Dynamic Splint For Pediatric Distal Radius Fractures

Spring 2013 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 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

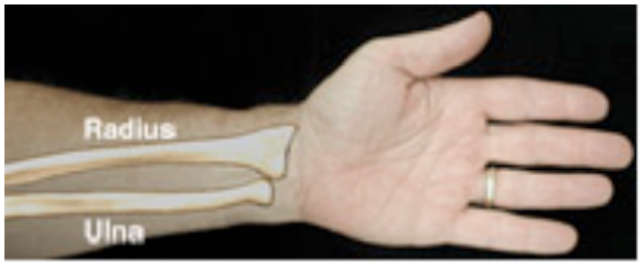

Figure 1: Bones of the forearm include the ulna (outer bone) and radius (inner bone). [2]

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

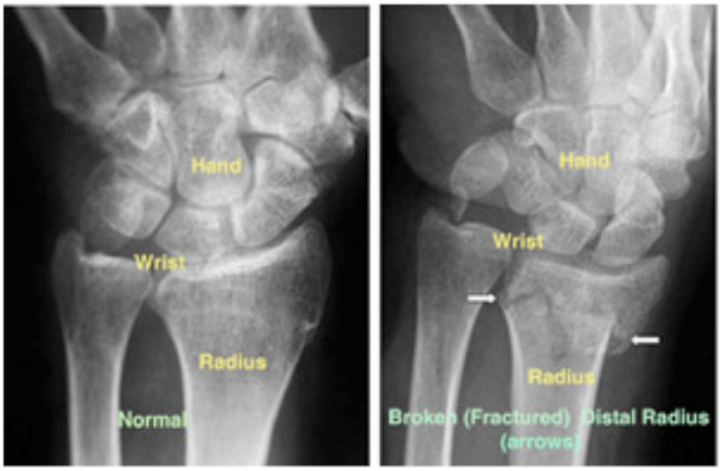

Figure 2: X-ray image of a normal wrist (left) and fractured wrist. [2]

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,

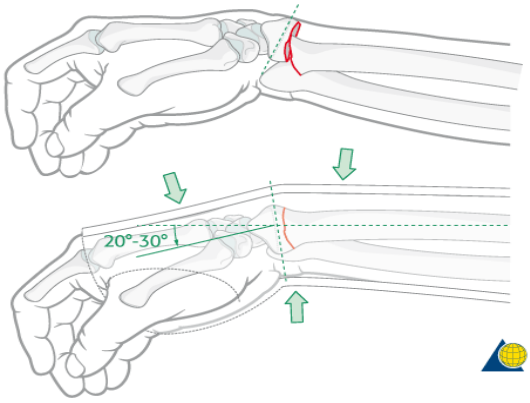

Figure 4: The top diagram shows the fracture and the bottom displays the reduced fracture and where the 3 loads need to be applied to keep reduction. [8]

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 32.

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 5. 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

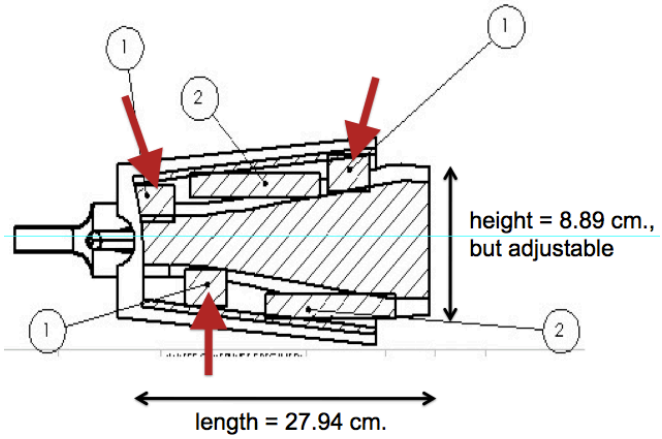

Figure 5: Side view of the final design made in SolidWorks. 1 indicates the inflatable pads, while a 2 indicates noninflatable pads. The red arrows indicate points of the three-point pressure positions created by the smaller inflatable pads.

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.

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 6 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

Figure 6: This is a photo of the A401-25 FlexiForce® Sensor. [9]

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.

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 6 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.

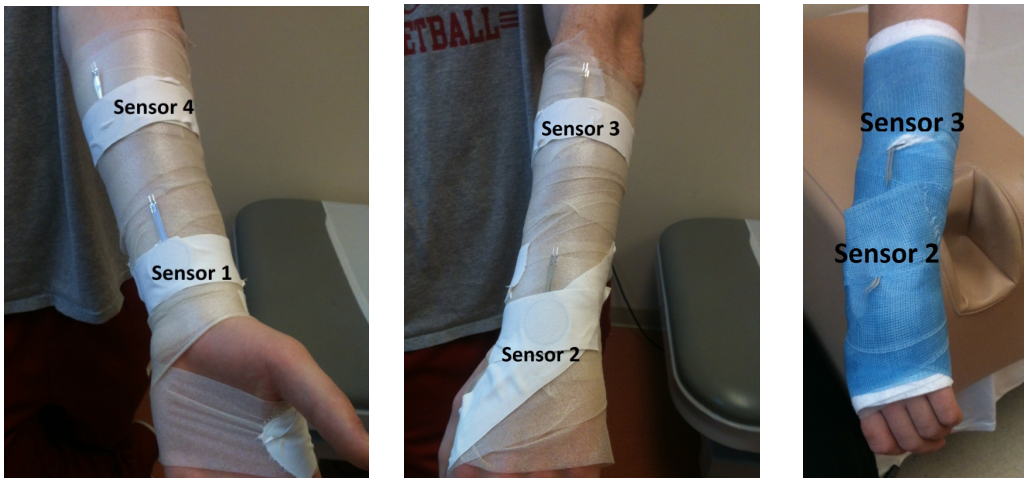

Figure 6: These images show the locations of the sensors as label in the pictures. The far left shows the anterior view of the left arm and the middle picture displays the anterior view of the left arm. The casted arm can be seen

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

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 7 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 7. 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.

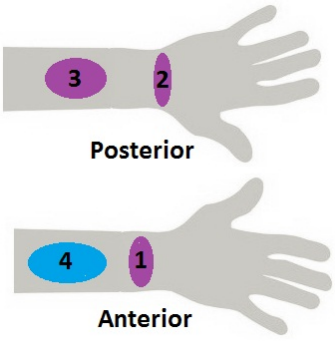

Figure 7: The areas where the splint must apply appropriate pressure depicted for left arm.

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.

6. Goals for this Semester

This semester, airbladders of the correct size and pressure must be obtained for construction of the final prototype. The airbladders may be purchased or constructed by the design team. Furthermore, more pressure testing will be performed by collecting more values of the pressures applied during testing and testing the final prototype. The timeline of this semester can be seen in Appendix 11.6.

6.1 Construct or Purchase Dynamic Airbladders

The challenge of last semester and continuing into this semester is obtaining airbladders with the correct air pressure and size for the final design. Currently, two different options are considered for obtaining the airbladders. The options include purchasing the custom airbladders from American National Manufacturing, Inc., a company

that specializes in RF Welding and contract sewing, or constructing the airbladders with materials found at the store and experimenting with the materials. As of now, both options are considered with equal time and consideration.

6.1.1 Custom Airbladders Constructed by American National Manufacturing Inc.

By purchasing the custom airbladders, it will ensure proper sealing of the airbladders so the bladders will be airtight. Although several companies have been contacted regarding this contract work, American National Manufacturing Inc. stated that it is possible to make the airbladders with the padding with a few adjustments to the design. First, the valve will be on the outside of the airbladder as shown in Figure 8. The valve utilized will be a fill-check valve.

Figure 8: The fill check valve to utilize in the custom air bladders from American National Manufacturing, Inc. [10].

Also, the airbladders will have I-beams on the inside of the airbladder to maintain its shape when pumped to the correct pressure. Otherwise, the bladder will blow up like a balloon. Currently, drawings in SolidWorks of the airbladder with the I-beams and correct positioning of the pads are in the process. After the drawings are finished, the company will be contacted again for a more price and time frame to obtain the customized pads.

6.1.2 Construction of airbladders

Due to time constraints and the possibility that the airbladders will not be constructed due to reasons unknown as of now, the design team is following the parallel path of constructing airbladders from materials found at the local store. Presently, experiments to analyze the behavior of the various plastics of different sports balls were executed. By utilizing a heat gun (UNGAR 1095 Dual Temperature Heat Gun) that reaches 1200°F, the plastic, as shown in Figure 9 formed the square edges by applying the heat while the plastic was placed over a box with square edges. Further testing will be performed on sealing the airbladders. The main issue with this technique is ensuring the seal is airtight.

Figure 9**:** Before using the heat gun (left) and application of heat with the heat gun as the plastic forms to the shape of the box.

6.2 Collect More Data for the Pressures Applied During Testing

More data points of the pressures obtained during casting will be collected with the aid of one of Dr. Halanski's fellows. The same procedure will be utilized as described in Section 5.1 Casting Pressures on page 8**.** By collecting more data points, it will show the

variability of casting between doctors by analyzing the range of pressures. If time permits, more doctors will perform the experiment and more data points of the pressures will be obtained.

6.3 Perform Testing on the Final Prototype

The client, Dr. Halanski, stated two different methods to test the prototype. First, to verify the prototype maintains the pressure, teammates will wear the splint for two weeks and will check the pressure frequently throughout the time frame. The protocol for the testing is will be written in the near future after more discussion with the client. Secondly, to check how it heals a fracture, the team will collaborate with the design team creating an Upper Extremity Fracture Model that assesses fracture model reduction. This testing depends on the progress of the other design team, but it will allow for analysis on the healing of the fracture with the dynamic splint.

7. Additional Design Improvements

In addition, to the modifications of the air bladders from last semester, the thickness will be reduced from 2 cm. to 1 cm. Furthermore, a custom airbladder pump will be created that allows for easy pumping and visual display of the pressure. This allows for easy-use by the user.

8. Budget

The overall cost for the project last semester was $508.13 as shown in Table 3. This includes the sensors that were used during our testing, pads for the prototype, and even a StabilAir Splint, another air based protective splint. The four pad sets were free due to errors made by the company from which the pads were purchased. These errors included late arrival and the shipping of the wrong pads originally. For our final prototype, we need

to fabricate pads. If the pads are custom made through a manufacturer, the believed price range for our prototype is $174.98 to $424.98, as seen in Table 4. These price estimates were from previous purchases and quotes from manufacturers. If we were to create the pads ourselves, the price of the prototype would be $44.98, as seen in Table 5.

Item	**Cost**
Force Sensors	$113.00
Pads Long	$81.90
Pad 1	$64.37
Pad 2	$39.37
Pad 3	$12.53
4 Pad sets	$0.00
Aircast	$171.98
Sleeve	$24.98
Total	**$508.13**

Table 3: Costs spent last semester.

Item	**Cost**
Hard Splint Cover	$0.00
Sleeve	$24.98
Custom Pads	$150 to $400
Total	**$174.98 to $424.98**

Table 4: Projection of a custom manufactured prototype

Item	**Cost**
Hard Splint Cover	$0.00
Sleeve	$24.98
Plastic Materials	$5.00
Adhesives	$15.00
Total	**$44.98**

Table 5: Projection of creating the pads ourselves.

9. Final Prototype and Deliveries for Use

At the end of the semester in addition to the final prototype, several documents will be prepared to utilize with the prototype. A manual will be created for descriptions on proper use. Furthermore, design schematics for a pediatric splint will be drawn to scale with the current prototype.

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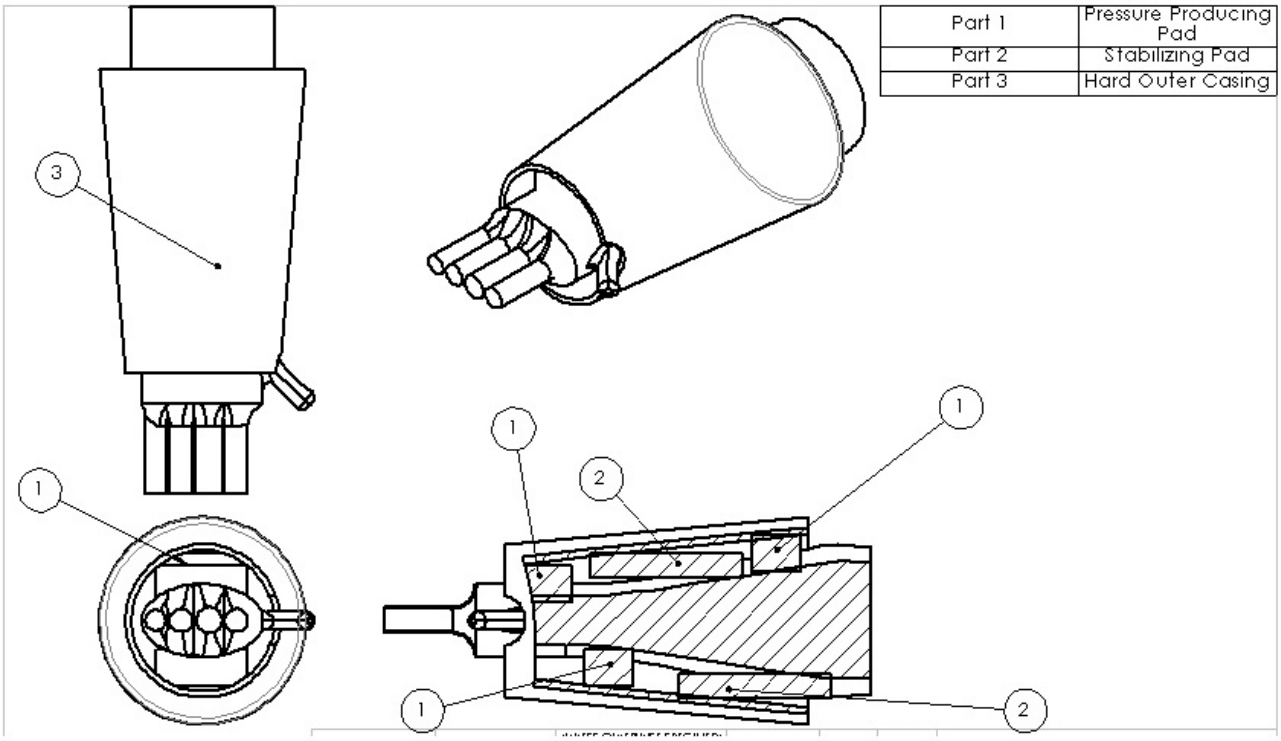
11. Appendix

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 [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

11.3 Sensor Calibration

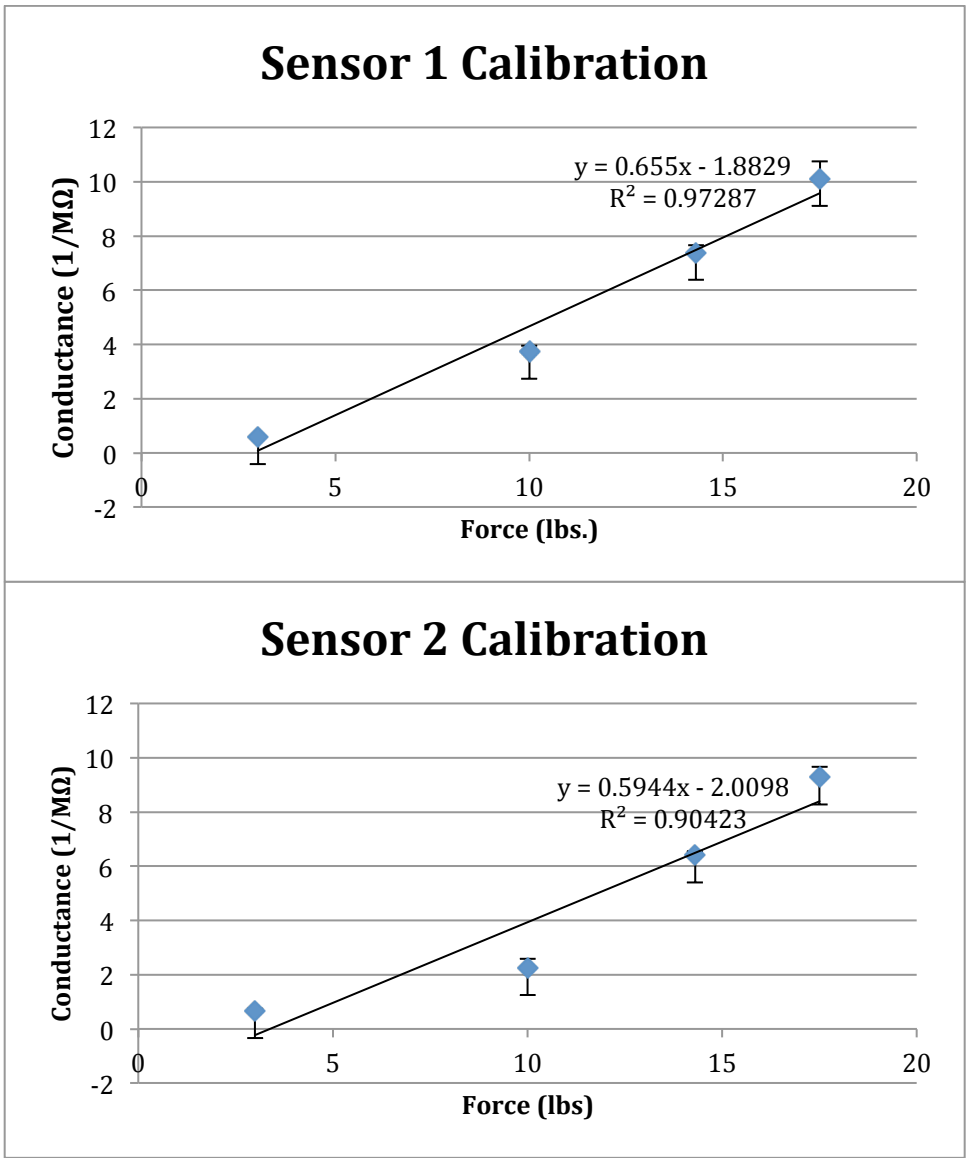
11.3.1 Calibration Measurements and Calculations

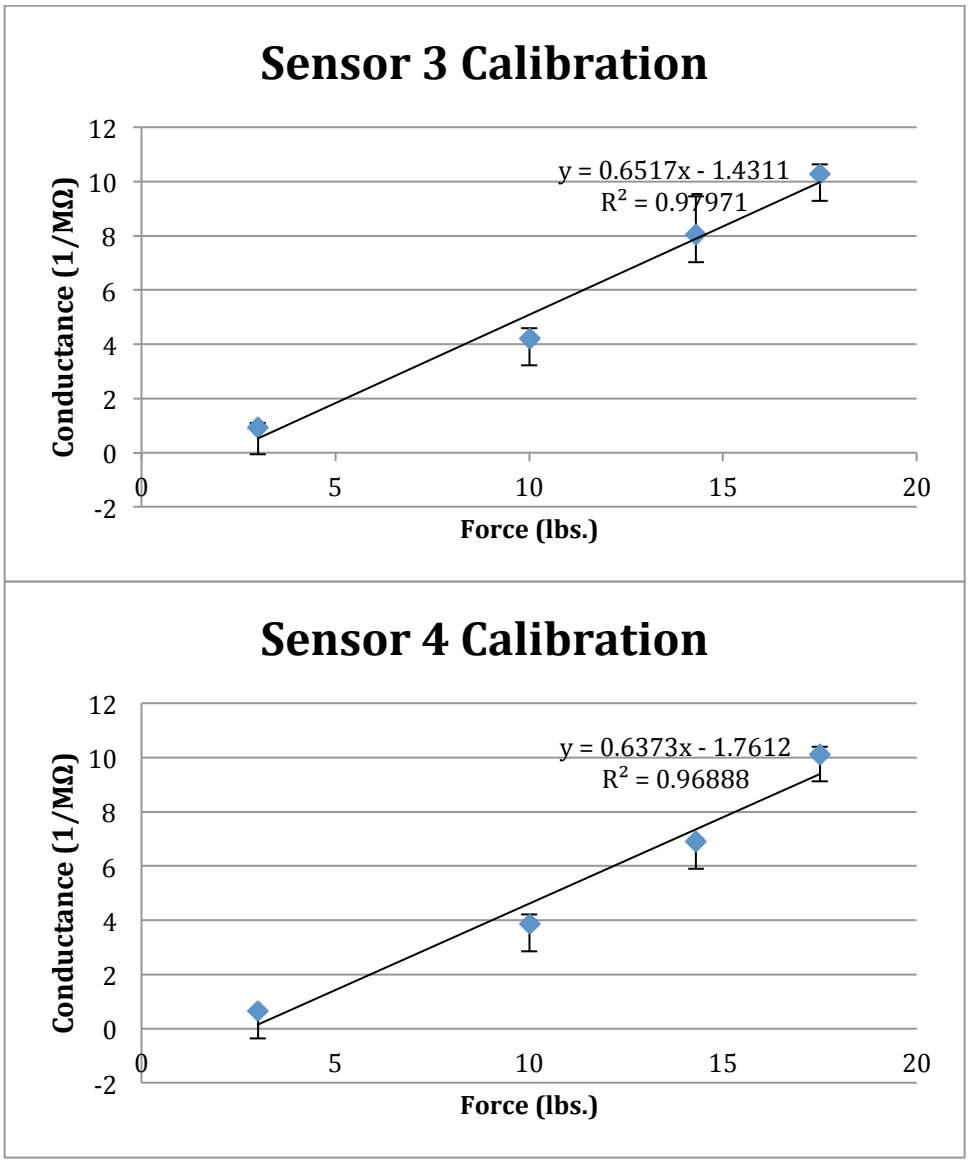
Sensor 1	Resistance MΩ				Sensor 1	Conductance 1/MΩ				Standard Deviation Calculations				
Pounds	Set 1	Set 2	Set 3	Average	Pounds	Set 1	Set 2	Set 3	Average	(Set 1 - Ave)^2	(Set 2 - Ave)^2	(Set 3 - Ave)^2	Averages	SD
3	1.71	1.61	1.81	1.71	3	0.584	0.621	0.552	0.586	1.78E-06	0.001223	0.00113	0.000786	0.028035
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	10.98 901	9.433962	10.10 799	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	0.540	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
y = 0.6517x - 1.4311
R² = 0.97971
Conductance (1/MΩ)
Force (lbs.)
12
10
8
6
4
2
0
-2
0
5
10
15
20
Sensor 4 Calibration
y = 0.6373x - 1.7612
R² = 0.96888
Conductance (1/MΩ)
Force (lbs.)

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	0.2 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	0.377	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	(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

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 PDS

Project Design Specifications- March 6, 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.

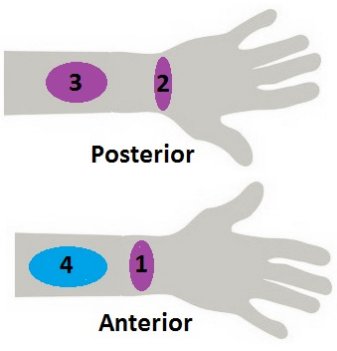
Client Requirements

- 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.

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

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.

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

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

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.

11.6 Timeline