Abstract

A device will be developed that will flex and extend the head about the neck in a fluoroscopy room. It will provide rotation about the spine isocentric to the normal rotation point for flexion and extension. Fluoroscopic examinations of the head and neck use a steady stream of X-rays to provide a real-time image that can be used to diagnose fractures that could not be seen with a simple X-ray. The device is designed to not obstruct X-ray imaging. Five preliminary designs have been discussed, and each was further analyzed in order to see which will be most effective. Future work will be required to test the final design's efficiency and its compatibility with a fluoroscope.

Problem Statement

Present methods of positioning an obtunded 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.

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 patient may be unconscious during the examination, and therefore would not be able to communicate to the specialist any pain they feel. 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 at the end of this report for a more detailed and technical list of requirements.

- The patient's safety is of utmost importance. The device should not further the injuries of the patient.
- The device must not obstruct fluoroscopic imaging.

- The device must be able to flex the neck twenty-five degrees (forwards) and extend forty-five degrees (backwards).
- The motion of the device should be smooth and steady to avoid patient injury and allow for careful examination.
- 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 universal for all types of people.
- The total cost of the prototype should be less than $500.

Background

I. Fluoroscopy

The primary function of fluoroscopy is to provide real-time imaging of dynamic processes as they occur (Schueler, 1116). There are many applications of fluoroscopy: tracking blood flow in arteries, evaluating the digestive or urinary tracts, or diagnosing female reproductive problems. 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 have been undetectable by other methods and are then diagnosed by a radiologist carefully observing a real-time image.

Several different types of fluoroscopes exist. For a two examples, refer to Figures 1 and 2.

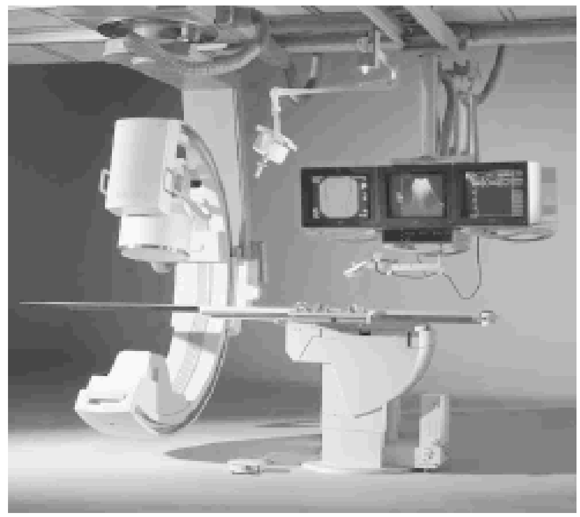

Figure 1&2- Examples of different types of fluoroscopes.
Schueler, 1123-1124

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 (Schueler, 1115). Today's fluoroscopic images are amplified and interfaced to a television or monitor display system. This process is outlined in Figure 3. 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.

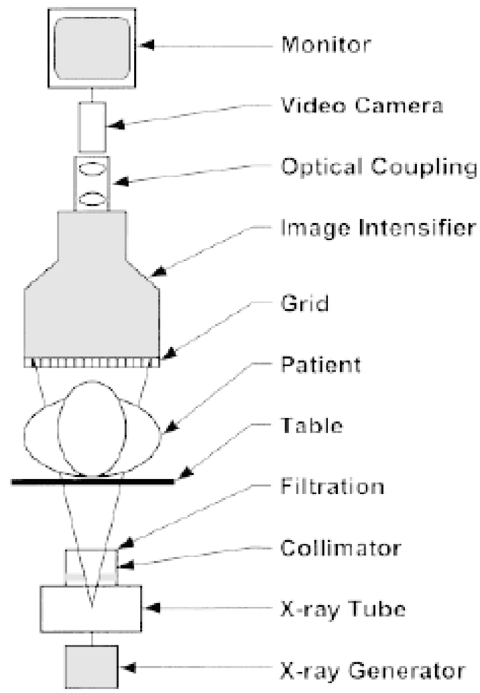

Figure 3- Schematic of a fluoroscopy machine. Schueler, 1117

II. Materials

The device must not compromise the imaging capabilities of the fluoroscope. Therefore, the materials it is composed of must not interfere too much 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 4 provides a 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.

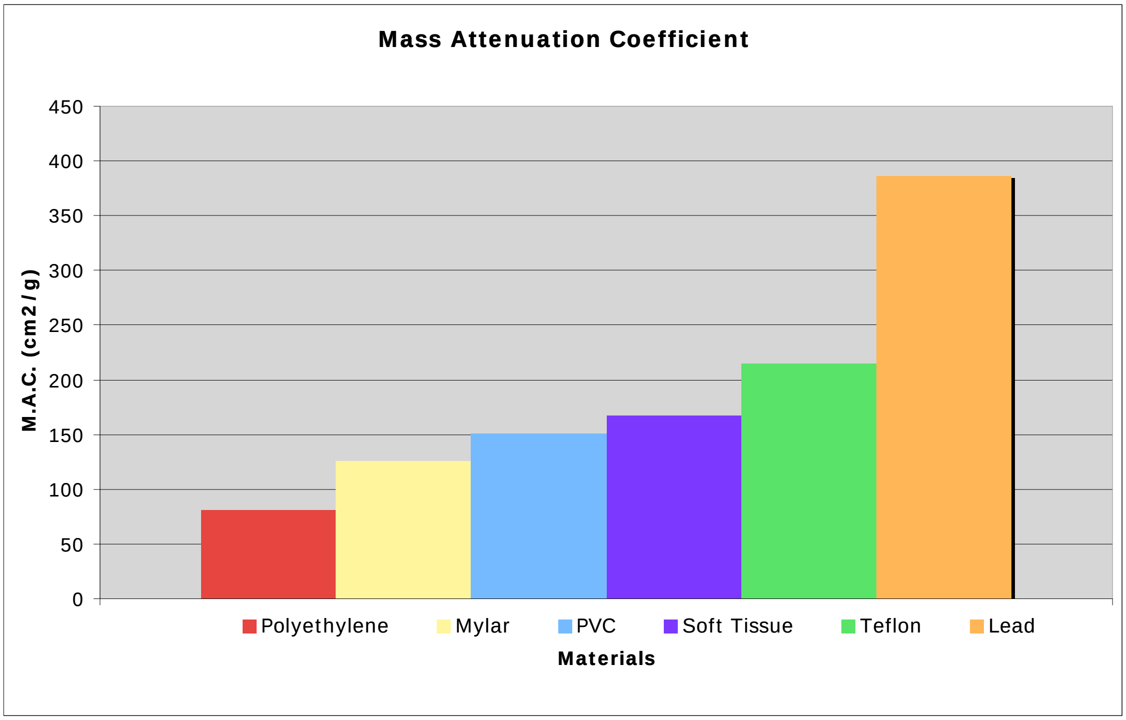

Figure 4- Mass Attenuation Coefficient Chart
http://physics.nist.gov/PhysRefData/XrayMassCoef/tab4.html

DESIGNS

I. Cable Design

This design uses two cables connected to a head support to provide the desired rotation. Changing the length of the cables provides the rotation. For example, to rotate the head forward, the cables would be shortened. See Figure 5 for an illustration of this design.

The major advantage to this design is its simplicity. Rotation is achieved by changing the length of cables, which could easily be accomplished by a “reeling” mechanism, much like how a fishing rod works. This allows for easy integration with a motor, which provides a rotating bar that could directly operate the reeling mechanism to provide automatic control of the device. With a motor, the rotation could be carefully controlled to provide smooth, precise, and therefore safe movement of the head support. The cables could be made of nylon fibers, which have low x-ray attenuation and can support the mass of a human head. Alternatively, heavy fishing line could be used to minimize costs while still providing exceptional strength.

This design has a few notable drawbacks. The cables and the support posts could take up too much space and could interfere with surrounding equipment. The cables would have to be thick enough to prevent being easily severed, which could pose a further space problem. The combination of these factors could prevent this design from being universal—it would have to be redesigned to work with each fluoroscopy table. Portability would also be a concern. The device may be difficult to transport due to the long support arms necessary to hold up the cables and reeling mechanisms. Safety is also a concern, as it could be possible for a patient's hair to become tangled with the cables.

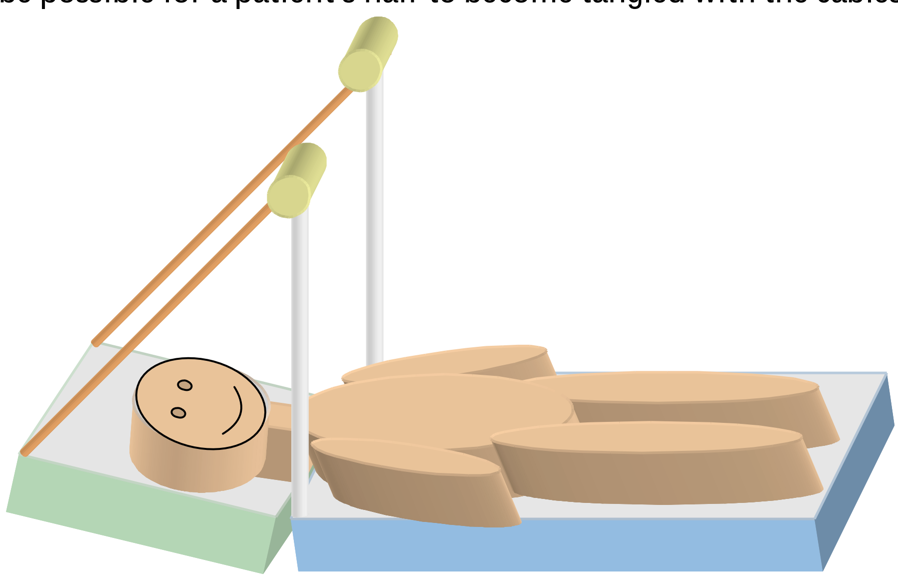

Figure 5- Picture of purposed Cable Design

II. Airbag Design

The second design that we chose to comply with our client's proposal is a completely different approach to flexing and extending the head. In this 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 6. The mat is made from one and a half inch thick resilient foam cover in heavy-duty vinyl, similar to a tumbling mat. The headpiece is made out of the same material and woven together to the mat. Under the headpiece, a piece of flat plastic is drilled into the mat to provide sturdiness and a place to attach the tracks. On top of the mat, a comfortable headrest made of foam is drilled into place. A strap is placed on either side of the headrest to fasten the patient's head down during the examination.

The second component of the air bag prototype is the tracks. These tracks consist of two pieces of plastic that are curved one hundred and fifteen degrees. These pieces of plastic will have a track carved out in which the headpiece will be guided through the complete flexion and extension. The degrees are marked on the sides of the tracks for reference. These thin pieces of plastic are spaced out twelve inches apart and connected to a board that is perpendicular to the mat (which is lying on top of the fluoroscopy table). The board is also attached to the mat at a ninety degree angle. The two thin, curved pieces of plastic are curved up on each side of the mat and headpiece. The headpiece has a rod which acts as a guide as it is escorted along the tracks.

The third component of the prototype is the airbag. The airbag is made out of a sturdy vinyl. The airbag also has a built-in bladder system which is made of a plastic. This bladder will provide more protection for the air. The airbag is then attached to the board that is ninety degrees with respect to the mat. The bag is also attached at regular intervals to the tracks and finally the headrest. It will then be able to inflate the full seventy degrees (forty-five extended and twenty-five flexed) necessary for the device.

The air source needed for the prototype comes from an air compressor. The air compressor is provided with 12 volts of potential and a maximum air pressure of two hundred and twenty pounds per square inch. This is more than enough pressure to inflate the airbag with a human head attached. The air compressor is managed by a simple switch which lets air in and out. In this way, one radiologist is able to control the angle at which the patient's head is positioned.

This device fits our client's requirements to some degree. All the materials are made out of low mass attenuation materials such as plastic, vinyl and foam. The device is able to accommodate different sizes and ages of patients without sacrificing comfort. Also, a single physician is able to manipulate the device with the use of a switch on the air compressor. The use of a single switch to move the patient’s head to various degrees will decrease the personnel needed to perform the examination and make the whole examination simpler for the physician. Finally, the air compressor allows movement of the head to be relatively smooth and steady because of the slow air flow into the airbag.

There are, however, several drawbacks to this design. The design is rather bulky and will be difficult to move and position by one physician. The device is not universal to different types of fluoroscopes. The device’s operation depends on hanging the apparatus off the end of the table. In the fluoroscopy room, this amount of space may not be available. Also, the device does not mimic the exact movement of the neck. This is due to the single hinge between the headrest and the mat. Finally, the design may not be precise to the exact degree. This may be necessary under the physician’s discretion.

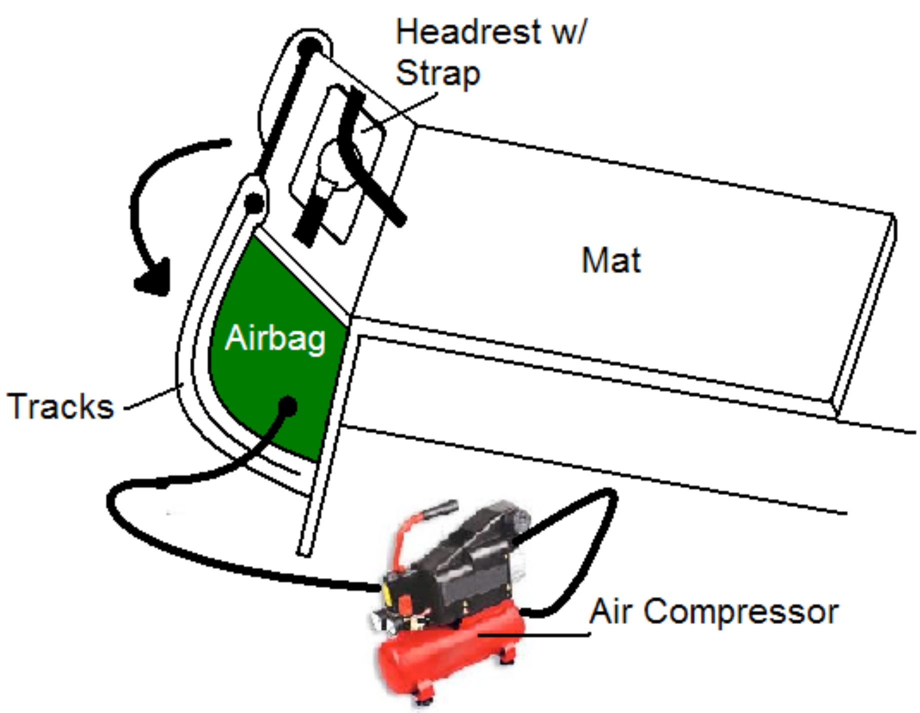

Figure 6- Picture of purposed Airbag Design

III. Jack Design

Another preliminary design incorporates a flat base that rotates as Figure 7. Also involved is a jack, possibly hydraulic. One major point of this design concept is that it mimics the natural movement of the neck no matter the path. The interaction between the rotation and the extension make it possible to mimic any path taken by the neck. The group decided that this was just too raw of an idea and we refined it into our next design idea.

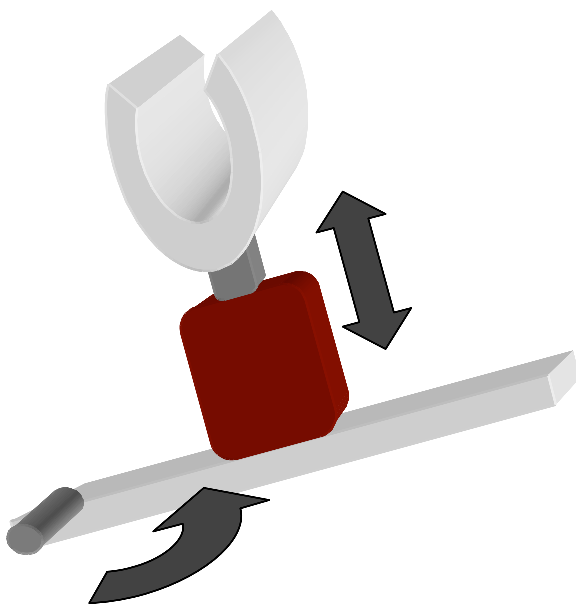

Figure 7- Picture of purposed Jack design

IV. Periscope Design

This design would consist of two extendable rods, attached to the head support, which was described previously, on one end and the other end both rods connected to each other, and also to an adjustable hinge, as Figure 8 depicts.

This design would also be able to mimic any path of rotation, specific to each individual, making the device more universal to all. The two moveable parts of the design, the extending rods and rotation around a hinged axis, enable a very precise movement. Ideally there would be a motor, operated by remote control, to power both movements.

The device would rest on the bench, and either be clamped down or held in place by the patient's own body weight. This would be possibly by extending a flat piece down the bench, while the patient lays on it. Also in order to ensure maximum rotation of the neck, the patient would have to lie on a four to six inch foam pad.

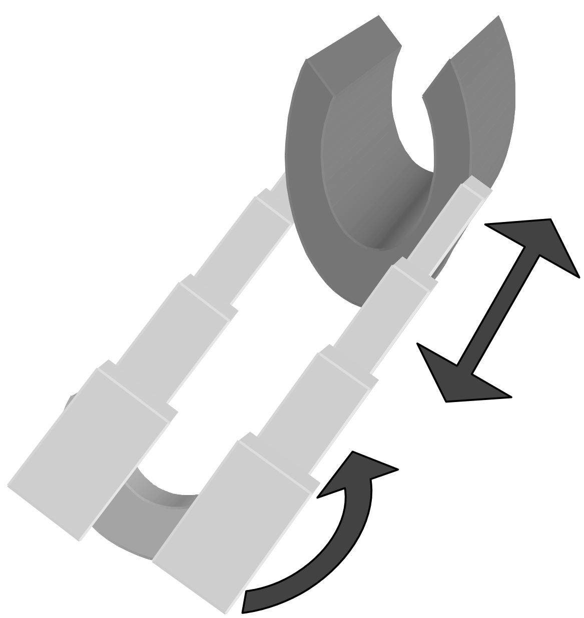

Figure 8- Picture of purposed Periscope Design

V. Haughton Design

Our final design is named the Haughton design, after our client. It consists of two arms extending from the base, holding the arms together will be, at the base, a rotational hinge, and the head support itself. The head support will be able to slide freely along tracks up and down the arms. Along with the head support will be a strap reaching across to secure the subjects head in place. A picture of an example head support can be found at Figure 10; this is a device made by GE, which we will either implement into our design or construct a similar device. With the rotation from the hinge and the free sliding ability of the head support this device will be able to mimic any natural movement of the neck. To see an illustration of this design refer to Figure 9. This design will work in correlation with the four to six inch pad described earlier and rest on the table. One of the benefits of this design is exactly that, it can rest on the table. The previous designs were implemented to extend from the normal fluoroscope table. Since this device rests on the table it makes it much more universal, the ability to work on different types of fluoroscopes as well as being extremely portable. Thus far the only draw back of this design is its complexity, for it is the most complicated of the designs.

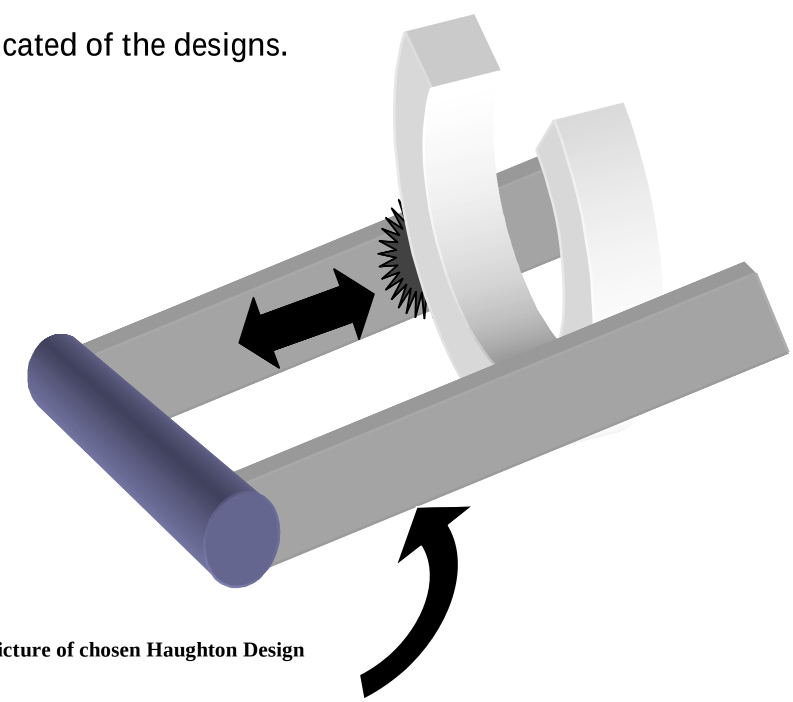

Figure 9- Picture of chosen Haughton Design

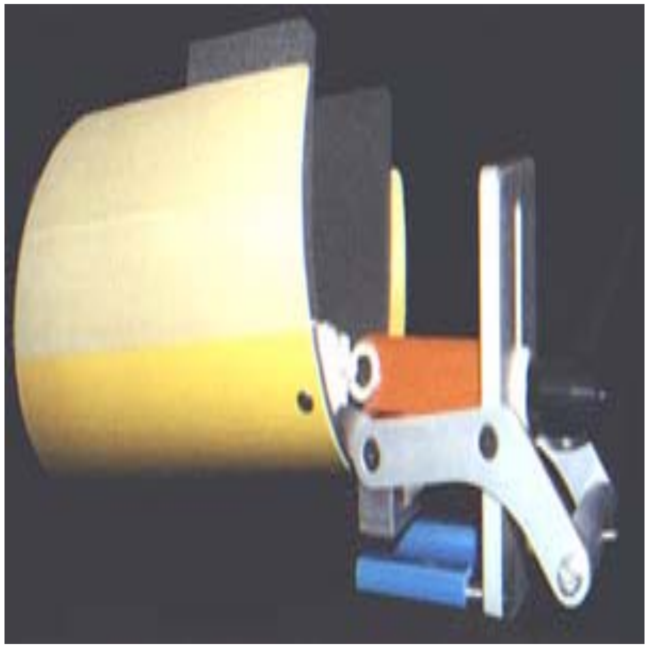

Figure 7- Picture of possible head support manufactured by GE.
http://apps.gehealthcare.com/apps2/accessories/productdisplay.jhtml?CATID=224163&PRODID=103604

Design Evaluation

In order to evaluate our three designs and make an educated decision on which prototype we will want to proceed with for the rest of the semester, we designed a concise table, Figure 10, which 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 "Portability" a total of 20 points. Out of a total of 20 points, we gave our Cable Design 10 points, the Airbag Design 15 points, and the Haughton Design 18 points. We felt that the Haughton Design was the most portable 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. Looking at this evaluation, we saw that our Haughton Design best fits our client's requirements. We will, therefore, proceed to the rest of the semester designing the Haughton Design for our client.

Category	Weight	CABLE	AIRBAG	HAUGHTON
Portability	20	10	15	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	58	85

Future Work

To complete the project, a significant amount of development remains to be done. The design is still in early stages and the details need to be worked out. The following is a list of the major tasks to be accomplished:

- Finalize the Haughton design.
- Obtain all necessary components and materials.
- Build initial prototype.
- Obtain human subjects testing approval.
- Test device on people.
- Test device on actual patient.

It is believed at this time that the project is on schedule and will be completed before the deadline. In order to achieve this, portions of the design have been prioritized. The initial goal is to design and build the head support assembly. Once that is completed, work on incorporating the motor, drive, and control systems will begin. After building the prototype, testing procedures will be developed and completed as quickly as possible.

Project Design Specification

Updated: March 1, 2006

Team Members:

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

Problem Statement:

Present methods of positioning an obtunded 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 many times daily. 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.

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

e. Size and Shape: The device must fit easily within a standard c-arm fluoroscope. The shape should allow for transport by one person. It also must be able accommodate a variety of head and neck sizes.

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

g. 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.

f. 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 device should cost less than $10,000 to manufacture in high quantities. 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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