MODEL FOR TEACHING CLOSED REDUCTION AND PINNING OF A PEDIATRIC SUPRACONDYLAR HUMERUS FRACTURE

FINAL REPORT

BME 200/300

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ABSTRACT

The supracondylar humerus fracture is the most common elbow fracture in children between the ages of 3-7. The surgical procedure to treat this fracture presents many possible risks for the child if performed by an inexperienced surgeon. There is a need for training models that properly simulate the pinning and reduction of the supracondylar humerus fracture and can be reused without compromising functionality. The team's solution was to modify a Sawbones model, which properly replicates the relevant anatomy, to simulate the surgery. The model was fractured, holes for pinning were pre-drilled, periosteum was attached, and a patch of skin was removed from the drilling site. To evaluate the model, the team received qualitative and quantitative evaluations of the model from doctors, residents, and other medical staff. This data was analyzed in Excel and deviations of the mean over multiple trials were calculated, thereby assessing the improvement areas needed for the model. It was concluded that the model was a good first iteration for the project.

I. Introduction

A. Motivation Impact

Pediatric supracondylar humerus fractures are the most common elbow fractures in children, and they represent 18% of all types of pediatric fractures [1]. The creation of a model for the closed reduction and pinning of pediatric supracondylar humerus fractures is essential to furthering the skills of orthopedic surgeons. Due to the prevalence of the surgery, surgeons need to be fluent in the skills and feel of the repair. Often, it is expected that the residents know how to accurately complete the surgery, but they do not have enough practice [3]. A model would help to eliminate the difference in ability and would ensure that every orthopedic doctor, all over the world, could better complete the surgery [2].

Currently, most bone representations that could be used for practice are realistic but not reusable for long periods of time. This is due to practice runs leaving many marks in the model, clueing the next user into how others have completed the technique [3]. One example of an existing model is the Sawbones: Pediatric Elbow with Supracondylar Fracture, which looks realistic but cannot be reused because of reasons stated above [4]. A model needs to fit both of those requirements in order for the doctors to gain the appropriate skills.

B. Existing devices

There are currently many bone models of pediatric humerus bones on the market [5,7]. There are even realistic skin envelopes [6]. It is rare however to find a model with a skin envelope attached to the bone and a pre-fractured model. There are patents that exist on the surgery method of closed reduction and pinning. However, there were not any patents on the training or training model for the surgery. The company Sawbones has a similar replica of both the bone and the skin envelope that the client requested. It is missing the fracture and other necessary modifications [4]. Sawbones is one of the few companies that has been known to have a similar model to the one asked for by the client.

C. Problem statement

Supracondylar humerus fractures are the most common elbow fracture seen in children; most of which require surgical intervention via closed or open reduction with percutaneous insertion of pins to maintain the reduction. The injury can be associated with neurovascular injury and as a result, is often done as an urgent or emergent procedure, many times overnight. In such a setting, experience in the procedure is vital to safe and efficient surgical intervention. This project aims to build a pediatric supracondylar humerus model and accurately simulate the closed reduction and pinning process.

II. Background

A. Physiology and Biology

Pathoanatomy

The anatomic layout of the supracondylar region is the following: it is posteriorly bordered by olecranon fossa, anteriorly by coronoid fossa, and on both sides by supracondylar ridges. In addition, the supracondylar area is situated in close proximity to neurovascular structures, such as the median and ulnar nerves. The area's proximity to neurovasculature can increase the risk of complications in the surgery. In general, supracondylar humerus fractures are often caused by a fall on an outstretched hand (extension-type injury). The olecranon fossa acts as the fulcrum of the break. It focuses the stress on the distal humerus and causes the fracture [8].

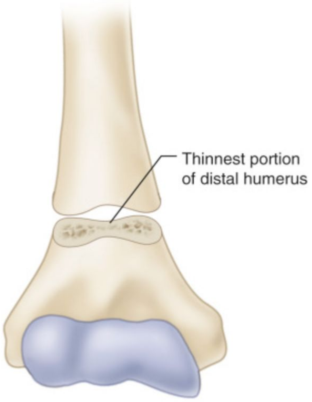


Figure 1: The thinnest portion of the distal humerus.

For this specific type of fracture, age is a critical factor of incidence. In children, the supracondylar area consists of weak, thin bone. From ages 6 to 7, the supracondylar area is undergoing remodeling which leaves it particularly thin, as shown in Figure 1, predisposing it to fracture. The peak years of injury are between 3 and 7 years of age, because of the timing of ossification in the humerus. The thinness of the supracondylar area will be reflected in the group's training model, as the team's focus is pediatric [8].

Classification of injuries

Supracondylar humerus fractures are defined as either extension or flexion type injuries, depending on how the patients falls. As stated earlier, extension type injuries make up the vast majority of these fractures (>95%). These extension type injuries are further broken down into different categories by the Gartland classification. There are four types of extension supracondylar humerus fractures, as illustrated by Figure 2.

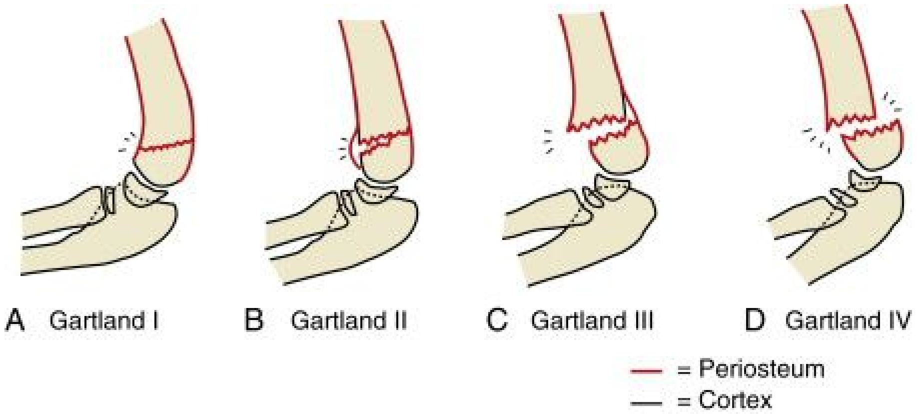


Figure 2: The four Gartland classifications of supracondylar humerus fractures.

Type I is non-displaced and appears to just be a line fracture. Type II is angulated but the posterior cortex remains intact. Type III is displaced in 2 or 3 planes. Type IV is a complete periosteal disruption. For the purposes of this project, the team's focus will be Type III injuries because it is the most common type of pediatric supracondylar humerus fracture [9].

Treatment

In order to treat both Type II and Type III fractures, the most common surgical technique is closed reduction and percutaneous pinning (CRPP). The severity of the injury and its proximity to neurovascular structures are the most important factors in the timing of the surgery. The preoperative assessment consists of a visualization of the affected extremity through a fluoroscopy detector. Fluoroscopy is a form of X-ray imaging categorized by the passing of X-rays through the desired location, where the rays reflect off of radiopaque tissues and cast a live image onto a fluorescent screen [13]. In the case of this procedure, bone tissues have a radiopacity greater than that of the X-rays, making them radiopaque [14].

Figure 3. Baumann's angle

The geometrical indicator that surgeons look for in an X-ray is Baumann's Angle. Bauman's angle is the angle between the shaft line and the parallel line to the lateral condyle physis. In a healthy humerus, the angle should be about 70-75 degrees. Anything greater is concerning for fracture with displacement [25] (See Figure 3).

After the assessment is complete, the surgeon performs a closed reduction on the patient, which means they correct the misalignment without opening up the patient. Closed reduction can be particularly challenging as the surgeon has to maintain traction while examining for misalignments in different planes with a fluoroscopic view. Once the closed reduction is performed, pins are percutaneously driven through the elbow to fix the bone into place [10]. The placement of these pins is pertinent to correctly setting the fracture. To decrease rotational torsion, pin distance across the fracture site must be maximized. The ideal distance can be achieved by angling one pin in the lateral column and another in the capitellum anlage as shown in Figure 4. To increase the strength of pin fixation, the diameter of the pins must be increased [15]. These intricacies involved with the procedure are what the team is to replicate in the model.

Figure 4: Correct (left) and incorrect (right) pin placement.

B. Design Specifications

The Product Design Specifications (PDS) is a collection of design requirements for the pediatric supracondylar humerus fracture model. These requirements are created by the client and the team has added what they think is necessary to better reflect the industry standard. The training model must be reusable, allowing for at least 5 years of pinning and reductions without defaulting, and must not be flammable or susceptible to heat damage. Furthermore, the training model must be an effective tool for the teaching of medical students by accurately mimicking the real surgery. This aspect includes having a realistic weight and feel, and should overall mimic the appearance of an actual pediatric arm. The budget of the model is confined to $222. The full PDS can be found in Appendix A.

C. Client Information

Dr. Pamela Lang is an orthopedic pediatric surgeon who is a faculty member at the University of Wisconsin-Madison School of Medicine. This is where she conducts research to advance the field of pediatric orthopedics and is responsible for the training of orthopedic pediatric surgery residents [11].

III. Preliminary Designs

A. Material Options

a. **Sawbones-** The Sawbones design option, as shown in Figure 5, utilizes Sawbones’ radiopaque pediatric humerus model and removable soft tissue envelope. It is made from solid foam with latex bands attached. The humerus model mimics the density of bone along with the periosteum that covers it. The soft tissue envelope resembles the muscle, fat tissue, and skin layers surrounding the bone and has the ability to be removed.

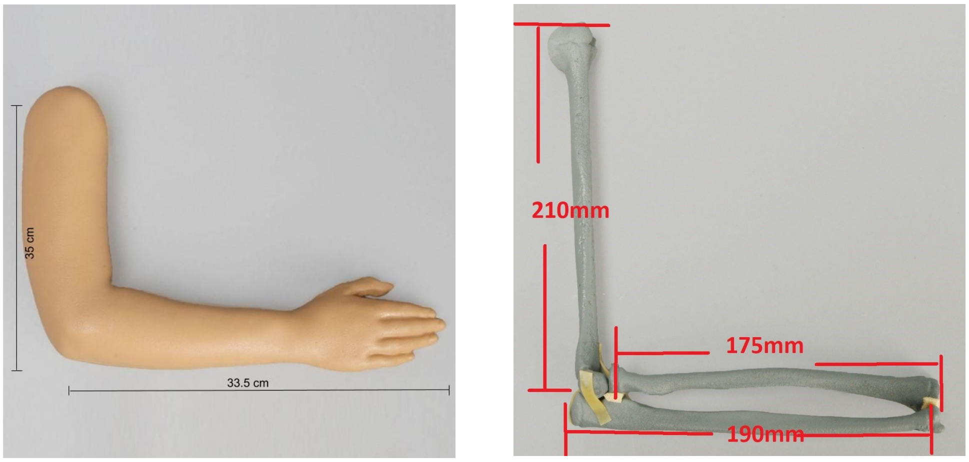


Figure 5. The Sawbones envelope and bone model with dimensions.

b. **Tough PLA and Elastic Resin-** This design consists of two 3D printed parts from the Makerspace. While the envelope uses elastic resin to parallel the stretchiness of the skin, the bone is printed from a tough PLA in order to resemble its hardness and density.

c. **Polycarbonate and Silicone-** This design utilizes a third party to create two 3D printed parts, allowing us more options for printing materials. The bone, which is displayed in Figure 6, is made out of polycarbonate to accomplish a realistic feel and give the educator a better ability to evaluate the pinning. The envelope is made from silicone to replicate the elasticity of the skin.

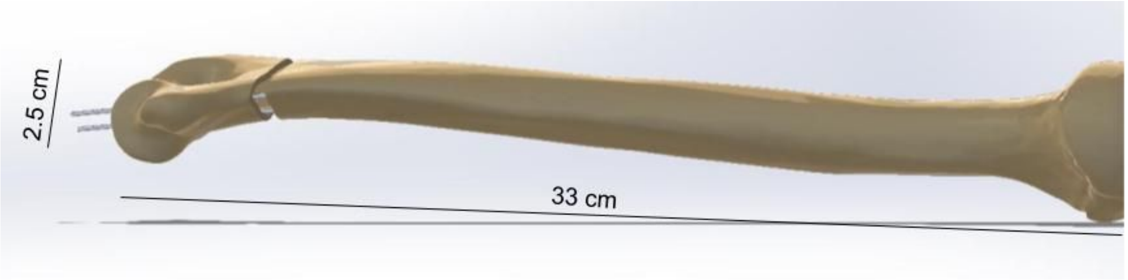


Figure 6. SolidWorks model of 3D printed humerus fracture.

B. Envelope Reusability Options

The envelope model must be modified to balance reusability and functionality. Since the model will be used multiple times, it needs to be able to withstand many drill holes.

The following are modification options, which are displayed in Figure 7:

a. **Unfilled holes-** There are three holes drilled through the envelope and into the bones in the correct position, and left unfilled. The idea is that the students would practice the correct way every time, and the model would not become “swiss cheese”.

b. **Styrofoam patch-** The bone has pre-drilled holes, with a small section of the soft tissue envelope removed where the pinning happens. This section is filled with styrofoam that can be replaced each time the model has been pinned. This allows the students for more realistic practice, where they are not shown exactly where to drill but can feel for the right positioning.

c. **Putty patch-** There is a small section of the soft tissue envelope removed where the pinning will happen, and the holes are pre-drilled. The cut out is filled with putty that reforms once the pins are removed. The reformable putty is convenient and once again allows for the reality of a blank slate for drilling with the ability to feel for the right positioning of the pins.

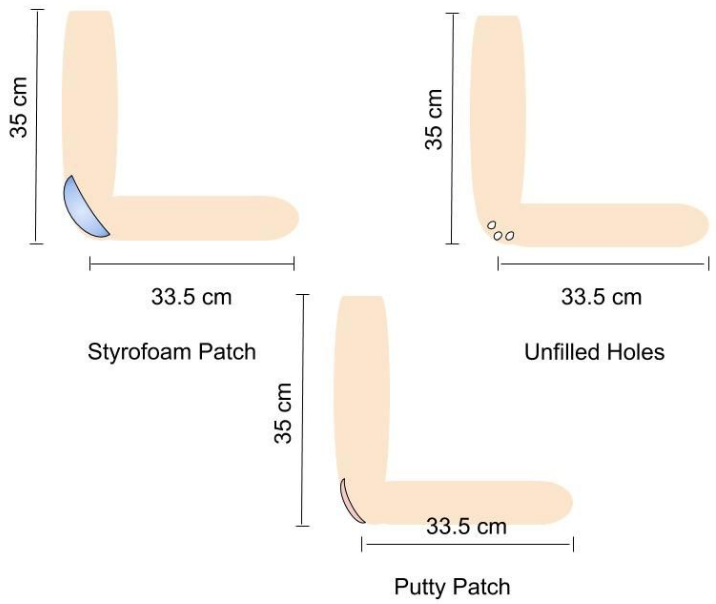
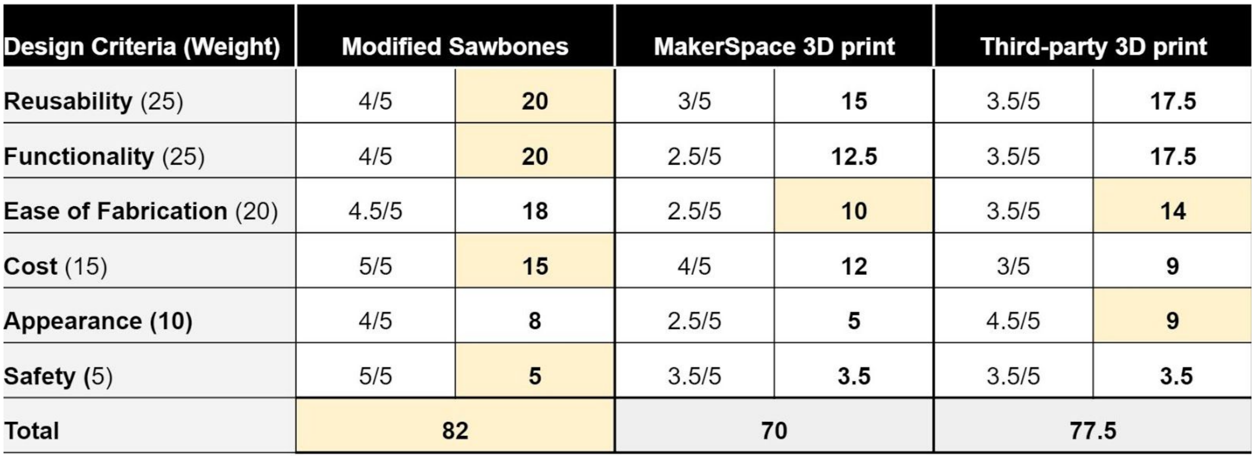


Figure 7. Options for modifying the envelope to withstand multiple tests.

IV. Preliminary Design Evaluation

In order to fully address the product design specifications, the team came up with two design matrices. The categories for the design matrix include reusability, functionality, ease of fabrication, cost, appearance, and safety. Reusability weighs the ability of the model to withstand repeated stress from the procedure. Functionality measures the model's potential to give the accurate feel of the surgery. Appearance evaluates how the look of the model compares to a real pediatric humerus. Safety, ease of fabrication, and cost represent what is expected. Reusability and functionality were weighted the highest because they were the most important to the client while safety was the lowest-rated because all model options are safe.

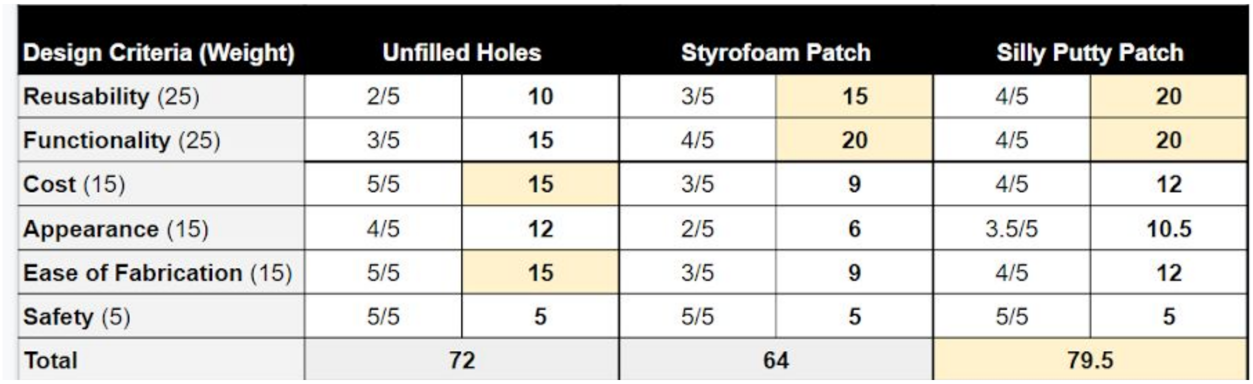
The initial design matrix, Table 1, was used to decide which fabrication process would be optimal. The options were: modifying a current design, using the Makerspace to 3D print the design, and contacting a third party to 3D print. In the end, the modified Sawbones was the highest-rated. It received the best scores in the two most important categories; reusability and functionality. The Makerspace option received the lowest score because the materials available at the Makerspace would not be able to accurately model the bone and, consequently, it is lacking in the two biggest categories. A third party print was a better option than the Makerspace because it would provide a greater portfolio of materials to create a realistic model. However, the development of an entirely new prototype would be more costly and would not have as great of an appearance as the Sawbones model. From the design matrix, the conclusion was drawn that the Sawbones modified model would produce the most optimal results for the product design specifications.



Design Criteria (Weight)	Modified Sawbones		MakerSpace 3D print		Third-party 3D print	
Reusability (25)	4/5	**20**	3/5	**15**	3.5/5	**17.5**
Functionality (25)	4/5	**20**	2.5/5	**12.5**	3.5/5	**17.5**
Ease of Fabrication (20)	4.5/5	**18**	2.5/5	**10**	3.5/5	**14**
Cost (15)	5/5	**15**	4/5	**12**	3/5	**9**
Appearance (10)	4/5	**8**	2.5/5	**5**	4.5/5	**9**
Safety (5)	5/5	**5**	3.5/5	**3.5**	3.5/5	**3.5**
Total	**82**		**70**		**77.5**	

Table 1: Design Matrix- Evaluation of fabrication options for skin envelope and bone.

In addition, the team also considered ways to make the envelope reusable. The second design matrix, Table 2, weighed three options to modify the drilling section of the model. The three options, unfilled holes, styrofoam patch, and putty patch, were each evaluated on critical criteria for the design. The main goals of the patch were for it to be reusable, removable, and functional. It was found that putty scored the highest in the two highest weighted categories: reusability and functionality. The unfilled holes scored the highest in all other categories: cost, appearance, ease of fabrication, and safety. Therefore it is the second-best option, and the team would take it into consideration moving forward. The styrofoam patch scored lowest in almost every category; and therefore, it was no longer considered. Overall, the design matrix led to the conclusion that the putty patch would be more reusable, have more of a skin-like feel, and would be easy to remove and mold.



Design Criteria (Weight)	Unfilled Holes		Styrofoam Patch		Silly Putty Patch	
Reusability (25)	2/5	**10**	3/5	**15**	4/5	**20**
Functionality (25)	3/5	**15**	4/5	**20**	4/5	**20**
Cost (15)	5/5	**15**	3/5	**9**	4/5	**12**
Appearance (15)	4/5	**12**	2/5	**6**	3.5/5	**10.5**
Ease of Fabrication (15)	5/5	**15**	3/5	**9**	4/5	**12**
Safety (5)	5/5	**5**	5/5	**5**	5/5	**5**
Total	**72**		**64**		**79.5**	

Table 2: Design Matrix- Evaluation of material options for skin patch over open bone.

Proposed final design

Moving forward, the team decided to modify a Sawbones model for the final deliverable. A zipper would be added to the Sawbones envelope to make the bone easily accessible while maintaining the closure tightness from surgery to surgery. In addition, the bone model would be fractured while keeping the periosteum from Sawbones intact to best replicate the type III injury. To allow for reusability, both the envelope and bone model would be drilled into. The drilled holes on the envelope would be hidden by a putty patch, such as butyl rubber.

V. Fabrication/Development Process

A. Materials:

a. **Radiopaque, Pediatric Humerus Model** - *Ordered from Sawbones.com.*
This humerus model was purchased as the main practice model and was modified by adding pre-drilled "pilot" holes and fracturing just below the elbow. The Sawbones model is primarily made out of solid cortical foam. The solid cortical foam provides greater visibility through fluoroscopy as well as simulating the density of the bone. Due to its physical properties, the cortical foam model was adequate at simulating the procedure.

b. **Soft Tissue Arm Envelope -** *Ordered from Sawbones.com*
This soft tissue envelope surrounds the bone model, representing the skin, muscle, and fat surrounding the arm. It was modified to include a replaceable opening on the elbow for testing of the pin driver. The model is made with a skin-like outer layer and a foam center.

c. **Zipper -** *Ordered from Amazon.com*
The zipper was intended to be used to close the modified soft tissue envelope. Through further testing, the team decided that the zipper would not be used moving forward, due to difficulties in installing the zipper onto the tissue envelope. Specifically the elbow flex did not lend itself to having the zipper applied, so the team decided that the previously installed velcro patches would work well for closing the envelope opening.

d. **Putty Patch -** *Ordered from Amazon.com*
The putty patch was purchased online . The putty was tested as a method of self-healing patching at the drilling site. After testing the putty with the model there were several issues found, most notably the putty would not adhere properly to the model and the putty would get into the holes. Based on the team's testing the putty patch was not used in this iteration.

e. **Bandages**- *Purchased at Walgreens*
The bandages were used as an easily replaceable patch over the drilling site. The bandages are disposed of and replaced between each use of the model.

B. Methods

Multiple steps were taken after the ordering of the materials in order to modify the already existing model components. Specifically, for the bone component, the two major modifications were fracturing and drilling of pilot holes:

a. **Fracturing** - The team tested multiple ways to fracture the bone model, including jigsaw, bandsaw, and coping saw.The coping saw allowed for the most control during the fracturing process, so the team decided to move forward with the coping saw.
b. **Pilot Holes** - Pilot holes were drilled in order to make the model more reusable and allow those using the model to evaluate how accurate their pin drilling was. This drilling was done by the client in order to insure accuracy of the pilot holes.

For the tissue envelope, the main modifications were creating an envelope opening, covering it, and removing the foam from the inside:

c. **Envelope opening -** An opening in the envelope was created to allow visibility of the drilling site. This required the placement of the bone within the envelope, and a marking of the pinning site. The opening was then cut out of the envelope using a scalpel.
d. **Covering of the Opening** - This was done to obscure the pilot holes during pinning. The holes were covered by the bandages between each test.
e. **Removal of envelope foam** - After receiving feedback on the model from the client, the team shaved down the inside of the envelope. This was done to thin the foam surrounding the bone so that the closed reduction of the model is more realistic.

C. Final Prototype images

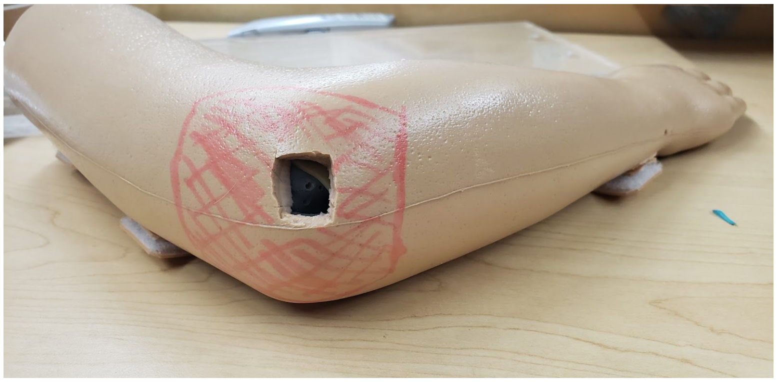


Figure 8: The testing site, model with bone inside

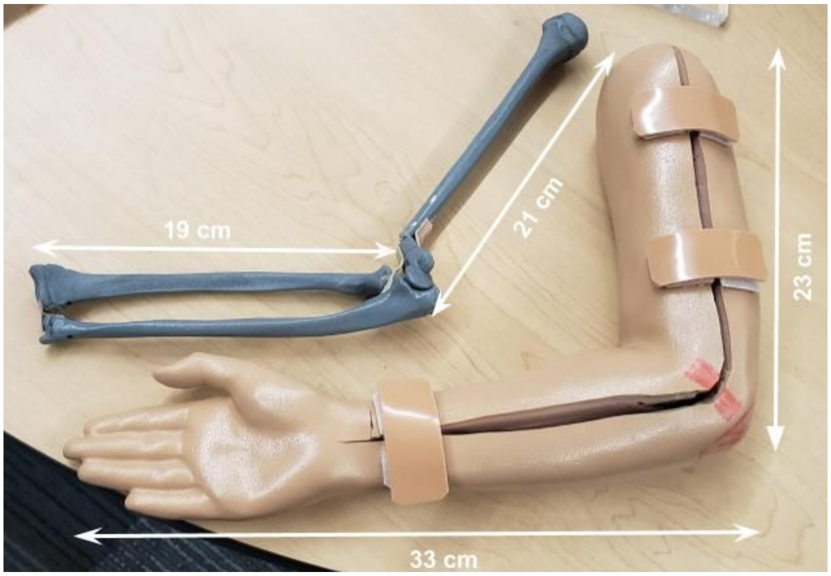


Figure 9: Bone and envelope separated

Above, Figure 8 shows the testing site and the envelope with the drilling site visible. Figure 9 shows the envelope and fractured bone separately.

V. Testing

In order to evaluate the model, UW-Health residents and medical staff were surveyed through a 13-item questionnaire after practicing closed reduction and percutaneous pinning (CRPP) on the model [Appendix D]. The questionnaire was designed to fit on two pages. The brevity of the questionnaire was motivated by scientific literature showing questionnaires longer than 10 minutes leads to a decrease in participation and quality of responses [24] .

The testing of the model took place at the University of Wisconsin Medical Foundation during a journal club for the orthopedic rotation. Medical residents, faculty, and fellows in the orthopedic department were chosen to evaluate this model because of the breadth of experience available. Though inexperienced medical residents are the target user demographic for this model, the team identified a critical need for feedback from evaluators with experience with both the fracture and the surgery. The evaluators practiced closed reduction and percutaneous pinning on the surgical model. In addition, the evaluators had the opportunity to remove the bone from the envelope to inspect it. Two members of the team were present and monitored the testing of the device.

In the questionnaire, the first 9-items were scaled questions (1 through 5) that evaluated the surgical model's appearance, functionality, and learning criteria. The appearance criterion was simply defined as whether "the skin looked life-like" and "the fracture looked life-like". On the other hand, the functionality criterion was defined as whether "the skin envelope felt life-like" and "the cortex could be felt while drilling". The learning criterion was based on how well the evaluators felt the model functioned as a teaching method for closed reduction and percutaneous pinning.

The remaining 4 items were free-response questions to gather holistic feedback on the surgical model and spark future work ideas. The questions specifically asked about what the evaluators learned from practicing with the model, as well as where the model could be improved. These last four items were optional, in order to let the evaluators share as much as they felt necessary.

VI. Results

In order to measure the reliability and internal consistency for each criteria (appearance, functionality, and learning), the team determined the standard deviation and a 95% confidence interval for each overall score. All statistical analysis of results was conducted in Excel.

In the appearance category, displayed in Figure 9, the skin envelope achieved an overall score of 3 and the bone fracture achieved an overall score of 3.8 (see Figure 10.) For the skin envelope, all evaluators (n=5) scored the visual properties with ⅗, which corresponds to the "average" rating. Thus, there was no standard deviation and no confidence level. On the other hand, the bone fracture was evaluated at 3.8 with a standard deviation of 0.44. The confidence level for the appearance score of the bone fracture was 39%. The residents scored the appearance of the bone fracture as 3.5 with a standard deviation of 0.7. All non-residents scored the appearance of the bone fracture as 4, which corresponds to the "good" rating.

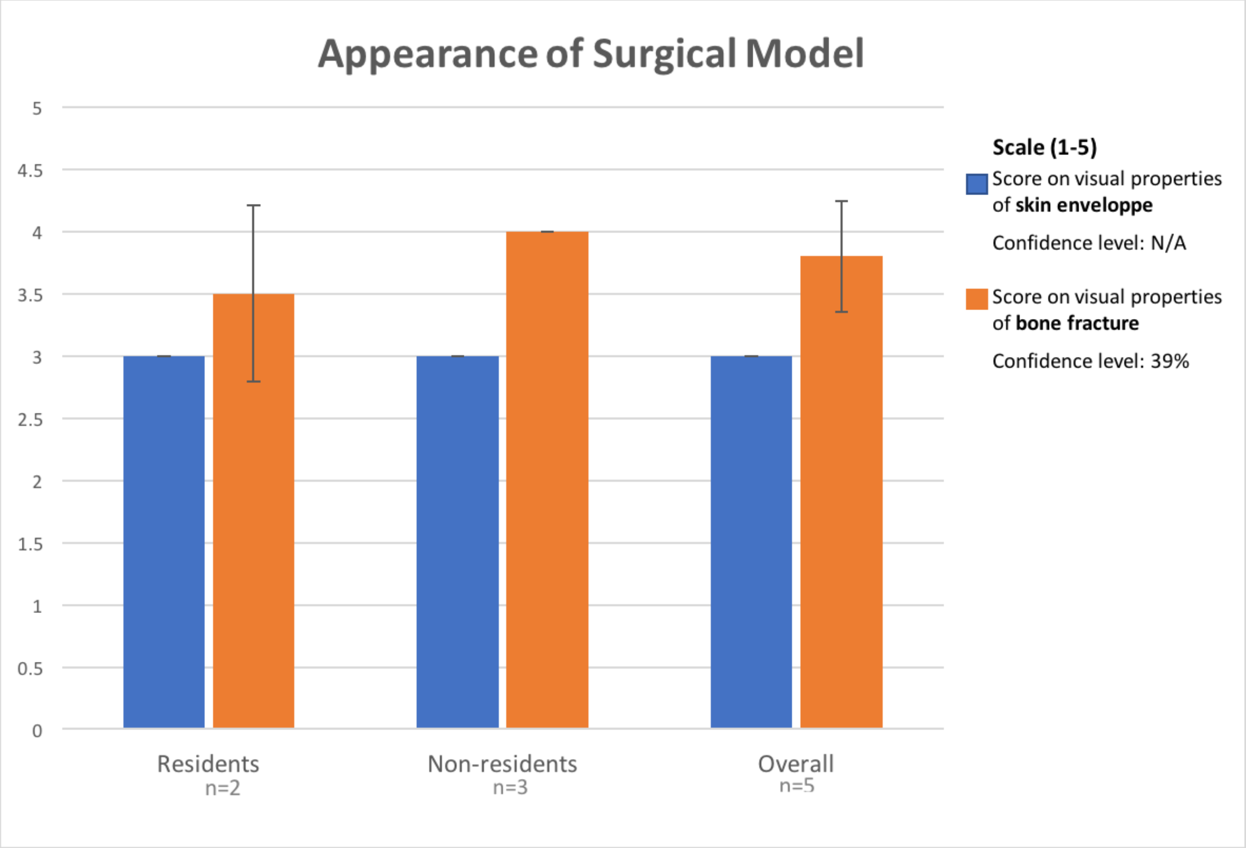


Figure 10. Appearance of Surgical Model. Comparison of mean scores for the appearance of skin and bone for distinct population groups.

In the functionality category, the skin envelope achieved an overall score of 3.2, the bone achieved a score of 4.2, and the fluoroscopic visibility scored a 4.5. The skin envelope was evaluated at 3.2 with a standard deviation of 0.733 at a confidence level of 73.3%. The residents scored the skin envelope at a rating of 3 with a standard deviation of 1, and the non-residents scored an average of 3.3 with a standard deviation of 0.577. On the other hand bone fracture was evaluated at 4.2 with a standard deviation of 0.391. The confidence level for the functionality score of the bone fracture was 39%. The residents scored the functionality of the bone fracture as 4 with no standard deviation. The non-residents scored the appearance of the bone fracture as 4.3 with a standard deviation of 0.577. Lastly, the functionality got an overall score of 4.5, and scored an average of 4.5 in all categories. The confidence level 50.6% and the standard deviation is 0.57735 (see Figure 11).

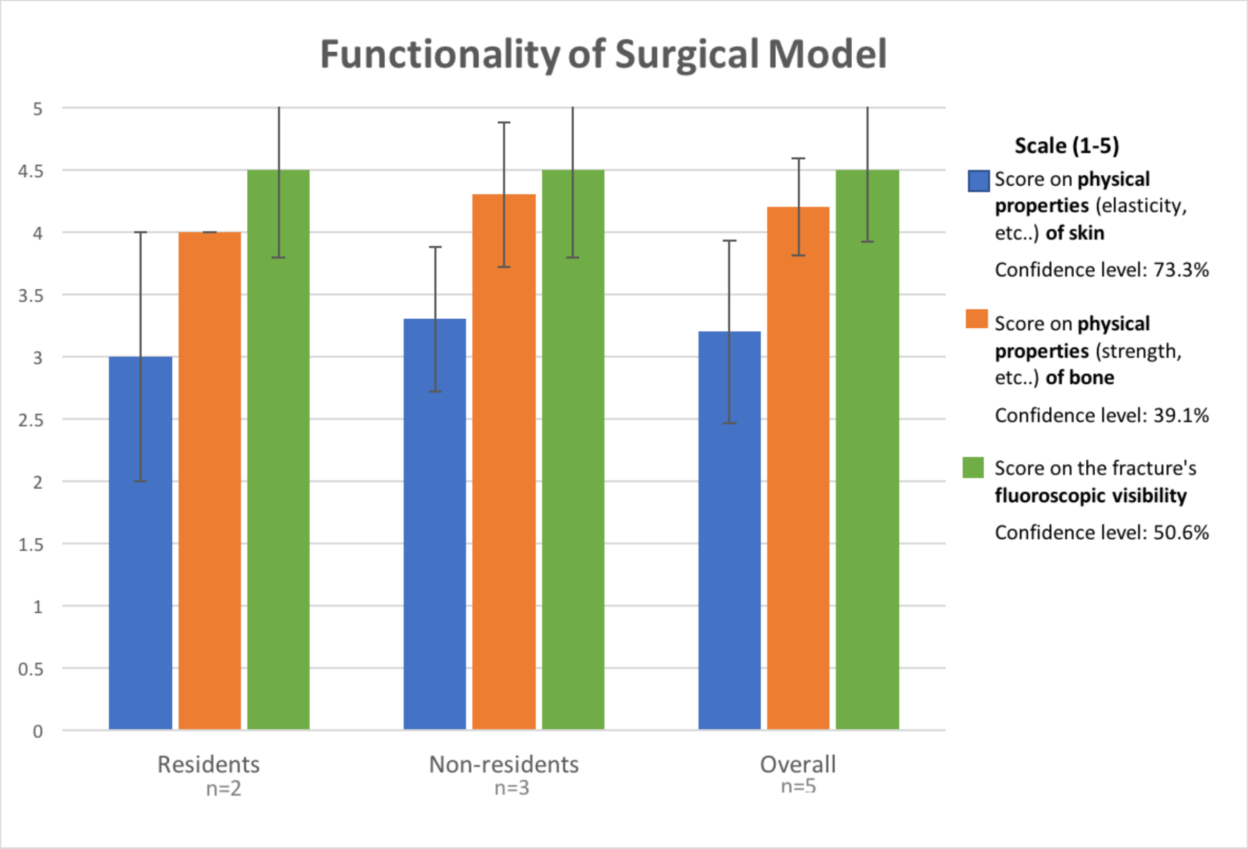


Figure 11. Functionality of Surgical Model. Comparison of mean scores for the functionality skin, bone, and fluoroscopy for distinct population groups.

In the learning criteria, the closed reduction achieved an overall score of 3.8 and percutaneous pinning 3.5. The closed reduction was evaluated at 3.8 with a standard deviation of 0.836 at a confidence level of 73.3%. The residents scored the closed reduction at a rating of 3 with no standard deviation, and the non-residents scored an average of 4.3 with a standard deviation of 0.577. On the other hand, the percutaneous pinning was evaluated at 3.5 with a standard deviation of 0.577. The confidence level for the functionality score of the bone fracture was 39%. The residents scored the percutaneous pinning as 3.5 with a standard no deviation of 0.71. The non-residents scored the appearance of the bone fracture as 3 with no standard deviation (see Figure 12).

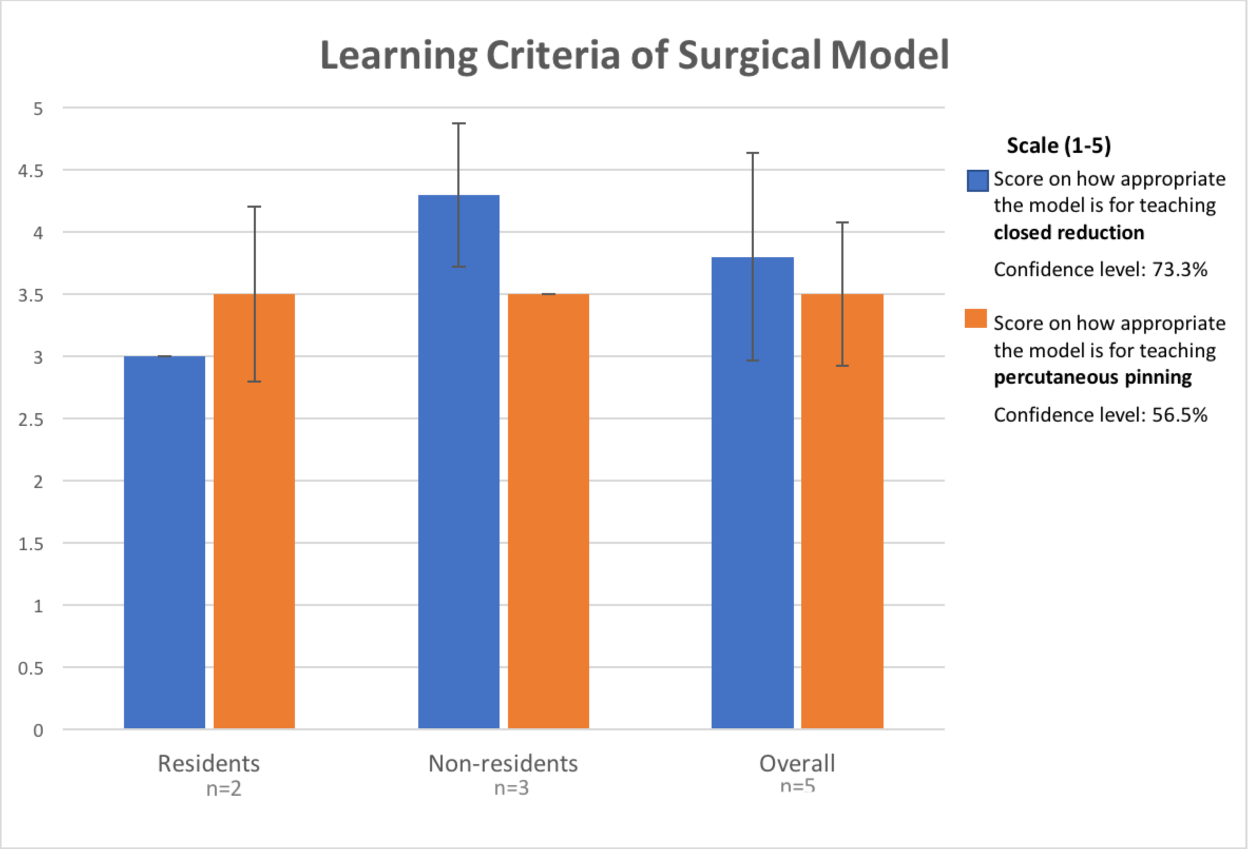


Figure 12. **Learning criteria of Surgical Model.** Comparison of mean scores for learning criteria of the closed reduction and perctunatenous pinning procedures for distinct population groups

VII. Discussion

Implications of results/changes made

After each test was performed, the team assessed and reevaluated the design plan. From the results of the putty stretch testing, the team decided to move forward without the putty. The displacement of the putty proved to be too extensive and would have clogged the pre drilled holes. Instead of using the putty, the team decided to use large bandages to cover the opening at the elbow.

As displayed in Figures 10, 11, and 12 the evaluations from the residents and doctors revealed that while the model was a good first prototype, it had some minor problems. In regards to the percutaneous pinning, the model received a 3.5 as it was a good teaching tool for correct location of the pins, but the drilling left the fracture site vulnerable to damage. The bone received excellent scores of 4.5 and 4.2 for fluoroscopic viewing capabilities and functionality respectively. On the other hand, due to the stiffness of the material, the envelope was docked points for functionality and appearance, receiving overall scores of 3.2 and 3. This being said, the overall closed reduction received a score of 3.8, losing points because of these discrepancies with the envelope and the rubber periosteum not providing adequate resistance.

From prior research on medical simulations, the team learned that the main focus of a simulation should be that it feel realistic. Therefore, the model needed to be reevaluated to address these areas that were not as realistic as intended. The team decided to proceed by recutting the fracture to make it more textured. A second rubber band was also added for extra resistance in the periosteum and the foam was shaved down from the model to reduce stiffness and allow the fracture to be felt through the skin. Because of time limitations, not all of the necessary modifications could be made, but that will be discussed further in future work.

Throughout the fabrication and testing process, the team also ran into some challenges and errors that could not be fixed. The model's fracture was cut too high on the humerus and therefore the holes were drilled at a difficult angle. This error came from a lack of real life exposure to these types of pediatric supracondylar fractures, meaning a lack of knowledge of the exact location.

Ethical considerations

When testing and refining this model, it was necessary to be aware of the importance of positive results. It is hard to uniformly grade performance, thus the results may contain human bias. However, when analyzing the data, bias had to be identified to be sure that the model was functioning as expected. The simulation is intended to teach students how to perform a serious procedure on a real child. Therefore, it is pertinent that they are better prepared for the operating room after using it, or there could be lifelong complications for the child.

VIII. Conclusions

The fracture of the humerus is one of the most common injuries in children; therefore, the closed reduction and pinning of a pediatric supracondylar humerus fracture is a procedure frequently administered. The current issue is that residents do not have enough practice with this type of surgery and there are no current models that they can practice with. The goal of the model is for it to be used in trials in order to train students in this procedure. The best way to effectively make the model in time was to modify a humerus model that was purchased from Sawbones.com. Many modifications of the model were made to fit the needs of the client. The bone was fractured and holes were pre-drilled so that the residents would practice placing the pins correctly each time. A rubber band was attached to the humerus to represent the periosteum. A section was removed from the skin envelope to expose the holes during drilling in order to protect the model from damage, and bandages were added over the removed section to hide the holes during the practice of aligning the pins (before drilling). Foam was cut out of the skin envelope so that the closed reduction could be felt and to increase the envelope's flexibility.

Overall the model was satisfactory to both evaluators. The realistic feel of the model was extremely important to the design and was replicated well. The skin envelope had a minor downfall in that it was locked in the flexed position, while most patients are seen with a straight arm and completely displaced bone. To maintain the reusability of the model, the residents had to follow certain steps regarding the drilling of the pins. These steps prevented damage to the model but required that the drilling site be visible, which is less than ideal in replicating the actual surgery. It has been concluded that the modifications that were made to the model helped to realistically simulate the procedure, but the model could still be improved with future work.

Future Work

The team has accomplished a lot throughout the semester, meeting many of the requirements set by the client. Even though the design was successful, there are still many things that would need to be changed for future use of the model. For iterations of the model in the near future, utilizing our current Sawbones model, cutting out some of the foam as well as some of the outer skin layer would improve flexibility at the elbow. For iterations further in the future, looking into possible 3D printing methods using a less rigid and therefore more anatomically accurate material, could be a possible direction for this project to go.

In addition, the team would like to implement a photoresistor sensor on the area around the drilling site to notify the operator of any errors. It would greatly increase reusability because it would decrease the chances of drilling damaging the bone. Another reusability effort would be to implement some kind of self-healing patching method such as butyl rubber, which is an elastomer that could possibly self-heal.

Lastly, a final aspect of the project that could be improved is the testing sample size. Due to time restraints on data collection, the data currently has low confidence intervals and does not fully assess the model. In addition, the team could assess the model in a continuous improvement format in a future semester with a biweekly switch between testing and fabrication. Overall, this prototype was a good first design for a model simulating the closed reduction and pinning of a pediatric supracondylar humerus fracture.

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Appendix A: PDS

Model for teaching closed reduction and pinning of a pediatric supracondylar humerus fracture - Team Funny Bones - BME 200/300

Product Design Specifications
September 20th, 2019

Client:	Dr. Pamela Lang		
Advisor:	Benjamin Cox		
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Function: Supracondylar humerus fractures are the most common elbow fracture seen in children, most of which require surgical intervention via closed or open reduction with percutaneous insertion of pins to maintain the reduction. Experience in the procedure is vital to safe and efficient surgical intervention. This project aims to build a pediatric supracondylar humerus model that is capable of accurately representing the conditions in which the surgery takes place and evaluate whether simulated reduction and pinning can improve a resident's ability to perform the procedure.

Client requirements

- The client needs a model of a pediatric supracondylar humerus fracture to train medical students.
- The model needs to have a completely displaced fracture that can be reset via closed reduction by medical students. The fracture should include the periosteum that surrounds it and the bones must be radiopaque.
- The model should include a muscle layer, fat layer, and skin layer surrounding the bone in order for students to practice pinning.
- The model must be reusable.

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements: The humerus model will be used for monthly training sessions by three resident physicians. During the training sessions, the model should withstand repeated reduction and pinning. The reduction will consist of realignment at the fracture site. The pinning will consist of punctures with surgical grade K-wires driven by a needle.

b. Safety: The primary safety concern with the humerus model occurs during the pinning procedure. The design should mitigate any injuries caused by operator error by providing an information flyer along with the model.

c. Accuracy and Reliability: The criterion of reliability is that, after repeated usage, the humerus model still has the appearance of an arm and that the fracture can be dislocated and relocated. In addition, the envelope of the model should not sustain excessive tearing from the pinning. Excessive tearing is defined as tearing that reveal more than 20 mm^2.

d. Life in Service: The model must be reusable, meaning the fracture can be reset and the pins can be placed multiple times. It must be functional for at least 5 years.

e. Shelf Life: The humerus model will be stored in a temperature and humidity controlled environments in an orthopedic surgery storage room.

f. Operating Environment: The model will be stored in a temperature and humidity controlled environment. During use there may be some heat from the drill used to drive the K-wires that the model would be exposed to. This heat should not be enough to melt plastic or damage the materials used to build the model.

g. Ergonomics: The model should most realistically replicate the feeling of supracondylar fractures, and be adjustable without excessive force being applied by the trainee using the model. The expected torque from the pin driver was researched and should be 140 in-oz at or above 750 RPM, thus the model should be able to withstand this without breaking [20].

h. Size: Size should approximately mimic a human child's arm between the ages of 4-7. For reference, the average arm length for a 7 year old male is 567mm [16].

i. Weight: There is no requirement for how much the product should weigh. The goal would be to stay close to a child's actual arm weight, in order to give an accurate representation.

A child in this age range weighs anywhere from 31 to 50 pounds [22] and 6% of body weight tends to be weight of the toal arm [21]. This for a child in that range would be 1.86 to 3 pounds.

j. Materials: Flammable materials are not to be used anywhere. Regarding the materials for the bones, the team is to avoid any type of metal as a metal pin needs to be able to be driven through the model.

k. Aesthetics, Appearance, and Finish: The shape of the model should mimic a child's arm, with an outer layer that feels like skin as well as a layer that resemble muscle and fat. The bone itself should resemble a human bone, including through imaging.

2. Production Characteristics

a. Quantity: The client requested one functional model.

b. *Target Product Cost*: The client requested a target cost is $222.

3. Miscellaneous

a. Standards and Specifications: There are no national or international standards for recreating a model for surgical practice. The model should not have to get FDA approval because even as a medical device it presents a low risk of illness or injury to patients, as it is not used on patients[19].

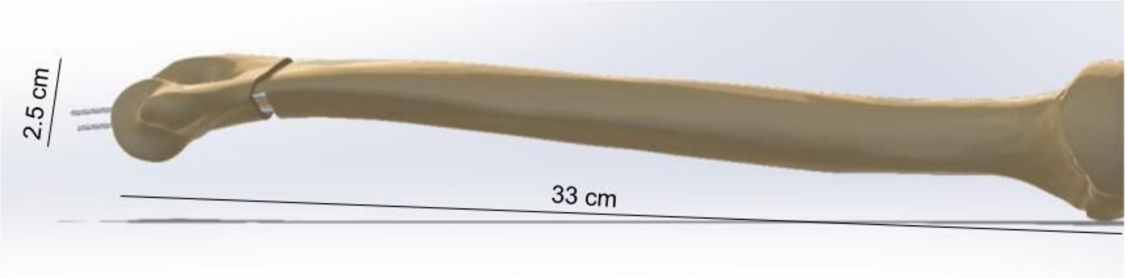
b. Customer: The customer would like the model to represent a real arm including skin, fat, and muscle. The customer likes the idea of having pre-drilled holes and the ability to reuse the model. She also wants the model to be able to teach the residents the specific feel that this surgery requires and wants them to be able to use the same tools they would use in an OR. Another big aspect of the project is making sure that it can be reused, and that it would be beneficial to be able to pull back the skin/fat layer and analyse the work that has been done.

c. Patient-related concerns: The device will not be used on patients. It is strictly for student training purposes.

d. Competition: On the provided website, sawbones.com, they do sell a pediatric model of a supracondylar humerus fracture, and would allow for a look inside of the elbow where the fracture has taken place[17]. This model however does lack the ability to have holes drilled, as is, repeatedly without greatly damaging the model. There were no patented models that match this description, but there may be something to take from several patents analysing the ideal pinning process. For instance, the process in which the fracture is held may be important for building an appropriate model [18].

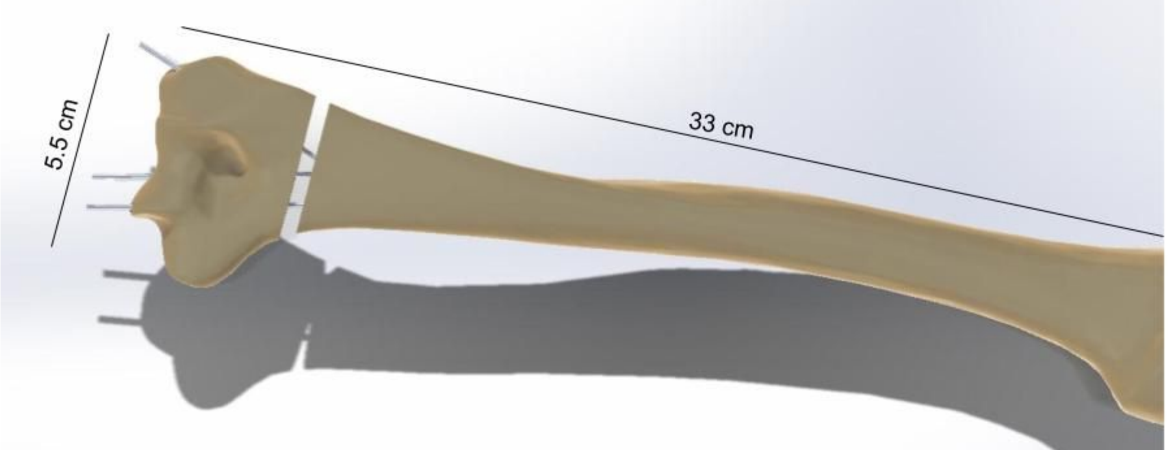
Appendix B. Solidworks images

Side View

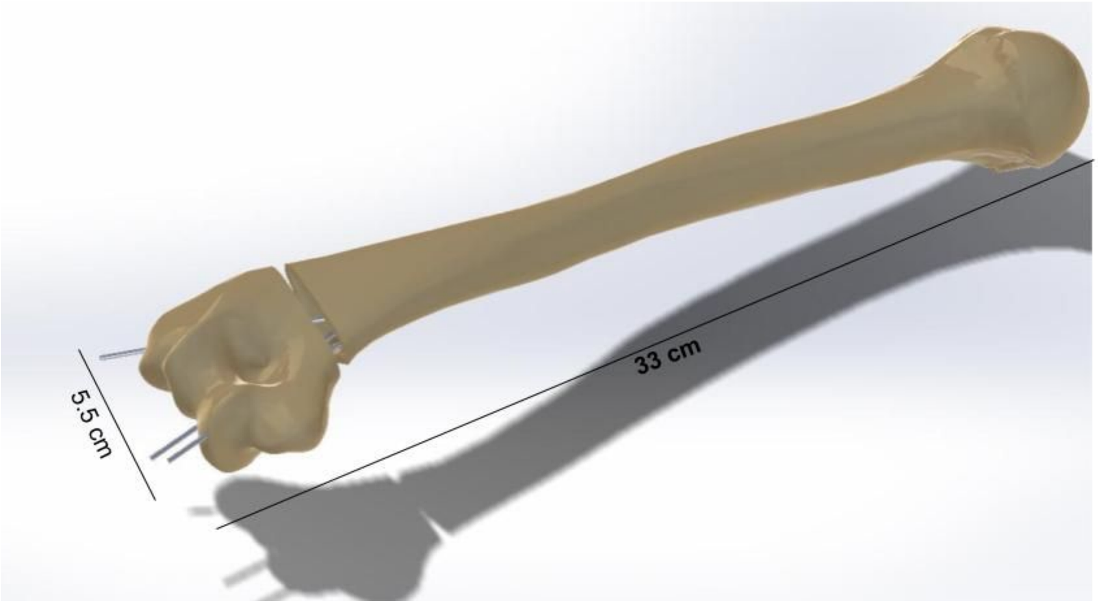


Isometric View - Lateral direction

Top Down View



Isometric View - Medial direction



Appendix C: Expenses

Item	Description	Place Purchased	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1									
Sawbones soft tissue envelope model	A model of the envelope surrounding the pediatric humerus	Sawbones	Sawbones	1530-13-1	9/30/19	1	90$	90$	https://www.sawbones.com/arm-right-pediatric-soft-tissue-envelope-for-bone-assemblies-1530-13-1.html
Pediatric humerus model	a model that simulates the humerus bone of a pediatric patient and is radiopaque	Sawbones	Sawbones	1024-63	9/30/19	1	67$	67$	https://www.sawbones.com/elbow-right-pediatric-solid-foam-radiopaque-1024-63.html
Attachable zipper	a stick on zipper	Amazon	Vivosun	N/A	9/30/19	1	8.99$	8.99$	https://www.amazon.com/VIVOSUN-Heavy

									-Stick-Zipper-Barriers/dp/B01DNUIHGM/ref=sr_1_2?crid=1IJV660QG50FJ&keywords=peel+and+stick+zipper&qid=1569200251&sprefix=zipper+peel+%26%2Caps%2C144&sr=8-2
silly putty	putty for envelope patch	Amazon	Mack’s	N/A	10/14/19	1	$8.99	$8.99	https://www.amazon.com/Macks-Snoozers-Silicone-Putty-Earplugs/dp/B003ATFEUY/ref=sr_1_6?keywords=silly+putty+skin&qid=1571087475&sr=8-6
TOTAL:									**$165.99**

Appendix D: Testing Questionnaire

Pediatric Supracondylar Humerus Fracture

Evaluation Sheet

Are you a resident? (Circle one)	**YES**	**NO**
If so, what is your specialty?		
If not, what is your position?		

Evaluation of the Model (on a scale from 1-5)	1= Very Poor	2= Poor	3= Average	4= Good	5= Excellent
1. Is the bone fracture realistic? (Resembles how a real bone would fracture)	**1**	**2**	**3**	**4**	**5**
2. Is the skin envelope realistic? (Skin is comparable to human skin)	**1**	**2**	**3**	**4**	**5**
3. Does the model feel like a bone? (When drilling, the different cortex's can be felt)	**1**	**2**	**3**	**4**	**5**
4. Does the model feel like skin? (When drilling, the different surrounding layers can be felt)	**1**	**2**	**3**	**4**	**5**
5. Are the pins easily visible with fluoroscopy? (Can accurately see where the pin is located)	**1**	**2**	**3**	**4**	**5**
6. Was this model helpful in learning to reduce the fracture?	**1**	**2**	**3**	**4**	**5**
7. Was this model helpful in learning to pin the fracture?	**1**	**2**	**3**	**4**	**5**
8. In your opinion how was the condition of the model after many uses? (Are previous trials visible?)	**1**	**2**	**3**	**4**	**5**
9. If you had to do the surgery tonight do you feel more capable?	**YES**	**MAYBE A LITTLE**	**NO**		

FREE-RESPONSE QUESTIONS *(→ Flip page)*

Have you learned anything from using this model? Name one way you can improve your performance on this procedure. ____
____
____

In your opinion, what part of the simulation was most important?____

____
____

What went well? What was challenging? ____
____
____

What would you change about the model?____
____
____

If you have any questions or advice you would like to personally convey to the team please contact: Maïsha Kasole - Team Communicator (kasole@wisc.edu).