet and ankles that are not seen in a radiograph. A radiograph is taken with the patient bearing weight, whereas the CT scan is not, sometimes resulting in conflicting images. There is currently no standard device used with CT imaging to ensure the feet and ankles are held in a consistent, standard position, as well as simulate the patient bearing weight during the scan. For this reason, a device was constructed for use with a General Electric CT scanner that would simulate weight-bearing conditions – to match the conditions of a radiograph – and have the feet set together in an upright position. Continued work with the prototype includes modifying the device so that it is more appealing and adapting it for use with MRI.

Problem Statement

While nearly all feet radiographs are shot with the patient bearing weight, computed tomography (CT) scans of the feet and ankles are done in non-weight bearing conditions. A device that applies a load to the feet during a CT scan, thus better simulating the anatomic alignment of the bones and tissues under physiologic loading, is needed. The device must also secure the feet upright and together, in order to establish a standard position for CT imaging of the feet and ankles.

Background

Computed Tomography

Computed tomography is an X-ray-based medical imaging modality. The basis of X-ray imaging is that different materials or tissues have different X-ray attenuation, the fraction of a beam that gets scattered or absorbed by the material per unit thickness. As a material’s attenuation coefficient increases, the amount of energy that can pass through the material decreases. Bones have a much higher coefficient of attenuation than soft tissues, creating contrast between bone and soft tissue in X-ray images. The CT scanner takes projections from many angles and builds the output using a reconstruction algorithm. The intensity of the resulting image is a map of attenuation. CT provides both 2D cross-sectional images and 3D renderings, which can allow for easier human interpretation of complex anatomical geometries.

Our client, Dr. Schreibman, uses a GE Lightspeed 64-slice model, as seen in Figure 1. The patient lies down on the table and a technician secures the patient with padded straps before the scan is conducted. During the scan, the table moves at a constant velocity through the hole in the gantry while technicians monitor the process through an adjacent control room. According to our client, typical scans are completed in 20 seconds or less.

Figure 1
This is a picture of the CT scanner our client uses. The device is located near the gantry at the end of the table.

Our client is specifically interested in CT imaging of the feet and ankles. Areas of interest to our client include the Lisfranc joint (tarsal-metatarsal joint [4]) and the posterior tibial tendon (connects calf muscle to the navicular bone, which contributes to the arch of the foot [6]).

Generally, patients that have chronic, unexplainable foot pain, the source of which cannot be found using other imaging modalities such as X-ray radiographs, resort to CT. It is not known specifically how the images will differ in loaded versus unloaded conditions, but it is hypothesized that there will be anatomic subtleties only visible when the feet are imaged under a load. For example, our client has observed feet that have a high arch when unloaded flatten out when a load is applied. The hypothesis will be tested in a research study with this device, as discussed in the future work section of this report.

In addition, there is currently no standard position for CT imaging of the feet and ankles, making comparisons between different images difficult or impossible. This device would help to establish a standard position: the feet together and upright, or perpendicular to the legs.

Client Requirements

Our client's requirements for the foot loader are listed as follows:

1. **Low X-ray attenuation:** all materials in the scanning field, defined from the ankle to the bottom of the foot, must be radiolucent in order to avoid interfering with or creating artifacts in CT images.
2. **Apply load to feet:** the device must be able to apply an adjustable load of up to 50 pounds to the feet.

3. **Measure the load:** the device must be able to measure the load with an accuracy of ± 1 lb.
4. **Hold the feet:** the feet must be held securely for the duration of the scan (usually under 30 seconds, according to our client). They should be positioned together and upright, with the feet perpendicular to the legs.
5. **Portable:** the device must be lightweight and easily movable by one technician.
6. **Cleanable:** the portions of the device that come in contact with the patient must be cleaned easily and resistant to common disinfectant chemicals that are used for cleaning after each scan.

For a more detailed description of the design requirements, please see the Product Design Specification in the Appendix.

Materials

Several criteria were considered when selecting materials for the device:

1. **X-ray attenuation:** any material in the scanning field must be radiolucent to avoid interfering with CT imaging.
2. **Strength:** must withstand reaction forces from load on feet.
3. **Weight:** lightweight materials are required to improve portability.
4. **Cost:** low cost materials are preferred.

A material's X-ray attenuation varies with the energy of the X-rays passing through it [8]. Dr. Schreibman conducts his ankle CT exams at 120-140 keV and 100-400 mA. For these energy levels, the Hounsfield scale (unit: HU) quantifies the radiodensity, or relative transparency of a material to X-rays [3]. The standard defines air at -1000 HU and water at 0 HU. A material's HU value is also often referred to as its CT number. Figure 2 displays the CT numbers for various materials [7]:

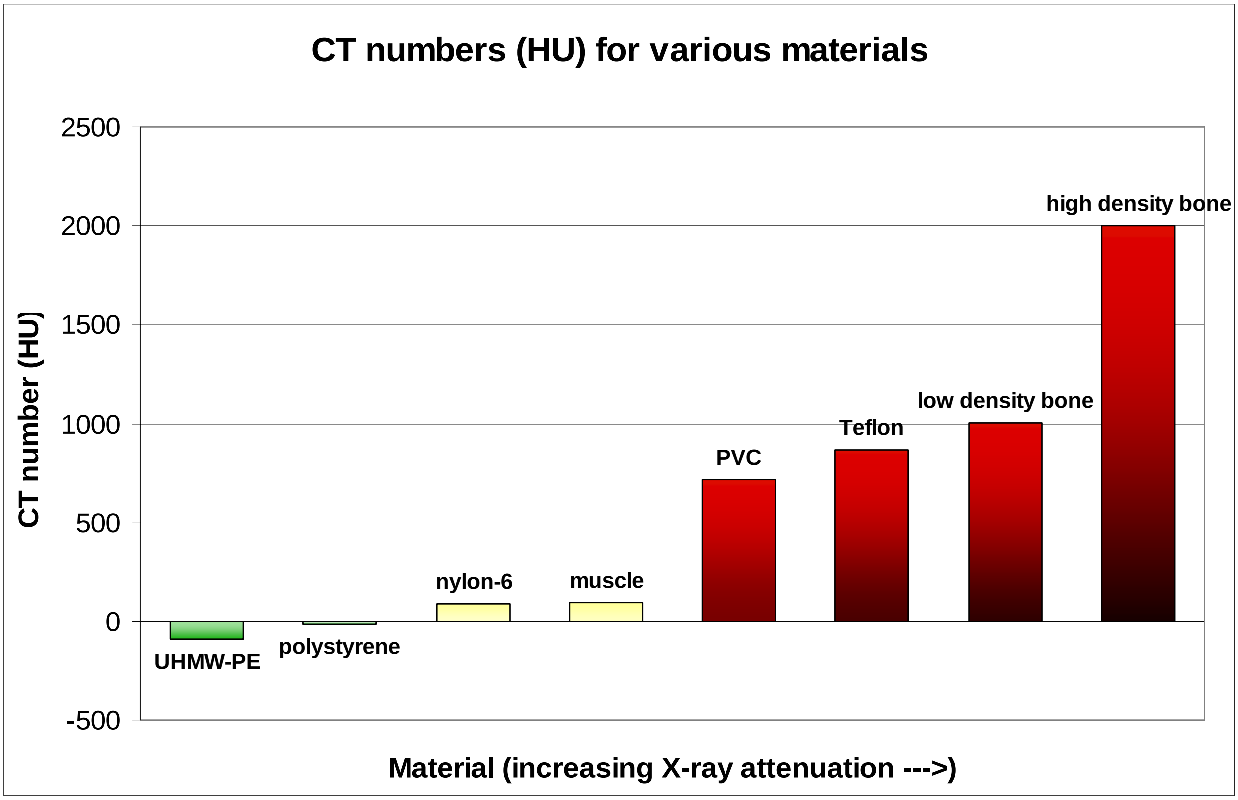

Figure 2
Graph of the CT numbers obtained from Schneider, *et al.* [7]. This is a measure of each material's attenuation. The values are relative to water, which has a CT number of zero.

As seen in Figure 2, polyethylene, UHMW-PE, has a very low CT number of –89—the lowest out of the common thermoplastics on the graph. Once it was known that polyethylene has exceptionally low X-ray attenuation, its other properties were investigated.

Two large plates of a phenolic-paper composite material, called NP843, were donated by Norplex-Micarta. According to the company, this material is extensively used in the medical industry for X-ray tabletops, as it is strong and radiolucent. This material will be used for the final prototype.

Previous Semester

Overview

The mechanism used to apply the force to the feet is a pneumatic air bladder. The device consists of two parallel plates, one stationary and connected to the CT table, and the other capable of linear motion in the horizontal direction only. The bladder will be attached between the two plates, with a tube running from the air bladder, through the back plate, and connecting to the air pump, to be described in detail later. The patient will be in control of the force being applied to their feet, being able to cease inflation if discomfort occurs, via a remote control. As the bladder inflates the two plates spread apart, thus applying a force onto the feet.

Preliminary Prototype

A side view drawing of the final design can be seen in Figure 3. Every GE Healthcare CT table is equipped with a standard connection port for table accessories and the final design made use of this. A GE Healthcare CT head holder was cut and used to connect the device to the table. The head holder was made out of a carbon fiber composite. Attached to the head holder is a 12”x12”x0.5”stationary plate made of UMHW polyethylene. Two blocks, each 4”x1.5”x1.5”, made of the same polyethylene material were welded to the back of the stationary plate. Two 3/8” diameter holes were then drilled through each of the two blocks and through the head holder. Two 3/8” diameter rods were placed through the drilled holes on each side of the head holder, effectively fastening the stationary plate to the head holder. An inflatable air wedge was placed between the stationary plate and a free-sliding 12”x12”x3/8” plate, called the “load plate”. The air bladder is inflated via a manual hand pump and release valve. The pump would ideally be operated by the patient but could also be operated by the technician if the patient was incapable of doing it. There is a 6’ long vinyl hose that connects the air bladder to the hand pump. To ensure the load plate did not rotate, four 4” long x 3/8” diameter UHMW polyethylene guide rails were implemented. A mechanical scale was connected to the load plate via Velcro straps to measure the load. After placing the device in the actual CT scanner, some minor adjustments were needed. These include the length of the tube and, more importantly, since the GE table has a curved top, both the bottom of the stationary plate and the bottom of the load plate needed to be cut to the same curvature. The components of the final prototype are summarized in Figure 4. Pictures of the final prototype in the actual CT scanner can be viewed in Figure 5.

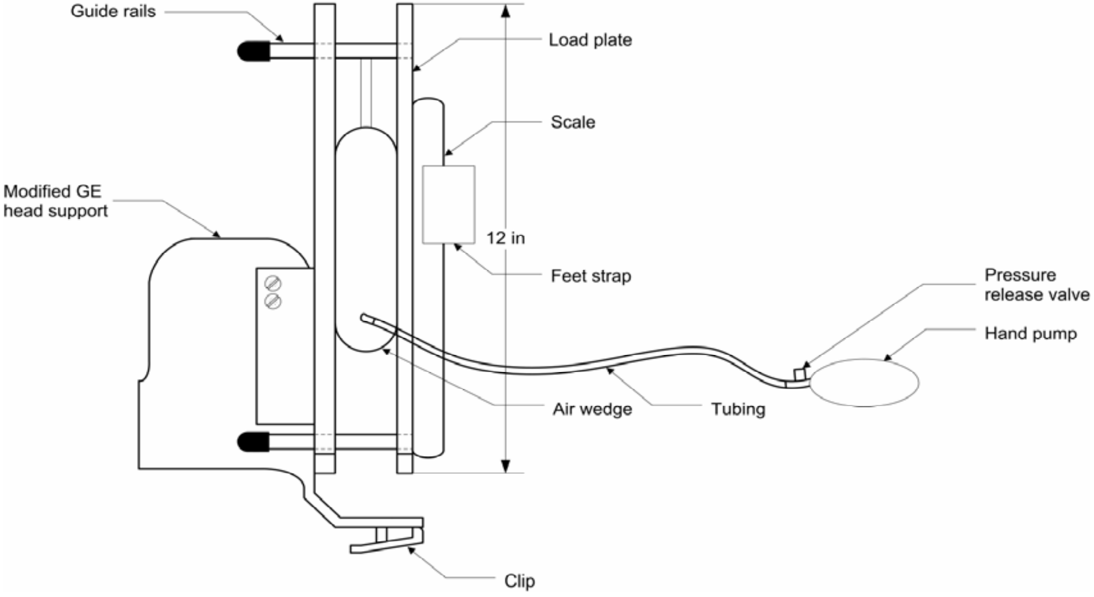

Figure 3
Side view computer aided drawing of the final prototype. The force is generated by an inflatable air wedge located in-between the two plates. The air wedge is inflated via a hand pump operated by the patient. The load is temporarily measured by a scale underneath the patient’s feet. The head holder is used to have the correct connection between the device and the standard GE table.

Component	Description	Price
Inflatable vinyl air wedge	Generates the load on feet; includes pump and valve	$34.22
12x12x1/2" UHMW sheet	Rear plate, mounted to head support	$10.94
12x12x3/8" UHMW sheet	Load plate	$8.48
1'x1.5"x1.5" UHMW bar	Connects rear plate to head support	$8.15
Strap	Secures feet in upright position	$6.99
Velcro	Fastens the strap	$5.99
Mechanical scale	Temporary force measurement mechanism	$5.97
10 ft long vinyl tubing	Allows patient to operate pump	$3.99
5'x3/8" diameter UHMW rod	Guide rails to prevent load plate torsion	$3.80
Shoe lace	Used to hang air wedge from top guide rails	$1.99
Electrical tape	Temporary nuts on guide rails	$1.99
GE carbon fiber head support*	Fits CT table with proprietary clip mechanism	$0.00
	Total cost:	**$92.51**

Figure 4
A summary table of the final prototype components with description of function and cost.

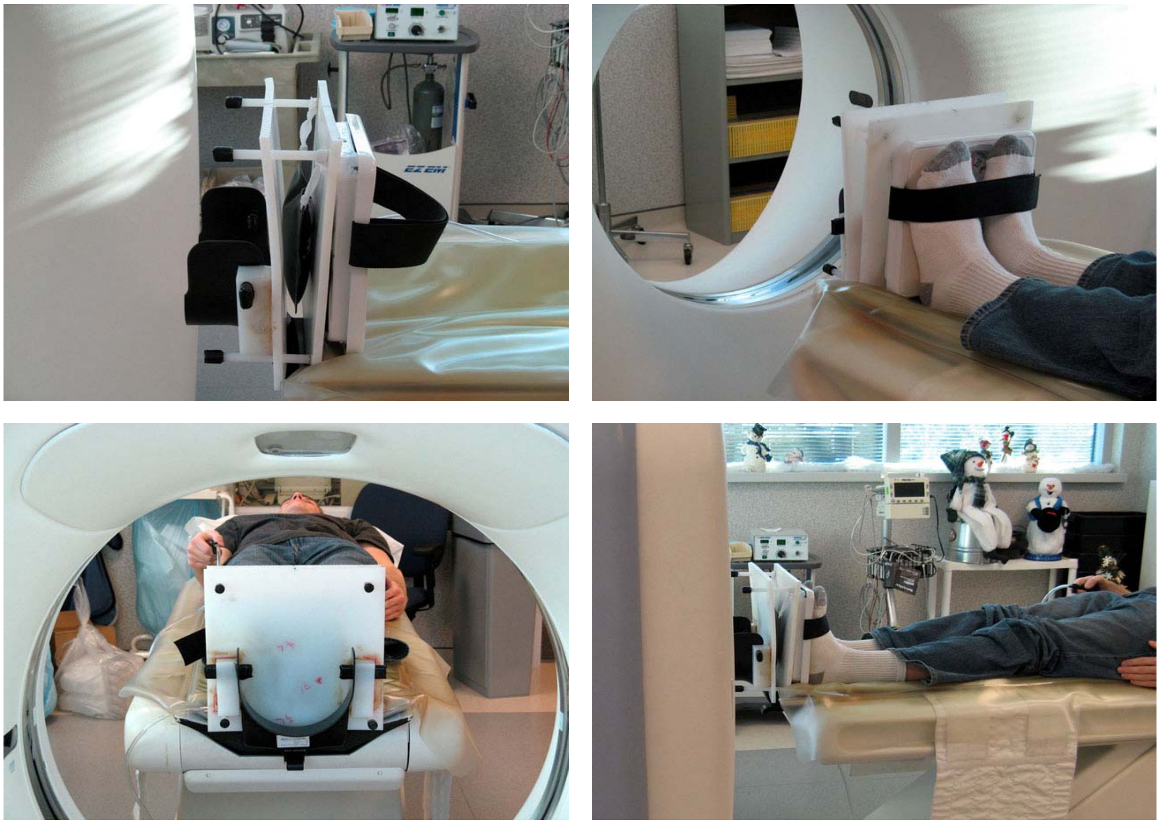

Figure 5
Pictures of the device in the CT scanner. The picture in the top left is a side view of the device. The picture in the bottom left is a picture of the bottom of the prototype through the gantry. The picture in the top right is an angled view from the patient's perspective. The bottom right picture shows a wider view from the side.

Current Device Components

Air Bladder and Force Measurement

As mentioned previously, there will be an air bladder that will inflate between two plates to create the force being applied to the feet. There are a couple necessary attributes that the air bladder must entail. First, the ends of the bladder must be flat. This is indirectly measure the amount of force being applied to the feet. Pressure is related to force in the following equation:

$$Pressure = \frac{Force}{Area}$$ **Equation [1]**

The pressure in the bladder can be measured simply by an air pressure gauge, such as Figure 6a shows, or, more desirably, through a transducer designed to convert pressure to a voltage output, as Figure 6b displays. This voltage can then be manipulated with simple circuitry to represent the force being applied and displayed with a simple LED.

Figure 6a
Digital air pressure gauge to measure the pressure in the bladder.

**http://www.ashcroft.com/*

Figure 6b
Air pressure transducer, which converts air pressure to a voltage, which can be manipulated with simple circuitry to output the force.
**http://www.ashcroft.com/*

Theoretically, the plates should not move in any significant amount, because as the bladder inflates, the stable feet should not move, allowing the pressure in the bladder to increase without causing the plates to move. However, with the previous prototype, 2-4 inches of displacement was observed. For this reason, the bladder should be able to inflate 2-4 inches.

The final requirement is that the bladder must be cost effective. Since the air bladder needed for this application is quite specific, they are not readily available, and most are only available if custom built. After contacting a variety of air bladder companies, the price range for a bladder built to the specifics noted in Figure 7 is between 300 to 700 dollars. Since this is out of our desired price range, an eight inch inflatable vinyl cube was purchased, as depicted in Figure 8. The ends are flat and the bag is capable of extending up to eight inches, which will be applicable. Since the cube has eight inch sides, the surface area is 64 square inches. The desired amount of force to be applied to the feet is 50 pounds. Therefore, using Equation 1, the pressure necessary is approximately 0.8 psi.

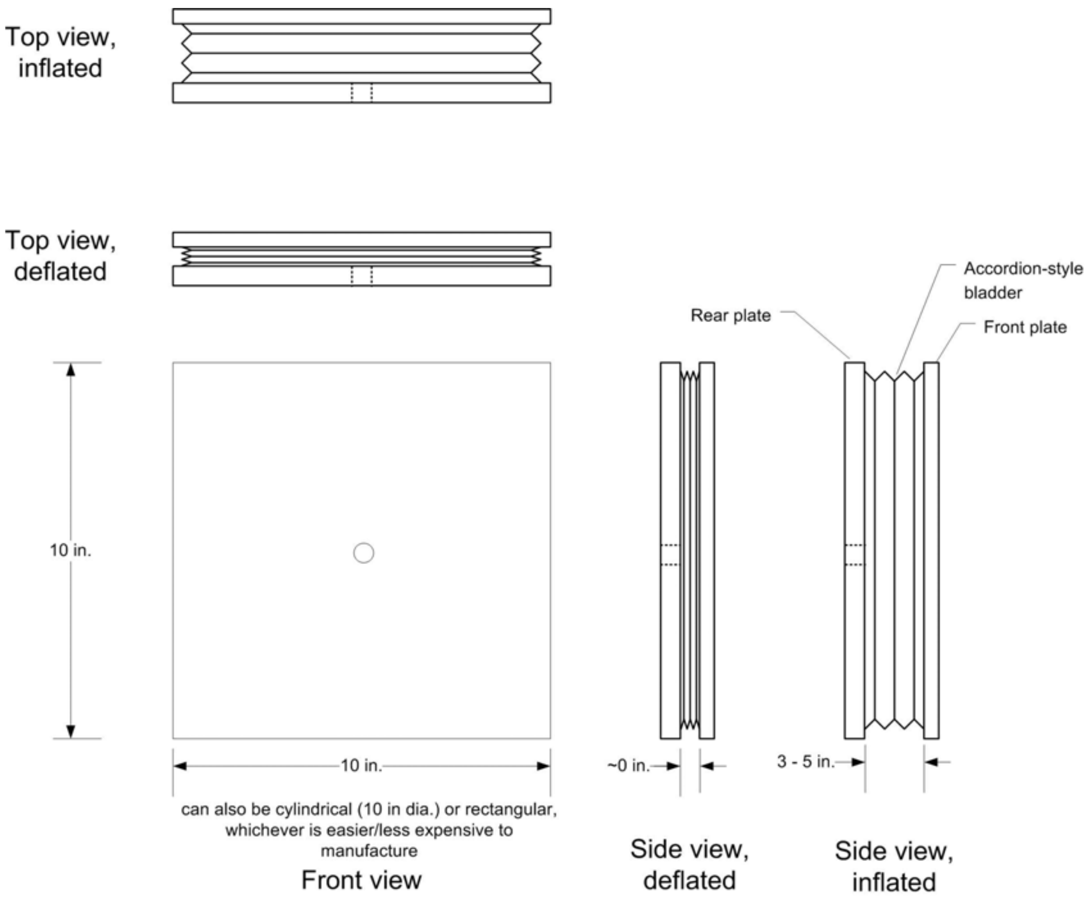

Figure 7
Drawing of ideal air bladder, which was sent to various air bladder companies.

Figure 8
Picture of an inflatable cube, which was purchased to act as the air bladder.
**http://www.myofficeitems.com/*

Pump

An electric pump would be ideal for inflating the air bladder. Our current prototype uses a manual hand pump. This was disadvantageous since some patients may have weak or arthritic hands and may not be able to inflate the bladder to the necessary pressure. An electric pump could be remotely operated with a hand held control, requiring only the push of a button to inflate the bag.

The important criteria that were considered when searching for a pump were as follows:

1. *Battery operated* – the pump should be able to be powered by alkaline batteries for portability. Alkaline batteries would be ideal since they are relatively inexpensive and widely available.

2. *Remote controlled* – the pump should be able to be remote controlled so the patient can operate it to inflate the bag up until pain or discomfort is experienced.

3. *Pressure and flow* – the pump should be able to operate at pressures of ~3 psi or less (we only need ~1 psi but this number includes a safety factor) and provide a flow of ~1 L/min (estimate).

4. *Size* – the pump should be as small as possible for portability.

Several types of electric pumps were considered, ranging from consumer air mattress or aquarium air pumps to industrial pumps. The consumer grade pumps were generally less expensive and more readily available than the industrial pumps. An example is the Rena Air 200 pump, as depicted in Figure 9, which offers a maximum pressure of 3.4 psi and a maximum flow rate of about 1.8 L/min [1]. These specifications fit with what we needed and the pump was relatively inexpensive at about $20. The major disadvantage to this pump was that it needs to be plugged into an AC power source, so a power inverter would be required in order to power it with DC alkaline batteries, adding cost and bulk.

Figure 9
The Rena Air 2000 pump, a possible pump for our device.
* *http://www.planetrena.com/aquarium-air-pumps.html*

Industrial diaphragm pumps were looked into for their small size and low power requirements. A DC powered diaphragm pump from Hargraves Fluidics was found that met all of our requirements. The CTS E107-13-060 pump operates on DC power at 6 V with a current of approximately 200 mA at a pressure of 1 psi and can be seen in Figure 10. Its maximum continuous operating pressure was 12 psi and had a flow of about 1.8 L/min at 1 psi. It was also very small, measuring 2.09 x 1.27 x 0.80 inches [2]. This pump can be powered by four 1.5 V alkaline batteries in series using a relatively simple circuit, as pictured in Figure 11a. To allow for remote control, a switch could be inserted into the circuit to turn the pump on or off. If the pump's flow is too high at 6 V, a potentiometer could be inserted into the circuit to allow for the flow to be adjusted by altering the voltage delivered to the pump, as pictured in Figure 11b. Both a switch and potentiometer could be operated by the patient with a wired, handheld controller. Since this pump met all of the required criteria, it was ordered directly from Hargraves Fluidics for ~$50. A separate release valve will eventually need to be purchased and integrated with the handheld controller in order to release air from the bladder.

Figure 10
The CTS E107-13-060 pump, the current air pump to be implemented into our design.
**http://www.hargravesfluidics.com/pdf/CTS_new.pdf*

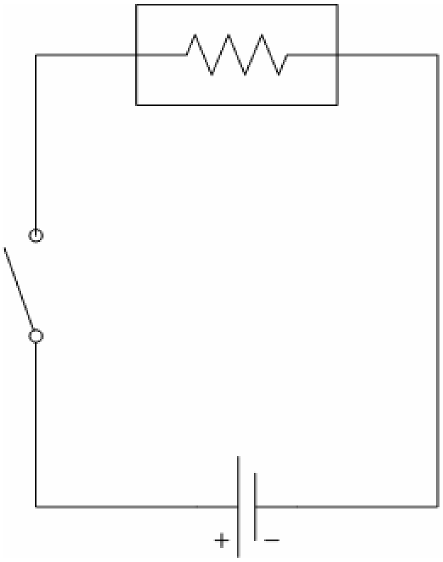

Figure 11a
A possible circuit if the flow rate of the pump is relatively low, all that is needed is a voltage source and a switch to turn the pump on and off.

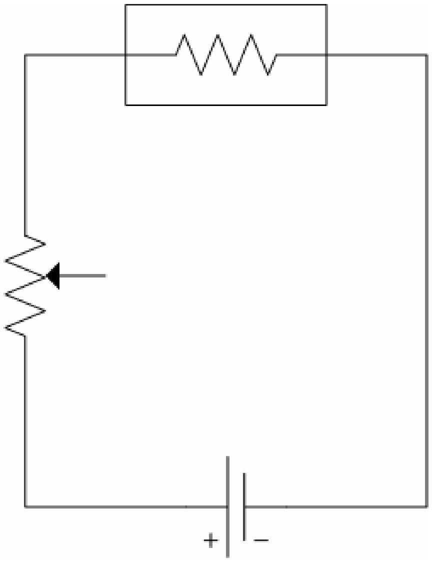

Figure 11a
An alternative circuit if the flow rate is too great and it must be variable. A potentiometer is implemented to adjust the voltage being supplied to the pump.

Linear Motion

One of the problems with the prototype designed was that the plates did not always move parallel to each other. There are a couple of reasons for this: the air wedge between the plates, the guide rails, and stationary foot plate. The air wedge by design has a valve at the bottom that prevents the plates from aligning parallel to each other both when the wedge is inflated and deflated as seen in Figure 12. Also, the wedge does not inflate uniformly – it bulges in the middle compared to the edges, so the plates have opportunity to wobble. The guide rails are made of Ultra-High Molecular Weight (UHMW) Polyethylene. The material is not very rigid – the rods can be bent by hand fairly easily. During the manufacturing of the prototype, to attach the guide rails to the moving foot plate heat was applied to secure the two together. However, the heat warped the plate so that it became slightly curved. This distortion affected the stationary plate, as the holes cut for the guide rails were slightly larger than needed to make sure they would slide through. In summary, faulty movement of the device was a result of these three factors during the manufacturing process.

This semester, to correct this problem, one of two ideas will be applied to the linear motion of the foot plates: using a stronger, more rigid material for guide rails or design a mechanism similar to a scissor-lift. For the original idea of guide rails, the stronger material could be carbon fiber, nylon, or Kevlar. From McMaster, nylon is fairly inexpensive compared to the other materials and easy to fabricate [5].

For the scissor-lift design, four links – two on each side – would be attached as shown in Figure 13. This design should ensure proper horizontal motion, keeping the plates parallel. However, the actual building of this would be very complex, time consuming, and expensive.

Figure 12
Pictures of the device inflated and deflated.

Figure 13
An example of a scissors lift, the ideas used for linear motion may be used in our design.
**http://www.sourceequipment.com/p2536-lift-table.jpg*

Due to financial constraints, the guide rail mechanism will be pursued. However, during the course of testing the prototype, if the guide rails do not sufficiently aid the movement of the plates, then guide blocks will be added to support the design. There should be enough time and money to make these adjustments if necessary.

Feet Attachment

The prototype from last semester employed a Velcro strap that was threaded through a bathroom scale, as shown in Figure 14, to secure the feet to the scale and plate. The problems with this are that Velcro is not very durable – wears out over time – and the bathroom scale is made of metal, which violates our design goal of using no metal whatsoever in the device.

Figure 14
Front side of the previous prototype, illustrating the foot straps.

For modification of these problems, straps made of polypropylene webbing will be used to secure the feet to the plate. To provide additional support, heel cups, depicted in Figure 15, will be attached near the bottom of the movable plate.

Figure 15
Heel cups that were purchased to help stabilize the foot on the device.
* *http://stores.ebay.com/AmericanRx-Health-and-Beauty-Store*

Future Work

There are several activities to be completed by the end of the semester. First, a patent search will be conducted to confirm that no device similar to the CT foot loader exists. Then, an application will be sent to WARF to determine if the device can be patented. Meanwhile, the device will be built and a circuit for the pump and transducer will be constructed. A drawing of the proposed final design is shown in Figure 16. Once this is completed, testing will commence with running the device through a CT scanner with a phantom. Finally, IRB approval will be obtained so that this device can be scanned with human volunteers and a research project can be conducted.

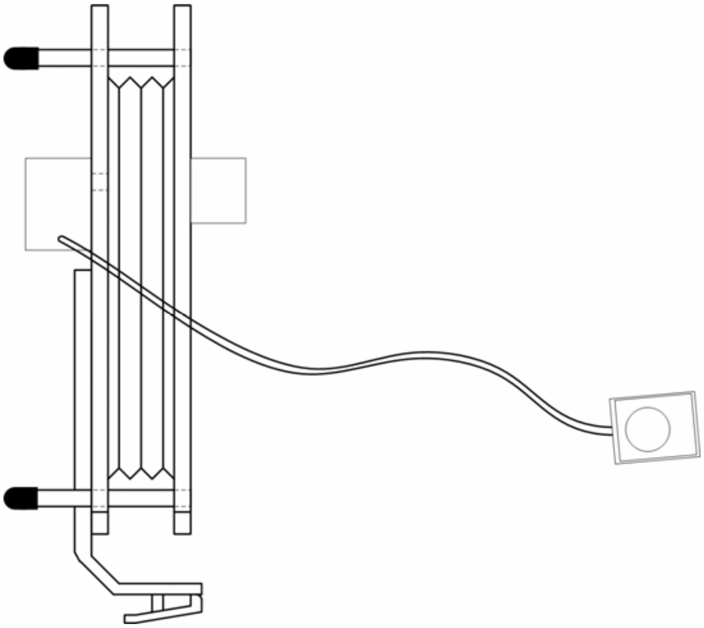

Figure 16
Drawing depicting the purposed final design.

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Project Design Specification

March 14, 2007

Team Members: Arin Ellingson, Anika Lohrentz, Ben Schoepke, Alice Tang

Problem Statement:
The ankle and foot are commonly scanned using computed tomography machines. There is currently no device for positioning the feet during a CT scan. This device will hold the feet in the proper position, apply a measurable load to the feet to simulate realistic conditions, and will not interfere with CT imaging. It will be portable and easily cleaned.

Client Requirements:
- Hold feet securely
- Apply measurable load to feet
- Must not obstruct CT imaging
- Easily moveable by one person

Design Requirements:
1. Physical and Operational Characteristics
a. Performance Requirements- The device must provide a measurable load upwards to 50 pounds.

b. Safety- The device must comply with standards for medical devices established by the FDA. It must be CT compatible and cause no harm or discomfort to the patient.

c. Accuracy and Reliability- Results must be reproducible. The device must be accurate to within ± 0.5 lbs.

d. Shelf Life- The device must last 10-20 years and be stable enough for use numerous times per day.

e. Operating Environment- Must not be corroded by the disinfecting solution. The device must be able to withstand X-ray bombardment.

d. Ergonomics- Must be able to support human feet comfortably.
Operation of the device should be easy to use, and not interfere with the standard CT procedures. It should also not significantly lengthen the scan. The handle should not require excessive torque and easily be within reach of the technician.

e. Size and Shape- Must fit within the CT scanner, a diameter of 70 cm. It should be sufficiently small to allow easy movement and storage. It should be able to fit a variety of different size feet.

f. Weight- Must be under 40 lbs to allow easy lifting for a single technician to ensure easy portability.

g. Materials- Must have low X-ray attenuation. It should be sufficiently rigid and strong to prevent flexion and breakage.

f. Aesthetics- It should be smooth, elegant, and safe-looking.

2. Product Characteristics:

a. Quantity- Preferably three, but only one is required.

b. Target Product Cost- The device should stay within the client budget, ideally under $500 for a working prototype and under $1000 to manufacture.

3. Miscellaneous:

a. Standards and Specifications- The device should comply with the guidelines setup up by the FDA for medical instruments. Further information is available online at the FDA's website. The device is subject to performance and safety standards without exemption, for its classification.

b. Customer- The customer will primarily use the device in CT scanners; therefore, its use should tailored for use in CT scanners.

c. Patient-related concerns- The device will have to be disinfected between uses.

d. Competition- Similar devices exist for holding the feet, however none provide a measurable load on the feet.