Hip Aspirate Model to Teach Physicians

BME 300/200
October 19, 2016
Client: Dr. Matthew Halanski - American Family Children's Hospital
Advisor: Professor William Murphy - Department of Biomedical Engineering
Team Members: Catharine Flynn- Team Leader
Leah Fagerson- Communicator
Emmy Russell- BSAC
Frank Seipel- BPAG
Desiree Flouro- BWIG

Abstract

The rarity of pediatric septic arthritis in children makes it difficult to train new physicians to safely perform a hip aspiration procedure to diagnose and treat the condition. Septic arthritis is an urgent situation, so the lack of experience that newer physicians have can create a serious problem in this emergency. 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 such a model to effectively train resident physicians in the procedure. The proposed design uses artificial tissues that mimic the properties of real human tissue molded around an artificial hip joint incorporating all anatomical features relevant to the aspiration procedure. The model will be evaluated based on how accurately it models the experience of performing a hip aspiration on a real human.

Table of Contents

I. Introduction

Septic arthritis is a painful infection in a synovial joint that causes a buildup of excess synovial fluid. When the affected joint is a hip, this buildup occurs on 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 treatment procedure. Septic arthritis of the hip, however, is an orthopedic emergency when it occurs in a child. Postponing the fluid aspiration increases fluid buildup, blocks off the blood supply, rapidly degrades cartilage, 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, acetabular 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 and the lack of design information publicly available. The Kyoto Kagaku model is meant to practice diagnosis of developmental hip dysplasia, rather than septic arthritis.

There are currently no known existing products on the market to specifically simulate 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. An aspiration insert will be developed to model the 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 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 three main approaches for hip aspiration are the anterior, medial, and lateral approaches with the lateral approach being 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 or medial 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 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].

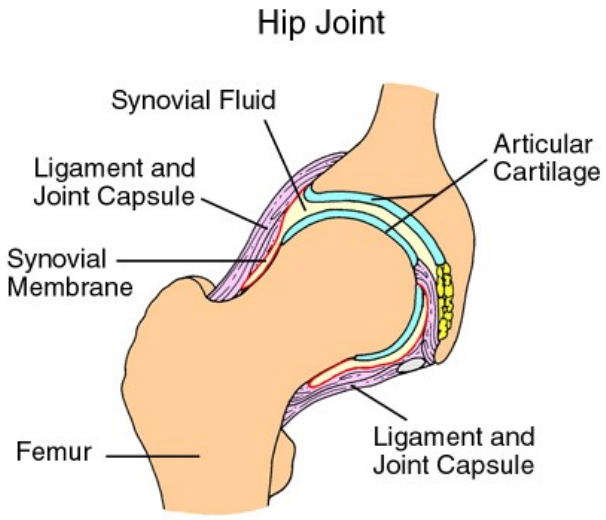


Figure 1: Hip Joint Anatomy [8]

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 is a 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 with both an anatomical and an aspiration insert. 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. All anatomical structures relevant to the procedure, including the femoral vein, artery and nerve, should be represented in the model. 180 needle insertions should be able to be performed before any replacement is necessary. 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 capsules as well as of bones and the needle when viewed under ultrasound. The model had to be submerged in water, though, in order to produce these 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 before it can be made marketable.

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 silicon 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

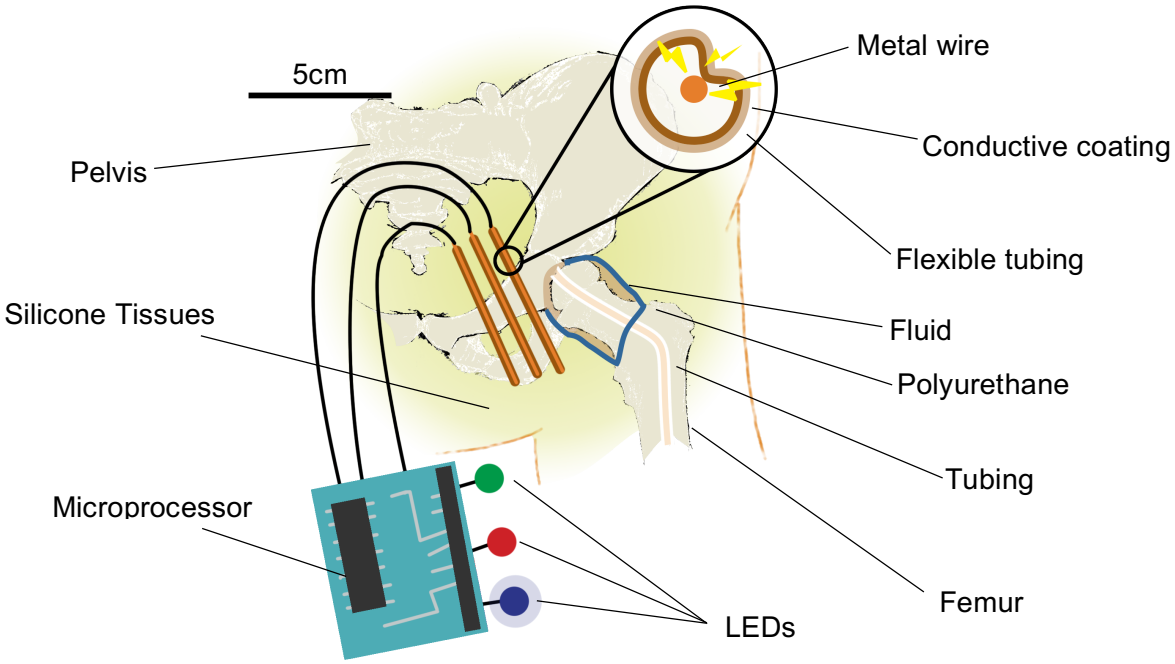


Figure 2: Fluid with Electronic Feedback Design

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, above).

Fluid Without Electronic Feedback

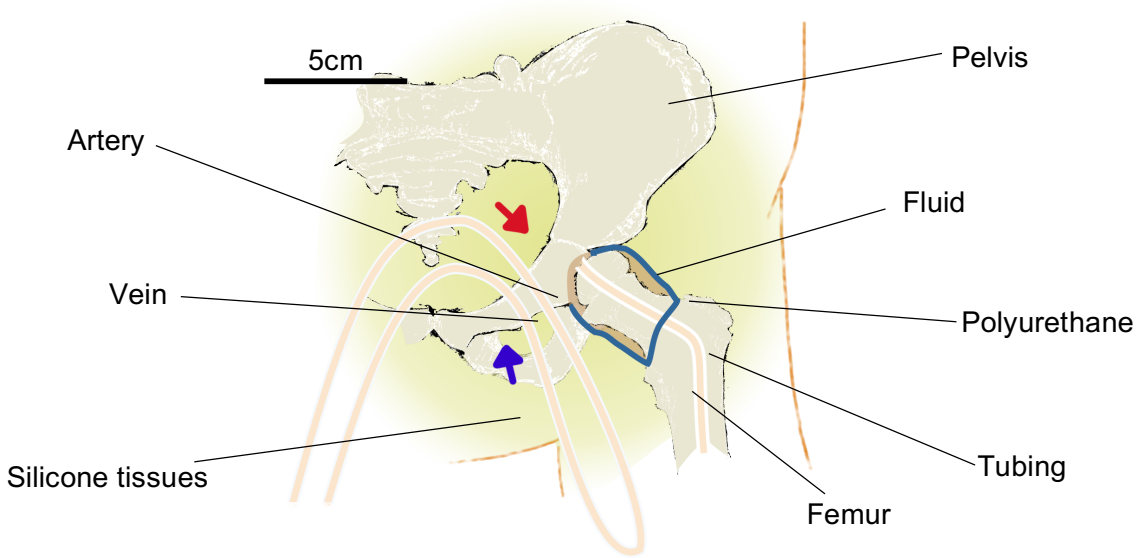


Figure 3: Fluid Without Electronic Feedback Design

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, above) 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, p 4).

No Fluid with Electronic Feedback

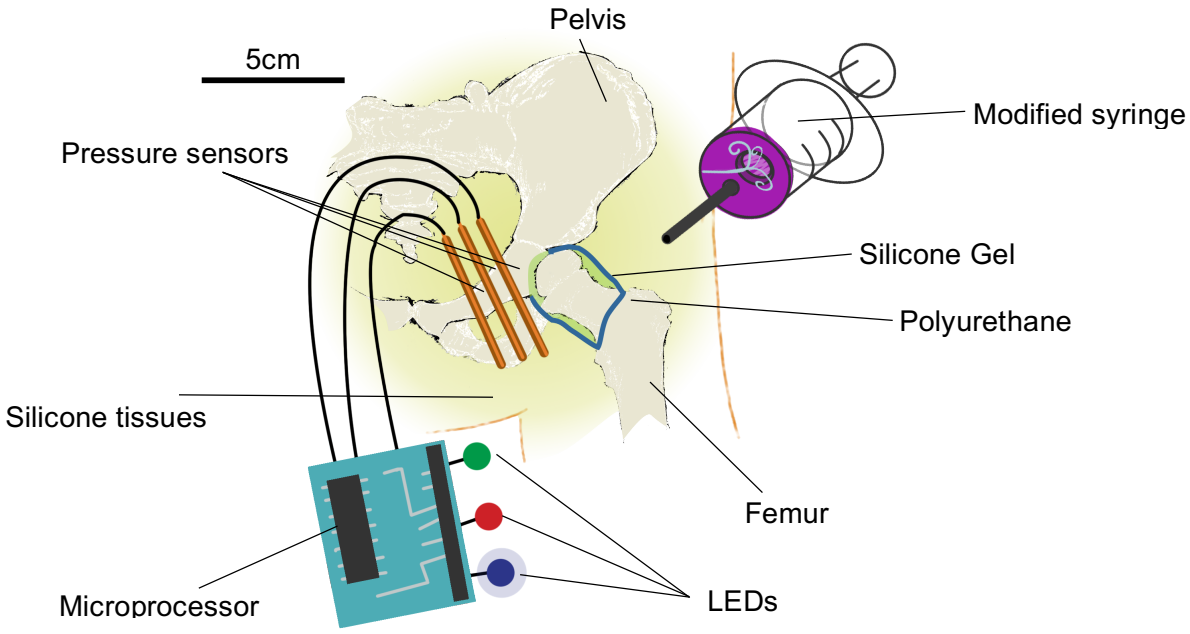


Figure 4: No Fluid with Electronic Feedback Design

Preliminary design utilizing a modified syringe and a pressure sensor. The microprocessor, syringe, and needle are not drawn to scale. See Figure 2 (p 4) for more detail on the pressure sensor function. See Figure 5 (p 7) 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 design, Fluid with Electronic Feedback (p 4). The proposed design is shown in Figure 4 (above).

No Fluid Without Electronic Feedback

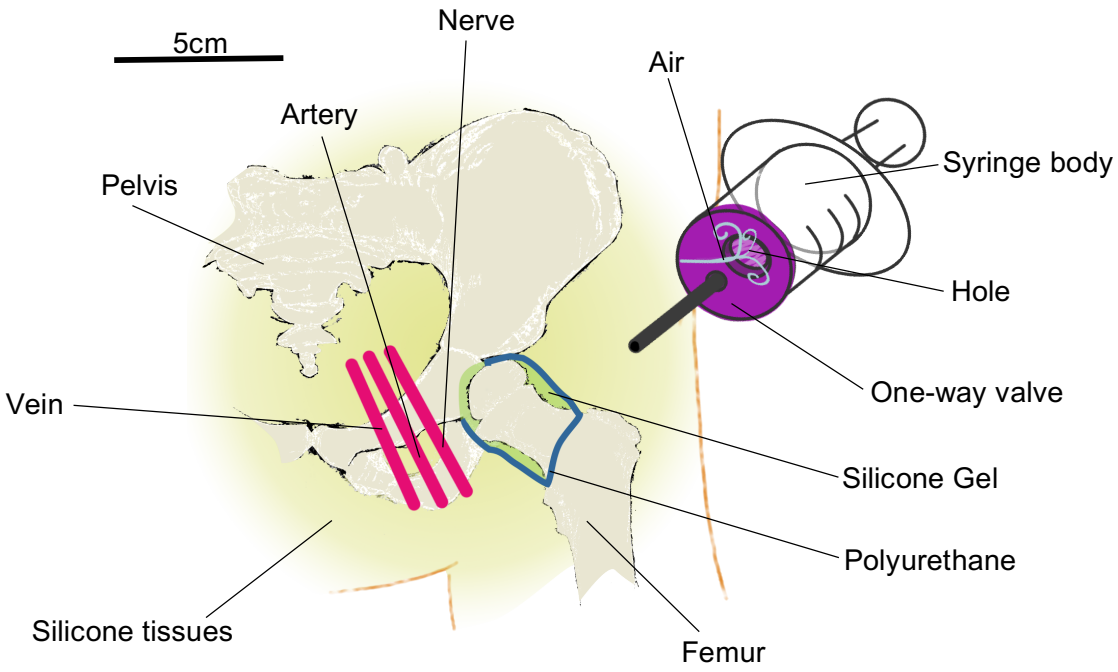


Figure 5: No Fluid Without Electronic Feedback Design

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, above). 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

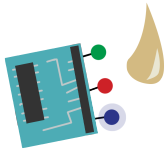
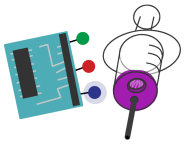
Design / Criteria (weight)	Fluid with Electronic Feedback 		Fluid without Electronic Feedback 		No Fluid with Electronic Feedback 		No Fluid without Electronic Feedback 	
Anatomical Accuracy (20)	3/5	12	5/5	20	2/5	8	4/5	16
Surgical Accuracy (20)	1/5	4	5/5	20	1/5	4	4/5	16
Reusability (15)	2/5	6	2/5	6	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**

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.

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 highest for the same reason as anatomical accuracy; the ultimate goal of the model is to increase the safety of the procedure by providing more accurate practice to 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, and so achieve this part of the criteria. The designs differ in surgical accuracy by having different ultrasound and X-ray compatibility. The real procedure will be guided by this technology, so the model will ideally be compatible with both, and the 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 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 as well as replace any needed parts. This is not ranked as highly because the goal is for parts to be reusable and therefore fabrication and replacement should not occur often.

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 and so it is 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 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. Future Work

As the design process proceeds, more research will have to be done on the specific materials to be used for the artery, vein, joint capsule, and soft tissues so that they have acoustic impedances as similar to those of a real artery, vein, joint capsule, and soft tissue. This will lead to the most accurate ultrasound image. A material that could potentially work for the artery and vein is polyethylene because it has a Z value similar to blood (Table 2, below). Polyurethane has a similar Z value to ligaments, which is good because it can be used for our joint capsule. However, cellulose has a Z value higher than soft tissue which may be an issue if it is used for the joint capsule. The proposed fat mimic is the silicone mix Ecoflex 30, which when combined with cellulose powder, becomes ultrasound visible. Silicone was also found to be a good fit for other soft tissues. In order to ensure the right materials are used, further research and testing must be done.

US data table for plastics

Material	Vl[m/s]	D:Kg/dm3	Z[MRayls]
ABS	2230	1.03	2.31
Acrylic plexiglas	2750	1.19	3.26
Adiprene	1689	1.16	1.94
Bakelite	1590	1.40	3.63
Cellulose Butyrate	2140	1.19	2.56
Delrin	2430	1.42	3.45
Epotek 301	2640	1.08	2.85
Ethyl vinyl acetate	1800	0.94	1.69
Neoprene	1600	1.31	2.1
Mylar	2450	1.18	3.0
Nylon 6/6	2600	1.12	2.9
Polycarbonate	2270	1.22	2.77
Polyester casting resin	2290	1.07	2.86
Polyethylene	1950	0.90	1.76
Polyethylene high density	2430	0.96	2.33
Polyethylene low density	1950	0.92	1.79
Polypropylene	2470	0.88	2.40
Polystyrene	2320	1.04	2.42
Polyurethane	1700	1.04	1.80
PVC	2380	1.38	3.27
PVDF	2300	1.79	4.2
Scotch tape 2.5 mils thick	1900	1.16	2.08
Vinyl rigid	2230	1.33	2.96

Vl = longitudinal sound velocity [m/s]
D = density [kg/m3]
Z = acoustic impedance [MRayls]

Table 2: Acoustic Impedances for Common Plastics [11]

Past teams' research and further research indicated that PMMA is a common option for synthetic bone grafts. Also, Sawbones provides anatomical bone models with various muscles attached or no muscles attached. The type of bones will be chosen based on the features of the proposed final design and what best fits its needs.

The design matrix led to a proposed final design that does not contain fluid nor an electronic feedback system, thus, to simulate the pressure of aspirating fluid, a syringe with a one- way valve will be used. In order for users to be able to pull the syringe plunger out after the needle is inserted, a separate hole will be put into the syringe to allow air to enter the chamber. Testing will need to be performed to ensure it simulates the pressure associated with aspirating fluid. Since the synovial membrane in the proposed model does not contain fluid, a proposed idea is to have a self-healing polyurethane capsule filled with viscous silicone gel. Since there is no electronic feedback system, a physical feedback system can be used because the user should be able to feel the needle hit a hard material. The material that seems to be the best fit is polyethylene for the vein, artery and nerve. However, this might not be enough feedback so a dye will be added to the artery, vein, and nerve. This will tell the user if they hit any of the listed parts because when the needle is pulled out the tip will have a dye on it. Further research and testing on this idea needs to be done as the project proceeds to ensure its accuracy.

The largest foreseeable difficulty is finding the right material combination that will be ultrasound and X-ray compatible, but with the research that has been done and the future testing that will be done, the right materials for the design will be found. Another difficulty may arise when it comes to testing, since there is no easy access to ultrasound or X-ray machines on campus. Time will need to be scheduled with the client in order to use the space he has to complete the testing of our materials. This could be challenging due to the time constraint and the fact that the project is being fabricated on campus and the necessary testing machines are elsewhere. Going forward, planning needs to happen so that when the machines are needed, there will be access to them. Another step in the fabrication process would be molding of the joint capsule, tissues and fat around the bones. This brings up another difficulty because no team members have molding experience nor are there any molds that can be used. Thus, molds must be made and then casted carefully to ensure that everything is in the right place.

Before fabrication begins, the right materials and mixtures of materials must be found so that making and casting the molds can begin. Before casting the molds, everything must be fabricated inside the joint capsule along with the vein, artery, and nerve. The synovial membrane must be fabricated with a self healing polyurethane capsule filled with a viscous silicone gel. The vein, artery, and nerve will be made of polyethylene rods coated with a dye that can give physical feedback if hit by the needle. For further fabrication, the correct mixtures of silicone will need to be found for the various tissues so that they have similar acoustic impedances to that of native tissues.

The end goal of this project will be a model with quantifiable feedback. One aspect of quantifiable feedback will come from the needle. The needle either will or will not have dye on it, indicating the resident's failure or success. Images of the prototype will be taken under ultrasound and X-ray and be compared to a human hip image. An imaging processing program such as ImageJ will be used to compare how closely the prototype resembles the native hip structure.

VI. References

[1] T. C. C. Foundation, "Septic arthritis," Cleveland Clinic Center for Continuing Education, 2000. [Online]. Available: http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/rheumatology/septic-arthritis/. [Accessed 12 October 2016].

[2] M. R. J. Scarfone, "Pediatric septic arthritis: Background, Etiology, Epidemiology," 2016. [Online]. Available: http://emedicine.medscape.com/article/970365-overview#a6. [Accessed 12 October 2016].

[3] C. Tidy, "Septic arthritis symptoms. How to treat septic arthiritis?," EMIS Group plc., 11 August 2016. [Online]. Available: http://patient.info/health/septic-arthritis-leaflet. [Accessed 12 October 2016].

[4] Mayo Clinic Staff, "Septic Arthritis," Mayo Foundation for Medical Education and Research, 19 December 2015. [Online]. Available: http://www.mayoclinic.org/diseases-conditions/bone-and-joint-infections/home/ovc-20166652. [Accessed 15 September 2016].

[5] Kyoto Kagaku CO.,LTD, "Products: Imaging Phantoms for ultrasound/ Radiology exam training," 13 July 2015. [Online]. [Accessed 10 October 2016].

[6] G. Stacy and B. Hansford, "Musculoskeletal Aspiration Procedures," *Seminars in Interventional Radiology,* vol. 29, no. 4, pp. 270-285, 2012.

[7] "Aspiration of the Hip Joint - Wheeless' Textbook of Orthopaedics," 2016. [Online]. Available: http://www.wheelessonline.com/ortho/aspiration_of_the_hip_joint. [Accessed 16 October 2016].

[8] Children's Hospital of Wisconsin, "Anatomy of a joint," 2016. [Online]. Available: http://www.chw.org/medical-care/rheumatology/conditions/anatomy-of-a-joint/. [Accessed 16 October 2016].

[9] J. Brand, S. Schwartz and M. An-adirekkun, "Hip Aspiration Model to Teach Physicians-BME 301: Final Report," 2016.

[10] A. Acker, B. Li, E. Olszewski, M. Scott and C. Sullivan, "Pediatric Hip Aspiration Model to Teach Physicians," 2014.

[11] "Ultrasonic data values for plastics," 2016. [Online]. Available: http://www.signal-processing.com/us_data_p.html. [Accessed 3 October 2016].

VII. Appendix

Project Design Specifications

Hip Aspirate Model to Teach Physicians
October 19, 2016
Advisor: William Murphy
Team Members:

Catharine Flynn - Team Leader
Leah Fagerson - Communicator
Emmy Russell - BSAC
Desiree Flouro - BWIG
Frank Seipel - BPAG

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.