HIP ASPIRATION MODEL TO TEACH PHYSICIANS

BME 301: Final Report

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Abstract:

Septic arthritis of the hip is a bacterial or fungal infection that can lead to lifelong debilitation if left untreated. Performing a hip aspiration is the most effective way to both diagnose and treat this disease. This technique involves inserting a needle into the upper portion of the groin and puncturing the joint capsule membrane to withdraw synovial fluid [1]. Our team was tasked with designing a reusable model of an infant hip joint that allows surgeons to practice performing a hip joint aspiration. Currently, no models on the market facilitate practice of this procedure, despite its importance. We have modified a two-year-old-sized doll with an anatomically accurate replica of a hip joint. A balloon secured over the femoral head easily inflates with water to mimic the infected synovial fluid in the joint capsule space. Our model is reusable, as our tissue layers can withstand multiple punctures, and the balloon can be replaced between uses. Though uniaxial testing of our synthetic tissue layers yielded results that deviate from true biological properties, newer materials would likely ameliorate this problem. Moving forward, efforts should be made to improve the model's ultrasound compatibility, anatomical accuracy, and manufacturability. Overall, our prototype is a successful step toward what can ultimately be a life-saving device.

Introduction:

Septic arthritis is an inflammation of the joints caused by a bacterial or fungal infection that spreads through blood [1]. Although this rare orthopedic disease can be seen at any age, it occurs most commonly in infants under two, the elderly, and those with weakened immune systems. This disease classified as a genuine orthopedic emergency [2]. Symptoms include fever, swelling at the joint, and intense joint pain [3]. Aspirating the infected synovial fluid within the hip joint capsule is the most effective method for diagnosing and treating the disease. Treatment with oral antibiotics is also used in some cases [2, 4]. Failure to diagnose and treat septic arthritis can lead to loss of the growth plate, joint dislocation, and destruction of the articular cartilage. This severe tissue necrosis can lead to lifelong discomfort and debilitation [2]. For this reason, it is particularly important to quickly treat this disease when it occurs in infants. In addition to being an extremely debilitating disease, knowing how to perform a hip aspiration is also a required skill that medical residents must master before becoming doctors.

Although the hip is one the joints most commonly affected by septic arthritis [1], there is no model on the market that allows for X-ray or ultrasound-guided hip aspiration, either on infants or adults. Laerdal has a model of an infant's torso and legs that is used to train medical professionals how to diagnose hip dislocation. However, testing for hip dislocation is very different from performing a hip aspiration. There is no joint capsule on this model, and therefore it does not fulfill the needs of our client [5]. A number of companies, such as 3B Scientific, sell functioning models of adult-sized hip joints. However, these lack overlying layers of tissue, are too large to mimic aspiration of an infant hip, and cannot adequately retain fluid [6]. Sawbones has a fully encased model of an adult male hip joint. This model includes overlying layers of soft tissue, an acetabulum, and a femur with cancellous inner bone material. However, this model does not approximate an infant and it does not have an accurately represented joint capsule that can retain fluid. It therefore cannot facilitate hip aspiration practice [7]. Thus, there is certainly a need for our model as current products do not allow for hip aspiration. Our client, Dr. Matthew Halanski, had designed and fabricated a hollow infant leg using plaster molding (Figure1) as a proof of concept. In this design, water inside a balloon mimics the synovial fluid below the synovial membrane. The fluid could theoretically be aspirated using a needle. This model is not suitable for teaching purposes, but it provides a solid foundation on which future designs may be built.

Figure 1: Dr. Halanski's initial prototype. The model is made from a plaster mold. The inside of the model is hollow so it can accommodate a balloon containing fluid [8].

To fill the substantial need for a hip aspiration model, our group designed and fabricated a model that is more suitable for teaching residents how to perform a hip aspiration procedure in infants. This involves designing a joint capsule and fabricating a complete, working prototype. The materials used can align with those researched by the fall 2015 design group, which is the last design group to have worked on this project. Ultimately, the model should be an anatomically accurate, fully assembled product made with synthetic materials that simulate the mechanical properties of skin, muscle, soft tissue, and joint capsule membrane material. It must be able to withstand multiple needle insertions before being replaced and it should contain a synovial fluid mimic which can be aspirated.

Background

Client information

Our client, Dr. Matthew Halanski, is a faculty member at the UW School of Medicine and Public Health. He earned his residency in orthopedic surgery. His interest lies in paediatric orthopedics.

Hip Joint Anatomy

The hip joint is a ball-and-socket structure where the femur meets the acetabulum of the pelvis. The pelvis itself is formed by two hip bones, the sacrum, and the coccyx. Each hip bone is composed of three individual bones that fuse near the end of the teenage years: the ilium, ischium, and pubis [9]. The joint capsule membrane is attached to the articulating bones of the hip. The capsule is composed of thick bundles of collagen fibers, which adhere to the bone [10]. The strong iliofemoral, pubofemoral, and ischiofemoral ligaments fully encircle the hip joint, creating the joint capsule. The combination of the acetabulum-femoral head interface, the strong joint capsule, and additional muscles and ligaments attached to the joint capsule successfully limit the mobility of the hip and therefore stabilize it. Joint movement is limited to flexion, extension, adduction and abduction [9]. The three most powerful muscles in the thigh are the adductor longus, the adductor mangus, and the adductor brevis. These muscles are responsible for stabilizing the hip. The adductor longus helps pull the leg back toward the middle of the body, the adductor mangus helps keep the lower limb positioned beneath one's center of gravity, and the adductor brevis helps adduct the thigh [11]. The femoral artery, which connects to the adductor longus, can be palpated in order to guide needle placement [12]. In addition to bearing extraordinarily large loads, the hip joint must also minimize friction. For this reason, both the acetabulum and the surface of the femoral head are lined with cartilage. Located within the joint capsule space are bursae, which are fluid filled sacs. These bursae are lined with synovial membranes that secrete synovial fluid, which is a viscous, sticky lubricant that further assists with painless joint articulation. Cartilage and synovial fluid, in combination, is "three times more slippery than skating on ice" [9].

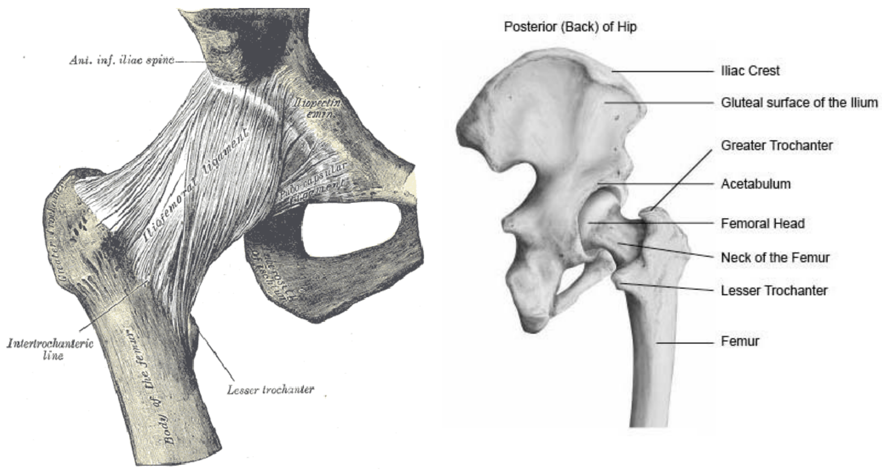


Figure 2: Anatomy of hip. A: Ligaments link pelvis and femur together. B: Bones of the hip joint [13].

Hip Joint Aspiration

Aspirating repeatedly is uncomfortable for the patient and difficult for the surgeon, so it is essential that the procedure is done correctly. To correctly aspirate synovial fluid from a hip joint, the leg must be abducted and the needle carefully guided through the outer layers of tissue into the joint capsule space. There are three approaches, each of which utilizes a slightly different angle and needle placement [12, 14]. In most cases, ultrasound technology and x-ray fluoroscopy are used to guide the needle into the joint capsule [9]. Once fluid is obtained from a hip aspiration, it can be used for diagnostic tests if necessary [15].

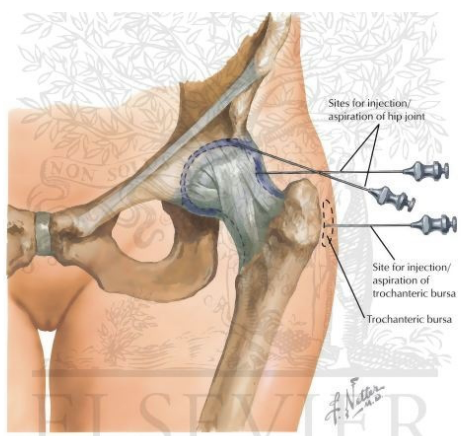


Figure 3: Sites on injection/aspiration of hip joint (the top two needle directions) [16].

Preliminary Designs

Removable Balloon Design

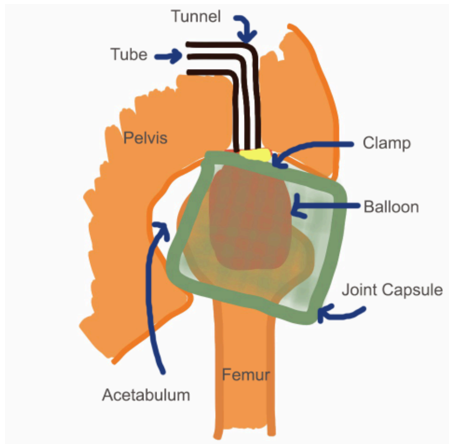


Figure 4: A sketch of the removable balloon design

The Removable Balloon design involves a single-use balloon acting as the synovial membrane, which can be secured to the end of a flexible tube via a clamp or rubber band. This tube can be completely removed from the model through a tunnel carved out in the pelvis so that the balloon can be replaced externally between trials. Once re-inserted, the balloon will rest on top of the femoral head at which point it can be filled with fluid through the tube using a syringe.

The remaining layers of the model (skin, fat, and joint capsule mimics) will be layered on top of the balloon where it sits. The benefit to having this unidirectional, layered design is that the fabrication will be drastically simplified relative to models involving more complex shapes. Each of these layers will be able to withstand multiple punctures and will be secured in place to achieve model cohesion. However, they will also be easily removed to allow for replacement after a significant number of trials have been conducted. While practicing physicians will still be able to experience puncturing each of these individual layers, it is important to note that this design does not accurately represent the internal anatomy of a human infant.

Tupperware Design

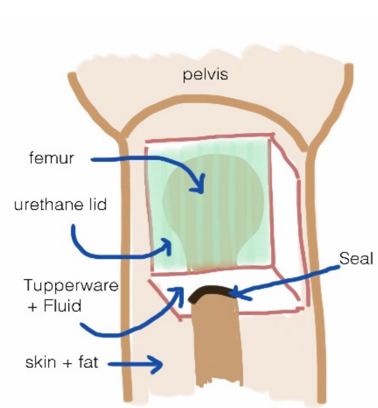


Figure 5: A sketch of the Tupperware design

In the Tupperware design, a Tupperware container will mimic the joint capsule of an infant hip joint. The synovial fluid mimic is contained in a rectangular or cubic Tupperware that encloses the head of the femur. The lid faces the side in which the needle will be inserted. The lid will be made from a urethane material found by the previous design group, which has self-healing and resalable properties. This lid should withstand many needle insertions before being replaced. The head of the femur or the Tupperware itself will not be directly connected to the pelvis. Instead, the leg will be connected to the acetabulum via a piece of removable or semi-removable skin and fat tissue. This mechanism will allow the urethane lid to be replaced after a significant number of uses. It will also allow for fluid to be refilled between uses.

This model allows for easy fabrication and use, since the components need not be replaced after every needle insertion and there is no mess that occurs after each injection. However, the model will not be very anatomically accurate as the shape of the Tupperware does not mimic the real shape of the human hip joint capsule.

Femur-Flation Design

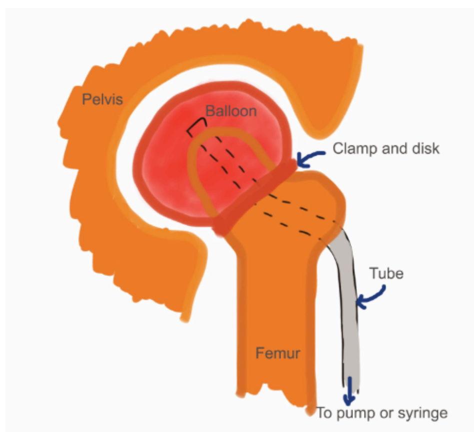


Figure 6: A sketch of the Femur-flation design

The Femur-Flation model strives to accurately represent the distribution of fluid within the joint capsule space. A protruding disc will be secured just below the femoral head. This disc will create a physical separation between the radiopaque bones and the overlying layers of skin, fat, and joint capsule tissue. If necessary, a similar disc can be secured around the perimeter of the acetabulum. A balloon will serve as the membrane mimic. This balloon will need to be replaced with each use. It will wrap around the femoral head (possibly around the protruding disc as well) and be secured with a clamp just above the disc. This will prevent fluid leakage. A hollow cavity will begin at the top of the femoral head and will extend through a portion of the bone as well as some of the overlying soft tissues, ultimately creating an opening in the side or back of the leg. A hollow tube will be inserted into this opening and up through the opening in the top of the femoral head. A pump or syringe attached to the external end of this tube will be used to push fluid through the tube and into the balloon, thereby inflating the balloon and allowing it to fill the empty space created by the protruding disc. By inflating the balloon in this manner, the joint capsule membrane is in a spherical shape and the joint capsule fluid is distributed evenly around the entire joint capsule space. A layer of self-sealing polyurethane will wrap around the balloon in a removable fashion, simulating the fibrous joint capsule.

The femur and pelvis will be held together by the overlying layers of soft tissue. The skin, fat, and muscle will be assembled into a single rectangular strip. This strip will wrap around the leg 360^{o}, securing to itself on the underside of the leg, likely with Velcro. To prevent the upper and lower portions of the limb from separating, this strip will also be permanently secured to one half of the leg as well as temporarily attached to the other half of the leg. With this design for the overlying tissues, it will be easy to gain full access to the femoral head so that the balloon can be easily replaced between uses.

Preliminary Design Evaluation

The final three preliminary designs were compared using a number of carefully selected criteria. The following comparisons were made:

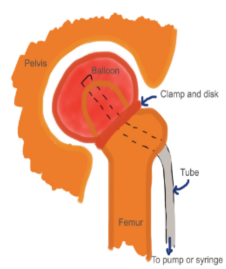
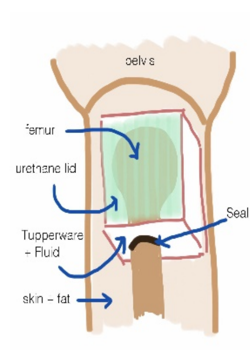
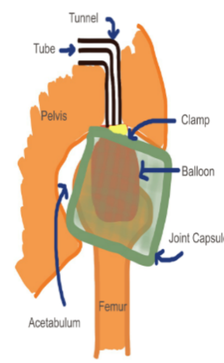
Categories	Weighting	"Femur-Flation"		Tupperware Capsule		Removable Balloon	
Picture							
Ease of use/ Reusability	20	3/5	12	5/5	20	3/5	12
Ease of fabrication	15	2/5	6	4/5	12	4/5	12
Cost	5	4/5	4	2/5	2	4/5	4
Durability	10	4/5	8	5/5	10	2/5	4
Anatomical Accuracy	20	5/5	20	2/5	8	1/5	4
Surgical Accuracy	25	5/5	25	3/5	15	4/5	20
Safety	5	5/5	5	5/5	5	5/5	5
Total	**100**	**80**		**72**		**61**	

Figure 7: The Design Matrix

Ease of use/reusability was weighted very heavily because it is extremely important for our design to facilitate hassle-free repeated uses. It is important for residents to be able to quickly and easily reset the device and practice once more. Reusability is also key. The device must facilitate many uses before replacing any major, costly components. The Tupperware design scored highest in this category because the self-sealing urethane lid allows for multiple needle insertions prior to any membrane replacement. Comparatively, the other two designs require the membrane mimic (the balloon) to be replaced after each use.

Ease of fabrication had significant weight as well because it is important to ensure that the final design can feasibly be created. This category has a slightly lower weight, however, because none of the designs are so complex that feasibility truly becomes a concern, though some designs would possess more difficult fabrication challenges. The Removable Balloon and Tupperware models both scored equally high in this category because both are much simpler designs with fewer interconnecting components. This simplifies fabrication.

Cost has very small weight because the budget for this project is relatively high compared to the amount of materials still needed. Further, all of the designs require very similar materials and therefore will cost similar amounts. The Removable Balloon and Femur-Flation models scored highest in this category because these joint capsule designs can be made with mainly inexpensive materials (tubes, plastics, balloons, etc.). The Tupperware requires purchasing Tupperware and using a larger amount of self-sealing polyurethane, which raises the cost.

Durability was given a relatively small weight as well because the models will be handled with care and will be used in medical settings. They will not be subjected to any extreme strains or conditions that would require extreme durability. Further, all models assume essentially the same overlying layers of skin, meaning the durability in that regard would be equal across the designs. The Tupperware model still scored highest in this category because it can be punctured multiple times without anything needing to be replaced.

Anatomical accuracy was one of the most heavily weighted categories because it is extremely important for the final design to accurately mimic the anatomical components of the body. This is essential because the device will be used as a teaching tool for a surgical procedure. Therefore, the anatomy of the model must teach residents proper anatomical information. When comparing anatomical correctness, the main considerations were the geometry of the joint capsule (which is spherical in the body) and the fluid distribution within the joint capsule. The Femur-flation design scored highest because the design allows for a relatively realistic joint capsule membrane geometry as well as a very realistic fluid distribution. The Tupperware model has a square joint capsule geometry, which is very inaccurate. However, it does allow for fluid to completely fill the joint capsule space. The removable balloon model scored the lowest because fluid does not fully encase the femoral head.

Surgical accuracy was tied with anatomical accuracy in terms of weighting. It was ranked equally highly because, once again, the model is being used to teach residents how to accurately perform a life-saving surgical procedure. It is imperative for the final model to accurately mimic the steps a surgeon would perform when aspirating fluid from an infant hip. When comparing designs within this category, the main considerations were the feel of the joint capsule membrane (it should resist the needle before puncturing), the size and shape of the joint capsule membrane, the ability to aspirate fluid, and the ability to move the leg into the proper position. The Femur-flation design once again scored highest in this category because of the shape of the membrane mimic, the fluid distribution, and the membrane mimic material (self-sealing urethane will resist the needle before popping). Additionally, the model for the skin will make it easy to bend and rotate the infant leg. The Tupperware model scored lowest in this category because the tupperware itself will make the leg more difficult to rotate.

Safety received a low weighting because the models do not have any toxic materials, sharp components, or other dangerous elements. Additionally, the models do not need to meet any biocompatibility requirements (other than being safe to touch). For these reasons, all of the models scored equally highly for safety.

Overall, the Femur-flation design displayed the highest score. This was primarily due to its significant anatomical advantages. This is the final design that will be fabricated.

Fabrication/Development Process

Materials

The final design incorporates skin, subcutaneous fat, and urethane joint capsule materials formerly researched by the previous semester's design team. These materials were used because they already underwent extensive testing and successfully demonstrated that they satisfy the client's main requirements of mimicking the mechanical properties of human tissue in addition to being ultrasound compatible. The skin was created from a silicon and polyester composite while the subcutaneous fat was fabricated from a silicon base mixed with cellulose powder for ultrasound visibility. A urethane rubber was used to mimic the joint capsule material. All three of the aforementioned materials were already purchased by the previous design team and thus did not impact the budget for the semester.

A pediatric, radiopaque pelvis and a pediatric, radiopaque femur were purchased from Sawbones Inc. These bones were chosen to provide X-ray compatibility and because they should ideally fit into a two-year-old sized mannequin made from memory foam. Nine inch balloons were used to simulate the synovial membrane substitute because testing results showed that these balloons were the most appropriately sized.

Methods

Tissue layers

Skin materials were first laid on a piece of nude-colored fabric in a 12x12cm wooden mold, followed by a subcutaneous fat layer after the skin dried. Because the skin was not sprayed with Universal Mold Release, the fat layer adhered to the skin.

After the fat had cured, a mixture of urethane materials was poured on top. However, the urethane materials did not completely adhere to the subcutaneous layer. Thus, superglue was used to join the two layers.

Femur

The pediatric femur was cut at approximately 4" from the top of the femoral head. This is because the pediatric femur that was purchased was significantly larger than expected and therefore did not fit appropriately into the mannequin's upper left leg. The femoral head was also drilled so that a tube could be inserted which would be used to inflate the balloon.

Hip

The pediatric pelvis purchased was significantly bigger than the hip of the mannequin. Thus, the pelvis and the iliac crest were cut. Only the left side of the pelvis was used. Memory foam from the lower left abdomen and upper left thigh was removed and the trimmed radiopaque bones were placed in the cavity.

Final Prototype

Figure 8 shows the final prototype which consists of a two-year-old size mannequin in which part of the radiopaque pelvis is inserted into the lower abdomen. The radiopaque femoral head, as shown in figure 8, is fit into the acetabulum.

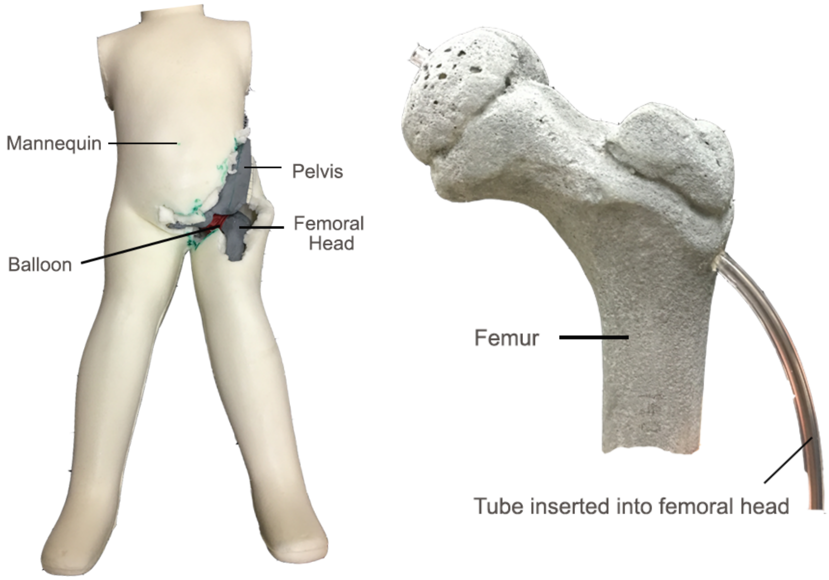


Figure 8: (Left) The prototype without tissue layers, (Right) The femoral head with a tube inserted to inflate the balloon

Before each use, a new 9" balloon will be placed over the femoral head and inflated using a syringe connected to the small tube. The femur, together with the inflated balloon, is then placed into the acetabulum. The tissue layers that have been cut to the correct size are then laid over the cavity. To perform the hip joint aspiration, a needle is inserted through the tissue layers to puncture the balloon and aspirate the fluid.

Testing:

Balloon Testing

The first test conducted was to determine the correct balloon size for our model. Before beginning fabrication, we needed to ensure that the model's central mechanism of aspirating fluid out of a water balloon fastened to the femoral head was even possible; otherwise we would be wasting our time by spending an entire semester developing a model that was destined to fail since the beginning. To do this, we filled 5", 9" and 12" water balloons with approximately 5mL of water from a sink faucet and carefully pulled them over the femoral head while trying to spill as little water as possible. Once loaded, a rubber band was wrapped around the base of the femoral head to ensure a tight seal. Next, a needle was slowly brought into contact with the balloon from an angle and additional pressure was applied until the membrane was either punctured or the entire balloon exploded, as was the case in figure 9. We expected the smaller balloons to explode violently due to the higher internal pressure and the larger balloons to possibly retain their integrity upon being punctured due to the lower internal pressure. We hoped for the latter outcome for at least one of the balloon sizes so that they could be compatible with our model.

Figure 9: A needle punctures a water balloon, resulting in an explosion of water.

Puncture Testing

The goal for these tests was to determine whether the materials we had fabricated to mimic the tissue layers were adequately resalable. This was important in order to guarantee sufficient reusability, one of the main design criteria in the PDS. After fabricating the skin, fat, and urethane joint capsule layers, we tested each of the materials by puncturing them with a needle ten times in the same location to determine the experienced resistance and resealing properties, as is shown in figure 10. Qualitatively, we were then able compare the feeling of puncturing these materials to the feeling of sticking needles through real human tissue based on our experiences in the cadaver lab. We expected to find increasingly diminished resistance with each successive puncture but enough resistance to adequately compare to real human tissue.

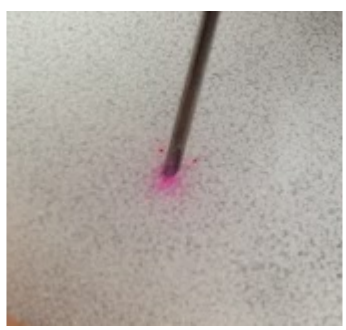


Figure 10: A needle puncturing a marked location on the urethane joint capsule layer.

Tensile Testing

The skin and fat mimics were subjected to tensile testing in order to determine their elastic moduli and compare them to that of real human tissue. We cut small, rectangular specimens of both materials using a razor blade and loaded them into the MTS Criterion machine to perform a tensile test as shown in figure 11. Each material was tested three times in order to determine an average elastic modulus. We expected the materials to adequately reflect the mechanical properties of real human tissue as this test had already been conducted by the previous semester's design team with overwhelmingly positive results.

Figure 11: A skin mimic sample undergoing tensile testing.

Ultrasound Testing:

The final test conducted was to examine the model's ultrasound compatibility which is one of the major techniques used to help physicians guide the needle into the joint capsule properly. The model was brought over to the UW hospital and hooked up to a Siemen's ultrasound machine. Unfortunately, coupling gel was not enough to establish a strong enough signal and the model had to be submerged in a tank of water in order for its components to show up on the ultrasound.

Results

The balloon testing resulted in the 9" water balloon being chosen as the proper size to use with the model. When punctured, the 5" balloon violently exploded due to the small amount of volume enclosed and the relatively thin membrane. This would not be suitable for use in the model as it would disrupt the aspiration procedure and make it near impossible to withdraw fluid. Furthermore, the 5" balloons were very hard to fit over the femoral head in the first place due to their relatively small size and would prove to be a tedious task when prepping the model for repeated uses. The 12" balloon, on the other hand, was too large for this application and the internal pressure was not significant enough to allow for the needle to puncture the membrane before deforming to the point where the needle came into contact with the bone itself. If inserted at an extreme angle, eventually the membrane would relent but this required an abnormally large amount of force which is not practical for our purposes. Luckily, the 9" balloon behaved between these two extremes by getting punctured with relative ease but remaining intact so that fluid could actually be aspirated. Thus, this was the balloon size we chose to use for our model.

With the puncture testing, we found that all three of our materials resembled the feeling of puncturing real human tissue. More importantly, however, all of the materials retained a significant amount of resistance even after 10 successive punctures in the same location. They even outperformed our expectations in this regard proving that they are indeed very reusable materials. While all of the materials did have slightly higher resistance for the first needle insertion as expected, this resistance was well retained in the later trials and we are confident the assembled tissue layers will be able to sustain a substantial number of aspirations prior to needing to be replaced.

The results from the tensile testing were not as positive as the measured experimental young's moduli for the skin and fat were substantially lower than what is reported in the literature. The observed stress-strain curves for the two materials (three trials each) can be seen below in figure 12.

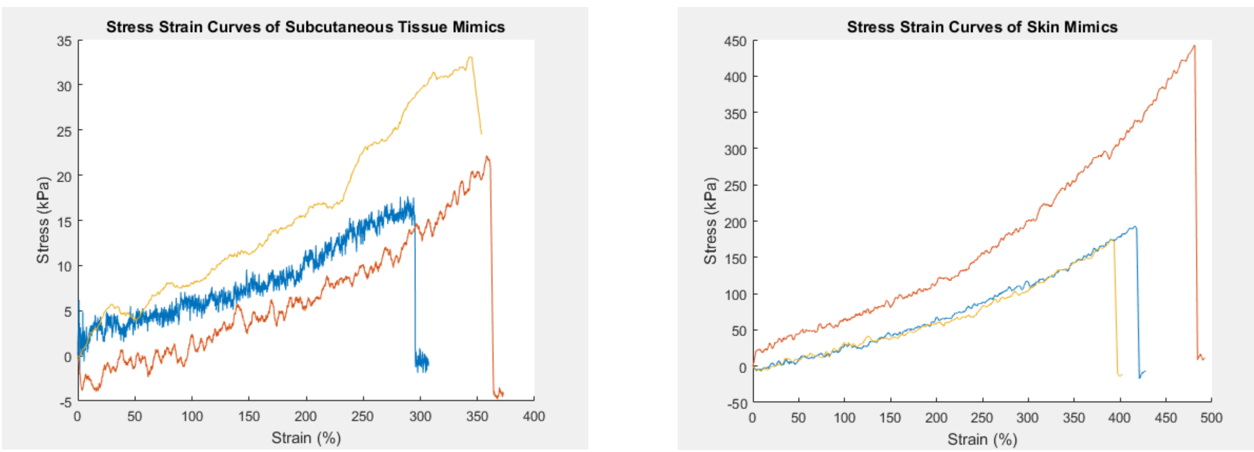


Figure 12: Experimental stress-strain curves for fat (left) and skin (right) mimics.

From these graphs, the young's moduli (E) can be extracted as the slopes of the linear region. The average modulus for the fat was merely 61.6Pa while for skin it was only 445Pa; these values are substantially lower than the 80 and 2.31kPa reported in the literature for fat [17] and skin [18] respectively Reasons for these extreme discrepancies will be covered in the discussion section below.

Finally, while we needed to submerge the model in water in order to conduct ultrasound testing which is far from practical, the images we observed (figure 13) came back very clear.

Figure 13: Left: The skin, subcutaneous fat, and urethane joint capsule tissue mimics. Center: The acetabulum and femoral head. Right: A needle piecing the joint capsule space.

As the above images show, the skin, fat and joint capsule layers all show up as separate, distinct entities while the outlines of the bones are easily discerned. Additionally, the needle, when present, is quite prominent which verifies the fact that ultrasound can be used as a guidance technique.

Discussion

After an entire semester of design, we now have a completely assembled and working prototype for practicing the infant hip aspiration procedure. By using the materials that the previous design team had already researched and validated, our group was able to immediately focus on developing the mechanism for the actual procedure itself. The design we came up with meets the major requirements set out by the client including achieving sufficient reusability and allowing for fluid to be drawn out from the joint capsule space. While functional in the sense that an entire hip aspiration procedure can be properly conducted, our model can still be improved in a variety of ways.

The most obvious modification would be to get bones that actually fit the size of the mannequin. As it stands right now, we had to cut off a sizeable portion of the femur as well as split the pelvis in half just to get them to fit inside the mannequin at all. Despite being labeled as "pediatric" sized on the Sawbones website, these radiopaque bones were far larger than expected and in the future, obtaining properly sized bones should be a main priority. In the event that radiopaque versions of these smaller bones do not exist on the market, normal bones can be coated in an optically active paint as an alternative.

While the mannequin itself is the correct size, it could also be improved to better meet the needs of the model. First, getting a mannequin that allows for greater leg movement would be a huge step forward because hip aspirations are most commonly performed on fully abducted legs, which our model currently does not support. Second, it may be worthwhile to use a mannequin made out of a different material because the solid foam of the current model looks fairly unprofessional when hollowed out. While we did our best to make the current iteration as presentable as possible using an inner fabric lining and glue, a hollow, plastic model might be a better choice next time around. It is worth noting that future mannequins do not necessarily need to be of the entire infant: a section consisting of just the lower abdomen and upper thighs is enough to practice a hip aspiration.

As far as the tissue mimic materials are concerned, one of the reasons for why the observed mechanical properties during testing are so far off compared to the literature could be that they are simply too old. Our group used the same cans of Ecoflex 30 and Econ 80 for the skin/fat and urethane layers that the past group has ordered back in the fall of 2014. The cans themselves indicate that the material should be used as quickly as possible after opening and it is quite possible that they were expired when we began fabrication. This would explain why the young's moduli we observed were orders of magnitude lower than what the previous group had reported in their final paper. Thus, we believe that if we were to order brand new materials, then the experimental mechanical properties would match up more closely with what is reported in the literature. Besides that, fabricating a thicker subcutaneous layer and thinner urethane joint capsule would also provide a more realistic experience for practicing physicians.

Finally, additional work needs to be done in order make the model compatible with imaging techniques to guide the needle in properly. Unfortunately, our group had trouble getting in contact with a technician to assist with X-ray fluoroscopy and so we were not able to conduct those tests during the semester. However, given the fact that we specifically ordered radiopaque bones, we expect to garner positive results when these tests are ultimately conducted. Using ultrasound, on the other hand, will require quite a bit more work before it can be used as a guidance technique. When testing our model with this technology, the only way to establish a proper coupling was to submerge the entire mannequin in water. This is obviously not a practical way to perform a hip aspiration procedure and additional research must be done in order to find materials which are naturally ultrasound compatible.

Conclusion

Demonstrating proficiency when performing a hip aspiration is a requirement for future physicians and is an important means of treating an extremely painful, debilitating disease. In spite of this, there are currently no models on the market that allow medical students to practice this procedure. Thus, there is significant market potential for widespread distribution of a working model. Our final design achieves a very accurate portrayal of the synovial fluid distribution within the joint capsule. This is accomplished by securing a balloon over the femoral head and inflating it with fluid using a tube that runs through a cavity *within* the femoral head. This joint capsule design worked extremely well, though there is room for improvement. The bones ordered from Sawbones are too large for a two-year-old-sized doll, which is problematic as the model must simulate hip aspiration of an infant. Additionally, the acetabulum of the radiopaque pelvis that was used was too large in comparison to the femoral head that was used. While the balloon model is very effective, stretching a balloon tightly over the femoral head may be somewhat cumbersome for residents to do after each attempt. Improvements should be made so that this process is streamlined. The mannequin used in the final design accurately mimicked the size of a two-year-old, which was very important. However, the model did not allow for abduction of the leg into the proper position. Future groups should consider other doll options as the base of their model. Additionally, though our synthetic tissue layers were ultrasound compatible, the doll itself cannot feasibly be used with ultrasound technology as it must be submerged in water. Improvements should be made so that the final product is truly ultrasound compatible and x-ray fluoroscopy compatible. Overall, our joint capsule design and working prototype is the foundation for a successful final model for which there is considerable need. Should additional steps be taken to improve upon the work completed this semester, our design can certainly become an extremely effective teaching tool that will ultimately save lives.

Future Work

Moving forward, one of the most important aspects to address is improving the overall ease of use. While inflating a balloon over the femoral head using a tube drilled through the bone provides a very easy mechanism for refilling the model's fluid reservoir, the process of taking apart the different layers and prepping for another trial is currently moderately cumbersome and can be streamlined in the future. For example, permanently attaching the tissue layers to the rest of the model can greatly reduce the amount of effort spent forcing the layers into the correct position. Additionally, adding a drainage system for removing excess water would help keep the model dry and immediately ready for successive uses.

Another facet which could be improved is the model's anatomical accuracy. While the issue of getting tissue layers that more accurately reflect the mechanical properties of what one would expect to find in real patients has already been covered in the discussion, modifying the design to adhere more towards the correct geometry is another task altogether. The joint capsule should enclose the space directly around the femoral head rather than exist as a uniform flat layer as it is in its current state. Including more key anatomical structures such as the femoral artery would also prove to be valuable additions as they would help practicing physicians know where to insert the needle in the first place.

The final stage for this project would be to adapt the model for marketability. While the current prototype is a step above a proof of concept, it is not yet at the point where it could be marketed to medical schools around the country. In order to do this, the overall integrity, stability, and cohesiveness of the model would need to be vastly improved. This would mean selecting less flimsy materials, creating smoother, sharper edges, and developing a plan for larger-scale manufacturing. Once all of the previously described modifications have been made, this product has a real chance of making it to the market given its massive need throughout the nation.

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Appendix A: Fabrication Protocols

Skin Mimic "Painting" Protocol

1. Spray Universal Mold Release on to surface where mixture is to be placed
2. Following directions for Ecoflex 30:
    a. Stir X mL Part B thoroughly
    b. Add an equal amount of Part A, and mix thoroughly for about 2 minutes.
3. Wrap polyester (swimsuit liner) on a mold of an infant lower body shape. We used staples in order to get the liner the desired shape.
4. "Paint" a thin, even layer of Ecoflex 30 gel over the swimsuit liner.
5. Let dry for at least 4 hours for material to set into an elastic skin mimic.

Joint Capsule Protocol

1. Following directions for urethane rubber:
    1. Mix desired volume of Part B thoroughly
    2. Add an equal volume of Part A and mix together for at least 2 minutes
2. Rotational Mold Technique:
    1. Spray Universal Mold Release on to surface where mixture is to be placed
    2. Pour the mixture around the edges of a cylinder
    3. Rotate at a constant spinning velocity for 10-20 minutes

4. Once mixture is partially set (slightly stiffer, will still be sticky), put the mixture around a tube with the desired inner diameter
5. Rotate until mixture has set enough so that it will not drip
6. Let dry 12-24 hours

3. Inner + Outer Diameter Technique:
    1. Spray Universal Mold Release on to surface where mixture is to be placed
    2. Use a rod with a diameter that matches the desired inner diameter of the capsule (i.e. the diameter of the femoral neck in the model or SLIGHTLY smaller because material stretches)
    3. Use a tube with an inner diameter that matches the desired outer diameter of the capsule (i.e. 1-3 mm larger in diameter than the rod)
    4. Put the rod steadily inside the tube, and pour the mixture in between the two
    5. Let dry 12-24 hours

4. After initial cylindrical shape has set, fit around femoral head of bone mimic and in the concave space of the acetabulum.

    1. Seal with a new mixture of equal Part A: Part B in liquid form.
    2. Add super glue (gorilla glue) as necessary to create an air-tight, sealed joint capsule

Fat Mimic Protocol

1. Mix a 2:2:3 mass ratio of Ecoflex 30 Part A: Ecoflex 30 Part B: Silicone Thinner
    a. To fill the size of the infant model, about 266 g: 266 g: 400 g
2. Add 1% of the total mass of cellulose powder
    a. ~9.3 g of Sigmacell Type 50 Cellulose
3. Mix all the contents thoroughly and let the liquid mixture set in the skin mimic layer* that had been previously created (to maintain structural integrity, stabilize the skin with the setting fat mimic in a sand bath)

In the future, the bones connected by the urethane rubber capsule will be set into place before pouring and setting the fat mimic into the entire model. For testing purposes this semester, a human bone was set in the skin and the liquid fat mimic poured around the space of the bone for proof of concept and for ultrasound testing

Appendix B: PDS

Product Design Specification - 1.31.2016
Hip Aspirate Model to Teach Physicians

Client: Dr. Matthew Halanski (halanski@ortho.wisc.edu)
Advisor: Dr. Ed Bersu (etbersu@wisc.edu)
Team Members:

- Jessica Brand (jtbrand@wisc.edu), BME 301 - *Team leader*
- Stephen Schwartz (saschwartz@wisc.edu), BME 301 - *Communicator, BPAG*

- My An-adirekkun (anadirekkun@wisc.edu), BME 301 - *BSAC, BWIG*

Function:

Septic arthritis of the hip is a rare orthopedic disorder most common in infants under two which, if left untreated, can cause lifelong pain and discomfort. Currently, there is no model on the market which allows residents to practice X-ray and ultrasound-guided hip aspiration, the most critical technique in confirming the diagnosis. The client, Dr. Matthew Halanski, requests that a base infant hip model be developed for training purposes. The design from fall of 2014 will be refined and innovated upon to better meet the client's long-term goals. Ultimately, the model should be a fully assembled product made with synthetic materials that simulate the mechanical properties of skin, muscle, soft tissue, and fibrous tissue.

Client Requirements:

- Produce a fully assembled hip model of an approximately 18-month-old infant
  - One leg/hip of model should accurately mimic human hip rotation
- Model must be reusable
  - Either has an inexpensive part replacement or is a single, durable device
- Model must contain synthetic skin, soft tissue, and joint capsule material that mimic the mechanical properties of these substances in the body when punctured with a syringe
- Model must contain synthetic skin, soft tissue, joint capsule, and bone material that produce accurate images with both ultrasound imaging and fluoroscopy
- Model must contain fluid that can be aspirated with each use

Design Requirements:

1. Physical and Operational Characteristics

a. *Performance Requirements:* The model must use materials that accurately mimic the layers of the body that a needle passes through when performing a hip joint aspiration. This includes an outer layer of skin (dermis and epidermis), muscle, fatty tissue, and fibrous tissue connecting the femur to the pelvis (the joint capsule). The model may be used sporadically for physician training. When in use, the model must facilitate repeated needle insertion. This can be accomplished in two ways. Either the model can have an easily removed and inexpensive component that accommodates 1-10 needle insertions, or the model as a whole must accommodate at least 100 needle insertions. Our model must accommodate 45° flexion of the hip for each attempt at the procedure. Ideally, the surgeon should be able to feel a synthetic adductor brevis muscle within the model.

b. *Safety:* The model must be nontoxic to users. It will contain fluid which must be isolated from any electrical components that may be included. Any sharp components must be covered so the model is safe to handle.

c. *Accuracy and Reliability:* The model must contain fluid so physicians can determine whether or not they successfully aspirated the hip joint. It must facilitate accurate ultrasound and fluoroscopy imaging.

d. *Life in Service:* Each aspiration procedure takes approximately 1-2 minutes [1]. The model must accommodate any number of procedures that are attempted at a given time. Lengths and frequencies of training periods may vary.

e. *Shelf Life:* The model must remain functional for at least one year when stored at room temperature in dry conditions.

f. *Operating Environment:* The model will be used in resident training facilities such as hospitals and medical schools. The model will most likely be used at room temperature. It is unlikely that it will be used under any extreme operating conditions.

g. *Ergonomics:* The model should be handled easily by residents who are practicing hip aspiration procedures in infants. Palpating the model should somewhat replicate palpating a real infant hip.

h. *Size:* The hip model will be the size of an approximately 18-month-old infant. The average height of an infant of this age ranges from 31.0" - 33.1" [2]. Since the model will include the bottom part of the body below the hip, the length of the model is likely to be approximately half of the child height, that is, between 15" - 17".

i. *Weight:* The weight must not impede the portability of the model.

j. *Materials:* The materials should not be toxic when in contact with the skin of users. The materials used for skin, soft tissue, joint capsule, and bone should produce accurate images using ultrasound imaging and fluoroscopy. 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 self-healing to allow for multiple needle insertions before being replaced. The exact number of needle insertions they must accommodate will depend on the final design (whether a modular portion of the model will be replaced, or if the whole model will accommodate 100+ insertions). The joint capsule material must notably resist puncturing more so than the other materials.

k. *Aesthetics, Appearance, and Finish:* The model should resemble the appearance of a human infant hip.

2. Production Characteristics

a. *Quantity:* One infant hip model will be manufactured.

b. *Target Product Cost:* The grant originally awarded to fund this project has since expired and thus the current budget for this semester is $500. Some materials that were purchased for the previous group's model will ideally be repurposed to cut down on costs and shipping times.

3. Miscellaneous

a. *Standards and Specifications:* While the model itself is not subject to any regulations, it will be used in conjunction with both X-ray fluoroscopy and ultrasound technology, which must comply with standard FDA regulations [3],[4].

b. *Customer:* The target customers will be medical schools and hospitals seeking to train residents in infant hip aspiration. Alternative customers include physicians, surgeons, and medical researchers.

c. *Patient-related Concerns:* The practice procedure will not be performed on actual patients and so there are no patient-related concerns for this project. However, the model should mimic the anatomy of an infant hip as best as possible so that residents will be comfortable performing the hip aspiration on actual patients after they have demonstrated adequate procedural efficiency.

d. *Competition:* There are currently no marketed models which simulate this unique surgical procedure; the lack of training equipment was a key piece of motivation for the original grant being awarded.

Appendix C: Costs

	Amount	Total Price
Firefly Store Solutions: Flex-Kid Mannequin 1-2yr	1	$67.00
Sawbones: Full Pediatric Pelvis with Radiopaque properties	1	$89.00
Sawbones: Pediatric Femur with Radiopaque Properties	1	$36.00
Smooth-on: Ecoflex 30 Parts A and B	1	Already available
Smooth-on: Universal Mold Release Aerosol Can	1	Already available
Smooth-on: Silicone Mold Compound Thinner	1	Already available
Smooth-on: Econ 80 Urethane Rubber Part A and Part B	1	Already available
Amazon: 5” Dart Balloons	1	$8.22
Amazon: Water Sport Balloons Refill Kit, 500-Pack	1	$6.10
Amazon: Biodegradable Water Balloons 100 Pack	2	$5.74
Amazon: 25 feet Aquarium Oxygen Tube	1	$4.99
Party City: 9” Balloons Pack	2	$7.00
Party City: 12” Balloons Pack	2	$7.00
Unknown: Nude-color skin	1	Already available
Target: Paintbrushes	1 pack	$6.00
Target: Plastic Cups	1 pack	$3.00
Total Price	$240.05	