

Support System for Lumbar Puncture Procedure

Final Design Report

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§ 1. Abstract:

Lumbar puncture procedures are gaining significance in the scientific community in analyzing diseases of the brain and spinal cord. A device was designed to increase patient comfort while maximizing curve of the spine to open up the space between the lower lumbar backbones, which facilitates collection of spinal fluid. A portable device that would support the head, arms, and feet of a patient during lumbar puncture procedures was desired. A desktop massage unit was modified to fit over a central PVC column. The column was supported by the base of a desk chair with lockable wheels. In addition, a height-adjustable, angled foot rest made of polypropylene was attached to the PVC column. Testing the device on patients to ensure stability and maximum spinal curvature is necessary.

§ 2. Problem Statement:

To design a device to support the patient's arms, head, and feet during lumbar puncture procedures. Obtaining maximum spinal curvature to open up the space between the lumbar backbones is critical for success of the procedure. Keeping the patient comfortable while maintaining proper positioning remains a challenge.

§ 3. Project Motivation:

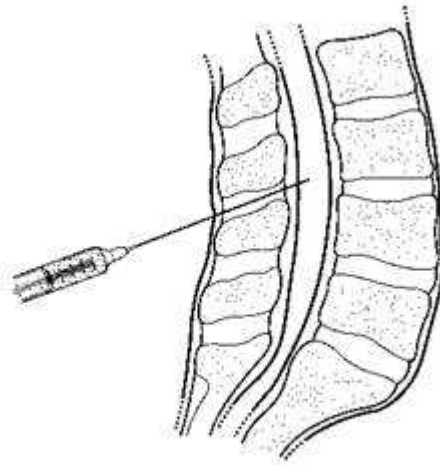
Our client, Dr. Cynthia M. Carlsson, strives to understand the effects of vascular risk factors and their treatments on the development and progression of Alzheimer's disease. She is currently conducting clinical trials to evaluate how cholesterol-lowering medications called statins affect blood, spinal fluid, cognitive, and MRI perfusion biomarkers for Alzheimer's Disease in asymptomatic middle-aged adults at risk for the

disease. To study these changes, Dr. Carlsson collects cerebral spinal fluid from patients using the lumbar puncture procedure.

§ 4. Background:

The lumbar puncture procedure is performed by inserting a needle in the L4-5 interspace, aiming towards the navel [1]. Insertion is much easier when the spine is curved because it facilitates the separation of the lumbar backbones.

Figure 1. Diagram of needle insertion into lumbar interspace. [1].



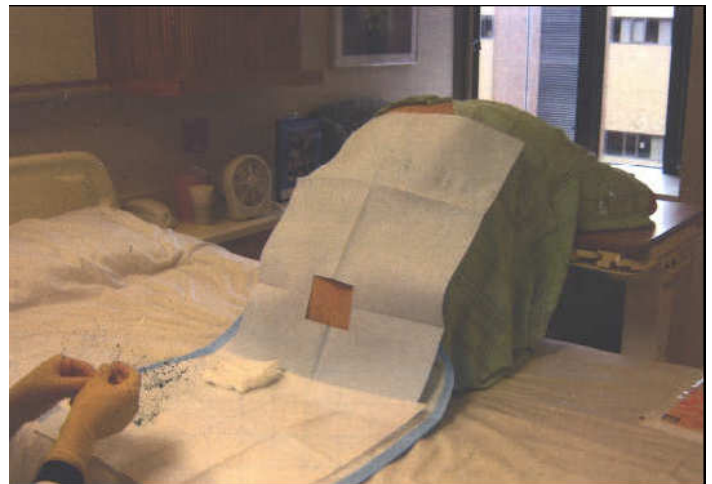
Lumbar puncture procedures can be done in a lateral position, with the patient lying on the edge of the bed. While this position may work for some individuals, it is not ideal for patients who are obese due to misalignment of the spinal cord. Therefore, our client prefers the upright sitting position for performing the spinal tap procedure.

§ 4 a. Current Set-up:

This procedure is done with the patient sitting on the edge of the height-adjustable bed (30”), with feet propped up on a chair (20”) and the head resting on a doughnut-shaped pillow on the bedside table (40”). The patient’s arms also rest on the bedside table (See Figure 2). This position is uncomfortable for the patient because his/her head is

approximately 3.5 inches from the table which does not permit proper air flow. Further, taller patients' knees typically come in contact with the bottom of the table, which creates additional discomfort. Since the wheels on the table are not lockable, the table could move away from the patient during the procedure causing misalignment of the spine. In order to prevent this from happening, additional persons are required to help position and secure the patient during the procedure. Another drawback of this set-up is that the only height-adjustable component is the hospital bed making it difficult to achieve optimal positioning for patients of various heights.

Figure 2: Current positioning of a patient for lumbar puncture procedure. *Left Picture:* Notice that the patient's head is very close to the table, minimizing air circulation [2].



§ 4 b. Competition:

Currently, there is no equipment specially designed for lumbar puncture procedures; however, researchers at the Department of Neurology at Johns Hopkins Medical Institution have utilized massage chairs for a similar procedure, spinal catheter insertion (See Figure 3) [3]. Researchers found that the massage chair provides a stable

platform that allows patients to maintain proper position without the need for additional personnel to monitor the patient. The head rest minimizes the possibility of breathing obstruction, and the seated position allows for proper spinal alignment.

Our client informed us that massage chairs do not maximize curvature of the spinal cord necessary for the spinal tap procedure due to the limited range of adjustability of the chair.

Figure 3: *Left picture:* Standard massage chair. *Right picture:* A massage chair being used by researchers at Johns Hopkins for a spinal catheter insertion [3].



§ 5. Design Constraints

Our goal is to design a functional supporting unit for lumbar puncture procedures. Maintaining patient comfort while maximizing the curve of the lower back to optimize the access to the lumbar interspace is important. Hence, the device must help achieve a balance between properly positioning the patient's spine and ensuring patient comfort during the procedure. The device must be adjustable to accommodate individuals ranging

from 155 to 188 centimeters tall and should fit in all hospital rooms. Further, during the lumbar puncture procedure, the patient will be seated on a height-adjustable hospital bed; this is to ensure that the patient can immediately lie down if he/she feels light-headed from the procedure. Therefore, the supporting device must accommodate the use of a hospital bed (30 inches high) and provide comfortable head, arm and foot rests. Moreover, due to insufficient storage space, the unit must allow for easy transportation between procedures. Since maintaining the same position throughout the duration of the procedure is critical, the device must be sturdy and support the patient without tipping. Finally, the supporting unit must be produced under the client's \$500 budget.

§ 6. Preliminary Design Ideas

Based on the client's design criteria, three different design ideas including a one piece, two-piece and a desktop unit with a foot rest were proposed. All three designs included cushioned head and arm rests. Moreover, the head rest has a hole in the center for air circulation. A design matrix was used to rate each of the proposed designs on comfort, stability, expected spinal curvature, ease of manufacturing, adjustability, portability, and cost. This design matrix reflects our initial thoughts about the preliminary designs; however, later in the design process, we realized that incorporating all three designs in our prototype would be most effective.

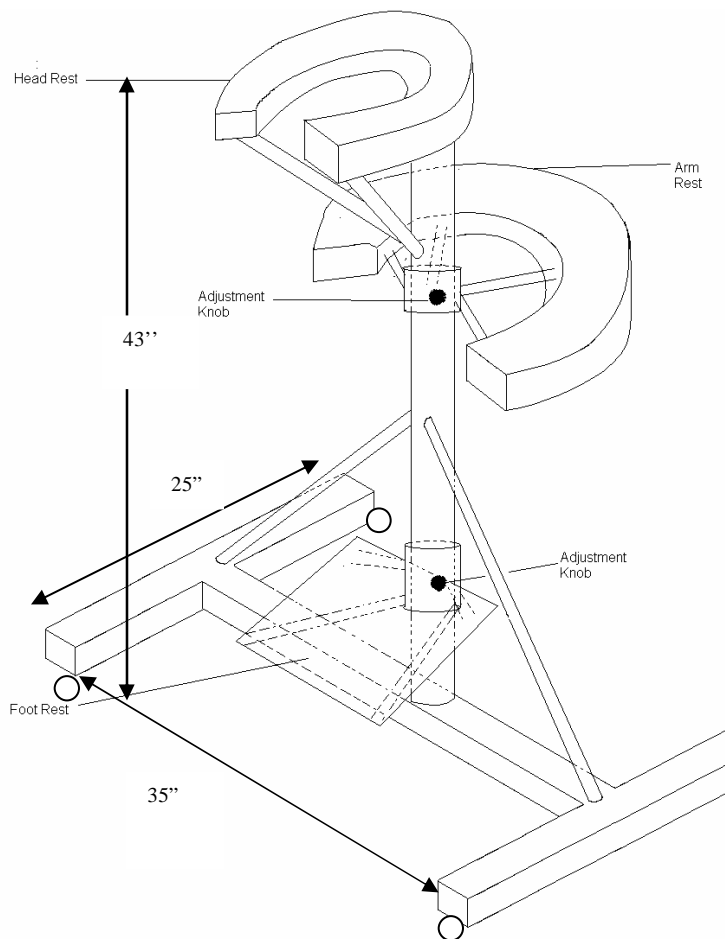
§ 6 a.Design #1- One-Piece Unit

Our first proposed design is a one-piece unit, where the head, arm and foot rests are attached to a central column. The central column is adjustable and can vary in length using a system of push button tabs similar to those used on standard crutches. The head

rest is directly attached to this central rod and can be adjusted vertically by raising and lowering the central column. Two cuffs, one attached to the foot rest, and the other to the arm rest, are placed over the central rod and allowed to slide vertically. Once the cuffs are adjusted to the desired height, they can be held in place with a screw that can be tightened and loosened by hand with an adjustment knob.

A base with two supporting rods that connect to the central rod supports the one-piece unit. The base of the unit has wheels that can be locked in place with brakes when being used by the patient and can be unlocked during transportation (Figure 4).

Figure 4: One-piece unit.



Some advantages of the design include ease of transportation and proper weight distribution throughout the unit. Since the device does not have any removable parts and has lockable wheels, it can be easily transported from room to room. Also, since there is only one central column, patients with long legs should find it easy to avoid contact with the arm rest because its width allows the patient to place his/her legs around it. This is a significant difference from the current positioning technique where tall patient's legs are frequently in contact with the bottom of the bedside table. Furthermore, the broad base and the support columns help stabilize the device and prevent it from leaning from side to side during use.

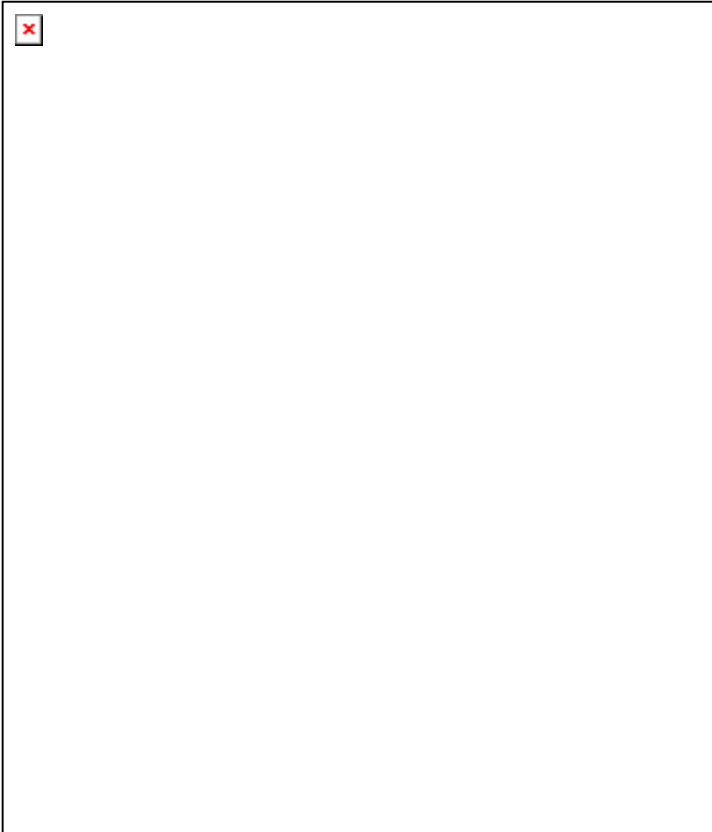
Although all three of the rests can be adjusted, there are several disadvantages to this design. First, this device may not give the maximum curvature since the foot rest cannot slide towards or away from the user. Although adjusting the feet vertically is important in patient comfort and in providing spinal curvature, proper positioning of the feet in relation to the arms and head is also critical in curving the spine, especially with tall patients. Next, several adjustment knobs and other mobile parts on the central rod may increase the difficulty of fabricating the device.

§ 6 b. Design #2- Two-Piece Unit

The second design option is a two piece stand-alone unit with a base and a central column with attached head and arm rests. The column is adjusted vertically to raise and lower the head rest. The arm rest is attached to the central column by a cuff to adjust its placement on the device. Further, the base will have locking wheels to facilitate transportation. The foot rest is a separate but fully adjustable unit, which can be adjusted

for height as well as angle to fit each patient's needs. The foot rest will be able to lock onto the base during transportation (Figure 5).

Figure 5: Two-piece unit. For dimensions, see Figure 4.



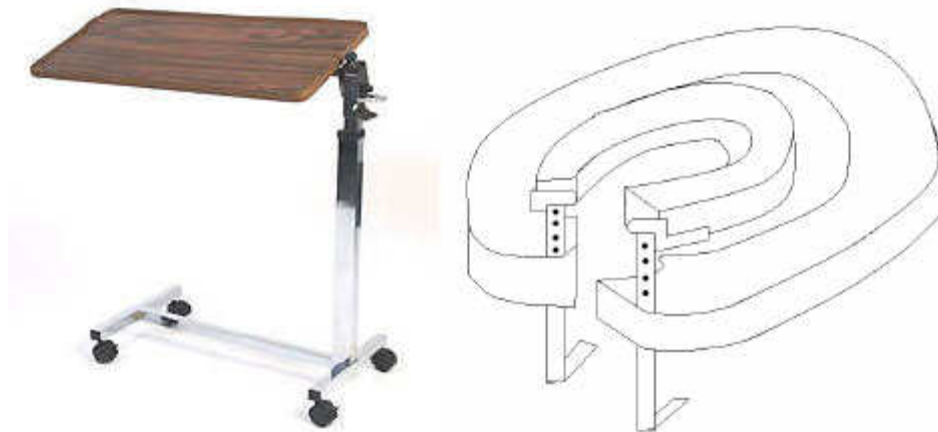
Since the foot rest is not attached to the base, it can be moved horizontally with respect to the bed, head, and arms to accommodate patients with varying leg lengths. The legs can be positioned to avoid contact with other parts of the device and will provide more comfort to taller patients compared to the current set up. Stability is another important factor in the design since patients must remain still during the procedure. This unit will have a wide base with sturdy supports to prevent it from tipping from side to side. Furthermore, the wheels used during transportation will lock when the unit is in use

to prevent it from rolling. A significant drawback to this design is the difficulty transporting both pieces. However, to aid in transportation, the design may incorporate a latch to attach the foot rest to the arm and head rests.

§ 6 c. Design # 3 Table -Top Unit

The third design is a two piece table-top unit, which includes a height-adjustable foot rest similar to the one used in the second proposed design and a separate unit containing the arm and head rests. The arm and head rests will attach to the bedside table present in all hospital rooms. Metal clamps hold the unit onto the table, and the arm rest lies on top of the table. The height of the head rest will be adjusted by moving it to a desired height and locking it in place using a pin. Since the table height is also adjustable, the height of the head rest may also be altered by raising or lowering the table (Figure 6).

Figure 6: Table-top unit. Left: Height-adjustable bedside table [4]. Right: table-top unit clamps onto table [4].



Given that the unit attaches to the table, it does not utilize as much material as the other two designs and will be less expensive to construct. Another advantage is that the design utilizes existing equipment, the bedside table, available in all of the hospital rooms in which this product will be used. One major disadvantage to this design, however, is that it is less adjustable than the other designs due to its immobile arm rest. Similar to the

current set up, the table may pose considerable discomfort to taller patients when their knees contact the table. The horizontal bar at the base of the table (Figure 6) may also interfere with the positioning of the foot rest, thus limiting how far in and out the foot rest can be placed. This design is also less sturdy because the bedside tables do not have locking wheels, which could result in the unit slipping during the lumbar puncture procedure. Another disadvantage of this design is that there is limited air flow for the patient since the table is placed directly beneath the head rest. In addition, transporting the device will be laborious since it has two separate components.

§ 7. Design Matrix

Each of the three proposed designs were rated based on the following criteria: comfort, stability, curvature of spine, ease of manufacturing, adjustability, portability, and cost.

Figure 7: Weighted design matrix.

Criteria	One piece unit	Two piece stand-alone unit	Two piece table attachment
Comfort (10)	7	7	6
Stability (10)	9	9	5
Curvature of Spine (10)	7	9	6
Ease of manufacturing (10)	5	9	7
Adjustability (10)	7	9	3
Portability (5)	5	3	3
Cost (5)	4	4	5
Total (60)	44	50	35

Cost and portability were weighted less than all other criteria since the budget was nearly \$500 and since portability was not the primary issue that our client was faced with. It was much more important to properly position the patient for maximal spinal curvature while providing a comfortable support. Out of possible 60 points, the two-piece unit scored highest overall with 50 points, followed by the one-piece unit and finally the two-piece table-top design. The one-piece and two piece stand-alone units scored equally in the comfort category while the table-top unit scored lower due to insufficient air flow and the immobile arm rest. In terms of stability, the two-piece and the one-piece units were rated higher than the table-top design because the latter uses the table present at each hospital room that cannot be locked in place. Since the tables have wheels at the base and are unstable, they do not provide the proper support needed. Next, the two-piece unit was given the highest rating for spine curvature. Since the table-top unit does not have an adjustable arm rest, the arms and the head will be aligned close to each other and may not allow the user to open up the spinal column as much as they could.

The two-piece unit also would be the easiest to manufacture since the foot rest can be ordered on-line and the components can be easily assembled. The one-piece unit would require building a central rod with adjustable lengths, and cuffs that adjust to varying diameters, which may be tedious and laborious to machine. Further, unlike the two-piece and the table-top designs, the one-piece design requires building a foot rest compatible to the central column. The two-piece unit was rated the highest for adjustability over the other two designs. Although the two-piece table attachment allows the user control over the position of the head and the foot rests, the arm rest is stationary and is clamped onto the table. In addition, the one-piece design is cumbersome when

adjusting the height of the head rest. Since the head rest is directly attached to the length-varying central rod, each time the height of the head rest is altered, the cuffs for the arm rest and the foot rest also need to be adjusted. The one-piece design was rated highest in portability because transporting a single unit with wheels is more convenient than moving a two-piece unit. Finally, the cost estimated for the two-piece table attachment is the lowest since it does not have as many supporting columns, a base unit or adjusting knobs compared to the other two designs. Overall, the two-piece unit was rated the highest and is the preferred design over the one-piece and the table-top units.

§ 8. Final Design

Although we preferred the two-piece unit, ultimately, we chose to construct the one-piece unit for a number of reasons. Our client preferred the portability of a one-piece device. By designing the one piece unit, problems that may have arisen due to the separate foot rest have been avoided. These problems include the footrest becoming separated from the base of the device and lost, and difficulty in transportation as our client would have had to transport two pieces of equipment each time the device was moved. In addition, the one piece option was financially favorable. Had the two piece unit been constructed, a separate footrest would have been purchased. The cheapest foot rest that was compatible with our design was over \$200 to purchase. As an alternative to a separate foot rest, a much less expensive foot rest constructed using PVC and polypropylene was designed to attach to the central column of a one-piece unit.

Our final design consists of four major components: the base, the footrest, the central support column and the desktop massage chair. The base for the device was obtained by separating base and the column of a typical desk chair. A piece of 5.5" X

2.5" PVC was fit over this column and was held in place with epoxy. Since the inner diameter of the PVC and the outer diameter of the chair column were only a few thousandths of an inch different, the piece fit extremely tightly over the column and bolts were not required to hold the two together. The wheels were removed from the desk chair and replaced with lockable wheels that were fastened to the base with nuts and bolts. A 2.5" to 2" adapter was primed and fixed to PVC with epoxy. The 16" central column was then attached to this piece. Since this was found to be an unstable point in our design, the PVC was bolted to the adapter to minimize the movement of these pieces with respect to each other. Holes were drilled through the central column at 2" intervals so that the footrest could be adjusted from 16.5" to 28" using a pin. The footrest was constructed by first manufacturing a 15" X 20" frame of PVC. Four 90° elbows were used to make the frame. A T piece was bored out so that it slid freely up and down the central column. This served as the point of attachment for the footrest to the central column. A 15" X 20" piece of polypropylene was fastened to the PVC frame with nuts and bolts. The bolts were positioned at points of possible rotation if the foot rest was subjected to pressure and the epoxy was to come free. The foot rest was placed over the central column and designed so that it was positioned at approximately 30° above the horizontal to promote patient comfort. Traction tape was added to the polypropylene of the foot rest to prevent the patient's feet from slipping during the procedure. A 3.5" X 4" X 1" sheet of steel raised was fastened to the chest support of the desktop massage chair using lag bolts. A central hole was cut into this piece, and the central column was inserted into this hole and bolted. Final dimensions of the rest components are as follows: arm rest 38" from the

floor, width 11 X 12"; chest rest width 9.5 X 10.5" at an angle of 47.23 ° from the horizontal and a height 43" from the ground; head rest 48" from the floor.

Figure 8: Final prototype with dimensions



Our design has many advantages over the current set-up. First, since the device is one unit and has lockable wheels, it is easily transported about the hospital. Also, the lockable wheels, used in conjunction with the floor mats will prevent the unit from slipping on the surface of the hospital floors with normal use. Since the device supports the feet at an angle so that the toes are above the heel, the patient's feet should be comfortable throughout the procedure. Also, the foot rest raises the feet so that the spine is curved but allows room for the knees to go on either side of the arm rest so that they are not obstructed in any way. This is in contrast to the current set-up for the procedure in which a person over 6 feet tall would likely have their knees pressing against the bottom of the table used to support the head and arms. Also, the arm rest is padded and at a level even with the patients heart. This is also an improvement from the previous set-up in that the table that was being used prior to this device was not padded and the arms were at the level of the head. This causes discomfort to the patient because blood flow to the arms is reduced as they are raised above the heart; the hard surface of the table also causes further discomfort. This device supports the chest of the patient which increases comfort since they are not relying on their arms and back to hold them in the desired position. Finally, the head rest is padded and facilitates air flow to the patient for breathing because of its doughnut shape and the lack of obstructions behind the cushion. The head rest is also angle-adjustable, which allows the patient to more comfortably curve his/her spine.

§ 9. Conclusion

The only ethical question in this situation is if it is truly safe and effective. This could only be determined by gaining IRB approval to test the device to see if it provides adequate spinal curvature, stability and comfort. The spinal curvature provided by the

device may be quantified to ensure that it fits the client's needs. However, we anticipate that our device will be much more supportive and stable than the existing set-up, and should therefore be ethical.

The device has a few minor flaws that could be improved upon. Currently, the height of the arm rest and chest support is fixed. Therefore, the unit is adjustable only because the researcher can rely on the height-adjustable bed to make the patient fit properly into the chair. Ideally, the head rest and arm rest component would be able to move up and down along the central support column so the bed could be positioned at the researcher's preferred height. In addition, refinement of the height adjustments for ease of use may improve the device.

Our unit represents a marked improvement for spinal tap procedures performed in our client's research study. Not only will it facilitate the procedure by opening the lumbar backbones, but it will also provide greater comfort and allow the patient to maintain the proper position for the duration of the procedure.

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APPENDIX 1- Product Design Specification
Lumbar Puncture
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Decemeber 13, 2006

Function: A device should be built to properly support the head, arms and feet of patients undergoing a spinal tap procedure. Use of the device should enable patients to curl their back as much as possible to open lumbar spaces for the procedure, while providing maximum comfort. Finally, the device must be adjustable to provide support for a variety of heights and weights.

Client requirements:

- Device must fit around an adjustable height hospital bed
- Should be adjustable so the patient can be positioned properly
- The device must incorporate an adjustable foot rest, an arm rest, and a head rest
- Must allow for maximal curvature of the spine
- It must be sturdy and should not tip over during use or adjustment
- The device should be built within a \$500 budget

Design requirements:

Our goal is to design a specialized chair to use for lumbar puncture procedures in the sitting position. Proper positioning of the person to open up the space between the lumbar backbones is critical for success of the procedure. Keeping the patient comfortable while maximizing the curve of the low back to optimize the access to the lumbar interspace is important, yet remains a difficult challenge using current positioning techniques.

1. Physical and Operational Characteristics

- a. *Performance requirements:* The device will be used for thirty minutes, four to ten times a month.
- b. *Safety:* During use, the device must provide adequate support to the patient and must be sturdy.
- c. *Life in Service:* We would like the device to last at least five years.
- d. *Operating Environment:* The device will be used in a hospital patient room and would not have to undergo extreme variations in temperature, pressure, and other external factors.
- e. *Ergonomics:* The device should be able to withstand patient's body weight ranging from 48-113 kg and must include cushions around the support areas to maximize comfort. In addition, the foot rest must be adjustable to accommodate patient heights ranging 155-188 cm.

f. *Size*: Since the device should fit within the space between the hospital bed and the wall surrounding the room, the dimensions of the device should not exceed three feet wide and three feet deep.

g. *Weight*: The device will be transported frequently within the hospital and will need to weigh less than 50 lbs.

2. Production Characteristics

a. *Quantity*: one needed for client, however, if the product is desirable, it can later be mass produced.

b. *Target Product Cost*: The total cost in producing the support device should not exceed our client's proposed budget, \$500. The nearest competition to the product, the massage chair, costs nearly \$200.

3. Miscellaneous

a. *Standards and Specifications*: We must obtain the Institutional Review Board (IRB) approval to test our product on humans.

b. *Customer*: The client would prefer an adjustable angle for the footrest.

c. *Patient-related concerns*: Since the device will be used by multiple individuals, it should be cleaned with hospital sanitizing spray between use. The design should maximize patient comfort.

d. *Competition*: The most popular supporting device used is a massage chair, however, our client reported that massage chairs do not provide enough curve to the spine to successfully withdraw spinal fluid. Further, there are no specialized chairs specifically designed for this procedure.