

Ultrasound Probe Holder

Final Design Report

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Abstract

Vascular reactivity studies will greatly increase the understanding of atherosclerosis, inflammation of the arteries. Advanced atherosclerosis may result in thrombosis, which causes heart attacks and strokes. Examining the brachial artery reaction to occlusion requires continuous acquisition of ultrasonic imaging during an atherosclerosis study, which last five minutes or more. Due to the length of the studies and the deviated wrist position that the sonographer must maintain throughout a trial, brachial artery imaging poses serious risks for development of carpal tunnel syndrome. A design was drafted for a prototype that would release the sonographer from holding the probe for the entirety of the trial. The position of the probe can be established with a train of ball and socket joints and then locked into place by the control of one lever. The prototype also contains a comfortable arm cradle that stabilizes the patient's arm. Future work will include verifying that the prototype's performance is comparable to that of a professional alone and if it provides a time saving aspect to the work flow.

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Problem Statement

To reduce the occupational hazards incurred while administering the study of arterial reactivity, a simple, stable, adjustable probe holder is needed. The functions provided by such a holder would reduce wrist injuries and could potentially improve productivity. The device should be able to be finely adjusted with 6 degrees of freedom and free the hands of the technician for the duration of the study.

Introduction and Motivation

The use of ultrasound for the study of vasculature health has become common practice in medicine. Ultrasound can be used for a variety of diagnostic techniques including arterial imaging and blood flow measurement. This design project focuses specifically on the use of ultrasound in vascular reactivity studies of the brachial artery. Reactivity studies are conducted on patients to monitor the epithelial response of the tissues to pressure changes in the vasculature (Coretti, *et. al.*, 2002). Abnormalities can be early indicators of atherosclerosis (Harrison, *et. al.*, 1987). Thus, improvement of the techniques for obtaining vascular ultrasounds can provide medical staff with a more effective and reliable means of diagnosis.

The reactivity study under specific focus for this project involves the use of ultrasound on the upper arm of a patient. The brachial artery is imaged for more than 5 min at one position. Typically, a sonographer will properly position the probe and then hold it in the desired position for the duration of the study. While the study is conducted and the vasculature is monitored, the blood flow through the artery is restricted with a tourniquet style blood pressure cuff downstream of the imaged area. As pressure builds up in the brachial artery, vascular response is observed, then after a certain time, the cuff is released, again eliciting a reactive response of the artery (Korcarz).

The limitations to this current method are not difficult to recognize. The reliance of a sonographer to stabilize the probe is not only inefficient, but also does not ensure that the same region of the artery is being imaged throughout the study. Furthermore, the practice of the study puts undesirable stress on the sonographer, who often must sustain unhealthy postures that may lead to musculoskeletal injuries, such as Carpal Tunnel Syndrome.

In this report, the specifications of how to stabilize and efficiently position an ultrasound probe have been investigated. Several different methods have been identified and analyzed. The application of a positioning system in to the broader specifications of the device are also addressed, including the task of holding the ultrasound probe and stabilizing the patient's arm to ensure image stability. The positioning device has been established. Preliminary evaluation of the prototype has shown to be successful. A comprehensive validation plan has been designed and is currently under institutional review for implementation.

Specifications

Below is an overview of the considerations for the design. For more detailed and quantitative specifications, see Appendix A for the Design Specifications.

Positioning Freedom

In order to correctly image the artery, the probe must have six degrees of freedom. The two lateral directions, along with the vertical direction, would be used mainly as a rough adjustment to find the artery. These movements would enable the sonographer to move the probe from its resting position to the upper arm of the subject. Once the probe is in position, the three rotational degrees of freedom would be used to obtain the best image possible since the probe must be perpendicular to the artery. The rotational movement will allow differential pressure to be applied to the arm, an important quality for image resolution. Finally, when the stimulus—the pressure applied to the lower arm—is removed, the artery may shift slightly and the probe will have to be readjusted.

Finding the correct position again may require all six degrees of freedom as modeled in Figure 1. Therefore, the probe's ability to move freely in all directions is a vital component of the design.

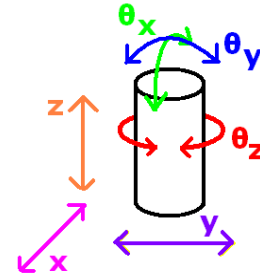


Figure 1 - Degrees of Freedom needed for proper positioning.

Adjustment abilities

The device should be easily adjustable and sensitive to fine tuned movements. When beginning a study, the sonographer will orientate of the probe with very subtle adjustments in order to obtain the proper cross sectional image of the artery. However, the location of the artery within a patient may be subject to slight shifts throughout a study due to the pressure changes on the arterial walls. The device must allow for quick, fine tuned adjustment of the probe position with as little complexity as possible. Similarly, minimizing the set up time of the exam and the required labor to position the probe is also essential. Simple but accurate adjustability is one of the main requirements of any design option.

Accommodation of Probe Varieties

The final design of the device should be able to accommodate a variety of different ultrasound probes. Although the general dimensions of different probes are within a common range, they can vary in their shape and orientation. Either a universal or modular clamping mechanism must be designed to accommodate the variety of probe shapes. Figure 2 shows three examples of common probe designs, each about 20 cm long and 8 cm wide.



Figure 2 - Variety of probes to be accommodated in design. All of similar sizes, but contours vary significantly

Ergonomics

The usability of this device is key to its success in improving ultrasound studies. The ultimate goal of the probe holder is to simplify the ultrasound procedure and improve its consistency. Therefore, considerable attention was given to the ease of use of the device, which is to allow the most freedom and control with the least amount of adjustments. The device must be able to integrate into the workflow without hampering or impairing the flexibility of the sonographer. A device which does not require much training to operate will be the most desirable.



Figure 3 - Image of ultrasound workspace layout. Sonographer (left) will be required to hold the probe in the shown position for 5+min. The wrist is in a radially deviated posture.

There is a significant element of occupational ergonomics to this device as well. A well designed device will reduce or eliminate the occupational stress on the sonographer associated with poor wrist postures (Figure 3). A sonographer holding the probe in the position shown has a radial deviation of the wrist which, over time, can put unhealthy pressure on the Carpal Tunnel and lead to musculoskeletal disorders (Keir *et al.*, 1997). In the laboratory where this device is to be implemented, OSHA limits a sonographer to one study per hour due to the stress that the procedure can induce on the test administrator (OSHA). The implementation of this design could potentially relieve some of the stresses associated with conducting these studies, and allow a sonographer to complete more studies in less time.

Design Considerations

Positioning Mechanism Options

Design Rating Criteria

Six main characteristics were taken into consideration when choosing a design for this project: cost, weight, gross adjustment, fine-tune adjustment, range and reliability. These criteria and their associated importance were determined by the client's requirements.

The most important aspect of this device is that it improves the ultrasound procedure. However, it must not impede the workflow and efficacy of the sonographer. The ability to make all the necessary adjustments is paramount to the integration of this device into a healthcare setting. The device should be able to make fine tuned adjustments as well as gross adjustments with the same efficiency.

The second most important criterion for this device is angular range. The device must ensure that the probe can be placed in a 100 degree range around the arm to accommodate the majority of patients, since arterial orientations within the arm can vary.

The reliability of the device is important for the quality of the image and it frees the sonographer to do other activities during the procedure. Ideally, the final product would be rigid enough that the

sonographer can set the probe in place and then do other things while the procedure is being conducted.

The weight of the device is taken into account because it increases the usability of the device. If the device is too heavy and bulky to adjust, then the sonographer will have a hard time using it and will struggle to make any adjustments.

Lastly, the cost must be considered. A vascular ultrasonic machine may cost between \$10,000 and \$20,000, so a budget of a few hundred dollars or more is not unreasonable. The primary focus of this project is on quality and functionality rather than cost. Even though minimizing the cost is always a goal, it is not a main goal for this project.

Option 1 – Articulated Arm

The articulated arm functions just like a human arm (Figure 4). There are two ball and socket joints and a hinge joint that provides 7 degrees of freedom. The entire device is controlled by one knob, which makes it easier to use and adjust. Fine tuning adjustments can be made at the end of the devices. The fine tuning will be beneficial if the artery shifts slightly as a result of the reduction in pressure. While this device is costly and bulky, it provides a wide range of motion. The device can hold its shape and the necessary pressure for long periods of time. It is easy to use, reliable and capable of supporting forces much greater than needed.



Figure 4 - Several Articulated Arm models. One knob at the corner joint tightens all three joints, allowing size degrees of freedom with one adjustment. From Noga Engineering.



Figure 5– Gooseneck that is made up of a series of ball and socket joints that can be tightened.

Option 2- Gooseneck

The gooseneck (Figure 5) is essentially many ball and socket joints linked together with a cable running through the middle. Each ball has limited rotation abilities, but the collection of all the joints allows the snake to have a wide range of motion. The cable can be tightened to act as a locking mechanism. It pulls all the links together so the friction between them does not allow them to move freely. With this design, the probe can be repositioned and adjusted easily. This design is very easy to use, cheap and relatively easy to replace in the event of a malfunction. A single knob makes the device easy to operate. The limitation to this concept is that the range of motion is restricted. A larger range of motion can be attained by increasing the length of the arm, but doing so reduces the maximum load capacity of the device.

Option 3 – Hybrid

The hybrid combines the gooseneck and articulated arm into one device. This provides the user with a wider range of motion with the probe and enables the sonographer to make small adjustments. The gooseneck is attached to the end of the articulated arm with the clamping mechanism at the other end. The articulated arm provides rigidity and gross adjustments while the

gooseneck enables easier fine-tuned adjustments and a wider range of use. This device is the most complicated and expensive and it is the heaviest of the three options

Design Matrix

The three design options were analyzed using the following criteria: cost, weight, gross adjustment, fine-tune adjustment, range, rigidity. Based on the client’s requirements, each category was given the following weights: cost – 5%, weight – 10%, gross adjustment – 25%, fine-tune adjustment – 30%, range – 20%, and rigidity – 10%. Based on the design matrix show below the hybrid design was chosen as the final design.

Table 1 - Design Matrix

| | Score | Arm | Gooseneck | Hybrid |
|-----------------------------|------------|-----------|-----------|-----------|
| Cost | 5 | 5 | 5 | 5 |
| Weight | 10 | 6 | 7 | 5 |
| Gross Adjustment | 25 | 22 | 17 | 20 |
| Fine-tune Adjustment | 30 | 15 | 28 | 28 |
| Range | 20 | 20 | 4 | 20 |
| Rigidity | 10 | 10 | 8 | 8 |
| Total | 100 | 78 | 69 | 86 |

Probe Clamping

3 Pronged Clamp

A 3 pronged clamp was implemented last semester (Figure 6). The prongs on the clamp fit around each size of probe and they can be tightened with screws to ensure that the probe does not move during the procedure. The prongs have a rubber casing around each tip to ensure that the probe is not damaged. The clamp’s rod attaches to the positioning device. However, initial testing by the client indicated that the usability of the 3 pronged clamp may slow the ultrasound procedure. Primarily, use of the device required more than one hand. The complexity of attachment to the positioning arm added unnecessary



Figure 6 -A 3 pronged clamp that could be used to hold the probes in position. The two screws are used to tighten the clamp when it is in the correct position.

complexity to the design. Therefore, more intuitive and user-friendly clamping was sought.

Plate System-“sandwich”

A plate system composed of two parallel HDPE plates that could be tightened to fit different sized probes was initially constructed this semester (Figure 7). The inner surfaces were lined with neoprene rubber to cushion the probe while several adjustable screws connected the two plates and could be tightened to secure the probes. Initial

testing of this clamping system by the client revealed that the design was not able to maintain the needed torque applied once the

positioning device was locked in place, due to a lack of rigidity in the HDPE. To add rigidity, one of the HDPE plates was replaced with an aluminum one. For both designs, however, it was difficult to switch probes and the system was bulky.



Figure 7 - Sandwich clamping concept

Velcro Straps

To reduce bulkiness and maintain rigidity, the final design consists of a small metal bar which attaches to the positioning device and the transducer is secured to the bar with Velcro (Figure 8). This design accommodates many sizes and allows for quick interchanging of probes. The Velcro straps provide enough rigidity so that the probe does not move under normal amounts of torque required to obtain a proper ultrasonic image.



Figure 6 - Velcro attachment concept

Arm Cradle

Arm cradles are needed to provide support for the arm so that it does not move during the procedure.

Dimensioning: Anthropometric Design Accommodations

The dimensioning of the arm cradle required considerable care to ensure the device would comfortably fit to a large range of patient sizes. Since two segments were used, the dimensions considered were the diameter of the cradle, and the lengths and spacing of each cradle. Approximations for limits were calculated based on anthropometric data from the US Army Survey completed in 1988. Using the normalized data from this survey, estimates for accommodation were made.

The dimensioning of the diameter of the cradle was specified to the bicep circumference, and therefore a calculation for the maximum size accommodated was taken for a male in the 95th percentile. This afforded a minimum inner diameter of 12.42 cm. Then, with the addition of a 0.63 cm of foam padding on the cylinder, the minimum inner diameter of 13.69 cm was determined. Based on available supplies a tube of inner diameter 14 cm was selected.

The length of the support segments were then calculated to accommodate the shortest arm lengths anticipated. From the same set of anthropometric data the total arm length, upper arm and forearm lengths of a 5th percentile female were calculated. The key data determined was the total arm length of

48.90 cm. In order to allow room for both the tourniquet style blood pressure cuff and the patient’s elbow, a spacing of 15.25 cm was determined optimal between cradles. The forearm and upper arm lengths of the smallest individual are 20.9 cm and 30.12 cm, respectively. The length of each cradle was selected to be 15.25 cm to accommodate for each arm segment.

The design of these dimensions were intended to allow for supportive positioning while avoiding any major pressure points that may disturb the results of the study. The cradle should be positioned such that the elbow is centered over the gap between supports. This avoids placing any significant pressure at the elbow, wrist or axilla. Complete calculations for the above dimensioning are shown in Appendix A.

Previous Design

From the anthropometric data above, a hollow acrylic cylinder was cut in half, lined with polyurethane foam, and mounted with wood supports (Figure 9). The acrylic tubes have an inner diameter is 14 cm, a length of 15.2 cm and the two segments are separated by 15.2 cm. The cradle was

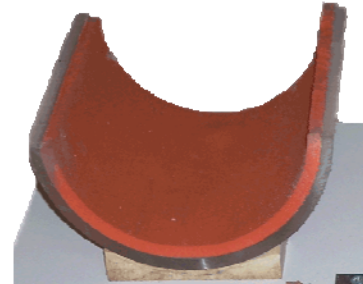


Figure 7 - Basic concept of cradle for stabilizing the forearm

lined with closed cell polyurethane foam to cushion the patient’s arm and to avoid pressure points on the arm. Wood supports attach the semi-circular cradle to the board. However, some concerns after preliminary testing indicated that the closed cell foam still appeared to be absorbing the gel used the ultrasound procedure and that the height of the arm cradle on the patient’s upper arm may cause some pressure points discomfort for larger patients.

New Design

The upper arm cradle’s height was reduced by 2.5 cm so that no pressure points would occur for patients with larger arms. Both arm cradles were then covered with black vinyl to improve the overall aesthetics while making it impervious to gels, washable, and more comfortable for patients.

Construction Budget

Below are the costs associated with the construction of the device including raw materials and prefabricated components. Some items do not have costs associated since they were obtained through scrap or surplus supplies. Costs do not include shipping and handling fees for materials. All construction was completed in the Student Shop in the College of Engineering at the University of Wisconsin – Madison.

Table 2 - Cost of materials used in construction of first generation prototype.

| Item | Supplier | Cost |
|------|----------|------|
|------|----------|------|

| | | |
|----------------------------------|---------------------------|---------------|
| Sheet Metal (1'x1') | Home Depot | 5.84 |
| Emory Paper | Home Depot | 5.47 |
| 23 3/4 x 48 Melamine | Home Depot | 11.98 |
| 1x4x2 Poplar | Home Depot | 2.63 |
| Positioning Arm w/ magnetic base | MSC-Direct | 229.02 |
| Acrylic Pipe | McMaster-Carr | 27.17 |
| 3 Pronged Clamp | Fisher Scientific | 39.83 |
| Silicon Foam Rubber | McMaster-Carr | 24.29 |
| 1/8" Low Carbon Steel | COE Machine Shop Scrap | 0.00 |
| 1/2" Wood Screws | COE Machine Shop Scrap | 0.00 |
| HDPE Black 1/8 In T | Grainger | 16.75 |
| Rubber Neoprene 1/8 In | Grainger | 16.75 |
| Stops Rust White Primer | Menards | 3 .97 |
| Stops Rust Gloss Black | Menards | 3 .97 |
| J-B Mini Adhesive | Menards | 2 .98 |
| 1/4-20x1 Hex Cap C | Menards | 0 .29 |
| 1/4 SAE Flat Washer | Menards | 0 .29 |
| 1/4-20 Hex Nut Coarse | Menards | 0 .29 |
| Dial Indicator and Holder | Harbor Freight | 31.70 |
| Nuts and bolts | Dorn Hardware | 09.56 |
| Vinyl Upholstry and Adhesive | Hancock Fabrics | 14.20 |
| Velcro Straps | McMaster-Carr | 14.20 |
| Total | | 449.39 |

Final Design

Based on the above analysis, a design for a modified prototype was drafted. The final design consists of the hybrid positioning device along with the Velcro strap clamping mechanism (Figure 10). The hybrid design provided the most range of motion while still being able to provide fluid adjustments and motion. The probe clamping mechanism proved to be the simplest design that was easy to use and the most reliable. Preliminary testing has verified its proof of concept while keeping costs at a minimum. When further testing has been completed, it will validate the design's ability to improve productivity and prevent occupational injury.



Figure 10 – Final design combining the hybrid positioning mechanism and the Velcro strap clamping mechanism.

Design Verification and Validation

The functional prototype presented above was used in several preliminary test environments to ensure its functionality and efficacy. However, a more thorough and quantitative test has been designed to verify the functionality of the device and validate how well it integrates into the study. Preparations for conducting these tests require approval from the Institutional Review Board (IRB) of the University of Wisconsin – Madison since the device will be used in a clinical setting with human subjects involved. The complete submission for institutional review is contained in Appendix C. This includes cover documents, the research protocol, consent forms for subject recruitment and conflict of interest disclosure. Below the protocol is broadly described. These tests are broken into two main categories: usability and efficacy.

Device Usability

The device should integrate into clinical work flows as seamlessly as possible. To score the procedural impact, several tests will be conducted with and without the device in use. Three certified ultrasound technicians are available to participate in the study. The technicians will individually conduct a series of typical brachial reactivity studies by traditional procedures without the device and aspects of set-up and execution will be timed and documented. Human subjects to be used will be recruited on a voluntary basis. The requirements for participation include that the subjects are of healthy adult age without vascular abnormalities. As a preliminary study, a sonographer will conduct studies on five patients without the device, and then five different patients with the device. The set-up and complete procedural times will be measured for each study.

The current resources to this study limit the number of available participants. Therefore, it is desirable to identify the statistical confidence of the data and determine if more participants will be needed in an expanded study to properly validate the impact on work design and study lengths. Once data for the five subjects in each study is taken, the mean and standard deviation will be used to calculate the confidence level of the obtained range. A confidence level of 95% will be sought to identify a confidence interval of expected average times of each study. If the results do not yield this level, the study will require expansion and recruitment of more subjects.

The ultimate goal is to identify if or by how much the use of the device may alter procedural times. It is expected that the initial set-up time with the device will be larger than without because more parameters of setup must be made before the study can begin. However, during study administration, the device may be capable of reducing the time necessary by eliminating time lost to readjustment. Also, with the sonographer freed from having to hold the probe to the patient, they may be able to complete other aspects of the study with more efficiency.

To supplement the timed data for setup times, anecdotal data will also be sought from each of the three technicians after they have used the device for an extended period. Feedback of ease of use of the device will be used for continual evaluation for potential modifications and improvements. The technicians are poised to directly benefit from an effective and improved device, so their feedback will be taken with significant weight.

Procedural Efficacy

As stated in above sections, one of the primary goals in the development of this device is the relief of occupational health hazards. Any increase in length of study may also be overcome by the ability to conduct more studies within a given time frame since less rest time will be required for sonographers between studies. It is important to verify that the device does not degrade quality of data obtained during a study. Because of the added stabilization, a more consistent image throughout a study may be obtained with the device and actually improve the quality of data.

To rate the impact of the device on data gathered, data from studies conducted with and without the device will be used. A sonographer will be presented with the data obtained by a different technician. Without being told whether or not the device was used, the sonographer will be asked to evaluate the

quality of data. The sonographers will rate image quality, ability to identify structures, and confidence in comparing morphological elements throughout a study, each on a scale of 1 to 10. A consistent image and ability to identify features in each image is crucial. The numerical ratings will be used to identify if one study provided more ability and confidence over another.

Once again, direct feedback will be asked from sonographers after completing each use with a series of question to rate the ability of completing the procedure with the device. Areas of questioning will include, but are not limited to, the ability to keep image consistent, the ability to regain a desired image if necessary and the ability to complete other tasks while the device is in use (i.e. use a second Doppler probe, engage a tourniquet to occlude blood flow, administer a treatment to the patient).

Potential Impacts of Results

Once results of ease of use and timing impacts of the device are known, it may be possible to reformulate workflows in atherosclerosis clinics. If the device is effective in freeing the sonographer from positioning and allows them to administer other tests, personnel required for some studies may be reduced. Once device effectiveness and efficacy is verified, large scale workflow analyses could be conducted to evaluate the impact the device may have in the workplace. While currently no comparable devices exist on the market, workflow optimization could benefit clinics and research laboratories around the country. If a market demand can be identified, intellectual property protection may be pursued.

Professional and Ethical Considerations

The testing protocol must be approved by the IRB since it will involve human patients. With certified ultrasound technicians, the risk is minimal to patients as the procedure will follow standard approved ultrasonic protocols. The only deviation between the study and normal procedures is that the transducer will be held by the prototype instead of being manually held by the sonographer. Once the use of the prototype has been approved by the IRB, testing can be done to determine the efficacy and ease of use of the prototype. The results will greatly benefit the ultrasonography field as testing procedures may be improved by maintaining current quality while decreasing occupational stress which can lead to the sonographer developing Carpal Tunnel Syndrome. Additionally, more comprehensive testing will be able to be completed since some of the OSHA safety requirements will no longer limit the number of studies that can be conducted in a given time period. The knowledge of Atherosclerosis and endothelial function may be improved with the completion of studies using the prototype.

Conclusions

The second generation probe positioning device has been constructed and verified to be functional on a preliminary basis. With a functional prototype fully constructed, future work will focus on carrying out the validation plan outlined above. That said, other potential improvements or added features to the device will be continually considered. Preliminary testing has shown the device is effective in meeting the main goals of the project: positioning freedom and prolonged stabilization of the probe to sustain an

image over an extended study. In achieving these goals, the device may relieve occupational health hazards and provide a potential for improved efficiency in the clinic and streamlined workflows.

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Appendix A – Anthropometric Calculations

Cradle Diameter:

- Bicep Circumference, Fixed (Measurement 11 Figure A1.a at Right):

Male Mean = 33.76 cm, SD = 2.72 cm

$$33.76 + 1.96 (2.72) = 39.07 \text{ cm}$$

Minimum Inner diameter = 12.42 cm

Selected Cylinder with inner diameter of 14 cm. to allow room for foam padding (0.64 cm thick).

Cradle Lengths:

- The maximum length of the cradles were determined from lengths of 5th percentile Females

- Upper Arm from Shoulder-Elbow length (Measurement 91 Figure A1.b at Right):

Female Mean = 33.58 cm, SD = 1.73 cm

$$33.58 - 1.96 (1.73) = 30.18 \text{ cm.}$$

- Forearm from Radiale-Styilion Length (Measurement 87 Figure A1.c at Right):

Female Mean = 24.33 cm, SD = 1.55 cm

$$24.33 - 1.96 (1.55) = 20.9 \text{ cm.}$$

- Total Arm Length from Sleeve Outseam Length (Measurement 97 Figure A1.c at Right):

Female Mean = 54.81 cm, SD = 3.02 cm

$$54.81 - 1.96 (3.02) = 48.9 \text{ cm}$$

For simplicity of construction, the length of each cradle was selected to be 15.25 cm to stay within the limits calculated. A 15.25 cm gap was added to give a total length of the cradle to be 45.72 cm, below the calculated minimum arm length

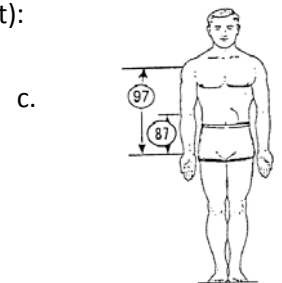
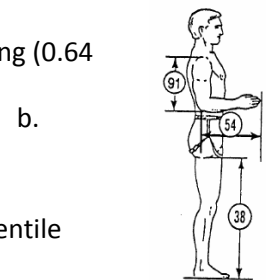
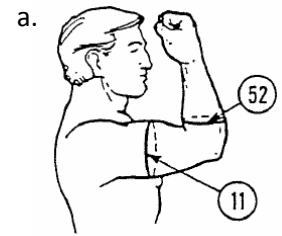


Figure A1 - Illustrations of dimensions used in anthropometric calculations.

a. Measurement 11 provided sizing for Bicep Circumference.

b. Measurement 91 was used for the Shoulder Elbow Length.

c. Measurement 87 was used for Forearm length, and Measurement 97 was used for total arm length

Appendix B

Project Design Specification—Ultrasound Probe Holder (Group 42)

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December 9, 2009

Function:

A simple, stable, adjustable ultrasound probe holder to aid in the ultrasonography of arterial reactivity. The holder would stabilize the ultrasound probe to improve image quality and reduce motion artifact for better diagnostic effectiveness. The device should reduce strain on the sonographer by decreasing the amount of time the probe is handled.

Client Requirements:

- Provides 6 degrees of positioning freedom
- Stable, no movement after being positioned
- Adjustable for small changes during study
- Cost efficient
- Ergonomic
- Cradle to stabilize patient arm
- Accommodate a variety of probe sizes

Design Requirements:

- 1) Physical and Operational Characteristics
 - a) *Performance requirements* – Easily adjustable without interfering with the ultrasound procedure, able to make small adjustments quickly, securely holds the probe, stabilizes the patient's arm while in use, must hold the probe stable for 5 to 10 min periods. It should function with 6 degrees of freedom. The device should move the probe to any position between 20° to 120° from horizontal.
 - b) *Safety* – The materials should not be hazardous, and should not interfere with the ultrasound procedure.
 - c) *Accuracy and Reliability* – The device should be able to make small changes quickly and hold its position throughout the procedure. Once the positioning device is set, the probe should have a 30° range of heel/toe movement.
 - d) *Life in Service* – The device should last at least 5 years.
 - e) *Shelf Life* – The device should be able to be stored indefinitely without compromising its integrity.
 - f) *Operating Environment* – The probe holder will be used in typical laboratory and clinical settings.

- g) *Ergonomics* – The device should be able to accommodate a large range of users (95th percentile male) without interfering with the ultrasound procedure.
 - h) *Size* – The platform of the device should be less than 3 feet long and 2 feet wide. The probe clamp should be small enough (12.7 by 10.2 cm) to fit into the sonographers hand once the probe has been secured.
 - i) *Weight* – The probe should be as lightweight as possible while providing a stable support. The device should be less than 30 kilograms
 - j) *Materials* – The materials should be cost efficient and should not interfere with the ultrasound procedure.
 - k) *Aesthetics* – The device should be aesthetically pleasing and blend in with the examination room.
- 2) Production Characteristics
- a) *Quantity* – Only one product is currently needed, but it should be designed with the intention of mass production.
 - b) *Target Product Cost* – The device should cost less than \$1000.
- 3) Miscellaneous
- a) *Standards and Specifications* – Because this device is only for research purposes, there are currently no standards.
 - b) *Customer* – The device will be used by medical personnel in a laboratory or clinical setting.
 - c) *Patient related concerns* – The device should not harm the patient.
 - d) *Competition* – There are currently some ultrasound probe holders in use, but none are available commercially.

Appendix C – IRB submission Forms

Document 1 – Cover Form

See Insert starting on next page.

Document 2 – Student Letter

We are Biomedical Engineering design students working on our capstone design project in the UW College of Engineering. Part of the curriculum is to verify that the prototype accomplishes the goals set up by our client, Dr. James Stein. Since this is part of an academic project, we are limited by the timeline of this semester and need to complete testing before December. We would appreciate it if you would expedite our application process.

The device will be used to hold an ultrasonic probe for atherosclerosis studies in a clinical research setting. Ongoing studies that might use such a holder already have been approved by regulatory boards, but their progress could be improved by use of an ultrasound probe holder. Dr. Stein's lab approached us to create a device that will allow them to reduce occupational risks, increase the number of patients they can scan in a day, and potentially improve image reproducibility over time. Currently, the sonographer holds an ultrasonic probe with his/her wrist in a deviated position, over the brachial artery for about five minutes. Our clients wish to eliminate this strain by having a device which will hold the probe for them once it has been placed.

The basic functions of the device will be to comfortably stabilize the patient's arm and to retain the probe's position once it has been locked into place. The probe will be grasped by an articulated arm which can accommodate any orientation of the probe along the patient's upper arm. The joints in the articulated arm have the ability to be loosened, repositioned, and then locked to place easily so the sonographer will be able to handle all operation independently (Figure 1).

The device does not directly interact with the patient and poses no danger. The aim of this protocol is to test the effectiveness of the device when compared to current procedures without the device. The protocol requires ten subjects and the testing could be completed within two weeks. We will appreciate a timely review of this protocol so that we may have adequate time to conduct our investigation.



Figure 1

Document 3 – Consent Form

University of Wisconsin-Madison

Research Subject Information and Consent Form

Title of Study: Prototype evaluation for ultrasonic probe holder to perform brachial artery imaging

Study Investigator: James H Stein, MD

Version and Date of Consent Form: Version 1, November 9, 2009

INVITATION AND SUMMARY

You are invited to take part in a research study that is testing a prototype (preliminary) ultrasound probe holder that was developed by biomedical engineering undergraduate students. Your participation is voluntary. Approximately 10 subjects will participate in this study. This study involves 1 visit. The main study procedure will evaluate if the prototype can act as a reliable substitute for a trained human holding an ultrasound probe while using ultrasound to bounce sound beams off of your upper arm artery. If you decide not to participate, any relationship you have with the University of Wisconsin-Madison (UW-Madison) or the University of Wisconsin Hospitals and Clinics (UWHC) will not be affected in any way.

PURPOSE OF THE STUDY

The purpose of this study is to test the effectiveness and ease use of the prototype probe holder.

WHAT WILL MY PARTICIPATION INVOLVE?

If you decide to participate in this research study, you will be asked to lie on a hospital bed during the procedure with your right arm extended for about 30 minutes. Your whole participation will last about half an hour.

ARE THERE ANY RISKS?

The main risk of taking part in this study is that your study information could become known to someone who is not involved in performing or monitoring this study. Your information will be saved under a random number and no personal information will be recorded.

ARE THERE ANY BENEFITS?

You are not expected to benefit directly from participating in this study. Your participation in this research study may benefit people working in the field of ultrasound,. The probe holder may assist the technician by minimizing fatigue and work related injuries secondary to repetitive use.

ARE THERE ANY COSTS?

There are no financial costs.

WILL I BE PAID FOR MY PARTICIPATING IN THE STUDY?

You will not be paid to take part in this study.

IF I DECIDE TO START THE STUDY, CAN I CHANGE MY MIND OR CAN I BE WITHDRAWN FROM THE STUDY WITHOUT MY PERMISSION?

Your decision to take part in this study is voluntary. You do not have to sign this form and you may refuse to do so. You may completely withdraw from the study at any time.

WILL MY CONFIDENTIALITY BE PROTECTED?

Researchers might use information learned from this study in scientific journal articles or in presentations. None of this information will identify you personally.

WHAT IF I HAVE QUESTIONS OR CONCERNS?

If you have problems, concerns, questions, complaints about the research or research- related injuries, you can contact the study investigator, the UWHC Patient Relations Representative, or University of Wisconsin Medical Foundation Patient Relations Representative. If you have any questions about your rights as a research subject, you can contact the UWHC Patient Relations Representative or University of Wisconsin Medical Foundation Patient Relations Representative.

The study investigator, James H Stein, can be contacted at 608-263-9648.

The UWHC Patient Relations Representative can be contacted at 608-263-8009.

The University of Wisconsin Medical Foundation Patient Relations Representative can be contacted at (800) 552-4255 or (608) 821-4819.

Authorization to participate in the research study:

I have read the information in this consent form, reviewed any questions, and I voluntarily agree to participate in this study. I have received a copy of this consent form.

Signature of Subject

Date

Signature of Investigator or Person Obtaining Consent

Date

Document 4 – Conflict of Interest Form

| | | | |
|--|---|------------------------------|--|
| University of Wisconsin-Madison Health Sciences IRBs Potential Financial Conflict of Interest (COI) Assessment Form for Applications for Initial Review of Research Involving Human Subjects Version Date: July 3, 2008 | | DO NOT WRITE IN THIS AREA | |
| This form must be submitted with all <i>Applications for Initial Review of Research Involving Human Subjects</i> . | | | |
| Protocol Title: "Prototype evaluation for ultrasound probe holder to perform brachial artery imaging" | | | |
| PI Name: James H Stein, MD | | | |
| | <p>Please note that research participation is restricted when individuals have a significant financial interest in the entity or entities. Does ANY of the study team involved in the design or conduct of the research study, or their immediate family*, have interests related to the research that meet or exceed one of the thresholds below:</p> <p>Compensation of \$20,000 or more in a calendar year from a business entity</p> <p>An ownership interest in a publicly traded business entity valued at \$20,000 or more or a 5% or greater equity interest</p> <p>An ownership interest in a privately held business entity</p> <p>A leadership position in a business entity (Leadership positions are positions with fiduciary responsibility, including senior managers (e.g. presidents, vice presidents, etc.) and members of boards of directors. Scientific advisory board membership is not a leadership position.)</p> <p>A proprietary interest in the research, such as royalties, patents, trademarks, copyright, or licensing agreement, including any agent, device, or software being evaluated as part of the research study [Do not include those managed by the Wisconsin Alumni Research Foundation (WARF)]</p> <p>If yes, identify the personnel who have this interest and include copies of any management plans or documentation of exceptions granted from the campus Conflict of Interest Committee to allow the personnel to participate in this study:</p> | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| | <p>Does ANY of the study team involved in the design or conduct of the research study, or their immediate family*, have a financial interest that requires disclosure to the sponsor or funding source?</p> <p>If yes, identify the personnel who have this interest:</p> | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| | <p>Does any of the study team receive incentives for recruiting human subjects or for any other purpose directly related to the study?</p> <p>If yes, describe the nature of the incentives:</p> | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| | <p>As PI for this protocol, I take full responsibility for the accuracy of the information provided in this form.</p> <p>PI Signature and Date</p> | | |

* "Immediate family" includes spouse and dependent children

Document 5 – Application for Initial Review

See Insert starting on next page.