Dynamic Splint for Pediatric Distal Radius Fractures

Spring 2013 Final 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 saw burns may harm or scare the child during removal of the cast. An alternative for the treatment of 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. Last semester, the pressures applied by a doctor during casting were collected and analyzed. Also, football pads were then tested and proved that airbladders can be utilized to mimic the pressures of casting. This semester, the airbladders will be modified for a better fit and the pressures produced will be tested. This design project will allow for a safer and more convenient treatment of pediatric distal radius fractures.

2. Background and Motivation

In the United States, 3.5 million children sustain a wrist fracture or distal radius fracture each year [1]. Typically, these fractures occur by falling and landing on an outstretched arm [2]. A distal radius fracture occurs when the radius, one of the two bones in the forearm shown in Figure 1, breaks near the hand. Forearm fractures are classified into six categories: buckle, metaphyseal, greenstick, galeazzi, monteggia, and growth plate fractures. The

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

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 physealfracture, whereas a fracture at the upper or lower portion of the bone without affecting a growth plate is a metaphyseal fracture [3]. Table 1 summarizes the different types of fractures.

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]

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 technique to reduce, or realign, the fracture. Unstable, or potentially unstable, fractures require casting to immobilize the fracture [4]. The casting procedure includes application of a stockinette followed by two to three layers of cotton padding applied circumferentially around the forearm. Wet strips of

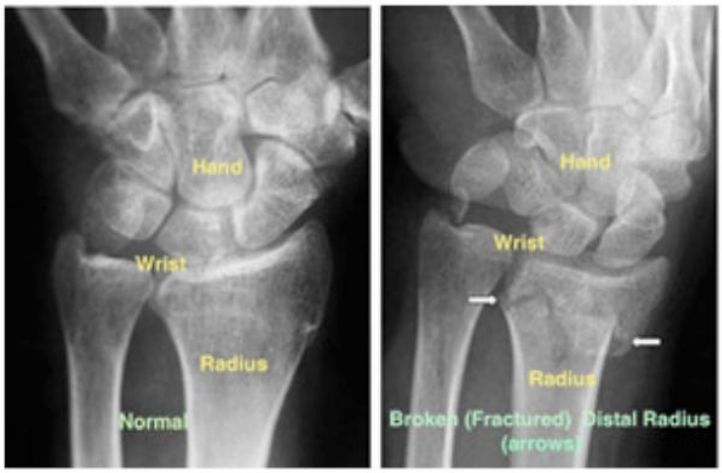

Figure 2: X-ray image of a normal wrist (left) and fractured wrist. [2]

plaster or fiberglass is then applied over the cotton and, after fully dried, provides 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 can hold the bone in the correct position [4]. To support a post-operative (or 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 [6]. This product differs from other splints because of the use of air-cells to maintain the wrist in proper position.

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

Although casting is a common treatment of fractures, it results in limited mobility and affects a child's daily lifestyle [7]. Furthermore, improper application of the cast may result in a poor fit that induces a loss of reduction or pressure sores. Often the large learning curve for the doctors in application of the casts causes the improper application. Doctors are not able to practice casting a broken bone until they encounter a broken bone since there is not a method to practice casting. Additionally, the saw to remove the cast, which may cause cast-saw burns, often frightens children. In addition to these complications, the medical bill for a forearm cast is $300 - $400 [4].

Recent studies have been done to compare the treatment of wrist buckle fractures (bones that crack but maintain alignment) using splints rather than casts, and the results

indicate children treated with removable splints had better physical functioning and easier time with daily activities [5]. In addition to this, splints are cheaper (typically around $30 for pediatric forearm splints [4]) and easier to implement.

3. Problem Statement

Splints have been proven as effective as casts for non-displaced distal radius fractures in adolescents and interfere less with daily activities [6]. 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.

3.1 Product Design Specifications (PDS)

Certain requirements must be achieved by our design to properly treat 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 to allow adjustment of pressure throughout the healing process, 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,

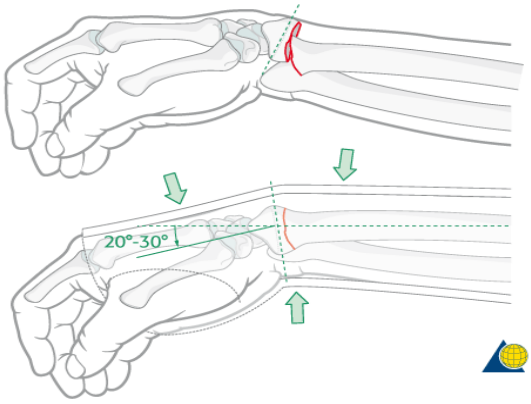

Figure 4: The top diagram shows the fracture and the bottom displays the reduced fracture and where the 3 loads need to be applied to keep reduction. [8]

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 31.

4. Final Design

The final design includes six pads attached to a typical splint for wrist fractures, a SolidWorks model of which is shown in Figure 5. The six pads included three non-inflatable pads that were there to provide stability for the splint and ensure the splint fits on the arm correctly. The other three inflatable pads will provide the 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. These pads were created using vinyl and a heat sealer or hair straightener to seal the edges. A sponge was also placed inside the pads to provide a soft shape while the pads were un-inflated. The pad locations were selected as to apply pressure at the same points as the typical casting technique. These points will be elaborated on in the testing section of this paper. A hard protective plate embedded in the splint located on the posterior side of the forearm will protect the arm from re-injuring the fracture. This is necessary to avoid setbacks to the fracture healing process. It is also

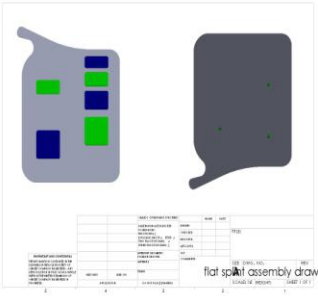

Figure 5. A SolidWorks model of the splint laid out flat. The blue pads are non-inflatable and provide stability for the splint. The green pads provide the three point pressure needed to successfully reduce the fracture.

important to note that all materials used are radiolucent. A moisture-wicking liner between the skin and the pads avoids irritating the skin and keeps the skin dry during extended use. The final prototype is displayed in Figure 6.

Figure 6: The final prototype with the far left is the anterior view with one exposed valve, the center showing the posterior with two exposed valves, and the far right showing the interior of the splint with the inflatable and noninflatable pads.

5. Testing

Several tests have been performed to analyze the pressures on the forearm. Since no scholarly articles have published the pressures applied on the forearm during casting, testing was completed to collect the values. Secondly, the prototype from last semester was tested and provided proof that the bladder design will work in providing the pressures obtained during casting. Lastly, the StabilAir Wrist Brace was tested for a comparison with the casting pressures.

5.1 Casting Pressures

To ensure the dynamic splint reproduces a cast's 3 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 7 from Tekscan which measure loads ranging from 0-25 lbs. [9]. 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 a linear relationship to the force applied to the sensor. The pressure was then estimated by divided 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.

Figure 7: This is a photo of the A401-25 FlexiForce® Sensor. [9]

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 repeat 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 8 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.

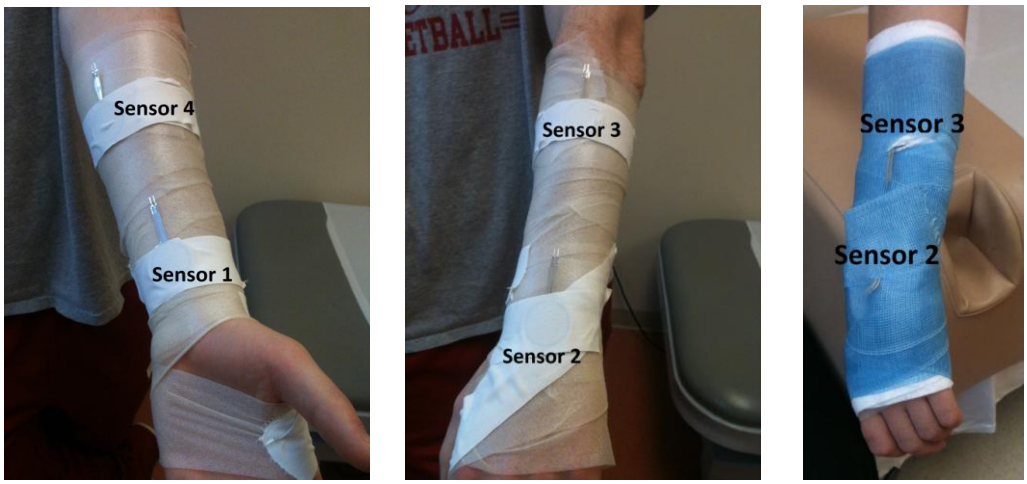

Figure 8: These images show the locations of the sensors as label in the pictures. The far left shows the anterior view of the left arm and the middle picture displays the anterior view of the left arm. The casted arm can be seen

Then, the arm was then casted by the 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 6. The doctor applied the 3 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 fiberglass 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.

5.2 Prototype Testing

After the construction of the initial prototype using the inflatable football helmet pads, the same experiment as the casting pressures was performed using the prototype. This was to test if inflatable pads were capable of producing the same pressures as casting. Three healthy adults were used. The sensors were placed in the same locations seen in Figure 6 using the same preparation with the pre-wrap and athletic tape. The splint was placed on the arm, and the pads were inflated. Three sets of measurements were taken: right after the pads were inflated, 5 minutes later, and 10 minutes later.

5.3 Stabilair Pressure Testing

Last semester, the StabilAir Arm Brace was purchased since it was the only splint on the market with an inflatable liner. This semester the StabilAir Splint was tested to compare the pressures to the casting pressures. Again, the same procedure was used and the sensors were prepared and place in the same locations as shown in Figure 6. Only two healthy adults were used for testing because the splint was a size small. Once the splint was place on the arm, the splint was inflated. An initial, 5 minutes, and 10 minutes after the inflation were when the three sets of measurement s were taken. For one case, the splint was cutting off the circulation of the hand, so some air was released to allow better circulation.

5.4 Pressure Results from Midsemester

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. The sensors were placed in the same areas shown in Figure 9 for all testing. 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 2 relate to Figure 9. It is shown that the inflatable pads are capable of producing the same pressures of as the casting. The StabilAir splint had slightly lower pressures compared to the casting. There also was not a significant difference in some of the pressures among the StabilAir pressures to create the 3 point pressure system needed for healing. This was seen in the inflatable pads.

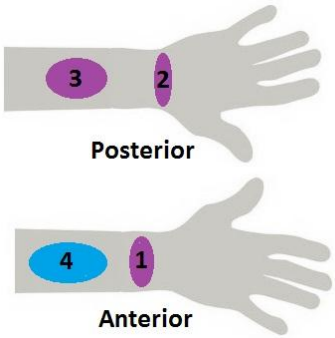

Figure 9: The areas where the splint must apply appropriate pressure depicted for left arm.

Area	Casting Pressure (psi)	Inflatable Pads Pressure (psi)	StabilAir Pressures (psi)
1	4.58	4.71	4.51
2	4.76	5.61	4.46
3	4.28	4.50	3.79
4	3.77	3.64	3.87

Table 2: The pressures need to be applied by the splint in specified areas determined by testing.

5.5 Testing of Final Prototype

Once the final prototype was successfully constructed two types of tests were performed. The first test was the same test performed to acquire pressures from casting, initial prototype, and StabilAir splint. The sensors were applied to the arm of two subjects in the same positions indicated by Figure 9. The splint was place on the arm, the Velcro straps fastened, and the pads were inflated using a handheld ball pump. The resistances were measured at the time of initial inflation then five and ten minutes later. The data was then converted into pressures. Then second test performed consisted of a longer duration of three hours. Initially the test intended to last a week for each trial, but time became a constraint so it was narrowed to three hours to allow for the collection of two trials. The sensors and splint was applied in the same manner with the pads being inflated after the splint was fastened to the arm. The resistance was measured at the initial application and each hour for a total period of three hours. The results are displayed in the next section.

5.6 Final Statistical Analysis

As mentioned before, pressure readings were recorded for casting, as well as our prototype. In order to determine whether the prototype pressures could replicate the castings pressures and whether the prototype could maintain these pressures over a period of time, t-tests were used to compare means. Using the t-test program in Excel, two t-tests were performed. The results can be seen in Figures 10 and 11.

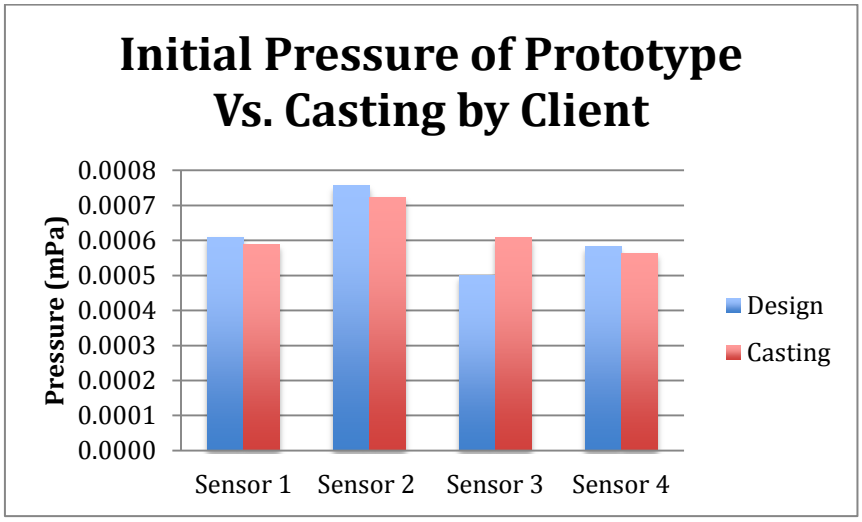

Figure 10: Pressure values obtained during the initial application of the splint or cast. No statistical difference between methods (p=0.848, 0.823, 0.950, 0.736, for sensor 1-4, respectively.)

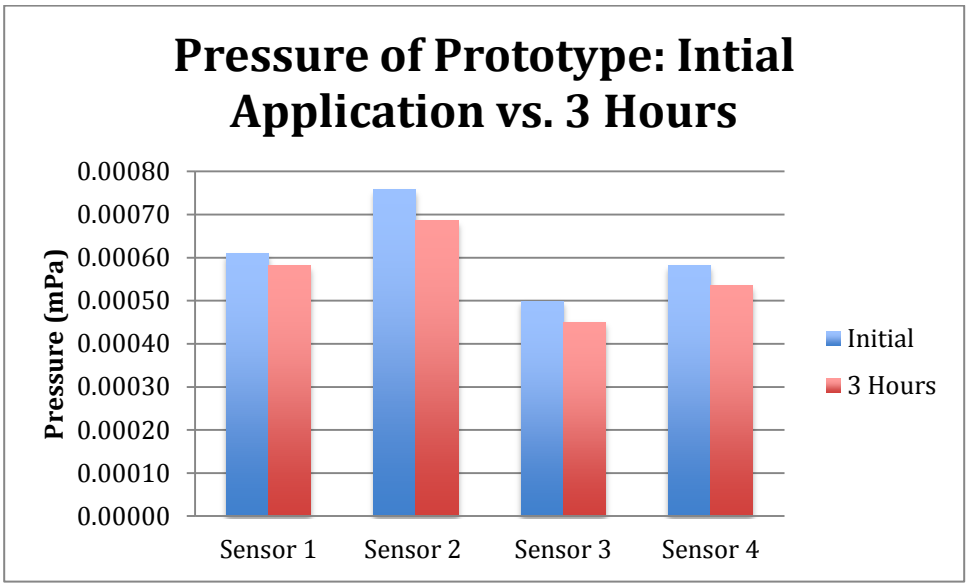

Figure 11: Pressure Testing of Prototype. Mean and standard deviation of each sensor at the initial application and three hours later. (P-value of sensor 1,2,3 and 4: 0.999, 0.999, 0.999 and 0.998, respectively.)

In each t-test, the data sets for each sensor were compared to itself in the other data set. The first t-test compared initial pressure readings of the prototype to the initial pressure readings of casting. For the initial pressures of the prototype, averages were as follows (for sensors 1 to 4 respectively): 0.609 +/- 0.011 mPa, 0.758 +/- 0.027 mPa, 0.499 +/- 0.018 mPa, and 0.582 +/- 0.021 mPa. For the initial pressures of casting, averages were as follows (for sensors 1 to 4 respectively): 0.589 +/- 0.042 mPa, 0.724 +/- 0.073 mPa, 0.608 +/- 0.152 mPa, and 0.564 +/- 0.050 mPa. P-values were 0.848, 0.823, 0.950, 0.736, for sensor 1-4, respectively. With these p-values, no statistical difference between methods can be seen. Therefore, the prototype was able to replicate the pressures of casting. In the second t-test, the data set of initial pressure readings from the prototype was compared to a data set of readings three hours later. For the 3 hour pressures of the prototype, averages were as follows (for sensors 1 to 4 respectively): 0.581 +/- 0.009 mPa, 0.686 +/- 0.009 mPa, 0.450 +/- 0.003 mPa, and 0.536 +/- 0.005 mPa. P-values were 0.999, 0.999, 0.999, and 0.998, for sensor 1-4, respectively. With

these p-values, no statistical difference between methods can be seen. Therefore, the prototype was able to maintain the pressure over a given period of time.

6. Budget

The overall cost for the final prototype was $73.00, as seen in Table 3, which includes the price of the heat sealer used to make the pads air tight. The splint was no cost to the design team as it was donated by the client, but the retail value of $20 was included in the total to better represent the price for making the prototype by hand. Based on estimates from companies which would be able to produce the inflatable pads and the price of splints, for this device to be mass produced in a quantity of 5,000 splints would result in each splint having an expense of $80.00.

Splint	**$20**
Padding	$3.00
Vinyl	$7.00
Nozzle (3)	$30.00
Heat Sealer	$13.00
Total	**$73.00**

Table 3: The total cost of producing the final prototype is displayed and includes the price of the heat sealer used to make the pads airtight.

7. Conclusions

After working on the project for nine months, the project was successful in that a working prototype proved that inflatable pads are capable of producing the same initial pressures as casting. There are some suggestions for future work if this project to be continued to be pursued. One is the completion of longer durations of wearing the inflatable splint to investigate if the splint is adequate enough to treat distal radius fractures. To further pursue more longitudinal studies, a few steps must be completed. In the short span of three hours, there was a decrease in pressures produced by the inflatable pads. This error has been contributed to the construction of the pads not being the most proficient method to create an airtight seal. Professional construction of airtight seals would account for this error and would be needed for the creation of a better prototype to be capable of testing periods ranging from 1 week to 2 months. Also depending on the time constraints, multiple prototypes might possibly be needed to be constructed. This would allow for multiple tests to be conducted at once. Further testing might also require IRB and FDA approval.

Additionally, the development of a hand pump to inflate the pads with an attachment which can measure the pressure of the pads would be a future step of this project. This would help doctors know what pressures the pads are inflated to and adjust accordingly. This could be modeled after the hand pump accompanied paired with the StabilAir splint. This hand pump has a bulb with two nozzles, one for inflation and the other for deflation. It is also equipped with a arbitrary indicator of the pad's pressure. Creating a device which would should the approximate range of the pressure, i.e. 2 psi compared to 4 psi, would allow doctors to adjust the pads appropriately.

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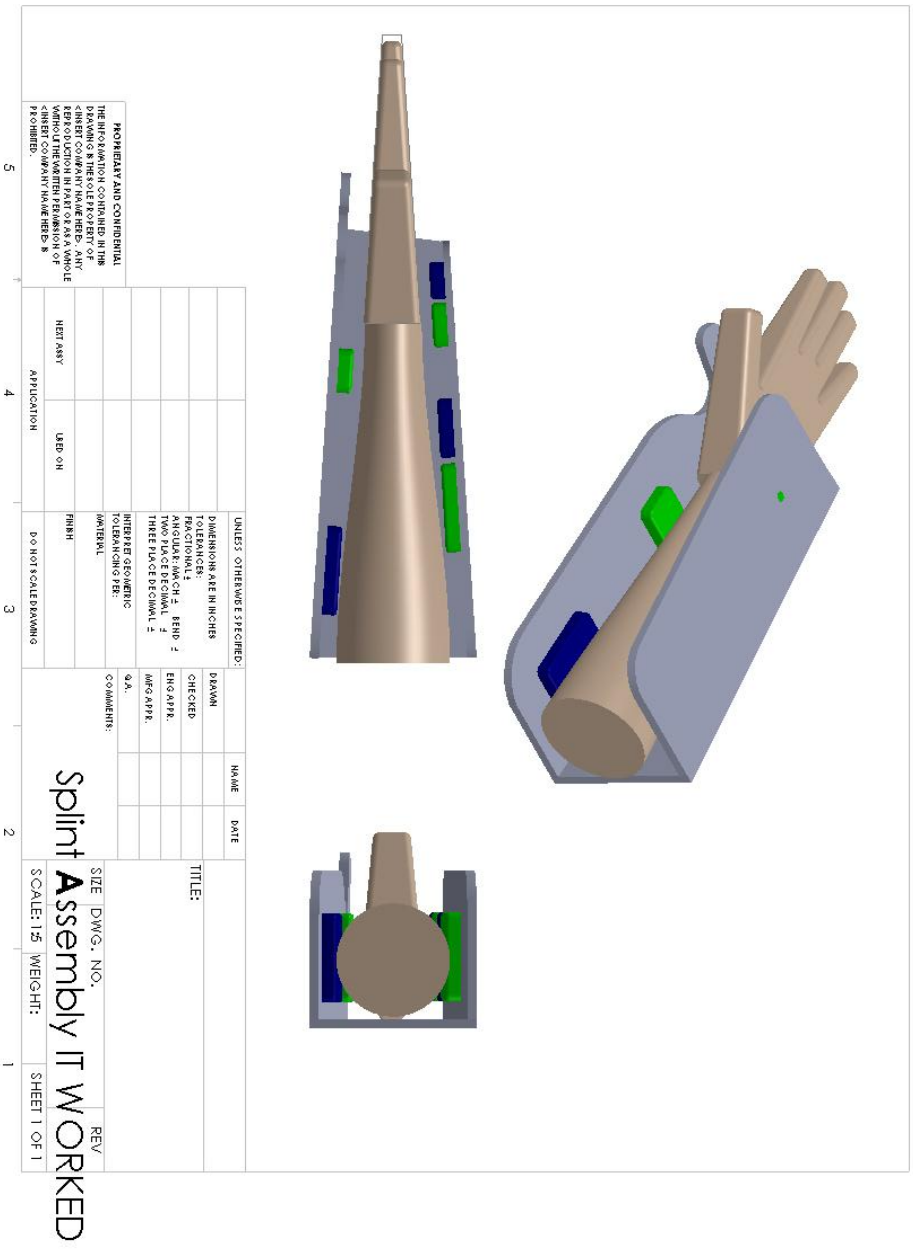
11. Appendix

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



Different Solid Works views of our final design. Green pads will be inflatable, and blue are non-inflatable.

11.2 Sensor Properties [9]

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

9.3 Sensor Calibration

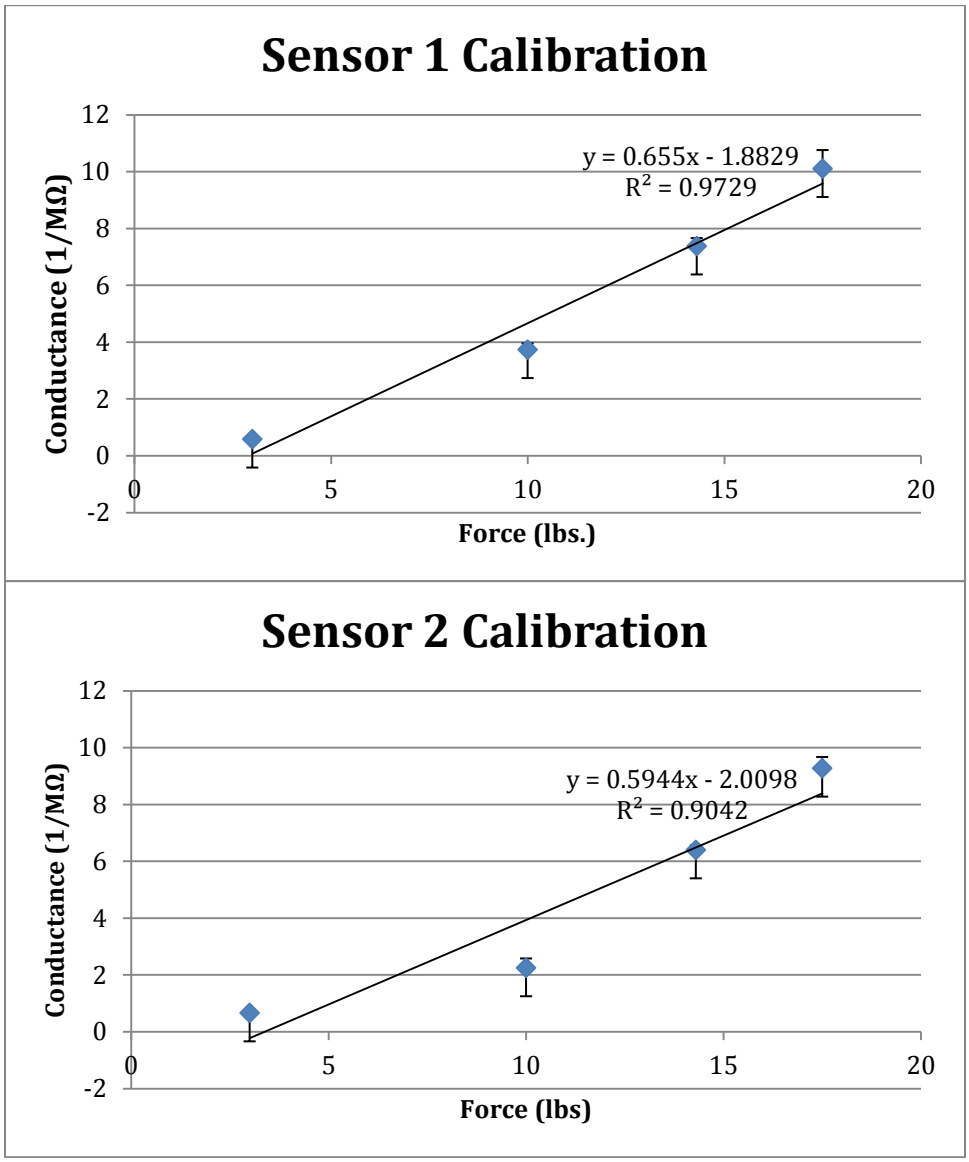
9.3.1 Calibration Measurements and Calculations

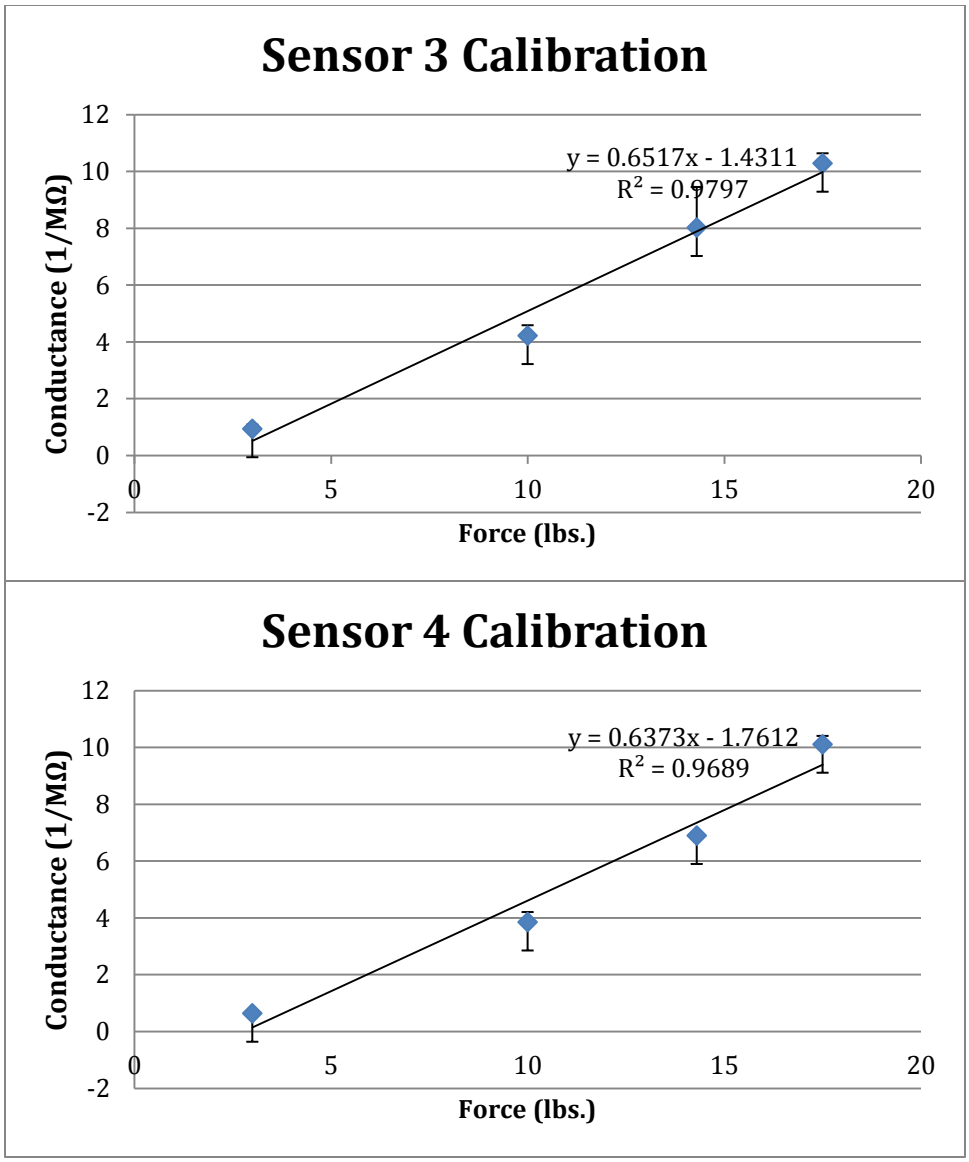
Sensor 1	Resistance MΩ				Sensor 1	Conductance 1/MΩ				Standard Deviation Calculations				
Pounds	Set 1	Set 2	Set 3	Average	Pounds	Set 1	Set 2	Set 3	Average	(Set 1 - Ave)^2	(Set 2 - Ave)^2	(Set 3 - Ave)^2	Averages	SD
3	1.71	1.61	1.81	1.71	3	0.584	0.621	0.552	0.586	1.78E-06	0.001223	0.00113	0.000786	0.028035
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	9.900 99	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	0.7751	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	3.8002	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	10.2000	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	0.5404	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	3.4484	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

9.3.2 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 = 0.9797
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 = 0.9689

9.4 Testing of Cast Pressure

9.4.1 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	0.2 92	0.335	0.331	0.3196 98	1	0.248	0.234	0.240	0.241
2	0.033	0.041	0.034	0.036	2	0.4 69	0.529	0.409	0.4694 73	2	2.654	3.070	2.695	2.806
3	0.318	0.486	0.458	0.420	3	0.8 26	1.036	0.909	0.9239 36	3	2.088	1.960	1.122	1.723
4	0.299	0.310	0.331	0.313	4	0.0 98	0.114	0.137	0.1166 82	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	0.3 77	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	0.6 57	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	0.1 03	0.08	0.071	0.085	4	3.205	1.148	0.621	1.658

9.4.2 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	(Lisle - Ave)^2	(Sean - Ave)^2	(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	(Lisle - Ave)^2	(Sean - Ave)^2	(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	(Lisle - Ave) ^{2}	(Sean - Ave) ^{2}	(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

9.4.3 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: $Force(lbs) = \frac{Conductance+2.0098}{0.5944}$
  - 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 $r = {Diameter}/{2} = 0.5\ in.$
  - $A = \pi r^2 = \pi(0.5\text{ in.})^2 = 0.7854\text{ in.}^2$
  - $Pressure\ (psi) = \frac{Force\ (lbs.)}{Area\ (in.^2)}$

9.4.4 Average Pressure at Each Point

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

Sensor	Pressure (psi)	SI Pressure (kPa)
1	3.48	24.01
2	3.59	24.77
3	3.30	22.75
4	2.56	17.82

9.5 PDS

Project Design Specifications- May 7, 2013
"Super Splint"

Team Members
Kate Howell – Team Leader
Molly Krohn - Communicator
Sean Heyrman - BSAC
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 most not irritate skin or cause pressure sores.
- Pressure lining must be dynamic and controllable.

Design Requirements

1. **Physical and Operational Characteristics**

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.

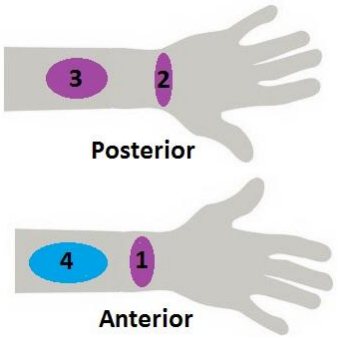


Figure 1: The areas where the splint must apply appropriate pressure depicted for left arm.

Area	Pressure (psi)	SI Pressure (kPa)
1	3.48	24.01
2	3.59	24.77
3	3.30	22.75
4	2.56	17.82

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

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.