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UW Madison Biomedical Engineering

Ultrasound Transducer Holder

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ABSTRACT

Advancements in ultrasound imaging software have made its use more prevalent in a clinical setting. Echometrix, a Madison-based startup company, recently developed innovative ultrasound video software involved in musculoskeletal diagnostics and rehabilitation. The software has great potential, however, requires the use of three hands in order to operate. A simple ultrasound transducer holder would eliminate this complication. The holder needs to be secured to the surface of the body and allow the transducer to be arranged over a location of interest (i.e. shoulder, leg, arm, etc.) and then locked in place. Two designs are proposed, fabricated, and tested proving that the concept is plausible. The design alternatives are critiqued and compared in order to determine the best possible design for the future. Effectiveness, structural integrity and ease of use are some of the factors taken into account when assessing the designs.

INTRODUCTION

ULTRASOUND BACKGROUND

Imaging with the energy created from ultrasound has become a very widely adopted diagnostic practice clinically. The general idea behind ultrasound imaging involves a transducer transmitting an ultrasound pulse that is reflected from the material it encounters within the body. Changes in impedance in the material alter the pulse that is echoed back from the material to the transducer. The time of flight of the echoes is used to determine locations of objects and, thereby, create an image. When using a gel or gel pad of known acoustic properties to form a complete contact surface between the transducer and a patient's skin, the transmittal and reception of waves can produce an image of a patient's internal tissues such as blood vessels and tendons. Such an image provides information about the patient's health. Other imaging techniques such as MRI and CT are also used clinically for this purpose and have been shown to provide a clearer image and more insightful information than ultrasound imaging. However, ultrasound remains relevant in clinical practice due to its portability, safety, and relatively low cost [1].

There are numerous factors that influence the amount of information that can be obtained from an ultrasound image. Properties of the transducer such as length and width of pulse transmitted affect the amount of axial and lateral resolution of the image produced [2]. This means that different transducers must be used for different situations. Also, the injection of a contrast agent may increase the clarity of a specific tissue that is the main focus of the image [3]. The skill and experience of the sonographer that is operating the transducer can have an effect on the image quality as well. The design of the software that is used in order to interpret the information received by the ultrasound transducer also affects the information obtained from the ultrasound. Our client, Echometrix, develops software for use with dynamic ultrasound imaging in order to diagnose and track rehabilitation of musculoskeletal conditions. Specifically, the software recognizes tendons and ligaments of interest on the image and then tracks pixels as the tissue of interest is stretched to measure the biomechanical properties such as stress and strain [4].

Tendons allow for skeletal movement by storing and releasing energy during muscular contraction. Knowledge of the mechanical and structural properties of tendons and how these properties are altered by injury can be highly beneficial to the treatment and recovery from the injury. Echometrix uses ultrasound technology to obtain a dynamic ultrasound image (CINE image) while monitoring the acoustic change associated with a dynamic tensile load applied to a specific tendon of interest. This is possible due to the theory of acoustoelasticity which states that the acoustic properties of a material will change as the material deforms under a load. The echo intensity reflected by the tendon increases linearly with the strain on the tendon and nonlinearly with the stress on the tendon. The software, *echoSoft,* made by Echometrix uses these relationships in order to determine the stress, strain, and stiffness of the tendon from the echo intensity received by the transducer [4]. The mechanical properties of the tendon are, thereby, found noninvasively. This method can be beneficial for determining mechanical and structural effects of injury as well as tracking the tendon's response to treatment.

The current method for using the ultrasound transducer with *echoSoft* is reliant upon three hands. One hand is used to position the transducer on the tendon to be studied. Once the desired image is obtained, the sonographer must use his or her remaining hand to apply stretch to the tendon. A third hand is then needed to record the image from the ultrasound machine. During this process, it is imperative that the transducer remain firmly pressed to the skin in a fixed position. Failure to maintain transducer contact with the skin can cause shadows in the image, as seen in Figure 1. Shadows such as this prevent the software from making accurate measurements. Gripping the transducer in such a way can cause physiological issues as well. Carpal tunnel syndrome is a condition in which the median nerve in the wrist is

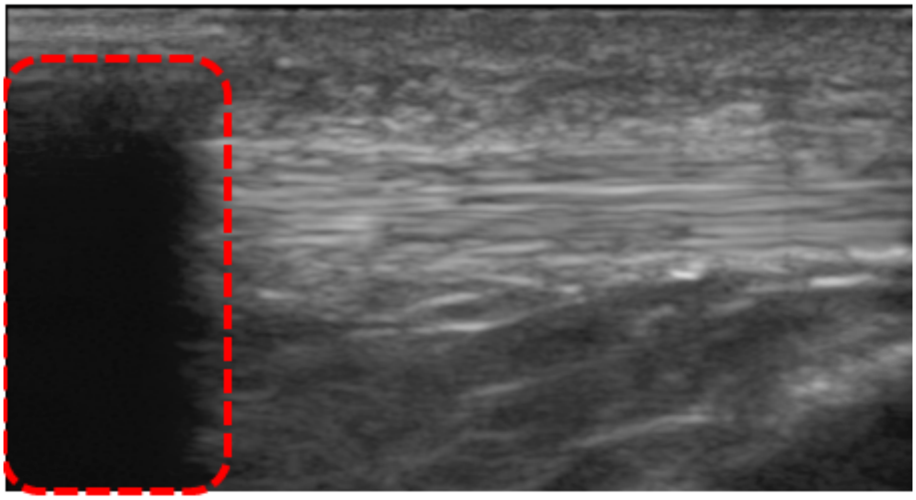

Figure 1: An ultrasound image of a tendon displaying a shadow (highlighted in red) due to detachment of the transducer

compressed, causing numbness, weakness, and burning sensations in the hand. A study conducted by Vanderpool, et al. found that 87% of cardiac sonographers reported at least one physical symptom of carpal tunnel syndrome [5]. The transducer holder will reduce this prevalence by not requiring that sonographers grip the transducer.

The software's reliance on the sonographer's ability to multitask is inefficient and can result in wasted time and resources. A device that would remove the need to hold the ultrasound transducer against the skin would eliminate one of the tasks that the sonographer is required to perform and allow more attention to be devoted to the other tasks. This will lead to an efficient and effective use of the software. The design of this device must take into account all factors that affect ultrasound image quality, including variable transducer size, site injection [6], and sonographer variability. A number of solutions have been proposed to address this problem.

PROBLEM STATEMENT

Ultrasound imaging has become more preferred than other, more insightful imaging techniques such as CT or MRI due to its portability and low price. Echometrix has developed ultrasound video software that would add to the diagnostic and prognostic value of ultrasound imaging techniques. The software adds another complication to the manual manipulation of the ultrasound transducer as the doctor will have a greater workload. Our client would like to develop a simple ultrasound transducer holder that can be maneuvered easily with six degrees of freedom and can be secured to the surface of the body over the location of interest in order to standardize the modern ultrasound technique.

DESIGN SPECIFICATIONS

To record a satisfactory image, the transducer must be positioned directly over the tendon. For this reason, the client wants a holder that must be attachable anywhere on the arms and legs of the patient. Upon attaching the holder to the appendage, the transducer must be able to translate across the plane of the skin to find the tendon. It is then pressed to the skin. The amount of pressure between the skin and transducer can slightly affect the resulting image, thus z-direction motion (in reference to Figure 2) is important. Rotation of the

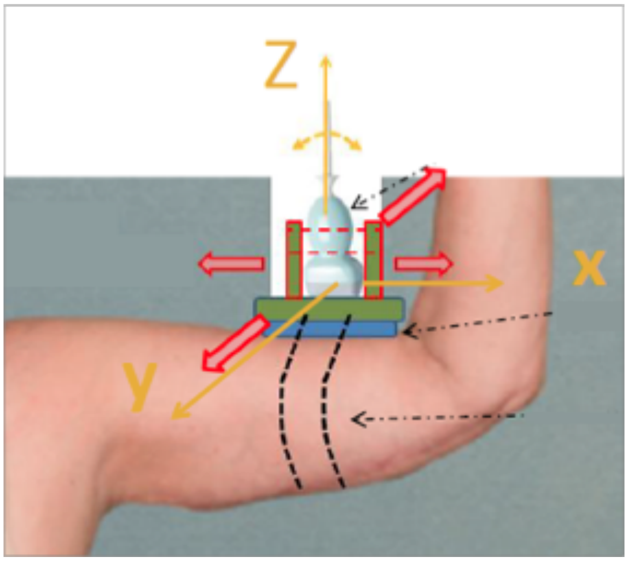

Figure 2: A representation of the reference axes of the transducer movement relative to the skin.

transducer about the x- and y-axes allows for the transducer to remain perpendicular to the skin in case the base is not flush with the skin once strapped into position. Additionally, rotation about the z-axis allows for both longitudinal and cross-sectional views of the tendon to be captured, which allows for versatility of use. This aspect is important since it allows the exact image to be replicated at a later point in time, permitting a sonographer to track recovery.

Upon positioning the transducer in the desired location, the device must remain in this fixed position. It should be able to withstand slight shifts due to possible patient movement without noticeable deviation from the original orientation. Furthermore, the device must be easily adjustable and able to accommodate fine tuning movements. As the tendon is stretched, the ability to quickly reposition the transducer to enhance quality is desirable. The capacity for simple and stable adjustment of the device is a main requirement for any design considerations.

Additional requisites of the device include the ergonomics of the design. For example, the use of the apparatus must be straightforward and intuitive; it should not require training to use the device. On the other hand, the holder must be comfortable for the patient to wear and cannot be overly heavy or else it will exert a large force on sensitive, damaged tissue. The client requested two prototypes that prove that the concept is plausible. The prototypes can then be compared in order to determine the best future action for the design.

DESIGN COMPONENTS AND CONSIDERATIONS

In order to determine a design that would maximize the transducer holder effectiveness, several options are discussed and evaluated. In all cases, the mechanism that will allow for translation in the in the directions parallel to the skin is a set of sliding carriages on rails (Figure 3). All cases will also be attached to the appendage via straps that are suspended from the rails. These straps will be wrapped around the appendage and secured together with Velcro. Two distinct pieces of the project are subjected to an extensive design process: the mechanism that will hold and rotate the transducer and the mechanism that will allow z-direction translation to increase compression on the skin. Multiple design alternatives for these two mechanisms were

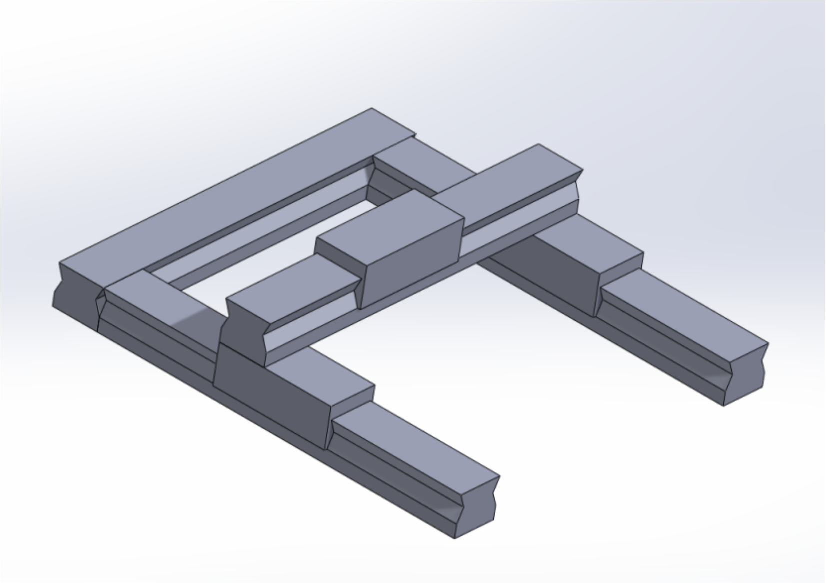

Figure 3: A diagram of the rail system designed for translation parallel to the skin (x-y plane).

considered in order to ensure that the concept is thoroughly investigated and that the best design was found. A design matrix was developed in order to compare the design alternatives.

Five main criteria were considered in the design matrix: ease of use, adjustability, ease of fabrication, durability and cost. Ease of use is the most important criteria as dictated by the client. The main purpose of the device is to decrease the work load of the clinician, and a device that is hard to use would be counterproductive. The most valuable asset to a clinician is their time, and so the device needs to be simple to operate and set up. The device also has to be lightweight so that it is comfortable for both the doctor and the patient.

Adjustability of the device is the second most important quality to the design. An ideal design would move easily and smoothly with little resistance, but also remain firmly in its place at the clinician's will. This would permit the clinician to use one hand to capture the image, and one hand to do the stretching exercises needed. Both fine and gross adjustments in the X-Y plane are necessary to gather an ultrasound image in the ideal location. The device also must allow the transducer to rotate 180°. This ensures either a longitudinal or cross sectional image of the desired tendon or tissue to be obtained. Ideally, the transducer would be able to rotate without significantly changing location on the patient's tendon.

Another important criterion is ease of fabrication. Echometrix plans to sell their software to allow economic ultrasound imaging to replace the highly expensive MRI scans. Therefore, the device needs to be easy to fabricate in order to be mass-produced. Additionally, the team needed a design that was feasible to construct. Fabrication was less significant that other aspects of the design because several components of the design were purchased.

Durability is another important aspect of the design. Due to the fact that this design will be used in hospitals, it has to be able to be cleaned with 70% alcohol, a health care standard. The device also has to be strong enough to counteract the resistance force supplied by the skin and the weight of the transducer. A successful product would have a functional life of several years without loss of effectiveness or strength.

The final criterion considered was cost. As with all medical devices, a product marketed with a lower price has a greater chance of widespread use. This is especially important because ultrasound imaging is being presented as a low cost alternative for MRI, so the holder must also be economical. Our client, Dr. Hirohito Kobayashi, was fiscally responsible for the materials associated with the project. Materials were to be purchased and an expense report was to be filed at the end of the term for reimbursement. A budget of $500 was established, with additional funding possible if needed (Appendix C).

DESIGN EVALUATION

ROTATION

The first complex aspect of the design was the mechanism that would allow the transducer to be rotated. This problem could be approached from several ways, so after discussing many options, the three top performers were evaluated.

Figure 4: An example of a rotating base system [7].

Concept 1 - Rotating Base:

The first option for allowing rotation was to use a bracket that would simply hold the transducer in place while the base itself would rotate. Similar to a dash mount cell phone holder, the point of attachment stays stationary and a base above the point of attachment rotates, while the arm that holds the device protrudes outwards. This design allows rotation in any direction and would likely be available as a prefabricated unit. These units also allow the tilt to be adjusted to some degree. Such units are typically composed of materials that are biologically safe, making this a viable option. This device stood out due to its adjustability, covering all the degrees of freedom needed. However, turning the device would significantly change the placement of the transducer, making the process of going from a lateral image to a cross sectional image a chore.

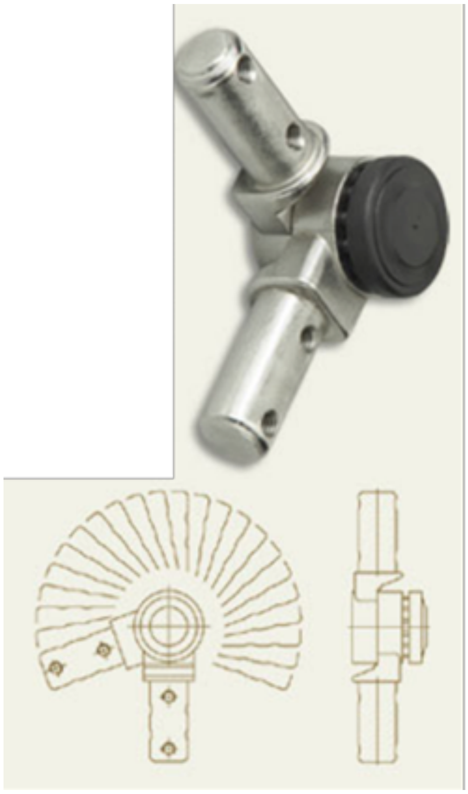

Figure 5: An example of a commercially available locking hinge joint [8].

Concept 2 - Hinge Joint:

The second design that was considered was a lockable hinge joint. What allows this joint to lock is a spring loaded pin that may be physically extracted, allowing a free range of motion. Once the pin is aligned with a slot, the spring snaps the pin back into the secured position, locking the joint at the desired angle. This joint is adjustable from 0^{o} to 220^{o}, locking in 10^{o} increments. This concept is illustrated in Figure 5. These increments would limit the adjustability of the device. Although the mechanism may be durable and strong, it requires two hands to adjust. Therefore the device is not the most ergonomic. This joint also fails to rotate, but could be coupled with the rotating base to allow for the desired degrees of freedom.

Concept 3 - Ball and Socket:

The final option considered was a simple ball and socket type joint, as seen in Figure 6. The joint would be tight enough that, once positioned, friction alone would maintain the desired position. It was determined that the most logical place to put the joint was below the bracket that would hold the transducer, similar to a joystick. This would allow for the most natural motion, mimicking the original movement by the sonographer using the transducer without a supporting device. Therefore this device would be extremely easy to use. This joint would allow for both rotational movement as well as allowing for the transducer to be tilted; however, a limitation of this design is that the transducer would be unable to rotate a full 90^0 to transmit longitudinal images. Nevertheless, this option would allow for an ideal joint due to the high amount of adjustability.

Figure 6: An example of a commercially available ball and socket joint [9].

Table 1: The design matrix for the three attachment options.

	Max	**Rotating Base**	**Hinge Joint**	**Ball and Socket**
Ease of Use	40	25	30	**35**
Adjustability	30	25	15	**30**
Durability	15	5	15	**10**
Fabrication	5	5	5	**5**
Cost	10	10	5	**5**
Total	100	70	70	**85**

Each of the 6 design options were evaluated over a general scale of effectiveness. Categories that were weighed heaviest included ease of use (40%) and adjustability (30%). Other categories included durability (15%), fabrication (5%) and cost effectiveness (10%). A higher score indicated a more satisfactory completion of the criteria. The scores were then compiled, giving a clear cut picture that the ball and socket joint was the best selection. All design options were tested independently of the sliding rails, since these rails would ultimately be incorporated into whichever design proved most applicable.

Z-DIRECTION MOTION

The second complex aspect of the design was the mechanism that would allow translation in the Z direction. An ideal design would require only one hand to achieve Z axis movement. It should also be able to lock in place and be finely adjustable.

Concept 1 – Pen:

The pen design resembled the mechanical component of a simple click pen. When a pen is clicked, a spring is compressed and a series of concentric shafts slide and shift a pin, allowing retraction of the pen point. The design would parallel this mechanism. This device was ideal because of its simplicity for the user; it would be able to be operated with one hand. However, this device would be difficult to fabricate and would quickly become bulky in order to gain the rigidity required to apply the necessary tension.

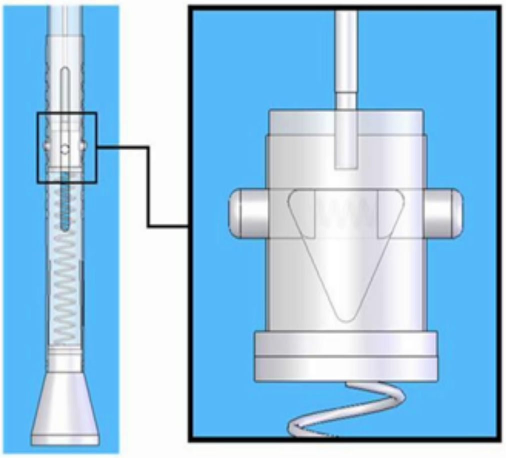

Figure 7: Representation of how a crutch exhibits translation [10].

Concept 2 – Crutch:

The crutch design utilized two cylinders to achieve Z direction movement. In the design, an outer shaft with holes contained an inner shaft with two spring-loaded buttons. When the buttons were compressed, the shaft was able to slide. A spring provided the lift for the inner shaft, as seen in Figure 7. The crutch was an appealing system because it was very simple, and would accomplish the task well. It would also be easy to disassemble in order to clean. Unfortunately, the 3 mm movement needed would mean the button would have a very small distance to travel. This would limit the strength of the device, and would necessitate the use of two hands.

Concept 3 – Screw:

The screw design drew on several fundamental concepts. In the design, the lower cylinder was threaded so that the screw could rotate within. A spring supported the upper cylinder. The upper cylinder was smooth, and had a slightly larger diameter than the screw. This allowed the upper cylinder to slide on the screw's shaft. The screw head was tangent to the upper cylinder. When the screw head would be turned, the spring is compressed and the transducer, which would be connected to the upper cylinder, is translated downward in the Z direction. This design was ideal because it could be operated easily with one hand. Additionally, the Z direction movement was adaptable; the clinician could get more or less translation based on the number of turns they applied to the handle. The device would lock in place due to the force put on the screw by the spring. However, this device would require machining which would increase the time required to fabricate.

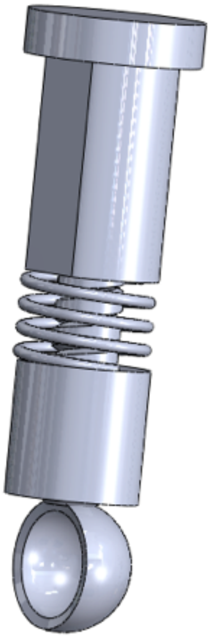

Figure 8: SolidWorks drawing of screw design for z-axis translation.

Table 2: Design Matrix for Z Movement Designs

	Maximum	Pen	Crutch	Screw
Ease of Use	40	40	30	**35**
Adjustability	30	15	15	**30**
Fabrication	15	5	5	**10**
Durability	10	5	10	**5**
Cost	5	5	5	**5**
Total	100	70	65	**80**

The three designs were entered into a design matrix (Table 2) and analyzed using the following criteria: ease of use, adjustability, ease of fabrication, durability and cost. The categories were given weights according to their importance as follows: ease of use (40%), adjustability (30%), ease of fabrication (15%), durability (10%), and cost (5%). A higher score indicated a more satisfactory completion of the criteria. Based on the design matrix, the screw design was determined to be the optimal final design component.

FINAL DESIGNS

Two prototypes were constructed at the request of the client. Both of the final prototypes consist of the same separate rail systems for translational motion parallel to the skin, as seen in Figures 9 and 11. Two rails arranged parallel to each other contain carriages within the rail that are capable of guided translation along the axis of the rail. A third rail arranged perpendicular to the other two rails is fastened to the carriages giving the entire third rail the ability to translate in the same direction as the carriages. Finally, the third rail also contains a carriage that is capable of movement along the rail's axis. It is on this third carriage that a transducer connection mechanism is fastened. The two parallel rails are connected by a perpendicular support beam at each end, forming a rectangular base. This rail system allows for the transducer to be translated anywhere in the plane parallel to the skin. Four Velcro straps positioned at the corners of the base will be used for attachment of the device to the body part of interest. A strap placed in each corner of the rail system is attached by a nut and screw. The double-sided Velcro allows for a great range of adjustability, since the entire surface of the strap can be utilized. This was an added benefit because it permitted a more versatile device due to the fact that it could be used on a patient's thigh or on a surface as small as a patient's wrist. Foam padding is attached in between the base and skin in order to provide comfort for the patient. Each prototype has a different transducer connection mechanism.

Prototype 1 (Screw and Spring):

The first prototype (Figure 9) has outer dimensions 19.7 cm x 18 cm. The rails were custom fabricated by using repurposed ceiling light mounts consisting of a steel channel that was crimped inwards at the top forming a slit. Two rails were cut down to a length of 18 cm. Two ¼" (0.635 cm) thick aluminum support beams were cut to a length of 19.7 cm and connected to the ends of the rails in order to form the base of the prototype. The slit running along the top of each rail is wide enough for the shaft of a M2.5 x 0.5 screw to easily translate run along the axis of the rail, but not wide enough for the head of the screw to fall through. A third rail was cut to 19.7 cm and an M2.5 x 0.5 screw is used to attach the ends of the third rail to the two parallel rails on the base. These screws are capable

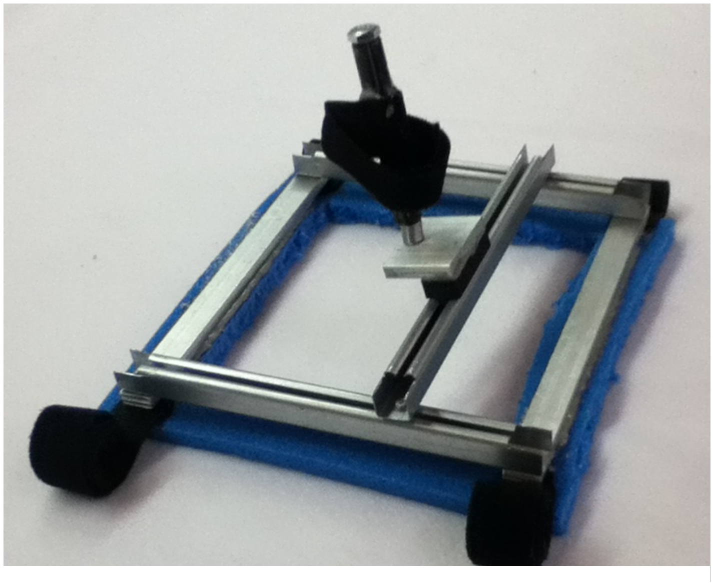

Figure 9: Picture of prototype incorporating screw and spring mechanism

of translating along the slits of the base rails and act as carriages granting the third rail translational motion along the axes of the base rails.

A specially designed carriage system that runs along the inside of the third rail was drawn using SolidWorks (Figure 10). This drawing was then created by using a 3-D printer. The carriage was shaped like an I-beam, allowing the thin portion to slide along the slit in the rail while the larger top and bottom prevented motion perpendicular to the rail. The I-beam carriage is used in order to hold the transducer connection mechanism.

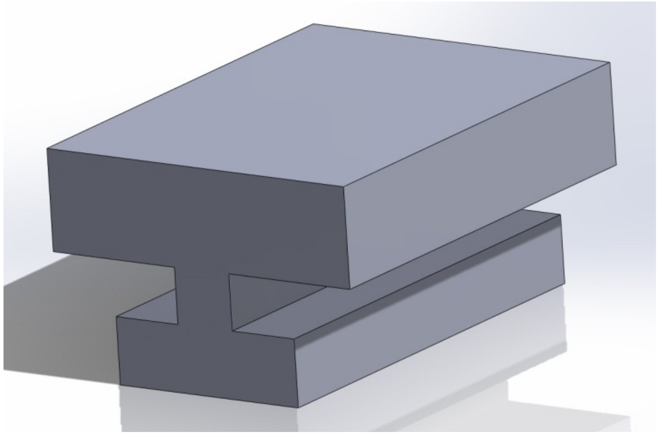
Figure 10: Plastic carriage used for translational motion and attachment of screw mechanism

The transducer connection mechanism is the screw mechanism explained in the previous section. In summary, a screw is partially screwed into the carriage on the third rail. Around the screw and immediately above the carriage is a spring connected to a sleeve. As the screw is screwed further into the carriage, the head of the screw will lower, pushing down on the sleeve and compressing the spring. The transducer is held connected to the sleeve so that, as the screw is tightened, the transducer will be lowered. This mechanism allows the transducer to be adjusted in the direction perpendicular to the skin. The prototype allows the sonographer to position the transducer however they please in the plane parallel to the skin and then lower the transducer to skin level using the screw mechanism. Velcro straps are used to bind the transducer to the holder.

Prototype 2: Ball and Socket

The second prototype can be seen in Figure 12. The outer dimensions of the second prototype are 19.7 cm x 19.7 cm. The rails and internal carriages for the second prototype were purchased prefabricated to ensure a smooth and secure fit between the two. These rails are aluminum, but much less bulky and are significantly lighter than those of the first prototype. They are mostly flat with a lip at the top of each side into which the


Figure 11: Low Profile Sleeve-Bearing Rails and Carriages from McMaster-Carr [11]

carriage can fit snugly, as seen in Figure 11. The perpendicular third rail is connected to the two parallel rails using the prefabricated carriages. The carriages are made of plastic with two threaded holes in the top of them. This allows the third rail to simply screw into one hole on the top of the carriages for translational motion along the axes of the parallel rails. The second hole atop each carriage is fitted with a screw that, when tightened, presses down on the bottom of the rail and holds the carriage in place with friction. This ensures that the carriages will not move once locked at the desired position. This design also incorporates two stabilizing aluminum beams at the end of the parallel rails.

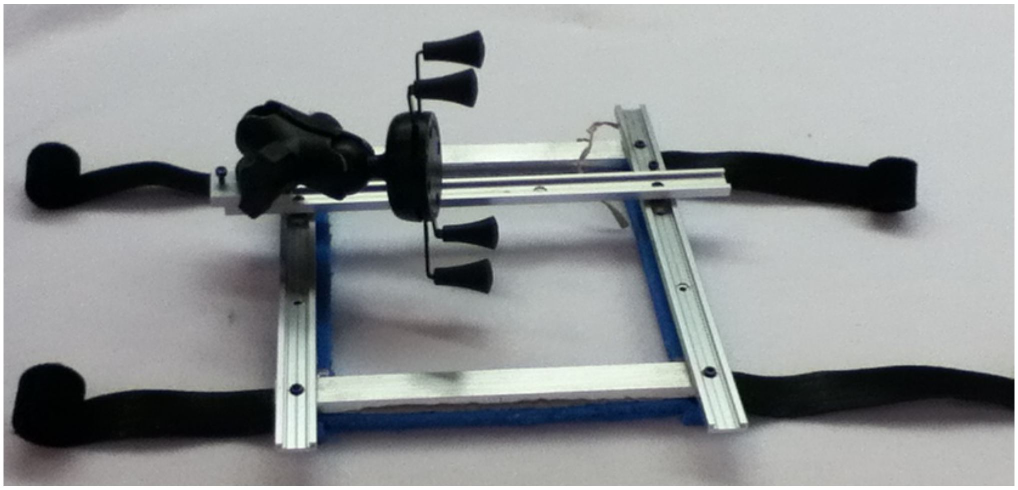

Figure 12: Picture of prototype including ball and socket mechanism

The third rail holds an adapted carriage with which to connect the transducer. An aluminum piece was fabricated that connects the carriage to a 1” diameter ball for a ball and socket joint. The connection adapter uses both screw holes on the carriage in order to ensure a strong connection and prevent any rotation. Another hole was fabricated in the adapter to allow a screw locking mechanism similar to the other carriages. Connected to the 1” diameter ball is a double socket joint. One ball is attached to the connection adapter, while the other is attached to the system used to grip the transducer itself. The socket consists of two pieces of plastic that clamp each side of the ball with enough force to prevent any further movement. Unscrewing a nut and bolt through the socket loosens the joint allowing free movement of the system. The compressive force on the two pieces is established by the tightening of a screw.

Figure 13: X-Grip Universal RAM Cradle [12]

Connected to the other end of the double ball and socket is a prefabricated gripping system to hold the ultrasound transducer, seen in Figure 13. The mechanism relies on torsional springs placing tension on four bars, creating an "X" shape in which to hold the transducer. The double ball and socket joint allows the transducer to rotate in all directions and simultaneously translate closer to the skin surface.

TESTING

FUNCTIONALITY

Qualitative testing and evaluation was done on the prototypes by the design group members in order to evaluate and compare the two prototypes.

Each design was strapped to various body parts in order to evaluate the effectiveness of the Velcro straps in attaching the device to the body. Since both designs have one Velcro strap at each of the four corners, the results of this testing were the same for both prototypes. Both of the prototypes were capable of firmly attaching to the limbs of the body. Once a tight attachment was made to either the arm or the leg, the prototypes remained in position even if the patient moved around. The padding on the prototype minimized discomfort and the straps did not cut off the blood flow to the distal tissues of the limb. Disruption of circulation could arise as a problem, however, for obese patients that have limbs that exceed the dimensions of the prototype. Finally, the prototypes were not successful in attaching around joints such as the knee, shoulder, or elbow. The rigidity of the base limited the attachment to relatively rigid areas of the body.

Each design was then evaluated on the ease of manipulating the transducer position. In this testing, the second prototype was superior by far. The first prototype was observed to have significantly weaker joints at the connection between perpendicular rails. The

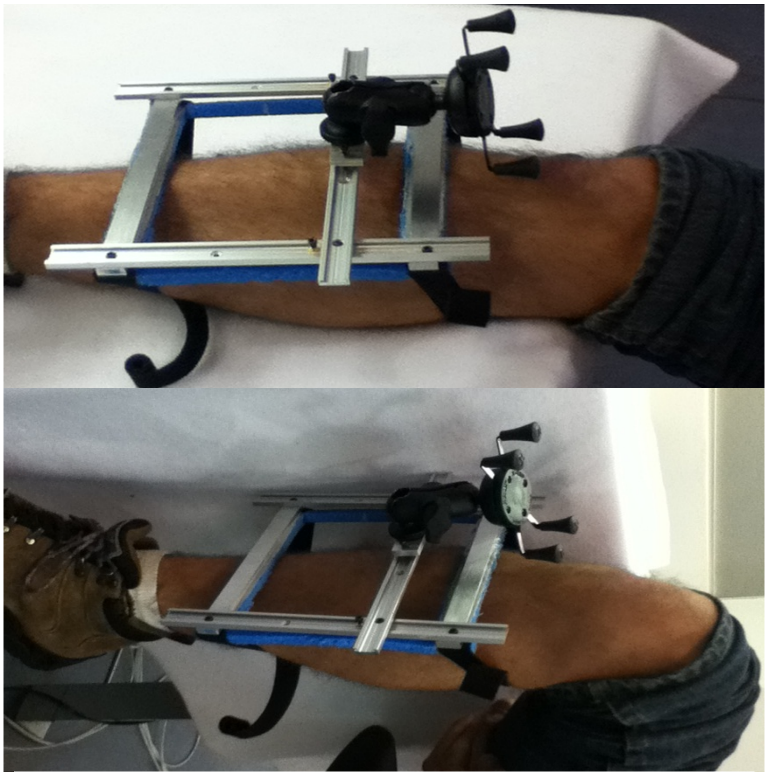

Figure 14: Holder fastened below knee. The mounted transducer can be positioned on the patellar tendon despite the holder not being directly on the knee. This can be seen in two states: extension (top) and flexion (bottom).

screws acting as carriages on the base rails were observed to tilt under the uneven weight of the screw mechanism and transducer. This tilted the entire third rail forward which, in turn, tilted the transducer forward into an undesirable position. Furthermore, due to this increased stress on the screws, the nuts involved in their fastening loosened with extended use. This made constant tightening of the screws necessary. In contrast, the second prototype had no observed tilt or wear with increased use. This made the second prototype much easier to adjust in the plane parallel to the skin.

The design of the first prototype does not allow rotation of the transducer after it has been attached to the device while the second prototype is free to rotate at all times. This made the adjustment of the transducer attached to the second prototype very similar to the natural motion of a handheld transducer. However, the rotation of the transducer had a minimum radius of rotation due to the length associated with the two ball and socket joints. Finer adjustments were made more difficult due to this minimum radius of movement. Fine adjustments perpendicular to the plane of the skin were very accurate on the first prototype with the screw mechanism allowing for easy adjustment. However, the second prototype was by far the more ergonomically friendly of the two prototypes.

Finally, the length of the multi-ball socket joints found in the second prototype provided significant benefits. Because the joint extends the transducer away from the carriage, the transducer can be positioned outside of the base and still be held by the mechanism. This is shown in Figure 14, where the transducer can be positioned on the knee even though the base is strapped to the area of the leg just beneath the knee. This is highly beneficial because strapping to the knee is very difficult and this eliminates that complication by holding the transducer over the knee without strapping to the knee. In contrast, the first prototype cannot position the transducer outside the area enclosed by the base and would therefore need to be strapped over the knee joint in order to be positioned over the knee.

THEORETICAL

Due to the fact that only one version of each design was produced, strength testing was conducted theoretically using material properties and mechanics of materials principles (Appendix B). Areas where failure was likely to occur were analyzed using a static approach. The rails, crossbars, and carriages of each design were analyzed. The first prototype proved fairly robust, with ultimate loads of 1,991 N and 247.9 N for the rails and crossbars respectively. In addition, the epoxied carriage can withstand 9,906 N before failure of the epoxy. The rails of the second prototype are constructed from aluminum, and thus have a smaller ultimate load of 36.6 N; however, the crossbars allow slightly more force before failure at 292.6 N. The plastic carriages, although contacting a relatively small area, can withstand a large vertical force of 2,938 N before failure. All values given here are well within the 10 N range as seen in the product design specifications (Appendix A), with the lowest factor of safety being approximately 3.66.

FUTURE WORK

The testing of the two different prototypes proved that the concept proposed by this design team is plausible. Two prototypes of a device that attach to a patient and hold an ultrasound transducer in a desired position were successfully fabricated and tested. The attachment of the prototypes to the body was a success for both of the prototypes and both were able to hold a transducer tight to the skin once attached to the body. Of the two prototypes, the ball and socket prototype proved to be the more user-friendly design and fit the design specifications laid out by the product design specifications more closely. There were aspects of both designs, however, that can be incorporated into the development of a final prototype.

The two ball and socket joints was a very successful and useful transducer connection mechanism, but had some flaws. The fact that the ball and socket joints were connected and controlled by the same locking mechanism meant that their motion was not independent of each other. A remedy to this would be to develop individual locking mechanisms for each of the ball and socket joints. This would allow for the locking of one of the joints to allow completely independent movement in the unlocked joint. Also, the locking of the rails involved tightening three different screws. This involves a tedious and undesired amount of work. A mechanism that would lock the transducer in place with one motion would be a much more efficient design. An additional flaw in the ball and socket joint was the minimum radius of motion limiting the accuracy of fine adjustments of the transducer location. This is where implementing some of the aspects of the first prototype may be beneficial. The first prototype was very successful in making fine adjustments in the z-direction. Implementing a screw mechanism into the ball and socket connection mechanism that could shorten the minimum radius of motion would regain the fine accuracy and precision that is lost by having a relatively large radius of motion.

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APPENDIX A:

Product Design Specifications

Medical Ultrasound Transducer Holder

Client: Dr. Hirohito Kobayashi
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Function

Ultrasound imaging, being portable and inexpensive, has become increasingly more preferable than other imaging techniques such as CT or MRI. However, high user dependency along with inexperienced and unskilled use of the ultrasound transducer has prevented it from widespread adoption. Our client is developing ultrasound video techniques that would create another element to the manual manipulation of the ultrasound transducer. Our client would like to develop a simple and elegant ultrasound transducer holder that can be maneuvered easily with 6 degrees of freedom and can be secured to the surface of most body parts in order to standardize the modern ultrasound technique.

Client Requirements

- Securely straps on to the surface of most body parts.
- Holds most of the commonly used transducers at any arbitral angle to body surface.
- Allows transducer to slide in two orthogonal directions.
- Allows transducer to rotate 90 degrees about the z-axis without any action such as removing and re-setting.
- Holder requires minimal or no ultrasound gel.
- Holder must have a disposable soft-pad (sit between skin and transducer) with known acoustic material property.
- Holder has to be created with material that can be cleaned with 70% alcohol used at hospital
- Allows transducer to change angle with the x-y plane to get desired image

Design Requirements

1. Physical and Operational Characteristics

a. *Performance requirements*: Device should be able to withstand repeated use, withstand the pressure needed to keep device secured to the skin without movement. Transducer needs to be able to rotate and translate freely and then be lockable when maneuvered to desired position. Transducer should be able to be moved to a position that is out of the way that allows space for a needle to inject dye into patient.

b. *Safety*: Should have padding between device and skin to prevent bruising. Moving parts should not pinch user.

c. *Accuracy and Reliability*: Device should remain stationary on skin and keep transducer stationary when locked into desired position. Movement of parts should require a consistent amount of force.

d. *Life in Service*: Device should remain operational for 5 years.

e. *Shelf Life*: Safe to store at room temperatures.

f. *Operating Environment*: Will be exposed to the clean conditions of a hospital. Will have contact with skin. Should have numerous users and patients. Device will be under enough pressure to attach securely to the patient.

g. *Ergonomics*: Should be user friendly and decrease the ultrasound technician's workload. Device functions should be intuitive and easy to learn. Device should be comfortable for the patient.

h. *Size*: Approximately 4 inches squared.

i. *Weight*: Device needs to be light enough to avoid discomfort. Less than a pound and a half.

j. *Materials*: Materials should be able to withstand cleaning with 70% alcohol. Materials should be strong enough to withstand the stresses involved in securing the device.

k. *Aesthetics*, *Appearance, and Finish*: Should look professional and not scare patient.

2. Production Characteristics

a. *Quantity*: 1 product will be needed.

b. *Target Product Cost*: Proposed budget: $500

3. Miscellaneous

a. *Patient-related concerns*: Device needs to be sterilized in between each use.

b. *Competition*: There is a table top holder, but nothing that is held to the skin.

APPENDIX B:

Constants:

Ultimate tensile stress of aluminum, σ_{alum} = 110 MPa

Ultimate tensile stress of PTFE, σ_{PTFE} = 30 MPa

Ultimate tensile stress of steel, σ_{stl} = 400 MPa

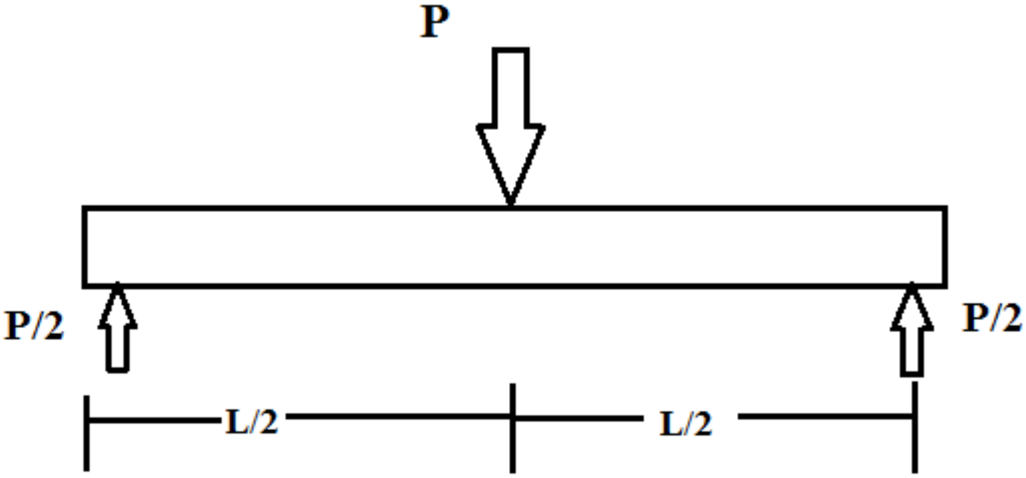
Ultimate tensile stress of aluminum-epoxy bond = 16.51 Mpa

Prototype 1

Rails (modeled as hollow square beams):

Dimensions – 0.0144 x 0.0144 x 0.18 [m] (thickness = 0.001 [m])

Free body diagram of rails/crossbars



Stress due to bending moments

$$\sigma = \frac{My}{I} \tag{1}$$

Maximum moment, M, at center of rail

$$M = \frac{P}{2} * \frac{L}{2} = P * \frac{0.18}{4} = 0.045 * P \qquad (2$$

Distance from neutral axis to point of maximum stress

$$y = \frac{1}{2} * 0.0144 = 0.0072\ [m] \qquad (3$$

Mass moment of Inertia

$$I = \frac{1}{12} b_1 h_1^3 - \frac{1}{12} b_2 h_2^3 = \frac{1}{12}(0.0144^4 - 0.0124^4) = 1.613 * 10^{-9}\ [m^4] \qquad (4$$

Substituting (2), (3), and (4), into (1), and using σ_{stl} = 400 MPa:

$$400 * 10^6 = \frac{0.045P * 0.0072}{1.613 * 10^{-9}}$$

$$P_{stl} = 1{,}991.4\ [N]$$

Crossbars:

Dimensions – 0.18 x 0.0144 x 0.0065 [m]

$$y = \frac{1}{2} * 0.0065 = 0.00325\ [m] \qquad (5$$

$$I = \frac{1}{12} bh^3 = \frac{1}{12}(0.0144)(0.0065^3) = 329.6 * 10^{-12}[m^4] \qquad (6$$

Substituting (2), (5), and (6) into (1), σ_{Alum}=110 MPa:

$$110 * 10^6 = \frac{0.045P * 0.00325}{329.6 * 10^{-12}}$$

$$P_{Cross} = 247.9\ [N]$$

Epoxied carriage:

$$\sigma = \frac{P}{A} \quad (7$$

Area of contact: 0.04 x 0.015 [m] = $600*10^{-6}$ [m^2]

Using (7) and σ_{epoxy}= 16.51 Mpa

$$16.51 * 10^6 = \frac{P_{epoxy}}{A} = 16.51 * 10^6 * 600 * 10^{-6}$$

$$P_{epoxy} = 9{,}906\ [N]$$

Prototype 2

Rails (modeled as uniform rectangular bars):

Top rail analyzed as it has no crossbar stabilizer.

Dimensions – 0.18 x 0.017 x 0.0023 [m]

$$y = \frac{1}{2} * 0.0023 = 0.00115\ [m] \quad (8$$

$$I = \frac{1}{12}bh^3 = \frac{1}{12}(0.017)(0.0023)^3 = 17.23 * 10^{-12}\ [m^4] \quad (9$$

Substituting (2), (8), and (9) into (1) and using σ_{ult} = 110 MPa:

$$110 * 10^6 = \frac{0.045P * 0.00115}{17.23 * 10^{-12}}$$

$$P_{Rail} = 36.624\ [N]$$

Crossbars:

Dimensions – 0.18 x 0.017 x 0.0065 [m]

Maximum moment is same as for rails, see (2)

$$I = \frac{1}{12}bh^3 = \frac{1}{12}(0.017)(0.0065)^3 = 389.05 * 10^{-12}\ [m^4] \tag{10}$$

Substituting (2), (5), and (10) into (1) and using σ_{ult} = 110 MPa:

$$110 * 10^6 = \frac{0.045P * 0.00325}{389.05 * 10^{-12}}$$

$$P_{cross} = 292.6\ [N]$$

Plastic Carriage (PTFE):

Area of contact –0.00488 x 0.02 [m] = $97.6 * 10^{-6}$ [m^2]

Substituting σ_{PTFE} and the area of contact into (7):

$$30 * 10^6 = \frac{P}{97.6 * 10^{-6}}$$

$$P_{PTFE} = 2{,}938\ [N]$$

APPENDIX C:

Expenses

Part Type	Part	Quantity	Unit Price	Total Price
Rails	9” rail segment	3	12.50	37.50
	U-channel rail	3	2.48	7.44
Hardware	3Mx0.5 socket head	6	.48	2.88
	Thumb screws	1	.98	0.98
	Nuts	4	.80	3.20
	Velcro straps-narrow	3	4.18	12.54
	Velcro straps-wide	1	5.96	5.96
	Spring	1	.75	0.75
	3/8”-16x3.5” bolt	1	1.30	1.30
	Cylindrical sleeve	1	1.05	1.05
Carriages	Carriages for 9” rail	4	5.36	21.44
	Carriages for U-channel rail	3	-	0.00
Ball and Socket	Aluminum double socket	1	13.77	13.77
	Composite double socket	1	8.81	8.81
	X-grip mechanism	1	22.84	22.84
	1” ball square base	1	6.04	6.04
	1” ball 3/8”-16 male	1	13.72	13.72
	1” ball ¼”-20 male	1	9.06	9.06
	1” ball ¼”-20 female	1	10.09	10.09
Stock	¼”x1.5”x36” Aluminum stock	1	13.32	13.32
Miscellaneous	Epoxy	1	4.99	4.99
	Camping Pad	1	7.88	7.88
	Subtotal			205.56
	Shipping		4.44+10.96+13.50+4.80	33.70
	Total			239.26