HIP ASPIRATION MODEL TO TEACH PHYSICIANS

BME 301: Mid-semester Report

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Team Members

Jessica Brand, *Team Leader*

Stephen Schwartz, Communicator, *BPAG*

My An-adirekkun, *BWIG, BSAC*

Client

Dr. Matthew Halanski, MD

Advisor

Dr. Edward Bersu, PhD

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Abstract:

Septic arthritis of the hip is a rare orthopedic emergency which, if left untreated, can lead to lifelong pain. The most effective diagnosis method for this disease is a hip aspiration, however, there are currently no educational models that allow residents to practice this procedure. Thus, a model of an infant hip joint has been designed for this purpose. It includes a removable strip of synthetic soft tissues with self-healing qualities which encases a fluid-filled balloon (mimicking the joint capsule). The balloon must be replaced with each use and proper balloon properties as well as the self-healing properties of the overlying tissue layers must be tested. Once fabricated, the device will help surgeons combat septic arthritis of the hip.

Introduction

Septic arthritis is an inflammation at joints caused by bacterial or fungal infection that spreads through blood to joints [1]. Although this rare orthopedic disease can be seen at any age, it is most common in infants under two, elderly, and those with weakened immune systems. If this disease is not treated properly, it can lead to tissue necrosis which causes lifelong pain and discomfort. Septic arthritis can be diagnosed by aspirating (drawing out) synovial (joint) fluid, blood, or imaging tests [2]. Antibiotics are usually administered to treat the infection, however, in the case where synovial fluid builds up too quickly, the fluid must also be aspirated [1].

Although the hip is one the joints most commonly affected [1], there is no suitable model currently on the market which allows residents to practice X-ray and ultrasound-guided hip aspiration in infants. 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 mimicking synovial fluid would be contained in a balloon inside the leg which could theoretically be aspirated using a needle. This model is not suitable for teaching residents but provides a solid foundation on which future designs may build on.

Figure 1: Dr. Halanski's initial prototype. The model is made from a plaster mold. The inside of the model is hollow so that a balloon containing fluid can be placed [3].

Dr. Halanski requests us to design and fabricate a model that is more suitable for teaching residents the hip aspiration procedure in infants. In this semester, we will focus on designing the joint capsule and the model will most likely be fabricated from the materials tested by the fall 2015 design group. 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 fibrous tissue and can withstand multiple needle insertions before being replaced. It should also contain a synovial fluid mimic which can be aspirated.

Background

Client information

Our client, Dr. Matthew Halanski, is a faculty member at 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 joint where the femur (thigh bone) meets the three bones (ilium, pubis, and ischium) that make up the pelvis [4]. The acetabulum (a deep socket), a strong joint capsule, and its surrounding muscle and ligaments provides the hip joint with a high degree of stability such that the joint movement is limited to flexion, extension, adduction and abduction [4]. The hip joint capsule, composed of iliofemoral, pubofemoral, ischiofemoral ligaments, is a dense, fibrous structure [4]. The space between the joint capsule and the femur contains a lubricant called synovial fluid, produced by a fluid-filled sac Bursa, which allows the joint to be flexed under high pressure without wear [4]. The hip adductor longus muscle, a long and triangular muscle, is located in the inner thigh allowing hip adduction and flexion [5]. This muscle can be used to help palpate the hip joint.

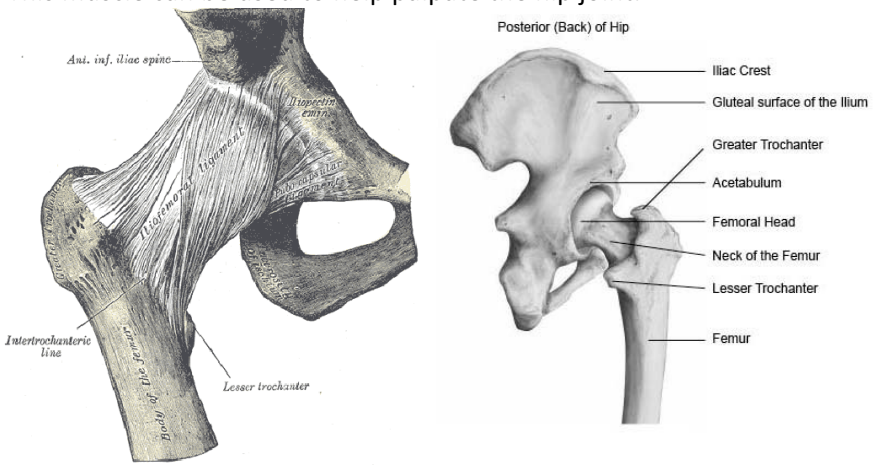


Figure 2: Anatomy of hip. A: Ligaments link pelvis and femur together. B: Bones of the hip joint [4].

Hip Joint Aspiration

Hip joint aspiration is a procedure performed to remove the synovial fluid from the joint capsule to relieve swelling or to obtain synovial fluid for diagnosing the joint's infection [6]. It involves inserting the needle through the joint capsule and using a syringe to draw out the fluid.

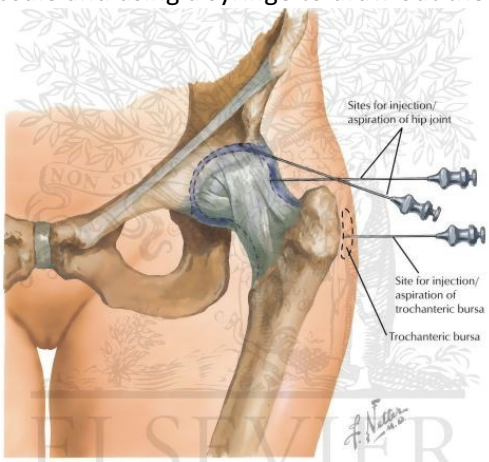


Figure 3: Sites on injection/aspiration of hip joint (the top two needle directions) [7].

Preliminary Designs

Removable Balloon Design

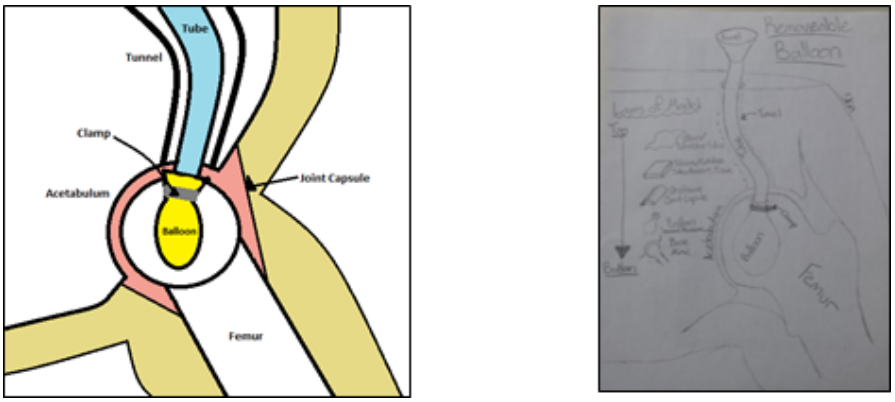


Figure 4: A sketch of the removable balloon design

The Removable Balloon design revolves around 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 in between trials. Once reinserted, 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 where the balloon sits. The benefit to having a 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 thus 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

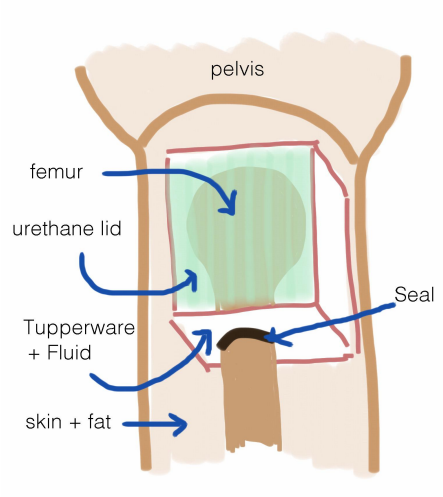


Figure 5: A sketch of the Tupperware design

In the Tupperware design, a Tupperware container will mimic the joint capsule of human hips. The synovial fluid mimic is contained in a rectangular or a cubic Tupperware that encloses the head of the femur with its lid facing the side in which the needle will be inserted. The lid will be made from urethane which was tested to have a self-healing and resalable property by the previous design group. This lid should withstand several 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 hip via a piece of removable or a semi-removable (removable at one side) skin and fat tissue so that the urethane lid and be replaced and the fluid can be re-filled after a few uses.

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

Femur-Flation Design

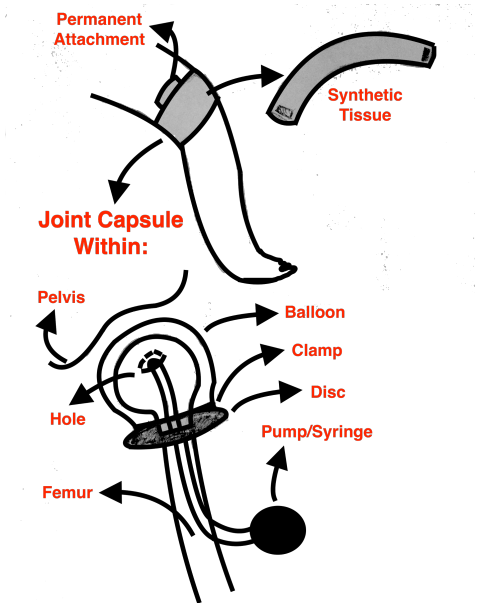


Figure 6: A sketch of the Femur-flation design

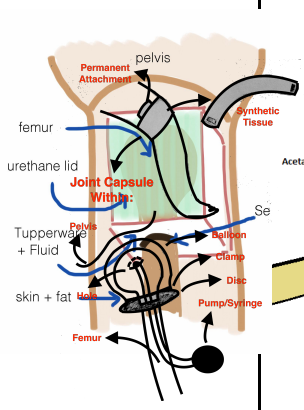
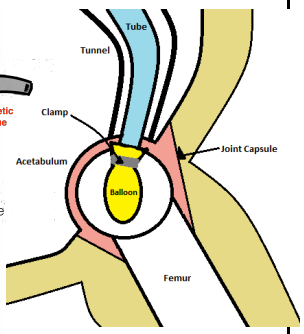
The Femur-Flation model strives to accurately represent the distribution of fluid within the joint capsule space. A protruding disc will be secured just below the femoral head. This disc will create a physical separation between the radiopaque bones and the overlying layers of skin, fat, and muscle. 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.

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°, securing to itself on the underside of the leg (likely via 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**	

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 bears a very small weighting because the budget for this project is relatively high compared to the amount of materials still needed. Further, none of the designs require significantly more expensive materials. The Removable Balloon and Femur-flation models scored highest in this category because these joint capsule designs can be made with all inexpensive materials (tubes, plastics, balloons, etc.). The Tupperware model requires self-sealing polyurethane, which raises the cost.

Durability was given a relatively small weighting as well. All of the models would be similarly durable. Additionally, 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. Regardless, the Tupperware model scored highest in this category because it can be punctured multiple times without anything needing to be replaced.

Anatomical accuracy was one of the highest 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 on 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), size and shape of joint capsule membrane (does the synthetic membrane mimic the size and shape of the membrane surgeons can puncture), ability to aspirate fluid, 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 (a properly inflated balloon will resist the needle before popping). Additionally, the model for the skin will make it easy to bend and rotate the infant leg. The removable balloon model scored second highest in this category due to the membrane material. The Tupperware model scored lowest in this category because the tupperware itself will make the leg more difficult to rotate, and the urethane may not provide an accurate membrane "feel."

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 scored the highest. This was primarily due to its significant anatomical advantages. This is the final design that will be fabricated.

Fabrication/Development Process

Materials Plan

The final design will incorporate the formerly researched materials from the previous semester's design team. This is because they have already undergone extensive testing and have 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 will be created from a silicon and polyester composite while the subcutaneous tissue will be fabricated from a silicon base mixed with cellulose powder for ultrasound visibility. A urethane rubber will be used to mimic the joint capsule material. All three of the aforementioned materials have already been purchased by the previous design team and thus will not impact the budget for the semester.

A pediatric, radiopaque pelvis and femur will be purchased from Sawbones Inc. to provide X-ray compatibility as well as the appropriate dimensions of the model. Finally, additional research and testing will be conducted in order to determine the most viable balloon membrane to use as the synovial membrane substitute and thus fluid container.

Methods Plan

At this point in the design process, the fabrication protocols (Appendix A) developed by the past semester's team will be used to fabricate the skin, fat, and joint capsule mimics. These protocols may need to be altered to better fit the needs of the current design but they will be followed as written for at least the initial fabrication.

Testing Plan

The final design involves a balloon membrane stretched around the femoral head and slightly filled with fluid. For a successful model, this balloon needs to be inflated enough so that it can be easily punctured by a needle without deforming to the point where the needle comes into contact with the bone; at the same time, it cannot be inflated so much that the rupture causes a burst strong enough to distort the model. Thus, a series of tests must be conducted in order to determine the best balloon material as well as the optimal extent of inflation prior to moving forward with the fabrication of the final design. For every balloon material considered, the test will be carried out as follows:

1. The balloon is stretched over a femoral head and secured at the base with a rubber band
2. 5mL of water is inserted via a syringe under the rubber band clamp
3. A needle is slowly pressed against the balloon until:

a. The balloon pops, in which case the resulting burst is qualitatively assessed on its amount of force according to the following criteria:

   i. Limited Force
   ii. Moderate Force
   iii. Extensive Force

b. The needle hits the bone, in which case an additional 5mL of water is inserted and step three is repeated

Once all of the balloons have undergone this analysis, the cheapest material will be chosen from those which produced bursts with limited force.

While extensive testing from the previous semester's design group has shown that the skin material closely mimics the mechanical properties of human skin, and that the fat material is ultrasound compatible, it will be necessary to repeat these tests to confirm the results and verify the correct fabrication of the materials. Furthermore, it will be necessary to test these properties as well as other elements of functionality once the model has been fully assembled. To do this, the balloon will be filled with the correct amount of water as determined by the aforementioned test, and each group member will attempt the hip aspiration procedure. If the model functions as intended, then the testing can be expanded to include current UW medical students. Feedback from both internal testing as well as the medical students will determine whether additional tweaking will be necessary.

Conclusions

While demonstrating proficiency in the hip aspiration procedure is a requirement for future physicians, there is currently no model with which medical students can practice. Thus, there is significant potential for widespread distribution of a working model. The final design selected achieves the most realistic portrayal of human anatomy due to the shape of the balloon encompassing the femoral head. This, when paired with adequate materials which mimic the properties of human tissue, will lead to a functional model capable of replicating the hip aspiration procedure as closely as possible. Moving forward, the most important next steps are to assess the functionality and feasibility of the final design through extensive testing, and starting fabrication in a timely manner.

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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.

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