

Project Design Specifications- March 6, 2013 "Super Splint"

Team Members

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Problem Statement

Splints have been proven as effective as casts for displaced distal radius fractures in adolescents and interfere less with daily activities. For fractures which need to be reduced, pressure is often needed to maintain the alignment usually achieved by casting the limb. If a splint existed with an adjustable pressurized lining that can be applied accurately and easily by the doctor, then patients could receive the needed pressure for proper healing without the inconvenience of a cast.

Client Requirements

- Device is designed for pediatric use for distal radius fractures.
- Materials must be radiolucent.
- The lining must not irritate skin or cause pressure sores.
- Pressure lining must be dynamic and controllable.

Design Requirements

1. Physical and Operational Characteristics

- Performance requirements:* The device must apply appropriate pressure to the correct areas to the forearm seen in Figure 1 and Table 1 to maintain alignment for 3-4 weeks. It must be able to withstand daily activities. The pressure should be dynamic and controllable. Initial application and removal should be easy to implement.
- Safety:* The materials must be biocompatible and hypoallergenic. The pressure needs to be distributed to not harm the skin. No loose small parts that could potentially become a choking hazard.
- Accuracy and Reliability:* The device must accurately apply pressure to correct areas seen in Figure 1 to facilitate healing of the bones. The device must be reliable to prevent a second intervention to realign the bone placement.
- Life in Service:* The device needs to perform for 6 weeks.
- Shelf Life:* Prior to use, the device may be stored for up to two years in a hospital store room.
- Operating Environment:* The splint will be worn during daily activities so it should be water resistant, nonconductive, and durable.
- Ergonomics:* The device needs to be able to be removed multiple times and reapplied during the duration of the device's use.
- Size:* The device must fit a palm width of 5.1-6.4 cm. and length of 14 cm. For commercial use, more size options must be available.
- Weight:* Device must not weigh more than half a kilogram.

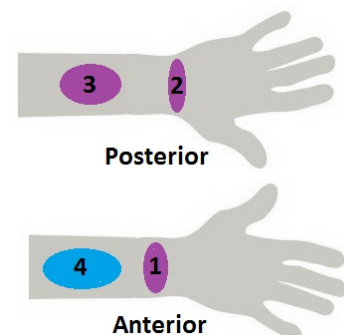


Figure 1: The areas where the splint must apply appropriate pressure depicted for left arm.

Area	Pressure (psi)	SI Pressure (kPa)
1	4.58	31.58
2	4.76	32.82
3	4.28	29.51
4	3.77	25.99

Table 1: The pressures needed to be applied by splint in specified areas determined by testing.

j. *Materials*: Device must be hypoallergenic, anti-microbial, radiolucent, light-weight, wicking material, and durable.

k. *Aesthetics, Appearance, and Finish*: The device will be available in two designs: the pressurasaurus and the pressure-raptor.

2. Production Characteristics

a. *Quantity*: One prototype for this semester is needed.

b. *Target Product Cost*: The prototype is estimated to not cost more than \$100.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval may be required.

b. *Customer*: The device must be comfortable, fashionable, and not cause pressure sores.

c. *Patient-related concerns*: The device should minimally hinder daily activities.

d. *Competition*: Competition includes casting, as well as other current splints.