BME 400 – SUPER SPLINT

Dynamic Splint For Pediatric Distal Radius Fractures

End of Fall 2012 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. An 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

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

In the United States, 3.5 million children sustain a wrist fracture or distal radius fracture [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: 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 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.

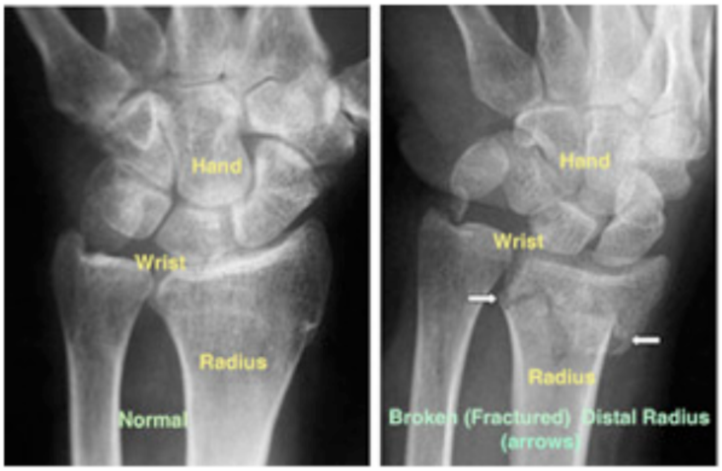
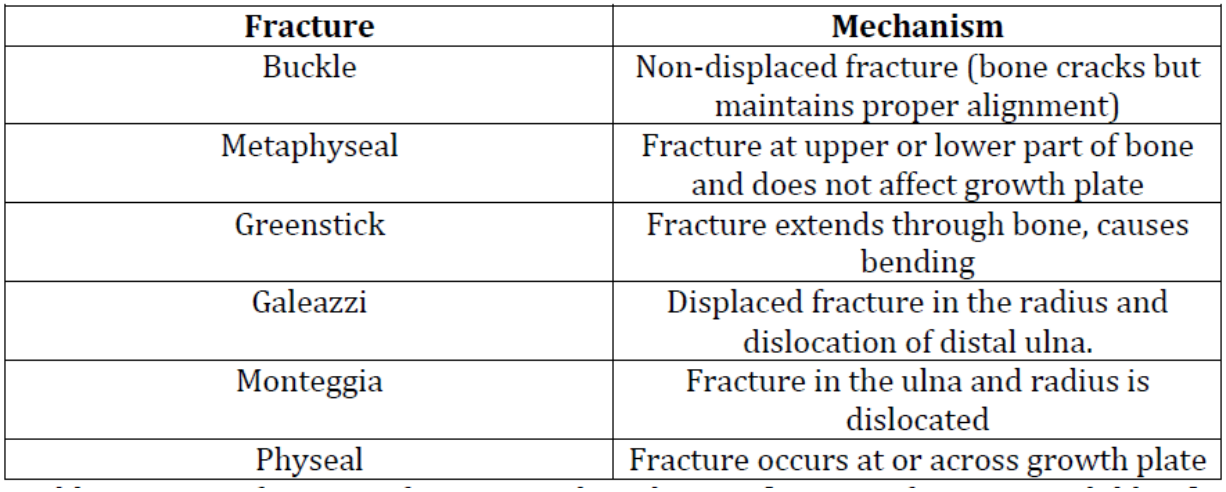


Fig. 2: X-ray image of a normal wrist (left) and fractured wrist. [2]



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 [5]. 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 [6]. In addition to this, splints are cheaper (typically around \$30 for pediatric forearm splints [5]) and easier to implement.

4. Current Methods

Fig. 3: The Aircast StabilAir Wrist Brace in use on a patient. [7]

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 [6]. Unlike a cast, the splint provides non-circumferential stabilization of a fracture. The splint is typically used in buckle fractures of the distal radius [6]. 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 [5]. To support a post-operative (meaning the fracture had to be surgically reduced) 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 equivalent pressurized air-cells for support. This product differs from 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 nondisplaced 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 15.

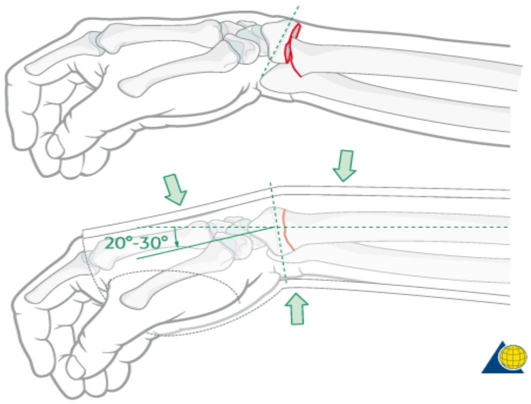


Fig. 4: The top diagram shows the fracture and the bottom displays the reduced fracture and where the 3 loads need to be applied to keep reduction. [8]

5.2 Design Alternatives

Three alternative designs address the need for 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 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. [9]

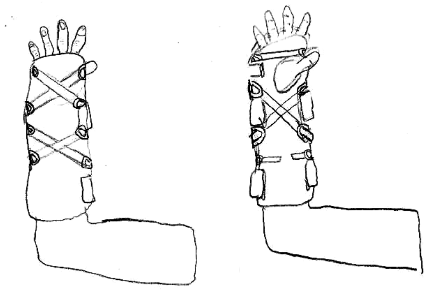


Fig. 5: This is what the inner layer would look like with the adjustable Velco crosses.

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 should take less time than casting as this design can just be slipped on and adjusted to the proper 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. [10]

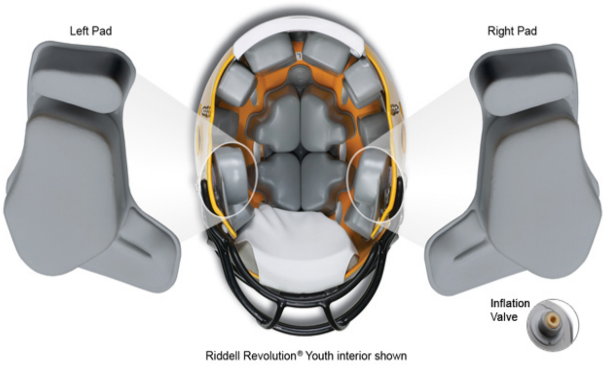


Fig. 6: The interior of a football helmet. The various interior pads are inflatable and provide support. [11]

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 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. [12 & 13]

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. [12]

To create the three-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 two pressure points on one half of the splint and one 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. [13]

5.3 Design Matrix

The design matrix compares the designs alternatives to the categories of reduction maintenance, ease of use, protection, pressure, biocompatibility, and cost. It can be seen in Table 2.

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.

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, and 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. Therefore, it was given a full score of 20 points. Finally, thermoplastic splints do not improve on the casting methods currently used due to the similarity of the application process. 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, provides 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 [9]), 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 [10]. Finally, thermoplastics are the most expensive alternative and were given 1 point for this category.

Conclusion

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.

5.4 Final Design

The final design will utilize the football helmet pads. The device will consist of a sample splint, generalized as two 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. Two of these pads will be located on the top half of the splint. One will be at each end on the splint: at the wrist end and at the base end. The other will be on the bottom half-cylinder, near the wrist. Long, larger pads located on the upper part of the forearm for stability of the splint to the arm. These long pads will not be inflatable/deflatable, since they will not aid in the healing process and only provide stability to the splint. These pad locations were selected as to apply pressure at the same points as the casting technique. These points will be elaborated on in the testing section of this paper. 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. This will also help in avoiding pressure sores. 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. It is also important to note that all materials used are radiolucent.

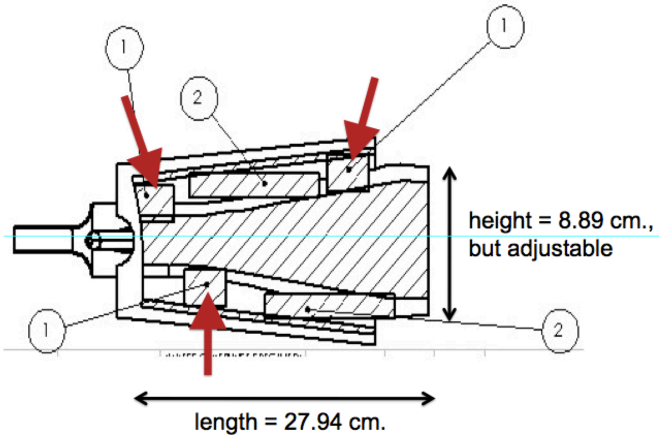


Fig. 8: Side view of the final design made in SolidWorks. 1 indicates the inflatable pads, while a 2 indicates noninflatable pads. The red arrows indicate points of the three-point pressure positions created by the smaller inflatable pads.

6. Testing

To ensure the dynamic splint reproduces a cast's three-point loading system, the pressure a cast applies to the arm needed to be determined. No scholarly article was found with any such pressure data. We performed a test to determine the pressure using piezoelectric sensors. The sensors used were A401-25 FlexiForce® Sensors seen in Figure 9 from Tekscan which measure loads ranging from 0-25 lbs. [4] The sensor's physical and performance properties can be seen in the Appendix in Section 11.2. The sensors can be passively or actively used. We used them passively by measuring the resistance the sensor produces from the applied load. The inverse of the resistance is used to determine the conductance. The conductance has

Figure 9: This is a photo of the A401-25 FlexiForce® Sensor. [14]

a linear relationship to the force applied to the sensor. The pressure was then estimated by dividing the measured force by the sensing area of the sensor. This is a rough estimation because the sensor measures the highest force instead of an average over the area.

Before conducting the experiment, the sensors were calibrated. A calibration curve can be obtained by applying known loads to the sensors and determining the conductance. First, the sensor must be conditioned by applying 110% of load (in this case 27.5 lb) to the sensor for 3 seconds and repeating this 4 to 5 times. Then to obtain the calibration curve, different loads, in the range of acceptable loads, were placed on the sensor and the resistance was measured using a multimeter. Three measurements were acquired for each load. Each sensor was individually calibrated. The resistance measurements were converted into conductance by inversing the resistance. Then the three measurements were averaged, and the average was plotted using Microsoft Excel. A linear trend line was determined for each sensor which provided the calibration curve. This information can be seen in the Appendix in Section 11.3.

The experiment was designed to measure the force applied to a casted arm. Three healthy subject were used all of which were from our design team including two males and one female, all 21 years old. All subjects had their left arm casted for a distal radius fracture. First, the sensors were applied to the arm of a subject. To do this, an initial single layer of pre-wrap was applied to the arm to protect the sensors from sweat or oils. The sensors were placed in the locations seen in Figure 10 and attached by athletic tape. Sensors 1-3 were placed were the three point-loading was to be applied by the doctor. An additional sensor (Sensor 4) was used to measure pressure at a non-loading section of the cast. The sensors were placed in a way so the 2-pin male square lead would still be exposed after casted in order to take measurements. The same sensor was used in the same location for all three subjects.

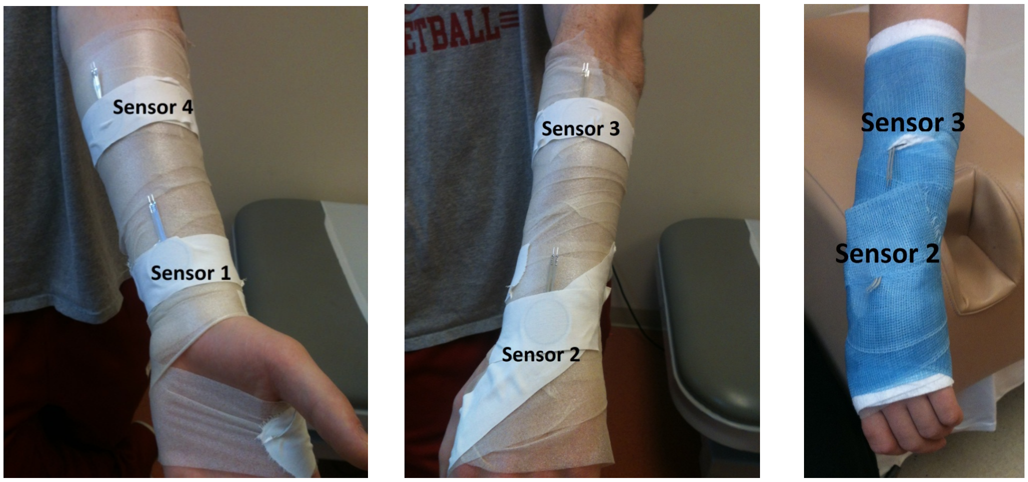


Figure 10: These images show the locations of the sensors as label in the pictures. The far left shows the anterior view of the left arm and the middle picture displays the anterior view of the left arm. The casted arm can be seen with the sensor leads stick outing in the far right diagram.

Then, the arm was then casted by our client, Dr. Halanski. First, he applied a layer of cotton padding over the sensors and arm which would also be done in a normal casting. Lastly, the fiberglass was wetted and casted onto the arm. Again, the fiberglass was applied to make sure the sensors' leads were still exposed as seen in Figure 10. The doctor applied the three-point loading using his hands and leg.

Three sets of measurements were recorded at different times. For each set, three resistance measurements were taken. The first set was taken while Dr. Halanski was setting the wet fiberglass. The second set of data was taken five minutes after Dr. Halanski stopped applying pressure and the fiberglass was partially dry. The last set taken 10 minutes after the cast had been set, and by that time the fiber glass was completely dry. The multimeter leads had alligator clips attached to them, and the other ends of the clip were applied to the sensors' pins. Each sensor was measured individually. The sensors were measured sequentially (i.e. 1 - 4). The monitor of the multimeter was hidden from the doctor's view to make sure it would not affect his technique. The data collected is displayed in the Appendix in Section 11.4.1.

When conducting the experiment, a number of variables may have affected data acquisition. If the person applying the leads to the sensor put any weight on the casted arm, the sensors would detect that force. It was also noticed that some material from the fiberglass coated some of the leads which possibly may have affected the resistance. In the future, to get better data, different doctors should be used to do the casting, along with more participants. If possible, children participants should be included to see if the pressure differs, since the splint is meant for children.

6.1 Results

Once all the data was collected, it was inserted into a Excel spreadsheet where the resistances were converted into conductance values, averages were determined along with the population standard deviation, the forces were found from the calibration graphs, and lastly, the pressure was determined by dividing the forces by the sensing area of the sensors. All of these calculations can be seen in the Appendix in Sections 11.4.2 and 11.4.3. The results are displayed in Table 3 relate to Figure 11.

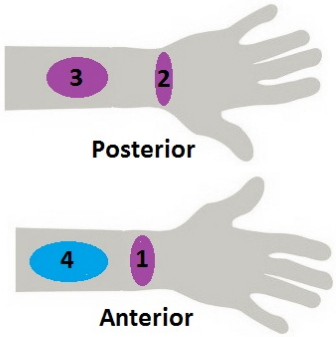


Figure 11: The areas where the splint must apply appropriate pressure depicted for left arm.

Area	Pressure (psi)	SI Pressure (kPa)
1	4.705599126	32.44392958
2	0.561172374	3.869143224
3	4.49643587	31.00180121
4	3.640978764	25.10363833

Table 3: The pressures need to be applied by the splint in specified areas determined by testing.

7. Expenses

The overall cost for the project this semester was $721.21 as shown in Table 4. This includes the sensors that were used during our testing, pads for our prototype, and even a StabilAir Splint, another air based protective splint. The cost for just the prototype was $319.96 which is comparable to the cost of a cast. However, if this was mass produced and the pads were custom made instead of pieced together from a much larger set of football pads, the splint would cost less than then cast price of $300-$400 as described by Dr. Halanski.

Item	Cost
Force Sensors	113
Pads Long	81.9
Pads Small 1	64.37
Pads Small 2	39.37
Pads Small 3	12.53
Pads Small Final	213.08
Aircast	171.98
Sleeve	24.98
Total	721.21

Table 4: All of the expensive from this semester.

8. Future Work

The dynamic air bladders will be tested on an arm to determine if the pressures exerted by the bladders match the desired pressures depicted in Table 3 and Figure 11. If the pressure does not reach the desired pressure, an alternative bladder will be researched and tested for use in the dynamic splint. After determining if the air bladders exert the correct pressure and if the device is a comfortable fit for the user, the design will be translated to a pediatric sized splint. Modification of the bladders and pads will be made in relation to the size of the pediatric splint. Further testing will be performed using a wrist saw bone of pediatric size to ensure the pediatric dynamic splint exerts the correct pressure. After comprehensive testing of the dynamic pediatric splint, it will be tested in clinical trials of pediatric distal radius fractures to determine its accuracy and reliability in vivo.

9. 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 than casting.

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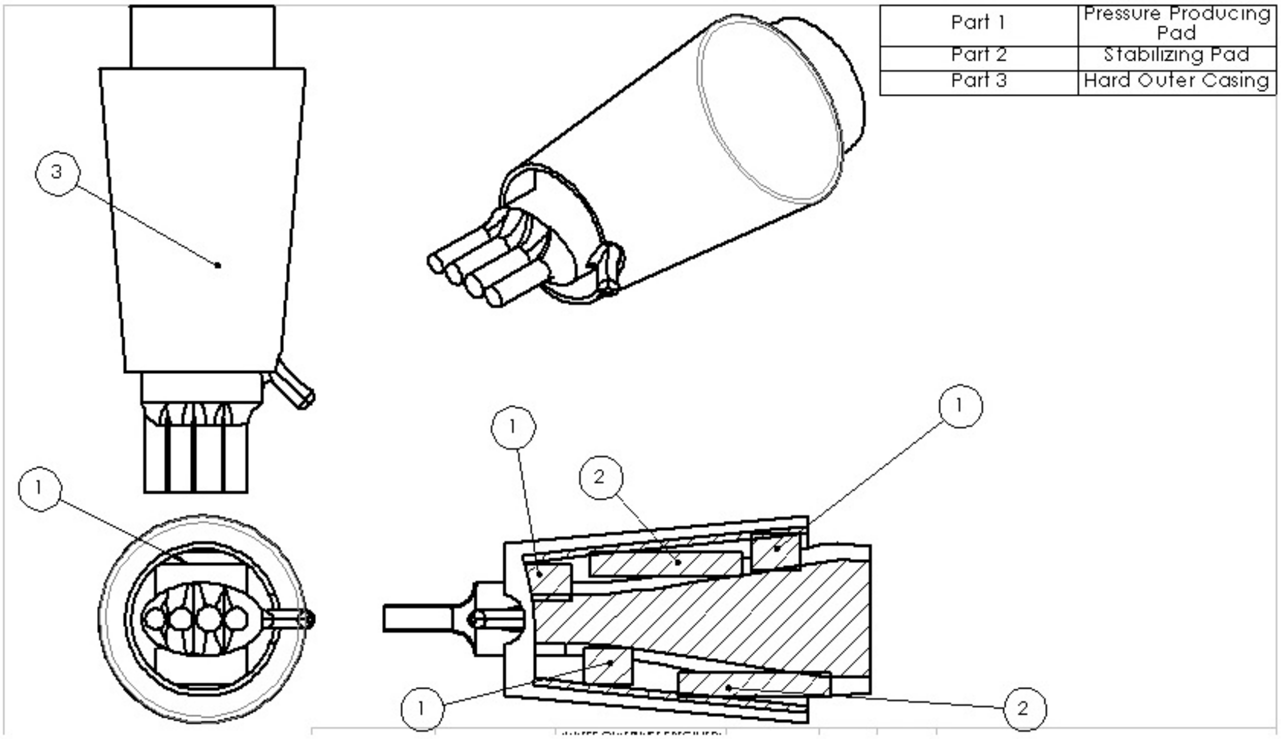
11. Appendix

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



Different Solid Works views of our final design. Smaller individual bladders will create the three-point pressure. The figure labels the different parts of the device.

11.2 Sensor Properties [14]

A401-25 FlexiForce Sensor	
Physical Properties	
Thickness	0.008 in (0.203 mm)
Length	2.24 in. (56.8 mm)
Width	0.55 in. (14 mm)
Sensing Area	1.0 in diameter (25.4 mm)
Connector	2 – pin male square pin
Typical Performance	
Linearity Error	<±3%
Repeatability	<±2.5% of full scale
Hysteresis	<4.5% of full scale
Drift	<5% per logarithmic time scale
Response Time	<5 microsecond
Operating Temperatures	15˚F to 140˚F (-9˚C to 60˚C)
Force Ranges	0-25 lb (110 N)
Temperature Sensitivity	Output variance up to 0.2% per degree F

11.3 Sensor Calibration

1.3.1 Calibration Measurements and Calculations

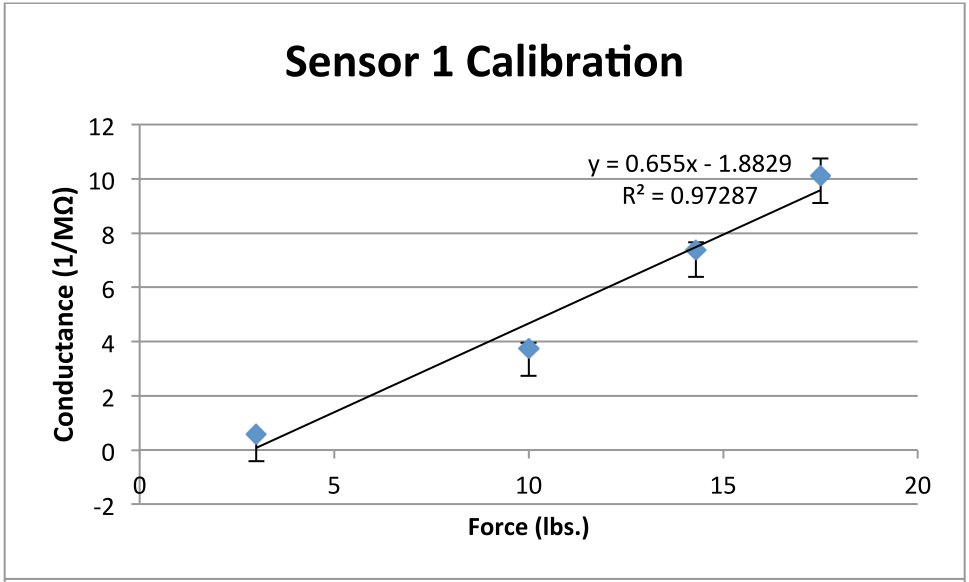
Sensor 1	Resistance MΩ				Sensor 1	Conductance 1/MΩ				Standard Deviation Calculations				
Pounds	Set 1	Set 2	Set 3	Average	Pounds	Set 1	Set 2	Set 3	Average	(Set 1 - Ave)^2	(Set 2 - Ave)^2	(Set 3 - Ave)^2	Averages	SD
3	1.71	1.61	1.81	1.71	3	0.584	0.621	0.552	0.586	1.78E-06	0.001223	0.00113	0.000786	0.028035
10	0.291	0.252	0.263	0.268	10	3.436426	3.968254	3.802281	3.735654	0.089537	0.054102	0.00443	0.049	0.222
14.3	0.131	0.133	0.143	0.135	14.3	7.633588	7.518797	6.993007	7.381797	0.063398	0.018768	0.15115	0.077	0.278
17.5	0.101	0.091	0.106	0.099	17.5	9.90099	10.98901	9.433962	10.10799	0.042848	0.776201	0.45431	0.424	0.651

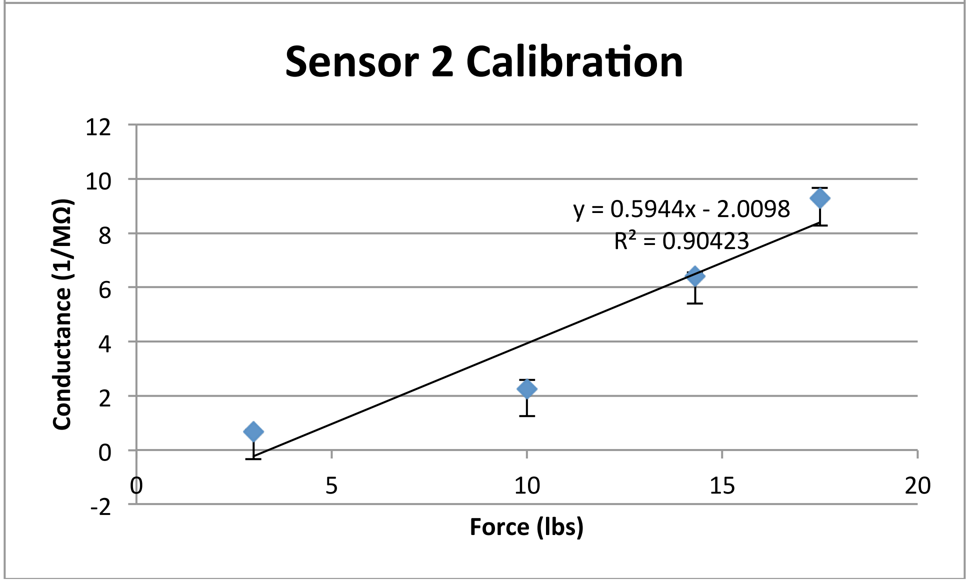
Sensor 2	Resistance MΩ				Sensor 2	Conductance 1/MΩ								
Pounds	Set 1	Set 2	Set 3	Average	Pounds	Set 1	Set 2	Set 3	Average	(Set 1 - Ave)^2	(Set 2 - Ave)^2	(Set 3 - Ave)^2	Averages	SD
3	1.52	1.75	1.31	1.526	3	0.657	0.571	0.763	0.664	4.01E-05	0.008611	0.00982	0.006	0.078
10	0.52	0.37	0.47	0.453	10	1.923	2.702	2.127	2.251	0.107629	0.203903	0.01524	0.108	0.330
14.3	0.16	0.151	0.158	0.156	14.3	6.25	6.622	6.329	6.400	0.022663	0.049272	0.00510	0.025	0.160
17.5	0.113	0.102	0.109	0.108	17.5	8.849	9.803	9.174	9.275	0.181793	0.278774	0.01032	0.156	0.396

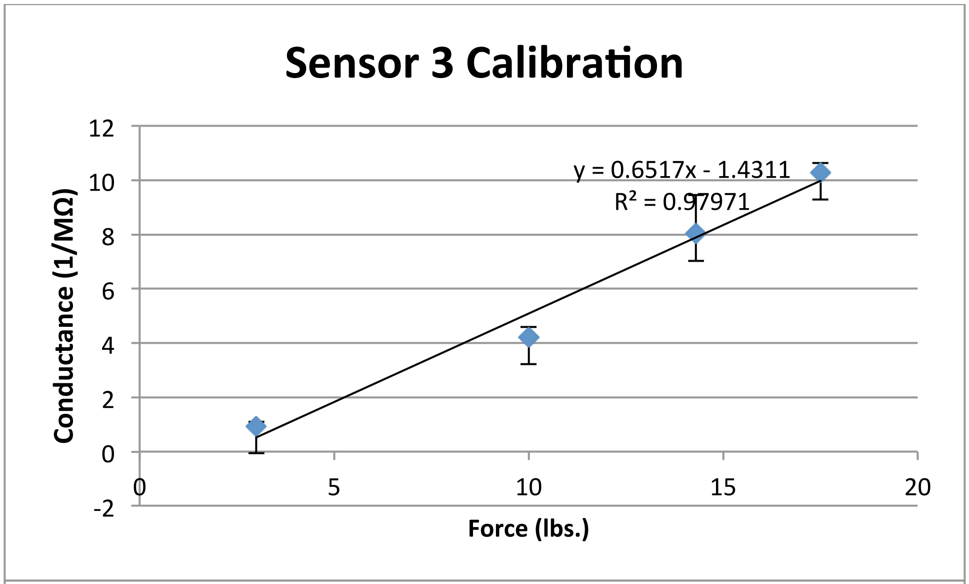
Sensor 3	Resistance MΩ				Sensor 3	Conductance 1/MΩ								
Pounds	Set 1	Set 2	Set 3	Average	Pounds	Set 1	Set 2	Set 3	Average	(Set 1 - Ave)^2	(Set 2 - Ave)^2	(Set 3 - Ave)^2	Averages	SD
3	0.9	1.33	1.04	1.09	3	1.111111	0.751	0.961	0.941	0.028764	0.035959	0.00040	0.021	0.147
10	0.213	0.263	0.24	0.238	10	4.694836	3.802	4.166	4.221	0.224272	0.175544	0.00298	0.134	0.366
14.3	0.1	0.15	0.135	0.128	14.3	10	6.666	7.407	8.024	3.901844	1.844231	0.38103	2.042	1.429
17.5	0.098	0.101	0.093	0.097	17.5	10.20	9.900	10.75	10.28	0.006697	0.148171	0.21787	0.124	0.352

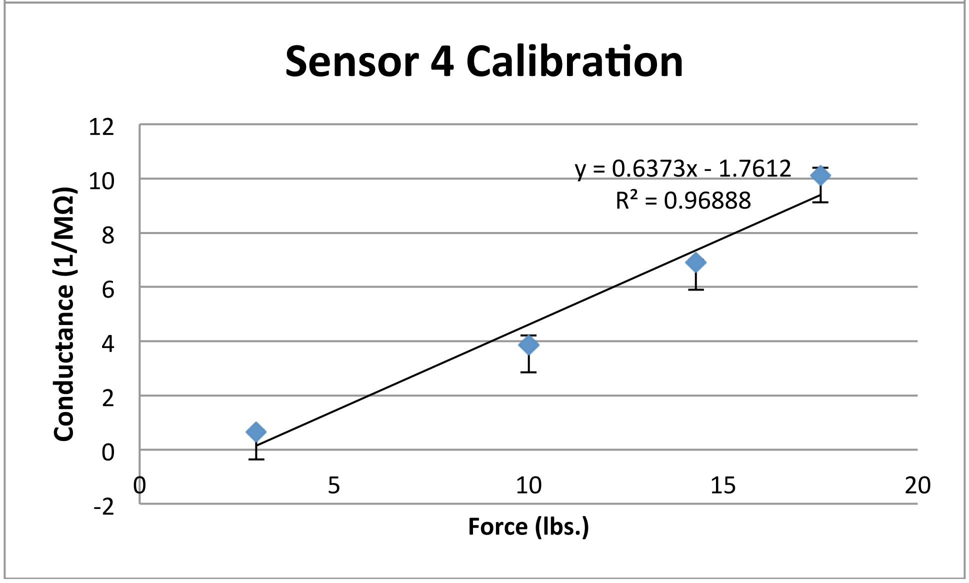
Sensor 4	Resistance MΩ				Sensor 4	Conductance 1/MΩ								
Pounds	Set 1	Set 2	Set 3	Average	Pounds	Set 1	Set 2	Set 3	Average	(Set 1 - Ave)^2	(Set 2 - Ave)^2	(Set 3 - Ave)^2	Averages	SD
3	1.51	1.85	1.38	1.58	3	0.662	0.540	0.724	0.642	0.000391	0.010390	0.00675	0.005	0.076
10	0.263	0.29	0.232	0.261	10	3.802	3.448	4.310	3.853	0.002637	0.164315	0.20858	0.125	0.353
14.3	0.148	0.143	0.144	0.145	14.3	6.756	6.993	6.944	6.898	0.019969	0.009013	0.00215	0.010	0.101
17.5	0.098	0.103	0.096	0.099	17.5	10.20	9.708	10.41	10.10	0.008883	0.160873	0.09414	0.087	0.296

11.3.2 Calibration Graphs for Sensors including Standard Deviation Error Bars






Sensor 3 Calibration
Conductance (1/MΩ)
12
10
8
6
4
2
0
-2
0
5
10
15
20
Force (lbs.)
y = 0.6517x - 1.4311
R² = 0.97971


Sensor 4 Calibration
Conductance (1/MΩ)
12
10
8
6
4
2
0
-2
0
5
10
15
20
Force (lbs.)
y = 0.6373x - 1.7612
R² = 0.96888

11.4 Testing of Cast Pressure

11.4.1 Measurement Collection

$$Conductance\ (\frac{1}{M\Omega}) = {}^{1}/_{Resistance\ (M\Omega)}$$

Lisle's Measurements					Sean's Measurements					Kate's Measurements				
Data Set 1: Initial Time					Data Set 1: Initial Time					Data Set 1: Initial Time				
	Conductance (1/MΩ)					Conductance (1/MΩ)					Conductance (1/MΩ)			
Sensor	Set 1	Set 2	Set 3	Average	Sensor	Set 1	Set 2	Set 3	Average	Sensor	Set 1	Set 2	Set 3	Average
1	0.295	0.273	0.301	0.290	1	0.355	0.274	0.320	0.317	1	0.008	0.008	0.011	0.009
2	0.403	0.438	0.510	0.450	2	0.527	0.473	0.478	0.493	2	0.010	0.008	0.009	0.009
3	1.534	1.307	1.161	1.334	3	1.049	1.189	1.023	1.087	3	0.014	0.009	0.014	0.013
4	0.427	0.416	0.344	0.396	4	0.176	0.131	0.126	0.144	4	0.011	0.006	0.006	0.008
Data Set 2: 5 Minutes					Data Set 2: 5 Minutes					Data Set 2: 5 Minutes				
	Conductance (1/MΩ)					Conductance (1/MΩ)					Conductance (1/MΩ)			
Sensor	Set 1	Set 2	Set 3	Average	Sensor	Set 1	Set 2	Set 3	Average	Sensor	Set 1	Set 2	Set 3	Average
1	0.322	0.310	0.331	0.321	1	0.292	0.335	0.331	0.319698	1	0.248	0.234	0.240	0.241
2	0.033	0.041	0.034	0.036	2	0.469	0.529	0.409	0.469473	2	2.654	3.070	2.695	2.806
3	0.318	0.486	0.458	0.420	3	0.826	1.036	0.909	0.923936	3	2.088	1.960	1.122	1.723
4	0.299	0.310	0.331	0.313	4	0.098	0.114	0.137	0.116682	4	1.804	3.125	2.319	2.416
Data Set 3: 10 Minutes					Data Set 3: 10 Minutes					Data Set 3: 10 Minutes				
	Conductance (1/MΩ)					Conductance (1/MΩ)					Conductance (1/MΩ)			
Sensor	Set 1	Set 2	Set 3	Average	Sensor	Set 1	Set 2	Set 3	Average	Sensor	Set 1	Set 2	Set 3	Average
1	0.390	0.384	0.414	0.396	1	0.258	0.309	0.281	0.283	1	0.221	0.201	0.263	0.229
2	0.052	0.042	0.051	0.048	2	0.377	0.507	0.427	0.437	2	0.449	0.403	0.413	0.422
3	0.147	0.140	0.151	0.146	3	0.657	0.819	0.840	0.772	3	0.644	0.452	0.540	0.545
4	0.980	0.799	0.636	0.805	4	0.103	0.08	0.071	0.085	4	3.205	1.148	0.621	1.658

11.4.2 Averages of Measurements and Standard Deviation Calculations

- Population Standard Deviation: $\sigma = \sqrt{\frac{\sum_{k=1}^{n}(x_k - \mu)^2}{n}}$ where μ is the average

Averages and Standard Deviations of Measurements								
Data Set 1: Initial Time								
	Conductance (1/MΩ)				SD Calculations			
Sensor	Lisle	Sean	Kate	Average	$(\text{Lisle - Ave})^2$	$(\text{Sean - Ave})^2$	$(\text{Kate - Ave})^2$	SD
1	0.290291	0.317037	0.0093363	0.205555	0.00718	0.012428	0.038502	0.139176
2	0.450798	0.493184	0.0094764	0.317819	0.017683	0.030753	0.095075	0.218717
3	1.334359	1.087307	0.0130049	0.811557	0.273322	0.076038	0.637685	0.573599
4	0.396203	0.144513	0.0083452	0.18302	0.045447	0.001483	0.030511	0.160666
Data Set 2: 5 Minutes								
	Conductance (1/MΩ)				SD Calculations			
Sensor	Lisle	Sean	Kate	Average	$(\text{Lisle - Ave})^2$	$(\text{Sean - Ave})^2$	$(\text{Kate - Ave})^2$	SD
1	0.321483	0.319698	0.2413402	0.294174	0.000746	0.000651	0.002791	0.037366
2	0.036337	0.469473	2.8067867	1.104199	1.140329	0.402877	2.898805	1.216828
3	0.420976	0.923936	1.723763	1.022891	0.362303	0.009792	0.491221	0.536444
4	0.313831	0.116682	2.4160622	0.948858	0.40326	0.692517	2.152687	1.040587
Data Set 3: 10 Minutes								
	Conductance (1/MΩ)				SD Calculations			
Sensor	Lisle	Sean	Kate	Average	$(\text{Lisle - Ave})^2$	$(\text{Sean - Ave})^2$	$(\text{Kate - Ave})^2$	SD
1	0.396569	0.283229	0.2291638	0.302987	0.008758	0.00039	0.00545	0.069756
2	0.048855	0.437441	0.4221773	0.302824	0.0645	0.018122	0.014245	0.179692
3	0.146287	0.772634	0.5458275	0.488249	0.116939	0.080875	0.003315	0.258926
4	0.805565	0.085846	1.6581173	0.849843	0.001961	0.583692	0.653308	0.64264

11.4.3 Force & Pressure Calculations

- Force determined by taking the average for that sensor during that data set in section 9.4.2 and plugging it into the calibration equations from 9.3.2
  - Sensor 1: $Force(lbs) = \frac{Conductance+1.8829}{0.655}$
  - Sensor 2: $Force(lbs) = \frac{Conductance+2.0098}{5.944}$
  - Sensor 3: $Force(lbs) = \frac{Conductance+1.4311}{0.6517}$
  - Sensor 4: $Force(lbs) = \frac{Conductance+1.7614}{0.6373}$
- Pressure was estimated by divided the force by the sensing area of the sensor
  - Diameter = 1 in. thus $r = {Diameter}/{2} = 0.5\ in.$
  - $A = \pi r^2 = \pi(0.5\ \text{in.})^2 = 0.7854\ \text{in.}^2$
  - $Pressure\ (psi) = \frac{Force\ (lbs.)}{Area\ (in.^2)}$

Data Set 1: Initial Time		
Sensor	Force (lbs)	Pressure (psi)
1	3.18848032	4.060206702
2	0.39159142	0.498652008
3	3.44124132	4.382072224
4	3.05071455	3.884775952

Data Set 2: 5 Minutes		
Sensor	Force (lbs)	Pressure (psi)
1	4.5604567	5.807279641
2	0.51021053	0.649701422
3	3.65192321	4.650354269
4	2.76353366	3.51908017

Data Set 3: 10 Minutes		
Sensor	Force (lbs)	Pressure (psi)
1	3.33698396	4.249311036
2	0.42026405	0.535163691
3	3.49998874	4.456881116
4	2.76353366	3.51908017

11.4.4 Average Pressure at Each Point

- Conversion between psi to kPa: 1psi = 6.894 kPa

Sensor	Pressure (psi)	SI Pressure (kPa)
1	4.705599126	32.44392958
2	0.561172374	3.869143224
3	4.49643587	31.00180121
4	3.640978764	25.10363833

11.5 Project Design Specifications

Project Design Specifications- December 10, 2012

“Super Splint”

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 most not irritate skin or cause pressure sores.
- Pressure lining must be dynamic and controllable.

Design Requirements

1. **Physical and Operational Characteristics**

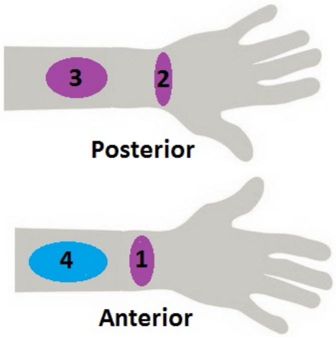


Figure 1: The areas where the splint must apply appropriate pressure depicted for left arm.

Area	Pressure (psi)	SI Pressure (kPa)
1	4.705599126	32.44392958
2	0.561172374	3.869143224
3	4.49643587	31.00180121
4	3.640978764	25.10363833

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

a. *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.

b. *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.

c. *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.

d. *Life in Service*: The device needs to perform for 6 weeks.

e. *Shelf Life*: Prior to use, the device may be stored for up to two years in a hospital store room.

f. *Operating Environment*: The splint will be worn during daily activities so it should be water resistant, nonconductive, and durable.

g. *Ergonomics*: The device needs to be able to be removed multiple times and reapplied during the duration of the device’s use.

h. *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.

i. *Weight*: Device must not weigh more than half a kilogram.

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.