Neck Extender/ Flexor to Facilitate Fluoroscopic Examination

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Abstract

In order to quantitatively diagnose cervical spinal instability in accident victims, patients are monitored with fluoroscopy as the neck is flexed and extended. To facilitate this fluoroscopic examination, a remotely controlled, motor driven device that mimics the natural motion of flexion and extension in the cervical spine is needed. The device is designed to be used during a fluoroscopy examination in place of manual movement and support given by a technician. Therefore, components of the device must not absorb the lateral x-ray beam used in fluoroscopy. Three designs to fulfill specified requirements are described and categorized by the type of mechanism: motor, gear and worm-box attached to the fluoroscopic table; motor and tracking gear independent of the table; and motor and linear actuator. Currently, the table independent gear tracking system is considered the best solution because it allows the headboard to rotate at the correct axis of the cervical spine. Future work includes selecting from motor and gear suppliers and identifying the optimal carbon fiber or other radiotranslucent materials to be used to construct the final prototype.

Problem Statement

Identifying traumatic cervical spinal instability, due to an occult fracture or ligamentous injury of the cervical spine, can be accomplished through a dynamic fluoroscopic examination. The fluoroscopy machine takes a real-time stream of images while the patient's neck is in motion. The disadvantages of the current fluoroscopic examination include: technicians and other medical staff currently are required to support and rotate the patient's head manually in extension and flexion thereby exposing them to radiation, achieving the desired slow, constant movement of the cervical spine at a constant speed is difficult, and positioning the fluoroscopic monitor exactly while moving the neck manually may be difficult. The goal for this semester is to design a device, suitable for manufacture, and capable of rotating the cervical spine at its axis in flexion and extension during this fluoroscopic procedure.

Motivation

Currently, practices of imaging comatose patients pose risks to not only the accident victim but also the hospital staff. Radiographs and CT do not detect all spinal fractures. MRI does not detect spinal ligament damage reliably, especially more than 72 hours after injury. Therefore the current examinations do not reliably detect all traumatic causes for spinal instability. Thus, a fluoroscopy examination is needed to observe how the vertebrae respond to movement. A mechanical device is essential to provide steady, controlled, quantitative movement of the cervical spine and also to minimize radiation exposure to staff.

Background Information

Cervical Spine

The cervical spine is composed of seven vertebrae, from the base of the skull at C1, down to the vertebra prominens of C7. The disks and the facet joint between these vertebrae facilitate movement such as extension and flexion. Most of the

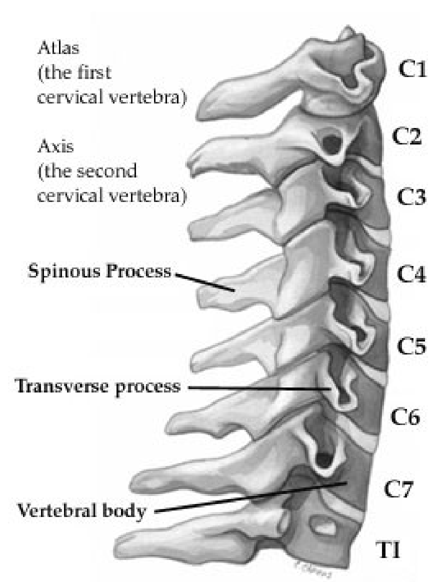

Figure 1: Diagram of the cervical spine, vertebrae C1 through C7

rotation in the cervical spine occurs at the atlanto-occipital joint between C1 and the skull, although the entire neck has some degree of mobility. The neck contains critical nerves and blood vessels in addition to the spinal cord itself. To protect these vital structures, the vertebrae are secured into position by ligaments. In the event of an accident or other injury, these ligaments can be damaged, endangering the nerves and blood vessels. If the neck is not immobilized and or handled with care, there can be very serious consequences such as severing the spinal cord or damaging other nerve pathways (Eidelson, 2007).

Extension and Flexion

The cervical spine is capable of extending and flexing in the sagittal plane of the body. Extension is defined as the movement of the head away from the chest, increasing the angle between the chest and cervical spine. Flexion is the movement of the head forward toward the chest, decreasing the angle between the cervical spine and chest. In order to best image this movement and the vertebral interactions, the procedure uses a lateral view along the coronal plane.

Figure 2: Extension and flexion of cervical spine (from left to right).

Fluoroscopic Imaging

A fluoroscopy machine takes x-ray images at a frequency of 30Hz, and displays them as a video on a computer or television monitor. This real-time feedback of the imaged area gives the radiologists the opportunity to observe bone movement and angiography. Each image exposes a patient to less radiation than a typical x-ray, but radiation exposure should always be kept to a minimum.

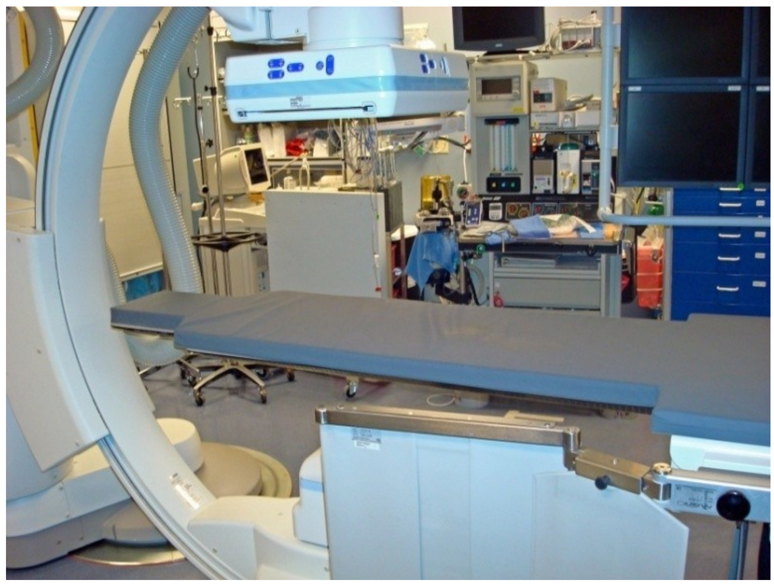

Figure 3: Fluoroscopy machine in UW-Hospital where procedure takes place

Fluoroscopy machines generate x-rays by converting low voltage electricity to very high voltage. This creates a beam of electrons that collides with a tungsten target that releases x-ray energy. Next, an x-ray tube concentrates the energy onto the body to be imaged (Rosewell Radiology Associates, 2006). Depending on the mass attenuation coefficient of the tissues imaged, the beam is reflected or absorbed. X-rays are detected by means of a specialized screen. The output from the screen is used to create an image. The images are quickly processed and displayed on a screen to provide rapid feedback to the staff on any changes in the area being observed.

Previous Work

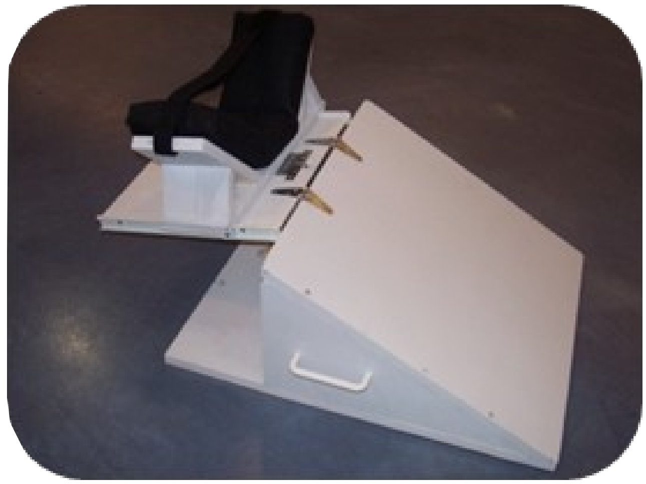

Figure 4: Prototype created from fall 2007

Past design groups have attempted to design a neck rotator; however, all of the designs that have been created have faults. In the last semester, a device was created that consisted of an inclined backboard and a rotating headboard. The headboard included a translating head-stabilizer which moved forward and back during rotation of the headboard. The headboard was rotated by a gear and motor system. There was a 4 inch diameter gear that was cut at an angle of 120 degrees and secured to the headboard. This gear was rotated by a smaller spur gear that had a 1 inch diameter. This spur gear was attached to the shaft of the motor, which was powered by a 12 Volt DC battery.

In tests of this device , several problems were discovered. The device was difficult to transport. After being moved, the neck positioner would not always operate due to problems with the connections to the panic switch. Another major issue with this design was that it did

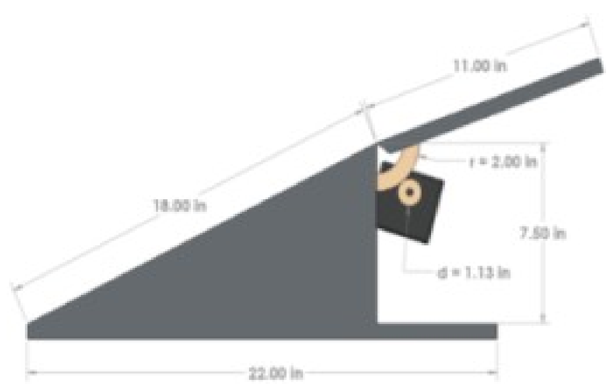

Figure 5: Prototype modeled on Solidworks

not rotate at a consistent speed of 2.5° per second. The motor would rotate the headboard about 1° per second faster during extension than flexion. This inconsistency is unsafe and does not follow the design constraints specified by the client.

The translation of the head-stabilizer on the headboard did not achieve the correct motion that is needed from the cervical spine. The device created an un-smooth motion, which could cause further injury to the patient. The headboard also did not rotate the cervical spine the entire desired range of motion.

Literature Search

There are no other mechanical neck positioners currently on the market. There are several stationary positioners and head stabilizers that are used for imaging. Some of the more inexpensive stationary positioners are created from foam molds. There are adjustable devices created from carbon fiber as well. AliMed® sells a device created by Accufix™ for use on an imaging system that will adjust the head to the right position. This device, however, will not rotate the cervical spine in a constant motion and will only allow for a still image. This costs, $2,848.00, which is expensive for a stationary device.

Figure 6: Accufix™ Tilting Radiotranslucent Head Holder

Design Constraints

The main concern of our client this semester, besides the safety of the patient, was that the device needed to be ergonomic. Past designs were not sufficiently refined for a hospital setting. Another new constraint that was added this semester by the client was that the device needed to allow the patient to lie flat at the initial position of the procedure, to eliminate the possibility of the patient sliding.

The device must provide a natural flexion and extension movement of the cervical spine, from 45° extension to 45° flexion. The cervical spine must rotate at a rate of around 2.5° per second. The device must also stabilize the patient's head and prevent unwanted lateral rotation. The angle of the cervical spine from neutral must be displayed on the device during the procedure.

The device must have smooth edges and must not have any pieces that protrude and could potentially harm an employee or patient. There must not be any radio-opaque material obscuring the lateral view of the cervical spine. Easy sterilization of all surfaces is necessary.

In order for an employee at the hospital to easily transport the device, it must weigh less than 20 pounds. The device must be easily storable. It must function correctly if not used it for a period of time.

A single person must be able to operate the neck positioner from a remote location, so as to minimize radiation to hospital staff and allow operation of the fluoroscopy machine and neck positioner from the same location. The budget this semester for materials is $250.00. The goal for final marketing price is under $10,000.00.

Alternative Solutions

Table Dependent Gear and Worm Box

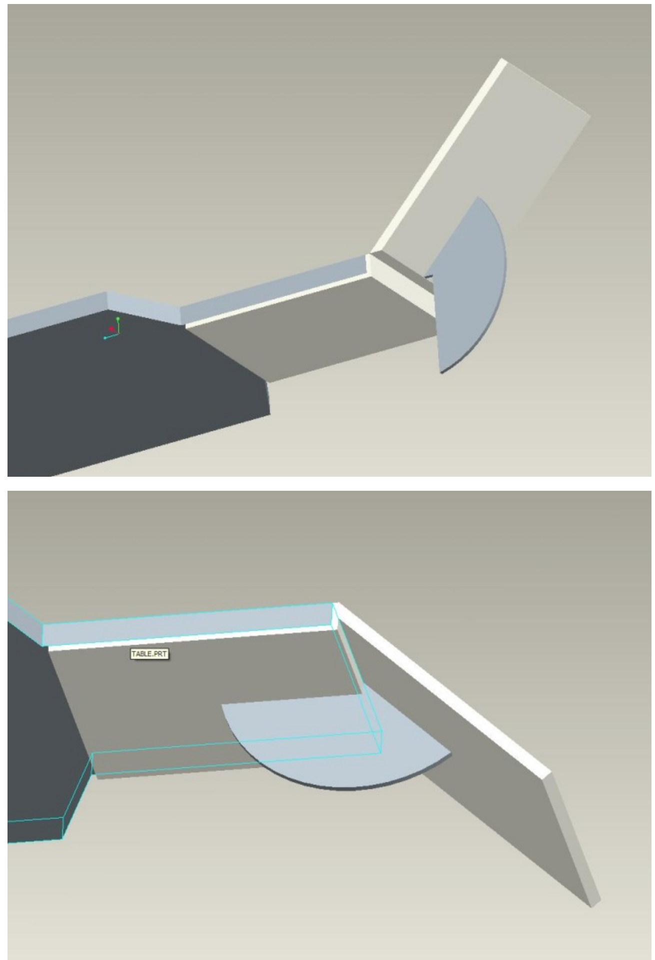

Figure 7: Diagram of Table Dependent Gear and Worm Box in extension and flexion

This device emphasizes the horizontal rather than the inclined position of the backboard in the previous semester's design. It includes a large diameter gear that is attached directly to the headboard, with a gear box driving the large gear through use of a spur gear. The motor and worm gear box in this device are stationary and attach to the bottom of the fluoroscopy table. Placing the motor and worm gear box into a small compartment under the table is advantageous because it helps prevent the device from detaching during transport, is more aesthetically pleasing, and can be easily sterilized if necessary. A cord connects the motor to an AC power source, and a remote controls the device. In this design, the center of rotation is at the hinge, which is attached to the end of the table and similar to previous designs.

Although this design is improved from previous semester's designs, there are many issues that could potentially arise if this design continues. The main problem is that the center of rotation of the headboard is not at the center of the neck. Because of the axis of rotation, there is a need for a translating headboard. Although there may be a translating headboard, the flexion and extension of the cervical spine may still not be at the correct axis of rotation. Similar to the previous design, a translating headboard is also a problem because unless the motion is very smooth there could be further injury to the patient. This design includes a large diameter gear that protrudes and is potentially unsafe for hospital employees. Since this design is dependent on the table, there is not much allowance for compliance with other fluoroscopy tables. Ideally the design should be adaptable to different types and manufacturers of fluoroscopy tables, making this another flaw of this design.

Linear Actuator

Another design that was proposed implemented a linear actuator instead of a gear system. This device was similar to the gear box system in that was dependent upon the table, and in that it also had the center of rotation directed at the hinge at the end of the table. This system has no exposed gears which is a safety advantage. This device works through a linear actuator driving the headboard that it is directly attached to. The linear actuator is connected at both ends with a rotating clevis. Again a cord connects the motor to outlet

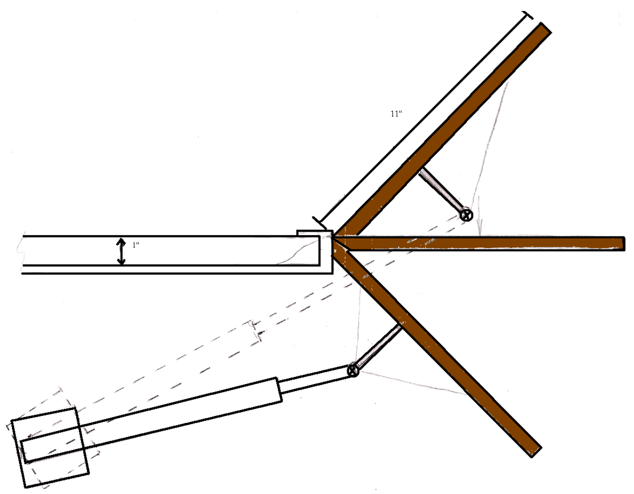

Figure 8: Drawing of linear actuator design.

power and the device is controlled by a wireless remote as in the gear and motor with gearbox design.

Ring and Guide Design

This design addresses two main flaws in the other design choices: having an axis of rotation at the neck, and independence of table attachment method. Although this design is potentially more complex to implement, its increased flexibility in use has been determined to outweigh its theoretical complexity.

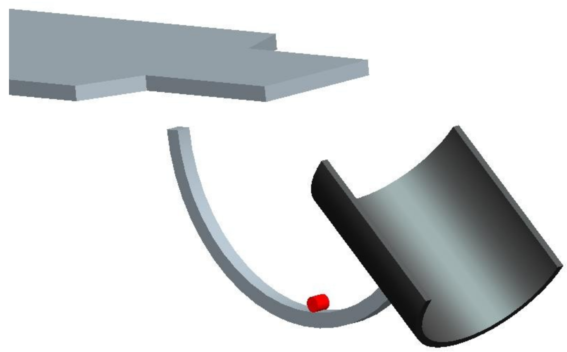

Figure 9: Model of chosen design.

The design eliminates a hinge or joint at the axis of rotation. This permits the placement of the axis of rotation at any point of our choosing, in our case, the center of the neck. This design would facilitate a fluid motion of the headboard to match the natural extension and flexion movement of the neck, reducing the need for extra moving parts to compensate for differences in axes of rotation between the patient's neck and the device. The elimination of a physical axis of rotation permits the device to operate completely independent of the table.

With an independent device, the table model and design would no longer need to be incorporated into the design of the device, as different adapters could then be created to join the table and the device. Also, adjustment of the position of the device relative to the table could then be designed into the various adapters and would not need to be integrated into the device design itself.

With these concepts in mind, a partial ring design was developed. Such a device consists of a partial ring, which would be a moving track to which the headboard would be attached. This ring and headboard is then driven by a stationary motor and guide system. Inside a small sterile shell, the motor and guide system is located beneath the plane of the table to provide the greatest range of motion, occupy the least space, and provide sufficient force to rotate the head in flexion and extension. The exact location of the stationary motor is yet to be determined, and would also be dependent on the mechanism of attachment to the table.

One of the major complexities of this design is the implementation of the ring and a fitting drive system. Reliability is an issue since all forces of the head, headboard, and weight of the ring itself is transferred to the drive box and motor. Thus much careful design will need to go into the fabrication of the drive and guide system to ensure a smooth and fluid movement, with ample support for the entire mechanism at no cost to reliability.

Design Matrix

When trying to decide upon which design to go with many factors were taken into account. The two most important constraints considered included safety and mechanics. Other important categories included aesthetics, ease of operation and reliability. The device we ended up choosing scored highest on nearly all categories. All of the designs had the same ease of operation.

	Gear and Motor with Gearbox	Floating Gear and Motor System	Linear Actuator
Safety (25)	15	20	19
Mechanics (25)	18	23	20
Aesthetics (15)	8	12	14
Ease of Operation (5)	4	4	4
Reliability (20)	12	16	14
	57	**75**	71

Figure 10: Design Matrix

Future Work

During the remainder of the semester we will select gears and a motor for the device. We will select a carbon fiber or plastic material for the headholder. This material will have sufficient radiotranslucency so the lateral imaging view of the cervical spine is not obscured. A prototype device will then be constructed. The prototype will be tested to demonstrate improvements from previous designs.

Potential Problems

Although our chosen design is the best option for the semester some problems have not been resolved. One problem is the identification of suitable motor and gear parts. Another issue is the torque output of the motor. In previous semester's prototypes, the speed of rotation of the cervical spine has not been consistent. It is essential that we choose a motor that will support the headboard and ring gear so that the speed of rotation is a consistent 2.5^{o} per second.

References

"Accufix™ Tilting Radiotranslucent Head Holder" Accufix™, 2008.

http://www.alimed.com/ProductDetail.asp?style=921115

"Cervical Spine Anatomy (Neck)" Steward G. Eidelson, 2007

http://www.spineuniverse.com/displayarticle.php/article1021.html

"Fluoroscopy" Roswell Radiology Associates, 2006.

http://www.roswellradiology.com/fluoroscopy.htm

Appendix

Product Design Specifications

Neck Extender and Flexor for Fluoroscopy Examinations

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Client
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Problem Statement:

Our project involves improving a motorized neck positioner for a patient during a 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° from neutral
- Operate at less than 2.5°/sec
- Stabilize patient's head during motion
- No interference with lateral fluoroscopic imaging
- Spine must be completely horizontal at neutral
- Include foam padding on head support with a head strap to prevent movement
- Final device must be compatible with GE and Siemens fluoroscopy units

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 digitally determine angle of elevation of neck
   - Operate at less than 2.5°/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
   - Include foam padding on head support with a head strap to prevent movement
h. Size
   - 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
   - Sturdy 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
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 capable of dynamic positioning