Hip Aspirate Model to Teach Physicians

BME 300/200
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Abstract

Septic arthritis is a buildup of synovial fluid on the femoral head due to bacterial infection–an urgent situation resulting in permanent joint damage if left untreated. The rarity of pediatric septic arthritis makes it difficult to train new physicians in safely and efficiently performing the hip aspiration procedure to diagnose and treat the condition. There are currently no models on the market that can be used to teach the aspiration procedure on a pediatric hip. This team's goal is to create a model to effectively train resident physicians in the procedure. The design uses artificial tissues that mimic the mechanical properties of real human tissue and are molded around an artificial hip joint. The design also incorporates all anatomical features relevant to the aspiration procedure. A modified syringe was created to simulate the pressure of aspirating infected fluid from the hip joint. The model's artificial joint capsule exhibits a Young's modulus below the target range of the native ligaments by a factor of ten, however, the modulus of the artificial fat is comparable to that of human fat tissue. There was not enough material available to include a skin layer on the model. The reusability of the model exceeds the goal based on self-healing tests. Overall, future work on the project should focus on ultrasound testing and the fabrication method of the joint capsule, as that has proven to be the most challenging part of the project.

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I. Introduction

Septic arthritis is a painful infection that causes a buildup of excess synovial fluid in the joint. When the affected joint is a hip, this buildup occurs around the femoral head. In the general population, there are about 2-10 occurrences of septic arthritis for every 100,000 people [1], [2]. About 20% of these cases occur in the hip [3]. Since this is a relatively uncommon condition, residents training to become orthopedic surgeons often receive little clinical exposure to the aspiration procedure. Septic arthritis of the hip, however, is an orthopedic emergency when it occurs in a child. Postponing fluid aspiration increases fluid buildup, blocks off the blood supply, rapidly degrades cartilage, deforms joints, and ultimately causes bone loss. These dangerous effects begin occurring after 5-7 days of infection. Patients whose treatment is delayed greater than a month have decreased chances of successful recovery and an increased chance of permanent bone deformation [1]. The most commonly affected groups are infants (aged 1-2 years) and the elderly (65+) [4].

Currently, Kyoto Kagaku has an infant hip sonography training phantom on the market. Anatomically, this model is very accurate. It represents the full body of a 6 week old and has adjustable joints and soft limbs. The femoral head, joint capsule, labrum, hyaline cartilage, and acetabulum can all be seen using ultrasound (US) imaging [5]. Their models are, however, expensive, priced at $4300 each. It would be difficult to replicate with the given budget of $500 and the lack of design information made publicly available. Additionally, the Kyoto Kagaku model is meant for practicing the diagnosis of developmental hip dysplasia, rather than treating septic arthritis.

There are currently no known existing products on the market to specifically stimulate the hip aspiration procedure. A pediatric hip base model will be developed using ultrasound and X-ray compatible materials that mimic the properties of human flesh. A model will be developed to mimic the hip joint with synovial fluid build up caused by infection. This will accomplish the ultimate goal of increasing the rate of successful surgeries by providing a hands-on, lower risk opportunity for orthopedic surgical residents to practice the procedure with surgical and anatomical accuracy.

II. Background

The most common, effective, method of diagnosing and treating pediatric septic arthritis involves aspiration of infected synovial fluid from the hip followed by the use of high dose oral or paternal antibiotics [2]. The aspiration procedure is performed under the guidance of X-ray fluoroscopy or ultrasound. The fluid is typically withdrawn using a 3.5 inch 20 gauge needle. The three main approaches for hip aspiration are the anterior, medial, and lateral approaches–the anterior approach is the most common [6]. It is important for the surgeon to avoid the femoral vein, artery, and nerve while performing the aspiration procedure to minimize patient discomfort. These anatomical features are typically located in the medial portion of the hip [6]. For the anterior approach, the pulse of the femoral artery is palpated and an entry point is marked approximately 2.5 centimeters lateral to the artery [7]. Local anesthesia is then administered and

the skin is prepared for the procedure [6]. The needle can then be guided towards the medial or lateral junction of the femoral head and neck, at the surgeon's discretion [6]. The needle is advanced into the joint capsule until it contacts bone where the aspiration is performed [6]. The joint capsule consists of fibrous ligament tissue lined with the synovial membrane, all enclosing the ball and socket joint formed by the femoral head and acetabulum (Figure 1, below) [6].

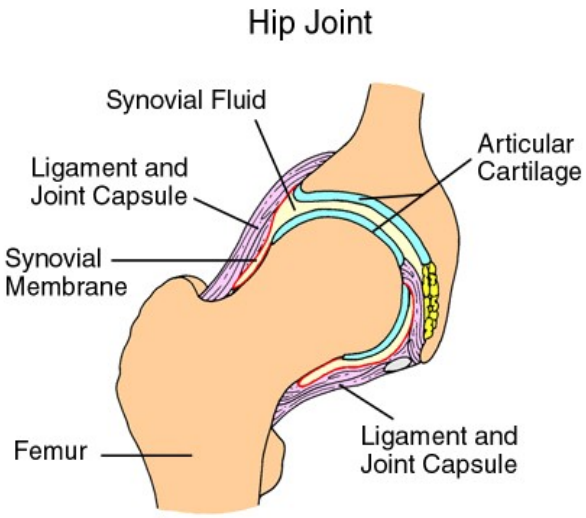


Figure 1: Hip Joint Anatomy [8]

Ball and socket joint of the hip formed by the head of the femur and the acetabular.

Client Information

Dr. Matthew Halanski is a board certified orthopedic surgeon and faculty member at the University of Wisconsin School of Medicine and Public Health. He completed his fellowship in pediatric orthopedic surgery and had interests in both clinical medicine and orthopedic research.

Design Specifications

The ultimate goal of the client is to create a base infant model that he can use to train resident physicians to perform the ultrasound guided hip aspiration. The client also requested the model provide the option to practice the anterior surgical approach to the hip. The current design team has chosen to focus on the aspiration model due to time constraints and the fact that aspiration is more commonly practiced than the anterior surgical approach.

The model must accurately resemble an infant hip for the aspiration procedure. It is important that the artificial tissues used resemble human tissue when viewed under X-ray and ultrasound. Specifically, the artificial tissues must have acoustic impedance values similar to that of native tissues. The fat mimic should be made of a material with an acoustic impedance close to 1.34 MRayls, the vein and artery should have the impedance of blood, 1.65 MRayls, and the

joint capsule ligaments should be about 1.71 MRayls. The Young's moduli of the materials should also mimic those of native tissues. Namely, the skin mimic should fall in the range of 150-250 kPa, fat mimic 25-60 kPa, and joint capsule material 1.5-4 MPa. All anatomical structures relevant to the procedure, including the femoral vein and artery, should be represented in the model. The model must last for at least three months with four practice sessions per month before any replacements are needed. The model should be able to accommodate 15 needle sticks per hour long practice session. The model should accurately model the size of a pediatric hip with a femur length of 18-20 cm and a weight of approximately 6 pounds or 2.72 kg [5]. A budget of $500 is available for the project.

The spring 2016 design team who worked on this project produced a functioning prototype that produced clear images of distinct layers of skin, fat and joint capsule as well as of bones and the needle when viewed under ultrasound. However, the model had to be submerged in water to produce any images because the coupling gel alone wasn't sufficient enough to establish connection between the different layers [9]. In addition to increased ultrasound compatibility, the product needs increased anatomical accuracy, more pleasing aesthetics, and greater reusability as mentioned above, before the product can be made marketable. Further details of the design specifications is included in Appendix A.

III. Preliminary Designs

Based upon the culmination of previous teams' work and research performed, the following designs were created. All the designs would use materials that were previously established as an effective substitute for the respective tissue. Various mixtures of silicone gel and cellulose powder would be used for the fat, muscle, and skin mimics [9], [10]. A radiopaque model of a pediatric hip and femur would be used as the support structure. The hip capsule would be made of self-healing polyurethane [9], [10].

Fluid with Electronic Feedback

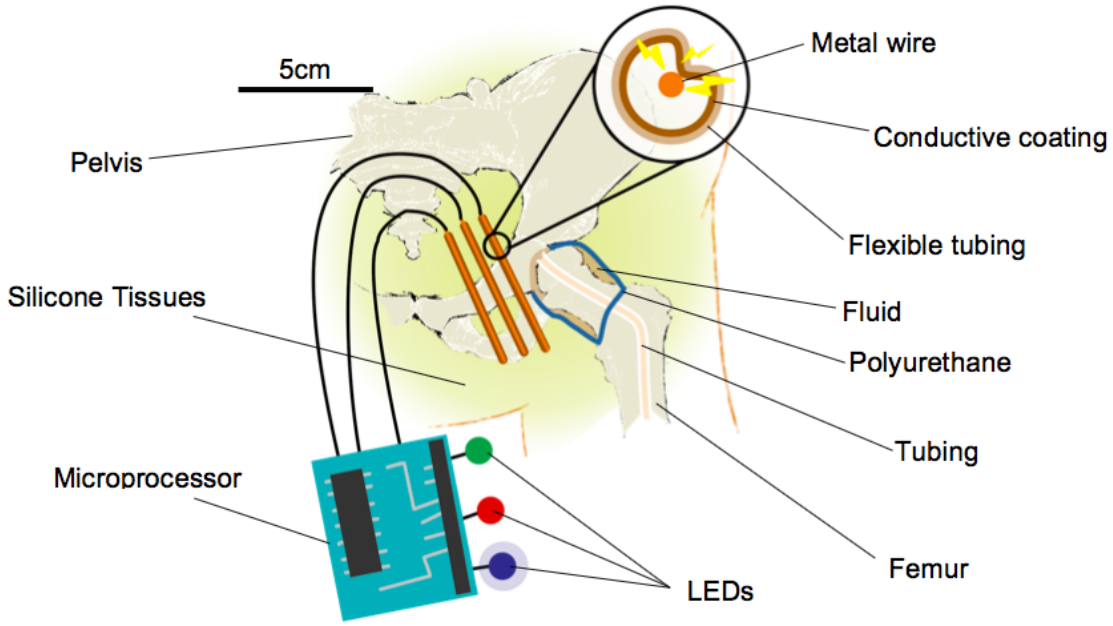


Figure 2: Fluid with Electronic Feedback

Preliminary design utilizing a pressure-sensitive electronic feedback system. The pressure-sensitive sensor is a flexible tube with a conductive coating on its inner surface. When the coating contacts the wire within the open space of the tube, a signal is sent to the microprocessor. The microprocessor is not drawn to scale.

Fluid would be aspirated from the hip capsule by needle. Following the procedure, the fluid would be replaced through a polymer tube threaded through the femur that opens into the space. Mineral oil was chosen as the fluid because of its antimicrobial properties and inability to conduct electricity. The non conductive property is important because the model also contains a pressure-sensitive electronic feedback system. When pressure from the needle completes the circuit, the system, would signal a microprocessor to light an LED corresponding to the anatomical feature (femoral vein, femoral artery, or femoral nerve) that was inappropriately struck (Figure 2).

Fluid Without Electronic Feedback

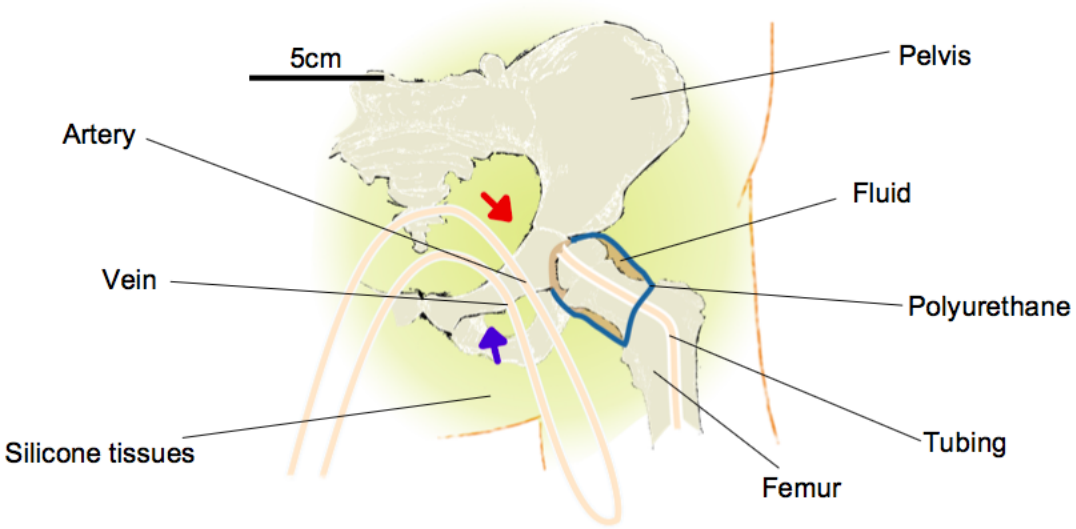


Figure 3: Fluid Without Electronic Feedback Design

Preliminary design utilizing fluid for aspiration and as a feedback system. The pulse would be simulated by pumping fluid through a flexible tube. The tube loops down over the pubis as the artery (pushing fluid distally), loops around the femur, and then goes back over the pubis as the vein (pushing fluid proximally).

This second design (Figure 3) was created so the resident physician would be able to feel the pulse of the representative femoral artery as physical feedback. This also has the benefit of appearing on color Doppler ultrasound. Color Doppler US is used to see movement of blood within the body by superimposing color over the grayscale ultrasound image. Fluid fills the joint capsule space using the same method noted in the previous design (Fluid with Electronic Feedback, p6).

No Fluid with Electronic Feedback

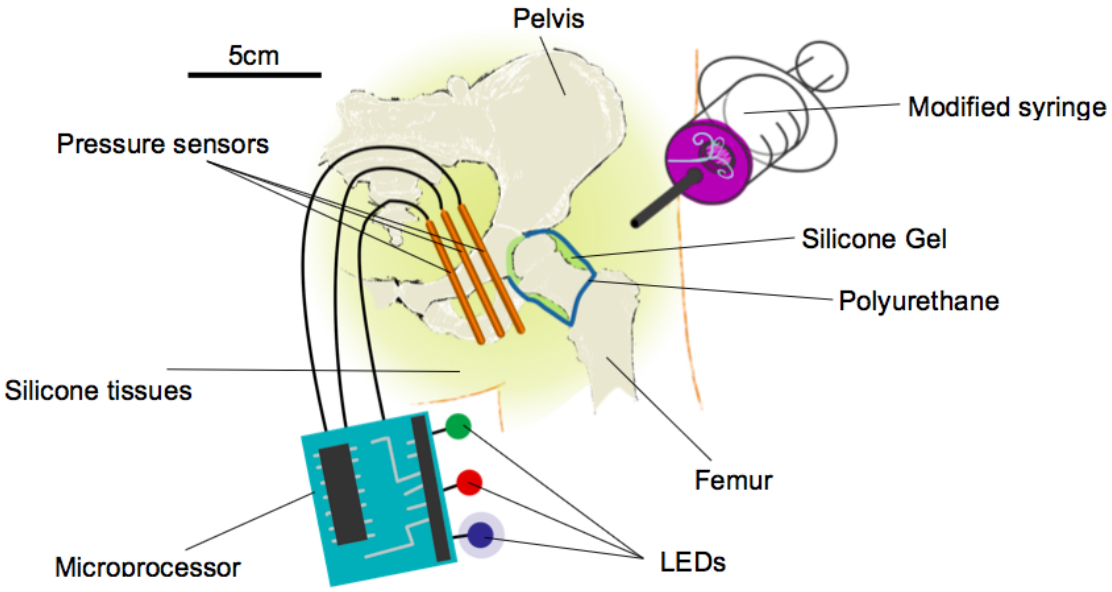


Figure 4: No Fluid with Electronic Feedback Design

Preliminary design utilizing a modified syringe and a pressure sensor. The microprocessor, syringe, and needle are not drawn to scale. See Figure 2(p 6) for more detail on the pressure sensor function. See Figure 5(p 9) for labeled components of the modified syringe.

Unlike the previous designs, this does not have fluid within the joint capsule. Instead, it has a viscous silicone gel. A modified syringe with a hole in its body will contain a one-way valve that would resist the withdrawal of air, providing similar resistance to the aspiration of the fluid from the joint capsule. This model would have the same electronic feedback method as previously noted in the Fluid with Electronic Feedback design (p6). The proposed design is shown in Figure 4.

No Fluid Without Electronic Feedback

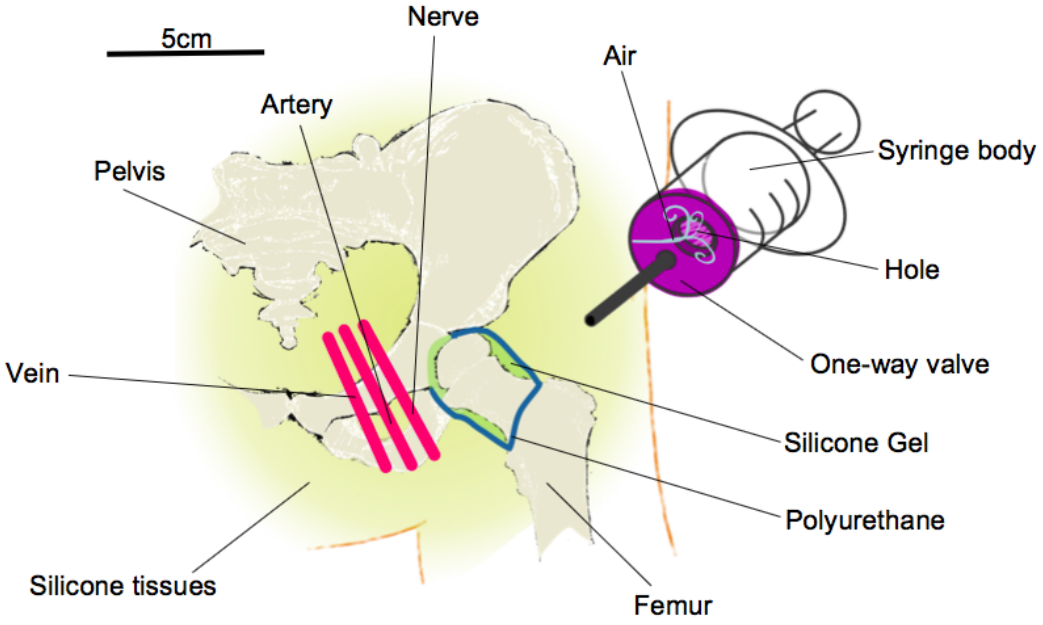


Figure 5: No Fluid Without Electronic Feedback Design

Preliminary design focusing on tactile feedback. Polyethylene rods represent additional anatomical features of interest (femoral vein, artery, and nerve). The modified syringe is not drawn to scale.

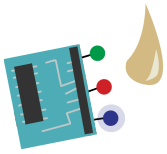
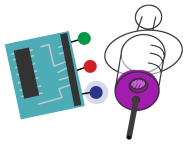
The modified syringe and gel-filled capsule are also used with this model. The femoral vessels and nerve would be represented by polyethylene rods in this design (Figure 5). Tactile feedback would be provided if the needle were to strike the hard rods. The rods would also be coated in a dye that would stick to the needle so it can be seen that a vessel or nerve was hit when the needle is removed. Polyethylene has similar acoustic impedance to blood, so the rods would appear on ultrasound and X-ray similarly to real blood vessels.

IV. Preliminary Design Evaluation

Design Matrix

Table 1: Design Matrix

The highlighted boxes indicate the highest scoring design(s) for each criterion. The initial scoring is out of five (shown in gray), the weighted score is to the right of the initial score.

Design / Criteria (weight)	Fluid with Electronic Feedback 		Fluid Without Electronic Feedback 		No Fluid with Electronic Feedback 		No Fluid Without Electronic Feedback 	
Anatomical Accuracy (20)	3/5	12	5/5	20	2/5	8	4/5	16
Surgical Accuracy (20)	1/5	4	5/5	20	1/5	4	4/5	16
Reusability (15)	2/5	6	2/5	6	3/5	9	5/5	15
Cost (15)	2/5	6	4/5	12	3/5	9	5/5	15
Ease of Fabrication (10)	1/5	2	2/5	4	1/5	2	3/5	6
Safety (10)	2/5	4	3/5	6	3/5	6	4/5	8
Aesthetics (10)	2/5	4	3/5	6	2/5	4	4/5	8
Total (100)	38		74		42		84	

* Scores are out of 5. Displayed as score | weighted score

Criteria

Anatomical Accuracy

Anatomical accuracy is defined as how closely the size, structure, and location of the model elements match human anatomy. This, along with surgical accuracy, is weighted highest because the purpose of a training model is to prepare physicians for what the procedure will really be like. All of the designs consist of a pediatric (age 2-5) size partial femur and pelvis. Therefore, the designs were ranked against each other based on the presence of synovial fluid, and the femoral nerve, vein, and artery.

Surgical Accuracy

Surgical accuracy is defined as how closely the procedure on the model matches the procedure on a human patient. This is also weighted the heaviest for the same reason as anatomical accuracy; the ultimate goal of the model is to increase the safety of the procedure by providing accurate practice experience for the residents. This includes the physical feel due to the mechanical properties of the materials. All designs incorporate the same cellulose, silicone, and smooth-on skin molds, thus achieving this criterion. The designs differ in surgical accuracy by having different ultrasound and X-ray compatibility. The real procedure will be guided by these imaging technologies, so the model will ideally be compatible with both, and the resulting images should appear similar to those of a human hip.

Reusability

Reusability is defined as the number of times the procedure can be performed on the model before parts need to be replaced. This is ranked second highest because, while it is possible to change parts in between uses, the goal is for the model to last 3 months with 4 practice sessions a month with 15 needle sticks per practice session.

Cost

Cost is defined as the combined price of initial fabrication components as well as any predicted replacement parts. Cost is also ranked second highest because there is a budget of $500 and the tissue materials used in every preliminary design are expensive, so there will be a very limited budget for the rest of the components.

Ease of Fabrication

Ease of fabrication is defined as the level of knowledge and skill required to fabricate the model and to replace any necessary parts. This criterion is not ranked highly because the goal is for components to be reusable–making fabrication and replacement a rare occurrence.

Safety

Safety is defined as the risk of danger presented to the physician by performing the procedure on the model. This includes the risk of electrocution as well as the risk of illness due to microbial growth. Safety is weighted low because the largest threat that the static model presents is the danger of harm from the needle the physician will be using, but this threat will be equally present in all four designs thus not a differentiating factor.

Aesthetics

Aesthetics is defined as the overall external neatness of the model, including realistic skin and body shape. Aesthetics also includes self-containment, meaning all electronics, pumps, etc. should be entirely encased within the model. This was also weighted low because the external part of the model is not what shows up on the ultrasound during the procedure.

Scoring

Fluid with Electronic Feedback

This design received a middle score for anatomical accuracy because the presence of fluid is more realistic. The fluid will mimic the physical properties of synovial fluid so that the resident will be able to use a real syringe and it will feel the same as the actual procedure. In contrast, incorporating an electronic feedback system is less realistic. The residents will have to rely on the visual (US/ X-ray) and physical feedback during a real surgery. They can't be dependent on a flashing light or buzzer to catch their mistakes.

This design received a low score for surgical accuracy because X-ray compatibility is crucial for this procedure and metal components would block X-rays. This outweighs the benefits of the experience of using real fluid.

The reusability is low because the fluid needs to be replaced after every use. There also needs to be maintenance on the electronic feedback system if it requires new batteries or rewiring. Electronic parts are also generally more expensive, and the continual repurchasing of fluid could add up, so this design has the lowest score for cost.

A low score was assigned for ease of fabrication because of the circuitry and medical knowledge that would be necessary. This also runs the greatest safety risk to the user because it combines electronics with fluids which could cause electrocution. Fluid alone also runs the risk of microbial growth over time. The low aesthetics score is due to the visibility of external wiring and circuitry.

Fluid without Electronic Feedback

This design received the highest score for anatomical accuracy because the presence of fluid and no electronics is most realistic. The fluid will mimic the physical properties of the synovial fluid, so when the residents practice, they can actually get the feeling of removing fluid from the membrane. Not incorporating electronics gives the residents more practice without relying on a feedback system because during surgery they will not have this. As mentioned before, residents can't rely on a flashing light or buzzers to catch their mistakes.

This design also scored the highest for surgical accuracy because it will be usable under X-ray and ultrasound without creating a problem for residents to see the components inside the joint capsule of the design.

The reusability is low because the fluid needs to be replaced after every use, which can get costly after time. While the ease of fabrication score was in the middle because there is no electronic feedback system to fabricate and code, but there is a pulse-simulating pump that would need to be fabricated instead. Safety also received a score in the middle because there are no electronics to run the risk of electrocution, but fluid can run the risk of microbial growth over time.

This design scored in the middle again for aesthetics because of the pump and tubes that will be sticking out of the design.

No Fluid with Electronic Feedback

This design scored lowest in anatomical and surgical accuracy because not only is there no synovial fluid or pulse like there would be in a human patient, the electronic components would also make the model not ultrasound or X-ray compatible.

This design received a middle score for reusability and cost because while there is no fluid to constantly replace, there is circuitry that may need to be fixed or replaced with many uses and would be more expensive to begin with.

It received a low score in ease of fabrication because it would require circuitry skills that the team lacks. This design scored in the middle again for safety and aesthetics because the circuitry will have protruding wires from the model which is both unrealistic as well as potentially dangerous.

Proposed Final Design: No Fluid without Electronic Feedback

This design scored high in anatomical and surgical accuracy because there are no electronics to make it unrealistic or incompatible with ultrasound or X-ray, however it did not receive a five, the highest score of the category, because in a real procedure there would be fluid to aspirate in the joint capsule. It received the highest score in reusability because there is no fluid or electrical components to be replaced between uses. It also scored highest in cost because there are no electronics or pumps needed, nor will new fluid need to be purchased.

This design had the highest score in ease of fabrication compared to the other designs because there will be no circuitry or pumps involved, however it did not receive a five because the valved syringe may still be difficult to design and fabricate.

No designs received a five in safety because all will require the use of a needle, which imposes a potential danger to the physicians. This design was ranked safest, though, because there is no threat of electrocution or microbial growth like the other designs.

None of the designs received a five in aesthetics because the difficulty of molding will result in skin that is not perfectly smooth. However, this design scored highest because it is the only one that will not have any wires, tubes, or pumps sticking out of the model.

V. Fabrication and Development Process

Materials

The final design incorporates polyethylene rods, a silicone fat substitute, polyurethane rubber for the joint capsule, and radiopaque bones. The silicone and polyurethane materials were chosen based on past teams' research successfully demonstrating that they mimic the mechanical properties of human tissue and their ultrasound compatiblility. The fat substitute was fabricated from a silicone base mixed with silicone thinner and cellulose powder for ultrasound visibility. A polyurethane rubber was used to mimic the joint capsule material because it showed similar mechanical properties to that of a real joint capsule. The silicone was the most expensive

material purchased and impacted the budget the most. Polyethylene rods were used to represent the femoral vein and artery because polyethylene has a similar acoustic impedance to that of blood and should therefore show up under ultrasound similarly to how a real vein and artery would. For the bones, a pediatric pelvis and femur were purchased from Sawbones. The bones were the next most expensive materials, especially the femur. These bones were chosen to provide X-ray compatibility since they have radiopaque properties as tested by Sawbones.

Plaster of paris made a mold around the positive to construct a negative for the model. The positive was made from past teams' bones, tinfoil, newspaper and duct tape. Mold release was sprayed to ensure that the positive mold would come out of the negative and that the final prototype would come out of the plaster of paris mold.

The team received syringes that were then modified to simulate the feeling of aspirating fluid. This was accomplished by putting a small hole towards the bottom of the syringe body to allow airflow. For a detailed list of materials and costs, see Appendix B.

Methods

More detailed procedures and amounts of all materials used in fabrication can be found in 0.

Creating the Mold

The first step in creating the prototype was creating a positive for the plaster mold. Leftover bones from the previous team's project were used to approximate sizing and positioning of the pelvis and left femur inside the positive so that the positive would be anatomically accurate to that of a child. Once the correct position was found to the obtained bones, newspaper, tinfoil, and duct tape were used to cover the bones and create the positive in the correct shape and size as seen in Figure 6.

Once the positive was complete, a negative mold was created using plaster of paris. A layer of plaster was poured into a large plastic bin and half of the positive was submerged into the plaster. Once this layer was dry, cling wrap and mold release was placed on top and then another layer of plaster was poured to cover the rest of the positive. Once completely dry, the entire negative mold was taken out of the bin and carefully separated into its two parts. This resulted in a negative mold with two distinct halves in the shape of our positive. The positive was then pulled out and the inside of the negative was left to fully dry.

Figure 6: Positive of Model for Molding

Positive created based on bones available from previous teams, the shape was approximated based on rough estimations of a child's bulk.

Joint Capsule

To create the joint capsule, polyurethane rubber was molded into a cylindrical shape with an inner diameter of 27.92 mm such that it would fit snugly over the femoral head. The polyurethane cylinder was then fitted over the femoral head in the correct alignment with respect to the acetabulum.

Molding the Prototype

The final step in creating the prototype was molding silicone as a fat substitute around the bones and joint capsule utilizing the plaster mold. Before the mold was poured, two polyethylene rods with 6.35 millimeter diameter were glued to the bones in the correct location with respect to the joint capsule to simulate the femoral artery and vein. In order to fit the bones with the correct orientation within the mold, the left half of the pelvis had to be removed along with approximately 3 cm off of the iliac crest. Prior to the silicone being poured, a small amount of hot glue was used to keep the bones in the correct orientation within the plaster mold throughout the molding process. Figure 7 illustrates the internal components of the model within the plaster mold. Universal mold release was sprayed throughout the interior of the plaster mold. The mold was then closed around the bones and sealed with hot glue and duct tape. The silicone fat substitute was poured into the mold through a hole created near the distal end of the femur.

Initially, when the silicone was poured into the mold, material leaked out of the mold seams. To mitigate this, extra duct tape, cling wrap, and plaster of paris was added. More silicone was then poured to replace what was lost due to leakage and left to dry overnight. It was necessary to destroy the plaster mold in order to remove the prototype.

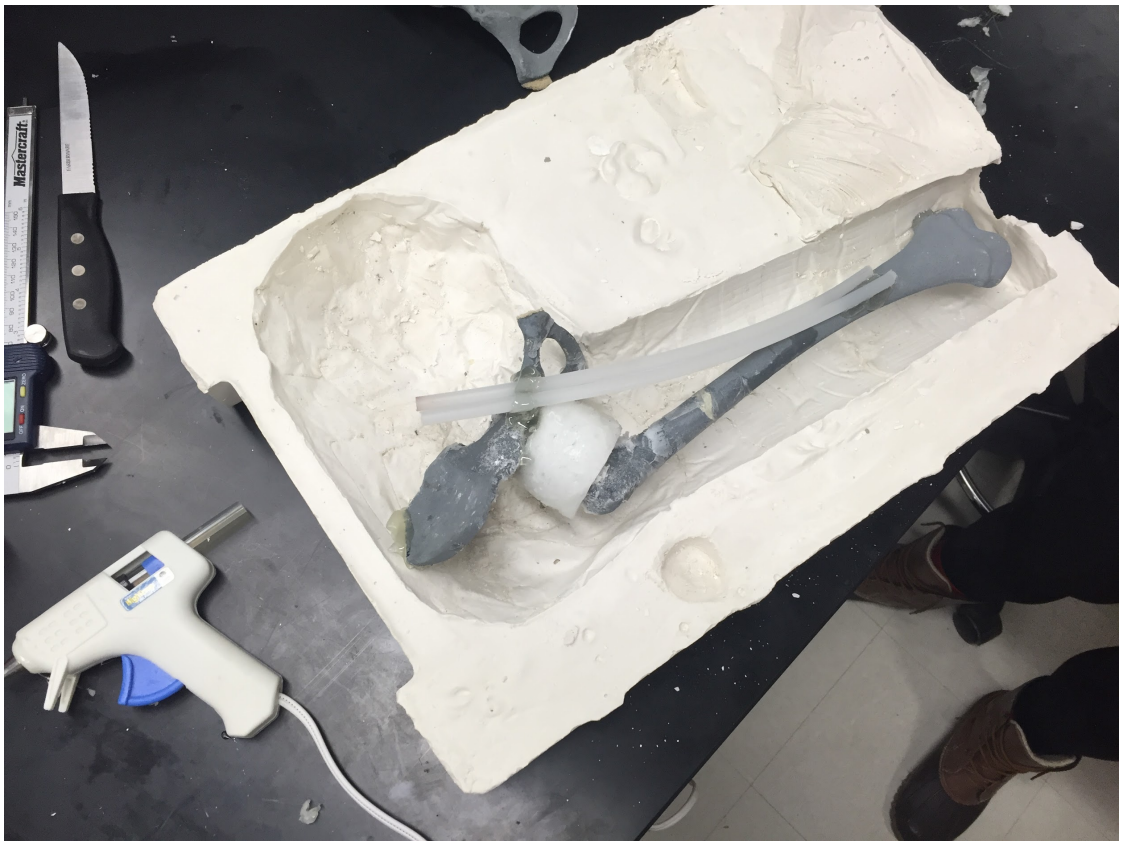


Figure 7: Placements of Bones within Plaster Negative

The bones were affixed inside the plaster of paris mold to maintain proper placement when the silicone was later poured in.

Modified Syringe

In order to simulate the aspiration of fluid from the joint capsule without incorporating fluid into the prototype, it was necessary to make a modified syringe to accompany the model. To accomplish this, a 20 gauge needle was heated and used to poke a small hole in the bottom of the syringe. This resulted in a small, clean hole in the bottom of the syringe, seen in Figure 9 (p18), allowing for airflow to simulate the proper suction of the synovial fluid in the aspiration procedure.

Final Prototype

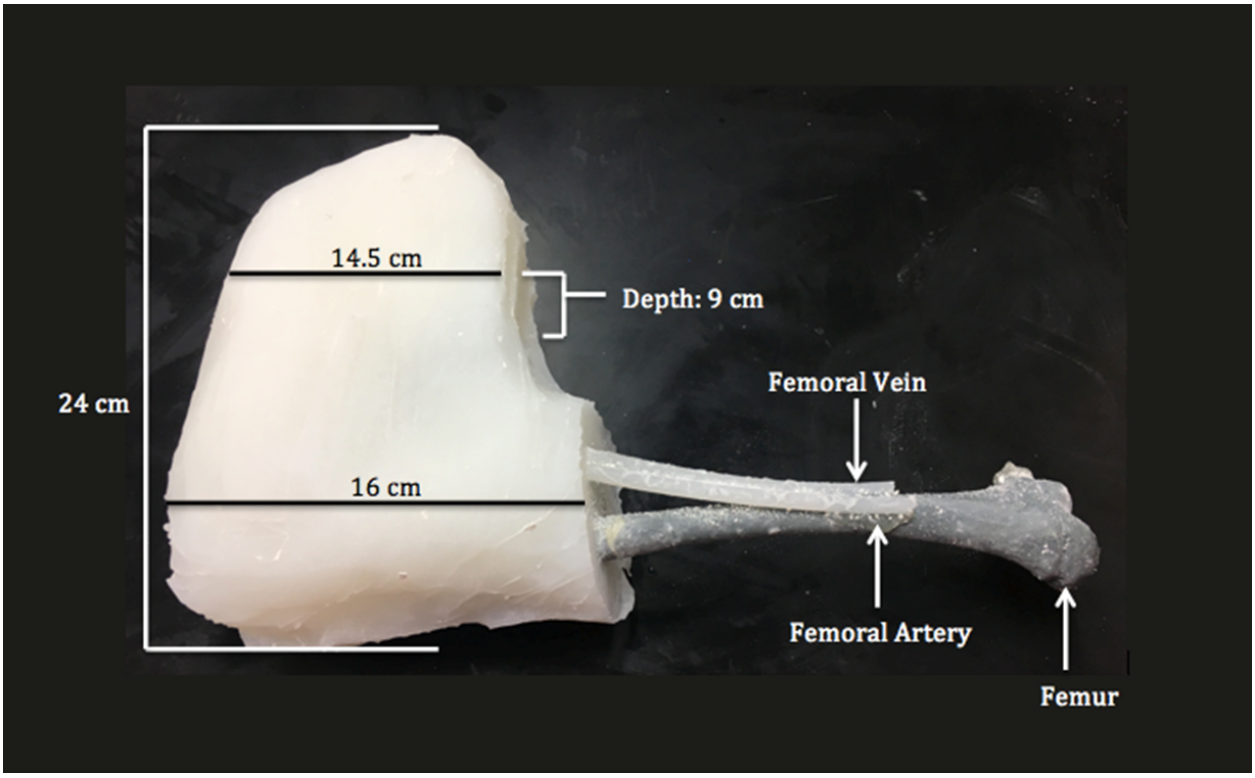


Figure 8: Final Prototype Model

Ventral view of the final prototype with labeled dimensions.

The final prototype, seen in Figure 8, includes a 30 cm long right radiopaque femur and the right half of its matching radiopaque pelvis. A 2:1 Part A to Part B ratio of Econ-80, a polyurethane rubber, makes up the 7 mm thick joint capsule surrounding the femoral head and connecting it to the pelvis. A 1:1 Part A to Part B ratio of Ecoflex-30, a silicone material, with 5% silicone thinner and 1% cellulose powder makes up the fat substitute encasing the pelvis and half of the femur. There are two 6.35 mm diameter polyethylene rods placed to represent the femoral vein and artery and provide tactile feedback. The overall weight of the prototype is 5.4 lbs or 2.45 kg. The model does not have the skin layer as planned because of the limited amount of silicone that was purchased.

The final design differed from the proposed final design in two ways. First, the viscous silicone gel that was proposed to be within the joint capsule was omitted and the solid polyurethane joint capsule was not intentionally filled. Second, the accompanying modified syringe was simplified. Rather than having a pressure valve in the syringe, a small hole was punctured in the body of the 10cc syringe to allow airflow and simulate the pressure of withdrawing infected synovial fluid from the joint capsule. It was fitted with a The syringe is 10 cc with a 3.5 inch 20 gauge needle, as seen in Figure 9.

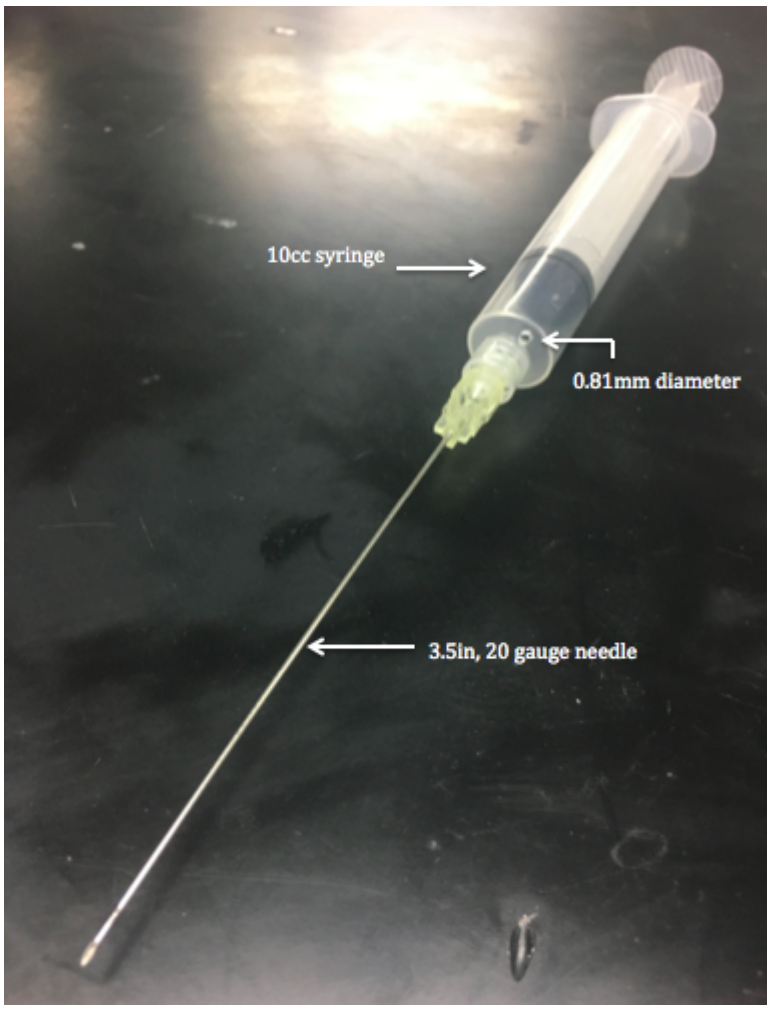


Figure 9: Final Prototype Syringe

A labeled view of the modified pressure syringe to simulate the withdrawal of fluid that shows the hole near the syringe/needle interface.

Testing: Materials Testing

To gauge material properties of the polyurethane and silicone, samples were created with varying composition of the polymer parts. These ratios were based on the product instructions as well as previous the previous teams' observations and are (Part A: Part B) 2:1, 1:1, and 1:2 silicone for the skin, 1:1 silicone with 1% cellulose powder and either 5% or 10% silicone thinner for the fat, and 2:1, 1:1, and 1:2 polyurethane for the joint capsule. These samples were formed into cylindrical samples 20mm in length and 14.45mm in diameter and allowed to set for five days.

MTS Testing

To replicate the behavior of human tissue, the various material samples were tested in compression to find Young's moduli within the ranges found for the respective tissues. The samples were compressed at a rate of 1mm/min for 10 minutes and the resulting force-displacement data was analyzed in Matlab to find the Young's modulus of the sample. A sample of the Matlab code that analyzed the force-displacement can be found in 0. Samples that fell within the ranges of the representative native tissue would be chosen for that tissue type in the model. If none of the samples fell within the desired range, the samples would be chosen based on the results of the puncture testing.

Puncture Testing

In order to choose material ratios that meet the reusability criteria, puncture testing was performed on one sample of different ratios of each material. The samples were cut into discs 2mm thick because this is the average thickness of a human joint capsule. On the sample discs, a dot was drawn in the center with a permanent marker. A 20 gauge needle was then used to puncture the sample (set on a styrofoam platform to allow for full penetration) in the marked location. Immediately after removal of the needle, it was recorded if a hole was visible to the human eye. If not, the sample was repeatedly punctured until a hole was visible. The puncture at which a hole was visible was recorded and defined as the critical puncture. At critical puncture, the time was then recorded for how long it took before there was no longer a hole visible to the human eye. This wes defined as the self-healing time.

By combining the critical puncture value, the self-healing time, and the fact that each hip aspiration procedure takes an average of 1.5 minutes, the number of procedures that could be performed within an hour was then calculated. These exact calculations can be found in Appendix D. A material that allowed for 15 or more procedures in an hour long training session would meet the short term reusability criteria.

VI. Results

MTS Testing

Force-displacement data, in conjunction with the cross-sectional area of the sample, was analyzed with Matlab to compute the stress-strain curve for each sample. The stress-strain curve was then analyzed find the Young's modulus of the sample. The outputted data for the Young's moduli can be found in Appendix D.

All of the values fell well below the target values. However, the polyurethane fat substitute materials were much closer to the target value for the fat when compared to the other material mixtures and their respective values. The Young's moduli of the joint capsule substitutes were much lower than the target Young's modulus found for the joint capsule, and varied widely between the different mixtures. The silicone mixtures were relatively consistent in their value when compared to one-another, but did not reach their target value. The samples' Young's

moduli are compared with their target values in Figure 10. No statistically significant conclusions can be drawn from these results as only one sample of each type was tested.

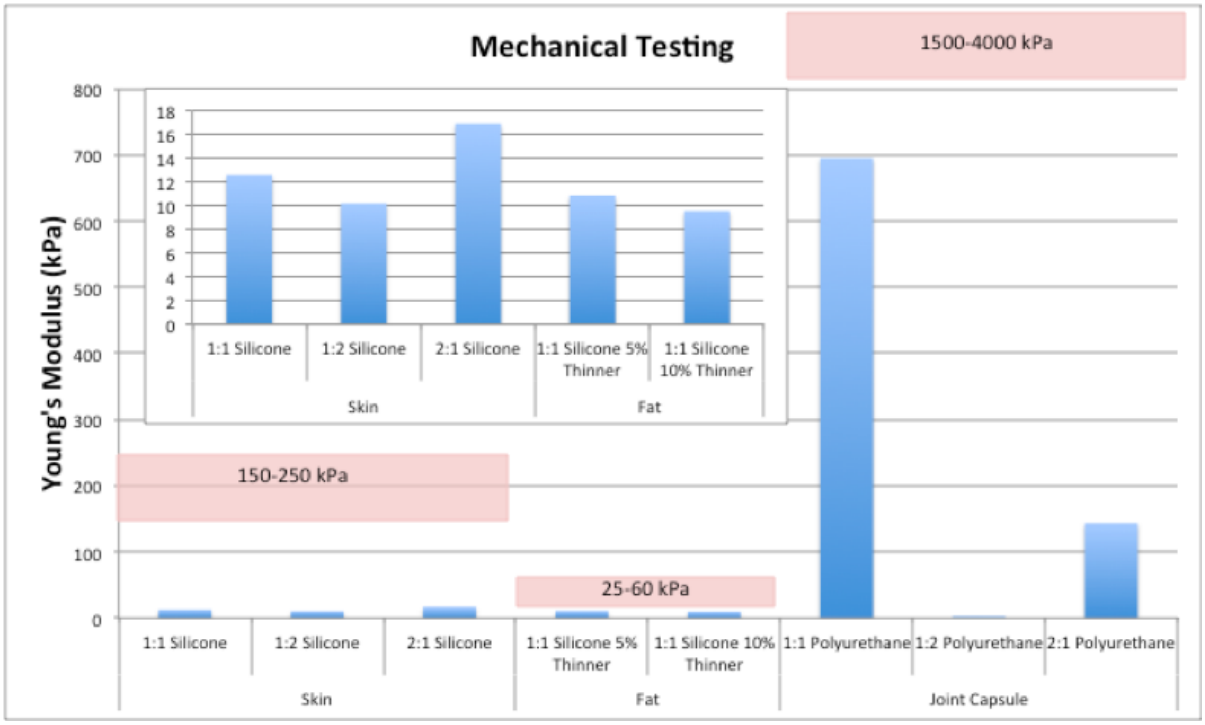


Figure 10: Summarized Results of Mechanical Testing

The Young's modulus of the different materials (blue bars) compared to the target ranges of the native tissue (red boxes).

Puncture Testing

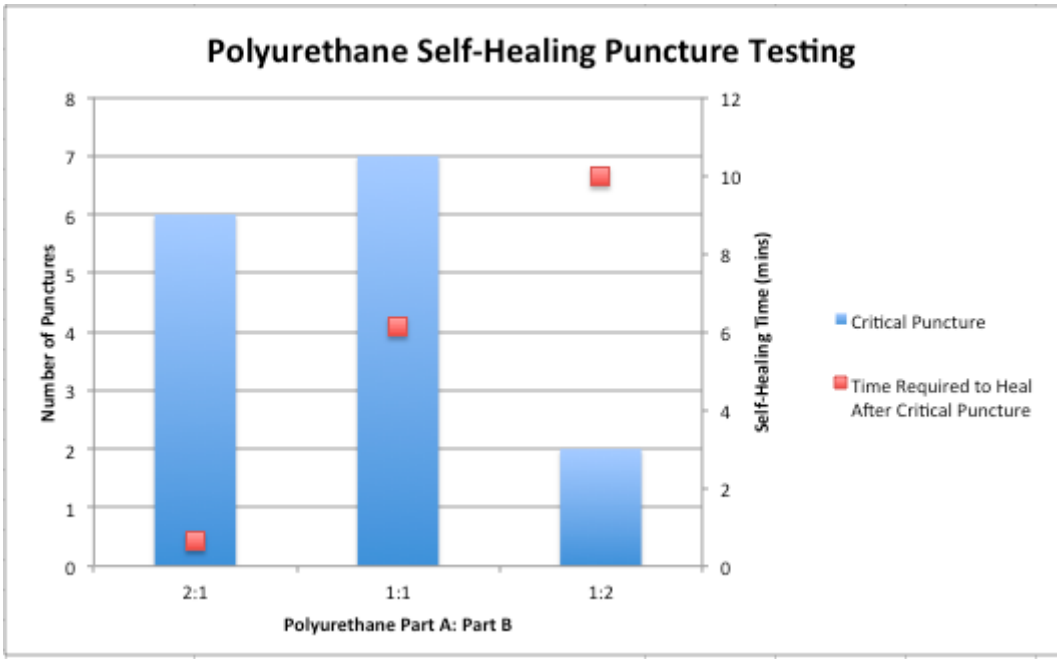


Figure 11: Summarized Results of Puncture Testing

A depiction of the number of punctures each sample could withstand before it no longer self healed immediately (blue bars) and how long it took for the material to heal after this critical puncture (red squares).

The 2:1 ratio of polyurethane showed a high critical puncture and the lowest self-healing time which can be seen in figure 11 and resulted in a total of 24 procedures per hour possible. The 1:1 polyurethane ratio only allowed for 7 procedures per hour while the 1:2 ratio mixture allowed for 5 procedures per hour. Only one sample was tested from each of the ratios, so no statistical data is available. The calculated 24 procedures per hour from the 2:1 ratio was the only sample that met the design criteria of at least 15 procedures per hour training session. For this reason, the final design was molded with polyurethane at a 2:1 ratio.

The same experiment was attempted for the silicone ratios but the first puncture was the critical puncture for all ratios and the self-healing time was greater than one hour for all samples, so the data was not indicative of self-healing. For these reasons, the chosen ratios for the skin and fat materials were based solely on their mechanical testing results.

VII. Discussion

MTS testing results revealed that all material samples fell below the target values of native tissues. The skin samples were all about ten times lower than the expected Young's moduli of 150-250 kPa. The fat materials were comparable, but still lower than their expected values of 25-60 kPa. The polyurethane joint capsule samples, however, fell far below the target values of 1.5-4 MPa of native ligaments. This signifies that different materials may need to be chosen in the future in order to closer mimic the elasticity of the human tissue. There are, however, possible sources of error unaccounted for in this MTS testing. Bubbles in the samples could have greatly altered the mechanical properties of the samples. Only one sample of each ratio was tested, so individual variance was not accounted for and should be in the future.

It should be noted that the mechanical properties of our artificial tissues would not affect the instructional value of our phantom as much as the appearance under ultrasound imaging. The most important part of the aspiration procedure is the ultrasound or X-ray guidance of the needle to the joint capsule without damaging any neighboring anatomical structures.

Puncture testing revealed that the team was able to meet the criteria of 15 punctures per hour-long practice session with the chosen polyurethane ratio of 2:1. There was not enough time for long-term testing to see if the criteria of 4 practice sessions per month for 3 months was achieved. As with MTS testing, bubbles in the samples could have affected the testing results and multiple trials were not run within each ratio as they should have been for control. Other possible sources of error include the fact that the drawn dot was larger than the gauge of the needle, so punctures could have deviated from the exact center of the disc. There is also possible error due to the fact that the hole was judged by the human eye, not a more quantifiable source such as an imaging software.

Because this puncture test did not return quantifiable results for the silicone samples, additional tests should have been performed to determine its reusability. Future testing, if given more time, includes repeating the MTS compression test after puncture to compare the mechanical properties. Similar mechanical properties before and after puncture would be indicative of good reusability.

The tests performed were designed to reduce ethical concerns. Ideally, these tests would have been performed with the molded samples and samples of the human tissues they were intended to mimic side by side. This would have given the best comparisons, considering values recorded in literature are highly varied based on other variables within each measurement. Taking skin, fat, and joint capsule samples from children age 2-5 years with septic arthritis brings forth many issues, both technical and ethical. While having a more accurate model for physicians to practice on would increase the likelihood of a successful procedure on a patient, its advantages don't outweigh the injury caused by obtaining these tissue samples for testing.

VIII. Conclusions

The goal of the project was to design a model that accurately simulates an ultrasound or X-ray guided hip aspiration procedure in order to train the physicians to treat pediatric septic arthritis. The final design consisted of polyethylene rods, polyurethane, silicone, radiopaque foam bones, and a modified syringe. The materials used met reusability criteria but fell short of the target mechanical values. Overall, the lack of ultrasound testing prevented the team from determining the level of success achieved by this design.

Due to time constraints, the team was unable to do ultrasound testing on the model. The team had planned to do ultrasound testing, but the team's availability did not correlate with the professional's schedule the team was in contact with. Also, the team was unable to do X-ray testing, so if more time was allotted, this would have been done to see if the model met the goal of being X-ray compatible. However, the team is confident the model will work under X-ray because the bones used had radiopaque properties as tested by Sawbones.

If given more time, the team would have liked to work with the orthotics department to fabricate a more replicable and anatomically accurate mold. The plaster mold the team made leaked and wasted a lot of materials during fabrication of the prototype. This led the team to not being able to accomplish the intended goal of covering the entire femur with the silicone mixture. In addition, the team had to break the plaster mold in order to get the prototype out, which made the plaster mold not reusable, and in turn made the prototype unreplicable. The prototype is not entirely anatomically accurate because the entire pelvis was unable to fit inside the plaster mold. The team was able to create a modified pressure syringe that included a hole towards the bottom of the syringe to allow airflow to simulate the feeling of aspirating fluid, but due to time constraints, the team was unable to test the syringe and if given more time, would have liked to test if the hole created a pressure similar to that created when aspirating infected fluid. The team would have liked to have added dyes to distinguish the artery and vein so the user would get objective feedback in addition to physical feedback. Implementing a pumping mechanism for the femoral artery would simulate palpation of the femoral artery which is important for the surgeon to determine the entry point for the needle. Color Doppler ultrasound is also used to detect the flowing of fluid through the artery and vein. Finally, the team would have liked to do puncture testing on the final prototype to see if it had similar mechanical properties to that of real human tissues.

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X. Appendix

Appendix A. Product Design Specifications

Function

Septic arthritis is a relatively rare, but dangerous condition that needs quick diagnosis and action. Due to the rarity, residents may receive little clinical experience with the aspiration procedure that is used as treatment and diagnosis of the condition, thus delaying treatment. The hip aspirate model will allow residents to perform the procedure in a practice environment. This will ultimately lead to a higher number of experienced surgeons and better patient outcomes.

Client Requirements

- Base infant model, aspiration insert, anatomic insert
- X-ray and ultrasound compatible
- Anterior surgical method option
- Replicable
- Reusable

Design Requirements

1. Physical and Operational Characteristics

a. Performance requirements

The model must accurately mimic a pediatric patient with septic arthritis. This includes the anatomical structures as well as the mechanical properties at the puncture site. Residents must be able to perform several needle aspirations on the model at any given time. The model should be X-ray and ultrasound compatible to perform the procedure properly. The model should be able to withstand multiple attempts (punctures by the needle) before any parts must be replaced.

b. Safety

The device should be safe for physicians to hold, carry, and practice the hip aspiration procedure on. The result of a failed technique must not harm the residents. Any sharp components must be covered for safe handling.

c. Accuracy and Reliability

The model should match the shape and size of a 2 year-old hip joint. The joint should have fluid uniformly surrounding the femoral head with similar viscosity to synovial fluid. The model must be completely X-ray and ultrasound compatible to guide the physicians as in a real aspiration procedure. The section of the model that will be punctured must mimic the mechanical properties of human skin (dermis and epidermis), fatty tissue, muscle, and the fibrous tissue of the joint capsule.

d. Life in Service

Each aspiration procedure takes 1-2 minutes. The model must last for at least three months with four practice sessions per month before any replacements are needed. The model should be able to accommodate 15 needle sticks per practice session.

e. Shelf Life

The model should be able to withstand multiple needle punctures during in each training session. Ideally, no parts will need to be replaced in between trials. The model should last for a few months of training sessions before any parts need to be replaced. The replaceable parts should be inexpensive and simple to replace. The model as a whole should last multiple years at a training facility or clinic when stored in dry, room temperature conditions.

f. Operating Environment

The model will mostly be used in a controlled, indoor environment. Under normal circumstances the device should not have to withstand extreme temperatures. The model will have to hold fluid to be functional so the materials will have to be be capable of this.

g. Ergonomics

The model should be able to handle all interaction and stresses of a hip aspiration while accurately representing a real child. This includes withstanding multiple insertions of a needle while maintaining the mechanical qualities of the artificial tissues.

h. Size

The model should be the size of a pediatric hip, age 2. This includes a femur that is 18-20 cm in length. The entire model should be 24x13x55 cm in size.

i. Weight

The model should be light enough to transport and store with relative ease while having enough weight to accurately represent an infant for surgery. The target weight is 6.1 pounds.

j. Materials

The materials used for skin, soft tissue, joint capsule, and bone should produce accurate images using ultrasound imaging and X-ray imaging. The mechanical properties of the skin, soft tissue, and joint capsule should also be comparable to those of an infant. The skin and soft tissue should be able to withstand many injections so that the model can be reusable. The joint capsule material must also resist puncturing more than the other materials.

k. Aesthetics, Appearance, and Finish

The model should resemble the appearance of a human infant hip as much as possible. It would be desirable, for aesthetic reasons, to have a full body infant model but it is not necessary. There should be no extensions beyond the body of the model.

2. Production Characteristics

a. Quantity

1 infant hip model

b. Target Product Cost

This semester's budget is $500.

3. Miscellaneous

a. Standards and Specifications

No regulatory requirements exist for this project. The client has noted that the model ought to be representative of the age group of 2-5 years of age.

b. Competition

There is no record of a competing model produced by another body that would fulfill the purpose of this model. Ultrasound phantoms exist for the aspiration of intraperitoneal fluid from the body cavity, such as the one developed by Blue Phantom. Kyoto Kagaku developed a pediatric phantom to train technicians in ultrasound of infants.

Appendix B. Materials

Cost Spreadsheet:

Category	Material	Vendor	Description/Part Number	Quantity	Unit Cost	Cost
Bones	Full Pediatric Radiopaque Pelvis	Sawbones	ERP # 1333-4	1	80	80
	Right Pediatric Radiopaque Femur	Sawbones	ERP # 1165-2	1	36	36
Tissues	Ecoflex 00-30 (skin, fat, muscle)	Smooth-On	Ecoflex 00-30 1 Gallon Unit	1	183.72	183.72
	Econ 80 (ligaments)	Smooth-On	Econ 80 - Trial Size	1	25.96	25.96
	LDPE Rod (vein, artery, nerve)	Small Parts	LDR-1190-60-01	1	16.65	16.65

Cost Spreadsheet (cont.):

Molding Necessities	Silicone Thinner	Smooth-On	Silicone Thinner - Pint	2	11.93	23.86
	Universal Mold Release	Smooth-On	Universal Mold Release - Aerosol Can	1	13.28	13.28
	Universal Mold Release	Smooth-On	Universal Mold Release - Aerosol Can (Previous Teams' Materials)	1	0	0
	Plaster of Paris	Home Depot	25 lb Bag	2	13.98	27.96
	5 Gallon Bucket	Home Depot	Mixing Container	1	2.97	2.97
	String	Home Depot	For Molding	1	2.47	2.47
	12 Gallon Bin	Home Depot	For Molding	1	7.97	7.97
Misc.	Paint Sticks	Home Depot		4	0	0
	Craft Sticks	Walgreens	50 count	1	1.49	1.49
	Previous team	Plastic Cups	Previous team	15	0	0
	Syringe Needles	Previous team	3.5" 20 Gauge needles	2	0	0
	Syringe Needles	Client	1.5" 18 Gauge needles	6	0	0
	Syringes	Client	10cc Syringes	3	0	0
					Total	420.84

Appendix C. Fabrication

Body Mold

- Make negative:
- Mix 6000 mL unpacked Plaster Paris with 3000 mL water in a bucket
- Pour into 16x21.6x12.6 in bin
- Suspend positive in mixture so that about half of it is submerged for approximately 3 minutes or until mixture is firm enough to hold

- Allow plaster Paris to cure
- Spray a layer of mold release
- Place a layer of plastic wrap down
- Spray another layer of mold release
- Pour enough of Plaster of Paris so that the positive is completely covered

Removing molds from containers

- Place a stirring stick (popsicle stick for joint capsule) along between the plaster of paris and the bin all the way to the bottom of the bin on each side of the bin to loosen the mold
- Have someone ready to catch the mold while someone else tips the bucket over and gently shakes it

Fitting the bones to the mold

- The bones were placed in the mold to get the correct orientation
- In order to get the mold to close around it, 3 cm were cut off of the back of the pelvis

Joint capsule mold

- An inner cylinder was created from aluminum foil and taped into the center of a plastic cup so that when the 2:1 polyurethane mixture was poured, it resulted in a hollow, cylindrical joint capsule of thickness of about 7mm.
- The joint capsule mold was put around the femoral head
- The femoral head was placed into the pelvis
- The joint capsule was hot glued to the pelvis so that the femur was in the correct orientation with the acetabulum

Appendix D. Data Analysis

MATLAB MTS Data Analysis Sample

Example of Code:

```
dia = 14.45; %mm
length = 2; %mm
area = pi*(dia/2)^2; %mm^2
stress = abs(N1./area); %N/mm^2 = MPa
strain = abs(mm1./length);

%Stress-Strain curve
plot(strain,stress)
grid on
```

```
title('1:1 Polyurethane')
xlabel('Strain')
ylabel('Stress (MPa)')

%Young's Modulus
eqn = polyfit(strain,stress,1);
kPa = eqn(1)*1000;
disp(['1:1 Polyurethane: ',num2str(eqn(1)),' MPa = ',
   num2str(kPa),' kPa'])
```

Output of Young's Modulus for Each Sample Mixture:

Skin:

1:1 Silicone: 0.012562 MPa = 12.5619 kPa
1:2 Silicone: 0.010162 MPa = 10.1622 kPa
2:1 Silicone: 0.016875 MPa = 16.8746 kPa

Fat:

1:1 Silicone 5% Thinner: 0.010839 MPa = 10.8386 kPa
1:1 Silicone 10% Thinner: 0.0095222 MPa = 9.5222 kPa

Joint Capsule:

1:1 Polyurethane: 0.69519 MPa = 695.1881 kPa
1:2 Polyurethane: 0.0010886 MPa = 1.0886 kPa
2:1 Polyurethane: 0.14329 MPa = 143.2893 kPa

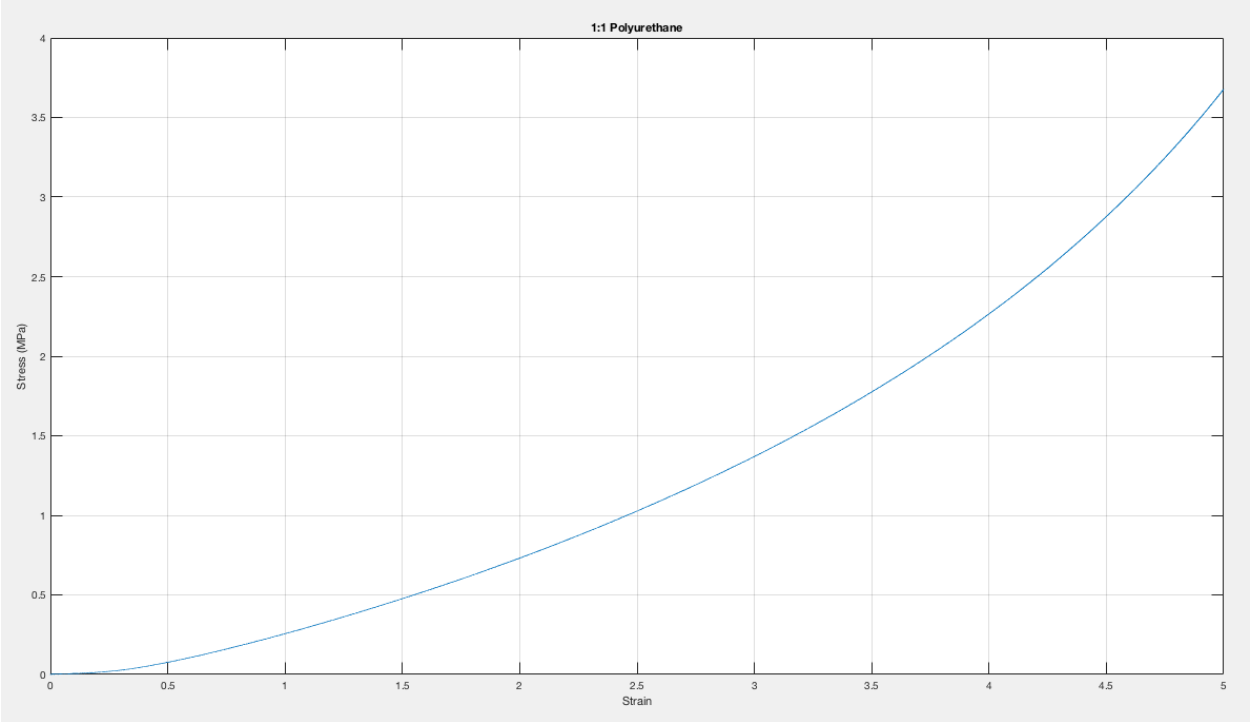

Figure D.1: Plot of Stress-Strain Curve

Sample output of MTS plot output using MATLAB code. The data illustrated is the 1:1 polyurethane mixture.

Data Analysis for Polyurethane Self-Healing Puncture Testing

The following analyses of the takes the number of punctures performed on the material just before the hole left by the syringe becomes visible ($P_{crit\text{-}1}$), the estimated time for the hip aspiration procedure (1.5 min per procedure), and the estimated time it takes for the material to self heal in minutes (T_H), to calculate the number of hip aspiration procedures that can be performed on the model within an hour (A_n).

$$A_n = \frac{60 - (1.5 * P_{crit-1})}{1.5 + T_H}$$

2:1 Parts Ratio

$$A_n = \frac{60-(1.5*5)}{1.5+\frac{39.01}{60}} = 24 \text{ procedures per hour}$$

1:1 Parts Ratio

$$A_n = \frac{60-(1.5*6)}{1.5+6.11} = 7 \text{ procedures per hour}$$

1:2 Parts Ratio

$$A_n = \frac{60-(1.5*0)}{1.5+10} = 5 \text{ procedures per hour}$$