ULTRASOUND PROBE HOLDER TO FACILITATE PERIPHERAL NERVE BLOCK PROCEDURES

Biomedical Engineering Design 301
FINAL REPORT
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ABSTRACT

Peripheral nerve blocks are a method currently used by anesthesiologists to prevent sensations of pain in an entire limb during a surgical procedure. Our client performs this procedure on a regular basis with the aid of a portable ultrasound machine and requested that our team design a device able to serve as an additional hand in the pre/post-operative room. In early March of 2007, a collaboration of engineering alumni from Dartmouth University and physicians at Dartmouth Hitchcock Medical Center went public with a product designed to accomplish the same goal. Following this announcement, our client expressed interest in purchasing this device (known as the "ultraStand™") but desired a redesign of the probe holder. During the second half of the semester, we developed a strong candidate for this design and produced an oversized prototype based on a ratchet-and-pawl mechanism. Future work will incorporate client feedback to improve design components and will involve miniaturization of the device.

PROBLEM STATEMENT

Ultrasound imaging is used by many physicians and technicians in the medical field to increase the success of performing nerve blocks. Unfortunately, to hold the ultrasound transducer and administer the anesthetic requires both hands of the physician. If other tasks need to be performed at this time, such as to thread a catheter, the physician is unable to do so without the aid of another person. To simplify the responsibilities of the anesthesiologist, a device should be developed to act as an extra hand to securely hold the ultrasound probe in place and be integrated easily into the ultraStand™ system.

BACKGROUND & MOTIVATION

Anesthetics are used to eliminate the perception of pain and other sensations during surgery and vary by producing either general, regional, or local effects. General anesthesia has the most widespread effect on the body because the anesthetic agent is circulated through the bloodstream. As a result, the brain, heart, and lungs are all affected, and a breathing tube is typically inserted into the patient's airway. In addition to its analgesic effects, general anesthetics also cause the patient to experience amnesia so there is no conscious recollection of the surgery. While this form of pain prevention is practical for more extensive surgical procedures, it is relatively more dangerous than other anesthetic methods due to the loss of the patient's protective reflexes such as coughing and breathing (Mayo Clinic 2006).

In contrast, local anesthesia and regional anesthesia are both used to block pain in a specific part of the body while allowing the patient to remain alert and maintain their protective reflexes. A smaller dose of anesthetic is required in local anesthesia, and it is typically injected into the site of the procedure. For example, anesthetic can be injected in the direct vicinity of a cut which needs to be sutured closed (Mayo Clinic 2006).

Regional anesthesia involves the injection of a larger amount of anesthetic to eliminate pain in a selected region of the body, such as an arm or a leg. This procedure is also known as a nerve block, because the anesthetic is injected through a large bored needle around a nerve or series of nerves that serve the appropriate region of the body. For example, an injection may be administered in the brachial plexus to eliminate pain in the entire arm (Figure 1). The anesthetic agent works by interfering with sodium and potassium currents into cells, thereby preventing nerves from reaching threshold and firing action potentials (eMedicine 2007).

Figure 1. Placement of an ultrasound probe in the brachial plexus region of the upper arm for a peripheral nerve block procedure.

Using nerve blocks to anesthetize a region of a patient's body can be favored over general and local anesthetic for a variety of reasons. First, it is considerably safer than general anesthesia because the patient's protective reflexes are not altered. Also, a smaller amount of anesthetic can be used in the procedure. In contrast with local anesthetic, there is minimal distortion of the surgical site because the anesthetic is not injected directly into the site. However, performing a nerve block requires a large amount of anatomical knowledge to reduce the risk of accidental nerve laceration or intravascular injection (Toronto Western Hospital 2006).

Beginning in the 1990's, it became increasingly common for anesthesiologists to use ultrasound imaging to guide needle placement during the performance of nerve blocks in the periphery. Without the use of ultrasound, the success rate of the procedure is around 80 percent, because

accurate delivery of the anesthetic is dependent on surface landmarks on the body. Ultrasound allows the anesthesiologist to visualize the nerve as well as the surrounding vascular, bony, and muscular structures (Figure 2). In addition, the real-time movements of the needle can be visualized for accurate placement and complete delivery of the anesthetic about the nerve (Toronto Western Hospital 2006).

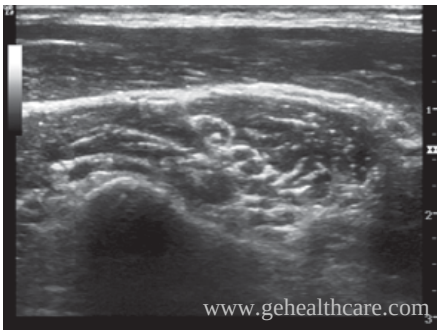

Figure 2. View of the brachial plexus nerve and surrounding tissues using the GE LOGIOe portable ultrasound machine.

During performance of peripheral nerve blocks, an anesthesiologist is commonly required to perform various tasks simultaneously. For example, one hand is required to hold the ultrasound probe and another hand is required to insert and manipulate the needle. Ejection of the anesthetic from a syringe requires the hands of another individual. In addition, it is sometimes necessary to thread a catheter through the needle for delivery of the anesthetic in the appropriate tissue. An independent probe holder would simplify theses tasks considerably for anesthesiologists performing peripheral nerve blocks.

CHANGES IN PROJECT GOALS

The scope of this project was altered significantly after the discovery of a suitable competing product following mid-semester presentations. During a search for information about the hand motions of the anesthesiologist during ultrasound imaging, our group noted a photograph with a device in the background labeled "probe positioning device." Several weeks later, the group was contacted by Aaron Gjerde, general manager of Wellan Medical, Inc., who informed us of the product's recent introduction to market. Our client Dr. Thomas Kloosterboer subsequently received information about the "ultraStand^{TM}" through the American Society of Anesthesiologists and expressed interest in purchasing it. After consulting with the group following the product's release, Dr. Kloosterboer maintained his support of the design project. However, rather than pursue production of the entire system, we were asked to create a novel design of the probe holder, which was deemed too bulky for his preferences during certain procedures.

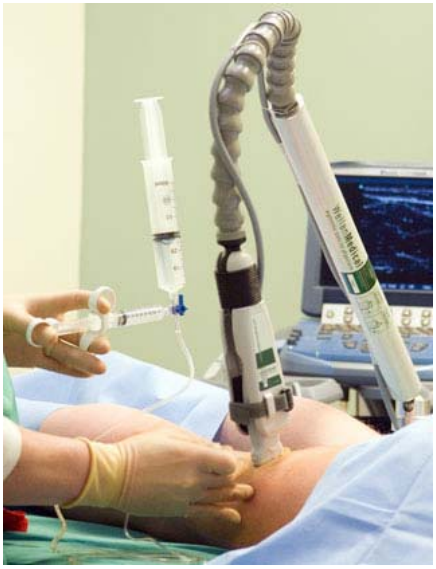

Figure 3. The ultraStand^{TM} probe positioning system (Wellan Medical Inc.)

DESIGN CONSTRAINTS

In order to fulfill the requirements requested by the client, the device must satisfy the following basic set of constraints (Appendix A):

- Attachment to the articulating arm component of the ultraStandTM produced by Wellan Medical, Inc. (Figure 3)
- Probes of varying shapes/sizes (produced by SonoSite & GE Healthcare) must be securely held in place (Figure 4)
- Fine motion and positioning must be easily performed with the force of one hand
- Normal handling of the probe by the anesthesiologist must be generally maintained by minimizing the holder's size and focusing on the ergonomic potential of the device
- Ultrasound transducers must not experience an excessive amount of force during or following the clamping motion

Figure 4. Various styles of SonoSite™ probes used at UW Hospital (SonoSite Inc.)

Furthermore, the device will experience heavy daily use once in place at the hospital, so any moving parts must be durable and easily replaceable. All parts must have a surface that is able to withstand chemicals in the environment (common cleaning solutions and ultrasound gel). Without being excessively bulky and thus obtrusive, the probe holder must be able to grasp at least three uniquely shaped objects with enough force to maintain control without damaging the probe.

The ergonomic nature of the probe holder is especially important due to the physician's close contact with this part of the device during manipulation of the probe. While the holder must satisfactorily perform its duties, it should not prevent the physician from using familiar motions during the procedure. The primary reason that our client requested a redesign of the ultraStand™ probe holder is that during peroneal nerve blocks (Figure 5), Dr. Kloosterboer has the patient lay on their back. The ultraStand™ design is too bulky and long to fit underneath the bent knee of most patients, so we have been challenged to design a probe holder that is smaller and more versatile in tight spaces.

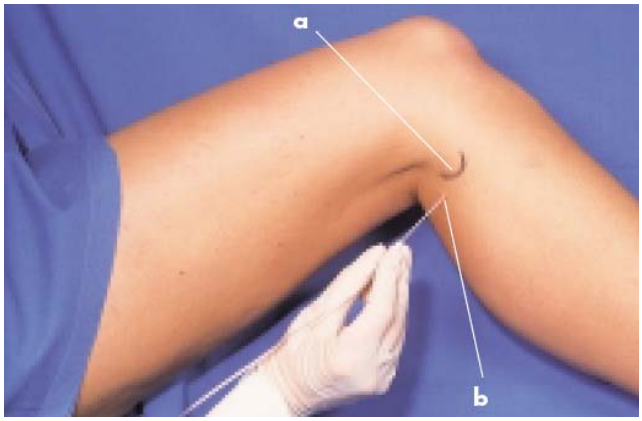

Figure 5. Common peroneal nerve block procedure. Head of the fibula (a) and location of needle insertion (b) indicated. (Meier G. *et al*.)

DESIGN CONSTRAINTS CONTINUED

Some of the characteristics of the device may fall under control by hospital and/or FDA regulations, which are currently unknown. Finally, the introduction of new ultrasound equipment in the future may necessitate redesign of device components in order to maintain the universal capabilities of the probe holder.

ALTERNATIVE DESIGNS

UW Hospital utilizes various probes manufactured both by SonoSite and GE to perform peripheral nerve blocks. While two solutions were considered (producing a set of clamps unique to each probe or a universal device capable of holding them all), we have chosen to pursue a single clamp design. Two clamps were proposed at mid-semester - one utilizes a buckle-like mechanism and two large foam "plates" to encompass most of the probe, whereas the other mimics how a hand would hold the probe and utilizes a ratchet-and-pawl mechanism.

Design #1: Foam Plate Clamp

The first probe consists of a Y-shaped device (Figure 6). Two pieces meet at a hinged point and are connected to the system's arm with a single rod. The hinged pieces are lined with compressible foam to avoid damaging the probe and to help increase universality by allowing the foam to conform to various shapes. Once placed around the probe, the two rigid pieces are held together with a buckle. The buckle can be closed in various positions in order to accommodate a range of ultrasound probe thicknesses. This probe would encompass the majority of the probe, and therefore would have to be ergonomically designed in order to ensure the comfort of the user. This design requires few fine adjustments, making it easily manipulated by a technician wearing gloves.

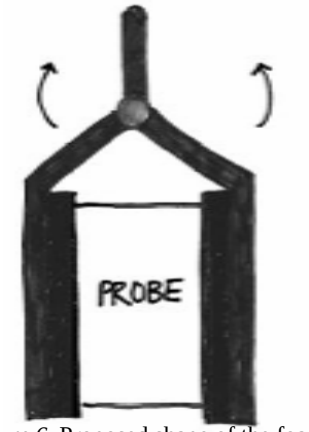

Figure 6. Proposed shape of the foam plate probe holder, with arms that swing up to release the probe.

Design #2: Quick-release Hand

The second proposed design operates on a lockable hinge in place of the buckle in the previous design (Figure 7). The area that contacts the ultrasound probe would be lined with foam as in the previous design. Two rigid pieces would form a U and meet at a point of rotation. This area would contain a gear with a detent or something that allows for rotational movement, locks in one position,

and allows free rotation in the other direction as a means of release. As the user pushes the two pieces together, the tension at the point of rotation increases, therefore creating the required clamping force. In order to release the probe from the clamp, the detent would be depressed (or whatever action is required to switch the hinge to free rotation), and the clamp is easily removed. This design would ideally be small and unobtrusive, potentially allowing the technician to continue to manipulate the probe without having the clamp as an intermediate between the hand and probe.

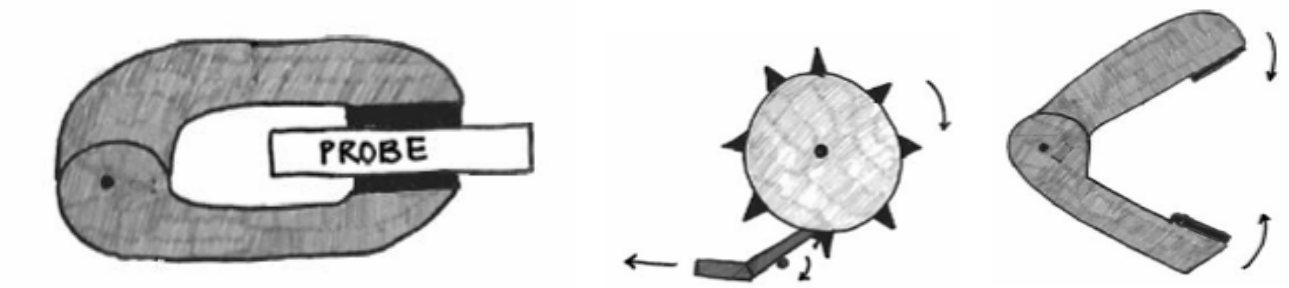

Figure 7. Proposed quick-release hand design: (left) Closed configuration, holder has minimal contact with the probe, (middle) Internal gear mechanism with stops to establish closed position with the ability to be released when the pin is disengaged, (right) Open configuration of holder demonstrating closing motion.

DESIGN MATRIX

Table 1. Evaluation of the probe holder designs based upon essential features (operation by technicians, obtrusiveness/size, and weight).

	Ease of operation (1-4)	**Size** (1-3)	**Weight** (1-3)	**TOTAL** (1-10)
Quick-release hand	3	3	3	9
Foam plates	2	3	2	7

Based on design matrix criteria (Table 1) and the competing device, the ratchet-and-pawl mechanism design was chosen and pursued. This design's motion is believed to be simpler and quicker than the steps required by the foam plate design to secure the probe in place. Using the ratchet-and-pawl mechanism, the user can close the jaws of the device with one hand, and also increase the clamping force incrementally by passing over more teeth in the ratchet. Conversely, using the foam plate design, which is incorporated into the ultraStand^{TM} design, would require closing the plates around the probe and securing the circumferential strap to provide the clamping force. Most likely this would require two hands and take longer to accomplish.

FINAL DESIGN

The current oversized prototype was constructed from ¼" polycarbonate to keep the ratchet-and-pawl mechanism visible and to minimize device weight. The upper and lower jaws are simple platforms lined with ¾" polyethylene foam blocks attached with epoxy. Engagement of the pawl with the ratchet is accomplished by the spring-loaded knob (Figure 10). The final version of the prototype also included a back plate with a ball-and-socket joint attached to demonstrate a likely mode of integration between the device and the ultraStand™ articulating arm. Current dimensions of the major components of the oversized device are provided below (Figures 8 and 9). Representations of components alone/as an assembly were produced in Solidworks (Appendix B).

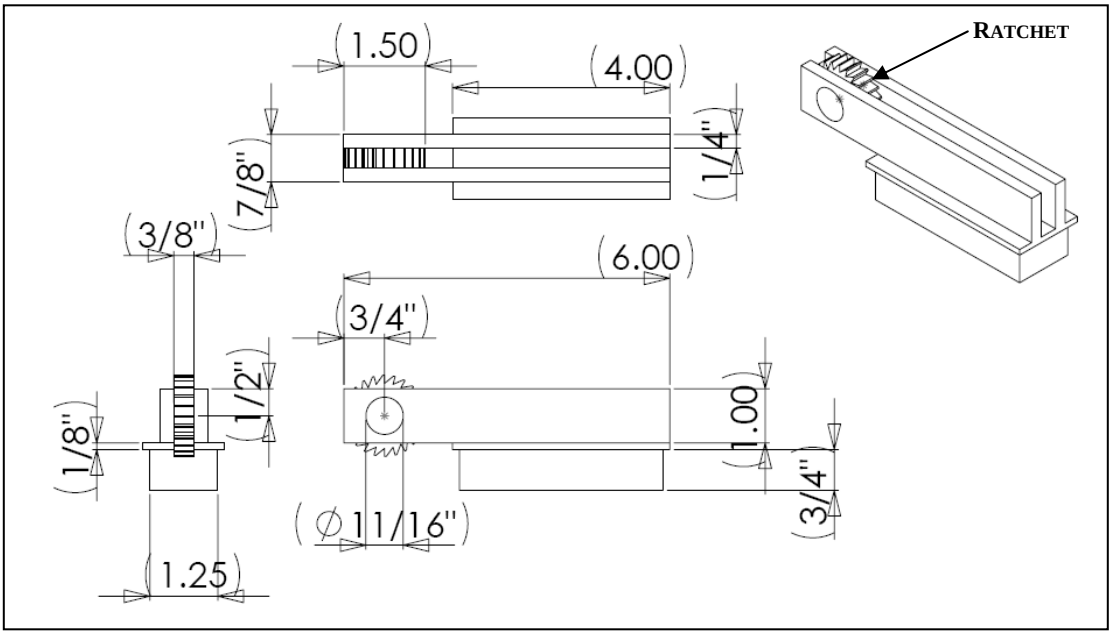

Figure 8. Basic dimensions of the top jaw of the current prototype

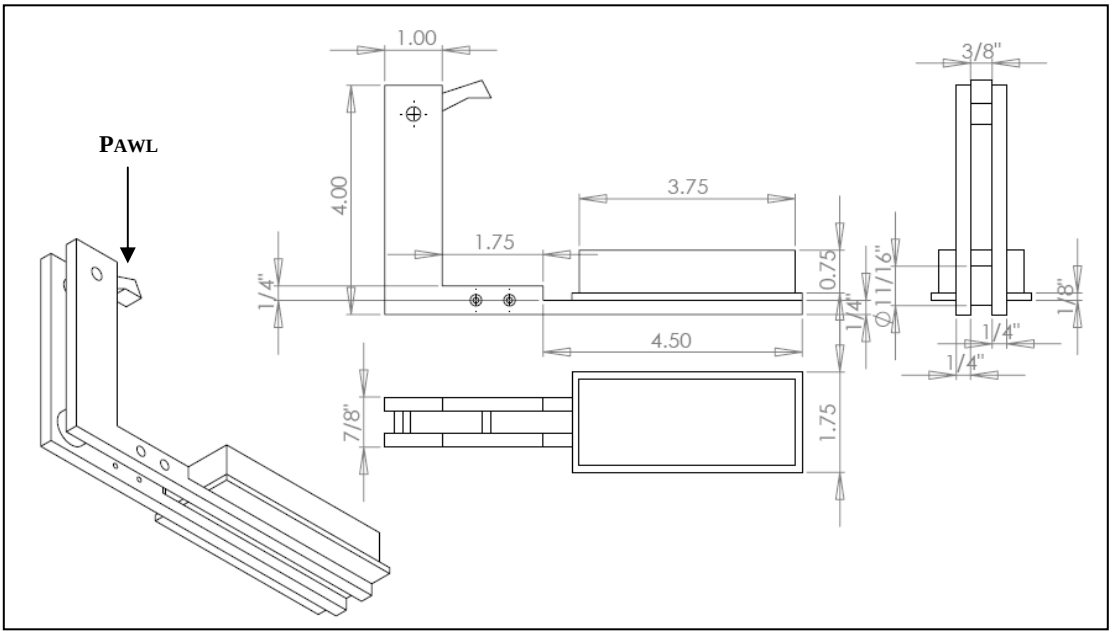

Figure 9. Basic dimensions of the bottom jaw of the current prototype

FINAL DESIGN CONTINUED

MATERIALS & COST ESTIMATES

DATE	ITEM	COST
4/11/2007	12”x12” sheet of ¾” polyethylene foam, adhesive back (white)	-
	12”x12” sheet of 1/8” ABS plastic (beige)	-
	12” long ¾” diameter Garolite rod	-
	Stainless steel ratchet (1.5” diameter, 16 pitch, 1-1/2” OD)	-
	11/16” diameter, 1’ long Teflon® PTFE rod	
	SUBTOTAL	$77.45
4/13/2007	Stainless steel pawl to match 1.5” ratchet	-
	5/8” diameter, 1’ long Teflon® PTFE rod	-
	SUBTOTAL	$52.13
4/23/2007	1” x ½” zinc corner brackets	$3.29
	Pin and rubber o-rings	$1.81
	Tax	$0.28
4/25/2007	24” x 24” (1/4” thick) gray-tinted polycarbonate plastic	$38.09
4/26/2007	Epoxy	$4.39
	Wire (50’)	$1.49
	Miscellaneous wire (electrical/insulated)	$0.60
	1” x ½” zinc corner brackets	$3.29
	¼” x ½” springs (6 pack)	$3.99
	3/8” x ¾” springs (6 pack)	$3.99
	7/16” x 1-1/16” springs (4 pack)	$3.99
	Miscellaneous hardware	$3.62
	Tax	$1.39
5/02/2007	Giotto Mini Ball Tripod Head	$14.76
	TOTAL	**$214.56**

CONCLUSIONS

For the next two semesters, we plan to work with the remaining portion of our initial $500 budget to create an ideal prototype for our client to use in conjunction with the ultraStand™. In order to accomplish this, we will first meet with Dr. Kloosterboer to obtain his input on the mechanics of the device, the ergonomics, and the ideal materials for the final design. We will consider revising the mechanics of the prototype based on client feedback and the need to further stabilize the ultrasound probe in the holder. Also, we will ask our client for his thoughts on the ease of operation of the device, including the placement and function of the quick-release mechanism.

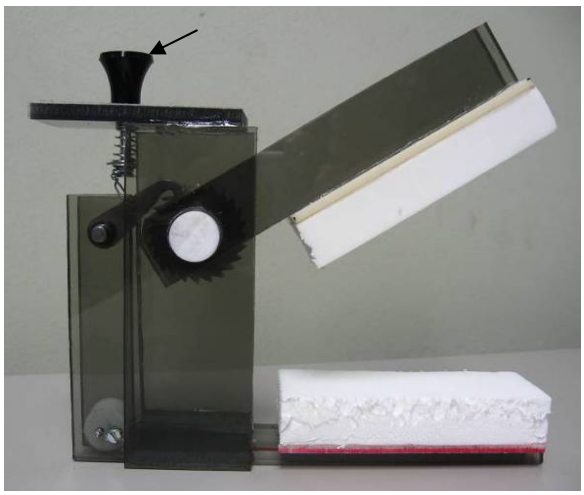

Figure 10. Photograph of current oversized prototype constructed in May 2007. Spring-loaded knob indicated by black arrow.

Concerning the materials for the final prototype, it is essential that a smaller pawl and ratchet be used in order

to miniaturize the device and improve its universality. The ratchet must have more compact steps in order to allow for continuous and secure clamping of the probe rather than discrete stops. In addition, we will focus on finding and testing low density foam that will adequately hold the probe, yet be suitable for use in the hospital environment. The foam we eventually choose to incorporate must be closed-cell or covered with a thin, waterproof material to prevent it from becoming water-logged or damaged. Closed-cell foam consists of individual pores or cells created by gas bubbles in the material during manufacturing, where isolated "shells" of the polymer aggregate to form a dense material with a high compressive strength. The cells are not interconnected as they are in open-cell foam, thus preventing any influx of substances from the environment (Figure 11). We will do adequate research to ensure that all materials used in our device conform to hospital standards.

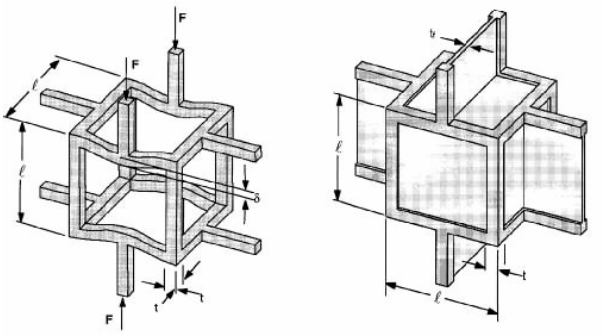

Figure 11. Schematic of open (left) versus closed-cell (right) foams demonstrating the isolative nature of the latter material (Plawsky, J.L. 2007)

Once all parts are obtained, we will construct our prototype based on our revised design. If the small size limits our ability to construct the device on our own, we will look into having parts of or the whole device manufactured professionally. After the device is constructed, additional testing will need to be completed to ensure the device's reliability and efficiency. As of the beginning of May 2007, our group has not had the opportunity to look closely at the ultraStand™ system. Dr. Michael Ford of the Department of Anesthesiology at UW Hospital (a colleague of our client) has purchased the product for his group but has not yet received it. We are therefore prevented from precisely defining how our probe holder will be incorporated into the ultraStand™'s articulating arm. Regardless, we must be sure to minimize the weight of future prototypes of the probe holder so as not to compromise the stability or function of the integrated arm. Once hospital approval has been obtained, the device will be incorporated onto the ultraStand™ arm for our client to use. If he is pleased with the results we will ultimately manufacture three probe holders to accommodate all of the ultrasound machines used in the UW Hospitals.

If the device is in fact successful and offers significant advantages over the existing probe clamp on the ultraStand™, we may pursue a patent with assistance from WARF. Currently the project is

purely academic and patenting is not essential. However, if our probe clamp is to be manufactured and commonly used as a modification to the ultraStand™ there are many legal issues that will need to be worked out. It may be necessary to obtain a license to use the patent held by Wellan Medical for the ultraStand™ device, or they may take an interest in gaining legal holding of our device. We have contacted WARF about these matters and will reestablish contact if a patent is probable.

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APPENDIX A: **PRODUCT DESIGN SPECIFICATIONS**

May 7th, 2007

FUNCTION: Ultrasound imaging is used by many physicians and technicians in the medical field to place nerve blocks. Unfortunately, to simply place the block requires both of the hands of the physician. If any other job needs to be done at this time, such as to thread a catheter, the physician is unable to do so without putting something else down. This device should act as an additional hand in that it should securely hold the ultrasound probe in one place and be able to withstand the resistance pressure of the patient's body when placed against the body.

CLIENT REQUIREMENTS:

The optimal device to be incorporated into the pre/post-operative room needs to:

- Attach to the articulating arm produced by Wellan Medical (known as the ultraStand™)
- Securely hold probes of varying shapes and sizes (manufactured by SonoSite and GE)
- Be small enough to be easily gripped with one hand
- Produce a force large enough to prevent rotation or movement of the probe (within the holder) upon placement at the target site without causing deformation to the probe itself

DESIGN REQUIREMENTS:

1. Physical and Operational Characteristics

a. *Performance requirements*: The device will be used several (10+) times every day, seven days a week. It will be operated in a sterile environment. Releasing the clamp should be an intuitive procedure to allow for the use of different probes during procedures.

b. *Safety*: Due to the fact that this device may have direct contact with patients, there may be several FDA or hospital rules that we need to follow.

c. *Accuracy and Reliability*: The holder should provide enough force to prevent unwanted motion of the probe within the clamp without damaging the probe itself.

d. *Life in Service*: Provided that this holder is able to stand up to heavy everyday use (10+ times a day, 5 days a week), a big factor in its life in service will be its ability to adapt to the changing technologies. For example, the introduction of new ultrasound equipment may require the design of a different clamp for attachment to ultrasound probes.

e. *Operating Environment*: The device will be used in a hospital; therefore, it will constantly be in a sterile environment and won't be exposed to dirt or any other weather-related hazards. The biggest concern here is that it will need to be cleaned after every use so it should be made of something that does not corrode with the regular use of neutral disinfectants.

f. *Ergonomics*: The device should be able to be used comfortably by the physician, so the probe holder must not be so large around that it cannot be easily gripped. Components of the clamp such as the quick-release knob should be ergonomically designed.

g. *Size/Weight*: The device should be small and light enough so as to not weigh down the articulating arm that it will be attached to. The clamp should also be small enough to allow the physician to directly manipulate the probe (rather than the probe holder) in order to closely mimic their natural and preferred motions.

h. *Materials*: The device needs be made of or covered with a material that can be cleaned with a typical multipurpose solution.

2. Production Characteristics

a. *Quantity*: We are going to focus on producing one prototype of the device, with the final goal of implementing at least three throughout the hospital (two SonoSite machines are in use at UW Hospital and one GE machine is used at the Madison Surgery Center).

b. *Target Product Cost*: Client has not specified at this time.

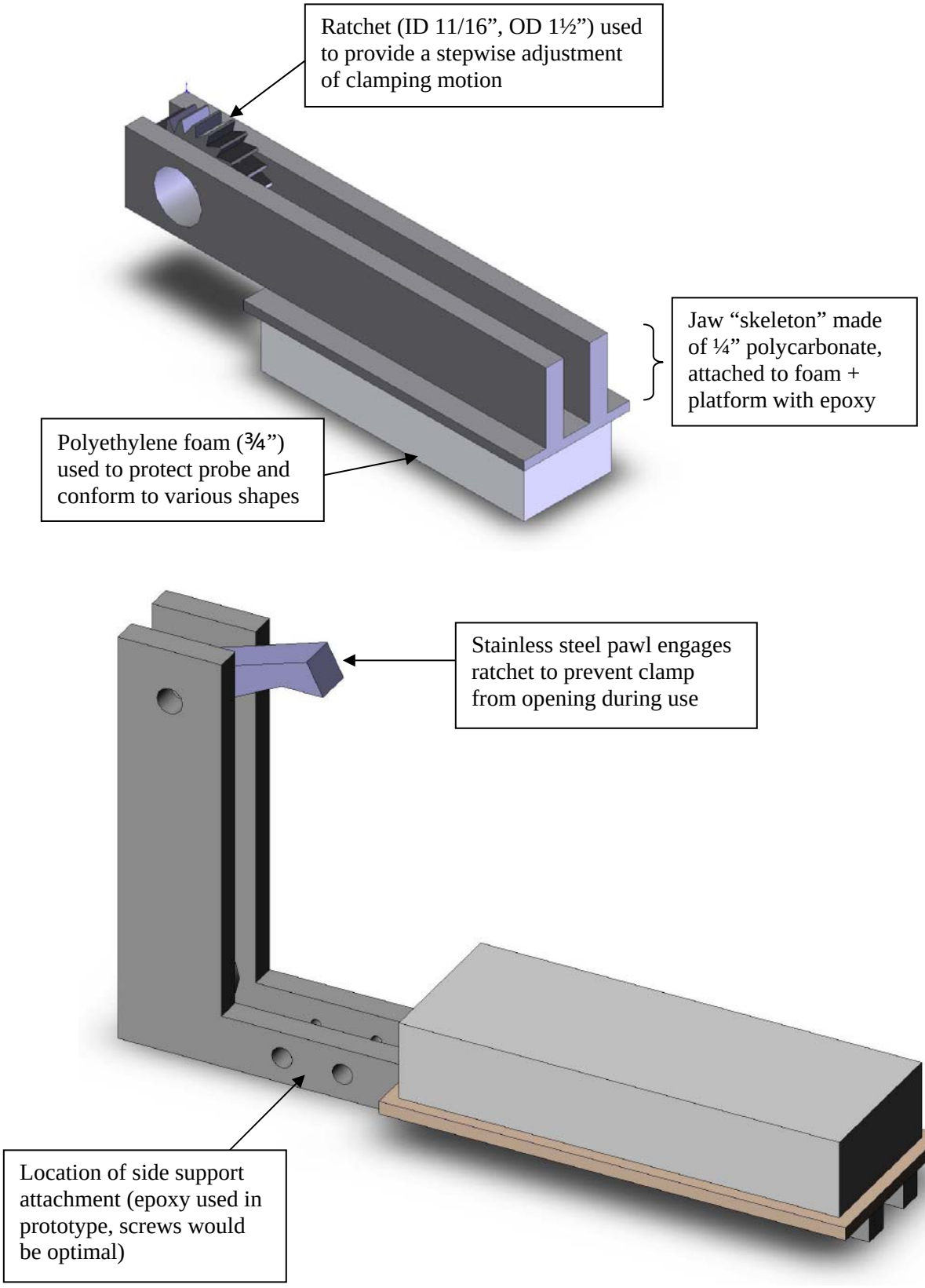
3. Miscellaneous

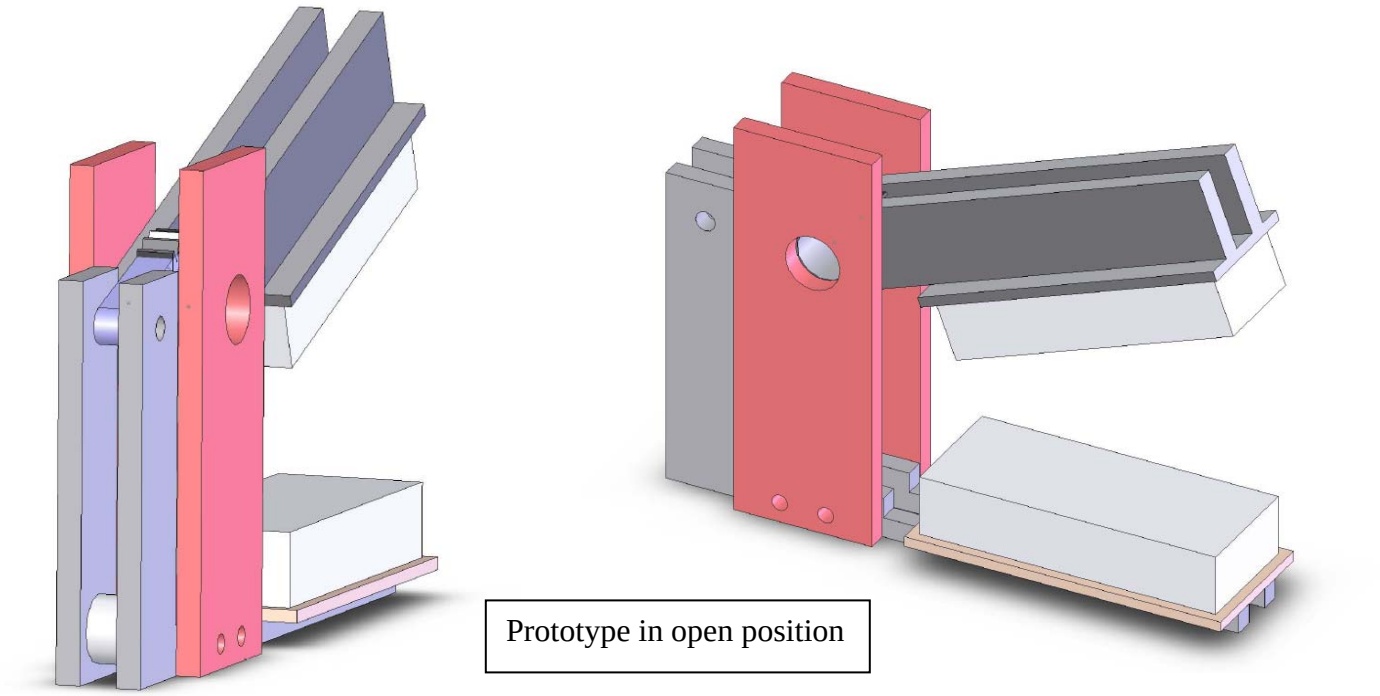
a. *Standards and Specifications*: The design must meet any requirements imposed on devices to be used in the hospital.

b. *Patient-related concerns*: The probe holder should include parts that are safe (i.e. corners should be rounded).

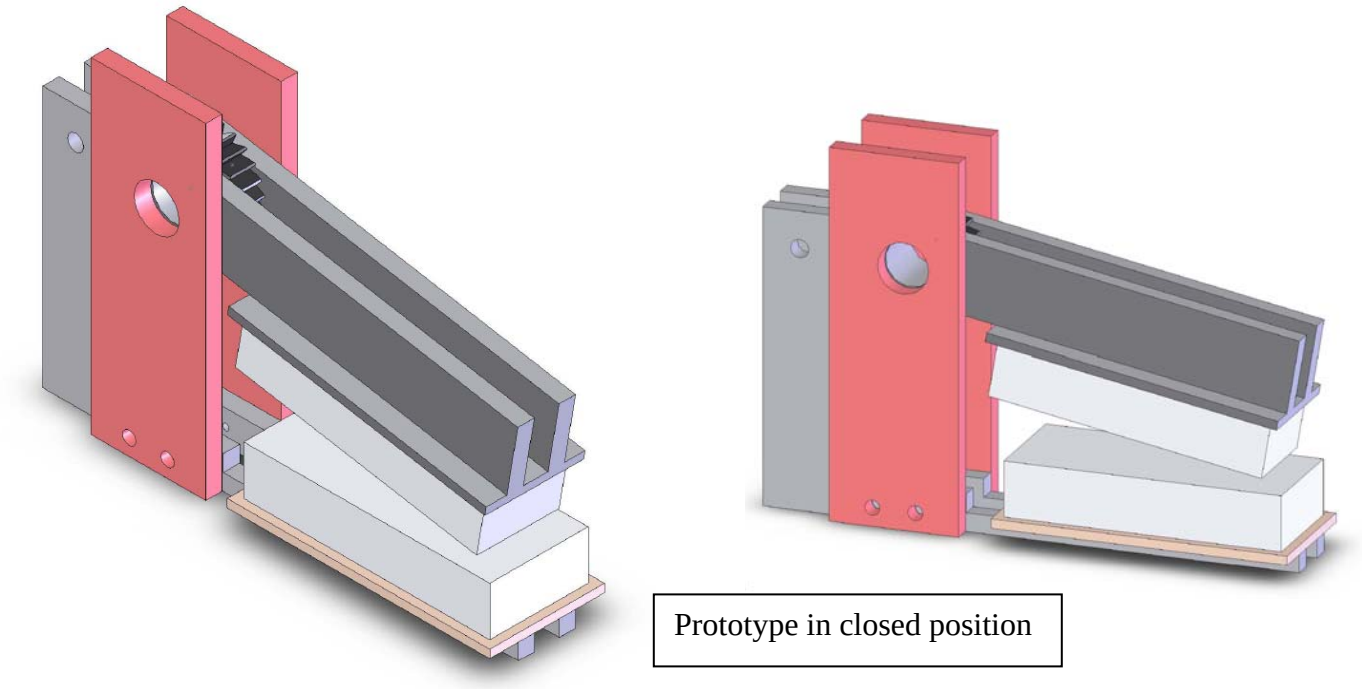
c. *Competition*: Articulating arms (most notably, the ultraStand^{TM} produced by Wellan Medical) are available, but the associated probe clamps do not meet the needs and desires of our client (especially with respect to size and obtrusiveness). Future commercialization of our design may require sublicensing Wellan Medical's current technology and collaboration with their company and WARF.

APPENDIX B: **PROTOTYPE – DRAWINGS**





Prototype in open position



Prototype in closed position