Neck Extender/Flexor to Facilitate Fluoroscopy Examination of an Obtunded Patient

Team Members

Alison Boumeester
Vidhya Raju
Susan Samreth
Peter Strohm

Advisor

Naomi Chesler, Ph.D.
Department of Biomedical Engineering

Client

Victor Haughton, M.D.
UW Department of Radiology

Abstract

In order to measure disk health through quantitatively reliable methods, a motorized device simulating natural neck extension and flexion during fluoroscopy examination is required. The device must not interfere with X-ray signals from the fluoroscopy imaging system and must provide rotation isocentric to the spine. Designs proposed to accomplish this task include the following mechanisms: worm-gear, gear actuator and linear actuator. Currently, the linear actuator is considered to be the most feasible solution because of its relatively simple mechanics. Future work will involve investigation of ways to modify actuators to achieve the desired rotational speed, among other characteristics.

Problem Statement

Determining disk health in the cervical spine is facilitated by the process of fluoroscopy, an imaging tool capable of capturing X-ray images of objects in motion. Currently, in order to image the cervical spine in motion, the patient's head is moved by technicians. This process is time-consuming and also exposes hospital staff to X-ray radiation from the fluoroscopy machine. In addition, the possibility of injury caused to the patient due to human error (from increased interaction between staff and patient), is increased. The goal is to create a device capable of simulating natural neck movement during fluoroscopy examinations. The device will function in order to facilitate precise determination of disk health in the cervical spine of obtunded patients.

Motivation

Current methods of imaging the cervical spine in motion pose significant risks to both the patients and staff. Human involvement in moving a comatose patient's neck increases the possibility of injury to the patient. He/she is not able to give feedback about how comfortable he/she is during the procedure. In addition, the staff is also exposed to high levels of radiation. The goal is to rectify these problems by designing a device capable of simulating extension and flexion.

Background Information

Cervical Spine

The region that the client is interested in imaging is the cervical spine, a portion of the spinal cord that is comprised of seven bones. These seven bones make up the neck, which connects the skull to the thoracic spine. The cervical spine serves a variety of functions, some of which include: facilitation of diverse head movement (which includes extension and flexion) and protection of nerve bundles that link the central nervous system to the peripheral nervous system. Determining the disk health between the vertebrae in this region is integral to assessing the physiological correctness of movement of the head with respect to the rest of the body.

Extension/Flexion

Anatomically, the terms extension and flexion apply to a diverse range of muscles in the body. However, when associated with the cervical spine, extension refers to the process by which the jaw moves upwards with respect to the neutral position. In flexion, the jaw moves downwards (Figures 1 and 2).

Figure 1: Neck Extension

Figure 2: Neck Flexion

Imaging the neck when it is stationary is less useful in determining disk health because pathophysiology is not immediately apparent. Movement forces interaction between individual vertebrae and the disks that connect them. Through analyzing these interactions during fluoroscopy, physicians are able to detect inhomogeneities caused by excess stress on certain disks, and are thus able to diagnose pathophysiological symptoms.

Fluoroscopy

Fluoroscopy is a method of dynamic, real time, X-ray imaging which allows for the surveillance of an object in motion. Applied to the human body, fluoroscopy provides the ability to view an x-ray movie of the internal fluids and structural movements within a specific system, including the skeletal, digestive, urinary, respiratory, and reproductive systems. The mechanism for fluoroscopic imaging consists of passing a continuous X-ray beam through the body part of interest. This signal is then transmitted and translated as a live display onto a TV-like monitor. In addition, image intensifiers are utilized to amplify and adjust image brightness (Schueler, 2000).

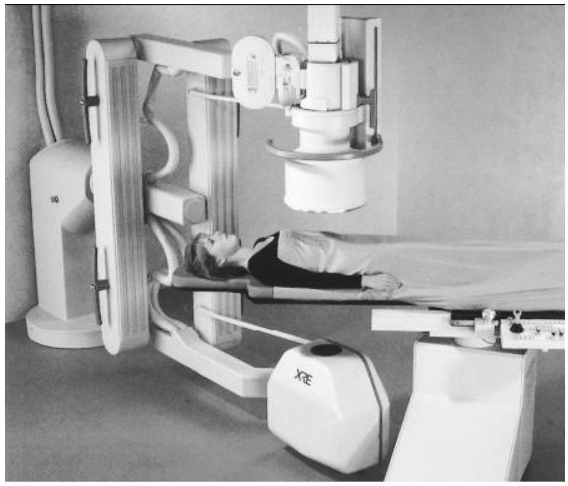

Figure 3: Photograph of a fluoroscopic imaging facility. A 35-mm cine camera is attached to the optical coupling accessory port between the image intensifier and video camera (TREX Medical Corporation, Littleton, Mass.)"

Fluoroscopy has many uses, but one of its primary uses is for the diagnosis of anatomical injuries. For example, this technology is applicable to the examination of bones, muscles, joints, as well as solid organs such as the heart and lung. Furthermore, it is also a critical aid in positioning the patient during interventional procedures such as lumbar puncture, biopsies as well as injections of anesthetics into joints or the spine (Schueler, 2000; Fluoroscopy, 2006). For this endeavor, fluoroscopy will be used as a diagnostic tool for patients experiencing spinal injuries by determining the disk health within a patient's cervical spine via dynamic extension/flexion X-ray images. It must be noted that cervical spine injuries affect 5-8% of patients who suffer traumatic brain injuries, and flexion/extension x-ray studies thru dynamic fluoroscopy play a crucial role in detecting instability and possible damage in the soft tissue of the cervical spine (Padayachee, 2006; Griffiths, 2001).

PDS Summary/Client Requirements

Of primary concern is the safety of the patient. Most patients using this device will be obtunded and may not able to specify comfort levels. Therefore, it is imperative that the device function autonomously, implying the need for motorization. The range of extension or flexion should span a 90-degree range, 45 degrees on both sides from the horizontally neutral position. The speed of the device should allow natural simulation of neck movement. As specified by the client, this rate is one degree per second, allotting about one minute to traverse the whole range of motion.

The device must be universal in its ability to easily accommodate the general adult's head. It should be portable and easily assembled by one person for smooth transfer between fluoroscopy rooms. In terms of operability, one person should be able to operate the device, preferably from a remote location. This will reduce exposure to X-ray radiation. In general, the prototype should minimize energy use and cost. The cost of constructing the prototype should not exceed $300.00.

Materials and Methods

The imaging tool implemented is fluoroscopy; this limits the choice of materials that can be placed in the region of imaging. Metals, for example, are not desirable in this region because they have high levels of X-ray signal attenuation. More desirable materials include plastics, which do not affect the X-ray signal strength to as large of an extent. Imaging of the cervical spine will be performed laterally. Thus, metals can be used directly under the fluoroscopy table, since the X-ray beam will be passing from side-to-side, rather than from top to bottom.

Schueler reports that carbon fiber composite materials fulfill the minimal x-ray attenuation requirements of fluoroscopy. Recommended materials for patient support pads include thin foam pads or Tempurpedic© pads (Schueler, 2000; Dr. Rannallo).

Design Alternatives

Design 1: Gear and Motor

One approach to facilitating neck extension and flexion involves a motor driven gear which controls a headboard supported by an internal gear guide. These mechanical components will be mounted to a sturdy frame attached to the table from beneath using straps (Figure 4).

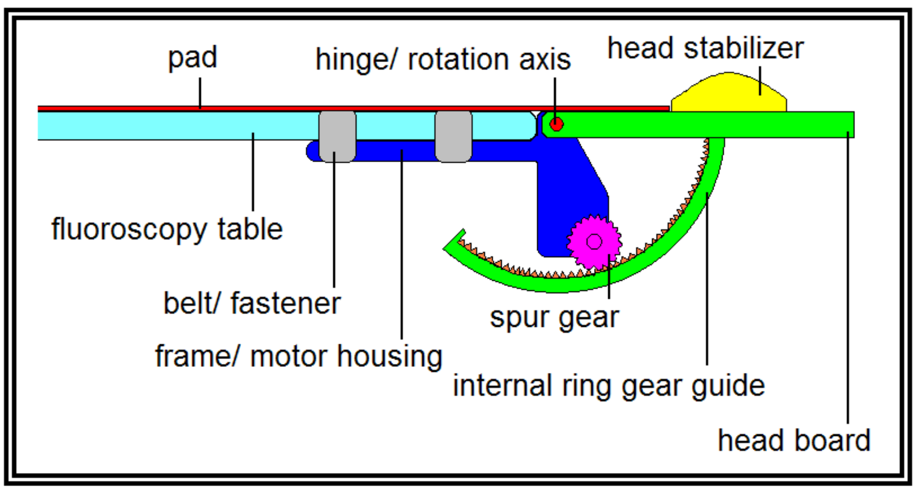

Figure 4: Gear and motor design.

This device will run from AC converted to DC, which powers the mounted bidirectional motor (present but not labeled in Figure 4). The rotations per minute (rpm) of this motor can be adjusted by controlling the voltage supplied. To ensure patient safety, this motor will start up smoothly so that there is no “kick” that could jerk the patient’s neck. The torque required of this motor will be sufficient enough to support the patient’s head both during the procedure and when the device is not in operation.

Attached directly to the motor shaft will be a small spur gear. By using a small gear as an intermediate between the motor and internal gear guide, a higher rpm motor can be used to achieve slower headboard rotation. This spur gear will completely mesh with the teeth of the internal gear to ensure there is no slipping or other mechanical failure.

The headboard and internal gear guide will be fused together such that as the guide is driven, the head board will rotate with it. This guide can be cut from an intact internal ring gear, such that when attached to the head board, the center of rotation is about the hinge. The arc cut for the guide will be at least ninety degrees to give a full range of motion, but it must also be small enough to achieve negative 45° without retracting into the underside of the table. An appropriate and reasonable range for this arc is between 110° and 130°. On the free end of the guide, a stopper or block will prevent the spur gear from driving beyond the end.

The main advantage to this design is that is relatively small compared to the other designs, discussed later. This allows for easier attachment and storage. Additionally, the rate of rotation will be constant throughout the range of motion.

On the other hand, there are also disadvantages to be considered. For one, a very specific motor is needed, which means either increased costs or compromising the design. To get the desired qualities, an independent company must custom build one, which severely constrains the budget. Compromising the design will risk patient safety, and may mean other specifications are not met, such as headboard rotation speed. Another disadvantage to this design is that an internal ring gear must be cut, and this could compromise the integrity of the material. If there is instability or folding in this part, the entire headboard could collapse, posing serious risks to the patient. The client expressed interest in possibly expanding the range of this device, but this design has limited potential to do so because the guide will hit the table's underside. Finally, although some fluoroscopy tables can accommodate a device that mounts underneath, not all do because they are a block-shaped rather than a panel.

Design 2: Worm Gear

Another approach involves a fusion between a motorized worm gear and rack and pinion to rotate the headboard (Figure 5). The top of the rack will be a smooth roller guide, so it is not fixed to the headboard during operation. Again, the headboard will rotate about a hinge level with the table surface, and the mechanical components mount to a frame strapped to the fluoroscopy table from beneath.

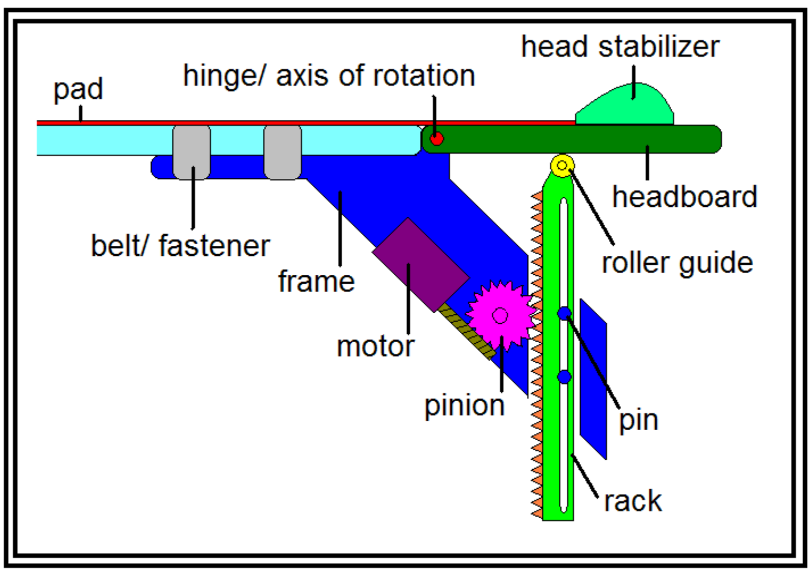

Figure 5: Worm gear design.

The torque and voltage specifications for this bidirectional motor are the same as for the first design. The same safety considerations must also be considered. This motor's shaft must be grooved, just as a screw is. This way, when meshed with the pinion, the spinning shaft rotates the gear. The difference in size between the shaft and gear means that the pinion rpm is lower than the motor. This configuration between the motor and gear is also known as a worm gear, but since the gear is also part of a rack and pinion, the components are referred to separately.

The motor driven pinion gear controls the vertical position of the rack, also referred to as a shaft. The rack is a toothed shaft driven by a partnered pinion gear. To hold this rack in a vertical position, a groove or track runs the length of it, and two pins are fitted. These pins ensure that only translation, not rotation, of the rack will occur. As this shaft is raised and lowered, the headboard does the same. The position of the shaft head beneath the headboard is not constant during operation, thus a roller guide will allow free movement while providing the same support. The headboard will attach and rotates about the same axis as in the previous design. These two designs differ in the direction and manner the force is applied. A sturdier material will be needed in this worm gear design to account for the more direct and changing forces.

Advantages of this design include simple installation and removal. The straps can be adjusted to fit tables of different widths, making it more universal. The upper range of motion has the potential to go beyond the desired 45°, just by using a longer shaft. This device can also be powered from an AC source, which is readily available in a hospital setting.

This design also presents disadvantages. First off, this design contains many moving parts that must work together in order for this device to operate successfully. With this increased complexity, there are more points where mechanical, electrical, or structural failure could occur. Another disadvantage of its size is increased stress on the belt attachment system, which either means more belts to support it, or the use of a lighter weight material which may not have the rigidity and strength needed for the frame. These issues when combined directly impact the safety of the patient, which can not be compromised. Another issue is the shaft itself. When retracted, it extends far beneath the table. There is the potential risk of hitting the floor or expensive medical equipment. Either way, the risk of damaging the device or existing equipment should be avoided. Also, this nonstandard design requires custom parts and assembly, which raises the budget and need for testing before implementation in a hospital environment.

Design 3: Linear Actuator

The third design (Figure 6) is similar to the previous two in that the headboard will rotate about a hinge. In this case, the rotation will be controlled by a linear actuator. This actuator will attach to an S-shaped board, which straps to the fluoroscopy table. The vertical movement of the actuator will be driven by an internal electric motor. This motor will be powered by an external power supply, which can be plugged into an electrical outlet. In order to adjust the speed of the actuator, the power supply must convert AC signal to DC signal and allow for adjusting the voltage to a specific amount. Varying and setting this voltage will allow fine adjustment of the actuator speed in order to provide the appropriate rotational rate. As in the worm gear design, this design also features a roller guide where the actuator supports the headboard.

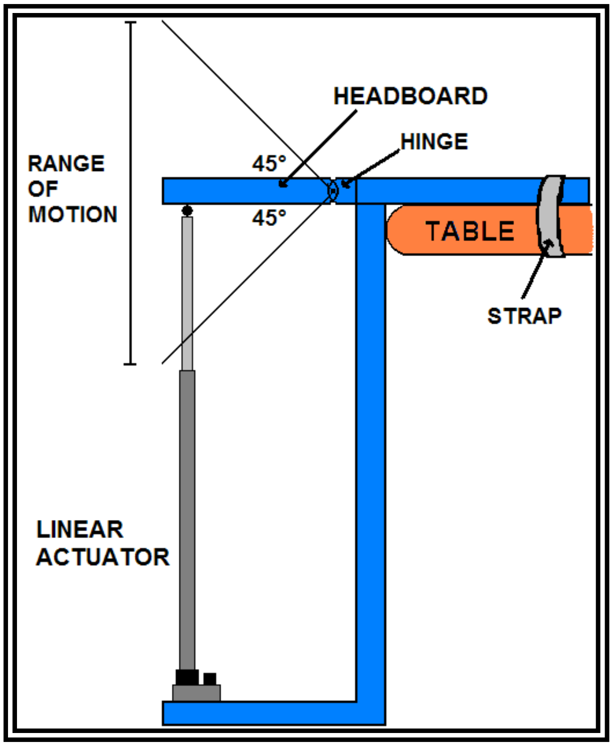

Figure 6: Linear actuator design.

This design offers unique advantages. It is easily constructed, containing only three main pieces: an actuator, headboard, and S-shaped board. Additionally, actuators can be purchased in a variety of lengths and speeds. Calculations of the final dimensions will determine which linear actuator to purchase. After obtaining the three components, construction will be relatively straightforward.

A disadvantage of this design is that it is longer than the previous two designs. The board will need to extend possibly as much as three feet below the table. As this distance increases, the straps must be able to support the additional weight and be able to counteract the moments produced. Furthermore, this additional weight will require the materials to be sufficiently strong to resist any bending or breaking. A small disadvantage of this design is that the rotational rate of the headboard will not be constant throughout the range of motion due to the linear movement of the actuator. However, the change in rate is relatively insignificant for the purposes of this project.

Design Matrix and Final Decision

A decision matrix (Table 1) was constructed in order to facilitate the final design decision. The criteria comprised in this matrix: safety, feasibility, mechanics and aesthetics. Weights were assigned to each criterion after weighting the most crucial in terms of addressing the problem statement. The team then evaluated each of the designs with respect to each criterion and designated a point value out of the total weight for each category. Safety, mechanics and aesthetics achieved very similar weights for each of the three designs. Feasibility was inevitably the deciding factor in the decision. The linear actuator received a high point value in this category because it was the simplest mechanically and thus, easiest to build.

Criteria	Weights	Linear Actuator	Worm Gear	Gear and Motor
Feasibility	40	39	20	25
Safety	30	25	27	22
Mechanics	20	16	15	15
Aesthetics	10	6	6	9
Totals	**100**	**86**	**68**	**71**

Table 1: Decision Matrix for Design Alternatives

Before construction, the addition of several elements should be considered. One component is the head stabilizer, mounted to the top of the headboard. Constructed out of a foam such as polyethylene, it will interfere minimally with the fluoroscopic imaging. Polyethylene foam is not only porous and full of air, but it has a low mass attenuation coefficient (MAC). The lower the MAC, the more transparent a material is to fluoroscopy. The head stabilizer will hold the head still and minimize lateral neck rotation during the procedure. When the MAC of materials is not the primary concern, materials can be chosen based on critical criteria such as strength, rigidity, density, and cost. This increases the feasibility of fabricating a successful prototype. A second component to consider adding is a thin pad running from the head stabilizer and over the table. This layer will protect the patient from any possible pinching at the hinge. It will provide comfort for the patient who may spend an extended period of time on the table, depending on the procedure.

Potential Problems

Although the linear actuator design is the most reasonable solution, it may present various problems. First, incorporating a power supply will not be a simple task. A small power supply must be found that can be modified for use with the linear actuator. Consulting someone with electrical engineering experience will be needed to determine the safest way to connect the supply to the actuator without. However, if research finds an actuator with the necessary range of motion and the appropriate speed (at its rated voltage), then there would be no need for an AC power supply, and a simple rechargeable battery could be used instead.

Another problem is that the rotational rate of the headboard will vary over the entire range of motion. This will occur because the actuator shaft moves up and down at a constant speed, but this motion is linear. The linear motion will result in faster rotation when the headboard is near its neutral position, and slower rotation when the headboard is nearing 45°. Calculations have revealed that the headboard will be rotating twice as fast near 0° than at 45°. This, however, should not be a major concern given that the headboard will likely be rotating less than 1° per second at any given time. For example, the rotational rate at 0° could be 0.90°/sec, and at 45° the rate would be 0.45°/sec. Because of these small rates of motion, the difference in rotational rate would likely be difficult to detect. Furthermore, given design constraints, a slight change in rotational rate should not seriously affect the analysis of neck extension and flexion. However, the varying rate is something to keep in mind when building the final design.

Lastly, appropriate materials must be found. The problem faced is of finding not only a material that does not interfere with fluoroscopic imaging, but also one that is readily available and easily machined. Research on supply companies online and speaking with individuals in the engineering workshop will aid in the decision making process.

Ethical Considerations

Some studies suggest that forced extension and flexion of a comatose patient's neck may induce more harm than good. Thus, it is reasonable to assume that the controller of the device will take this into consideration during operation. The device created must be thoroughly tested before implementing for use in a hospital setting in order to minimize health risks to the patients.

References

Block, W. F. (2007). Fluoroscopy facility tour

Eidelson, S. G. (2006). Cervical spine anatomy (neck). Retrieved March 1, 2007, from http://www.spineuniverse.com

Flexion and extension views of C-spine. (2007). Retrieved March 1, 2007, from http://www.wheelessonline.com

Fronczak, F. J. (2007). Design discussion

Griffiths, H. J. (2001). The use of forced flexion/extension views in the obtunded trauma patient. Skeletal Radiology, 31(1), 587-591.

Padayachee, L. (2007). Cervical spine clearance in unconscious traumatic brain injury patients: Dynamic flexion-extension fluoroscopy versus computed tomography with three-dimensional reconstruction. The Journal of TRAUMA Injury, Infection, and Critical Care, 60(3), 03/02/2007. Retrieved March 2, 2007.

Ranallo, F. (2007). Fluoroscopy facility tour.

Schueler, B. A. (2000). General overview of fluoroscopic imaging. RadioGraphics, 20(4), 1115-1126. Retrieved March 2, 2007, from Web of Science database.

What is fluoroscopy? (2006). Retrieved March 1, 2007, from http://www.healthsystem.virginia.edu

Appendix

Product Design Specification

Team Members:
Peter Strohm (Team Leader)
Vidhya Raju (Communicator)
Alison Boumeester (BSAC)
Susie Samreth (BWIG)

Client:
Victor Haughton, M.D.

Last Update: March 11th, 2007

Problem Statement: The project involves creating a neck positioner for a patient during fluoroscopy examination. The device must allow for extension and flexion of the head and cannot interfere with lateral radiographic imaging.

Client Requirements:

- must extend and flex the patient's neck
- the prototype must not interfere with fluoroscopic imaging
- must be remote control operated
- the design must be universal to all x-ray imaging systems

Design Requirements:
1. Physical and Operational Characteristics

a. Performance requirements:
- 45° of extension and flexion from a horizontal resting position
- Rate of rotation must be constant (approximately 1°/second)
- Device should result in a natural rotating motion of the neck
- Remote control operable from another room

b. Safety:
- Pose no risk of new or worsened neck injuries
- Doesn't impair or damage the fluoroscopy machine

c. Accuracy and Reliability:
- Reliably functions when operated by remote control
- Accurately simulate natural cervical vertebrae movement and rotation

d. Life in Service:
- Can handle at least ten patients per day
- Lifespan of at least two years
- Smaller components replaceable for maintenance

e. Shelf Life:
- Storable in room temperature sheltered environment
- Functional after extended periods of idle time

f. Operating Environment:
- Withstand repeated exposure to x-rays from fluoroscopic imaging machine
- Must 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:
- preferably operated remotely (reduces X-ray exposure to staff)
- easy attachment of patient to device

h. Size:
- must be appropriately fitted to dimensions of fluoroscopy examination table
- must be easily removable and storable
- must allow for easy maintenance and modification

i. Weight:
- light enough to be easily moveable by hospital staff
- heavy enough to ensure stable operation

j. Materials:
- metallic materials are not permissible in the area of examination (will interfere with X-ray signal)

k. Aesthetics, Appearance, and Finish:
- must blend appropriately with existing hospital machinery (white)
- must have smooth edges and texture to prevent injury during operation

2. Production Characteristics

a. Quantity:
- one unit needed for individual client

b. Target Product Cost:
- as specified by client for prototyping purposes, $200.00
- cost of manufacturing preferably less than $10000.00

3. Miscellaneous

a. Customer:
- should fit the average adult
- may be used on unconscious patients

b. Competition:
- patent search revealed no similar devices
- individual components of design may be patented