Facilitation of Dynamic Flexion & Extension of the Neck During Fluoroscopy

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Abstract

A device is needed to replace existing methods of extending and flexing an obtunded patient's neck during fluoroscopic examination of the cervical spine. A previous design achieved a full range of motion, but was cumbersome and difficult to attach because it hung off the end of the table. This semester's prototype includes a gear and motor system that is more ergonomic with strong consideration of patient safety.

Motivation

Patients with cervical spine injuries that are brought into the hospital are often imaged to determine the severity of their injuries, especially if the patient is obtunded and unable to provide feedback about his or her pain. If the injury occurred less than 72 hours prior to the time of imaging, an MRI scan can be preformed to diagnose spinal health. However, once 72 hours has passed, a healthy spine cannot be distinguished from an injured spine with an MRI. At that time, fluoroscopic imaging can be used (Medow, 2007). Fluoroscopic imaging allows for observation of movement and interaction of the vertebrae during neck motion. Detected abnormalities in movement may indicate injury. Currently, the hospital staff manually flexes and extends the neck during imaging (Medow, 2007). This unnecessarily exposes the staff to radiation. Also, this method lacks precision and repeatability. A safe and reliable device is needed that will flex and extend the patient's neck at a consistent rate.

Background Information

Cervical Spine

The cervical spine is anatomically defined as the first seven vertebrae of the spinal column, starting at the base of the skull. Compared to the thoracic or lumbar vertebrae, the cervical vertebrae are smaller in size. The cervical vertebrae serve as an anchor for muscles, tendons, and ligaments that facilitate movement of the head and neck. The neck is capable of a wide variety of motions, including lateral isocentric rotation, abduction and adduction, and extension and flexion (Saladin, 2007). Extension of the neck occurs when the angle between the chin and chest is increased (the head is leaned back, shown in Figure 1), and flexion occurs as the chin- chest angle decreases (the head is brought forward, as seen in Figure 1).

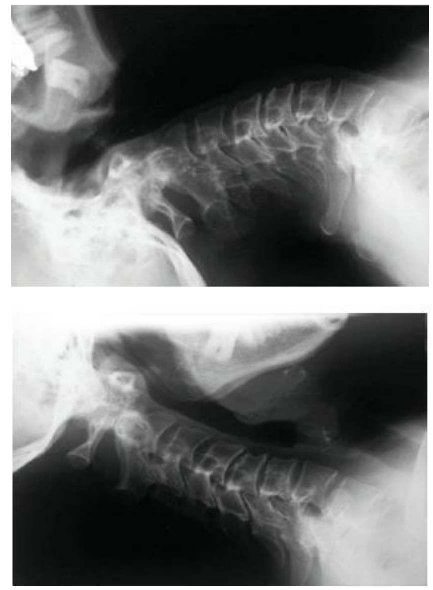


Figure 1 www.wheelesonline.com

Nerve tracts to vital organs and skeletal muscle pass through these first seven vertebrae. Damage to any of the nerve pairs or the spinal cord itself is a serious health concern. Lesions or severance can lead to permanent paralysis of part or all of the body, depending on the site of damage (Saladin, 2007). Victims of traumatic events, especially vehicle or motorcycle accidents, have their cervical spine immobilized by a protective collar to minimize the risk of aggravating an injury before they are diagnosed at a hospital. These patients may be conscious, but frequently they are obtunded and unable to communicate with medical staff about pain they may be experiencing. Even patients claiming no pain are still treated as if they may have fractured vertebrae, damaged ligament or disc, or even a direct injury to the spinal cord. Imaging the neck has become a routine procedure for patients at risk for cervical spine trauma. Analyzing the image data assists doctors in assessing the stability and health of the cervical spine before deciding whether or not the patient should remain immobilized in the neck collar (Medow, 2007).

Fluoroscopic Imaging

Fluoroscopy is just one of several tools used by medical professionals for imaging internal structures of the body. By taking a rapid sequence of x-ray images and immediately displaying them as they are processed, fluoroscopy provides medical staff with the ability to "see" in real time the dynamic behavior different tissues. To take the image, a focus beam of x-rays is passed through the ends of a c-arm oriented such that the ends face the region of interest (Figure 2) (Medow, 2007).

Figure 2
http://www.medical.toshiba.com/products/cv/Configurations.aspx

This provides the unique opportunity to observe the actual motion of tissues instead of a static image, as given by MRI or standard radiographs. The time of fluoroscopic procedures is kept to a minimum to reduce the exposure of the patient to radiation from the x-rays. By using dynamic fluoroscopic imaging, injuries that otherwise would have been missed by the static imaging can be detected. This is not to say that fluoroscopic imaging should be the lone method of imaging. It is common practice for several types of imaging to be used to ensure that no injuries or conditions are overlooked before a patient is released (Medow, 2007).

There are mixed opinions in the medical community on the benefits of dynamic fluoroscopic imaging for diagnosing injuries of the cervical spine. Studies have shown that it does not always result in uncovering missed injuries. For example, in a 2006 study, tomography and three dimensional reconstructions repeatedly accurately detected ligamentous injuries in the cervical spine, while the accuracy rate of dynamic fluoroscopy fell below that (Padayachee, et al., 2006). However, this study did not take into account the factor time plays in image quality. After a finite amount of time, roughly 72 hours post- injury, the physiology of the neck has changed such that MR imaging is more likely to show false positives (Medow, 2007). In another study, it was concluded that dynamic fluoroscopy was able to detect occult injuries that were missed by other imaging methods (Cox MD, McCarthy MD, Lemmon MD, & Wenker MD, 2001).

Current Methods

The advantage of utilizing fluoroscopy for dynamic imaging of the cervical spine is the ability to observe interactions of the vertebrae. For an optimal view, dynamic fluoroscopic imaging is typically done laterally while the patient lies on their back, and their neck is extended and flexed. In cases where the patient is obtunded, hospital staff must manually extend and flex the patient's neck. This is not a highly standardized procedure, so the results from one trial can't be directly compared to another. The patient's head is moved by supporting it from beneath near C1, or laterally on the parietal or temporal regions. With these techniques there are no means to ensure consistency in rotational speed or to inhibit extraneous neck translation or isocentric rotation. These factors all contribute to inconsistent and unrepeatable results that do not optimize the safety of the patient or the hospital staff (Medow, 2007).

Existing Technology & Previous Work

There are positioning devices currently available on the market. However, they are limited to static positioning, and do not offer ways to facilitate motion during dynamic fluoroscopic imaging. These products range from simple foam wedges, which force a patient to hold a very specific position, to more advanced concepts, such as those seen in the Rhodes MRI device. This device combines the idea of foam molding with springs, allowing the patient to rest on a more natural flexion or extension position (Neumatic Medical, 2007).

Previous work has been done in the development of a prototype to facilitate dynamic flexion and extension of the neck during fluoroscopy. The most recent one was based on a linear actuator mounted to a platform beneath the head of the imaging table that raised and lowered a headboard. While this device did achieve a full range of motion, it had drawbacks. Primarily, it was awkwardly shaped, making handling and storage difficult. It lacked a stable base for standing independently when not in use, and required clamping to keep it on the table. It was realized later that its size may also result in interference with the fluoroscopy machine's c-arm as it rotates into position about the patient. The platform extended about two feet below the table, putting it at risk for obstructing other equipment. It was decided that this project should be approached from a more ergonomic direction that melds mechanics with practicality while still emphasizing patient and user safety.

Design Requirements

The primary concern for the design of the neck positioner is the safety of the patient. Since the device will be used during the examination of an unconscious patient, and he or she will not be able to give feedback during the procedure, it must be comfortable as to not injure the patient unknowingly. The device must allow for smooth, stable rotation of the cervical spine to prevent further injury. The cervical spine must also be stable throughout the procedure laterally. Any translation of the cervical spine during flexion and extension must be avoided.

A range of 45° of flexion and extension of the cervical spine from the neutral position must be obtained. The angle of extension or flexion must be displayed during operation. The headboard also has to operate at a slow enough rotational speed (2° per second) so the examiner can detect any abnormal movement.

The device cannot have any sharp edges, corners or hinges that could pinch or irritate the patient. The materials must be radiotranslucent to not interfere with lateral imaging. Therefore, metals cannot be present near the area of imaging. The final materials should also be able to be sterilized between procedures without damage to components.

The positioner must accommodate an adult of average head, neck, and shoulder size, but does not have to accommodate children, as the procedure is only performed on adults. The device must be small enough to be stored, set-up and taken down easily. A single person should be able to operate the device from a remote location to minimize x-ray exposure to the hospital staff. The final commercialized device should cost less than $2,000 to manufacture.

Alternative Designs

Design 1: Vertical Actuator

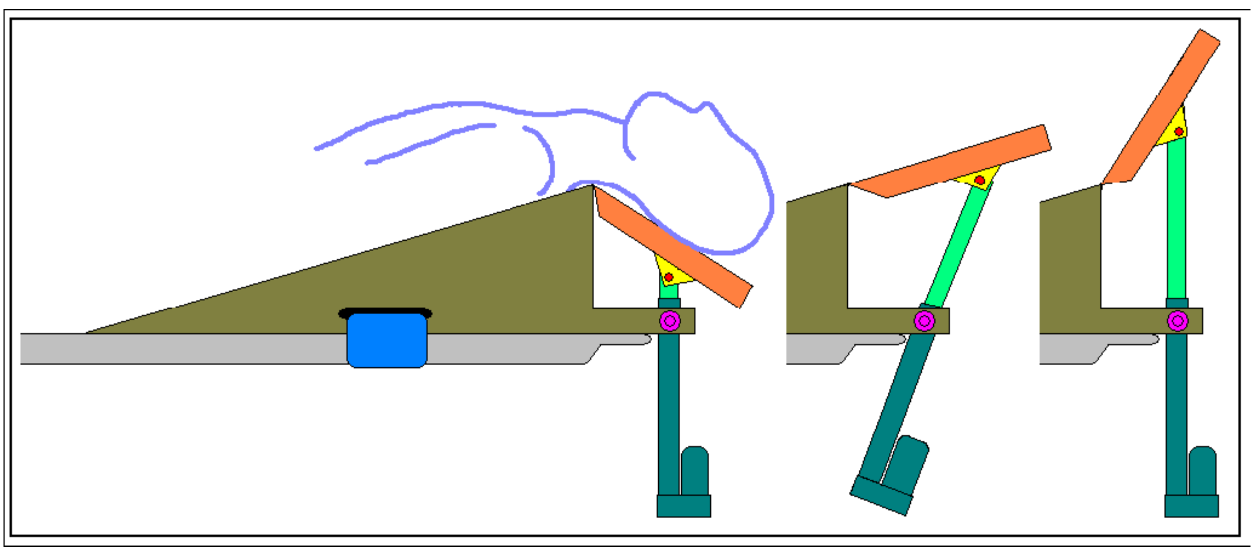


Figure 3: Vertical Actuator Design

The patient is laid with their torso on the ramp, neck across the hinge, and head on the headboard, as depicted in Figure 3 above. Attached by pin connection to the underside of the headboard is a linear actuator. Like in last semester's design, as the actuator extends and retracts, the headboard rotates about a hinge, resulting in the patient's neck flexing and extending. A second pin connection is made on the neck of the actuator. This provides the same support as last semester, but no moment is created in the actuator. The ramp raises the patient slightly, so the actuator doesn't hang too far below the table. To ensure the device stays on the table, a strap wraps around the table and secures the device in place.

This design resolves many of the issues found in last semester's work. Combination of the ramp and pin connection on the actuator's neck minimizes the amount of overhang and potential for interference with the imaging equipment. Pin connections prevent translation of the actuator, but do not incur moments. There is a decreased amount of stress in the frame and actuator by keeping the forces axial to the actuator.

While this design fixes issues found in the previous design, there are still issues it does not resolve. The shape and configuration of this device is still awkward for storage. The actuator is left exposed and is at risk for being damaged. The actuator itself is problematic because it still hangs off the end of the table and could interfere with other equipment. This concept also has limited potential for expanding the range of motion. The linear actuator speed would need to be reduced while maintaining its force and increasing length. This is not practical because the size of the actuator would increase greatly, and actuators of slower speeds often cannot exert the forces necessary to rotate the headboard under load. Although the strap would hold the device in place, it may not work with other imaging tables that have equipment or a solid base beneath the patient.

Design 2: Gear & Motor

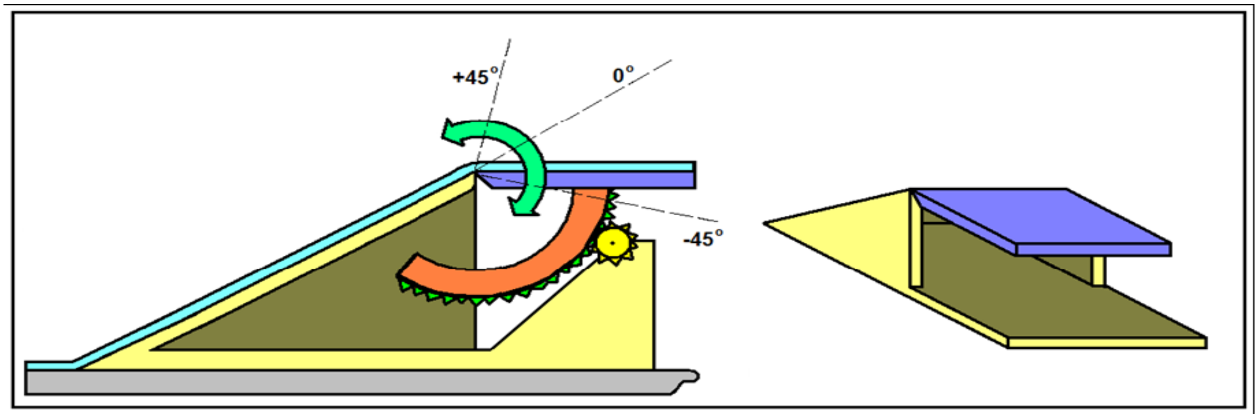


Figure 4: Gear & Motor Design

Like the first design, this design has the patient inclined and positioned so their neck flexes and extends as the headboard rotates. The configuration of this design keeps mechanical components above the table and within the frame when the headboard is in its lowest position. The mechanism of rotation in this design is based on a bidirectional motor driving a system of gears; see Figure 4. A large gear section (approximately 120°) is directly attached to the head board, with its center of rotation at the hinge. A smaller motor driven gear meshes with this gear section, so the headboard rotates in either direction depending on the drive gear. The ratio of sizes between gears can be selected based on the motor speed to achieve slow headboard rotation (2°/second). A small motor with a low rotation speed and high torque is ideal for this design. The torque must be sufficient enough to counter the moment of a load on the headboard, which is dependent on the weight and placement of the head. Assuming the human maximum load is fifteen pounds and the head rests ten inches from the hinge, then 150in*lbs of torque is needed.

This design has advantages not available with other designs. The gear and motor system can be completely housed and mounted to the frame above the table so there is no overhang or potential to interfere with imaging equipment. This also makes storage simple because it can be set on a flat surface without the risk of damaging key components. The mechanical parts of this device are not exposed, making it much more aesthetically appealing in a professional hospital setting. The biggest downfall of this design is its level of mechanical and electrical complexity. Multiple gears must be aligned precisely and coordinated with a motor in order to function appropriately. Also involved in this is setting limits to the range of motion. With an actuator there are limits to how far it can extend and retract, but here a motor can run in either direction as long as it is "on". More advanced circuitry is needed to prevent the motor from running the gear section too far in either direction by some type of position feedback system. To complete a functioning prototype that includes all of the desired features would go beyond one semester of work.

Design 3: Sideways Actuator

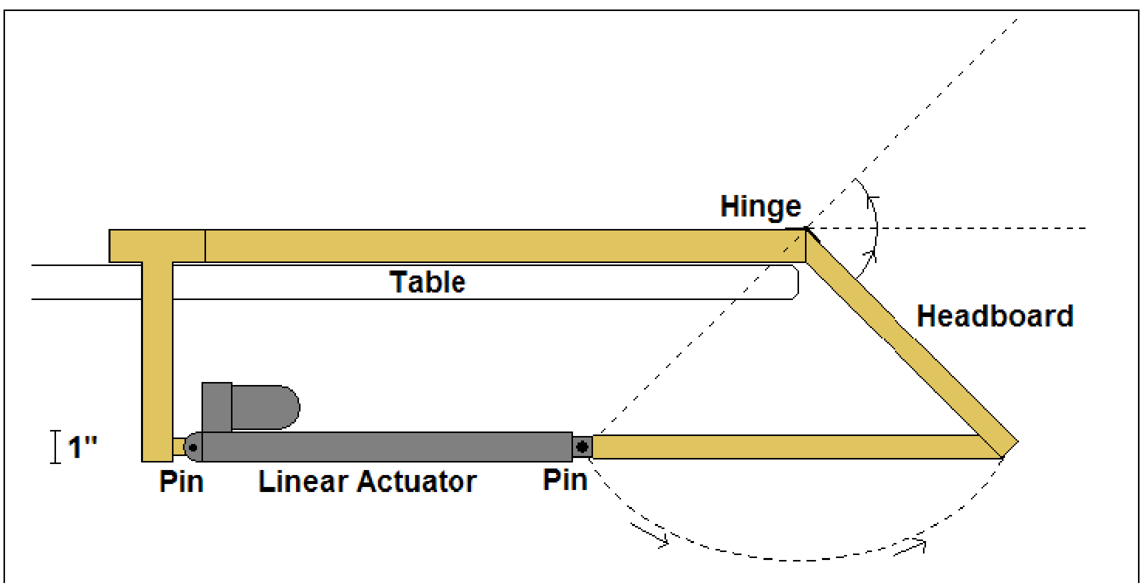


Figure 5: Sideways Actuator

Figure 5 represents the third proposed design, which consists of a wood frame and a linear actuator. The wood frame has a hole cut on the left side (not shown) to allow the device to slide onto the end of the table. Beneath the table, a linear actuator is pin connected to the frame and to a support piece leading to the headboard. As the actuator extends and retracts, the headboard rotates up and down, which flexes and extends the cervical spine.

This design has several advantages. First, it is relatively simple and easy to build. The patient can also lie flat on the table, unlike in the previous two designs in which the patient has to be elevated. This design also does not need to be strapped to the table. There are several disadvantages, however. As drawn, the actuator stroke length is about 12 inches, which will require the frame to be 2.5 feet long and 7 inches deep. This would make storage and set-up more difficult and cumbersome. In addition, this design does not allow for a variable rotational rate or range of motion. These parameters are fixed based on the speed, length, and position of the actuator.

Final Prototype

Frame

See Figure 6. The frame of the prototype is made of 5/8" thick pine and is elevated 25° so that the gears, motor, and batteries that power the device can be placed beneath the patient but also above the table. A thin rubber pad is situated beneath the device to prevent slipping during operation. An 11" headboard is attached to the top of the frame by two metal hinges. A wood head stabilizer, attached the headboard, secures the patient's head with a felt Velcro strap and small cushions (preventing unwanted isocentric rotation and potentially further injury). The stabilizer is able to slide up and down the headboard during motion, which provides a more natural neck extension and flexion, while reducing anterior translation. The frame is painted white to improve aesthetics and has handles on both sides for positioning and transportation. The device is small and compact, making it easy to set-up, use, and store.

Controls

See Appendix figures. During operation, the examiner will hold a toggle control box, which includes an on/off button as well as an up/down toggle switch. The toggle is momentary, meaning it must be held in an up or down position for the headboard to rotate. Releasing it automatically returns it to the neutral position and the device stops rotating. The patient, if conscious, can hold the panic button, which can automatically stop rotation at any point if he or she felt pain or discomfort. These controls, as well as the motor, are powered by a 12 V rechargeable battery, located inside the frame on the base of the device.

Gears and motor

See Figure 6. A 1.3 rpm @ 12 V DC electric motor directly turns a small metal gear, which turns a larger metal gear attached to the headboard (thus providing extension and flexion). With our dimensions and speeds, the headboard rotates at about 3.5°/sec and has a range of motion of ±35° from neutral. This speed is slightly greater than the goal of 2°/sec. However, after seeing our prototype at 3.5°/sec, both Dr. Medow and Dr. Haughton agreed that the faster speed was preferable. The rotational speed, however, is greater during extension than flexion. Increasing the range of motion would not be difficult, as it may include either using thinner materials for the headboard and frame, or hinging at the bottom of the headboard-frame connection (as opposed to the top, as it is currently). The total cost of the device was $103.33, with the electric motor being the most expensive part at $45.76.

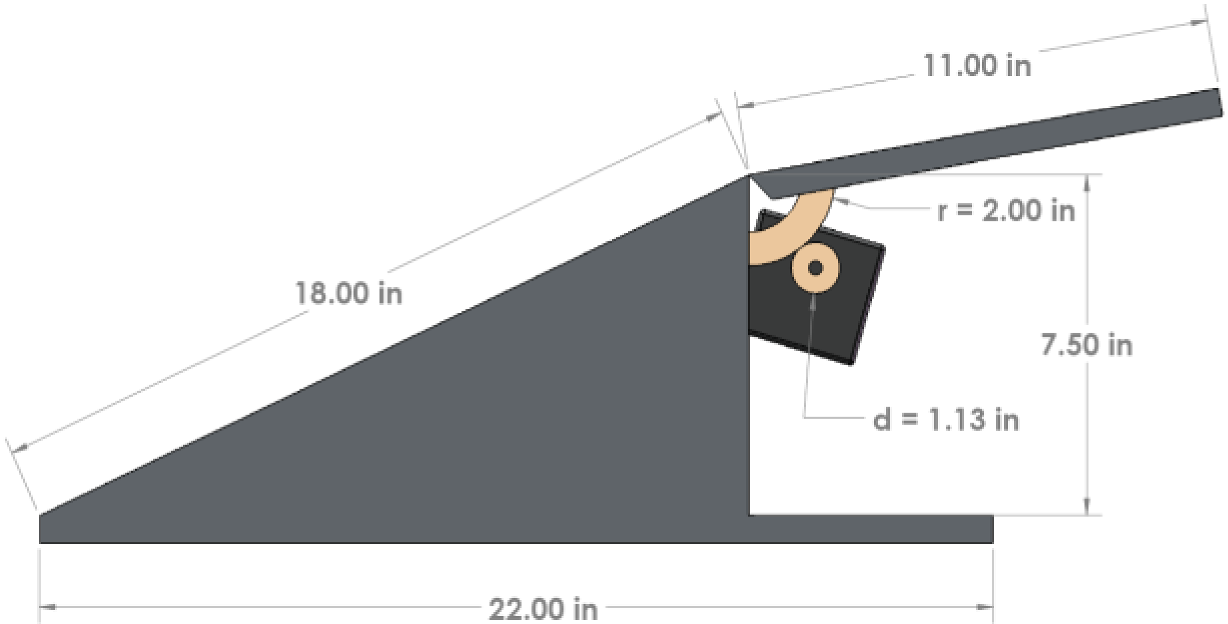
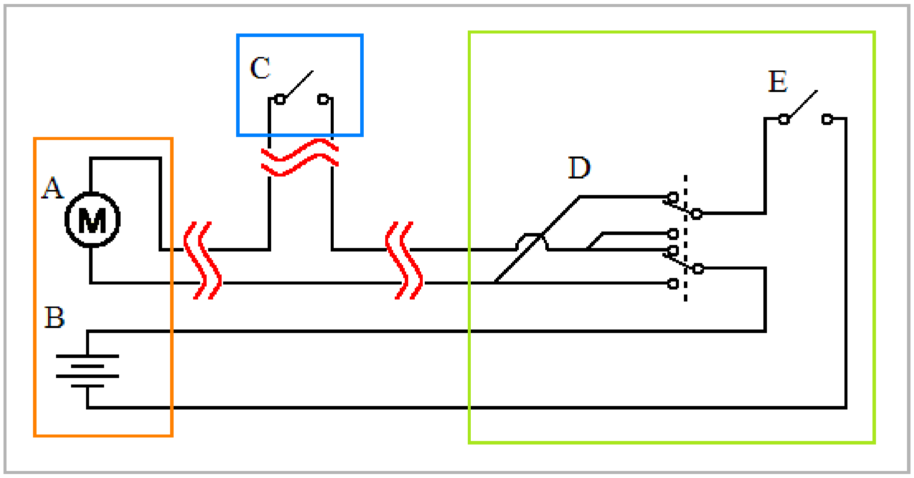


Figure 6 Final Design

Future Work

As testing and finally commercialization are our end goals, there are several adjustments that need to be made to the prototype. First and foremost, a stronger motor is needed to better maintain a constant speed during both flexion and extension rotation. The angle of elevation of the backboard should also be reduced as there is currently empty space between the bottom of the motor and the top of the frame platform. Research of thin, lightweight, radiotranslucent plastics and molds will be needed for replacement of the wood frame. Finally, development of a more refined and aesthetically pleasing head support is desired. Exploration of wireless controls, or possible integration of the controls into the fluoroscopy control panel would be convenient for the examiner. Also, if the panic button could be connected to the off button to the fluoroscopy machine, this would add an additional safety measure to the device. A digital protractor, which displays the angle of the headboard from neutral position, is necessary for feedback and data analysis. Lastly, development of a program allowing the user to set rotational speeds and angle limits for the headboard would optimize the procedure. After the final prototype is completed, testing must be done to ensure that the neck positioner satisfies all design requirements and incorporates any new ideas considered during design maturation.

Appendix



A. Bidirectional motor
  - 1.333rpm at 12V DC and 0.5 A
  - 50 in-lbs of torque

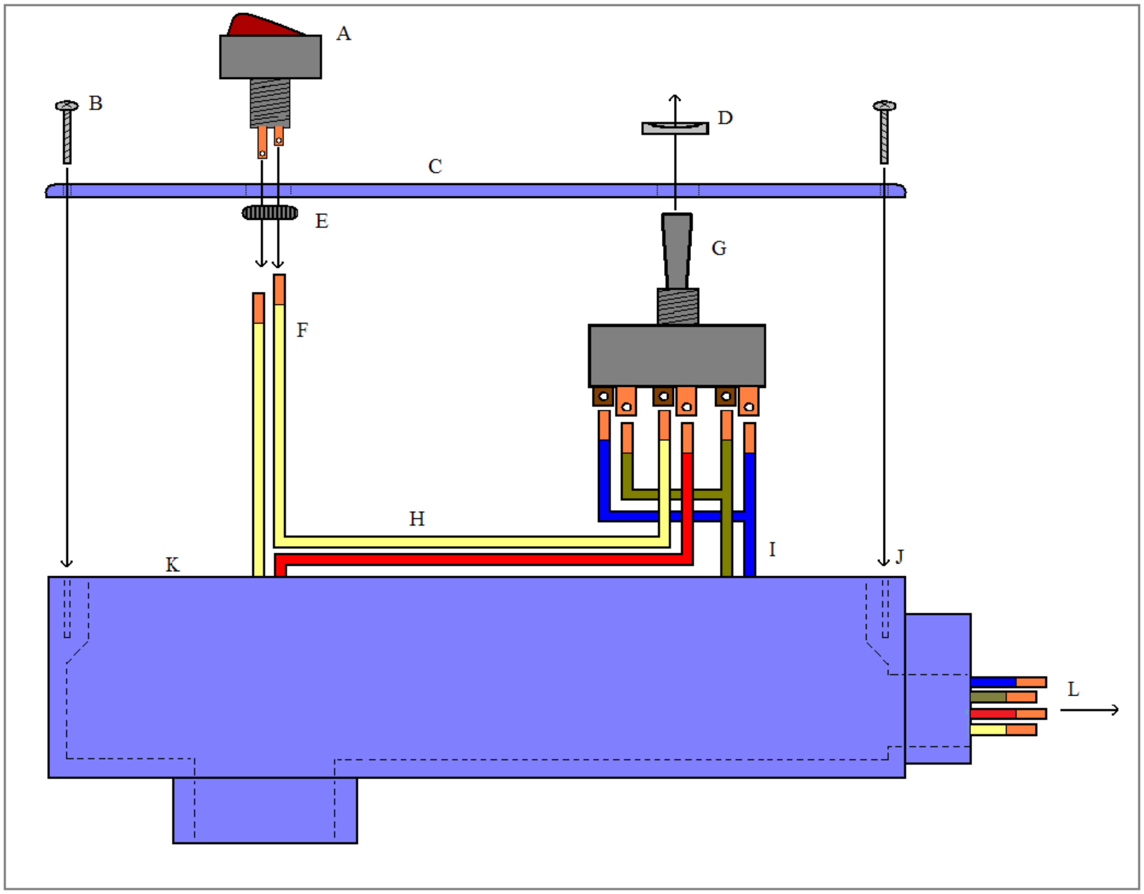
B. Power Supply
  - Rechargeable battery
  - 12 V and 8.0 Amp hours

C. Patient's Panic Button
  - SPST ON-OFF rocker switch
  - Rated for up to 12 V DC and 30 A

D. Doctor's Toggle Switch
  - DPDT (ON)-OFF-(On) toggle
  - Rated for up to 12 V DC and 20 A

E. Power Switch
  - SPST ON-OFF rocker switch
  - Rated for up to 12 V DC and 30 A

Figure 7: Circuit Schematic. Orange indicates components housed in the frame, blue is the panic button, and green indicates the doctor's controls.



A. Power Switch
- SPST ON-OFF rocker switch
- Rated for 12 VDC and 30A
- ¼" hole mount

B. PVC Case Screw
C. PVC Case Lid
D. Toggle Switch Nut
E. Power Switch Nut
F. Wire Leads
- Soldered between toggle switch and battery

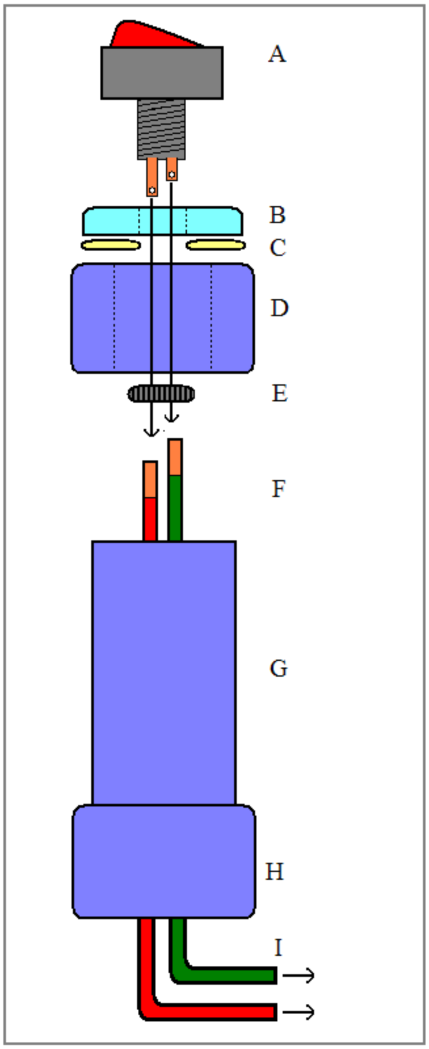
G. Toggle Switch
-DPDT momentary (ON)-OFF-(ON)
-Rated for 12VDC and 20A
- ¼" hole mount

H. Wire Leads
-From power switch and battery to toggle switch

I. Linear Actuator Lead Splitting
-Soldered to cross current path

J. PVC Case Screw Hole
K. PVC Case
L. Wire Leads
- From toggle switch to motor and battery

Figure8: Doctor's Controls, exploded view.



A. Panic Button
-SPST ON-OFF rocker switch
-Rated for 12 VDC and 30A
- ¼" hole mount

B. Plastic Disc
-Internal ring diameter of ¼"

C. Epoxy

D. Top pipe cap

E. Nut
-Secures rocker switch to hole

F. Wire leads
-Soldered to terminals of switch

G. Pipe shaft

H. Bottom pipe cap

I. Wire leads
-Form 8' tether to main cable

Figure 9: Panic Button, exploded view.

Budget

date	paid by	item(s)	cost
11.11.2007	Peter	wood, screws, bolts	$44.40
11.25.2007	Megan	drawer tracks	$5.26
11.28.2007	Betty Gavigan (BME Dept.)	1.3 rpm electric motor @ 12 V DC	$45.76
11.30.2007	Peter	paint, handles, screws	$13.17
12.6.2007	Alison	poster	$30.00
		TOTAL	$138.59

by person	
Peter	$57.57
Alison	$30.00
Megan	$5.26
BME Dept.	$45.76

Product Design Specifications

Neck Extender and Flexor for Fluoroscopy Examinations

Problem Statement: Our project involves creating a motorized neck positioner for a patient during fluoroscopy examination. The device must extend and flex the neck and cannot interfere with lateral radiographic imaging. This facilitated extension and flexion will aid in diagnosing ligament injuries.

Client Requirements:

- Extend and flex the neck +/- 45^o from neutral
- Operate at less than 2^o/sec
- Stabilize patient's head during motion
- No interference with lateral fluoroscopic imaging

Design Requirements:

Physical and Operational Characteristics

a. Performance Requirements
    - Operational by one person (preferably by remote control, or at a distance)
    - Motion should be smooth, to prevent further patient injury
    - Must flex and extend the neck +/- 45^o from horizontal
    - Must be able to determine angle of elevation of neck, either mechanically or digitally
    - Operate at less than 2^o/sec
    - Only move the head and neck of the patient.
    - No interference with fluoroscopy or the operation of the fluoroscopy machine
b. Safety
    - No sharp edges, corners, hinges that could pinch or tear
    - Stable at all times
    - Smooth movement to prevent further patient injury
    - Emergency stop (panic button)
c. Accuracy and Reliability
    - Angle measurement must be accurate within +/- 5^o
d. Life in Service
    - Must last for an extended period of time (5 years)
e. Shelf Life
    - Storable in room temperature
    - Functional after extended periods of idle time
    - Require minimal maintenance
f. Operating Environment
    - Tolerate repeated exposure to x-rays from fluoroscopic imaging
    - Withstand wear and tear from operation and movement by hospital staff

- Circuitry protected from damage due to humidity, fluid spills, temperature, or other adverse conditions

g. Ergonomics
   - Operation controls outside of range of the fluoroscopy scan
   - Easy to position patient on device

h. Size
   - Appropriately fitted to dimensions of fluoroscopy examination table
   - Easily removable and storable
   - Easy maintenance and modification

i. Weight
   - Less than 20lb, so it can be handled by staff
   - Heavy enough to ensure stable operation

j. Materials
   - Metallic and/or dense materials are not permissible in the area of examination (will interfere with X-ray signal)

k. Aesthetics, Appearance, and Finish
   - Fit under or above fluoroscopy table, but beneath hospital pad on table
   - Similar color and material as fluoroscopy table and pad (white and grey)
   - Smooth edges and texture to prevent injury during examination and handling
   - Able to be sterilized between patients without damage to components.

Production Characteristics

a. Quantity
   - One prototype, can be a larger scaled model of actual device
   - Potential to mass produce if marketable

b. Target Production Cost
   - Less than $250 for prototype
   - At most $1,000 to $2,000 for final product
   - Final product market value of approximately $10,000

Miscellaneous

a. Patient-related Concerns
   - Accommodate adult of average height and weight (not for children)
   - Be comfortable for patient unable to provide feedback because unconscious

b. Competition
   - Previous projects have produced positioning devices, but none were motorized
   - Individual components of this semester’s design may already have patents (motors, actuators, etc)
   - Patent searches yielded no existing devices with same specifications

References

Cox MD, M. W., McCarthy MD, M., Lemmon MD, G., & Wenker MD, J. (2001). Cervical spine instability: clearance using dynamic fluoroscopy. *Current Surgery* , 96-100.

Medow, D. J. (2007, September 23). Client Meeting.

Neumatic Medical. (2007). Retrieved December 2007, from Neumatic Medical.

Padayachee, L., Cooper, D., Irons, S., Ackland, H., Thomson, K., Rosenfeld, J., et al. (2006). Cervical spine clearance in unconscious traumatic brain injury patients: dynamic flexion-extension fluoroscopy versus computed tomography with three-dimensional reconstruction. *The Journal of Trauma* , 341-345.

Saladin, K. (2007). *Human Anatomy.* McGraw Hill.