CT Foot Loader

Final Report

May 9, 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. The device shown is the prototype from last semester.

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 [2]) and the posterior tibial tendon (connects calf muscle to the navicular bone, which contributes to the arch of the foot [3]).

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 [5]. 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 [1]. 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 [4]:

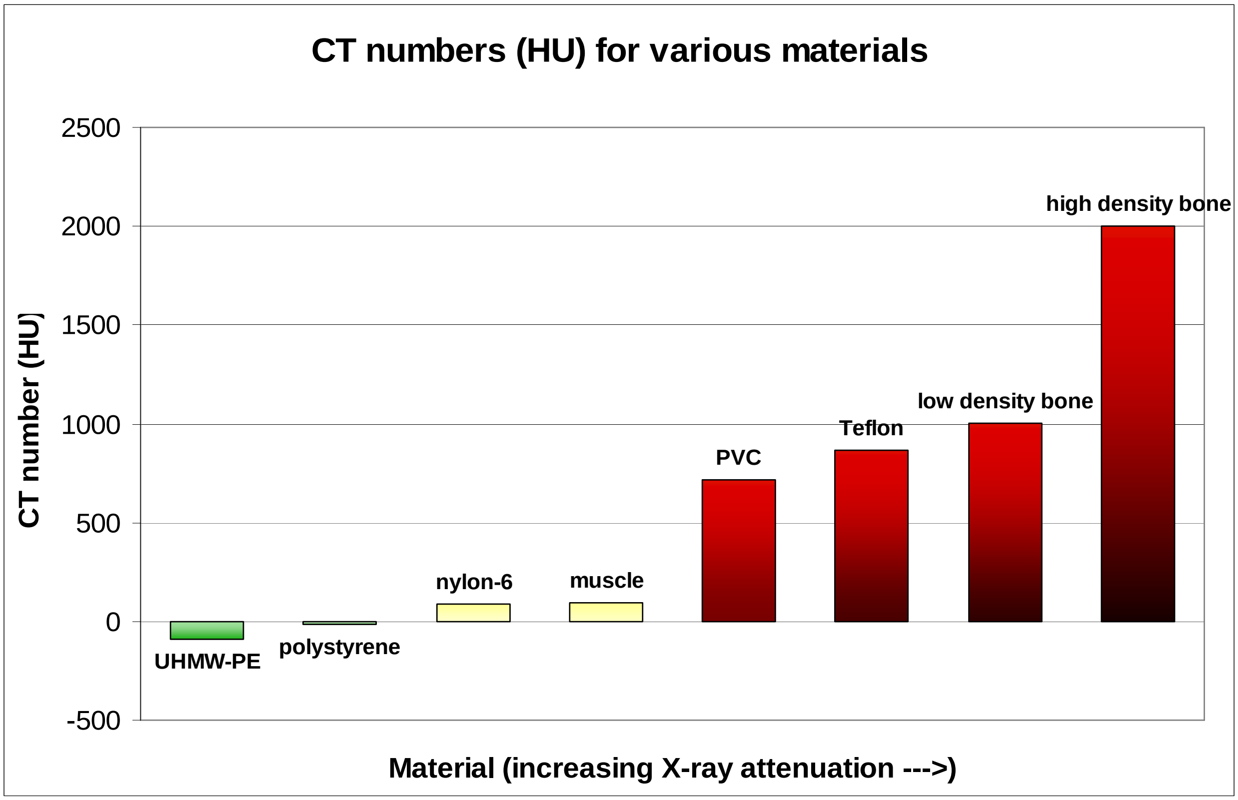

Figure 2
Graph of the CT numbers obtained from Schneider, *et al.* [4]. This is a measure of each material's attenuation. The values are relative to water, which has a CT number of zero.

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

Preliminary Designs

This section presents each of the preliminary designs that were brainstormed early on in the project. The reasoning used in this section also reflects the thought process that occurred at that stage of the project.

Cable Design

The cable design, shown in Figure 3, pulls the feet to apply a force via two cables attached to either side of a plate against which the feet rest. As the technician tightens the cables, they pull the plate, thereby applying a force to the feet. The cables are attached to a shoulder piece, not shown in the diagram below and held down by the weight of the patient. The force will be measured using a spring scale on each cable. This will let the technician know whether or not the tensions in the cables are equal, so an equal force will be acting on the feet.

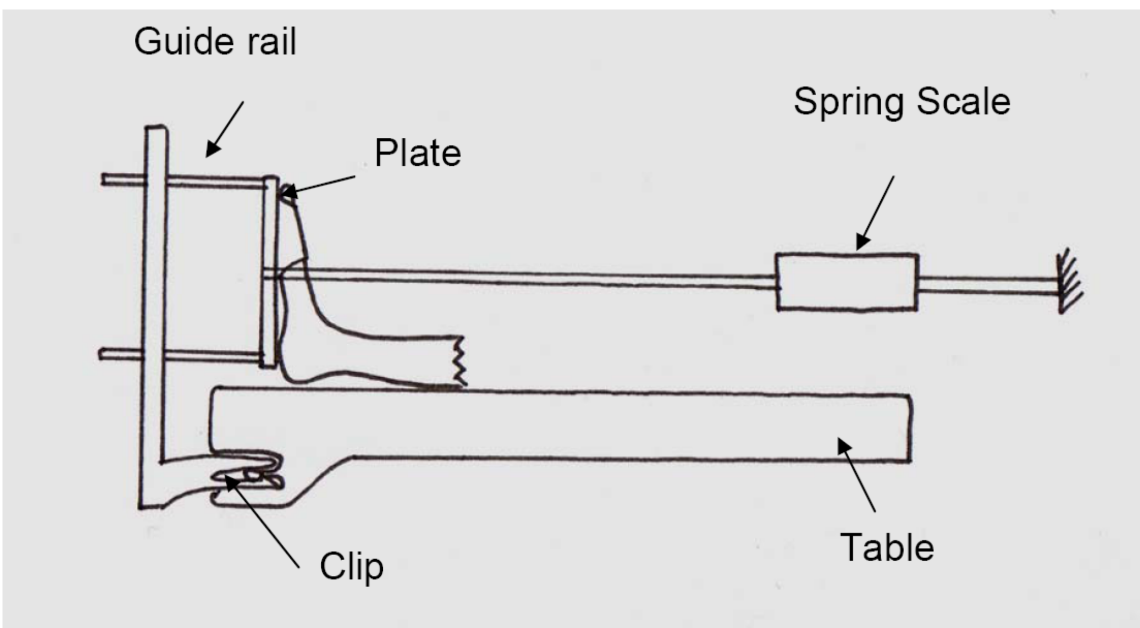

Figure 3
Side view drawing of the cable design. The cable pulls on the plate to apply a load to the feet. This load is measured by the inline spring scale.

Screw Design

Figure 4 displays the screw design, named for its use of a screw to drive a plate against the patient's feet. The screw is a large threaded rod with 1"-8 threads. A rod with a 1" diameter was chosen to ensure that it would be able to withstand the reaction forces from the load plate. The rod is driven by a long handle distal to the load plate. It was desirable to have a long handle to allow the operator to generate greater torque.

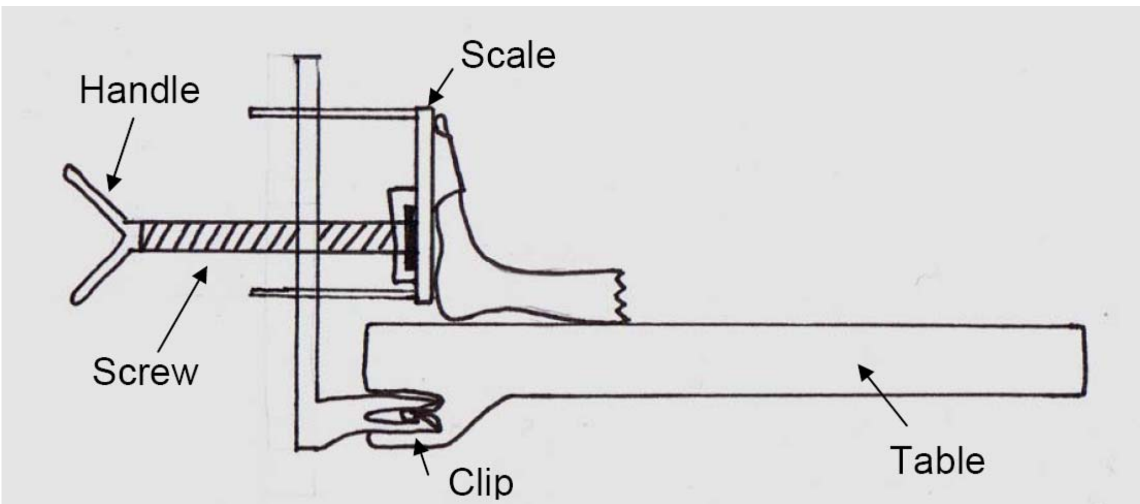

Figure 4
Side view drawing of the screw design. The force is applied by rotating the screw that drives the plate into the feet. The load would be measured by a scale or load cell based system

Pneumatic Design

The mechanism used to apply the force to the feet is a pneumatic air bladder, as shown in Figure 5. 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. 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.

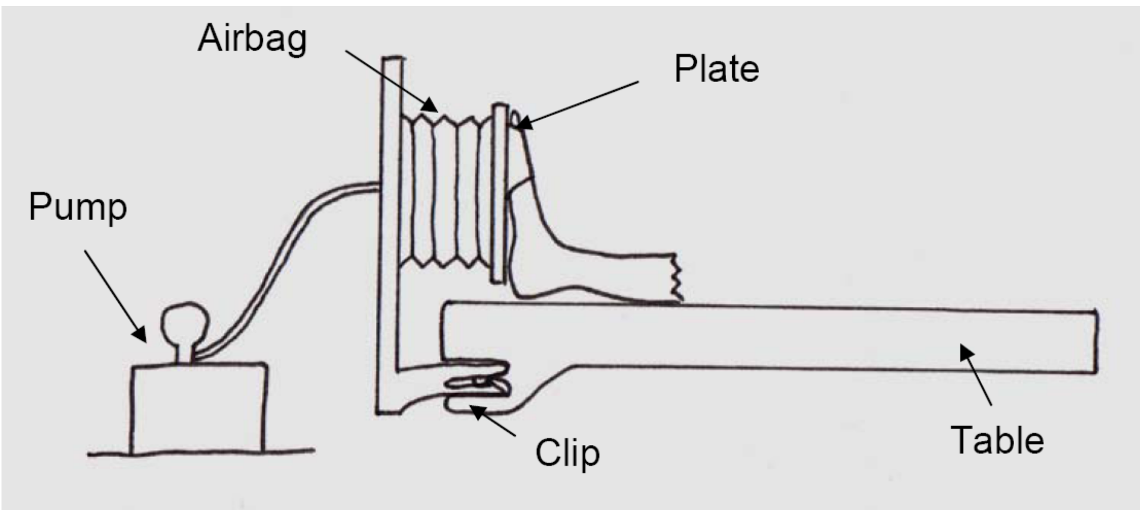

Figure 5
Side view drawing of the pneumatic design. The load is applied via an airbag in-between the two plates. The force is to be measured in relation to the amount of pressure in the airbag or by a scale or load cell based mechanism.

Preliminary Design Evaluation

The three preliminary designs were compared based on several weighted criteria. The criteria were discussed, defined, and weighted by the team before creating the matrix and are described in Table 1.

Criteria	Weight	Definition
Patient Safety	20	Patient safety was weighted the highest without question. A safe device would allow the load to be adjusted or removed quickly if the patient experiences pain.
Portability	20	Our client stressed that it was very important that the device be easily movable by one technician. It should be lightweight and easy to carry to another CT table.
Ease of use	15	The device must be easy to operate by one technician. It should not require excessive force or much effort to timely reach the desired load.
Accuracy	15	The load must be able to be accurately measured to within ± 1 lbs. (arbitrary goal)
Durability	10	The device must be wear and impact resistant in order to have 10+ year shelf life.
Comfort	10	The device should not be imposing (e.g., claustrophobic or frightening in appearance) to the impatient or create any additional discomfort.
Cost	5	Cost of all components should be minimized. Less than $300 is required.
Complexity	5	A less complex design is one with fewer parts and is estimated to be easier to manufacture.

Table 1
This figure describes the criteria from which the comparison matrix was constructed.

Each team member individually generated a comparison matrix using the established criteria and the averages were used to create the final matrix shown in Table 2.

Criteria	Weight	Screw	Pneumatic	Cable
Patient Safety	20	19.25	17.75	15.5
Portability	20	19	14.5	11.75
Ease of use	15	12	12.25	9.5
Accuracy	15	14	14	14
Durability	10	9	9	8.25
Comfort	10	9	9	3.25
Cost	5	4.75	3.5	3.5
Complexity	5	4.75	3.25	2.75
Total	**100**	**91.75**	**83.25**	**68.5**

Table 2
The comparison matrix. This was used to help select the final design using the criteria explained in Figure 6.

As seen in the matrix, both the screw and pneumatic designs scored highly and were presented to our client shortly after the preliminary designs were evaluated. Our client was particularly enthusiastic about the pneumatic design. He suggested that it would be easy to allow the patient to operate the pump and therefore allow them to increase the load until pain or discomfort was experienced. This was a significant advantage that had not been considered in the preliminary evaluation. It was found to be possible to allow the patient to operate the screw design as well but only if it were operated by a motor, which would add significant weight, cost, and complexity to the device. Thus the pneumatic design was selected to be the final prototype.

Preliminary Prototype

A side view drawing of the final design can be seen in Figure 6. 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. Pictures of the previous prototype in the actual CT scanner can be viewed in Figure 7.

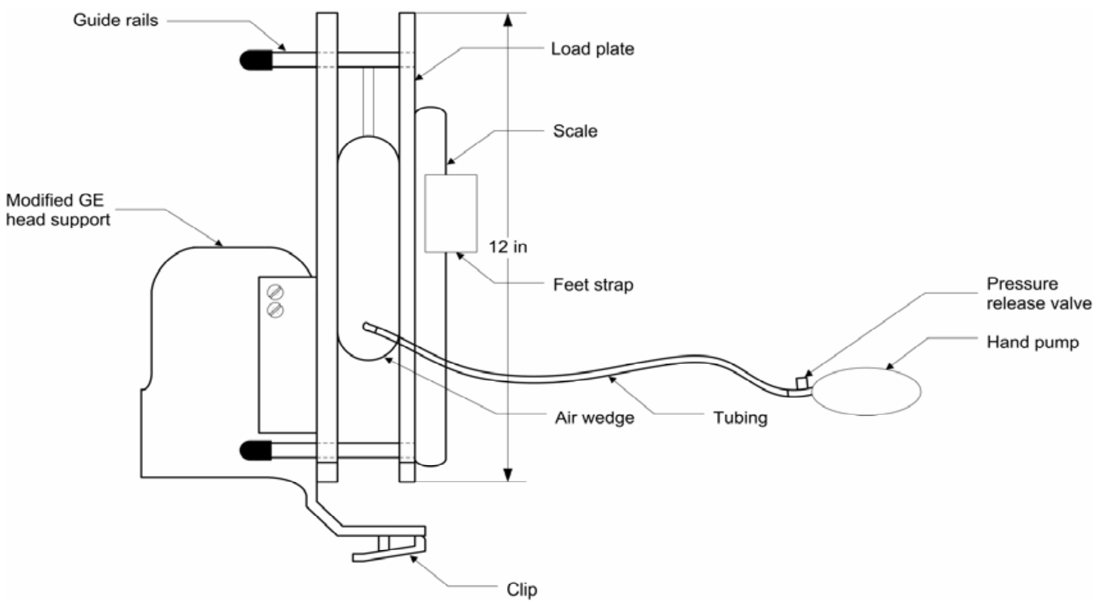

Figure 6
Side view computer aided drawing of the final prototype. The force is generated by an inflatable air wedge located in-between the two plates. The air wedge is inflated via a hand pump operated by the patient. The load is temporarily measured by a scale underneath the patient's feet. The head holder is used to have the correct connection between the device and the standard GE table.

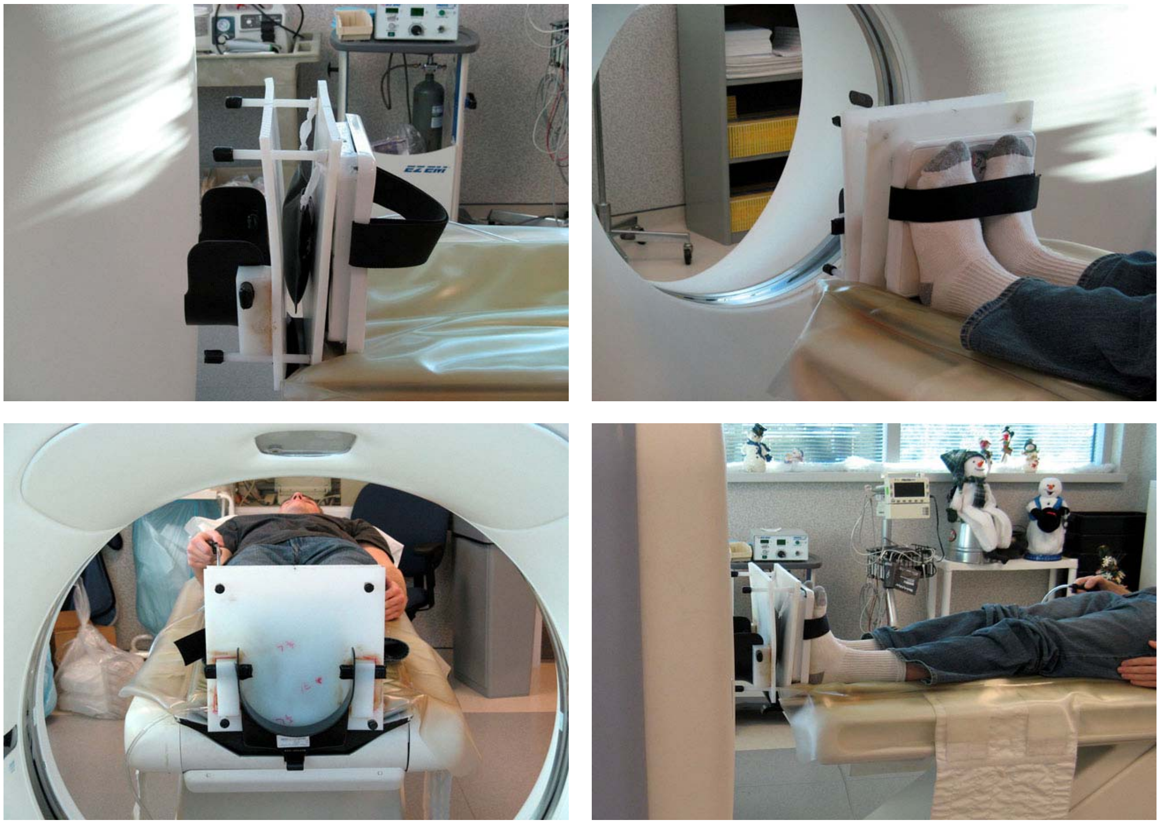

Figure 7
Pictures of the device in the CT scanner. The picture in the top left is a side view of the device. The picture in the bottom left is a picture of the bottom of the prototype through the gantry. The picture in the top right is an angled view from the patient's perspective. The bottom right picture shows a wider view from the side.

Final Design

Design Improvements

This semester, we focused on improving upon several aspects of the previous design: rigidity, air bladder, force measurement, pump, linear motion, feet attachments, and CT table attachment. A computer drawing of the final prototype can be seen in Figure 8 and photographs can be seen in Figure 9. To improve the overall rigidity of the prototype, the plates were constructed out of Thermoset laminate, a donation from Norplex-Micarta. This material provides the feet a stable surface without compromising the image quality. The feet are held in place by a polypropylene strap with aided support from heel cups. The force is applied by an air bladder, which is inflated via an air pump operated by a controller held by the patient. The hand held controller displays the force being applied to the feet. Four guide rails were used to ensure that the front plate moved linearly, keeping the plates parallel at all times. The subsequent sections outline more specifically the improvements made in the following areas: load generation, load measurement, and feet attachment.

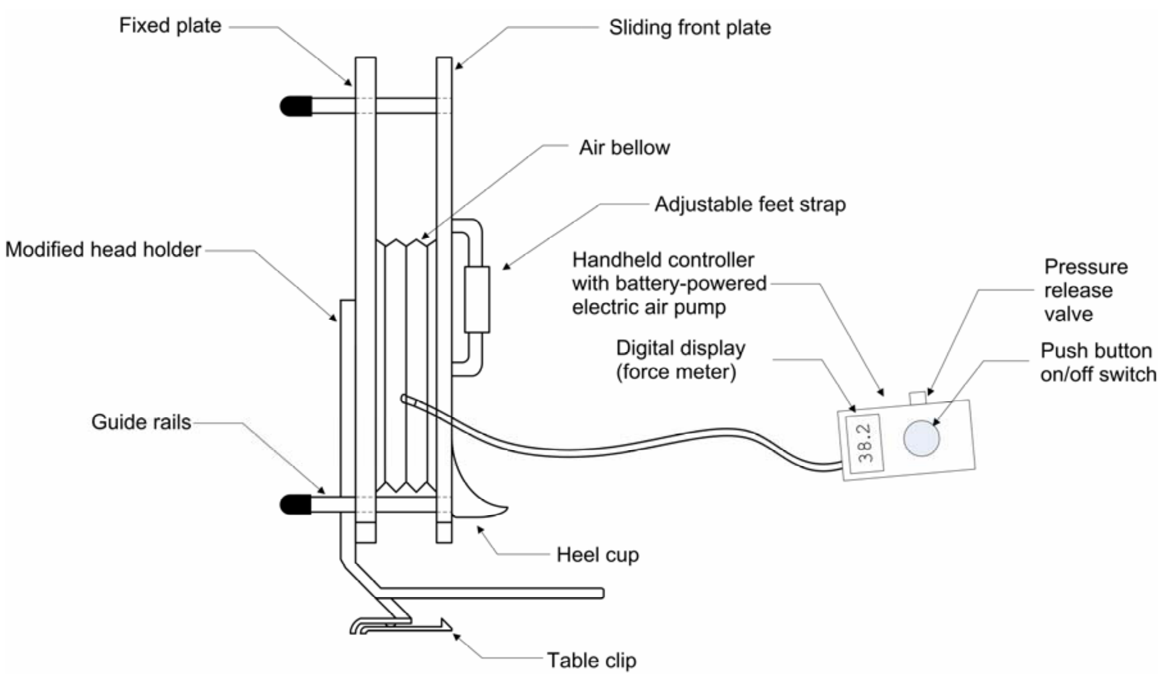

Figure 8
This is a schematic of our final prototype.

Figure 9
Photographs of the final prototype with a phantom foot in place, attached to the CT scanning table.

Cost Analysis

The following table (Table 3) is a break down of the purchases made for the device.

Item Description	**Price ($)**
Voltmeter	55
Air Bladder	4
Pressure Transducer	18
Lithium Batteries	18
Diaphragm Pump	48
Miscellaneous	70
Total	**210**

Table 3
Summary of this semester's expenses.

Load Generation

The patient's feet are loaded by a pneumatic mechanism. The source of the force is an air bladder adhered between the fixed rear plate and the sliding front plate. As the bladder inflates, the front plate is pushed against the feet with increasing force. Before the air bladder is completely inflated, the pressure in the air bladder relates linearly with the force being applied to the feet by Equation 1:

$$\text{Pressure} = \text{Force} / \text{Area} \qquad (1)$$

The air bladder used in the final prototype is depicted in Figure 10. It is made of vinyl and each face has a surface area of approximately 64 in^2. Using Equation 1, this meant that about 0.78 psi would be required to generate a 50 lb. load on the feet:

$$\text{Pressure} = (50 \text{ lb.}) / (64 \text{ in}^2) = 0.78 \text{ psi}$$

Thus the system requires relatively low pressures to generate loads sufficient for the design requirements.

Figure 10
The air bladder with Polyfilm sheath to prevent bulging.

An electric pump was chosen as the air source. The selected model was the Hargraves Fluidics CTS series diaphragm pump, part number E107-13-060, depicted in Figure 11. It was chosen for its small size, low power consumption, and low cost. Performance characteristics for the pump are available in the appendix.

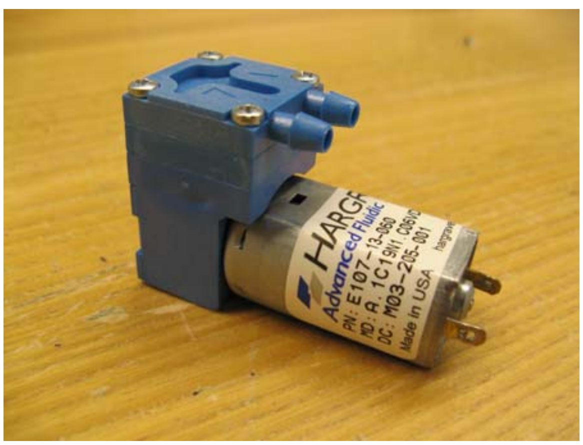

Figure 11
The diaphragm pump used to inflate the air bladder.

The pump outputs air into a continuous pneumatic circuit. It is connected to the air bladder, a release valve, and a pressure sensor via 3/16” vinyl tubing. Plastic tee fittings are used to split the air way.

Load Measurement

As shown in Equation 1, the pressure in the air bladder was linearly and directly related to the force being applied to the feet. Using this fact, the load being applied to the patient’s feet was indirectly measured by measuring the pressure in the pneumatic circuit and displaying the output as a force through calibration. Figure 12 provides a block diagram of the electrical pressure measurement circuit:

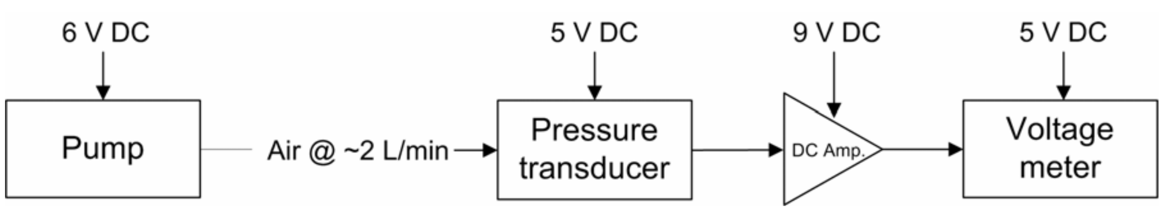

Figure 12
Block diagram of the pressure measurement circuit.

The pressure transducer is a Freescale MPX5100GSX pressure sensor. A data sheet for it is available online by searching for the part number. It outputs a voltage that varies linearly with pressure. This output voltage, however, has a non-zero offset that had to be corrected for using a separate power source (AAA battery) and adjusted with a potentiometer. This offset adjustment required very little power, however, and the battery life of the AAA battery should be several times that of the main batteries. The slope of the resulting voltage vs. pressure line was adjusted with a separate potentiometer. It should be noted that the output of the pressure sensor also depends on the source voltage provided for it. The calibration was conducted assuming the supply voltage would be a constant 9 V but batteries do not provide a constant output voltage over their lifetime. This is not accounted for in our circuit and is a source of inaccuracy in the force measurement.

The output of the pressure sensor is amplified using an LM324 single supply operational amplifier and fed to a panel mount voltage meter with an LED display. The voltage meter is a Datel DMS-30PC-2-BC. A data sheet for it is available online by searching for the part number. A detailed circuit schematic is shown in Figure 13:

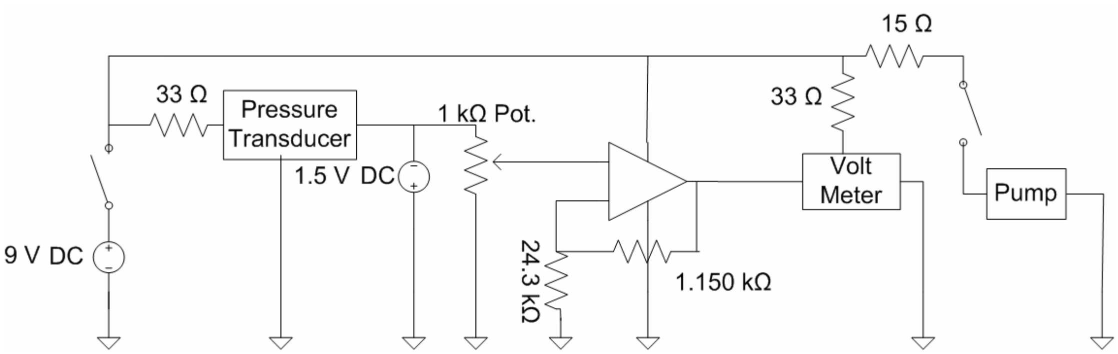

Figure 13
Schematic of electrical circuit used in final design.

Feet Attachment

There are two main components to attach the feet to the device: adjustable Velcro straps and heel cups. Four modified drawer handles were screwed and glued parallel to each other onto the moving plate, as shown in Figure 9, and Velcro straps were sewed onto the two in the middle. The Velcro straps were also sewn together so that straps for both feet would move uniformly up or down the drawer handles vertically, so feet of various sizes can fit onto the device. To provide additional support, heel cups, depicted in Figure 14, are attached as close to the bottom of the movable plate as possible.

Figure 14
Heel cups that were purchased to help stabilize the foot on the device.
* *http://stores.ebay.com/AmericanRx-Health-and-Beauty-Store*

CT Table Attachment

A GE CT headholder was modified and appended to the device to serve as a mode of attachment to the CT table. The headholder was chosen as the CT table attachment because it already contained the proprietary clip for a GE CT scanning table. When the headholder was first joined to the device via a combination of polyethylene rods and industrial strength glue, it rocked against the stationary plate. Thus, pieces of polypropylene straps were glued onto the stationary plate such that the headholder would no longer rock.

Conclusion

Future Work

Now that the assembly of the prototype is complete, some improvements can be implemented to improve its marketability. IRB approval will be obtained so that this device can be scanned with human volunteers and a research project can be conducted. To make the device more appealing, the design should be streamlined. For example, the circuitry can be incased into a handheld controller. Also, the force measurement accuracy will increase if the electrical circuitry is replaced with digital circuitry with a microcontroller. This way the force could be directly calculated using Equation 1 and the varying supply voltage of the pressure sensor could be taken into account. In addition, the device will become more versatile if an MRI attachment is acquired, since the device itself is already MRI-compatible. Finally, an application will be sent to WARF to determine if the device can be patented.

Ethical Considerations

When designing the foot loader, we considered the autonomy and safety of both the patient and the technician. The final design allows the patient to have autonomy and a safe environment. The air bladder itself provides safety in two different aspects. First, the patient pumps air into the air bladder and therefore controls the amount of pressure applied to the feet. This avoids a situation in which the technician pumps excessive amounts of air and causes pain or injury. Second, the air bladder deflates quickly, so if the patient feels excessive pressure, he or she can release air in a timely manner to avoid injury. In the case that the patient cannot generate air pressure because of impairment, he or she should find a means to communicate the optimal amount of force to be applied to the feet. Also, the entire foot loader is made of non-toxic materials.

By using the foot loader, the patient may receive a better diagnosis for his or her ailment and can receive the proper treatment. There is a possibility that scanning the feet without loading them may lead to misdiagnosis, which could cause the patient to incur further injury. This device has the potential to keep the patient safe as well as improve his or her physical condition.

In addition, the foot loader is designed to ensure the technician’s safety and ease of use. It is lightweight and compact, so the technician can easily carry the loader. If the technician drops the foot loader, he or she should not sustain permanent injury. In the case that the technician is operating the foot loader, they should find the circuitry incorporated into the design easy to use.

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Appendix

Product Design Specifications

May 7, 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.

Pump performance characteristics

Press	Flow	Current
0	1.9	140
4	1.1	270
8	0.8	340
12	0.6	380
16	0.4	400
20	0.2	390
24	0.1	350
28	0.0	290

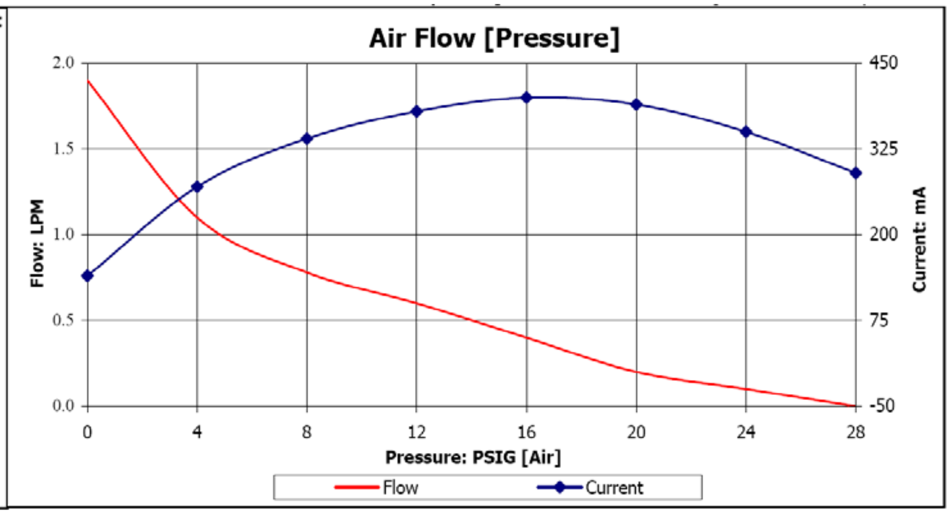

Figure 15
As shown on the graph, the pump has a low current draw and high flow at the pressures needed for this design (~1 psi).