Functional Model for Reduction of Pediatric Radial Head Subluxation

Team Name: Elbow Enthusiasts

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BME 200/300 Lab 301

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Function

Nursemaid's elbow occurs when a child's arm, typically between the ages of one and four, hyperextends, causing the annular ligament to partially slip off the radial head of the elbow [1]. The procedure to fix this is very simple: a physician will perform an elbow reduction by pronating the hand and extending the arm. This technique will almost always work, but if it doesn't, the physician will pronate the hand and flex the arm simultaneously. Most of the time, a popping sensation in the elbow indicates the reduction was done correctly. It is imperative that the physician supports the elbow with their thumb on the radial head with one hand while supporting the wrist with the other, the reduction will not work [2]. This procedure almost never has issues and is very easy to repeat once learned. However, some parents might be concerned if a physician is performing this procedure on their child for the first time. A functional model that can simulate a nursemaid's elbow and perform the reduction would solve this problem. This model would primarily be used during residency for training immediately before a physician performs the reduction. The model also needs tactile feedback indicating that the reduction is performed correctly, so physicians can get a feel for the technique.

Client requirements

The design must simulate a reduction on a toddler's arm as accurately as possible to best support training.

1. The design must provide tactile feedback during the reduction to best convey the feeling of the radial head being reduced.
2. Must look like a toddler's arm, including their wrist; fingers are not needed, all the way up to the bicep.
    a. Does not need to be an exact replica of the arm; needs bone structure but not accurate skin/muscle
3. Must require stabilization of the elbow and wrist while doing the reduction
4. The design must maximize the number of uses before needing to be repaired
    a. Although if the model is very accurate, they don't mind more frequent repairs
    b. Repairs include changing rubber bands that simulate the ligaments
5. It would be ideal if it was portable and around 2-3 lbs or less
6. A budget of around $300 is given, but can go above if really needed
    a. Wants to be as cheap as possible
7. Most importantly, the design is a working model that accurately teaches the reduction
    a. More important than making it look realistic

Design requirements

1. **Physical and Operational Characteristics**

a. **Performance requirements**: The pediatric elbow simulation model should withstand repeated use by medical professionals while maintaining the same range of motion with each use. There should be an audible “click” when the arm is rotated, and this click should occur after the same amount of rotation during each use.
b. **Safety**: The training model should have no exposed sharp metal or plastic parts that could harm a user. Additionally, since the model comes into contact with human skin, the materials should not cause harm. Therefore, per ISO 10993-10, any flexible polymers or rubbers used must be non-irritating and non-sensitizing [3].
c. **Accuracy and Reliability**: The training model should allow for the range of motion of a healthy pediatric elbow. The model should allow for 140° of flexion, 0° to - 10° of hyperextension, 85° for forearm supination, and 60° -70° for pronation [4].
d. **Life in Service**: The pediatric elbow simulation model should have a shelf life of at least 2 years under normal indoor storage conditions. The model should be stored in a cool, dry indoor environment around room temperature. Silicone rubber and other soft components should resist drying and cracking [5].
e. **Shelf Life**: The model should withstand at least 1,000 complete elbow reduction practice cycles before major structural failure. The model should continue to allow normal elbow flexion, extension, pronation, and supination. Parts that experience repeated stretching or wear, especially the artificial annular ligament, joint components, and silicone skin, should be replaceable without replacing the entire model [6].
f. **Operating Environment**: The model will be used in seminars and residency programs to demonstrate and provide training for reduction techniques. Additionally, models will be used for “Just-In-Time” training within the hospital.
g. **Ergonomics**: The shape and feel of the model will be as close as possible to a real toddler's arm to replicate real-life conditions.
h. **Size**: The total length, forearm length, arm circumference, and forearm circumference should be the same as recorded values for a child aged 1-3. For a 2-year-old, the total arm length should be between 13.8 and 14.11cm, forearm length 12.41, arm circumference between 15.59 and 15.64 cm, and forearm circumference between 15.04 and 15.05 cm [7].
i. **Weight**: The model should weigh no more than 3 pounds. It should be light enough that transporting and storing the model is not difficult. The weight should be similar to the real weight of a toddler-sized arm.
j. **Materials**: The model should use rigid artificial bones to represent the humerus, radius, and ulna. Silicone rubber should be used for the outer skin and soft tissue.

Flexible materials should be used for the annular ligament and joint to allow realistic movement and resistance [8].

k. **Aesthetics, Appearance, and Finish**: The model should look and feel similar to the arm of a 1 to 3-year-old. The outside should have a skin-like silicone layer that covers the bones and joint components. The surface should have a smooth finish with no sharp edges or exposed internal parts.

2. **Production Characteristics**
    a. **Quantity**: The client would like us to provide one unit of the final product, along with the necessary information to produce bulk quantities later on.
    b. **Target Product Cost**: The product should be designed to be produced and purchased affordably. The client did not specify a budget but indicated that roughly $300 should be sufficient for prototyping and fabrication.
3. **Miscellaneous**
    a. **Standards and Specifications**: The proposed model will not require FDA approval, as it will be used solely for training purposes. Given the model's intended use in the medical field, perhaps even in clinical settings, it may be deemed a medical device. Medical devices of this nature must be designed and used in compliance with ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," which outlines safe and unsafe materials for contact with intact skin [9]. The functional model does not need to be sterilized before or after use, classifying it as a "non-critical medical device" under ISO 17664-2:2021 [10].
    b. **Customer**: The customer is the University of Wisconsin (UW) Health. This is specifically made to target pediatric residents who need to practice radial head subluxation techniques for nursemaid's elbows. The model should provide residents with a repeatable training opportunity to develop proper technique and confidence before performing reductions on pediatric patients.
    c. **Patient-related concerns:** Patient comfort and satisfaction should be considered in the design, as pediatric patients will ultimately receive treatment from physicians who have practiced with the model. The training model should help residents learn proper hand placement, stabilization, and reduction techniques while minimizing unnecessary manipulation that could cause discomfort during the actual procedure. It should be mentioned that the model itself will not come in contact with the patients.
    d. **Competition**: Currently, there are few commercial materials available for practicing radial head subluxation reduction techniques. The training methods currently available at UW Health are word-of-mouth; however, the client mentioned that he has seen improvised models using skeletal sketches and elastic materials. One model was developed and produced by the University of Michigan. Their approach used two models representing the supination and

pronation reduction techniques. The models incorporated a 3D-printed plastic mechanism embedded within a silicone-based, child-sized arm form [11]. This existing design provides a useful reference for simulating pediatric anatomy and reduction mechanics.

References

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