Facilitation of Neck Extension and Flexion During Fluoroscopic Examination of an Obtunded Patient

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Abstract

In order to determine if an obtunded patient has suffered damage to the cervical spine, a flexion and extension motion about the neck +/-45 degrees is needed during the fluoroscopy examination. A device is necessary to aid in this movement as currently technicians manually provide the support the patient's head during the procedure. A previous solution was designed using a linear actuator, but there were several issues. Three new approaches have been developed including two more linear actuator models and a motor and gear design. The motor and gear design is most favored as it meets the most requirements. Future work includes researching gears and dimensions as well as the materials that can be used in the final product.

Problem Statement

Diagnosing cervical spine injuries can be done using fluoroscopy. Fluoroscopy is a medical imaging method that captures a stream of images of internal body components while they are in motion. In the situation at hand, patients are unconscious, thus unable to communicate injuries or move their head. In order to determine if the patient has suffered damage to the upper spine, a hospital technician must flex and extend the neck +/-45 degrees during the fluoroscopy process. This action increases the chances of injuring the patient as well as exposes the technician to radiation. The goal is to develop a device that can rotate the head in the required movement during fluoroscopic examination.

Motivation

Victims of car accidents or other injuries are brought into the hospital, and depending on circumstances will be imaged to determine if they have any spinal injuries. This is often the case if the patient is unconscious and unable to provide feedback to the doctor about pain they are experiencing. If less than 72 hours has passed since the injury, an MRI scan can be performed to assess the fluid content and diagnose spine health. If this time window passes, a healthy spine can't be distinguished from an injured spine, making MRI trivial. Fluoroscopic imaging of the neck in motion allows for the radiologist to observe how the vertebrae interact. Detecting abnormalities in movement may indicate injury. Radiologists performing this procedure are exposed to radiation as they manually flex and extend the head during imaging. This also involves a lack of precision and repeatability because flexion and extension won't occur at the same rate each time. A device is needed that will flex and extend the patient's neck at a consistent rate that takes into account safety concerns.

Background Information

Cervical Spine

The cervical spine, as seen in Figure 1, is composed of seven vertebrae, from the base of the skull at C1, down to the vertebra prominens at C7. Found in the neck, these vertebrae facilitate movement such as extension and flexion. Most of the rotation 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).

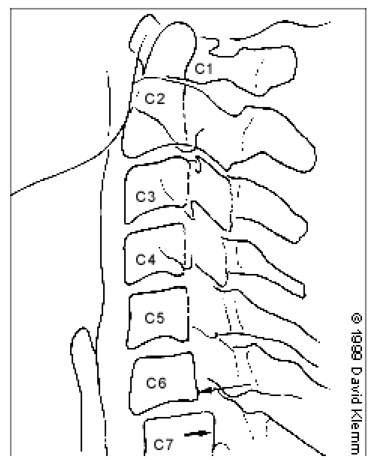

Figure 1: Cervical Spine

Extension and Flexion

The cervical spine is capable of extending and flexing in the sagittal plane of the body, see Figure 2. Extension is defined as when the head is brought back away from the chest, increasing the angle between the chest and cervical spine. Flexion is when the head is brought forward toward the chest, decreasing the angle between the cervical spine and chest. To best capture this movement and the vertebral interactions, a lateral view is best. The neck is capable of other types of movement, such as lateral rotation, but they are not of interest with this angle of imaging.

Figure 2: X-ray of Neck Flexion &Extension

Fluoroscopic Imaging

A fluoroscopy machine, shown in Figure 3, 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 on the area being imaged gives radiologists the opportunity to observe bone movement and angiography. Each snapshot taken exposes the patient to less radiation than a typical x-ray, but radiation exposure should always be kept to a minimum.

Fluoroscopy machines generate x-rays by converting low voltage electricity to very high

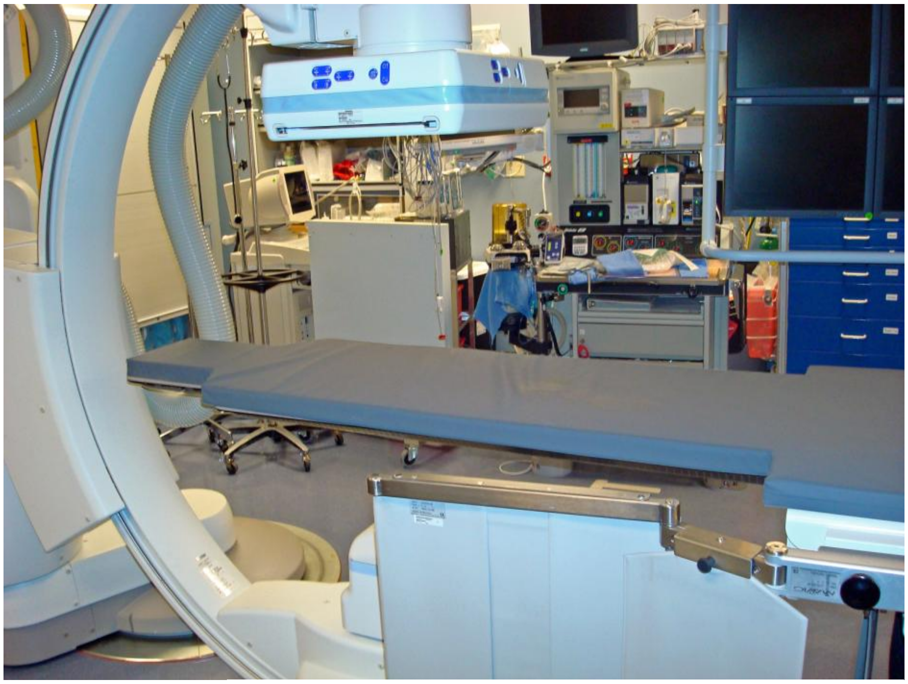

Figure 3: Fluoroscopy machine at UW Hospital

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 (Roswell Radiology Associates, 2006). Depending on the mass attenuation coefficient of the tissues imaged, the beam is reflected or absorbed, and the machine analyzes this to create an image. These images are quickly processed and displayed on a screen to provide rapid feedback.

Previous Work

A prototype from last semester was capable of the full range of motion desired, but there were flaws that needed to be addressed. As seen in Figure 4 to the right, it was configured to hang over the end of the imaging table a full two feet, which could interfere with the fluoroscopy unit's c-arm. The frame and actuator were prone to bending when the headboard was under load, which puts the safety of the patient at risk if structural failure ever occurred. Also, there was no simple way of attaching it to the table or to store it because of its awkward shape.

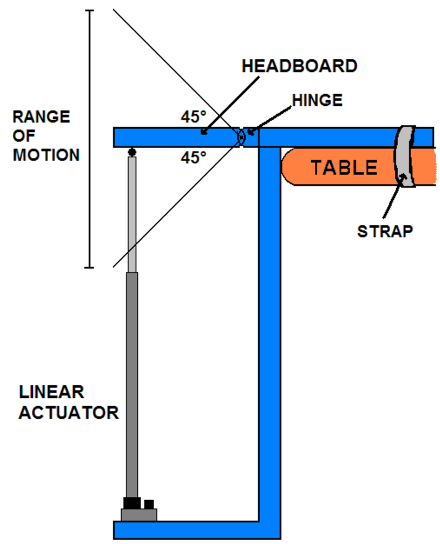

Figure 4: Last semester's prototype

Design Constraints

Patient safety is the primary concern for this device. A majority of patients using the device will be comatose and thus will not be able to specify comfort levels. The device should ensure no further injury to the patient. Therefore, the device should move extend and flex the neck smoothly and consistently, at rate of less than 2°/second. The device should also stabilize the patients head and inhibit lateral rotation. The range of extension or flexion should be 45 degrees on both sides from the neutral position, accurate within plus or minus 5 degrees. The angle of extension or flexion should be displayed during operation. Also, the device itself should have smooth edges and texture to prevent injury during examination and handling. It should also be able to be sterilized between patients without damage to components.

The final design of the device, in its material or structural design, must not interfere with x-ray imaging. Thus, dense materials such as metal are not permissible in the imaging field near the cervical spine. The device should be appropriately fitted to the dimensions of the fluoroscopy examination table and not interfere with the movement of the fluoroscopy machine's c-arm. It should be portable, easy to assemble, and relatively compact to store. One person should be able to operate the device from a remote location to minimize x-ray exposure of the hospital staff. The budget this semester is $200, but cost of manufacturing should not exceed $2,000.

Proposed Designs

Design 1: Vertical Actuator

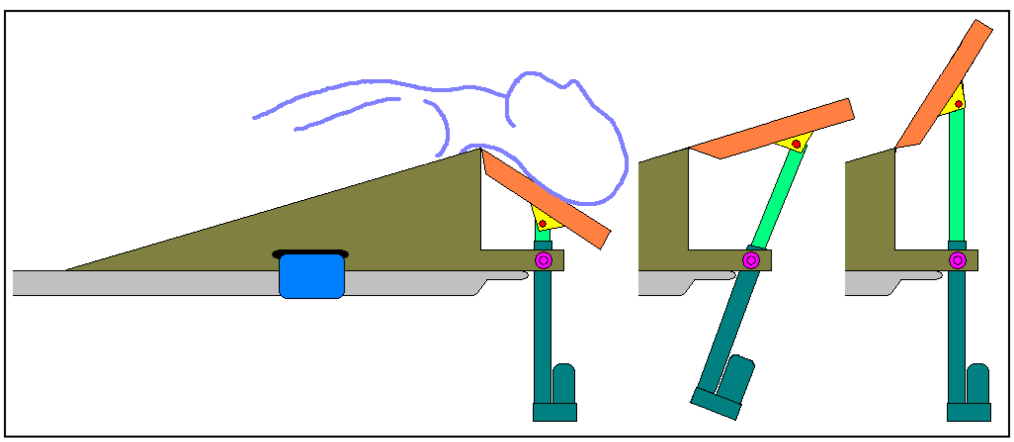

Figure 5: Vertical Actuator Design

The patient is laid with their torso on the ramp, neck across the hinge, and head on the headboard, as depicted in Figure 5 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

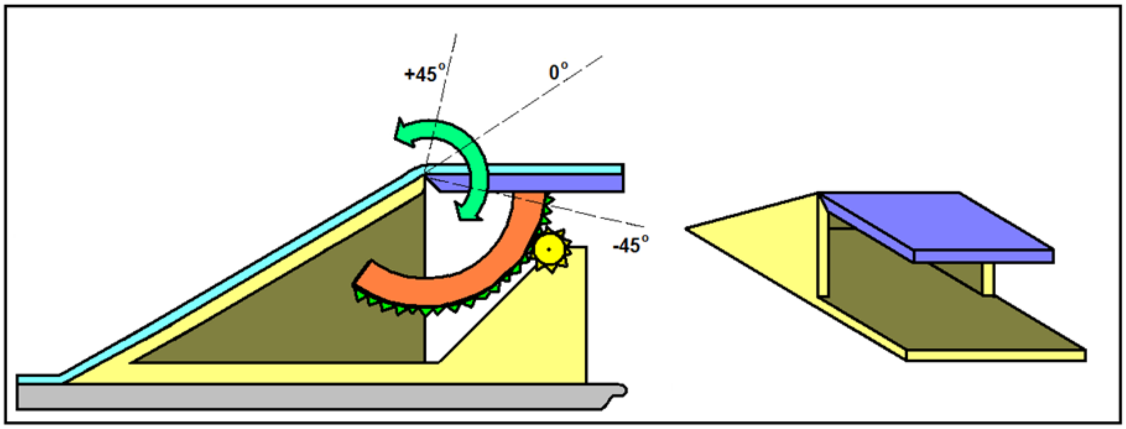

Figure 6: Gear & Motor Design

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 6. 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

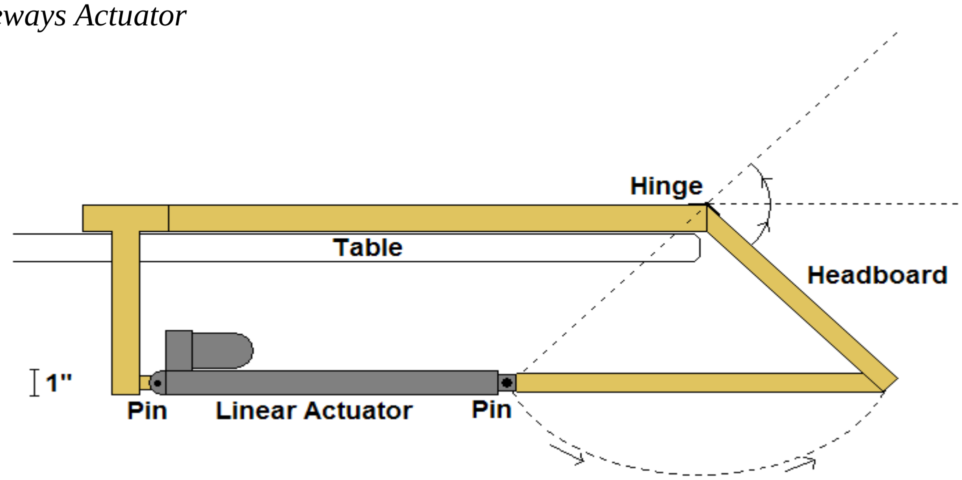

Figure 7: Sideways Actuator

Figure 7 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.

Chosen Design

Criteria	Vertical Actuator	Gear and Motor	Sideways Actuator
Safety (30)	25	24	25
Feasibility (20)	17	14	19
Expense (10)	8	7	8
Aesthetics (10)	5	10	7
Mechanics (30)	20	29	21
TOTALS	75	84	80

Table 1: Design Matrix

In order to evaluate which design to construct this semester, a design matrix consisting of five criteria was constructed. Feasibility, aesthetics, and mechanics vary the most between designs. The gear and motor design is the least feasible because it involves many moving parts. It would be difficult to integrate all these parts and build a successful prototype in a single semester. The sideways actuator design, on the other hand, would be relatively simple to build. The gear and motor design did receive the highest scores in aesthetics and mechanics, however. This design would look the most professional because it could be enclosed in a single box. The actuator designs have free hanging actuators, which would not be appealing for a hospital setting. Perhaps the gear and motor design's greatest feature is its variable rotational rate and range of motion. Changing these parameters would allow doctors to analyze cervical spine motion in a variety of different ways. In addition, it would be easy to store and set-up the gear and motor design. Based on these advantages, this is the design that will be pursued this semester.

Semester Goals

The duration of the semester will be spent construction a working prototype that demonstrates the gear and motor mechanism. This will require determining the exact dimensions of the gear and motor design while considering gear ratios and motor types, and finally assembling a prototype. To keep the prototype within the $200 budget, the frame will likely be constructed out of metal and wood instead of costly radio translucent plastics. Research will be done to find ideal materials and the best manufacturers to purchase them from.

Potential Problems

While the gear and motor design is the most practical solution, it is not the easiest. First, determining the gear ratio will prove difficult. Research will be necessary in understanding the dynamics of the gear and many calculations will have to be used to find the most favorable dimensions and kinematics. Deciding upon the angle of ramp elevation will also be a complicated process as minimization of the slope is optimal in order to maximize safety and stability.

References

"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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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° from neutral
- Operate at less than 2°/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° from horizontal
   - Must be able to determine angle of elevation of neck, either mechanically or digitally
   - Operate at less than 2°/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°
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