MEDICAL BOOT WITH INTEGRATED BONE STIMULATOR

A thesis submitted to the
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by

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ABSTRACT

Bone growth stimulation is the process of using a pulsed electromagnetic field to increase the intracellular calcium in a bone to strengthen and heal nonunion fractures. This process has an array of different application techniques. These techniques present many problems during the process. In some applications the stimulator can become disconnected, waking the patient if they are asleep. The stimulators are bulky and some immobilize the patient. Medical boots are also used while a patient has a stress fracture. These boots are used to stabilize the foot and prevents any stress from being applied to the metatarsals. These boots do not present any problems and will be used as only a part of this project.

This project combines medical boot technology with bone growth stimulation technology to create a product that is not yet on the market. This project included designing different concepts for the coil, then determining which concept was the best by using a weighted design matrix. Once a concept was chosen, the next steps included creating a fixture to create the coil, creating the coil, soldering the coil to a commercially available controller and finally covering the coil with material to secure it. Once the coil was created it was the attached to the boot with the controller.

This project was designed to target customer needs and expectations. This was accomplished by making the bone stimulation device more portable and more convenient for patients to use. Instead of immobilizing the patient during the stimulation process, this project will allow patients to use the stimulator while walking around in their medical boot.

ACKNOWLEDGEMENTS

First off, I would like to thank my wife Amanda Drakeford for her continued support throughout this process, as well as, Dr. John C. Tepper for answering all of my questions throughout this process. I would also like to thank Professor Amir Salehpour and all others who helped and supported me through this process.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

INTRODUCTION

BACKGROUND

In order to speed up the healing process in bone fractures, bone growth technology has been widely used by orthopedics and prescribed by doctors. Some bone growth technology utilizes the principles of Wolff's law which states, "Biologic systems such as hard and soft tissues become distorted in direct correlation to the amount of stress imposed upon them;" applying this principle allows for effective use of electrical pulses to stimulate bone growth (1). In a study published in August of 2010, two-thousand, three hundred and seventy-nine soccer players were studied and monitored to see the occurrence of stress fractures; four percent of these athletes were diagnosed with stress fractures (2). Pulsed electromagnetic fields (PEMF) utilize this principle in the application of bone growth stimulation. A pulsed electromagnetic field induces stress at a fracture thus mimicking Wolff's law and stimulating bone growth. This process can be used on non-unions fractures which are broken bones that fail to heal. Another type of bone stimulation technology is the use of ultrasound. Ultrasound bone technology utilizes low intensity ultrasound pulses to stimulate bone growth (3).

In addition to bone stimulation individuals who suffer with stress fractures in their feet are required to wear a medical boot. These medical boots are designed to alleviate the stress from the problematic area which is typically the foot. By stabilizing the foot and leg allowing the heel to absorb the stress this allows for minimal stress to be applied to the foot. Below in figure 1 is an example of a boot for a better understanding of what it looks like.

Figure 1 - Example of Medical Boot

Current bone stimulation technology may cause patients to be immobilized during the stimulation process. This may cause some inconvenience for patients if they have to maintain one position during the stimulation process. When the patient completes the stimulation process while asleep, the stimulator can fall off, disconnect or wake the individual from sleep because of being uncomfortable.

The focus of this design project is to re-design the medical boot with an integrated bone stimulator. Thus combining the two previous technologies, it provides patients with a single product that will eliminate the need to have two separate products during the fracture healing process. The integration of these two products will enhance the healing process because of the physiologic loads applied to foot while walking in a boot (4). This project will allow the patient the mobility current bone growth technology does not allow as well as the comfort and support current boot technology offers.

EXISTING BONE STIMULATION PRODUCTS

Since there are no existing products similar to this design project this section will focus on the two separate products in which this design project will combine, which are bone stimulation technology and a medical walking boot. Figure 2 below is an example of a combined magnetic field bone stimulator. This technology (combined) uses two external coiled-copper transducers to create two parallel low-energy magnetic fields (5).

Figure 2 - Combined Magnetic Field Stimulator

These stimulators are used for thirty minutes a day and it is recommended that patients be immobilized during the stimulation (6). As noticed in Figure 2 the stimulator is bulky and not portable which may cause problems for some users.

Figure 3 is a pulsed electromagnetic field bone stimulator. This stimulator does allow for better mobility because of it being light-weight and small, but with longer application duration this product is not as portable as patients would like (7).

Figure 3 - PEMF Bone Stimulator

Figure 4 is another example of a pulsed electromagnetic field bone stimulator (8). As seen in the figure below the stimulator is small, portable and light weight, but, if the patient uses this stimulator on a foot it would limit the amount of walking the patient could do.

Figure 4 - PEMF Bone Stimulator

Figure 5 is an example of a bone stimulator which utilizes ultra sound technology.

Figure 5 - Ultra Sound Stimulator

This technology requires twenty minutes of use and it applied directly to the fracture site (9). Like other products previously mentioned this product also presents problems which may restrict the movement of patients.

EXISTING BOOT PRODUCTS

Current boot designs are relatively similar throughout the market in design but none integrate bone stimulation technology. In Figure 6 below, is the Donjoy MaxTrax ROM Walker. This boot provides enhanced stability with a wider base as well added comfort with padding under the foot (10).

Figure 6 - Donjoy MaxTrax ROM Walker

Figure 7 is an example of the Bledsoe Hi-Top Boot. This boot is designed as a flexible and attractive alternative to casting for the mid-tibia or fibula to mid-foot area and also for second and third degree ankle sprains (11).

Figure 7 - Bledsoe Hi-Top Boot

Current bone stimulation technology is quite useful but lacks the portability this design project will present. Along with bone stimulation technology patients suffering from fractures are advised to use a medical boot. These boots are similar in design throughout the market and use, but none integrate bone stimulation technology resembling the proposed design in this project. (See appendix A for more information).

CUSTOMER FEEDBACK, FEATURES, AND OBJECTIVES

SURVEY ANALYSIS

Thirteen surveys were returned and analyzed to determine the customer needs. The surveys were completed by athletes who are more prone to being diagnosed with stress fractures (12) (See **Appendix B** for full survey and customer results). The survey included product features. The first half of the survey focused on customer importance as they were asked to rate the importance of features on a scale from 1-5 with 5 being the most important. The results in the table have been sorted from most important to least important.

	Avg Customer Importance:
Comfort	5.0
Safety	4.8
Ease of use	4.4
Portability	4.2
Ease of adjustment	4.2
Resistance to weather	4.1
Length of use	4.0
Appearance	2.2

Table 1 – Average Customer Importance

Based upon the results from the survey, customers deemed comfort, safety and ease of use as the three most important factors. From this, a multiplier was added signifying the factors which the designer deemed important. Figure 2 below shows the multipliers that the designer chose.

	Designer's Multiplier
Portability	1.2
Safety	1.1
Resistance to weather	1.1
Ease of use	1.0
Length of use	1.0
Appearance	1.0
Ease of adjustment	1.0
Comfort	1.0

Table 2 – Designer Multiplier

The designer chose to increase the importance of portability by twenty percent because current boot and bone stimulation technology does not offer the portability that this design will offer hence the twenty percent increase. The designer also chose to increase the importance of safety and resistance to weather by ten percent because with the integration of the bone stimulator this design will have to be safer and better equipped to handle all weather conditions.

The second part of the survey asked customers about current satisfaction of the two products on a scale from 1-5 with 5 being the most important. Table 3 below provides the information provided by the customers.

	Current Satisfaction
Ease of adjustment	3.8
Ease of use	3.8
Length of use	3.6
Appearance	3.6
Safety	3.6
Portability	3.6
Resistance to weather	3.0
Comfort	2.8

Table 3 – Current Satisfaction

Based upon the current satisfaction results provided by the survey the designer generated a planned satisfaction for the features. This is stating that if the designer was to give this design and another survey to the customers, the customers will be more satisfied with the new design. Table 4 below provides the designers planned satisfaction.

	Planned Satisfaction
Portability	4.0
Ease of use	3.9
Ease of adjustment	3.9
Length of use	3.6
Appearance	3.6
Safety	3.6
Resistance to weather	3.2
Comfort	3.0

Table 4 – Planned Satisfaction

As noticed in table 4 the designer plans to improve every feature most importantly portability. With a current satisfaction rating of 3.6 the designer plans to improve portability to a 4.0 rating.

From these results the designer was able to determine the relative weight for each feature providing the most important features. Table 5 below provides the results.

	Relative Weight:
Portability	16%
Comfort	15%
Safety	15%
Resistance to weather	13%
Ease of use	13%
Ease of adjustment	12%
Length of use	11%
Appearance	6%

Table 5 – Relative Weight

Based upon the analyzing of the survey results the, designer was able to determine that portability, comfort and safety are the three most important features. (See Appendix C for full results)

PRODUCT FEATURES AND OBJECTIVES

The product objectives come from the list of customer features determined from the survey. These customer features were cross-referenced with engineering characteristics and rated for a strong to weak relationship. The list below ranks the features in order of customer importance followed in parentheses by the percent of importance. These product features and objectives are:

1. **Portability** (16%)
    a) Detachable carrying straps.
    b) Will not be 15% heavier than the average weight of current products.
2. **Safety** (15%)
    a) The boot with integrated stimulation technology will operate in a safe electrical and medical manner.
    b) Individual will not notice bone stimulator wiring.
3. **Comfort** (15%)
    a) Additional bulk from bone stimulator will not be noticed.
    b) Same comfort level as current boot technology.
4. **Resistant to weather** (13%)
    a) Stimulator and components will be protected from water.
    b) The boot itself will be designed to the same requirement as boots in current market.
5. **Ease of use** (12%)
    a) Detachable power supply for charging the bone stimulator.
    b) Not more difficult than putting a regular boot on.
6. **Adjustment** (12%)
    a) Small force will be required to strap in leg.
7. **Length of use** (11%)
    a) Similar to current bone stimulation technology.
    b) Similar to current boot technology.
8. **Appearance** (6%)
    a) Will appear rigid with proper supports similar to current boot technology.
    b) No loosely hanging parts.

PRODUCT DESIGN AND DEVELOPMENT

During the brainstorming phase four concepts were mentioned and discussed. The first concept discussed involved a plastic housing with a flexible coil inside the housing. This can be seen below in figure 8.

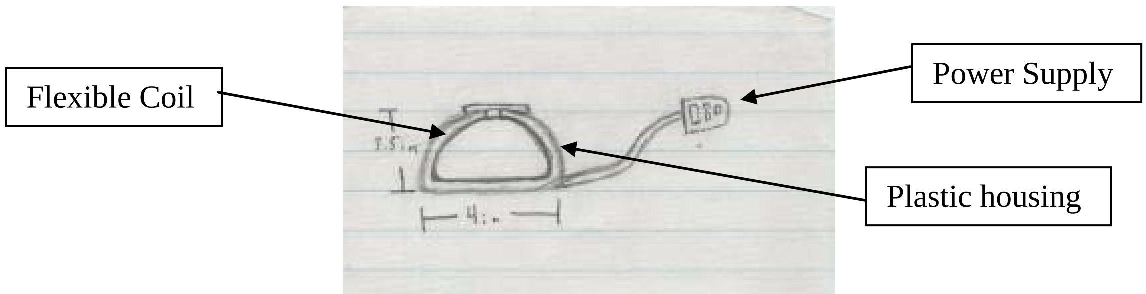

Figure 8 - Plastic Housing

The plastic housing will be lined with a soft cloth material similar to current material used to protect pulsed electromagnetic field coils. This will provide the patient with added comfort. The plastic housing will also act as a clamp to tightly secure the housing to the foot then placed inside the boot. The dimensions seen in the figure are fitted for a shoe size of eleven and a foot that has a max width of four inches. With these dimensions it will allow for a clearance of three-sixteenths of an inch so that it is a secure fit to the foot but not too constricted. The power supply would then attached to the boot and securely fastened to the front of the boot. This concept also presents problems with comfort. The housing section that will be under the foot will interfere with the patient’s ability to walk comfortably.

The second concept discussed was the flexible double coil. This concept can be viewed in figure 9 below.

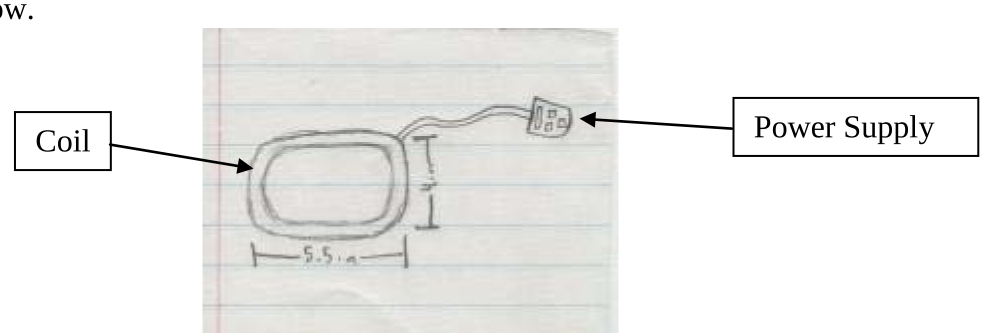

Figure 9 - Flexible Double Coil

This concept utilizes two coils, one for the top of the foot and another for the bottom of the foot. One coil will cover the entire foot starting from the ankle and ending at the start of the toes. The bottom coil will cover the same area as the coil on the top. The coils will then be covered by a soft cloth material similar to current material used to cover bone growth stimulators to provide comfort and protection. The coils will be connected by an elastic material with an embedded copper wire. This concept presents many problems one being that the two separate coils add weight. This concept also will have a higher material cost and some discomfort with one coil being placed under the foot. Also, the added complexity of the connection for the two coils may cause connection problems if the wires somehow become detached from the coils.

The third concept discussed was a single flexible coil. This concept can be seen below in figure 10.

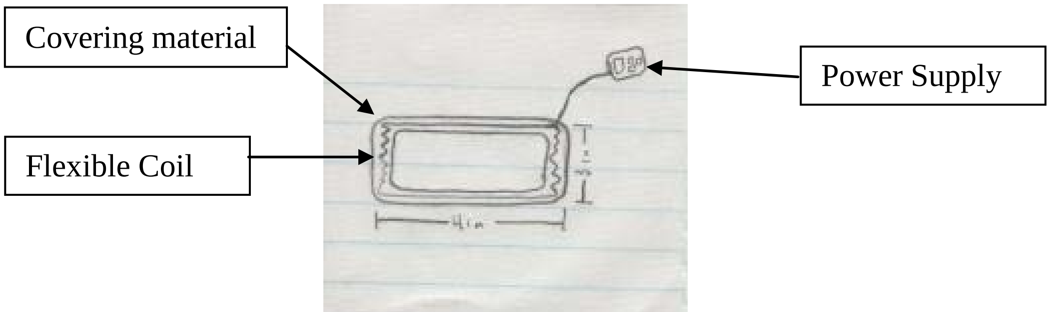

Figure 10 - Single Flexible Coil

This concept utilizes one coil in which is flexible and will be placed around the foot. As seen in the figure the sides of the coil are constructed in way similar to a spring to allow for the coil to fit any part of the foot. The entire concept will be four inches long and three inches in width. These dimensions are based upon a size eleven foot with a width of three and thirteen-sixteenths of an inch. The coil will be covered by a soft, stretchy material to provide comfort and protection. The power supply will be attached to the front of the boot allowing for the weight of the power supply to be distributed on a wider base. This concept provides many advantages because it will be flexible and lightweight. The disadvantages of this concept include the sides of the coil. With the coil wound like a spring on the sides it could lead to the wire breaking rendering the coil ineffective.

The last concept discussed was the coil strip. Figure 11 below provides a visual as to what this concept will look like.

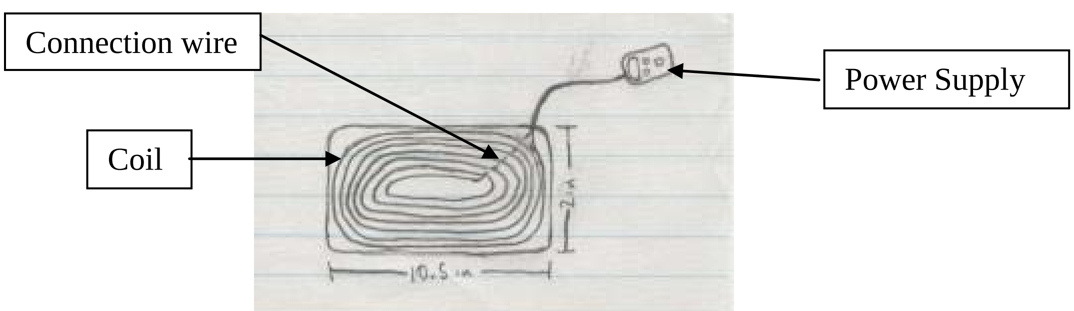

Figure 11 - Coil Strip

This concept utilizes a coil that is placed between two strips of material similar to material used currently to protect bone growth stimulators. The strips will measure ten and half inches long by two inches wide so that the strip can be placed around the foot. The material will provide the patient with comfort and will also allow a strip of Velcro to be used to secure the strip to the boot. Also, there will be a flexible plastic sheet underneath the coil so when the patient goes to wrap the strip around his or her foot the coil will be supported. The connection wire seen in figure 11 is the wire that will connect the end of the coil to the power supply. The power supply will then be placed and secured on the front of the boot.

A weighted design matrix was used to determine which concept was the best option. A five point scoring scale as seen below in Table 8. The scoring scale ranges from zero to four, zero being inadequate and four being excellent.

5-Point Scale	Description
0	Inadequate
1	Weak
2	Satisfactory
3	Good
4	Excellent

Table 6 - Scoring Scale

The design factors used have similar features as the features listed in the Quality Function Deployment chart seen in Appendix C. The relative weights from each feature were readjusted to sum up to one. Once the relative weights were finalized each feature for each concept was scored. The final table can be viewed below in Table 9.

	Weight		Plastic Housing			Flexible Doubled Coil			Flexible Single Coil			Coil Strip		
Design Criterion	Factor	Units	Magnitude	Score	Rating	Magnitude	Score	Rating	Magnitude	Score	Rating	Magnitude	Score	Rating
Portability	0.16		Satisfactory	2	0.32	Satisfactory	2	0.32	Good	3	0.48	Excellent	4	0.64
Ease of use	0.13		Good	3	0.39	Good	3	0.39	Good	3	0.39	Good	3	0.39
Appearance	0.11		Satisfactory	2	0.22	Satisfactory	2	0.22	Satisfactory	2	0.22	Good	3	0.33
Safety	0.15		Excellent	4	0.60	Good	3	0.45	Good	3	0.45	Good	3	0.45
Ease of adjustment	0.13		Satisfactory	2	0.26	Satisfactory	2	0.26	Good	3	0.39	Good	3	0.39
Resistance to weather	0.13		Excellent	4	0.52	Good	3	0.39	Good	3	0.39	Satisfctory	2	0.26
Comfort	0.19		Weak	1	0.19	Satisfactory	2	0.38	Good	3	0.57	Excellent	4	0.76
Totals	1				**2.50**			**2.41**			**2.89**			**3.22**

Table 7 - Concept Weighted Design Matrix

As seen in the table concept four or the Coil Strip is the best concept. The coil strip concept provides the best option for the most important factors, portability and comfort scoring excellent in those two categories.

FINAL DESIGN

The final design consists of the flexible coil, a flexible plastic strip and two pieces of material to protect the coil and flexible plastic strip. Below in figure 12 provides a side view of the final design.

Figure 12 – Side View Final Design

An exploded view of the final design can be seen below in figure 13.

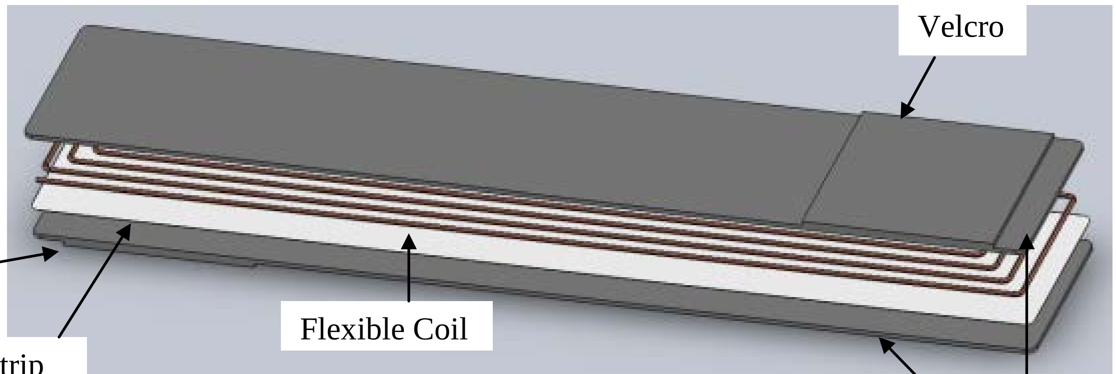

Figure 13 – Exploded View of Final Design

In Figure 13 the entire layout is labeled to provide a better understanding of what the final design will look like. The procedure for using this design will require the patient to wrap the design around the target area of the fracture then Velcro the two sides together.

ASSEMBLY AND DETAIL DRAWINGS

The drawings will provide the complete assembly with measurements for each part. The assembly and detail drawings list are located in the Appendix G.

BILL OF MATERIALS

The Bill of Materials as listed in Table 8 identifies all necessary parts and quantities required to build a new electromagnetic coil along with the protective covering for the coil, needed materials, and bone stimulation device. This Bill of Materials includes cost estimates for individual parts and the total cost of the assembly.

Item	Description	QTY	Cost Per	Cost
1	Fabric-Tac	1	$ 6.99	$ 6.99
2	Soldering Kit	1	$ 10.99	$ 10.99
3	Magnet Wire	3	$ 9.99	$ 29.97
4	Neoprene Material	1	$ 10.99	$ 10.99
5	Template Plastic	1	$ 3.49	$ 3.49
6	Pair 2 CKT Molex	2	$ 4.19	$ 8.38
7	PK10 22-18 Gage	1	$ 2.19	$ 2.19
8	Vinyl Tape	1	$ 2.49	$ 2.49
9	Orthofix Stimulator	2	$ 59.99	$ 119.98
11	Super Glue	5	$ 1.99	$ 9.95
12	Doubled Sided Tape	1	$ 4.99	$ 4.99
			Total Cost	**$ 210.41**

Table 8 - Bill of Materials

FABRICATION AND ASSEMBLY

ELECTROMAGNETIC COIL

The electromagnetic coil was designed using a fixture made of a sheet of steel. This sheet of steel was cut to eleven inches then four bolt holes were drilled into the steel sheet, and then bolts were place in the four corners to create a fixture for the coil. Once the fixture was completed, magnet wire was tightly wrapped around the bolts to create a coil. This can be seen below in Figure 14.

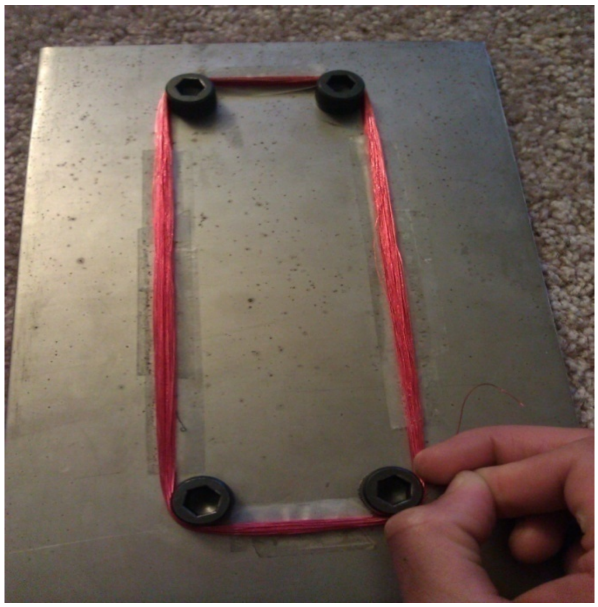

Figure 14 - Fixture and Coil

The completed coil can be viewed below in figure 15. Tape was used to keep the coil tight to help make the electromagnetic field stronger.

Figure 15 - Completed Coil

Next, the coil was wrapped in electrical tape to keep it secure as well as, to keep the coil tightly constructed to help the electromagnetic field. The coil was then placed in Neoprene material to help keep the coil protected and to allow for the patient to wrap the coil around their foot. This neoprene material is a soft, flexible material that will add the comfort needed stated in the product objectives. This can be viewed below in Figure 16. Once on the material, a second piece of material placed on top and Fabric-Tac ® glue was used to secure the coil between the pieces of material.

Figure 16 - Completed Coil on Material

FINAL ASSEMBLY

The final assembly included soldering two wires from the coil to the Orthofix ® controller then attaching the coil and controller to the medical boot. To achieve this, the Orthofix ® controller was taken apart and the two wires from the coil were soldered to the appropriate locations on the controller, so that the correct voltage was supplied to the coil. Once this was completed, Velcro strips were placed on the back side of the controller and on the medical boot so that the controller could be easily attachable and detachable from the boot. Below, in Figure 17 is the finished assembly of the unit.

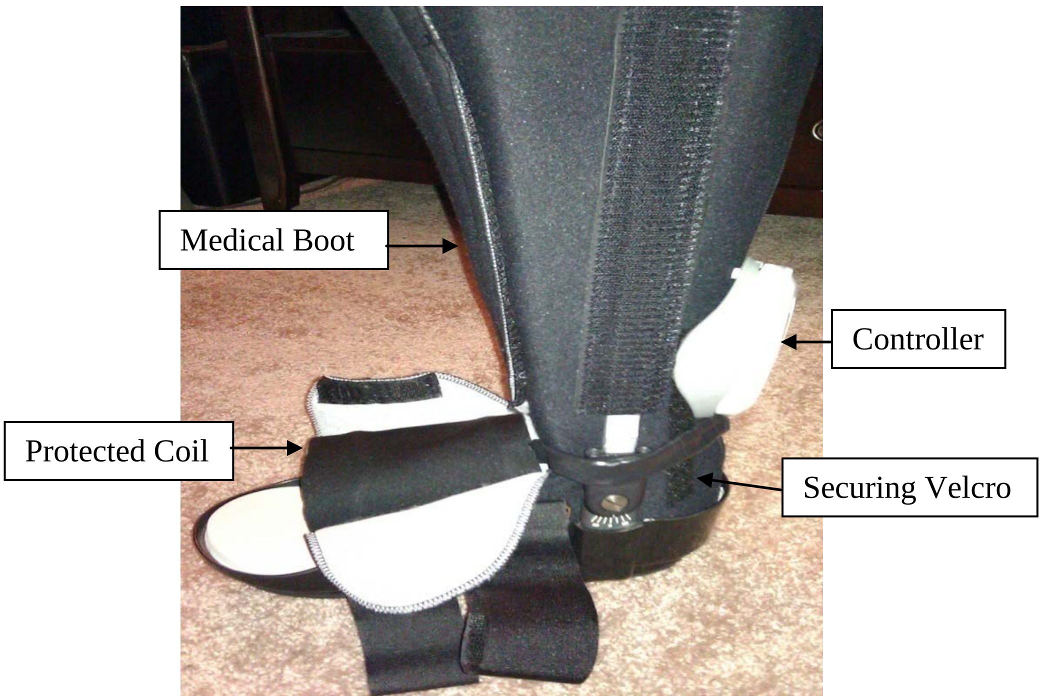

Figure 17 - Completed Unit

TESTING AND PROOF OF DESIGN

TESTING METHODS

The testing method involved using a smaller coil and a scope to measure the electromagnetic field of the coil I designed. To successfully measure the coil, I created a smaller coil and connected it to the scope. This can be viewed below in Figure 18.

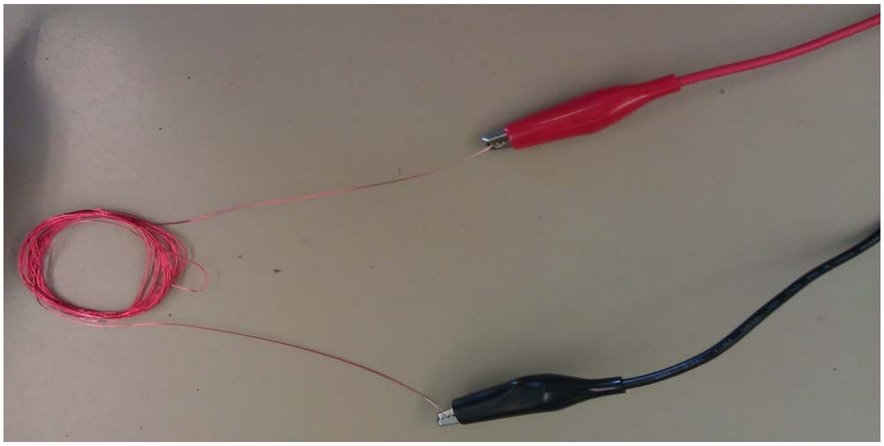

Figure 18 - Testing Setup

TESTING RESULTS

The scope test provided the level of the pulsed electromagnetic field of the created coil, the results of the test can be viewed below in figure 19. An electrical engineering professor was able to determine the values of the positive and negative portion of the pulsed and those were then compared to the theoretical values provided by Dr. John C.Tepper (13).

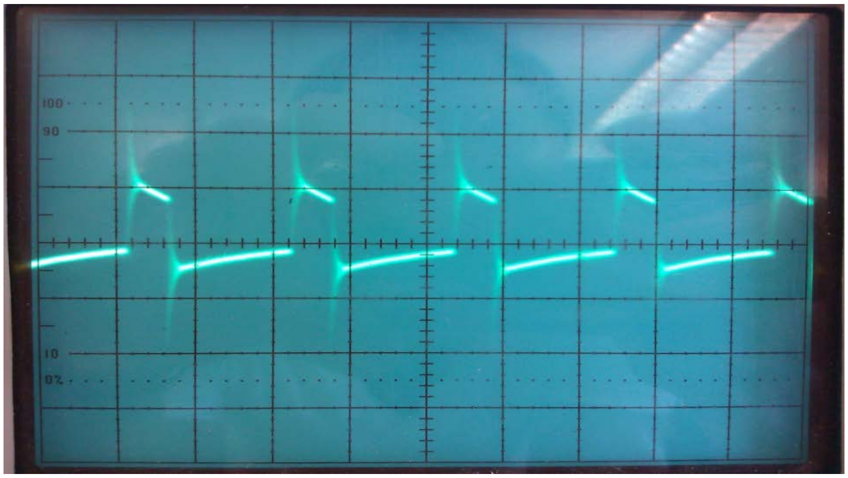

Figure 19 - Testing Results

The comparison of values can be viewed below in Table 11. As seen in the table, the project measured values had a percent error value of twenty-seven percent for the positive portion and twenty-eight percent for the negative portion. The reason for the high values of percent error is because of the increase in size and decrease in the number of turns of the created coil, in comparison to the coil for the theoretical values.

Theoretical values
Positive portion: 22 Tesla/s
Negative portion: 7 Tesla/s
Measured Vales
Positive portion: 16 Tesla/s
Negative portion: 5 Tesla/s
Percent Error:
27% for positive portion
28% for negative portion

Table 9 - Testing Results

PROOF OF DESIGN

When compared to the Proof of Design agreement as listed in the Product Features and Objectives List in Appendix D this design meets most of the criteria in the following way:

Portability
1. Medical boot with bone stimulator attached weighs no more than 15% of the average weight of current medical products.

Safety
1. The device is not harmful in anyway and all components are secure.

Comfort
1. Coil goes unnoticed when wrapped on foot and the comfort of the boot is comparable to current boot technology.

Resistant to weather
1. Unit has protective material around coil.

Ease of use
1. This device has an attachable and detachable power supply.
2. This device requires the same effort as putting on a regular medical boot.

Adjustment
1. Putting on stimulation device requires small amount effort.

Length of use

1. Comparable to current stimulation and medical boot technology.

Appearance

1. Rigid with no loosely hanging parts.

PROJECT MANAGEMENT

SCHEDULE

The project schedule began November 22, 2010 with the completion of the proof of design contract. The project timeline covered 28 weeks ending June 6, 2010 with the presentation of the final report. The dates shown in table 10 are the major interval dates for the project.

Medical boot with integerated bone stimulator																					
MILESTONE DATE				Winter Break			Winter Quarter										Spring Break		Spring Quarter		
Week #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Month		Dec					Jan				Feb				Mar				Apr		
Dates:	11/22 - 11/28	11/29 - 12/05	12/06 - 12/12	12/13 - 12/19	12/20 - 12/26	12/27 - 01/02	01/03 - 01/09	01/10 - 01/16	01/17 - 01/23	01/24 - 01/30	01/31 - 02/06	02/07 - 02/13	02/14 - 02/20	02/21 - 02/27	02/28 - 03/06	03/07 - 03/13	03/14 - 03/20	03/21 - 03/27	03/28 - 04/03	04/04 - 04/10	04/11 - 04/17
Task																					
Proof of Design Contract	28																				
Concept sketches			12																		
Design Product (Solid Works)						2															
Design Freeze							3														
Talks with Deaconess/Biomedical about project													21								
Test/Tuning Product																					18

Table 10 - Schedule

Initially, this project was going to be rapid prototyped and discussions with Deaconess or the biomedical engineering departments were going to happen. After further discussion, the project took a different route and rapid prototyping as well as speaking with Deaconess or the biomedical engineering department was deemed unnecessary. A more accurate schedule can be viewed below in Table 11.

Medical Boot with Integrated Bone Stimulator																									
MILESTONE DATE			Winter Break			Winter Quarter										Spring Break		Spring Quarter							
Week #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Month		December					January				February				March				April				May		
Dates:	11/23 - 11/29	11/30 - 12/06	12/07 - 12/13	12/14 - 12/20	12/21 - 12/27	12/28 - 01/03	01/04 - 01/10	01/11 - 01/17	01/18 - 01/24	01/25 - 01/31	02/01 - 02/07	02/08 - 02/14	02/15 - 02/21	02/22 - 02/28	03/01 - 03/07	03/08 - 03/14	03/15 - 03/21	03/22 - 03/28	03/29 - 04/04	04/05 - 04/11	04/12 - 04/18	04/19 - 04/25	04/26 - 05/02	05/03 - 05/10	05/11 - 05/17
Task																									
Proof of Design Contract	28																								
Concept sketches			12																						
Solid Work Drawings						2																			
Design Freeze							3																		
Commercial Parts Purchase													21												
Design Fixture															7										
Assembly Unit																						25			
Testing																									17

Table 11 - Actual Schedule

BUDGET

The budget consists of two parts. The first part is the estimated cost of the entire project to completion, including purchased parts. This initial estimated budget will then be compared to the actual cost after completion of the project when all purchased parts and services are recorded. The complete budget can also be seen in Appendix E.

Cost ($)		Part/Process
$1,500.00		Rapid Prototyping (Anza Product Development Specialists Quote)
$3,500.00		Stimulator
$ 250.00		Medical Boot
$5,250.00		**Subtotal**
$1,050.00		Misc Expenses (Estimated at 20%)
$6,300.00		**Total Budgeted Cost**

Table 12 - Proposed Budget

The actual budget as shown in Table 13 includes an updated overview of the total cost. The reason for the disparity in cost is because rapid prototyping was not done and the price of the bone stimulation device was lower than expected.

Item	Description	QTY	Cost Per	Cost
1	Fabric-Tac	1	$ 6.99	$ 6.99
2	Soldering Kit	1	$ 10.99	$ 10.99
3	Magnet Wire	3	$ 9.99	$ 29.97
4	Neoprene Material	1	$ 10.99	$ 10.99
5	Template Plastic	1	$ 3.49	$ 3.49
6	Pair 2 CKT Molex	2	$ 4.19	$ 8.38
7	PK10 22-18 Gage	1	$ 2.19	$ 2.19
8	Vinyl Tape	1	$ 2.49	$ 2.49
9	Orthofix Stimulator	2	$ 59.99	$ 119.98
11	Super Glue	5	$ 1.99	$ 9.95
12	Doubled Sided Tape	1	$ 4.99	$ 4.99
			Total Cost	**$ 210.41**

Table 13 - Actual Budget

CONCLUSION/RECOMMENDATIONS

This project helped create a device that is not currently available in the market of bone stimulation and/or medical boot devices. Not only is this product currently not available, it builds upon current bone stimulation and medical boot technology to enhance the way a patient can treat stress fractures in the foot. The development of this device meets and exceeds most of the customer desired features for importance and potentially will create more advancements in the treatment of stress fractures.

If this device was to be made for the marketplace it is recommended that one look into smaller options for controller, such as, using a smaller screen and lighter controller. This will decrease any discomfort the current controller may have while attached to the boot.

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APPENDIX A: RESEARCH

Email with Doctor, Oct. 2, 2010 Keith Kenter, Doctor, Cincinnati, OH, 45219. Thanks Antione, Great project. As you know bone stimulators can be either internal (placed surgically) and external. They work by electrical stimulation and thought to align the electrons in the bone. This stimulates osteoblasts, the cells of bone, to lie done more callous. The current is also thought to stimulate the production of bone morphogenic proteins (BMP) to produce more bone. Another type of bone stimulator with pulse ultrasound. Electrical stimulation requires at least 8 hours per day and U/S can be done in 20 minutes per day. I am not sure if more time is better. There probably has to be a 'rest' period for the cells to recover. I like the idea of bone stimulation while the patient walks. I believe that walking in a protected device, like a boot, will also apply physiologic loads to the bone and thus also stimulate healing. Pathologic loads, such as running, can slow the healing in an injured bone. Hence the balancing act, which you are very familiar. To my knowledge there has been no study comparing natural healing with using bone stimulators healing for stress fractures. We have tried to do this study at UC but it is very difficult to do and we need a lot of patients. There is very good data to show that bone stimulation helps with spinal fusion surgery and with other complete fractures, such as the collar bone or clavicle.

 http://apps.djoglobal.com/bonestim/medpro/problemfractures.asp 9/28/10 **CMF OL1000** djogloblal.com The CMF OL1000 is a lightweight device and comes in 5 sizes which accommodate a large variety of fracture sites. The treatment is initiated with the press of a button, and the unit counts down from 30 minutes and lets the patient know treatment is finished with an audible tone.	30 mins of use Restricts movement Bulky No surgery Has to be worn at the same time everyday

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http://www.biomet.com/trauma/products.cfm?pdid=4&majcid=47&prodid=267 9/28/10 **EBI Bone Healing System** biomet.com
Introduced in 1979 as a noninvasive alternate or adjunct to surgery. Indicated for nonunion fractures, failed fusions and congenital pseudarthrosis. Flexible treatment coil can be placed directly over fracture site.</td>
<td>Min 10 hours of use
Use of crutches allows for better movement
Connectors disconnect at times
Lightweight
Cost-effective treatment
Pain-less
No surgery needed
FLX ® flexible treatment coil</td>
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http://www.orthofix.com/products/physio-stim_biobonegrowth.asp?cid=42 9/28/10 **Orthofix Model 3303 Physio-stimulator** orthofix.com
The Pulsed Electromagnetic Field (PEMF) bone growth stimulation delivered by Physio-Stim is a safe, nonsurgical option for long bone nonunions. Physio-Stim may be worn over a cast, orthopedic brace, or clothing without lessening its effectiveness. Physio-Stim has everything you need in one compact, lightweight unit including success rates as high as 88%, and it comes with a written guarantee of healing.</td>
<td>Min 3 hours of use
Can be placed over a cast
If not applied on foot, it can be worn during daily routine
Can only be used if the nonunion defect is less than one-half the width of the bone
Cannot be applied to flat bones</td>
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</table>

 http://global.smith-nephew.com/master/EXOGEN_ULTRASOUND_BONE_HEALING_SYSTEM.htm 9/28/10 **Smith & Nephew EXOGEN Ultrasound Bone Healing System** global.smith-nephew.com The EXOGEN Ultrasound Bone Healing System is the only bone healing device approved to accelerate fracture healing of indicated fresh fractures. It is approved to treat fractures that will not heal (established non-unions) as well as appropriate fresh (recent) fractures	20 mins of use Only stimulator to use ultrasound stimulation Can be used with a cast and with out

 http://www.dme-direct.com/donjoy-maxtrax-rom-walker/ 10/3/10 **Donjoy MaxTrax ROM Walker** dme-direct.com The NEW Donjoy MaxTrax ROM Walker by Dj Orthopedics, is a cam walker that provides protected range-of-motion following trauma or post-operative procedures. This cam walker boot has ROM settings between 45 degrees plantar-flexion and 30 degrees dorsi-flexion in 7.5 degree increments. The uprights on the side of this foam walker will lock in a fixed positions of 0, 7.5, 15, 22.5, and 30 degrees plantar and dorsi-flexion to satisfy any surgeon's protocol, and can be broken down to accommodate short tibia/fibula lengths. The MaxTrax ROM walking brace features comfortable foam sole and a rubber rocker bottom for improved comfort during ambulation.	$199.95 Wider footbed for increased stability. Swiveling D-rings allow for criss cross or parallel strapping. Cushioned inner/outer sole are designed to absorb shock upon heel strike. Breakdown uprights for short tibia/fibula. One-piece design keeps seams away from post surgical areas. Anterior/posterior and medial/ lateral shells for compression and support. Pediatric sizing through extra large.

 http://www.dme-direct.com/bledsoe-hi-top-boot/10/3/10 **Bledsoe Hi-Top Boot** dme-direct.com The Bledsoe Hi-Top Boot is designed as a flexible and attractive alternative to casting for the mid-tibia or fibula to mid-foot area and also for second and third degree ankle sprains. The Bledsoe EZ Set Hi-Top Boot is designed for range of motion from 20 degrees of dorsi-flexion to 40 degrees of plantar-flexion in 10 degree increments.	$159.95 Aluminum boot shell and upright system that Low profile rocker bottom helps eliminate pelvic tilt and alleviate low back pain Fast, easy to put on Unique rocker design Contains 2 layers of pads that contour to the ankle shape and support the ankle for total control Ultra-breathable foam wrap for maximum comfort

APPENDIX B: CUSTOMER SURVEY AND RESULTS

WEARABLE BONE STIMULATOR
CUSTOMER SURVEY

The purpose of this survey is to gather information regarding the importance certain features for a bone stimulator combined with a medical boot.

How important is each feature to you for the design of a bone stimulator?
Please circle the appropriate answer. 1 = low importance 5 = high importance

							Average
Portability	1	2(1)	3(1)	4(6)	5(5)	N/A	4.2
Ease of use	1	2(1)	3(1)	4(3)	5(8)	N/A	4.4
Length of use	1	2(1)	3(4)	4(2)	5(6)	N/A	4.0
Appearance	1(7)	2(2)	3	4(2)	5(2)	N/A	2.2
Safety	1	2	3	4(3)	5(10)	N/A	4.8
Ease of adjustment	1	2	3(2)	4(6)	5(5)	N/A	4.2
Resistance to weather	1(1)	2	3(2)	4(4)	5(6)	N/A	4.1
Comfort	1	2	3	4	5(13)	N/A	5.0

How satisfied are you with the current bone stimulator?
Please circle the appropriate answer. 1 = very <u>UN</u>satisfied 5 = very satisfied

							Average
Portability	1	2	3(2)	4(3)	5	N/A	3.6
Ease of use	1	2	3(1)	4(4)	5	N/A	3.8
Length of use	1	2	3(2)	4(3)	5	N/A	3.6
Appearance	1	2	3(2)	4(3)	5	N/A	3.6
Safety	1	2	3(2)	4(3)	5	N/A	3.6
Ease of adjustment	1	2	3(2)	4(2)	5(1)	N/A	3.8
Resistance to weather	1	2(1)	3(3)	4(1)	5	N/A	3.0
Comfort	1	2(3)	3	4(2)	5	N/A	2.8

Thank you for your time.

APPENDIX C: QUALITY FUNCTION DEPLOYMENT ANALYSIS

Antione Drakeford Medical Boot with integrated bone stimulator 9 = Strong 3 = Moderate 1 = Weak	Weight	Material	Carrying straps	Rigidity	Asthetics	Firmness of hold	Size	Integrataion of stimulator	Protecting stimulator	Customer importance	Designer's Multiplier	Current Satisfaction	Planned Satisfaction	Improvement ratio	Modified Importance	Relative weight	Relative weight %
Portability	9		9				3			4.2	1.2	3.6	4.0	1.1	5.6	0.16	16%
Ease of use			3			9		3		4.4	1.0	3.8	3.9	1.0	4.5	0.13	13%
Length of use								1		4.0	1.0	3.6	3.6	1.0	4.0	0.11	11%
Appearance		3		3	9		1			2.2	1.0	3.6	3.6	1.0	2.2	0.06	6%
Safety		3		9		9		3	9	4.8	1.1	3.6	3.6	1.0	5.3	0.15	15%
Ease of adjustment		3				9		3		4.2	1.0	3.8	3.9	1.0	4.3	0.12	12%
Resistance to weather		9							9	4.1	1.1	3.0	3.2	1.1	4.8	0.13	13%
Comfort	9	3	1	3		3	9	3		5.0	1.0	2.8	3.0	1.1	5.4	0.15	15%
Abs. importance	2.73	2.63	1.92	1.95	0.55	3.96	1.86	1.73	2.52	19.9					36.1		
Rel. importance	0.14	0.13	0.10	0.10	0.03	0.20	0.09	0.09	0.13								

APPENDIX D: PRODUCT OBJECTIVES

Portability (16%)

1. Detachable carrying straps.
2. Will not be 15% heavier than the average weight of current products.

Safety (15%)

1. The boot with integrated stimulation technology will operate in a safe electrical and medical manner.
2. Individual will not notice bone stimulator wiring.

Comfort (15%)

1. Additional bulk from bone stimulator will not be noticed.
2. Same comfort level as current boot technology.

Resistant to weather (13%)

1. Stimulator and components will be protected from water.
2. The boot itself will be designed to the same requirement as boots in current market.

Ease of use (12%)

1. Detachable power supply for charging the bone stimulator.
2. Not more difficult than putting a regular boot on.

Adjustment (12%)

1. Small force will be required to strap in leg.

Length of use (11%)

1. Similar to current bone stimulation technology.
2. Similar to current boot technology.

Appearance (6%)

1. Will appear rigid with proper supports similar to current boot technology.
2. No loosely hanging parts.

APPENDIX E: SCHEDULE

Medical boot with integerated bone stimulator																												
MILESTONE DATE					Winter Break		Winter Quarter										Spring Break		Spring Quarter									
Week #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
Month		Dec					Jan				Feb				Mar				Apr				May					Jun
Dates:	11/22 - 11/28	11/29 - 12/05	12/06 - 12/12	12/13 - 12/19	12/20 - 12/26	12/27 - 01/02	01/03 - 01/09	01/10 - 01/16	01/17 - 01/23	01/24 - 01/30	01/31 - 02/06	02/07 - 02/13	02/14 - 02/20	02/21 - 02/27	02/28 - 03/06	03/07 - 03/13	03/14 - 03/20	03/21 - 03/27	03/28 - 04/03	04/04 - 04/10	04/11 - 04/17	04/18 - 04/24	04/25 - 05/01	05/02 - 05/08	05/09 - 05/15	05/16 - 05/22	05/23 - 05/29	05/30 - 06/06
Task																												
Proof of Design Contract	28																											
Concept sketches			12																									
Design Product (Solid Works)						2																						
Design Freeze							3																					
Rapid Protoytpe Product										31																		
Oral Design Prep/Report															28													
Create Working Model															7													
Prep/Design Report Due																14												
Test/Tuning Product																					18							
Prep/Present Demo to Advisor																								9				
Demo to Faculty																										16		
Final Oral Report																											23	
Finalize/Turn In Final Report																												30

APPENDIX F: BUDGET/BILL OF MATERIALS

Cost ($)		Part/Process
$1,500.00		Rapid Prototyping (Anza Product Development Specialists Quote)
$3,500.00		Stimulator
$ 250.00		Medical Boot
$5,250.00		**Subtotal**
$1,050.00		Misc Expenses (Estimated at 20%)
$6,300.00		**Total Budgeted Cost**

Item	Description	QTY	Cost Per	Cost
1	Fabric-Tac	1	$ 6.99	$ 6.99
2	Soldering Kit	1	$ 10.99	$ 10.99
3	Magnet Wire	3	$ 9.99	$ 29.97
4	Neoprene Material	1	$ 10.99	$ 10.99
5	Template Plastic	1	$ 3.49	$ 3.49
6	Pair 2 CKT Molex	2	$ 4.19	$ 8.38
7	PK10 22-18 Gage	1	$ 2.19	$ 2.19
8	Vinyl Tape	1	$ 2.49	$ 2.49
9	Orthofix Stimulator	2	$ 59.99	$ 119.98
11	Super Glue	5	$ 1.99	$ 9.95
12	Doubled Sided Tape	1	$ 4.99	$ 4.99
			Total Cost	**$ 210.41**

APPENDIX G: ASSEMBLY AND DETAIL DRAWINGS