Specification and Design of a Smart Brace to Correct Pectus Carinatum

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ABSTRACT
Pectus Carinatum, also referred to as “pigeon chest,” is a deformity of the chest characterized by a protrusion of the sternum and ribs. It is a rare disorder, occurring in 1 out of 400 people. It occurs most frequently in males. There are currently two forms of treatment available: surgery or a corrective brace. The latter is what this paper will focus on with emphasis placed on improving the corrective brace method of treatment by formulation of a smart brace. The success of the current brace depends on cooperation of the patient wearing the brace between 14 to 24 hours a day and careful adjustments made on the force applied to the protrusion area as healing progresses. Currently, there is no way of analyzing data on a quantitative basis. Doctors only have the word of their patient regarding consistency of wear, and assessment of healing is done on the physical appearance of the patient’s protrusion area alone. This paper will discuss the concept of a smart brace which will improve the effectiveness of the current brace by adding force sensitivity, area detection, and data logging capabilities.
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INTRODUCTION
Pectus Carinatum is treated either by surgery or with a corrective brace. The latter is the most common form of treatment because it is much cheaper and eliminates the risks associated with surgery. Although it is the preferred method of treatment, it is a rather arduous process that depends on three variables: patient compliance, pressure application on the sternum, and patient age. The brace method of treatment requires patient compliance over a wide range of time. It is estimated that full recovery, using the brace method, is reached between 2 to 4 years. This time period is most dependent on how often the patient wears the brace. Patients typically range between the ages of 8 to 16, which usually results in a lack of consistency in wear of the brace. An important factor in how often children wear the brace is comfort and the aesthetic quality of the brace.

The other important variable to consider is how much pressure is applied to the sternum protrusion. Studies have shown that a load that exceeds 21.5 lbs will cause pressure ulcers, irritation of the skin, which becomes very painful to the patient. The pressure applied to the sternum protrusion is, of course, dependent upon how much surface area the sternum protrusion is subjected to a given load. As it stands, doctors assume that the sternum protrusion makes contact with the entire chest pad in calculating the resulting pressure. This assumption is subject to error because no two patient’s chest protrusion profile is the same. Consequently, pressure readings on the sternum protrusion are often incorrect and can be very painful.

Currently, doctors have no way of assessing the effectiveness of the brace, other than visually inspecting the protrusion region for reduction. Additionally, doctors have no consistent way of detecting how often a patient is wearing the brace. The latter is the most important variable in recovery in terms of restoring the sternum to its normal shape and in terms of speed. With no quantitative analysis on patient treatment, doctors have no real way of assessing how effective the brace is, and how to make improvements on the brace.

As it stands, the procedure for Pectus Carinatum patients starts off with an initial check-up, where the doctor assesses the sternum region. Here, the doctor measures the rigidity of the sternum protrusion in order to determine how much initial force to place on the sternum region. Often, the younger the patient, the less rigid the sternum will be. Hence, the recovery time for younger patients is typically shorter than for older patients. Research has shown that the optimum time to begin treatment on a Pectus Carinatum patient between the ages 8 to 12 all the way up to 18. Usually males stop growing between the ages of 18 to 21, thereby making it very hard to reshape the sternum. Once the rigidity is determined, doctors assess the shape of the sternum protrusion in order to select the right size chest pad for the patient. The doctor then
holds the chest pad against the patient’s sternum and compresses the protrusion until it returns to a normal position or until 21.5 lb load is applied. Doctors have a device that automatically converts the force into a pressure based on the assumption that the sternum is in contact with the entire chest pad. The doctor fits the brace on the patient and prescribes how often the patient should wear the brace. After a prescribed time, usually 4 to 6 weeks, the patient has his or her first follow-up appointment. Here the doctor will assess the patient to see how the brace is working, how comfortable it is, and how often the brace is being worn. Any pressure adjustments are made. If the patient is feeling discomfort, the pressure is reduced. If the patient feels comfortable with the brace, the pressure is left alone. If no real changes are detected, the pressure can be increased as long as the load applied does not exceed 21.5 lbs. This process continues up until full recovery is reached.

Our team will improve the treatment of Pectus Carinatum patients by designing a smart brace, which will address the above mentioned limitations of the current brace, which are lack of force distribution on the sternum region, inaccurate contact area detection, and insufficient qualitative data to analyze results.

We will accomplish this by integrating sensors within the current brace to detect force along critical spots of the sternum protrusion, creating a computer program that will detect how much of the sternum protrusion is in contact with the chest pad, and implementing a data logger within the current brace to store and send data to doctors to conduct quantitative analysis on results.

The smart brace design has three critical features:

- **Force Sensitivity**: Provides the brace with the ability to measure the force distribution over the patient’s sternum region.
- **Area Detection**: Allows the brace to detect how much area the patient’s sternum protrusion is in contact with the chest pad.
- **Data Logging**: Collecting, and delivering data related to force and pressure distribution to doctors for quantitative analysis on results to improve treatment.
BACKGROUND

Because the chest wall remains relatively flexible in young people until they reach early adulthood wearing a brace over the carinatum deformity can push the chest wall down into a normal shape.

The problem is getting patients to wear braces as directed. To work, braces must be worn for many hours a day and exert enough pressure to reshape the chest. Discomfort and skin breakdown are common side effects of traditional bracing techniques, often causing young patients to abandon treatment.

Surgeons at Children's Hospital of The King's Daughters began to offer a brace that is easier for children to wear in 2009. The Dynamic Compression Brace (DCB) was developed by pediatric surgeons Marcelo Martínez-Ferro and Carlos Fraire in Buenos Aires, Argentina, where pectus carinatum is more common than it is in the United States.

The basic concept behind the Dynamic Compression Brace is to use the precise amount of pressure needed to reshape the chest without causing ulcers or so much discomfort that the child will not wear the brace. A special device measures the pounds per square inch that the brace exerts, which is adjusted monthly as the chest slowly assumes a normal shape.

In six years of treatment with 208 patients, Drs. Ferro and Fraire determined that keeping the starting pressures below 2.5 PSI helped avoid the sort of problems that often cause children to give up on treatment. During that time, more than half of their patients completed treatment and of those, 88.4 percent had results that were judged good to excellent in a double blind subjective scale. Average time for wearing the brace was just over 7 hours a day for around 7 months.

Although the DCB has shown great improvement in compressive brace treatment, doctors are still finding it cumbersome to analyze the effectiveness of the treatment because they have no way to track how compliant patients are and they have no quantitative data to assess how well the pressure on the chest is reducing the protrusion area. As a result, Dr. Kelly has partnered with Old Dominion University in attempts to improve the current brace in order to give it the ability to remedy the above mentioned shortcomings.
DESIGN, ANALYSIS, OPTIMIZATION, AND APPLICATION

Initial Design

The smart brace design is a modification of the current Dynamic Compressive Brace. The only modifications being made are to the chest plate and chest pad. The chest plate will be modified in order to fit a housing unit on the brace. The housing unit will contain the data logger, blue tooth data transfer device, and battery. The chest pad will be modified in order to improve upon force sensitivity and area detection. Seven FlexiForce ® sensors and one load cell will be integrated into the chest pad and input into the data logger.

The design for the housing unit can be seen, below, in Figure 1.1.
The chest pad design is modeled after the concept of keys on a computer. The pad is made into a grid. Within that grid each box has a certain area. Sensors will be placed within certain squares within the grid based on the optimum formation of sensors. An algorithm will be made to convert the alerted sensors into an area that corresponds to each sensor. These areas will be summed in the data logger to produce a final contact area. Additionally, a load cell will be placed between the brace plate and the chest plate to detect the overall force being applied to the patient to ensure that the force does not exceed 21.5 lbs. Figure 1.2 shows 3 different sensor formations. Figure 1.3 shows how the chest pad of the smart brace is an improvement on the current DCB. In the smart brace, the sensors will act as nodes that detect contact. Based on which sensors are turned on, the data logger will read a corresponding area which will approximate with more accuracy the actual contact area.

Figure 1.2: Three different sensor formations

Figure 1.3: The pad on the right is the current chest pad on the DCB and the pad on the right is the smart brace pad. The current pad assumes perfect contact with the chest pad. The smart brace pad, detects the actual contact area.

The sensors will be placed inside of the chest pad. A thin layer of the chest pad will be sliced away and the sensors will be placed inside. An adhesive will be placed on the surface of the open pad, which will fix the sensors in place. The top layer of the chest pad will then be placed over the sensors with an adhesive. Figure 1.4 shows how the sensors will be placed within the pad.
The sensors must be tested to ensure they are compatible with the data logger and that they
detect a force within the range needed for the purposes of our study. As before mentioned, the
force exerted on the pad cannot exceed 21.5 lbs. The sensors are designed to detect a force up to
1000 lb. The sensors have a built in error of plus or minus 3 %. The load cell will serve to gage
how much overall force is being exerted on the pad to ensure that the max force of 21.5 is not
reached. Testing will be performed on a prototype chest plate group which will consist of a
rubber pad, aluminum plate and housing unit. Upon completion of testing, the prototype will be
presented to Dr. Ferro for proposal.
Optimization

Pressure Plate

Our initial design of the sensory pressure pad was to place the sensors inside the pad itself. Upon completing a test on the Flexiforce Sensors, it was determined that in order for the sensors to work properly, a puck device needed to be incorporated into the design. Therefore, we had to change our initial design of the pressure pad. We decided to place the sensors on a pressure plate instead of inside the pad itself. The new design can be seen in figure 2.1.

![Figure 2.1: A magnification of the new pressure plate with the pad and the arrangement of the sensors.](image)

We also changed the arrangement of the sensors in order to accommodate a 7 sensor arrangement. We initially planned to use 8 sensors but we determined that a 7 sensor design would give us optimum coverage of the sternum area. The final sensor arrangement can be seen in figure 2.2.
Figure 2.2: Final sensory formation used in prototype

For future optimization, we will improve the sensitivity of the pressure pad by incorporating more sensors into the pad. The more sensors we can use the more accurate our data will be. Because we were limited in the amount of sensors we could use we could not design the smart brace the way we would have like to. A ideal sensory arrangement can be seen in figure 2.3.
Figure 2.3: Ideal sensory arrangement model using 40 sensors.

**Pectus Program Summary:**
Background:

The Flexiforce \textsuperscript{©} sensors output a voltage reading to the datalogger that ranges from 0 to 3.3 volts, since the datalogger is supplying each of the sensors with 3.3 volts. If no force is being applied then each sensor should theoretically be outputting a voltage of 0.0 and the voltage reading then increases as the applied force increases. The datalogger takes the incoming voltage and stores the value onto a microSD card as a 10-bit integer value. The data is stored in a text file called LOG01 and these files will simply be referred to as 'log' files from now on. Whenever the datalogger is reset or powered on a new text file is created that is still named LOG but followed by a number that is one greater than the highest current text file name. For example, if the datalogger is reset and there are currently log files 01 - 11 then the new file is called LOG12. The datalogger will create up to 256 of these files before it refuses to hold anymore data. Since we have design the datalogger to record data from seven different force sensors, the data for each sensor is stored in a separate column in the text file. For example, every reading taken by sensor three will be stored in the third column of the text file.

Coding Constraints:

With this knowledge about how the data is stored, a few possible problems had to be sorted out before the code was written. First, the brace is supposed to be worn everyday which means that there will be a minimum of 365 log files taken in one year assuming that only one log file is created each day. Although it is likely that more than one text file will be created each day because the datalogger can be switched on and off and a new file is created each time that this happens. However, the datalogger only holds 256 log files and the brace is usually worn for longer than one year. This required us to figure out a method to be able to create more than the maximum 256 files that were allowed by the datalogger. In addition, all of the log files that are being stored on the datalogger are different sizes since the data will not be retrieved off of the datalogger at the same time each day. Therefore, the code needs be able to store data of variable lengths. The last constraint that we faced in starting to code was in finding a way to take the stored force data and to create graphs for each sensor that showed the force versus time for that sensor. We also hoped to create a graph that displayed the distributed pressure over the entire brace pad.

Program Creation:

Having taken these problems into consideration, we began to build the program. A vector object is capable of storing a variable size of objects and the vector object can grow or shrink during the execution of a program. Therefore, vector objects were selected to be used to store the data from the datalogger and this removed the problem of the log files being different sizes [xxxxx]. Seven vectors were created to represent each sensor and as each line of data from the datalogger is read into the program the corresponding data value is stored into its vector. At the same time an eighth vector is created that increments a counter by one each time a new line of data is read.
from the datalogger, the count value is multiplied by 1.5 which represents the 90 seconds between each data reading, and the value is then stored into a time vector. This vector will later be used to form the 'time' axis on the two-dimensional force versus time graph.

To solve the problem of hitting the maximum allowable number of log files on the datalogger, we decided to delete each data file after it was read from the datalogger. While solving one problem, this also made the program a little more complex because we now needed a way to store the data that was coming from the datalogger. Therefore, a system was created to store the data. The method chosen to store the data was fairly simple in design and is based on a time function that can be called in C++. Each time the program is executed, the time function is called to bring up the current month, day, and year. The program then checks a specified directory to see if a folder with the current month's name exists and if it does not a folder with the name of the current month is created. Then the program looks inside of the month folder and looks for the current day. If the current day is not found then a folder containing the month, day, and year is created. In this manner, a new folder will be created each day to store all of that specific days data inside.

The program was then setup to read all of the log files that were currently on the datalogger, store all of the data into the seven sensor vectors and then to output the seven vectors into a file inside of the current day's folder. This serves to store the original, unaltered information taken from the datalogger since the files on the datalogger are erased after they have been read. The data from each sensor is then converted from the 10-bit integer value that is stored on the datalogger back into a force reading. Seven files are then created in the current folder containing the data for each of the applied forces per sensor along with the corresponding time interval values. Next the forces per sensor are converted into pressure values based on the areas that they cover on the brace pad. These values are sent to a different file in the folder so that they can later be used to create the three-dimensional distributed pressure graph. A final file is stored inside of this same folder containing information for the physician to be able to quickly look over and clearly see all of the relevant information that they need. This file contains the current date and the values of the average forces and pressures per sensor along with the average distributed pressure over the entire brace pad.

Figuring out how to graph the data turned out to be the most difficult part of the program. Gnuplot was selected to graph both the two-dimensional and the three-dimensional plots. Gnuplot is a freely distributed software and it is able to create a wide variety of graphs based on either equations or points. In order to properly use gnuplot within the program, gnuplot has to be executed by the program and a text file has to be sent to gnuplot containing all of the details about the graph that it is supposed to create. Therefore, a text file is created whenever the code is executed that contains commands to be sent to gnuplot that tell gnuplot to make seven, two-dimensional force versus time graphs and one, three-dimensional distributed pressure graph. When the program is run, the user sees a graph for each sensor that displays the applied force over time for that sensor along with two horizontal lines that represent a maximum and a
minimum force level. If the force is constantly over this line then too much force is being exerted onto the chest and the user can see that the brace needs to be loosened. If the force is below the minimum line on any of the sensors then these sensors are not receiving enough force. However, this does not necessarily mean that the brace needs to be tightened because the chest deformity may be isolated to a different portion of the brace pad. In this case, further tightening the brace would exert too much pressure on that region and will cause pain to the patient.

The three-dimensional graph displays the average pressure for each sensor using the just retrieved values from the datalogger. This graph gives both the patient and the doctor a visual conformation that the brace is working like it is supposed to. The graph can also serve as a good device for measuring how far the patient has come in the treatment process. When the patient first begins treatment a great deal of pressure should be seen isolated to a particular region which will show a spike on part of the graph. As the treatment process progresses and the deformity slowly levels back into a regular chest shape, the distributed pressures should be spread more and more evenly across the brace pad and the graph will look more leveled and flattened out. By being able to see the visual progression of the treatment process over time, the patient should be more enthusiastic about wearing the brace and this will hopefully cause the patient to wear the brace more often and speed up the treatment process.

CONCLUSIONS

The smart brace will improve the quality of the current DCB by improving the force detection, improving the area detection, and incorporating data logging capability. The design of the current brace will not change, just the capability of the brace. There is no current brace in practice that possesses data logging capability to treat pectus carinatum patients. This will drastically improve the ability of doctors to assess the effectiveness of the nonsurgical compression treatment method. With this data, doctors will be able to improve overall treatment of pectus carinatum by decreasing treatment time, improving patient comfort, and create new ways to treat pectus carinatum.
APPENDICES

APPENDIX A: FORCE DISTRIBUTION WITH VARYING LOAD
APPENDIX B: SENSOR TO PAD AREA ERROR
APPENDIX C: UPDATED GANTT CHART
REFERENCES

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