

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

Final Report

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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 was investigated and built with slight changes in design with respect to connection and adjustment joints. Testing revealed that the prototype met client expectations; however, future work includes further testing in an ICU setting and design modifications.

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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. Typically, the patient's leg must be held in a position that is optimal for placement of the catheter. This position may be difficult to maintain during the procedure and often requires the assistance of another individual. 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 the leg and the pannus, if necessary. This can be both hard work and can crowd the operating room. 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 in the operating room.

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 located 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 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.

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 anatomical 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 and the S-shaped curve the vein makes is straightened. This makes it easier for the physician to locate the vein, insert the catheter and proceed to feed the catheter into the vena cava.

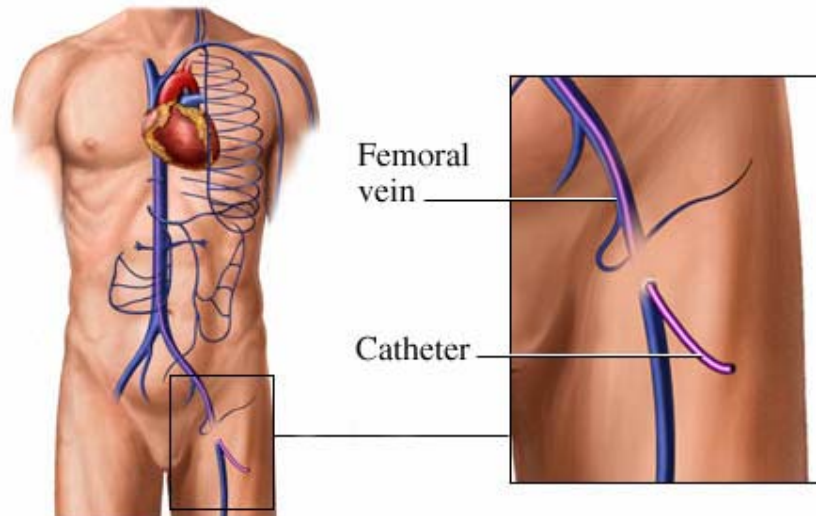


Figure 1- Femoral vein anatomy and insertion site for femoral vein catheter



Figure 2- Optimal leg position for femoral vein catheterization

Because the insertion site for the femoral vein catheter is so close to the pubic area and inguinal, 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, and is most commonly located in the abdominal region.

Sometimes, due to the size of the patient, their pannus may 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 that requires the presence of another person to hold the pannus. The size of the pannus can be quite strenuous to pull back and if after the procedure the pannus is left to cover the operating area, chances for infection arise. Therefore, our design must also incorporate a method for retracting the pannus during the operation and also allow the ability to be left on after the procedure to thwart the possibility of infection.

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 blood and the fact that the device will be coming into contact with the patient's skin. A disposable device is also much less of a 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 landmarks 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 have a lower leg on either lower extremity. 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.

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 30 to 45 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.

While there are several leg positioning devices on the market, none provide access to the femoral vein as well as the current manual procedure. Most notable was a device described in a May 1997 article in the *Association of periOperative Registered Nurses Journal*. In the article, the device was used as a leg positioner to harvest the saphenous vein in a 1997 study to identify preoperative, intraoperative, and postoperative factors associated with the development of pressure ulcers among patients undergoing cardiac surgery. Since the saphenous vein is located near the femoral vein, this device may also work for the femoral vein catheterization procedure.

The device is a positioning and support surface that rests on the lower half of the operating room bed mattress. Its purpose is to elevate, position, and stabilize the patient's lower extremities so that the saphenous veins are accessible for harvesting. By doing this, it keeps the patient's legs stationary and allows the circulating nurse to monitor the patient's body alignment, anatomic features, and physiologic considerations. Linen is placed between the patient and the device to avoid direct skin contact (Lewicki, 1997).

Another peer-reviewed leg positioning device available is the Siegel MAST Intraoperative Leg Positioner. In contrast to the previously mentioned product, the Siegel is available for purchase. According to a December 2005 article in *Surgical Products*, it is designed to free the operating room staff to be more productive by eliminating the need for second assistants to hold and position the leg. The device automatically locks at any position required by the surgeon. However, it is designed for knee surgery procedures, rather than femoral venous catheterizations (Intraoperative Leg Positioner, 2005). For this reason, it probably would not perform well enough for our client's expectations. The device, shown in *Figure 3*, is designed to allow the patient's leg to extend off the end of the bed to allow the surgeon to move around the leg easier.



Figure 3- Siegel MAST Intraoperative Leg Positioner (Intraoperative Leg Positioner, 2005).

There is also a patent available for a simple leg positioning device that may be suitable for femoral venous catheter insertion procedures. It is US Patent #3,931,654 (*Figure 4*) and is expired. This device is not adjustable, and is therefore not as effective as the one that we propose. As far as a pannus restraint, there is one patented device: US Publication #2006/0180158, as shown in *Figure 5*. This device is very similar to one of our early designs for an abdominal restraint, which utilizes an elastic band.

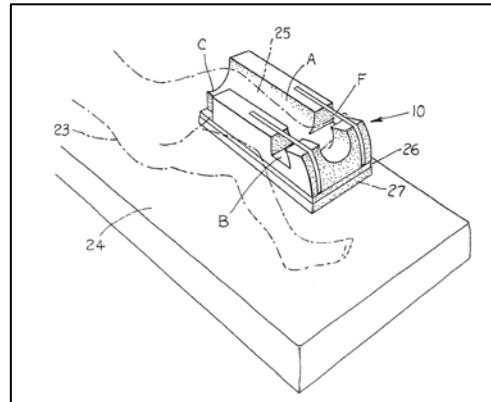


Figure 4-US Patent #3,931,654 (Spann, 1976)

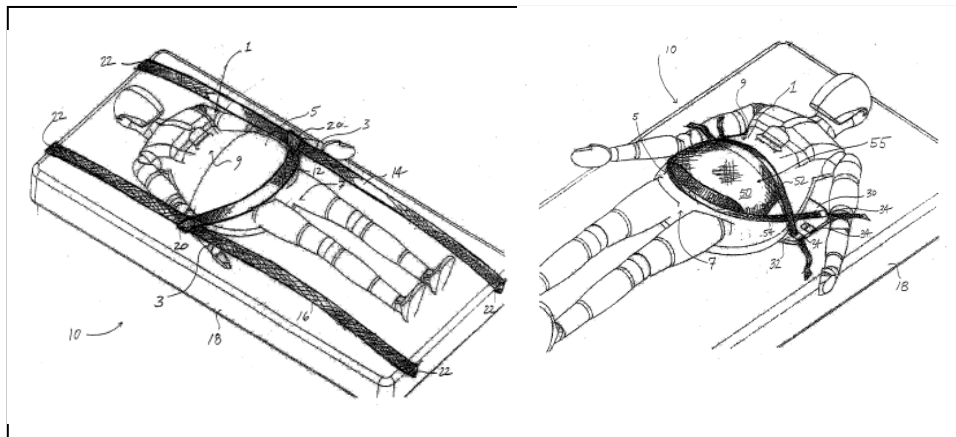


Figure 5 - US Publication #2006/0180158 (McKnight, 2005).

Despite the competitive findings of other leg positioners and a pannus retractor, none of these devices are designed to both position the leg and retract the pannus together. For this reason, our device is the first to incorporate both of these abilities into a single product for femoral venous catheterization.

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 lower calf region 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 6* below.

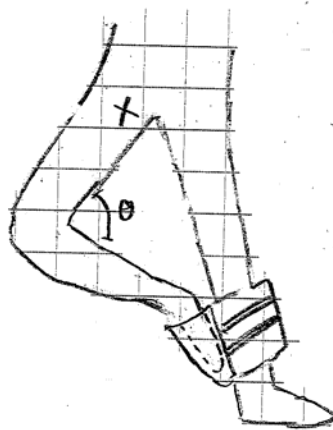


Figure 6- Design #1: Foot holder

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 as mentioned by our client outweighed the advantages. It was brought to our attention that some patients in the 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 shaped for the leg can be used for support while the rest of the foam wedge shaped to contour to the position desired by the target leg. See *Figure 7*.

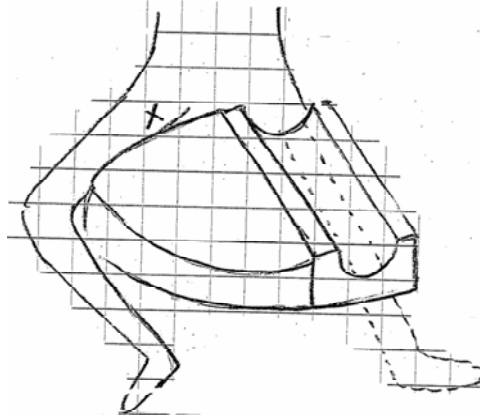


Figure 7- Design #2: Foam wedge

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 between the patient's legs. Dr. Jaffery commented on this point, mentioning that this interference is less than ideal.

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 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 8* for the design concept.

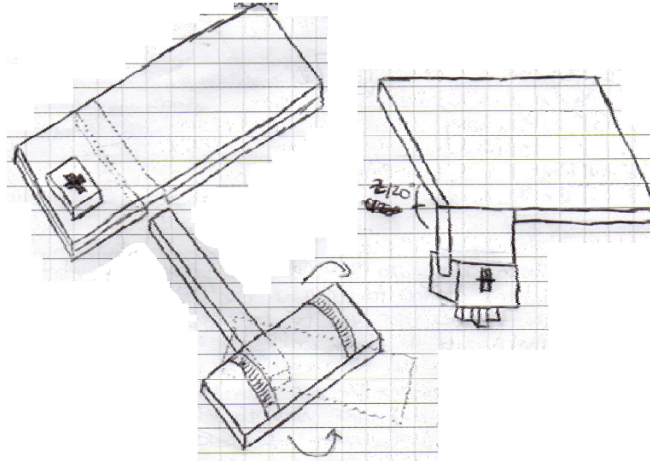


Figure 8- Design #3: Rod and counterweight three-component design

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 9*. The options were evaluated based on four criteria: client interest, cost, component expectations, and versatility.

	<u>Rod and Counterweight</u>	<u>Foam Wedge</u>	<u>Foot Holder</u>
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 9- 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.

Final Design

Since proposing a final design at mid-semester, the team made a few modifications to the design before beginning construction of the prototype. They are as follows:

- 1) In the proposed final design, the rod used to attach the leg board to the counterweight plate slid in and out of the counterweight plate to adjust its length. Since this only allowed the rod to be fixed in one position with respect to the counterweight plate, we decided to modify the design to have the rod slide along a dovetail joint along the width of the counterweight plate. This would allow maximum customization of position for the rod, and also allow for a quick transition if it was necessary to switch legs during the procedure.
- 2) In the proposed final design, we also chose to have the leg board be able to rotate around an axis and lock in place, in order to achieve the proper angle for the procedure. However, deciding upon a way to quickly allow the board to rotate, but yet be securely fastened when not rotating proved to be difficult. Therefore, we decided to fix the angle of the leg board with respect to the rod, but then allow it to be moved up and down the length of the rod. Choosing to alter the design in this fashion allowed for a more simplistic attachment that still provided the amount of customization necessary for the procedure.
- 3) Finally, in the proposed final design, the pannus retractor was going to be set at an angle away from the field where the catheterization was set to occur, in order to open up the field more efficiently for the physician to perform the procedure. However, given the constraints of the tooling machinery available to us, we were unable to devise a plan to successfully secure the pannus retractor at an angle. We therefore chose to have the pannus retractor built so that it was perpendicular to the counterweight plate. This also allowed us to place two attachment locations on the counterweight plate, so that the ambidexterity of the device as a whole was not compromised. It should be noted that neither the change in 1) nor 2) compromises the ambidexterity of the device as well.

Figure 10 shows the contrasting designs of the preliminary and final designs.

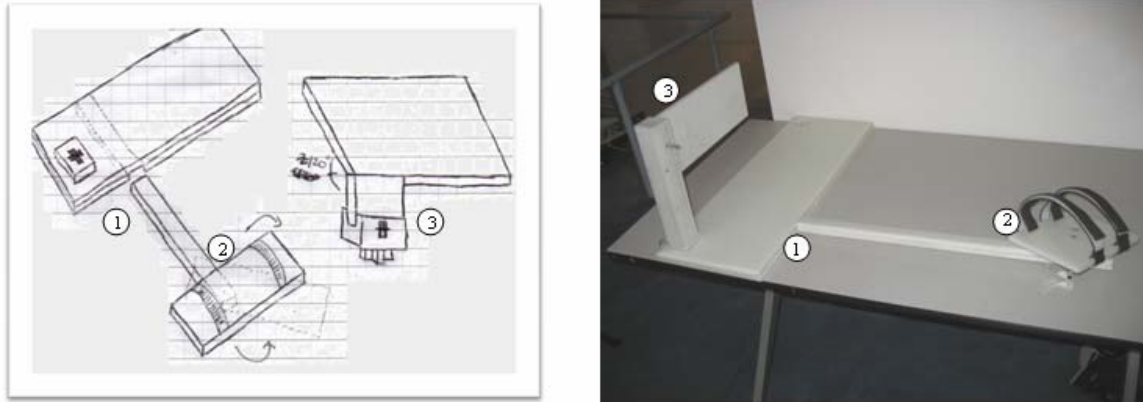


Figure 10-Preliminary design vs. Final design- locations of the changes between the proposed final design (left) and actual final design (right) are shown. The numbers shown on the figures correspond to the numbers in the text.

Materials and Methods

In order to build our prototype, the team purchased a variety of parts. While they were not all purchased at the same time, the list of purchased items includes:

- A sheet of HDPE 48" x 48" x 1/2"
- A HDPE Rod 8' long with 1/2" diameter
- 3M adhesive spray
- Velcro
- A two piece ground clamp
- Metal corner braces
- Bicycle seat quick release mechanism
- Zinc screws: size #6; 3/4" long
- Two 1/4" x 3" pins
- Acrylic latex caulk
- JB Quik adhesive
- 2" plastic shelf braces
- Dove tail and round router bits
- Sandpaper
- White spray paint

The total cost for all materials used for the project was \$238.88. *Figure 11* shows below the main components of the constructed prototype.

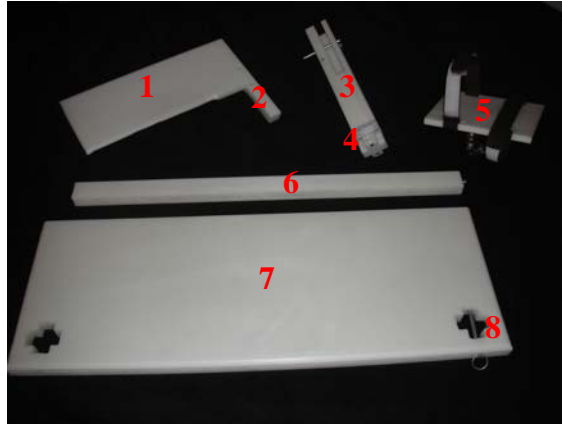


Figure 11- Parts of the Prototype- (1) Pannus retractor, (2) Pannus retractor rod, (3) Pannus retractor support base, (4) Male cross attachment, (5) Leg board, (6) Leg rod, (7) Counterweight plate, (8) Female cross attachment.

Refer to numbers in the figure above for the design procedure.

After tracing all of the parts out onto the HDPE sheet, the following parts were cut out using the table saw and jig saw:

- Pannus retractor (1)- one 6" x 14" piece
- Pannus retractor rod (2)- two 10.5" x 1" x 1/2" pieces
- Pannus retractor support base (3)- four pieces of 12" x 1.5" x 1/2"
- Male cross attachment (4)-one 2" x 2" by 1/2" square (for bottom), two 2" x 2" x 1/2" crosses (attachment to (8))
- Leg board (5)- one 7" x 8" piece
- Leg rod (6)- two 1.5" x 30" x 1/2" pieces
- Counterweight plate (7)- two 30" x 11" x 1/2" pieces

Since the counterweight plate, pannus retractor support base, pannus retractor support rod, cross attachment, and leg rod all had been cut in two pieces each 1/2" thick, these corresponding pieces were glued (and where necessary, were also mechanically fastened by screws) to build the pieces to the proper thickness of 1".

The male cross attachments were fastened to the base of the pannus retractor support base, and two female cross attachments (8) – two 2" x 2" x 1" crosses – were milled out of the counterweight plate on opposite corners of the long sides of the counterweight plate with a 1" drill bit. Each cross was centered 1.5" from the two sides of the counterweight plate it was closest to. We finished made the precision cuts for the female cross using a small drill bit in the mill and a jig saw. All cuts and surfaces were sanded and filed as well.

Holes were also drilled into the pannus retractor rod and support base to allow for a pin to be set to adjust the height of the pannus retractor. A hole was drilled into the

counterweight plate for a pin to aid in the support of the pannus retractor, and a brace was added to the bottom of the pannus retractor support base for stability.

The mill was also used to cut out the slots for the Velcro straps on the leg board, and to create the dovetail joint on the counterweight plate. This dovetail joint was made on the long side of the counterweight plate opposite of where the female cross attachments were milled from. In order to create the male fastener to be used in the dovetail joint, a 5/8" bolt was tapped into the leg rod and its head was ground down and squared off to fit into the dovetail joint.

The leg board was attached to the ground clamp using two bolts. One bolt connected the center of the ground clamp to the center of the leg board, while the other connected one end of the clamp to the board. The second bolt at the end of the clamp secured the leg board at the fixed 35° angle. The bicycle seat quick release was attached to the other end of the ground clamp, to allow it to open and close easily.

Finally, three edges of the top face of the counterweight plate (the edge with the dovetail joint was excluded) were rounded with a router, and the three edges of the pannus retractor were also rounded using the router. Later in the building process, the three-piece pannus retractor was replaced by a two-piece system, where one-half of the pannus retractor rod was cut with the pannus retractor, so that it was all one piece.

Figure 12 shows a SolidWorks drawing of the final prototype with dimensions.

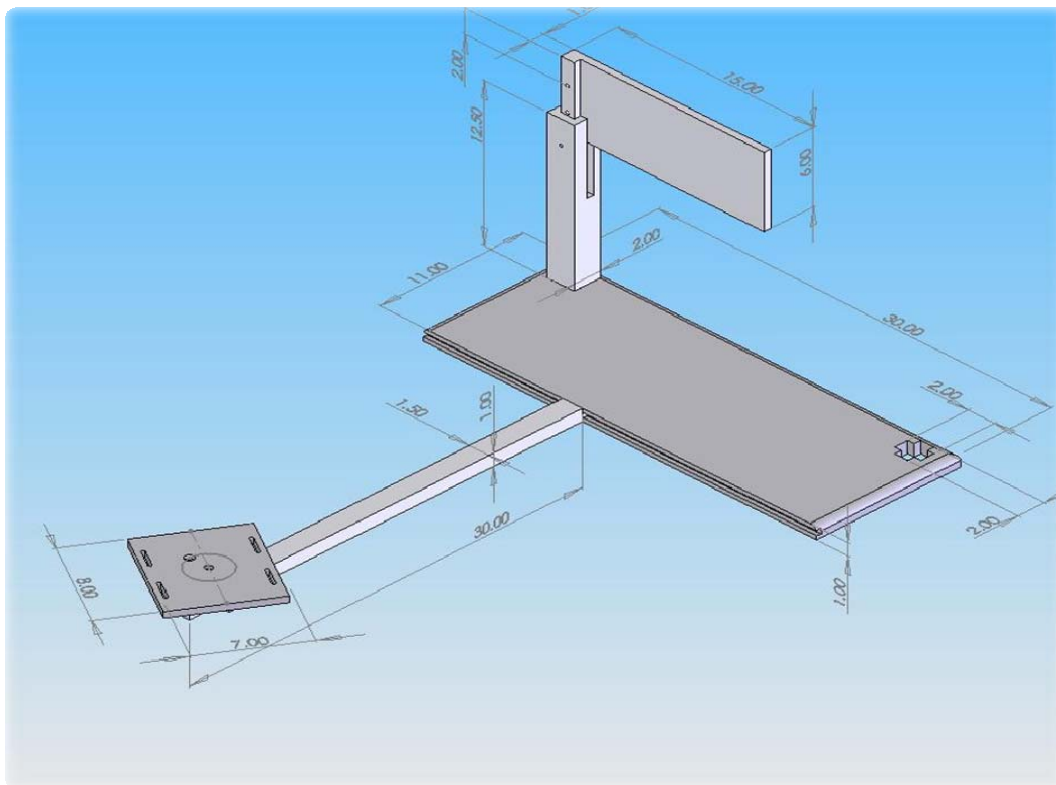


Figure 12- SolidWorks representation of final prototype

Testing

The leg positioner prototype was tested on a small sample of participants (n=10) in the lower workshop of the Engineering Centers Building. The primary goal of the testing was to determine if the leg positioned properly by securing the patient's leg with the correct hip and knee angle requirements as given to us by our client. The pannus retractor device was not used during this preliminary testing as a specific population sample would be needed to evaluate this attachment. Parameters measured during testing included: the angle of the abducted and externally rotated hip, the angle of the flexed knee, the height and weight of the participant, and the time needed to successfully position the leg for each individual.

The ten participants chosen at random ranged in height from 62 inches to 75 inches. Although each participant's weight was taken, it was found that each person's weight was fairly proportional to their height, and was not included in the analysis. The average time needed to successfully position the leg for each individual was approximately 46.7 seconds, with minimal delays in positioning those towards the beginning of the testing.

Figure 9 shows the resulting hip and knee angles measured for each participant as a function of height. As the graph indicates, the hip angle measurement for all participants stayed relatively constant as shown with the linear trend line, which is a positive result. However, slight variability with the knee angle, shown with a positively sloping linear trend line, caused those on the extreme ends of the height spectrum to not reach the optimal knee angle. Despite this variability, it was concluded that the abduction and external rotation of the hip was the most important parameter in positioning the leg. Therefore, slight variation in the flexion of the knee across the ten participants was not seen as a concern.

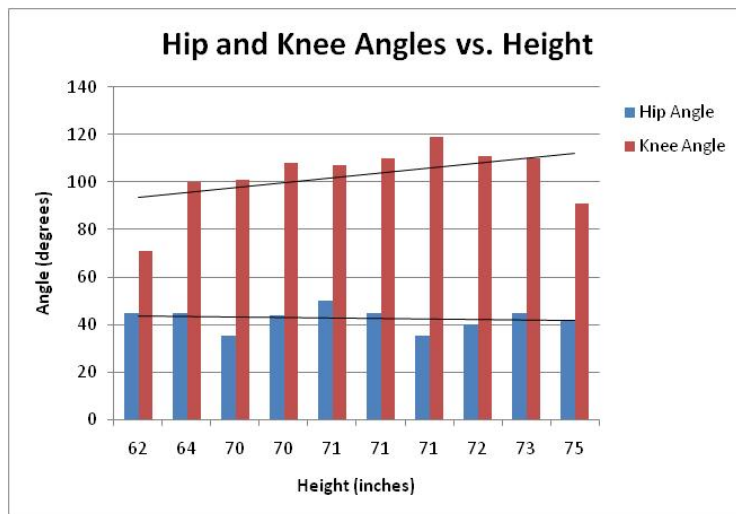


Figure 13- Hip and Knee Angles vs. Height- Hip angle measurement across all participants was constant, while slight variation in knee angle can be seen on the outskirts of the height measurements. Despite this variability, knee angle measurements are not a concern due to the fact that the hip angle causes the majority of the leg positioning.

Conclusion

The leg positioner prototype has satisfied the majority of the original client expectations. The design properly secures the patient's leg in the optimal position for placement of a femoral vein catheter. Based on our testing, we were also able to match our client's desired lower extremity angles of 45° - 60° for the hip angle and 100° - 135° for the knee angle, with secured angles of 45° and 100° , respectively.

The need for an attachable pannus retractor was also satisfied with our design; however, due to inadequate machinery to reduce the thickness of the HDPE plastic, it could not be angled away from the field of operation (*Figure 14*).



Figure 14: Pannus Retractor in use- the final prototype was not able to incorporate an angled pannus retractor to open up the operating field for the physician

The prototype also does not slip or rotate on the bed surface or interfere with the operation field. Additionally, the design accommodates patients missing either of their amputated by way of the dovetailed sliding rod, fixed-angle cuff, and ambidextrous pannus retractor.

The only client expectation that could not be completely satisfied was the disposability of the entire prototype. Produced from HDPE, the leg positioner and all of its components cost approximately \$200 to produce. The maximum manufacturing cost of the prototype that our client was willing to let be disposable and a one-time use was \$50.

Ethical Implications

The long-term goal of this leg positioning device is to implement it in an intensive care unit (ICU) setting. Therefore, eventually human test trials will be required to ensure that

the device will actually work during a real procedure. Anytime human subjects are to be utilized in test procedures there are strong ethical implications. Similar to our initial ten subject test, this test would be conducted on a strictly volunteer basis (no monetary benefit to the subject). Ensuring that the subjects would not have an incentive would help prevent the patients from making decisions influenced through external, unethical factors.

Future Work

There are several aspects of our current design that must be addressed in the future. The team was able to perform some preliminary testing to see if the leg positioner was able to secure the leg at the client desired angles. Further testing is needed to observe how the positioner performs in a clinical setting. This will allow us to see how well it facilitates the clinician in the placement of the femoral venous catheter. Testing will also allow us to observe the ease of use of the device in the intensive care unit.

There are several design modifications that need to be made in the future as well. The client had originally wanted the pannus retractor to be angled away from the operating area. He felt that if the pannus retractor was perpendicular to the counterweight board it could obstruct the surgeon's view. We were unable to angle the retractor because of a lack of appropriate machinery. This modification would keep the operating area clear of the imposing pannus retractor. The leg rod connection to the bottom board must also be modified. The original design called for a male dovetail joint profile to connect the leg rod with the bottom board's dovetail joint track. The lack of a router table made this cut unfeasible. We used a bolt cut to fit the female profile of the bottom board dovetail track. This connection method did not allow a tight junction between the rod and board and because of this, caused binding when the rod position was changed. The bottom board is made out of high density polyethylene; this makes it very heavy. In the future the bottom board could be either hollow or an array of holes could be cut out of the middle of the board. This would save money on materials and make it easier to use in the operating room. The bottom board could also be constructed out of different material as well; further research must be done to find an appropriate substitute.

Appendix A- PDS

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

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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
- comply with given hospital safety standards
- cost under \$250 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 procedure of 30-45 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
 - v. Joints of device must not be susceptible to pitching

- c. Accuracy and Reliability
 - i. Abduct and externally rotate hip between 45-60°
 - ii. Flex knee between 100-135°
 - iii. Many adjustments settings for proper positioning
 - iv. Constant stability
- d. Life in Service
 - i. Must be operable for 30-45 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 somewhat comfortable for the patient, as they could be awake during the procedure, but this is not a priority.
- g. Size
 - i. Must be adjustable or fitted to accommodate all 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. 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. 8 – 12 kg
- i. Materials
 - i. Materials must be either disposable or sterilizable, or have disposable or sterilizable parts
 - ii. Hypoallergenic: No latex
 - iii. Possible materials: High-density plastics, stainless steel, rubber, viscoelastic foam, gel
- j. Aesthetics, Appearance and Finish
 - i. Needs to appear suitable for hospital use

2. Miscellaneous:

- a. Standards and Specifications: The device must
 - i. Accommodate all ICU hospital beds
 - ii. Allow for ideal knee-bend angle for procedure (100-135°)
 - iii. Accommodate for patients of all sizes (within reason)

- iv. Be disposable or sterilizable
- 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*

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