

BME 400 – SUPER SPLINT

Dynamic Splint For Pediatric Distal Radius Fractures

Mid-Semester Report

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1. Abstract

Casts are currently the main treatment for pediatric distal radius fractures. Doctors apply the cast differently from patient to patient, and improper application due to lack of practice may result in a loss of reduction and pressure sores due to a poor fit. Furthermore, cast-saw burns may harm the child during removal of the cast. A different alternative for treatment of buckle fractures of the distal radius fractures are splints. Splints are cheaper, easier to implement, and more convenient, since it can be taken off when desired. However, current splints do not apply three-point pressure loading to maintain reduction. The goal of this design project is to design a splint with a lining that allows for dynamic and controllable pressure loading. The final design includes a splint with individual pads that can be inflated and deflated to the desired pressure. This will allow for a safer and more convenient treatment of pediatric distal radius fractures.

2. Background

Wrist fractures, or distal radius fractures, account for 40% of all pediatric fractures [1]. The forearm includes two bones, the ulna and radius bone as shown in Figure 1. A distal radius fracture occurs when the radius breaks near the hand. Most frequently, the distal radius breaks by landing on an outstretched arm [2]. Forearm fractures are classified into six categories:



Fig. 1: Bones of the forearm include the ulna (outer bone) and radius (inner bone). [2]

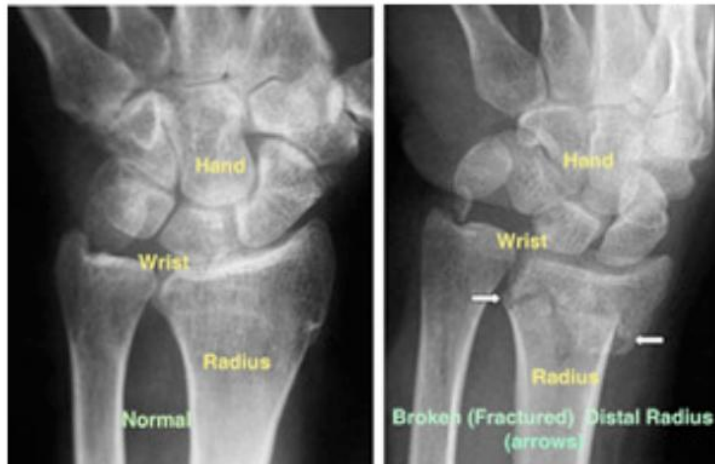


Fig. 2: X-ray image of a normal wrist (left) and fractured wrist. [2]

of the injury, a doctor utilizes an x-ray to visualize the injury as shown in Figure 2. Depending on the extent of the injury, a doctor may use a cast, splint, or surgical techniques to reduce, or realign, the fracture.

buckle, metaphyseal, greenstick, galeazzi, monteggia and growth plate fractures. The fracture may be non-displaced (the bone cracks but remains aligned) as in a buckle fracture, or displaced (the bone cracks completely and does not align) as in a Galeazzi fracture. If the fracture affects the growth plate, it is classified as a physeal fracture, whereas a fracture at the upper or lower portion of the bone without affecting a growth plate is a

metaphyseal fracture. Table 1 summarizes the different types of fractures. To understand the extent of

Fracture	Mechanism
Buckle	Non-displaced fracture (bone cracks but maintains proper alignment)
Metaphyseal	Fracture at upper or lower part of bone and does not affect growth plate
Greenstick	Fracture extends through bone, causes bending
Galeazzi	Displaced fracture in the radius and dislocation of distal ulna.
Monteggia	Fracture in the ulna and radius is dislocated
Physeal	Fracture occurs at or across growth plate

Table 1: Types of forearm fractures and mechanisms. [3]

3. Motivation

Casts result in limited mobility and affect a child's daily lifestyle. [4] There is an increase of cast complications due to doctors spending more time practicing surgery and less time focusing on casting techniques. Some of these complications include the following: poor fit leading to the loss of reduction, pressure sores, and cast-saw burns. In addition to these complications, the medical bill for a forearm cast is \$300 - \$400. [1] Recent studies have been done to compare the treatment of wrist buckle fractures using splints to the casts, and the results indicate children treated with removable splints had better physical functioning and easier time with daily activities [4]. In addition to this, splints are cheaper (typically around \$30 for pediatric forearm splints [1]) and easier to implement.

4. Current Methods

Unstable, or potentially unstable, fractures require casting to immobilize the fracture [5]. After the application of a stockinette, the doctor applies two to three layers of cotton padding circumferentially around the forearm. Plaster or fiberglass is applied over the cotton to provide a stable, outer layer [5]. Unlike a cast, the splint provides non-circumferential stabilization of a fracture. The splint is typically used in buckle fractures of the distal radius [5]. If a splint or cast cannot effectively immobilize and reduce the fracture, surgical intervention may be utilized to stabilize the fracture. Stainless steel or titanium metal pins, plate and screws, an external fixator, or any combination would hold the bone in the correct position [1]. To support a post-operative distal radius fracture, the Aircast StabilAir Wrist Brace was designed to immobilize the wrist as shown in Figure 3. It is comprised of two shells and two air-cells with equivalent pressure for support. This product differs from



Fig. 3: The Aircast StabilAir Wrist Brace in use on a patient. [6]

other splints because of the use of air-cells to maintain the wrist in proper position.

5. Problem Statement

Splints have been proven as effective as casts for displaced distal radius fractures in adolescents and interfere less with daily activities [4]. For reduction of fractures, pressure is required to maintain the alignment which is 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 reduction and healing without the inconvenience of a cast.

5.1 Product Design Specifications (PDS)

Certain requirements must be achieved by our design for pediatric distal radius fractures. It must apply appropriate pressure to the correct areas on the forearm in a three-point pressure loading, as seen in Figure 4, to maintain alignment for three to four weeks while withstanding daily activities. The device must accurately apply pressure to the correct areas to facilitate healing of the bones. The pressure should be dynamic and controllable, as well as non-irritable, and eliminate the chance of pressure sores. Initial application and removal should be easy to implement. The materials used must be hypoallergenic, anti-microbial, radiolucent, light-weight, breathable (similar to a wicking material), and durable. The dimensions of the device must fit a palm width of 5.1-6.4 cm. and total length of 14 cm. The complete PDS design can be seen in the Appendix on Page 12.

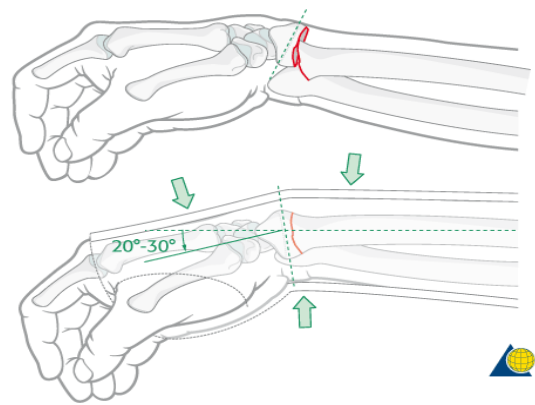


Fig. 4: The top diagram shows the fracture and the bottom displays the reduced fracture and where the 3 loads need to be applied to keep reduction. [7]

5.2 Design Alternatives

Three alternative designs address the need of a dynamic pressurized splint. Each design utilizes a different mechanism to maintain the reduction of the fracture for proper healing. The design alternatives include Velcro, air bladders, or thermoplastic to stabilize the fracture.

5.2.1 Velcro

The first alternative design utilizes crisscrossed Velcro straps to apply the three

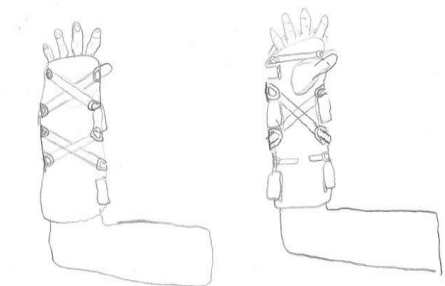


Fig. 5: This is what the inner layer would look like with the adjustable Velcro crosses.

areas of pressure as seen in Figure 5. An initial padding layer is placed on the forearm with loops to contain the Velcro on the three areas of pressure. The doctor places the Velcro straps through the loops and tightens the straps to the desired pressure. Although the Velcro is easy to apply with the guide of the loops, the exact pressure applied is unknown. A waterproof, breathable covering would be placed over the Velcro straps and padding layer. This design would be relatively inexpensive since the pressure mechanism is made of Velcro which runs about \$0.50 per yard and less than a yard would be needed. [8]

5.2.2. Football Pads

The next design alternative uses air bladders to provide the pressure needed for reduction of the fracture. Unlike generic air bladders, football helmet pads can be inflated in groups rather than individual air-cells. This allows for grouping of pads in areas with equivalent pressure. The application process of the design is significantly shorter than casting as the pads

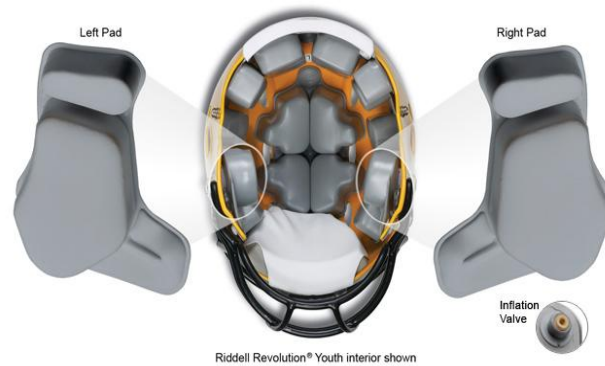


Fig. 6: The interior of a football helmet. The various interior pads are inflatable and provide support. [10]

are inflated to an exact pressure.

Furthermore, the football pads are manufactured in many sizes and shapes as they are created for children and adults

and are made for different areas of the helmet, e.g. ear pads. These different shapes and sizes can be seen in Figure 6. The variety of size and shapes allow the pads to be ordered so that they fit in a splint easily and without using excess space. Despite these advantages, football pads come with added cost over normal air bladders. A whole set of replacement football helmet pads will cost around \$30. [9]

5.2.3 Thermoplastic

The final design alternative is a thermoplastic used in current splinting and casting methods. However, this material commonly does not provide three-point pressure for fractures when used in splints. Thermoplastics are plastics that have a temperature at which they become pliable. Typically, the plastics are placed in hot water, around 150 degrees Celsius, for around 30 seconds to 1 minute depending on the thickness of the plastic. Afterward, the plastics are placed on padding placed on



Fig. 7: A sample thermoplastic splint. It was molded to fit the patient's body by heating the plastic and then molding it into the final shape before it cools. [11]

the skin and molded to the shape of the arm. This

molding process takes about 1 minute before the plastic cools and loses the pliability. Once the plastic cools, the thermoplastic will maintain its shape. [11 &12]

To create 3-point pressure from these splints, the doctor creates the splint one half at a time and put the appropriate amount of pressure on the fracture. This is only slightly easier than a casting process because there are only 2 pressure points on one half of the splint and 1 on the other which allows the doctor to be more specific with the molding. Also, these plastics can be remolded in case of errors or for use in practice for new doctors. Unfortunately, these plastics are fairly expensive for splinting. A 45 x 60 cm sheet can cost around \$80. While this is enough material to make multiple splints, it can still be rather expensive compared to our other designs. [12]

5.3 Design Matrix

Category (Points)	Velcro Straps	Football Pads	Thermoplastic
Maintains Reduction and Pressure (30)	20	27	25
Easy to Application (20)	17	20	5
Protection/Stability (20)	10	15	20
Ability to Change Pressure(15)	8	12	5
Biocompatible/ hypoallergenic(10)	10	10	10
Price (5)	5	3	1
Total (out of 100)	70	87	66

Table 2: The design matrix with the three design alternatives being compared in six categories. The football helmet pads design did well in all categories and will be pursued as the final design.

The design matrix compares the designs alternatives to the categories of reduction maintenance, ease of use, protection, pressure, biocompatibility, and cost. As seen in Table 2, the football helmet pads won a majority of the categories and scored very highly throughout. Therefore, this design will be pursued for the remainder of the semester.

Reduction

This category is focused on the splint maintaining the pressure in the proper locations and ensuring that the bone will not move or shift during the healing process . This category was considered the most important to the overall design and was given a maximum of 30 points. The Velcro straps use shear stress to produce the pressure. This type of force on the fracture may work but it has not been proven in literature. Because of this, the Velcro straps were given

a score of 20 points. The football pads design provides direct pressure on the skin and was given a score of 27 out of 30 points. Finally, the thermoplastic splint provides direct pressure exactly where the doctor wants it. However, this is much more difficult to quantify the pressure given to the fracture and was given 25 points.

Ease of Application

Since doctors lack extensive training on the casting process, the designed splint needs to be as easy to use as possible to avoid complications from unskilled applications. This category was rated highly to ease the overall learning process to apply this splint, as such it was given a maximum of 20 points. Velcro straps are extremely easy to apply but give very little feedback as to whether the pressure is correctly placed. Hence it was given a score of 17 points. The football pads are very easy to apply, as the only thing that is necessary to adjust is the pressure of the individual bladders. Hence, it was given a full score of 20 points. Finally, thermoplastic splints do not improve on the casting methods currently used. This was the main reason for a low score of 5 points in this category.

Protection

Protection of the fracture is important in preventing the bone from fracturing or breaking further; hence, this category was given a high score of 20 points. The Velcro straps do not provide a strong protection of the fracture, so it was given 10 out of 20 points. The next design alternative, football pads provide some added protection against further damage, so it was given 15 points. Thermoplastic splints have a hard protective covering of the fracture, giving it a score of 20 points in this category.

Ability to Change Pressure

In order to adapt the splint to the changing conditions during the healing process, the splint needs to be able to change the pressure of specific areas over time. Since this is the client's preference, but not as important as the above categories, it was given a total score of 15 points. Changing pressure with Velcro strips is relatively easy. However, this method loses points due to changes in the pressure when the splint is taken off and reapplied, giving it a score of 8 points. Football helmet pads are easy to inflate or deflate to get the desired pressure, which made the score for this alternative 12 points. Thermoplastics are difficult to change the pressure, as it requires another round of heating and reapplication. Because of this inconvenience, thermoplastics got 5 points here.

Biocompatibility

Because the product will be in constant contact with the skin of the patient, the design needs to be biocompatible in all areas including not producing any pressure sores. Since this is an important area of concern it was given a 10 point maximum score. All of our design alternatives are fairly biocompatible and hypoallergenic. Also, none of the designs apply

pressures at a specific point that may cause pressure sores. Because of this, all designs received a full 10 points in this category.

Cost

Since this product needs to be competitive in the market to see any use, the cost of the design was ranked at a high score of 5 points. Velcro is extremely cheap (\$0.50/yard [8]), giving it a very high score in this category, 5 points. Football pads are more expensive and cost around \$30 each. Therefore, football pads were given a score of 3 for this category. [9] Finally, thermoplastics are the most expensive alternative and were given 1 point for this category.

5.4 Final Design

The final design will utilize the football helmet pads. The device will consist of a sample splint, generalized as two, symmetrical half cylinder shapes in Figure 8.. Three small pads will provide three-point pressure loading and will easily be inflated/deflated by the doctor with a pump for correct healing of the fracture. One long, larger pad located on the upper part of the forearm for stability of the splint to the arm. A hard protective cover placed circumferentially on the device will protect the splint from normal daily activities that could harm the fracture. A liner between the skin and the pads avoids irritating the skin. A guard on the posterior side of the forearm extending to the palm prevents full flexion and extension of the wrist. This is necessary to avoid setbacks to the fracture healing process.

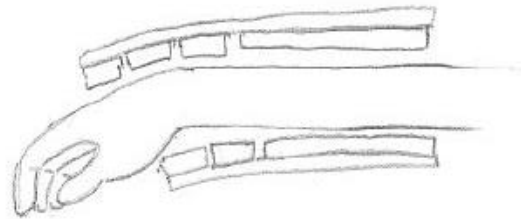


Fig. 8: Side view of the final design. Smaller individual bladders will be near the fracture to allow three-point pressure.

5.5 Estimated Budget

Our client has given us a preliminary budget of two to three thousand dollars total for both semesters combined. Current research determined each football replacement pad costs around \$30. [9] Five pads will be needed, placing the total cost of the air bladders around \$150. More research is needed to further price the rest of the materials. Using the sample splint, which was received from the client, as the outer covering for the design, some modifications to it will need to be made to accommodate the pads inside. However, this splint already has protection and sizing already built in, making it much easier to create our prototype. The only things we will need to purchase will be the pads and an inner sleeve to protect the skin from the pads. Wicking material sleeves can be purchased for around \$10-30 and will be enough to protect the skin from direct contact with the pads while still allowing the pressure to be

transferred to the forearm. [13] This will put the overall cost of our design at around \$170.

6. Future Work

After selection the final design, the first major task to accomplish is material selection and acquisition. At the moment, current websites have been researched to determine where to order materials. More research into the shape, size, and type of materials is required to select the appropriate materials desired. The football pads will need to be inflated on their own, and come in two different sizes: three small pads and one long large pad. The hard protective cover will need to be able to attach to the football pads, be able to molded to the correct shape, and protect the wrist from normal daily activities that could harm the fracture. The liner needs to be non-irritating to the skin.

Pressure testing of the current casting method is required to determine the exact pressures of the three-point pressure for the air-bladders. To do this, the team will use pressure sensors in the correct pressure point places. A doctor will cast over these sensors and the pressure needed to correctly heal the wrist fracture will be recorded. The air pads will then made to have a similar force on the wrist.

A prototype will then be fabricated by the end of the current semester. This leads to the future work for next semester, in which the prototype will be tested on saw bones. This will showed areas of improvement that need to be made to improve the device. By the end of next semester, a finished prototype will be fabricated.

7. Conclusion

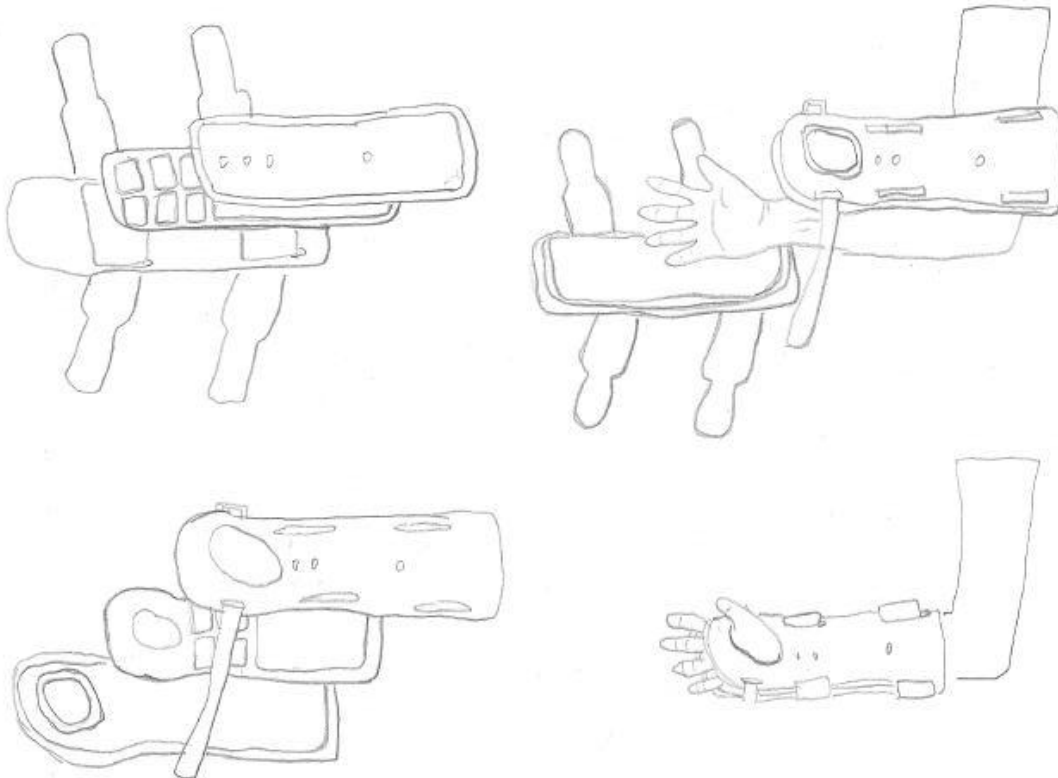
Distal radius fractures are one of the most frequent fractures experienced by children. The current treatment of using casts inconveniences lifestyles and increases the risk of complications such as poor fit and cast-saw burns because doctors are spending more time focusing on surgery and less time practicing proper casting techniques. Many studies in the past decade have shown splints to be just as effective as casts for certain distal radius fractures including buckle fractures. The only disadvantage current splints have is the lack of a three-point pressure loading needed to keep reduction. To eliminate this drawback, we will design and test a splint with dynamic and controllable lining containing pads which can be inflated and deflated to the proper pressure. This design will maintain the reduction while being more convenient and easier to implement and remove.

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9. Appendix

9.1 Final Design – There will be three layers: a lining, the bladders, and hard shell.



9.2 Project Design Specifications

Project Design Specifications- October 24, 2012
“Super Splint”

Team Members

Kate Howell – Team Leader
Sean Heyrman - Communicator
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Lisle Blackbourn - BWIG

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 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 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.
- Materials:* Device must be hypoallergenic, anti-microbial, radiolucent, light-weight, wicking material, and durable.
- Aesthetics, Appearance, and Finish:* The device will be available in two designs: the pressurasaurus and the pressure-raptor.

2. Production Characteristics

- Quantity:* One prototype for this semester is needed.
- Target Product Cost:* The prototype is estimated to not cost more than \$100.

3. Miscellaneous

- Standards and Specifications:* FDA approval may be required.
- Customer:* The device must be comfortable, fashionable, and not cause pressure sores.
- Patient-related concerns:* The device should minimally hinder daily activities.
- Competition:* Competition includes casting, as well as other current splints.