Abstract

A device was developed that flexes and extends the head about the neck in a fluoroscopy room. It provides rotation about the spine isocentric to the normal point of flexion and extension. A prototype was developed to provide a mechanical reference for a future, refined device. Future work is required to test the final design's efficiency, and another device is required to provide compatibility with a fluoroscope and remote operation.

Client Biography

Our client is Dr. Victor Haughton, a professor of Radiology at the University of Wisconsin – Madison. He graduated from Harvard College in 1961 and Yale University School of Medicine in 1968. On June 9, 2004, he was elected the 42nd President of the American Society of Neuroradiology. He has focused his professional life on the science of neuroimaging and its anatomic underpinnings. Recently he has focused his research on disk degeneration. Dr. Haughton feels that a neck flexor in association with fluoroscopy could provide quality images of the disks in motion and help to diagnose such disk degeneration [6].

Background

I. Fluoroscopy

The primary function of fluoroscopy is to provide real-time imaging of dynamic processes as they occur [8]. There are many applications of fluoroscopy: tracking blood flow in arteries, evaluating the digestive or urinary tracts, or diagnosing reproductive problems in women. These applications of fluoroscopy require the use of a contrast-enhancing material. This material is either ingested or injected into the body, increasing the contrast of otherwise indistinguishable vasculature or tissue. Diagnosing bone fractures is another major use of fluoroscopy. In this specific application, our device assists with the diagnosis of spine or neck fractures. Such fractures may be undetectable by other methods and can be diagnosed by a radiologist carefully observing a real-time image [1].

Several different types of fluoroscopes exist. For two examples refer to Figures 1 and 2. Figure 1 depicts a more rigid fluoroscope, mainly used for obtaining images of the middle body area, such as the digestive or reproductive tracts. Figure 2 is known as a C-arm fluoroscope, the type our device must be designed to work with.

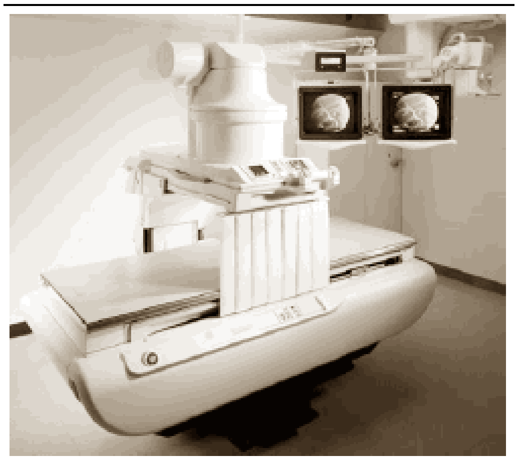
Figure 1: Rigid Fluoroscope [8]

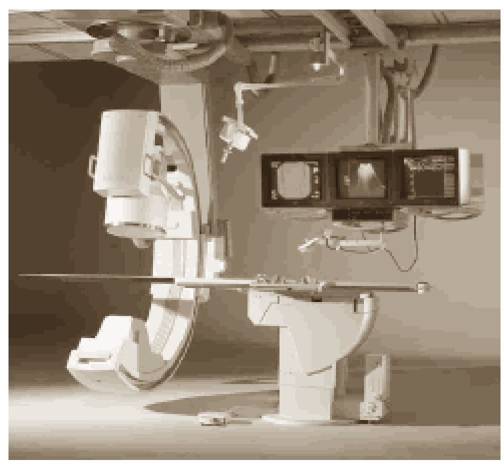
Figure 2: C-arm Fluoroscope [8]

Historically, the first fluoroscopes produced a faint image on a fluorescent screen; the image was so dim that the physician needed to train his or her eyes to view it [8]. Today's fluoroscopic images are amplified and interfaced to a television or monitor display system. The process begins at the X-ray generator, where the X-rays are produced. The rays pass through the body and are amplified by an image intensifier. The final image is displayed on a monitor for real-time viewing. The implementation of the amplifier greatly improved the utility of the fluoroscope, making it easier to use and expanding its diagnostic capabilities [2].

II. Materials

The final device must not compromise the imaging capabilities of the fluoroscope. Therefore, the materials it is composed of must not interfere with X-rays. The mass attenuation coefficient of the material, μ/ρ, is a quantity used to determine how many photons (such as X-rays) penetrate a material. A higher coefficient corresponds to better shielding. Therefore, materials with low mass attenuation coefficients are required for this application. Figure 3 provides a

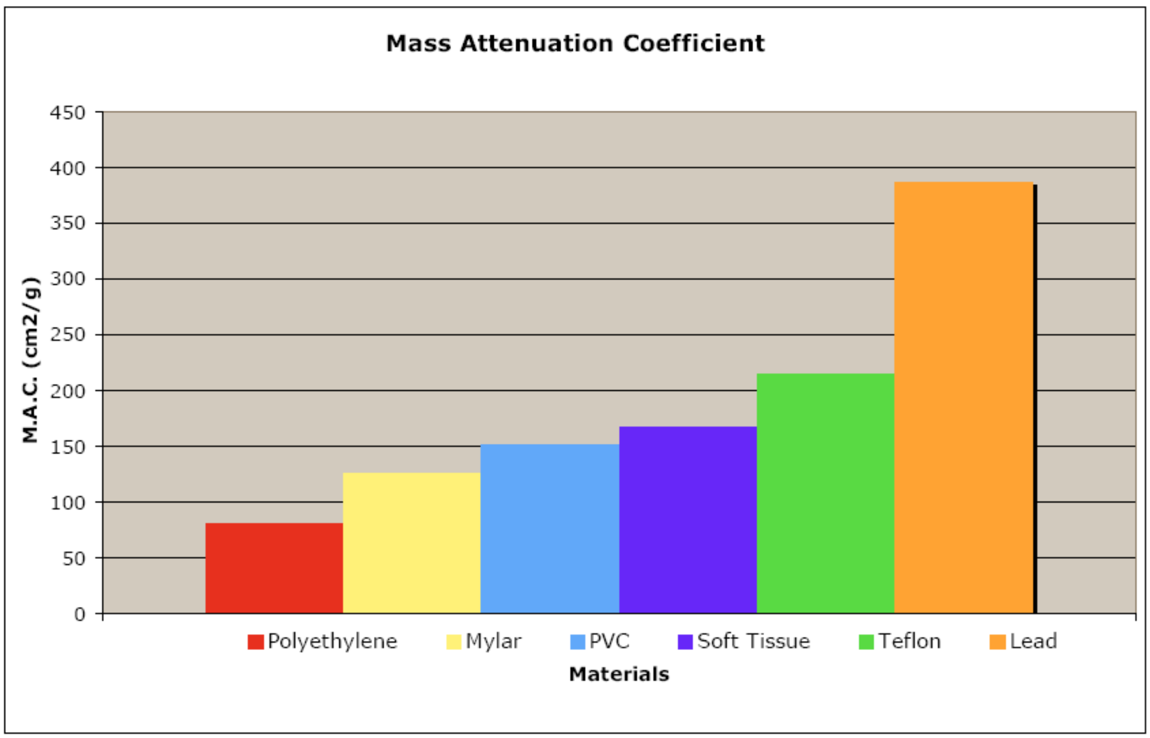

Figure 3: Mass Attenuation Statistics [9]

comparison of the mass attenuation coefficients for various materials compiled from data provided by the National Institute of Standards and Technology (NIST). This chart was generated by averaging the mass attenuation of each material over the entire range of photon energies provided by the NIST.

Problem Statement

Present methods for positioning patients to perform a fluoroscopic examination of a fractured neck are inefficient and unsafe. A technician must physically move the patient's head in various positions with their hands while the examination is taking place. This procedure is potentially dangerous for the patient and time consuming for the radiologist. The device to be designed will flex and extend the head about the neck in a fluoroscopy room. The device is designed to prevent obstruction of X-ray imaging. It provides rotation about the spine isocentric to the normal rotation point for flexion and extension.

Motivation

The current method used to examine a patient's neck during a fluoroscopic examination is both dangerous and time-consuming. It requires three people. A specialist wearing X-ray shielded gloves holds the patient's head and moves it as directed by a radiologist during the examination. A technician is required to adjust the table, while the radiologist watches the fluoroscope in order to make a diagnosis. This method is dangerous for several reasons. The specialist could accidentally move the patient's neck too quickly or could drop the patient's head, resulting in further injury. Additionally, the specialist and the technologist are exposed to a significant amount of X-ray radiation.

Our client has asked us to design a remotely operated device to replace the functions of the specialist and the technician, requiring only a radiologist to perform the examination. This would drastically increase the safety of the procedure for both the patient and the physician, as well as save time and money. These factors would allow fluoroscopy to be used more frequently than it is now, hopefully resulting in the faster diagnosis of neck injuries.

Client Requirements

Our client has many specific requirements for the device, listed below. See the product design specification located reporting Appendix A for a more detailed and technical list of requirements.

- The device must not obstruct fluoroscopic imaging.
- The device must be able to flex the neck twenty-five degrees, forward, and extend forty-five degrees, backward.
- The motion of the device should be smooth and steady.
- The device should provide one person operation, preferably via a remote-control mechanism.
- The device should be portable and capable of being transported by one person.
- The patient's head should be secure inside the device, and only movement of the neck and head is necessary.
- The patient should have easy access into and out of the device and the device should be universal for all types of people.
- The total cost of the prototype should be less than $500.

Alternative Solutions

When attempting to address the design problem that our client proposed to us, we brainstormed many creative alternative project designs. Each of these designs provided a different solution to the same design problem. These designs were then thoroughly evaluated based on how the characteristics of each design would best fit our client's requirements. We then chose the best design within the requirements to proceed with for the rest of the semester.

Cable Design

One of the designs that we proposed was to flex and extend the neck with the use of cables. This design used two cables connected to a head support to provide the desired rotation. Rotation was achieved by changing the length of cables, which could easily be accomplished by a "reeling" mechanism, much like how a fishing rod works. With a motor, the rotation could be carefully controlled to provide smooth, precise, and therefore safe movement of the head support. See Figure 4 for an illustration of this design.

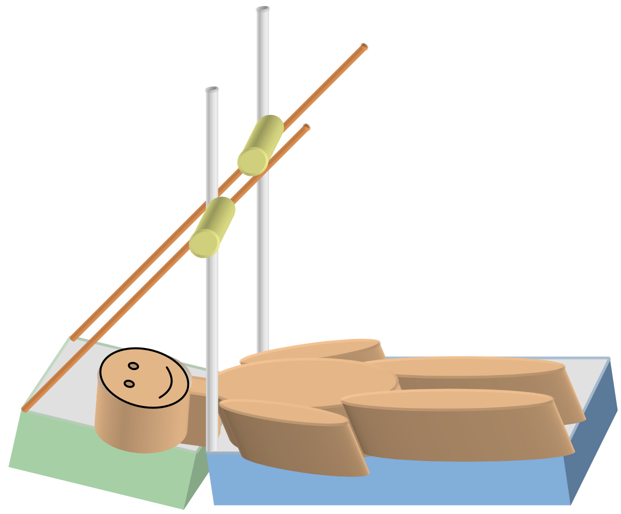

Figure 4: Cable Design

Airbag Design

Another solution to our design problem was a completely different approach to flexing and extending the neck. In the airbag design, the main force that moves the head is air pressure. Picture pumping up an inflatable pillow: your head would first be grounded on the deflated pillow. As air is pumped into the pillow, your head raises off the ground until eventually the pillow is full of air. The same concept was used in designing the airbag prototype. The process involved in our device would pump air from an external source into the airbag of the device which would then move the patients head to various degrees.

The design includes three major components which are all integrated together: the headrest and mat apparatus, the tracks, and the airbag as shown in Figure 5. The patient's head would be placed into the headrest. Using an air compressor, air would be pumped into a vinyl bag located under the patient's head. The degree of rotation, which could be read on the side of the tracks, would be based on the amount of air pumped into the bag. A valve on the air compressor would decrease the amount of air in the bag.

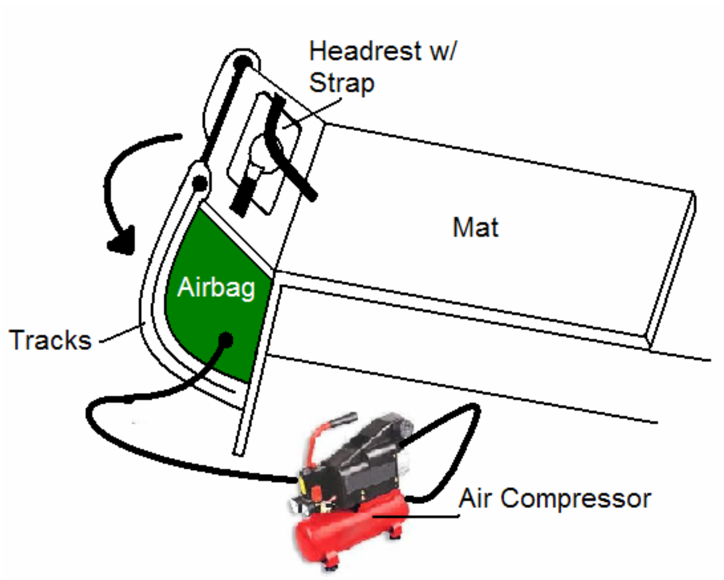

Figure 5: Airbag Design

Haughton Design

With the Haughton design, our main focus was to achieve the exact rotation of the neck. Before eventually coming to the idea of the Haughton design, we came up with two preliminary designs that gave us some clues on how to achieve such rotation.

With the jack design, Figure 6, the rotation of the neck would be achieved by the use of hydraulic jack. With the extension and contraction of the jack in conjunction with the rotation of the platform, we could possibly achieve the rotation of the neck. The problem with this idea was that we would have to set up the hydraulic and the platform so they would both be in sync with one another to achieve a natural rotation of the neck. Considering the differences in sizes of people and the many rotations that could possibly occur, this was an overly difficult solution to our problem so the hydraulic jack idea was disregarded.

To sidestep the use of a jack, we brainstormed the periscope design. This design consisted of two extendable rods attached to the head support on either side. The head support would then be able to rotate about the attachment axis while the rods are extended and contracted. Figure 7 is a provided image of the design. Ideally there would be a motor, operated by remote control, to power both movements. The problem to the periscope design was how we would be able to extend and contract the rods effectively while still rotating them through the whole motion. Once again the problem lied in coordination of the extension-contraction of the arms and the rotation of the base.

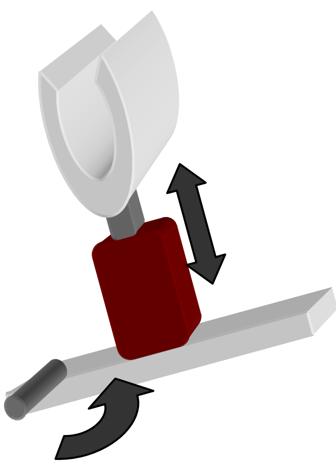

Figure 7: Jack Design

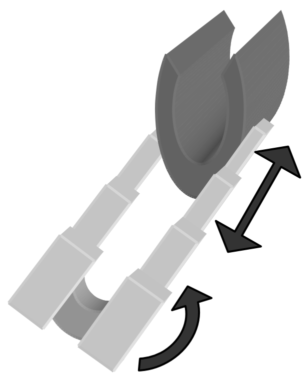

Figure 6: Periscope Design

Using the ideas of rotating arms through the various degrees of extension and flexion and a head support that that would be able to rotate around an attached axis, we came up with the Haughton design. This design consists of two arms extending from the base (Figure 8). The base would be rotated by either a hand crank or ultimately a motor. The base would then rotate the arms through the degrees necessary for our design. The arms would contain tracks that would extend up the sides of the arms. The head support would be attached to sliders which would allow free movement up and down the tracks of the arms. The head support would also be allowed to rotate about the axis of the attachment. With the use of sliders, we eliminated the use of a hydraulic jack. The only movement we would have to concern ourselves with would be the rotation of the base.

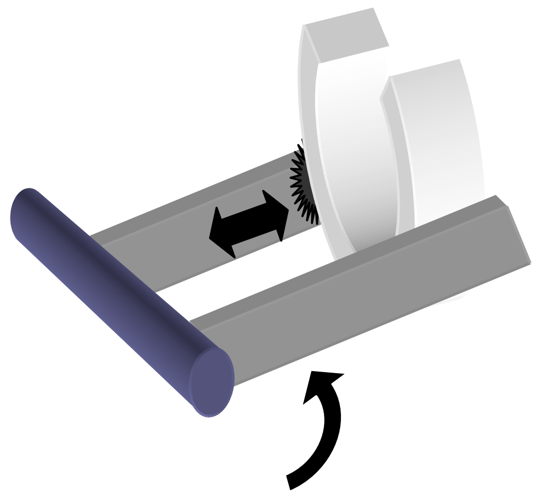

Figure 8: Preliminary Haughton Design Sketch

Evaluation

For our evaluation of each design, we constructed a concise table, Table 1, where we ranked our designs in various categories. These categories are part of our client's requirements and integral to the success of our design. We took a total of 100 points and weighted the categories based on importance to our client. We gave 20 points to the most important categories, 10 points to the next important categories, and 5 points to least important categories. With these possible point values assigned to each category, we gave a fraction of these points to each prototype based on their performance in each category. For example, we gave the category "Neck Movement" a total of 20 points. Out of a total of 20 points, we gave our Cable Design 10 points, the Airbag Design 14 points, and the Haughton Design 18 points. We felt that the Haughton Design provide the most natural movement of the neck out of the three designs and thus gave it the most points.

We then added up all the points earned by each of the three designs to see how each design complies best with our client's requirements. The Haughton Design won out with 85 points out of a possible 100 points while the Cable Design and the Airbag Design came in 64 points and 60 points respectively. We felt that the Cable Design was overall too bulky and slightly dangerous with the cables. Also, the integration of the motorized reeling mechanism would be a cumbersome obstacle to overcome. The Airbag Design was also too bulky and rather inaccurate way to more the neck precisely. Also, the natural movement of the neck would not be achieved with this design. We chose the Haughton Design because we felt that the design significantly weighed the other designs in the most important categories. Looking at this evaluation, we saw that our Haughton Design best fits our client's requirements. We therefore proceeded the rest of the semester designing the Haughton Design for our client.

Category	Weight	CABLE	AIRBAG	HAUGHTON
Portability	20	10	17	18
Easy Of Use	10	8	6	8
Cost	10	10	8	5
Neck Movement	20	10	14	18
Patient Safety	20	12	16	20
Durability	10	5	7	8
Complexity	5	4	3	3
Accuracy	5	5	1	5
TOTAL	100	64	60	85

Table 1: Design Matrix

Evolution of final design

Data Acquisition

An experiment was conducted to determine the limits and natural curvature of neck rotation. To accomplish this, each team member laid on a flat surface in front of a large grid for reference. Each person rotated their neck at discrete intervals and photographs were taken for later analysis. See figure 9 for an example.

Figure 9: Neck Rotation Pictures

The data from this experiment is illustrated in figure 10. This showed that the natural rotation of the neck was not perfectly circular, which needed to be accounted for in the final design.

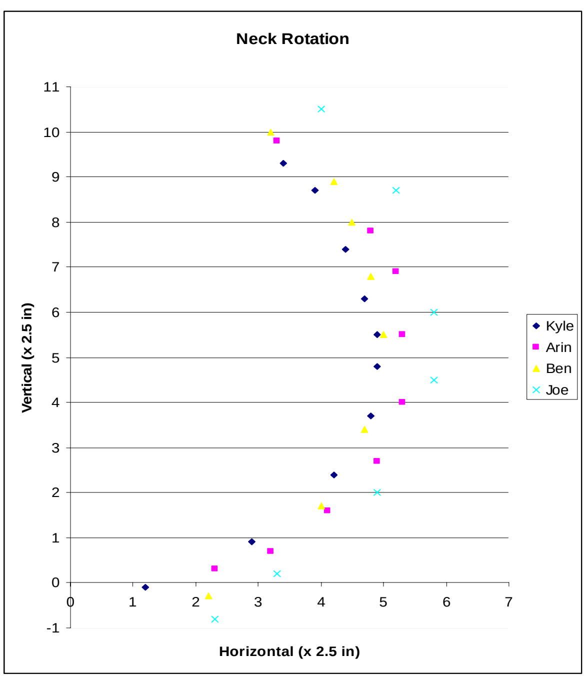

Figure 10: Neck Rotation Data

Final Design Details

The final design went through many revisions and evolved significantly throughout the design process. Figure 11 initial sketch shows the original concept behind the Haughton design.

The Haughton design concept revolved around four major components:

- Head support.
- Support arms and track.
- Hinge and table connection.
- Power source and power transmission.

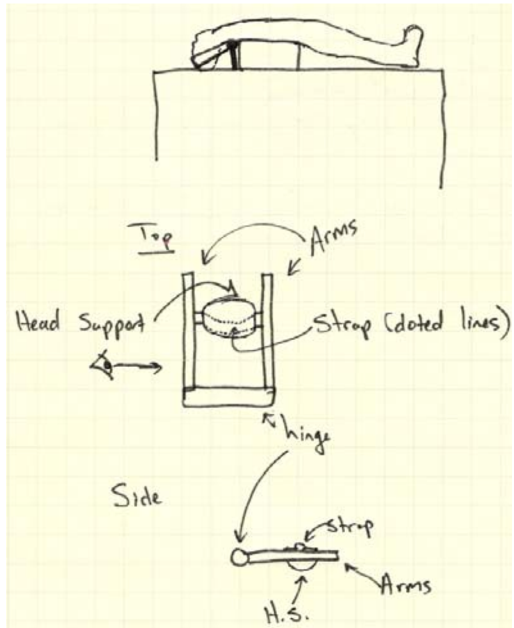

Figure 11: Original Haughton Design Sketches

The design evolution of these four components is described below.

Head Support

Obtaining a head support proved to be a challenge. It was initially believed that a head support could be machined out of raw materials, but after more consideration, it was decided that a pre-made head support would be a better option. A pre-made head support provided better ergonomics and cut down on the time necessary to design and machine a head support. Our client had a contact at GE Healthcare, so GE head supports were investigated. It was quickly discovered that GE's head supports were too expensive for the project budget, ranging from $600 to $1850. A meeting was held with our client to discuss this, and he offered to contact GE to determine our options. Shortly thereafter, GE generously donated a suitable head support for the project. A photograph of the unaltered head support is shown in figure 12.

Figure 12: GE Head Rest

The head support required modification to be incorporated into the final design. It was cut approximately in half in order to remove part of it that hindered neck rotation.

Support Arms and Track

The support arms by which the head rest would be supported by is interrelated with the track by which the head support would slide on. The support arms were made out of a rectangular block of polyvinylchloride (PVC); no problems were encountered while selecting the support arm material. Three track and support arm assembly designs were brainstormed. First, casters would roll along the top of the support arms back and forth. This was potentially dangerous because the caster was only in contact with the support arm on the top of the support arm, meaning they were two different pieces and the caster would be able to be separated from the support arm. This led us to our second design idea: an outside track. The main idea of this was to create a guide system outside of the support arm. The last design idea was to either purchase a plastic track or machine a T-slot on the inside of the PVC to act as a track. After failing to find a pre-made plastic track, the latter idea was chosen. However, it was discovered that the student machine shop did not carry the correct T-slot cutter we needed to machine the slot. The correct drill bit could be purchased from MSC Industrial Supply Co.; however, the price ranged from $106 to $226. We decided on an alternative solution due to time constraints.

The alternative design resorted to using a readily available metal track. While the metal would interfere with fluoroscopic imaging, the design would serve as a proof of concept. A metal track was purchased and fastened to the outside of a 1”x1”x13” piece of PVC. The next hurdle was finding a wheel that fit the track. The wheels purchased were slightly small for the track, but it was bent accordingly to fit the wheels.

Hinge and Table Connection

The original idea for connecting the device to a fluoroscopy table was to extend a flat piece of plastic for the patient to lie on. The patient’s own body weight would hold the device in place. It was determined that this idea would make our device less stable and too bulky for one person to transport. Instead, two C-clamps were used to hold the device securely to the table.

Power Source and Power Transmission

Our client initially suggested that we incorporate a worm gear and motor into our design. A worm gear is a gear that interacts with a worm to transfer the direction of rotation (Figure 13). This gear, in association with a motor, would provide slow, smooth, and accurate rotation of the device and allow for operation by one person.

Figure 13: Worm Gear [5]

Our initial priority was to include a simple hand crank in our prototype and then possibly add a motor later. This was the plan for the majority of the semester, but we decided to do some research into what type of motor would be needed. This would tell us if it was at all feasible to include a motor given our constraints. Our research began online, and showed that there is an abundance of motors available.

Certain specifications were required of our motor. A rotational speed of about 1 RPM would provide the desired rotation at a reasonable speed and in an adequate time frame (about 12 seconds). Research on worm gears showed that the average efficiency was about 30% (see Appendix B). This meant that if our motor ran at 10 RPM, the required torque output would be 60 in-lbs. If the motor ran at 20 RPM, the required torque output would be 120 in-lbs.

We decided to meet with a Mechanical Engineering professor on campus to discuss what type of motor would meet these specifications. We met with Professor Frank Fronczak on April 11, 2006. After hearing our design description, he suggested that a gear motor, or gear head motor would be most beneficial to our design. This type of motor incorporates a series of stages that greatly reduce the output speed of the motor. Seeing as most motors run at speeds in the hundreds or thousands of RPM, this reduction would be of great necessity. A gear head motor running at 20 RPM and a 20 tooth worm gear would produce the desired 1 RPM output.

Upon researching such motors, it became obvious that cost and meeting specifications would both provide problems. Gear motors ranged greatly in price, averaging in the low hundreds of dollars. Each motor also had a number of specifications, and finding a motor that met all of our needs in such a short time would be very difficult. Research into worm gears also provided several setbacks. Worm gears that were made entirely of plastic were inexpensive, but came in a very limited range of sizes. They also were very inefficient. These problems pushed us to build our prototype using a simple hand crank. This crank would still be able to show if the design worked properly, and a motor could be incorporated at a later time after further research had been done. We were able to obtain a hand crank by donation. This crank was used in our prototype to rotate the arms of the device.

Final Design Overview

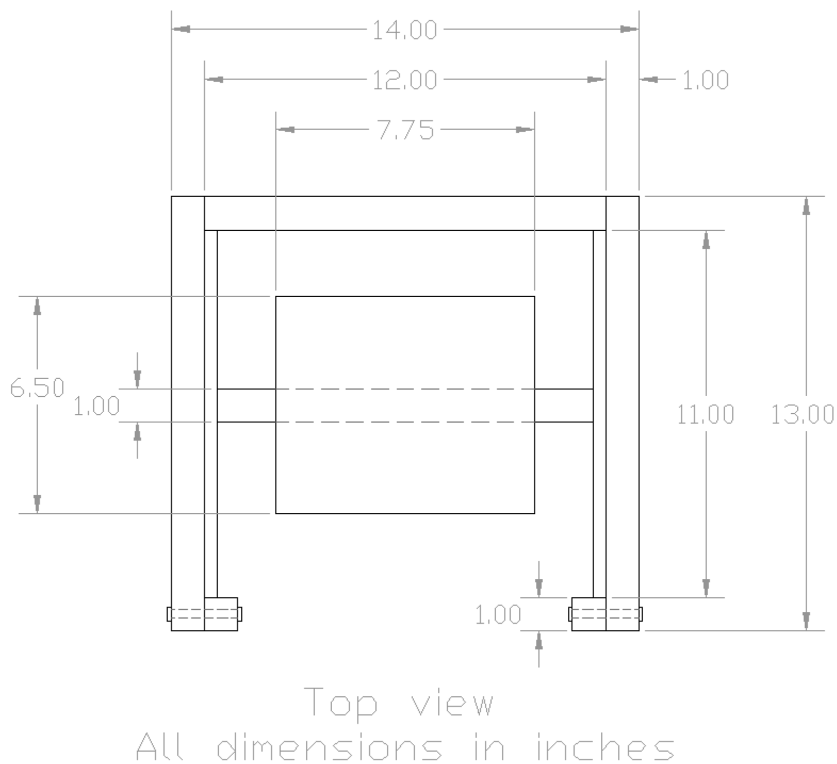

Figure 14: Dimensions of Haughton Design

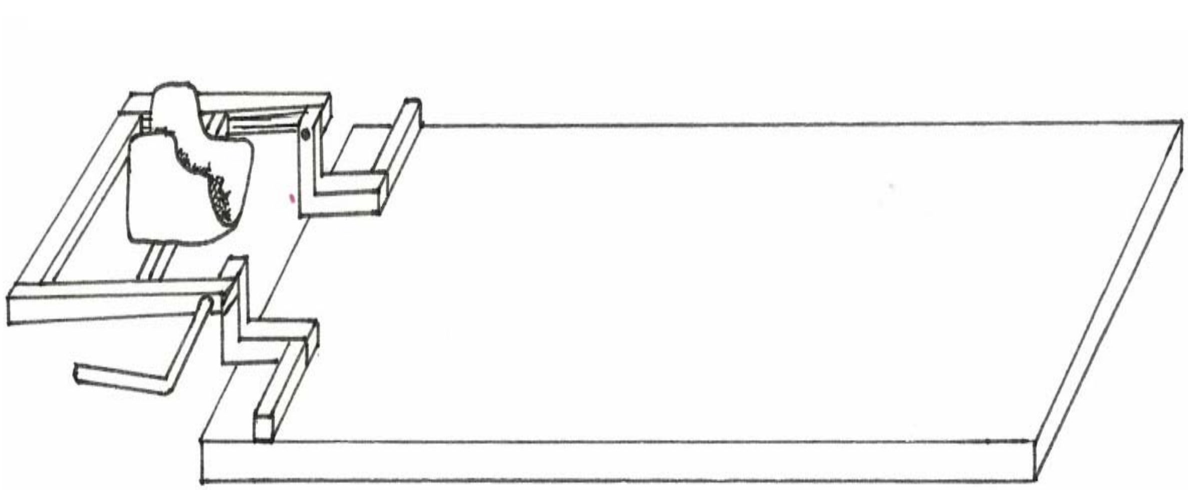

Figure 15: Haughton Design

Final Design Components

Head rest

GE Healthcare Metal-Free Carbon FiberAxial Headholder

Donated by GE, valued at $601.00

Part number E8004TK

Max load: 75 lbs

PVC structural components

Machined from McMaster Carr Part number 8660K43 - $51.64

Material: PVC, type 1

Tensile Strength: 7300 psi

Impact Strength: 0.8 ft-lbs/in

Track

Purchased from Menards - $2.87 each

Track wheels, purchased from Menards - $4.99

Hand crank

Donated by Jerome Ellingson

Other

Fasteners/washers/bolts - $5.71 total

Conclusion

Future work will be needed to produce a fully functional and accurate design. There are also ethical considerations that need to be kept in mind when creating such a device.

Future Work

Future work would include research into companies that could help in construction such a device. The device would need to be made entirely of plastic, or some other material with a very low mass attenuation coefficient.

Adding a motor to the device to provide rotation by remote control would also be a future necessity. This would require some type of gear motor that would interface with the device to provide rotation at the desired speed and also run on power from a wall outlet (AC). Motor specifications can be found in Appendix B.

Late in the semester we found a fiberglass track that could be used in the design. Fiberglass is a material with low mass attenuation, and the track would provide the desired movement of the head rest.

Design Construction

The construction of the design would most likely require the assistance of a plastics company. Certain parts (e.g. track, screws, etc.) are most commonly made of metal and are difficult to find in plastic form. A company that specializes in creating custom made plastic constructions could custom make such parts. This would most likely add to the cost of construction, but is required to create a functional device.

Additional Testing

Upon completion of the device, testing would be needed to ensure its safety and accuracy. Certification from the IRB would be required to test on human patients. Trials in the fluoroscope would be needed to show that the device does not block any imaging, cause any severe discomfort, or have any structure problems with the machinery (e.g. too large, too heave, etc.).

Appendix A

Product Design Specification

Updated: April 26, 2006

Team Members:

- Arin Ellingson: BSAC
- Joe Ferris: Leader
- Kyle Herzog: Communications
- Ben Schoepke: BWIG

Problem Statement:

Present methods of positioning a patient's head while performing a fluoroscopic examination of a fractured neck are inefficient and unsafe. A technician must physically move the patient's head in various positions with their hands while the examination is taking place. This procedure is potentially dangerous for the patient and time consuming for the radiologist. The device to be designed will flex and extend the head about the neck in a fluoroscopy room. The device is designed to prevent obstruction of x-ray imaging. It provides rotation about the spine isocentric to the normal rotation point for flexion and extension.

Client Requirements:

- *Improve current design*
- *Increase ease of operation*
- *Accurately mimic natural neck movement*
- *Must not obstruct x-ray imaging*
- *Cost efficient*

Design Requirements:

1. Physical and Operational Characteristics

a. Performance Requirement: The device must be capable of rotating the neck 45 degrees backward (extension) and 25 degrees forward (flexion). This rotation must also mimic the natural rotation of the neck.

b. Safety: The device must comply with all medical safety regulations. It must be comfortable for use with a variety of sized patients. The device must move slowly and smoothly to prevent injury. Sharp edges should be covered with padding. The head must be held securely during operation. The device must not get tangled with patients' hair.

c. Accuracy and Reliability: The device must operate successfully over repeated uses. The rotation must be smoothly adjustable with one degree of sensitivity.

d. Life in Service: The device must be capable of being used daily, but will likely be used once or twice a month. It should have a lifespan of ten years minimum.

e. Operating Environment: The device must be capable of withstanding the conditions encountered in a fluoroscopy room. Its operation must not be impaired by x-rays.

f. Ergonomics: The device must be comfortable for the patient. It should also be easy to use and require only one person to operate.

g. Size and Shape: The device must fit easily within a standard c-arm fluoroscope. The shape should allow for transport by one person. The head support must be able accommodate a head width of up to seven inches.

h. Weight: The device must be less than twenty pounds to be easily transported by one person.

i. Materials: The device must be strong enough to avoid deformation over repeated uses. Material must have a low mass attenuation coefficient to minimize x-ray shielding.

j. Aesthetics, Appearance, and Finish: The appearance should be appropriate for a hospital setting.

2. Product Characteristics:

a. Quantity: One device is required.

b. Target Product Cost: The prototype should cost less than $500 to build.

3. Miscellaneous:

a. Standards and Specifications: The device should comply with all regulations established by the FDA for medical instruments. More information can be found on the FDA website.

b. Customer: The customer will typically use the device in a fluoroscopy room, so all design choices must take the conditions of such an environment into account.
The preferred focus is on extension, with optional side-to-side rotation functionality.

c. Patient-related concerns: The patient must feel comfortable, and the device must not cause claustrophobia.

d. Competition: No similar device currently exists.

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