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Ultrasound-Guided Regional Anesthesia Nerve Block Simulator

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Regional Anesthesiology Nerve Block Simulator

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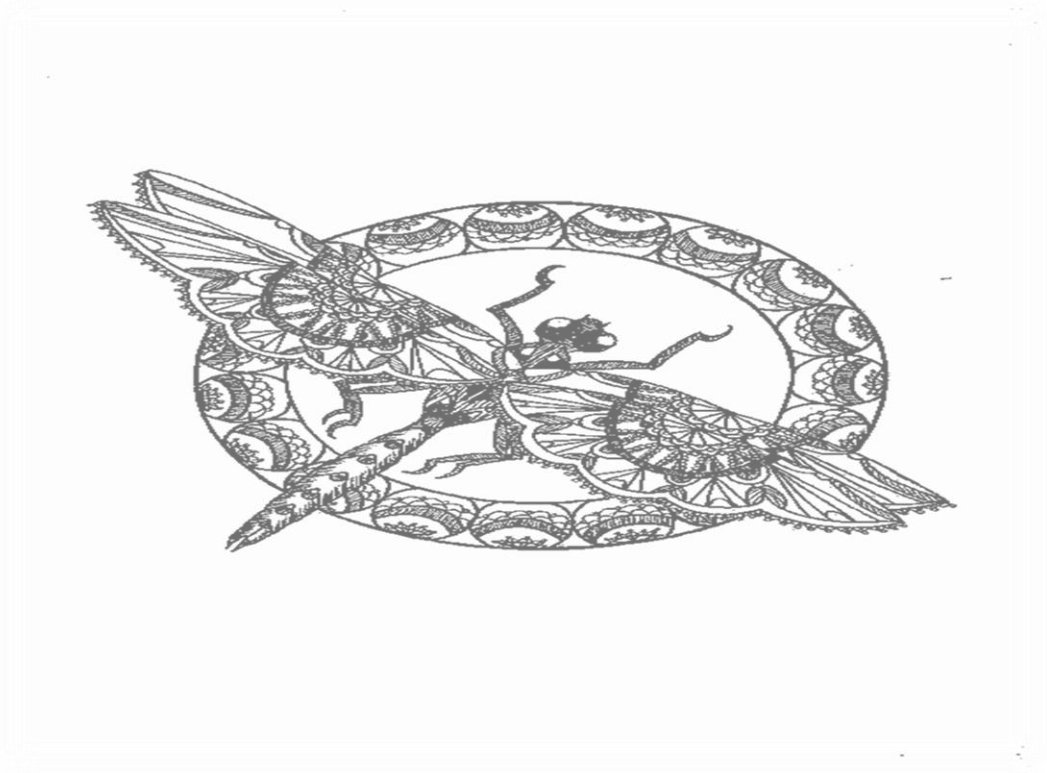

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Executive Summary:

The purpose of this senior design project is to come up with a novel design that acts a model for an ultrasound-guided supraclavicular brachial plexus block procedure. This model will be a gel that models the tissue and anatomy of a human in the supraclavicular area. Also, it should be able to reproduce a lifelike ultrasound image. This would be ideal for resident anesthesiologists who need to practice the nerve block procedure during their spare time. This will allow them to become better at the procedure, and not take as long or stick the patient as much.

Work Breakdown Structure:

Phase #1

1) Understood stakeholder needs
    a) Met with Dr. Langdon and discussed preliminary needs
    b) Shadowed Dr. Langdon to observe nerve block procedures
    c) Closing Event: Finalized needs with Dr. Langdon
2) Defined the system functions and requirements
    a) Understood how a nerve block procedure works
        i) Shadowed Dr. Langdon
    b) Met Dr. Langdon and discussed required functions of model
    c) Dr. Langdon and the group met and discussed the device and what it should be able to do. He described the procedure and how the device should be able to simulate each important step. Dr. Langdon specified that the device must be geometrically correct. Also, the device must feel like the real thing. Thus, the different layers of tissue must well represent and the tension of putting the needle through each layer must be accurate. The

densities of all structures must be completely accurate as well because that is what will result in the ultrasound image. He pointed out that the last important step is to have a way to inject the liquid and remove it when finished. Another goal would be the accurately represent the pulse of the arteries but this is a want and not a need.

d) Closing Event: Met with team to finalize system requirements

Phase #2

3) Generated design concepts, including models or roughs
    a) Researched anatomy of areas of interest
    b) Understood model requirements
    c) Researched necessary materials
        i) Researched physical properties of anatomical structures
    d) Researched manufacturing processes
        i) Chose most appropriate manufacturing processes for different structures
    e) Closing Event: Shared research with all team members
        i) Chose most appropriate materials and processed with team members
4) Evaluated alternative solutions
    a) Determined the reasons for the need for alternative solutions
        i) Determined what is wrong with the current design
    b) Researched alternative designs
    c) Researched alternative manufacturing processes
    d) Closing Event: Met with team to share individual research
5) Selected among alternatives
    a) Met with stakeholders to share research

i) Got input from stakeholders on how alternative solutions can satisfy requirements

b) Closing Event: Met with team to decide on alternative design if necessary

Phase #3

6) Developed a preliminary design
   a) Confirmed that solution satisfies all functions and requirements
   b) Confirmed that model can be manufactured using a previously agreed upon method to manufacture components
   c) Confirmed that the anatomy of areas of interest has been correctly determined
   d) Closing Event: Contacted manufacturers to confirm that their facilities can be used

Phase #4

7) Prepared a model or prototype
   a) 3D printed of a prototype model
   b) Casted the model by appropriate technique
8) Tested and evaluated the design
   a) Evaluated the prototype for fluid drainage and the right tissue feeling
   b) Tested the model at the hospital
9) Improved the design
   a) Re-evaluated the model for possible issues and malfunctioning

Phase #5

10) Built final device
   a) Built the final model by the previously agreed manufacturing technique
11) Communicated the design

a) Discussed and evaluated the final device with stakeholder and the class instructor

Background:

Ultrasound simulator is a Regional Anesthesia Ultrasound Training Block Model. The regional anesthesia ultrasound training model is an excellent training tool for assisting clinicians develop, practice and maintain the skills necessary to use ultrasound for guiding regional anesthesia, vascular access, and nerve blocking procedures. This ultra-durable ultrasound-training model assists clinicians in the acquisition and interpretation of Sonographic images of nerves as well as developing the psychomotor skills of guiding needles to simulated nerves and vessels in the human patient.

This medical ultrasound-training model is constructed from a polymer ultra-durable tissue and is extremely realistic in ultrasound imaging characteristics and feels like real human tissue. The ultrasound guided regional anesthesia peripheral nerve block ultrasound model contains simulated vessels and nerves. The position of the nerves allow for users to evolve their ultrasound procedural techniques from acquiring and targeting solitary nerves to more advanced techniques involving targeting multiple nerves.

Designed for new users as well as more experienced users who are refining their procedural skills. The vessels and nerves can be accessed using ultrasound guidance. Simulated anesthetics can be injected into the model to verify needle tip location and to practice the entire regional anesthesia procedure. Fluids are automatically expelled so that the model can be used repeatedly for training.

This medical simulation trainer will perform well using any ultrasound imaging system configured with the appropriate transducer (recommended ultrasound transducer; high frequency linear array ultrasound probe 5.0 – 12 MHz). Our uncompromising quality allows clinicians to utilize the model and repeatedly practice the procedure without the high costs of replacing disposable parts. This ultrasound model is excellent for specialties including anesthesiology (anesthesiology), emergency medicine, radiology, surgical training programs, ultrasound training programs, simulation centers, surgical skills

centers, medical education facilities, and ultrasound manufacturers for ultrasound education and demonstrations.

Problem Definition:

Functions: The system serve the single purpose of enabling anesthesia physicians to practice nerve blocks in up to three different procedures.

Performance Requirements: The system has many different performance standards that all relate to making the simulation of the procedure as real as possible. The first is to have the device feel just like human flesh. In addition the device must also be able to perform the "pop" noise when the needle enters the fascial layer. In relation to these requirements the device is able to withstand the needle prick thousands of times to make it reusable and efficient. Another performance ability of the device is to be able to inject the needle contents into the device and be able to expel the contents when the procedure is finished. This serves to make the procedure more real and reusable as well. Lastly, the device is able to perform in work with an ultrasound. This step is crucial because it is how the physician guides the needle.

Interface Requirements: The interface of the device will look just like a gel block. The physician can interact with the device by holding the ultrasound probe to the location desired and insert a needle into the desired location on the device. The physician is also able to interact with the device by initiating the drainage mechanism.

Non-Functional Requirements: The device have a high reliability. The device does not have any issues with the placement of the anatomical structures, as this would mislead the physician and not result in he or she learning the proper procedure. The drainage mechanism does not fail. If the injected contents are not removed from the device the device cannot be used again. Finally, the gel of the tissue is able to withstand the test of time and use. We envision at least a 5-10 thousand-use life to start with although this would be

hard to test initially. There do not seem to be any special safety considerations outside of the obvious (do not eat, use near open flame, etc.).

Enabling Requirements: It was produced on a low cost and fast level. The testing of the device was also relatively simple, as one would just need a physician to verify the anatomical structure placement and compatibility with the ultrasound. Based on the nature of the device, if a product fails it would need to be replaced. Besides the drainage mechanism, there will not be much on the device that would be "replaceable" without replacing the entire device. This is a con but as it is a closed gel block there is not really a way around this. When the device has finished its life we envision it being recyclable.

Constraints: The constraints of this device were mainly two things: the life of the device and how real the procedure simulation is. The life of the device will most likely end up being related to the cost. We were sure that we could make the device durable for a decent length of time, but to increase the life further would mean using more expensive materials. Unfortunately, the simulation can only be so real, and nothing will ever be exactly like the real thing. Thus, we got the device to operate on a level that makes the simulation as real as possible.

Concept Development

Original Ideas

- Minimal External Life-likeness

  The purpose of this feature was to reduce costs and complexity of the device. After consulting with the stakeholders the most important external landmark is the clavicle bone, and really the only one needed. Thus we wanted our device to include this but not much else.

- Anatomically Correct Ultrasound Image

The purpose of this was to ensure a correct simulation of the procedure. This was an original design because the models lower in cost were not anatomically correct. By only including the necessary landmarks but also being anatomically correct, our device was the first like it in the market.

- Simulation of Fascial Layer Pop

  Once again the purpose was to correctly simulate the procedure; more so than any other product on the market as none others simulated this "pop". Our first model included some IV tubing and a flexible material but came nowhere near to simulating the correct feel. A hollow space (gel then air, no barrier) was the tried but not implemented because of not finding a way to include a drainage system. Our final design used a Tyvek sheet rolled into the correct dimension and then coated with DragonSkin. This correctly simulated the correct feel of the fascial layer.

- Correct Simulation of Tissue Expansion

  We needed the nerve bundle to be able to expand when injected with the material, and for this expansion to show up correctly on the ultrasound. Our first idea was to fill our nerve bundle with gel in the hopes that it would expand but this idea failed. In the end we constructed our nerve bundle to be a sealed pressurized tube. When injected the tube would will even more and expand. A drainage system was included to drain the amount that was added during the procedure.

- Pulsing of Artery

  We wanted to include this feature to help the physicians find the nerves. At first we wanted to include and automatic pulsing but were unable to do so. We ran out of time so

this feature was not included, but a simple pump and tubing connected to the device could simulate the pulsing of the artery in future work.

Standard Ideas

- Correct Tensile Strength of all Layers

  The purpose of this was to make the model as correct as possible. The skin needed to resist more than the subcutaneous fat layer and the fascial layer also needed to give the correct resistance (see "Fascial Layer Pop" above). This resulted in us researching the tensile strength of human skin and fat. After determining these facts we then researched the gel market for gels that would correctly match this. DragonSkin was used resulting in the correct resistances but was not compatible with the ultrasound. Eco-Flex was then used because it did work with the ultrasound. However, we did have to experiment with adding more silicone thinner to make the resistance correct.

Product Description

The cross section of our model accurately matches the cross section of the area surrounding the brachial plexus nerve bundle. The cross section of the area surrounding the brachial plexus nerve bundle is shown below (Figure 1a) and the cross section of our model is shown below in Figure 1b. In our model, the brachial plexus is the structure on the far left with the subclavian artery directly adjacent to the brachial plexus nerve bundle. The subclavian vein is further to the right of the subclavian artery.

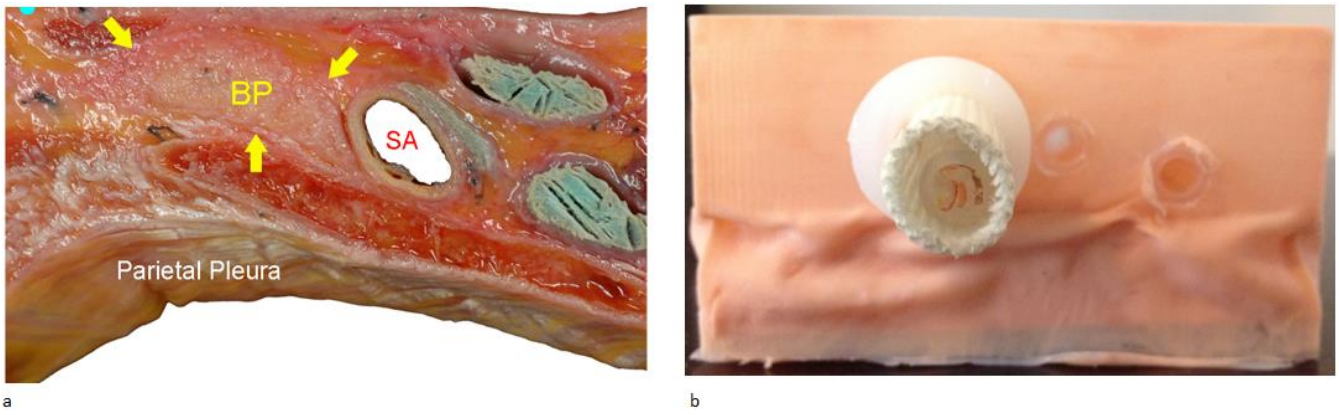

Figure 1: (a) The actual cross sectional anatomy of the area surrounding the brachial plexus nerve bundle. This is what we want our model to look like from the side. (b) Side profile of our model displaying how the cross section of our model accurately matches the cross sectional anatomy of the area surrounding the brachial plexus nerve bundle.

The components used to make the model were the Ecoflex material, which made up the bulk of the model by simulating the tissue of the area, the brachial plexus structure which was created using Tyvek, the subclavian artery and nerve which were also created using Tyvek, and a 3D printed ABS plastic “lung” piece which was used to simulate the presence of the lung in the ultrasound if the ultrasound was able to penetrate the model to that depth. The components were integrated by using a 3D printed plastic mold (Figure 2) that could hold all the structures together. The mold consisted of two pieces that were placed together when creating the model and could be separated once the model was created so that the model could be removed from the mold.

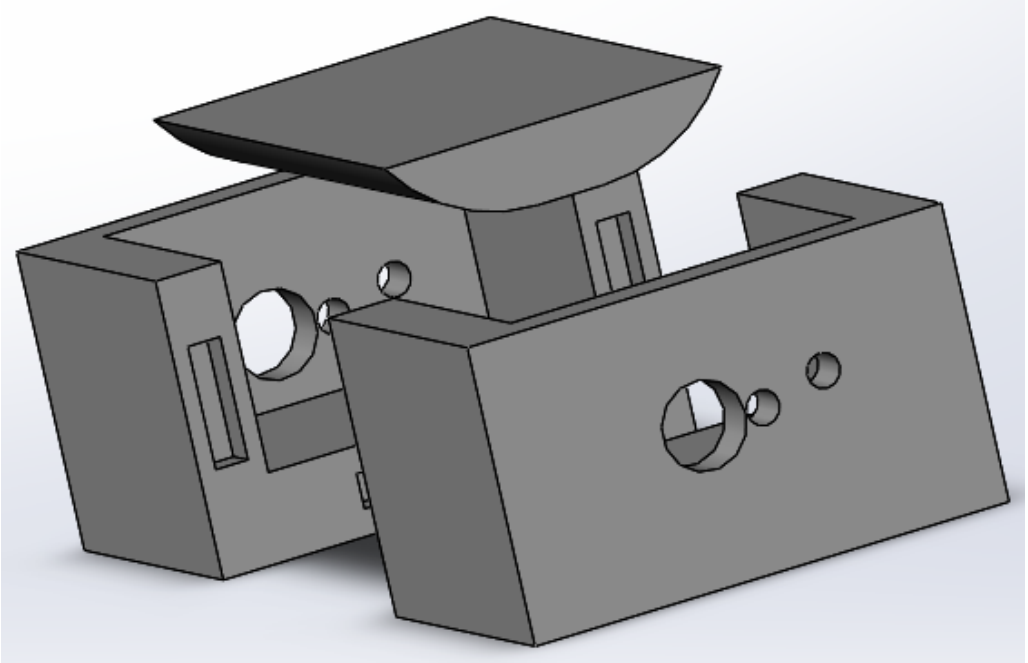

Figure 2: Shows how the two pieces of the mold can fit together in order to create the model. The lung piece is integrated into the top of the mold after the Ecoflex gel has been added so that it can create an accurate ultrasound.

After the mold was put together the inside of the mold was coated with a combination of materials called Dragonskin and Thivex, which were used to made the skin which made up the outside of the model. The internal structures were added (Figure 3) before the Ecoflex material was added to the model.

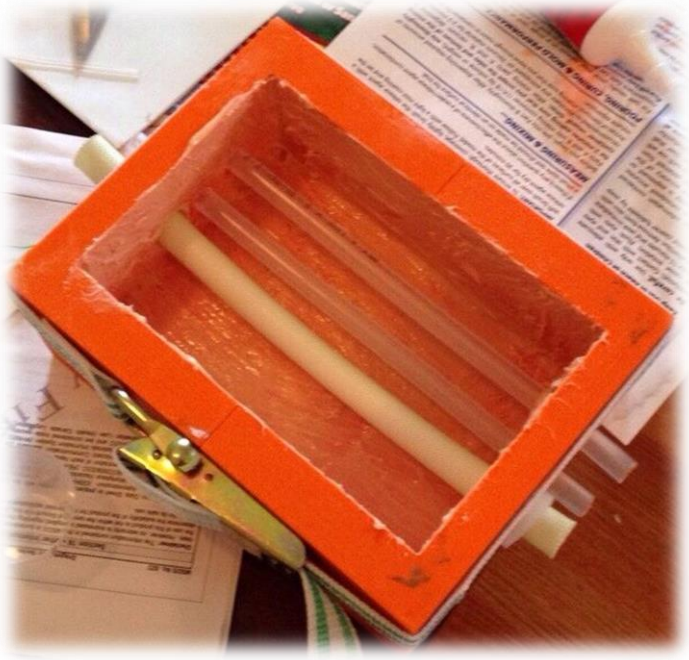

Figure 3: Shows the inside of the mold coated with Dragonskin and Thivex and the internal structures that been added to the mold by being held in the holes in the sides of the mold.

One issue that held back the quality of our first model and would have significantly worsened the quality of future models was the size of the lung piece that was integrated into the model. As shown below in Figure 4a the lung piece was made to fit perfectly inside of the mold. When this piece was designed in SolidWorks we did not consider that the inside of the mold would be lined with Dragonskin and Thivex which made it impossible to fit the lung piece inside of the mold without damaging the skin layer. Also it made it so that it was impossible to place the lung in the mold and then fill the remaining space with the material used to make the tissue which resulted in an inconsistency in our model due to a large air pocket that was present just above the lung piece (Figure 1b). Figure 4b below shows how the revised size of our lung piece compares to the inside of the mold and this new piece allowed us to apply the Dragonskin and

Thivex layer to the inside of the mold and also allowed us to properly fill the mold with Ecoflex after the lung was placed in the mold.

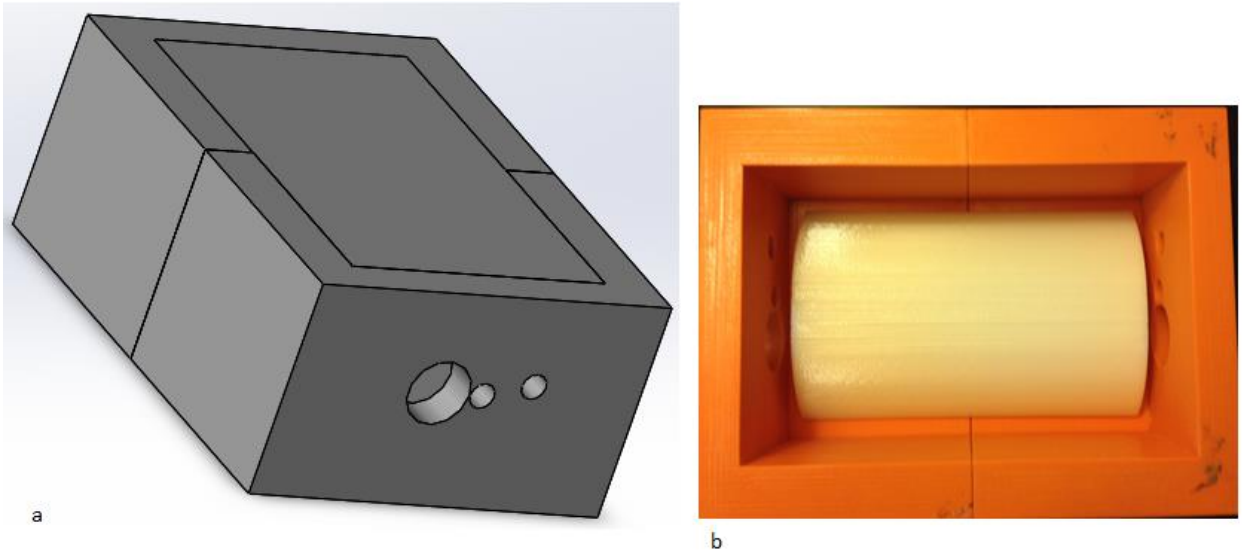

Figure 4: (a) The lung piece, represented by the rectangle on the top of the 3D model, fits perfectly in the mold with no room on the sides. (b) The revised lung piece fits inside of the mold with plenty of room on the sides for the Ecoflex material to flow by and also leave the skin layer undamaged.

The novel feature of our model was the tactile sensation of the fascial plane which surrounds the brachial plexus nerve bundle. This structure was created by wrapping a piece of Tyvek around a metal tube which was then coated in Dragonskin material. This was allowed to dry and then the metal tube was removed. The ends of the structure were sealed by using Dragonskin and a thin plastic tube was integrated into the structure in order to allow liquid to be removed from the structure. Figure 5a below shows the final fascial plane structure before it was integrated into the mold and Figure 5b shows the materials used to create the structure.

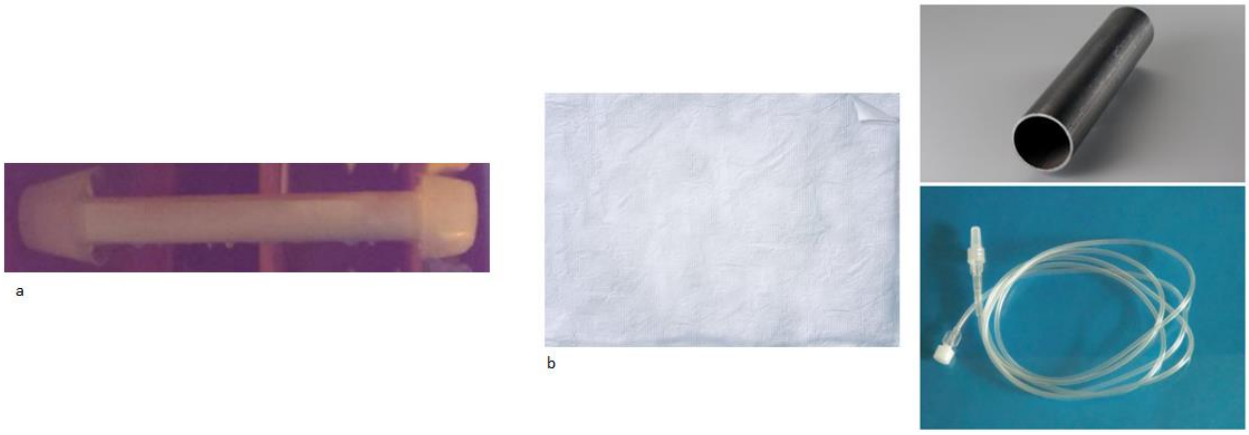

Figure 5: (a) The final fascial plane that we used before inserting it into the mold so that it could be integrated into the model. (b) The materials used to create the fascial plane: Tyvek, a metal cylinder, and small plastic tube.

During the entire manufacturing process we made three different models with changes made in each iteration. The first model (Figure 6) provided an inaccurate tactile sensation since we chose a poor material for the fascial plane. The lung piece was too large and created an inconsistency in the placement of the Dragonskin material that was used to create the bulk of the model and the Dragonskin material did not create a satisfactory ultrasound.

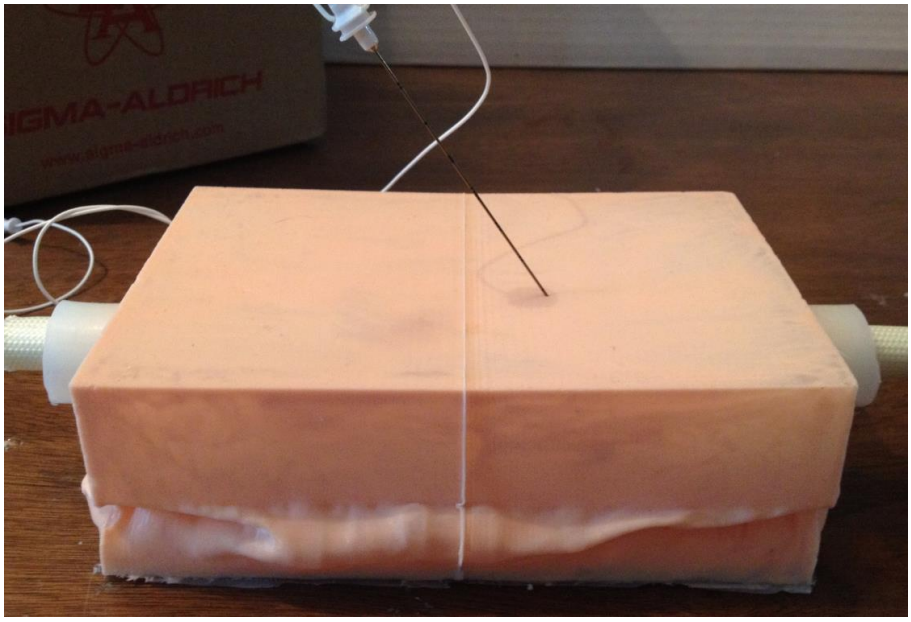

Figure 6: The first model that did not create a satisfactory ultrasound and had a large air pocket inside due to the size of the lung.

The second model created an accurate tactile sensation but the placement of the fascial plane was inaccurate because we changed our manufacturing process and did not successfully place it correctly. We also switched from Dragonskin making up the bulk of the material to Ecoflex. In Figure 7 below we can see that the placement of the needle is slightly different from the placement of the needle in the previous model due to the placement of the fascial plane. As a result the needle had to penetrate deeper than normal to reach the fascial plane. This model created a much more accurate ultrasound than the previous model and the needle was easily viewable in the ultrasound. Also the material was consistent throughout since the lung small enough to allow for the Ecoflex material to pass through it.

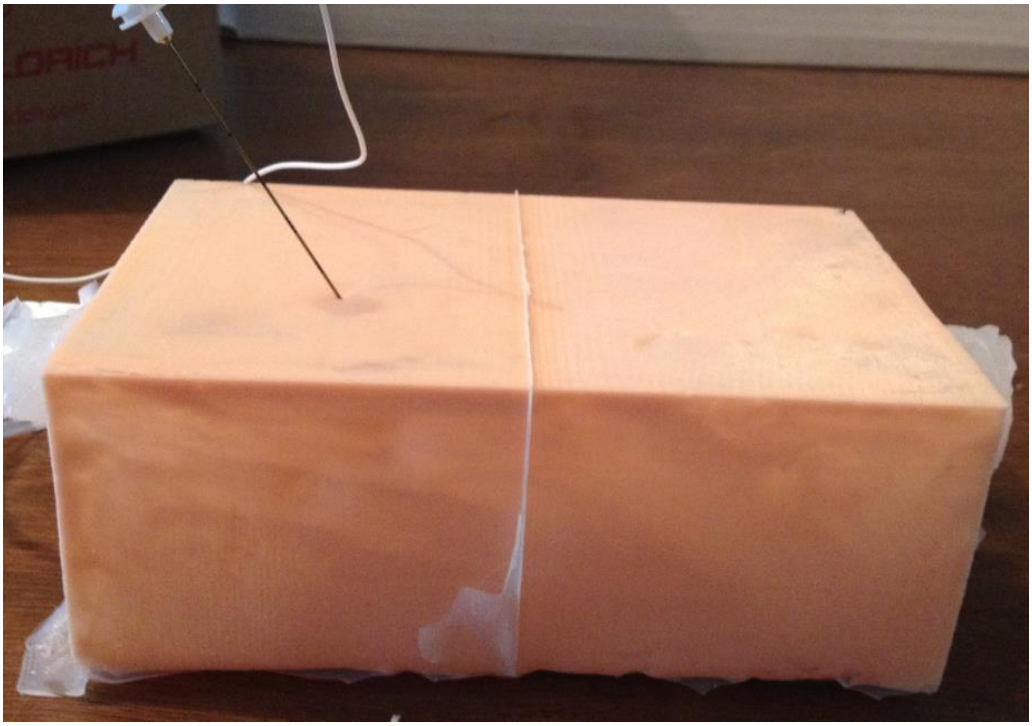

Figure 7: The needle needed to penetrate much deeper in the model before reaching the fascial plane.

Our final model created an accurate tactile sensation and the placement of the fascial plane was correct since we reverted back to our old manufacturing procedure. The depth of the needle can be seen below in Figure 8. However this time the ultrasound was not as accurate as the second iteration because there were many air bubbles present in the Ecoflex material.

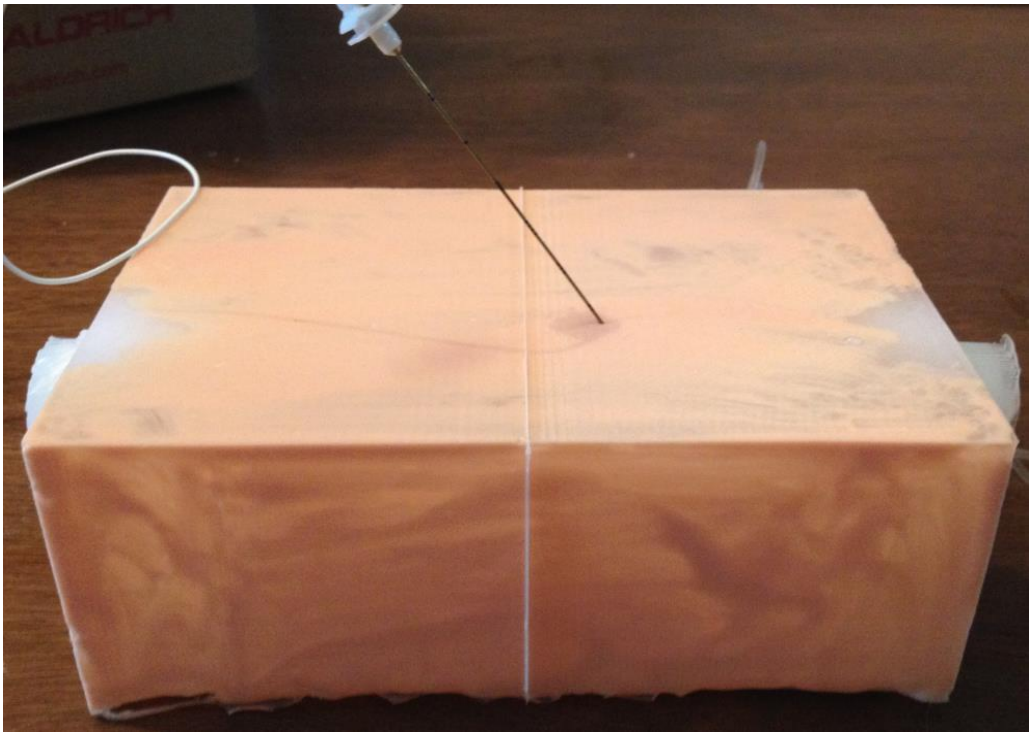

Figure 8: The needle does not go as deep as the second iteration indicating that the placement of the fascial plane is correct.

When analyzing the ultrasound of the model we were looking for the brachial plexus nerve bundle, the subclavian artery, and the subclavian vein. If the ultrasound went deep enough we would also be able to see the lung but that would require using a lower resolution ultrasound. Figure 9a below shows the ultrasound of the actual anatomy of the area and Figure 9b shows an ultrasound of our second model which is centered on the brachial plexus of our model.

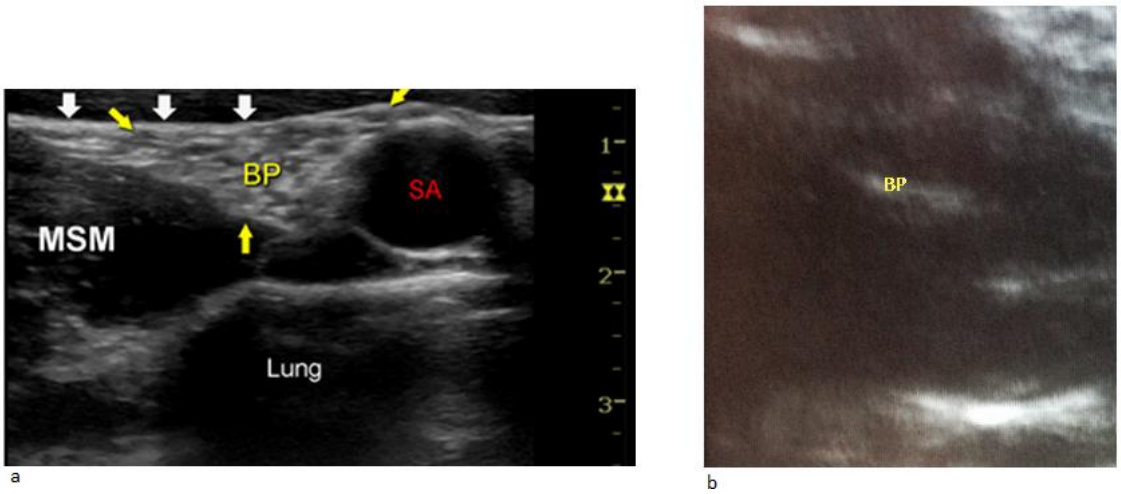

Figure 9: (a) An ultrasound of the actual anatomy of the area surrounding the brachial plexus. (b) The brachial plexus of the second iteration of our model.

Design Evaluation:

One of the functions that our model needed was that it needed to appear on ultrasound well and life-like, as the procedure is done with an ultrasound. Our model appeared on the ultrasound, and the brachial plexus, artery, and vein were pretty much visible. Also, it was very easy to see the location of the needle on the ultrasound. There was a problem with artifacts appearing on our ultrasound, as it is hard to produce the exact human-like picture. Also, we wanted our model to feel human-like as well. This was a problem because he had to sacrifice the ultrasound image for the feel being life-like. Resident anesthesiologist and our stakeholder evaluated our model. They said that the gel felt pretty life-like, but was a little denser than real human tissue. When we tried to improve this and use thinner, the model had more artifacts on the ultrasound. Also, another function our model needed to have is the tactile sensation, or "pop," felt when the needle goes through the fascia layer. This "pop" lets the physician know when they have entered in the correct part of the brachial plexus. Our stakeholder said this felt correct, and he could feel the "pop" when the needle went through the model's fascia layer. Another function that our model had to have was the ability to inject and empty fluid into the brachial plexus. This part of our model worked perfectly. A needle can be inserted into the brachial plexus, and any amount of liquid can

be injected. Then, there is a tube that is inside the brachial plexus, which comes out of the model and is attached to a syringe. This syringe is filled with the same amount of liquid injected, and can be detached and emptied after the procedure is complete. Another feature that our model need is anatomical correctness of the vein, artery, and brachial plexus. This was accomplished successfully by putting notches in our mold before it was 3D printed.

The total cost to replicate prototypes would be around $100 for each additional model. This is because our prototype cost around $400 to make with all of the materials in it, but about $300 of that is reusable materials. Therefore, each additional model will cost only about $100. This is relatively inexpensive compared to other models on the market. Medical simulation devices can easily cost a few thousand dollars. Therefore, we would be able to offer our model to hospitals at an affordable rate that they would be likely to buy.

Overall, this senior project has been beneficial and taught all of us a lot of lessons and experiences. Our model has steadily improved the more that we have worked on it. I believe that we accomplished all of the goals that we set out to, and we produced a product that could be used in the medical world. The more we continued to work on our model, the more that it improved. It could be used by residents across the country and help them train for the supraclavicular nerve block procedure. The model satisfied the functions laid our to us last semester by our stakeholder, and worked well in the end.

Recommendations and Future Work:

Our model is the only model like it on the current market, so there are no competition models. Therefore, it could become very profitable, as it would be very beneficial to any resident anesthesiologists. Our model will help residents get a feel for the procedure before they have to do it on real patients. Residents liked our model and it has a good ultrasound image and feels lifelike and operates well. Our model could potentially have a widespread impact as any resident could use it to train.

There is some future work that could be done on our model to improve it. One thing that would be good to add is pulsation in the artery. Physicians use the pulsation to help identify the brachial plexus, so having it would improve our model. Also, we could continue to work on the feel of the tissue to make it even better. This would include making the gel mixture feel better and also appearing more accurate on the ultrasound screen, with fewer artifacts. Another improvement we could make would be making a new 3D-printed mold that has a neck, shoulder, and clavicle imprint. This would add some external landmarks for the residents to identify without increasing the cost of the model. As we continued work, we would continue to consult residents on ways to improve the model. As well as this, our model could be expanded to other applications. We could use the same concepts to produce other nerve block models, or any other ultrasound-guided procedure.

It would take around another 4-5 months to get the prototype completely perfect with the current manpower available and the current time spent on it. Also, the additional cost may be around $2,000 for additional materials, 3D printing, etc.

As stated before, our product could potentially become very marketable, and be a widespread commodity in hospitals across the nation