Leg positioner to facilitate placement of central venous catheters in the ICU

Mid-Semester Report

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3-12-2008

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Abstract

The purpose of our project is to optimize the femoral vein catheterization process by building a device that will properly position the leg of the patient. The device must be able to flex the knee and abduct the hip to a certain angle to optimally expose the area of needle insertion. Our client has defined the following constraints for this design: disposability, integration within operating field, inhibition of leg movement, a stabilizing frame, and an additional attachment for pannus retraction. Our team has developed three possible designs to meet these criteria, the foot holder, foam wedge, and rod and counterweight designs. Client interest, component expectations, and versatility were deciding factors in choosing the proper design. The rod and counterweight system will continue to be investigated and built in the remaining time this semester.

Problem Statement

Each year many patients undergo femoral vein catheterization. Insertion of a femoral vein catheter is common in procedures where access to a large blood flow or a clear pathway to the heart is desired. Hemodialysis, angioplasty, invasive blood pressure monitoring and drug infusion are examples of such procedures. Insertion of the catheter can be difficult, as the femoral vein makes several turns before it meets the inferior vena cava. Often, the patient's leg must be put into a position that is optimal for placement of the catheter. This position may be difficult to maintain during the procedure, and often assistance is required to hold the patient's leg. Another complication during femoral vein catheterization is obstruction of the operating area due to the patient's pannus. Currently, a resident physician or nurse must hold both the leg and the pannus, if necessary. This can be both hard work and can crowd the operating environment. Development of a leg positioning device that both secures the patient's leg at the optimal angles and provides a method for retracting the pannus away from the operating field will provide tremendous assistance during an operation.

Background Materials

Femoral Vein Catheterization Procedure

Femoral vein catheterization is a fairly common procedure when a large blood source is required or access to the heart is needed. Physicians performing the procedure must know exactly where the vein is so that placement of the catheter can be quick and problem-free. The femoral vein is located medial to the femoral artery and distal to the inguinal ligament. When a central line is inserted into the femoral vein, the physician must take extreme care when inserting the needle. If the needle is inserted at too steep of an angle, the vein could be perforated. Perforation of the abdominal cavity is also a potential risk, and that is why most femoral vein catheterizations must occur distal to the inguinal ligament. The optimal insertion point is 1-2 cm distal of the inguinal ligament, 1-2 cm medial to the femoral pulse and at a 45° angle to the leg. This area can be made easier to access by positioning the patient's leg in advance (APLS, 2007).

Leg Positioning

Because the femoral vein is located towards the medial aspect of the leg it can be difficult to access when performing the procedure from the lateral side of the leg. Also, the femoral vein travels up from the leg and then turns medial once it is past the inguinal ligament, towards the center line of the body, so that it can meet with the inferior vena cava (Figure 1). Both of these geographical aspects of the femoral vein can further complicate the procedure. By positioning the leg so that the hip is abducted and externally rotated and the knee is flexed (Figure 2), the vein can be brought into clearer view. The S-shaped curve the vein makes is also straightened in the process. This makes it easier for the physician to locate the vein, insert the catheter and proceed to feed the catheter into the vena cava (Gray, 1918).

Because the insertion site for the femoral vein catheter is so close to the pubic and inguinal areas, infection and obstruction of the operating area can occur. The operating field must be kept sterile during the operation and relatively clean after. Both obstruction and compromising of sterility can occur when the patient has a large pannus. The pannus is defined as excess adipose tissues most commonly located in the abdominal region. This can hang down from the belly and cover the pubic and inguinal areas. Often an assistant must hold back the pannus so that the physician can insert the catheter. This is an inefficient method as it requires the presence of another person to hold the pannus. Also due to the size of the pannus it can be quite strenuous to pull back. If after the procedure the pannus is left to cover the operating area, the chances for infection can rise. The design must incorporate a method for retracting the pannus during the operation and also allow the ability to be left continually retracted after the procedure to thwart the possibility of infection (Jaffery).

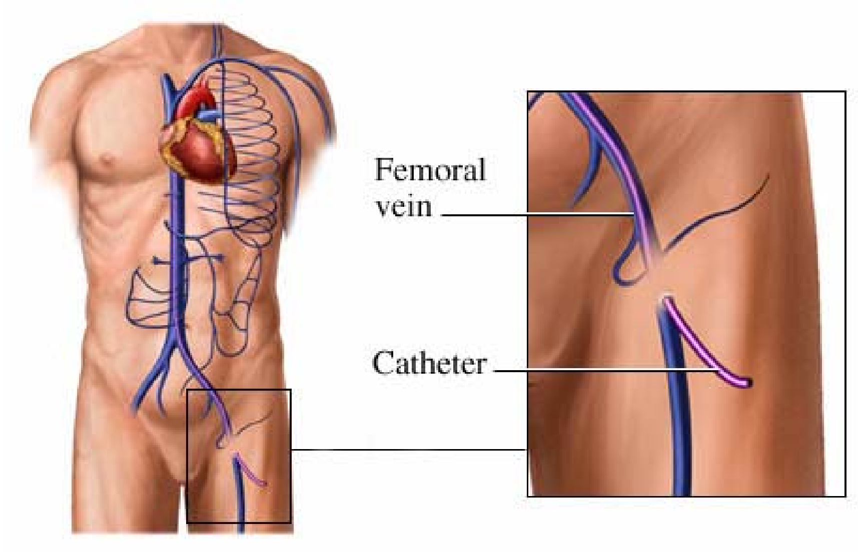
Client Expectations

The design must incorporate several key aspects. The design must be completely disposable. This means the design must be fabricated out of relatively inexpensive materials. The need for a disposable device comes from the possibility of contamination from both blood and the fact that the device will be coming into contact with the patient's skin. A disposable device is also much less hassle than one in need of sterilization.

The design must also keep the operating area clear. It cannot obstruct the operating field in any way. This means that the pannus retractor must be positioned so that it clears the inguinal ligament and any other land marks the physician needs to ensure proper catheter insertion.

The device must allow for either leg to be secured and operated on. Securing of the leg cannot rely on the assumption that the patient will not have handicapped legs (i.e. it is possible that a patient can be missing both of their lower legs). The operating leg must be secured at the set angle for the duration of the procedure.

The device itself must be secured such that it does not move during the procedure. Any slipping or rotation of the device would defeat the purpose and cause further complications during the procedure. The device must incorporate an attachable pannus retractor that can be attached or removed depending on if it is needed.



http://d.yimg.com/origin1.lifestyles.yahoo.com/ls/he/healthwise/n5551133.jpg
Figure 1- Femoral vein anatomy and insertion site for femoral vein catheter

Figure 2- Optimal leg position for femoral vein catheterization

Competition

The primary competition with such a leg positioning device for femoral venous catheter insertion is the current manual methodology. In this procedure, the physician relies on the assistance of a nurse or resident to restrain the patient in most cases. This consists foremost with the stabilization and restraint of the patient's leg. Since the hip must be extended and the knee flexed to allow for open access to the femoral vein, the assistant will position the leg in such a way manually – and then proceed to hold it for 15 to 30 minutes. It is obvious that such a method would be strenuous for the assistant if the procedure lasts too long. Furthermore, another nurse is needed approximately 45% of the time to restrain the pannus (Jaffery). This is even more difficult for the assistant, since restraining the pannus requires an awkward angle and considerably more strength.

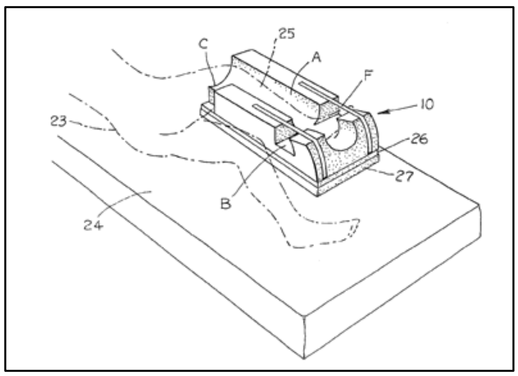


Figure 3- US Patent #3,931,654.

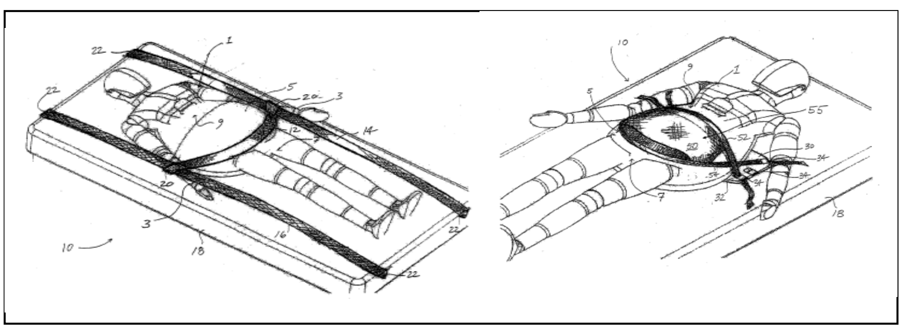


Figure 4- US Pub. #2006/0180158.

As far as devices that would mimic such a procedure, there is only one patent available that would be effective for femoral venous catheter insertion procedures. It is US Patent #3,931,654 (Figure 3) and is expired. This device is not adjustable, however, and is therefore not as effective as the one that we propose. As far as a pannus restraint, there is one patented device: US Pub. No. 2006/0180158, as shown in Figure 4. This device is very similar to one of our early designs for an abdominal restraint, which utilizes an elastic band. Our device however, will be the only one of its kind to incorporate both a leg positioner and a pannus restraint together.

Preliminary Designs

Design #1- Foot Holder

This preliminary design utilizes the patient's opposite leg to support the positioning of the knee and hip of the targeted leg. The design is a simple cuff that could be attached to the patient's lower calf by Velcro® straps. Incorporated within the design is a sleeve or pointed opening that would allow for the placement of the foot of the targeted leg. This sleeve would be flexible enough to conform to the foot, but also stable to create the proper positioning required. See Figure 5 below.

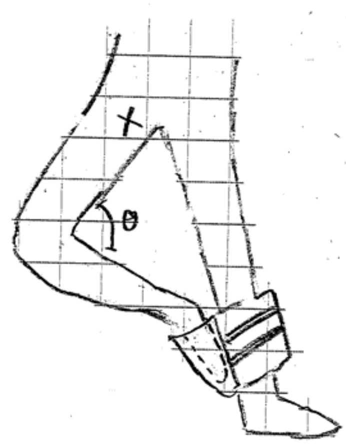


Figure 5- Design #1- Foot holder

The angle and extension of the knee and hip could be coarsely adjusted by positioning the cuff higher or lower on the patient's opposite leg. As the cuff and associated foot move higher up the leg, the greater the angle of hip abduction and knee flexion. The advantage of this design is its simplicity to manufacture and ease of use. However, the disadvantage mentioned by our client outweighed any possible advantages, as it was brought to our attention that some patients in an ICU needing femoral vein catheterization may not have an opposite leg in which to utilize this positioning device. In order to accommodate this constraint, our design must not require the incorporation of the opposite leg.

Design #2- Foam Wedge

The second preliminary design does not involve any adjustable mechanisms. A simple foam wedge could be designed and shaped in a way that supported the opposite leg while creating the proper position for the target leg. The design, while supporting the opposite leg does not require the full leg to be present. A canal-type design could be used to support the system around the opposite leg, while the attached foam wedge would be contoured to set the desired position of the target leg. See Figure 6 for a schematic of the design.

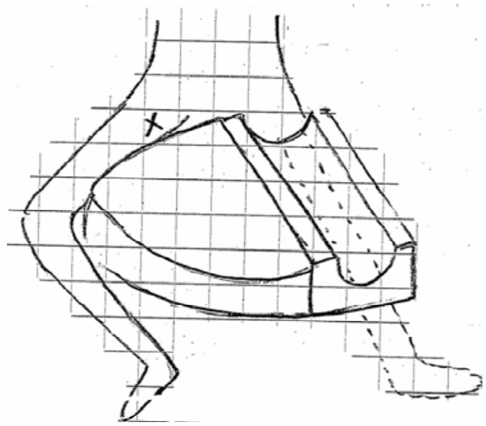


Figure 6- Design #2- Foam wedge

The advantage of this design is simplicity of manufacture and ease of use. Our team looked into memory foam that could be used to create the proper comfort level and support. A disadvantage of this design is the lack of adjustability. Production of a few different sizes of foam wedges would need to be developed to accommodate a range of patient sizes. However, the main disadvantage of the foam wedge is that it would interfere with any central lines, tubes, or wires that are running into between the patient's legs. Dr. Jaffery commented on this point, mentioning that the interference could be hazardous during the procedure.

Design #3- Rod and counterweight

In this design, a three piece system would be used to immobilize the patient's leg and hold the pannus back, if necessary. The first piece, the large plate would be slid underneath the patient to be used as the counterweight. The part of the plate with the "cross attachment" would not be underneath the patient as it will be used elsewhere in the design. Once this plate was in the proper location, the rod could then be fit into the plate through the channel and would be slid in and adjusted for the proper length. The rod would then be locked in, and the patient's lower leg would be would be moved to the proper angle and place.

The lower leg would then be attached to the board with some straps, and held securely in place. This would effectively immobilize the patient's leg, and would open up the site for the catheterization. Finally, if necessary, the third component could also be employed to hold the patient's pannus away from the operating site. This piece would have an attachment that would fit into the "cross attachment" area on the large plate. This component would attach on the side of the patient, and would hang across the patient's body. See Figure 7 for the design concept.

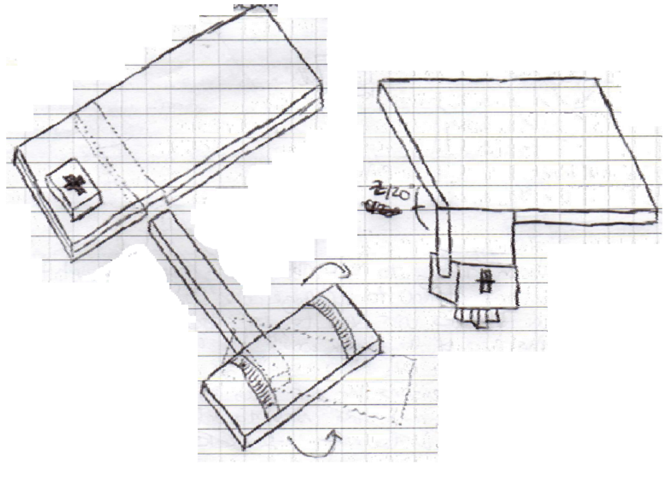


Figure 7- Design #3-Rod and counterweight three-component design

Advantages to this design are that it provides a very sturdy, accurate way to hold the patient's leg in place, and provides a way to very accurately position the patient as necessary. A disadvantage of this design is the number of components necessary for this design to work correctly, as well as the amount of time necessary to assemble it while being used in a procedure.

Design Matrix

The design matrix developed for the three aforementioned design concepts is shown below in Figure 8. The options were evaluated based on four criteria: client interest, cost, component expectations, and versatility.

	Rod and Counterweight	Foam Wedge	Foot Holder
Client interest (50)	50	20	5
Cost (10)	4	10	3
Meets component expectations (10)	10	5	5
Versatility (20)	18	8	4
Total	**82**	**43**	**17**

Figure 8- Design Matrix for three competing leg positioner designs

The heaviest emphasis was placed on our client's interest in the design, and whether he felt that it met his standards for a successful operation to occur smoothly. In our matrix, we also considered a few other criteria including the cost to manufacture this product, whether or not the design met all component expectations (leg restraint, pannus retractor), and how versatile the design was (i.e. could it be used ambidextrously on many sized patients with potential handicaps or other catheters or tubes placed near the site of ours?). Once we evaluated our options, we realized that the rod and the counterweight was the best choice, and decided to pursue developing a functional prototype.

Progress to date

Materials were ordered for this design on March 3, 2008, and arrived on March 6, 2008. Some parts are still to be decided upon and ordered, which include the various joints and attachments necessary to make our design adjustable. These parts will be researched and evaluated, most likely through trial and error and brainstorming.

Future Work:

With the plastic parts already ordered, we can now begin finalizing our design. This will consist of a computer-drawn schematic for precise dimensions, perhaps with SolidWorks. We will also conduct a force analysis of the device, particularly surrounding the rod, to ensure that it will withstand the abducting, adducting, flexion, and extension of the patient's leg. The force analysis could be done by hand or using Cosmos®. With this knowledge, we should be able to begin construction on a prototype immediately following spring break.

The remaining technical components required will focus on connection points. We must determine a suitable connection for the rod to the base plate, which will most likely utilize pushpins or screws. The most difficult connection is likely at the point of connection between the rod and the rotating leg cuff. This may be solved with a type of locking ball-joint that is able to swivel. A potential hinge would be similar to the one used in a camera tripod stand.

Finally, after the prototype is completed, we can begin preliminary simulated tests. These tests will be designed later, but most likely would involve one of us laying on the device and positioning our leg in the desired position. Time-permitting, we may also have the opportunity for Dr. Jaffery to utilize our device in the ICU, although sterilization protocol would require it be only for a one-time use.

Appendix A- PDS

Leg Positioner to Facilitate Placement of Central Venous Catheters in the ICU

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March 12, 2008

Function: A dual function device needs to be developed to aid in the placement of a central catheter through the femoral vein in a dialysis patient. This device would be used in an intensive care environment, on a standard hospital bed; however there is potential to expand its use in further cases. Most often, it is difficult to achieve the optimal positioning of the patient's leg because it requires the patient to lie in a specific position for a length of time which most often requires an extra person to hold the leg in place. A device must be developed that would aid in proper positioning and restraining of the lower extremity during femoral vein central venous catheterization. Also, in some patients, a portion of their abdominal pannus overhangs the site for catheterization. This device should also have an attachment that can retain the patient's abdominal pannus during the length of the procedure to prevent it from contaminating the sterile field.

Client requirements: The device must:

- be disposable
- be able to be sterilized around the area the catheter is to be inserted
- comply with given hospital safety standards
- cost about $50 to produce
- be able to hold the patient's leg in place and resist movement of the patient
- not rotate on the bed or fall out of position during the procedure
- provide an attachable device to hold a patient's abdominal pannus away from the sterile field

Design requirements:

1. Physical and Operational Characteristics

    a. Performance Requirements
        i. Disposable
        ii. Adjust hip and knee to proper angles of extension and flexion
        iii. Hold proper position for a maximum of 30 minutes
        iv. Lightweight but durable
        v. Easy to use

    b. Safety
        i. No latex material
        ii. Smooth surfaces
        iii. Locking mechanism for adjustability
        iv. Stabilizing mechanism for device as whole

c. Accuracy and Reliability
   i. Adjust hip angle from 0-70º
   ii. Many adjustments settings for proper positioning
   iii. Constant stability

d. Life in Service
   i. Must be operable for 30 minute catheter insertion

e. Operating Environment
   i. Sterile ICU hospital environment
   ii. Variant room temperature depending on patient care

f. Ergonomics
   i. Must be easy for doctor or clinician to assemble and operate.
   ii. Must be able to fit a wide range of leg sizes and be adjustable to accommodate different leg angles.
   iii. Should be comfortable for the patient, as they could be awake during the procedure.
   iv. Must be able to restrain either of the patient's legs.

g. Size
   i. Must be adjustable or fitted to accommodate wide range of leg sizes.
   ii. Must be able to fit inside of an intensive care unit.
   iii. Can't obstruct the operating area.
   iv. May need to be appropriate size to fit onto an intensive care unit bed.
   v. If positioned on the ground, must be appropriate size so as not to obstruct procedure.
   vi. Would be ideal to develop into a self containing 'kit' that would fit compactly in an ICU storage room to be readily accessible.

h. Weight
   i. Must weigh enough so as to be a stable platform, but not so much that it can't be lifted by a clinician.
   ii. 3.5 – 9 kg

i. Materials
   i. Materials must be either disposable or sterilizable, or have disposable or sterilizable parts.
   ii. Must have porous materials open to contamination.
   iii. Hypoallergenic: No latex
   iv. Possible materials: High-density plastics, stainless steel, rubber, viscoelastic foam, gel

j. Aesthetics, Appearance and Finish
   i. Must appear user-friendly, so that doctors and clinicians will want to use it.

2. Miscellaneous:

a. Standards and Specifications: The device must:

    i. Accommodate all ICU hospital beds
    ii. Allow for ideal knee-bend angle for procedure (to be determined)
    iii. Accommodate for patients of all sizes (within reason)
    iv. Be disposable

b. Customer (Doctor):
    i. Minimal training
    ii. User-friendly

c. Patient-related Concerns:
    i. Limit patient discomfort
    ii. Professional aesthetics

d. Competition:
    i. Manual method with nursing assistant
    ii. US Patent # 3,931,654: *Leg Positioner*
    iii. US Patent # 4,730,609: *Surgical Drape with Limb Securing Structure and Method for Securing Surgical Site*
    iv. US Patent # 5,010,900: *Lower Limb Positioning Apparatus and Surgical Drape*
    v. US Patent # 7,234,180: *Dynamic Surgical Table System*

Appendix B: References

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