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

Product Design Specifications
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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 [5].

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 [1].

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 [7] and 6% of body weight tends to be weight of the toal arm [6]. 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[4].

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[2]. 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 [3].

References

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