30.007 Term Paper – EmBrace (Group 2)

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Abstract

This project tackles the problem of lumbar braces for slipped disc patients being inadequate in strengthening the core and back muscles during rehabilitation and being uncomfortable to wear for long periods of time, making them less suitable for travel. Current treatment options include the use of rigid and compression lumbar braces for stability. Long-term usage of these passive braces leads to muscle atrophy and over-reliance on them, contradicting the objective of rehabilitation which is to restore functional ability and quality of life. Furthermore, constant compression and tight fittings around the lower torso increases discomfort. The proposed solution is EmBrace, a reactive travel brace designed to detect and initiate a corrective mechanism when the wearer is in an unsafe lumbar posture. The vest holds several components such as: flex sensor, solenoid valves, pressure regulator, air cartridge and inflatable tubes. The system activates via a flex sensor detecting unsafe forward flexion of lumbar vertebrae and opens the inlet solenoid valve. After activation, the air cartridge pushes air, controlled by a pressure regulator, into the inflatable tubes. Once the wearer returns to neutral lumbar posture, the outlet solenoid valve opens to release air. The success rate was measured by the maximum force produced by the inflatable tubes on wearer, which was a targeted 200N. This solution encourages slipped disc patients to keep a neutral lumbar spine position by engaging the required muscles to avoid activating the brace. It also allows a larger range of motion when uninflated and only restricts movements when inflated, thereby improving comfort levels.

I. Introduction

Every year, up to 2% of the population is diagnosed with a slipped disc [1]. According to one study, the majority of patients are working adults, with 73% of them ranging from ages 20 to 49 [2]. A slipped disc, also known as a herniated disc, occurs when the gel covering of a disc in the spine tears and shifts [3]. It is most common at the lumbar spine [1] and causes discomfort and pain when the gel presses on the nerve root [3]. Poor posture from the forward flexion of lumbar vertebrae when walking and sitting will aggravate the slipped disc [4]. This is particularly common during travel due to prolonged sitting and frequent standing and sitting movements [5].

Current treatment options involve the use of lumbar braces [6]. Presently available products that offer stability to the lumbar spine include rigid and compressive lumbar braces produced by leading orthoses support brands such as Bauerfeind and Futuro. While rigid braces are prescribed to restrict movement during the acute phase of diagnosis, which is when pain is most severe, compressive braces are often worn for post-acute support [7]. However, these compression braces rely on constant compression for support which increases the likelihood of muscle atrophy, dependence on the brace and further weakening of the back [6]. Thus, compression braces are not recommended for long-term use as they do not strengthen the core and back muscles, a core element of rehabilitation [6]. Additionally, since compressive braces are tightly wrapped around the lower torso, they are uncomfortable to wear for long periods of time [6], making them less suitable for wearing throughout the day and during long travels. Overall, the main impact of the project would be providing slipped disc patients with a reactive travel brace that facilitates muscle strengthening while providing adequate support for rehabilitation and is comfortable to wear for extended periods. The main benefactors and groups of concern are slipped disc patients, healthcare workers and caregivers. Given that the project is successful, the prototype can be used by people with lower back issues.

II. Proposed Approach

A. System Requirements

It is known that users place a high value on the product's ease of use [8]. As the neutral lumbar spine is usually in extension [9], flexion of 10° is beyond the range of angles considered to be a healthy spine posture. Since there was little research data on the force provided by back muscles at a 10° angle, experiments were conducted to find the minimum force required to push a wearer upright from a bent over position. This figure, which will be discussed in section IV, was found to be 188.76N. Additionally, it was important to consider that a person's body is always in motion and prefers to move without constriction. The brace should be breathable, and less heat should build up after wearing the brace, allowing for longer periods of use. Lower power requirements will minimize the number of batteries necessary, allowing users to avoid changing a large number of batteries while also reducing the product's weight. Lastly, a back brace should be lightweight and with lumbar braces on the market weighing 0.4 kg to 1.5 kg, targeting a mass of less than 1 kg is appropriate. EmBrace will thus be tested based on seven factors: usability, sensitivity, effectiveness, flexibility, heat, durability, and weight. Table I summarizes EmBrace system requirements.

TABLE I. SYSTEM REQUIREMENTS

Factor	Parameter	Target Value
Usability	Time taken to wear brace, adjust fit and calibrate bend sensor	1 min
Sensitivity	Angle when mechanism is triggered	10°
Effectiveness	Force exerted by inflatable on user	188.76 N
	Time taken to fully inflate	10 s
	Survey rating of rigidity between OPPO Lumbar Sacro Support and our brace when inflated	Average rating of our brace ≳ OPPO Lumbar Sacro Support
Flexibility	Survey rating of restrictive motion of flexion, extension, and lateral flexion between compression brace and rehabilitative brace	Average rating of rehabilitative brace > compression brace
Heat	Difference in skin temperature before and after wearing brace	< 2.0℃
Durability	Power consumption	10 W
Weight	Mass	≤ 1 kg

B. Concept Selection

Brief Description of your Concept Selection process: Pros and cons of initial ideas and your process to converge to your final approach. Include Pugh charts, initial concept ideas, etc.

During the design process, two methods of applying force to the back were explored (Fig.1). The first involved linear actuator motors connected to tension cables located along the erector spinae muscles to provide the tension force required to pull the wearer upright. The second employed a pneumatic mechanism along with inflatable tubes to push against the wearer's body and generate the force required to correct the wearer's posture. Both systems will only be activated when an unsafe forward posture is detected. Fig. 2 illustrates how the brace works during a walk cycle.
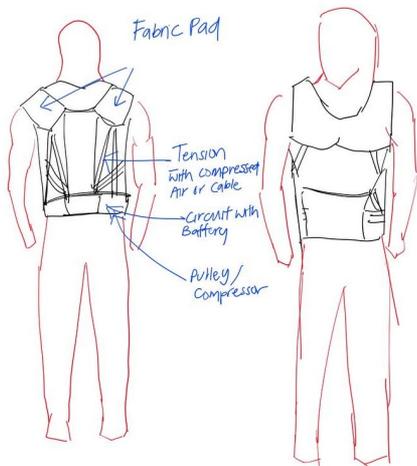

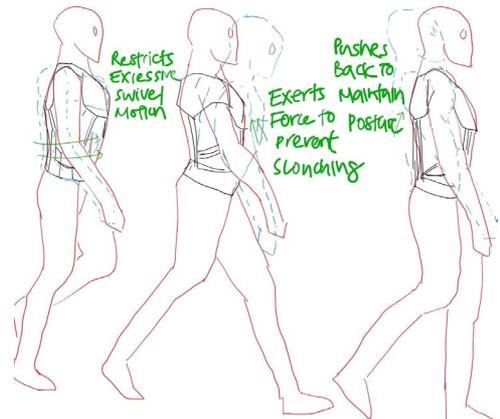Figure 1. Brace using either method

Figure 2. Walk cycle with reactive brace

To determine which idea to adopt, preliminary force and torque calculations were performed, and it was determined that the pneumatic mechanism was more feasible for the system's power needs. Additionally, a Pugh chart (Table II) was used to compare and analyze both methods with a set of criteria. The pneumatic method had a higher score than the motor method. Consequently, the pneumatic approach was chosen for the design of the brace.

TABLE II. PUGH CHART

Criteria	Weightage	Pneumatic	Motor
Usability	2	+	+
Comfort	3	+	0
Effectiveness	3	+	+
Feasibility	1	+	0
Weight	2	0	0
Breathability	1	0	0
Form Factor	1	+	0
Durability	1	0	0
Total	14	10	5

The next consideration was the design of inflatable tubes. Numerous designs with different sealing patterns as well as potential incorporation of elastic cords to increase tension is shown in Fig. 3. Subsequently, each design's ease of sealing using a heat sealer machine and evenness of inflation was evaluated to determine the best design. As the brace must be worn over one's clothing, a design incorporating the brace into a wearable vest was chosen to increase appeal for wearer and provide additional comfort. Fig. 4 shows the chosen design.
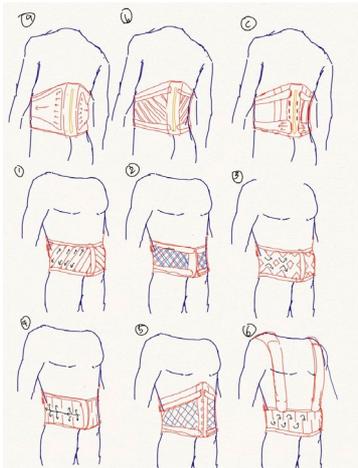
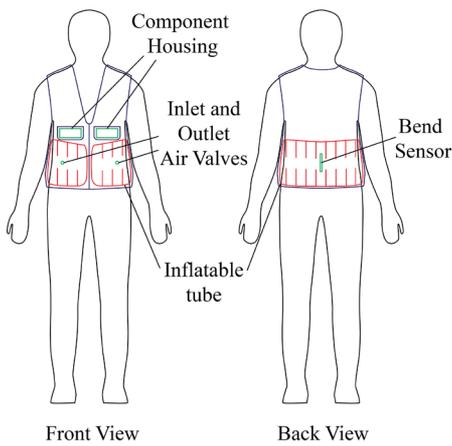Figure 3. Front and back designs for the inflatable tubes

Figure 4. Selected design

C. Concept Description

As mentioned, the reactive travel brace design included inflatable tubes wrapped around the lower torso with an 'H' shaped welding pattern such that the tubes run horizontally and vertically (Fig. 5). It restricts motion in two degrees of freedom systems, flexion, and extension, as well as lateral flexion.
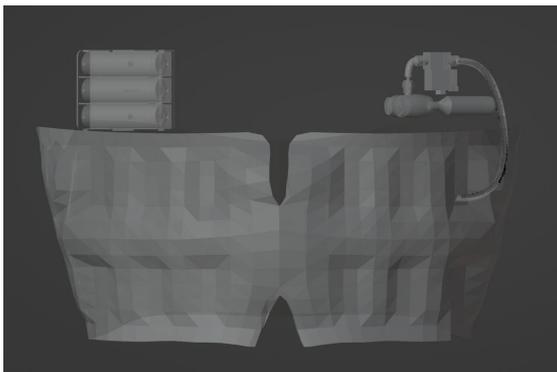

Figure 5. Horizontal and vertical tubes around the lower torso

Additionally, the flex sensor is fastened to the center of the brace on an elastic band (Fig. 6), which tightens around the wearer to keep the sensor in place. It will detect changes in the angle of forward flexion of the wearer.
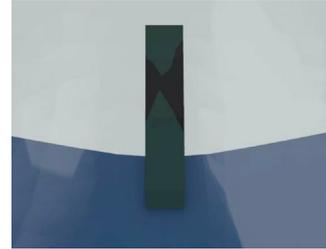
Figure 6. Flex sensor on elastic band which is in contact with lumbar back

Fig. 7 illustrates the placement of all components in the reactive travel brace.
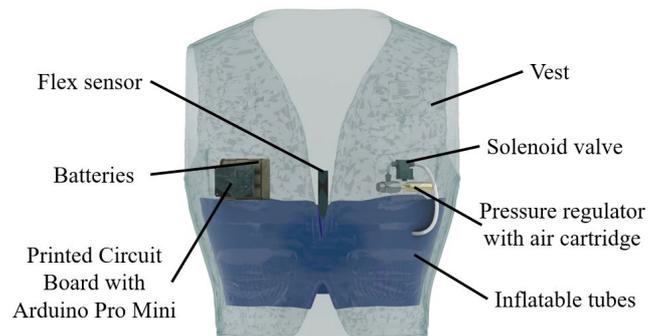
Figure 7. Full assembly

The functional diagram (Fig. 8) demonstrates the inner workings of the reactive travel brace. When worn, the flex sensor continuously reads the angle of forward flexion of lumbar vertebrae. The neutral lumbar spine posture is calibrated by pressing a button. When a forward flexion of 10° is detected and maintained for at least 3 seconds, the mechanism engages. Once activated, the inlet solenoid valve opens, and pressurized air inflates the tube to compress and push the wearer back to neutral lumbar posture. When the correct posture is held, the outlet solenoid valve opens to release air back to surroundings.
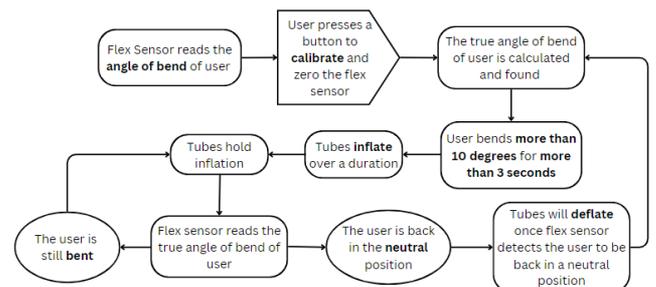

Figure 8. Functional diagram
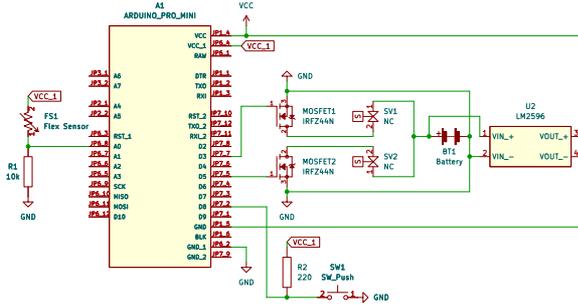
Fig. 9 shows the circuit diagram for the system.

Figure 9. Circuit diagram

III. MODELLING

A. Component Selection

Material

For the fabrication of inflatable tubes, the material used had to be heat-sealable and airtight. Initially, 70 Denier Nylon Ripstop fabric coated with Polyurethane (PU) was chosen as it was marketed to be impervious to wind and could be sealed due to the PU coating. However, it was found to be permeable to air particles and hence not suitable for the project. The second material tried and used for the first prototype was Polyethylene (PE) plastic. While it provided an airtight seal and was extremely light, it could not contain the necessary pressure to force the wearer upright. Therefore, the final prototype used Polyvinyl Chloride (PVC) laminated tarpaulin. When heat sealed, it was airtight and was able to contain enough pressure to generate sufficient force on the wearer which maintains the neutral lumbar position.

Pneumatic System

In the first prototype, a 12V direct current (DC) air pump was used to pump air into the inflatable tubes. However, the time taken to fully inflate it was over 30 seconds which exceeded the maximum time set of full inflation. Additionally, the DC motor generated excessive noise and had a large volume which caused uneven weight distribution for the brace. As such, a disposable air canister along with an inflator system was preferred over the motor for the final prototype.

Sensor

Both gyroscope sensors and flex sensors were tested to detect angle changes in the lumbar spine. The flex sensor placed at the lumbar back was found to be more accurate in measuring the changes in angle, making it more suitable for the use case.

B. Performance Predictions

Force Provided by Inflatable Tubes

The reactive travel brace uses 16g disposable CO_2 cartridges for inflation. An assumption made was for the volume of the inflated tubes to be 22 cylindrical segments and 1 larger rectangular cuboid segment. In order to model the force provided by the inflatable tubes, the radius of cylindrical segment is calculated using (1). The volume of each cylindrical segment and cuboid segment are obtained using (2) and (3) respectively. Equation (4) is the summation of (2) and (3) to give the total volume. Using the ideal gas law (5), the pressure exerted by the inflatable can be calculated. Force exerted by the inflatable can be obtained using (6).

Variable definitions:

r: Radius of segment [m]

h: Height of cylindrical segment [m]

l: Length of cuboid segment [m]

$V_{cylinder}$: Volume of each cylindrical segment [m^3]

V_{cuboid}: Volume of cuboid segment [m^3]

V: Total volume [m^3]

P: Pressure [Pa]

n: Number of moles of gas [mol]

R: Ideal gas constant [$Pa \cdot m^3 \cdot K^{-1} \cdot mol^{-1}$]

T: Temperature [K]

$$r = \pi/\text{width of each tube} \tag{1}$$

$$V_{cylinder} = \pi r^2 h \tag{2}$$

$$V_{cuboid} = 4r^2 l \tag{3}$$

$$V = 22V_{cylinder} + V_{cuboid} \tag{4}$$

$$PV = nRT \tag{5}$$

$$\text{Force} = P \times \text{Area} \tag{6}$$

$r = \pi / (60 \times 10^{-3}) = 19.09 \times 10^{-3}$ m

$V_{cylinder} = \pi (19.09 \times 10^{-3})^2 (80 \times 10^{-3}) = (9.1673 \times 10^{-5})$ m^3

$V_{cuboid} = 4 (19.09 \times 10^{-3})^2 (400.9 \times 10^{-3}) = (5.8439 \times 10^{-4})$ m^3

$V = 22 \times 9.1673 \times 10^{-5} + 5.8439 \times 10^{-4} = 0.002601$ m^3

n = 16/44.01 = 0.3635 mol

R = 8.314 Pa $\cdot$ m^3 $\cdot$ K^{-1} $\cdot$ mol^{-1}

T = 298K

P = (0.3635 × 8.314 × 298) / 0.002601 = 343223 Pa

Assuming only 50% of the brace's front surface is in contact with the front torso of the user, the effective area of inflatable which provides a force on the front of the wearer is a rectangular area of 440mm x 120mm = 0.0528 m^2

Force = 343223 × 0.0528 = 18250 N

For a design margin of 200%, the predicted maximum force the inflatable is able to exert on the user is 18280/3 = <u>6093N</u>

IV. RESULTS

A. Prototypes

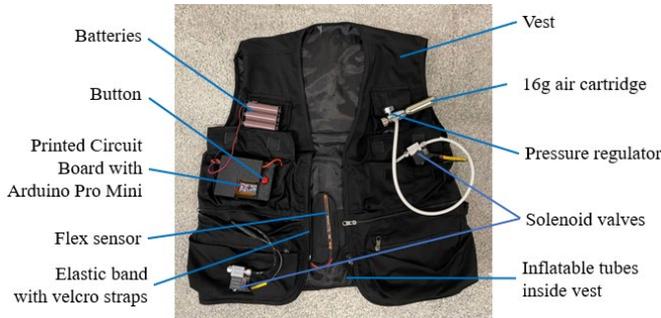*A. i.* Full prototype assembly (Fig. 10).

Figure 10. Full prototype assembly
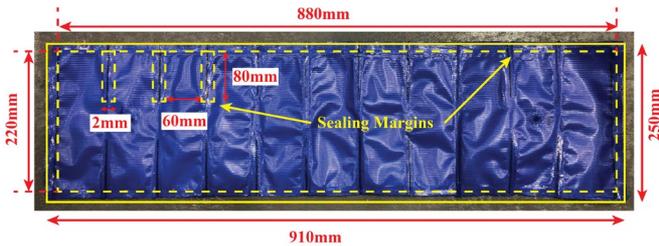
A. ii. Inflatable tube and its dimensions (Fig. 11).

Figure 11. Inflatable tubes and its dimensions

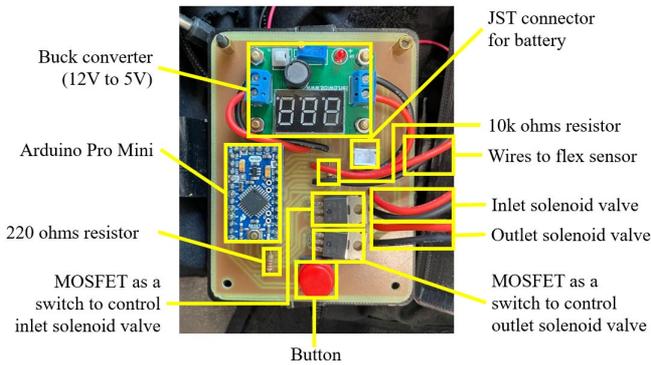*A. iii.* PCB and electrical components (Fig. 12).

Figure 12. PCB and electrical components

B. Experiments

B.i. Usability testing by timing the duration for people unfamiliar with the product to wear it (Table III).

TABLE III.   WEARING DURATION

Sample Size	15
Average Time Taken/s	33

B. ii. Sensitivity testing by bending the flex sensor (Fig. 13) and taking readings from the Arduino Serial Monitor.

Figure 13. Arduino Serial Monitor

B. iii. Effectiveness testing by timing duration for inflation and obtaining experimental data of maximum force exerted.

An experiment was conducted using a calibrated force sensor to measure the force against the wearer who is upright over the course of an inflation cycle. The time taken for full inflation is the time taken for the brace to provide maximum maintained force against the wearer. A recorded time of less than 10 seconds would indicate a more effective response time. The RP-S40-RT force sensor used has an area of 40mm by 40mm. It was placed along the center horizontal axis of the inflatable tube, which had the greatest surface area of contact with the wearer. For modelling purposes, the effective area of the inflatable which provided a force on the front torso of the wearer (Fig. 14) was 440mm by 240mm (Fig. 15). By scaling up the area of the force sensor to the effective area, the total force acting over the front of the wearer was found.
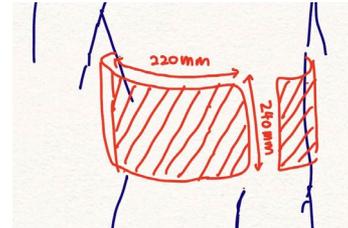

Figure 14. Visual representation of effective area around lower torso

Figure 15. Dimensions of effective area

Experimental results (Fig. 16) showed that full inflation required only 4 seconds and maintained an average maximum force of 4.2N over the force sensor area of 40mm x 40mm, resulting in a total force of 277.2 N. As the brace was relatively airtight, the maximum pressure in the inflatable was maintained at a constant level and the experiment was stopped after 5 seconds.
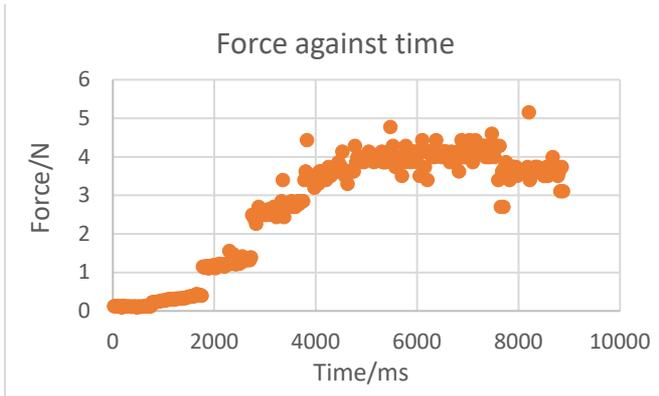
Figure 16. Force against time graph

B. iv. Effectiveness testing through rating of rigidity and flexibility testing through rating of ease of movement between OPPO Lumbar Sacro Support and EmBrace.

In this experiment, 15 individuals tried on both braces and were asked to score the range of motion during flexion, extension, and lateral extension on a scale of 1 to 10. A value of 1 indicated that it was difficult to move, while a value of 10 indicated that it was very easy to move. The lightest intensity of blue correlates to 1 and the darkest intensity of blue correlates to 10. The results (Fig. 17) showed that wearer felt that it was easier to move in the uninflated brace than the compression brace and that the inflated brace had a rigidity comparable to the compression brace.
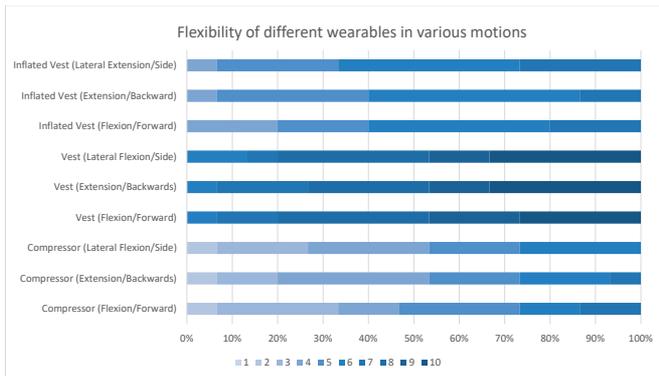
Figure 17. Flexibility in various motion

B. v. Comfort testing by measuring skin temperature before and after brace usage.

The experiment was conducted at a room temperature of 24C with the reactive travel brace worn for 10 minutes. A thermal imaging camera was used to determine the skin temperature. The results are shown in Table IV.

TABLE IV.   SKIN TEMPERATURE

Skin temperature before use (°C)	35.1
Skin temperature after 10 minutes (°C)	36.7
Difference in temperature (°C)	1.6

B.vi. Mass of Product (Table V).

TABLE V.   MASS

Item	*Mass (g)*	*Quantity*	*Total Mass (g)*
Inflatable tubes	180	1	180
PCB Board and Electrical Components	50	1	50
PCB board holder	53	1	53
Air Canister	59	1	59
Pressure Regulator	151	1	151
Batteries	45	3	135
Battery Holder	17	1	17
Solenoid Valve	85	2	170
Flex Sensor	-	1	-
Wiring	15	2 m	15
Air tubes	35	1 m	35
Vest	370	1	370
Total Prototype Weight			1235

B. vii. Power requirements through voltage and current reading (Table VI).

TABLE VI.   POWER CONSUMPTION

State	*Voltage (V)*	*Current (A)*	*Power (W)*
Both solenoid valves are off	12.4	0.03	0.372
Either solenoid valve is on	11.8	0.35	4.13

B. viii. Effectiveness test to find out how much force is needed to support the user back upright (Fig. 18).

An experiment was conducted using a calibrated force sensor to measure the force against the wearer who is initially bent with the angle measured by a flex sensor over the course of an inflation cycle. Results showed a gradual decrease in angle from 15 degrees back to an almost neutral position of 1.5 degrees as the brace was inflated and force provided by it increased. The average force when the force reached its maximum was recorded to be 2.86N, which scales up to 188.76N over the front region of the brace. This calculated value is lower than the experimentally calculated maximum value of force of 277.2N as seen in part *B. iv.* Hence, this suggests that the maximum force provided by the brace is more than enough to push a wearer upright from a bent position.
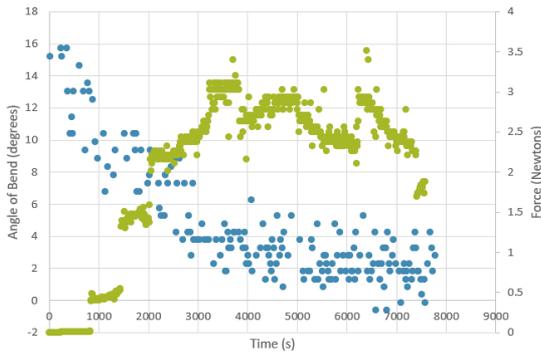
Figure 18. Force and bend against time graph

V. Discussion

From the experiments, the measured force provided by the inflatable tubes on the wearer at 277N was much lower than predicted value of 6093N. This was because the nature of fabric prevents it from being perfectly airtight and not all pressure from the air cartridge was used during the inflation to prevent the tubes from bursting. Another reason could be the use of the RP-S40-RT force sensor which may not have been sensitive enough to detect a wide range of forces. Additionally, there could have been an inconsistent contact area between the force sensor and the inflatable brace, resulting in reading of forces lower than expected. However, the measured force was still sufficient to push the wearer's lumbar spine back to its neutral position.

Table VII summarizes the results of the experiments conducted and how they compare to the target values.

TABLE VII.   SUMMARY OF EXPERIMENTAL VALUES

Factor	Target Value	Experimental Value	Target Met
Usability	1 min	33s	Yes
Sensitivity	10°	10	Yes
Effectiveness	200 N	277N	Yes
	10 s	4s	Yes
	Average rating of our brace ⪥ OPPO Lumbar Sacro Support		Yes
Flexibility	Average rating of rehabilitative brace > compression brace		Yes
Heat	< 2.0°C	1.6°C	Yes
Durability	10 W	4.13 W	Yes
Weight	≤ 1 kg	1.235 kg	No

From the experiments, almost all the target values were met by the final prototype brace. Although the mass of the brace was larger than the target value, the calculated mass included the base vest itself, which mass could be reduced by removing unnecessary compartments and embellishments. The final prototype is still considered a success as key working requirements such as the force and effectiveness were met.

VI. Future Improvements

Although fulfilling its purposes, the prototype can be further improved in multiple areas for better results. Firstly, the heat welding technique used to make the inflatable could be refined to make the inflatable component completely airtight to maintain the force generated on the wearer. Next, current tests are run using disposable CO_2 canisters which is costly and unsustainable. As such, rechargeable CO_2 canisters can be considered to reduce waste generated and improve user convenience without the need to purchase additional canisters. An automated and programmable pressure regulator can also be used to create a fully autonomous system without the need for wearer intervention in controlling the air released into the inflatable. For the testing phase, experiments using electromyography (EMG) data could be implemented to obtain more accurate results by calculating the forces exerted by the wearer's muscles instead of measuring contact forces.

VII. Conclusions

EmBrace (Fig. 19) started out as a reactive brace with either a mechanical string tension system or air pump pneumatic system. After calculations and experimentation, changes needed to be made and an air cartridge system was instead implemented to balance the power, time sensitivity and weight requirements of a flexible, travel brace. The result is a brace with a travel-orientated medical design to help patients lead the same lifestyles as before. The use of a reactive instead of passive design helps to reduce the dependency on external support to facilitate rehabilitation.

Figure 19. Final Prototype

During development, there were a lot of unpredictable, controllable parameters that went into the experimentation process. This was to be expected due to the nature of the project; targeting a specific human body function, making it impossible to set up a near perfect control experiment. Thus, geometrical assumptions had to be used to analyze the data.

For this year's 30.007, to suit the theme of travel, many

projects looked towards mobility devices and vehicles, which led to a lapse in focus towards the medical field. Most medical devices are designed without travel as a priority, which is a gap that was explored, leading to the creation of the prototype. EmBrace aims to be an alternative solution for slipped disc patients to travel, as well as inspire medical device developers to keep not just travel, but lifestyles in mind in their design.
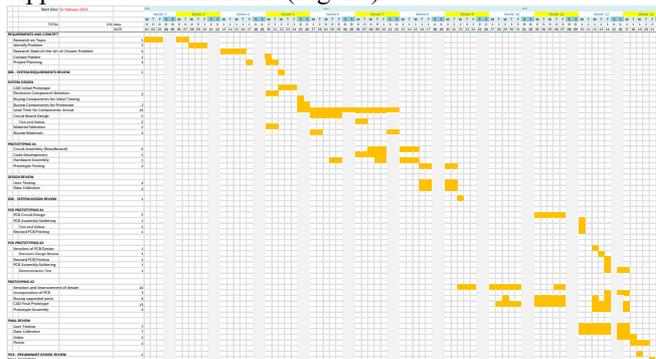
APPENDIX

Appendix 1: Gannt Chart (Fig. 20)

Figure 20. Gannt chart

Appendix 2: Final Budget (Fig. 21)
The total expense was $1490.14.

Figure 21. Final budget

Appendix 3: Failure Mode and Effects Analysis (Fig. 22).

No.	Function	Failure Mode	Effects	Causes	Severity (of event)	Occurance (probability of event occuring)	Detection (probability of event not being detected)	RPN
1	High pressure CO2 tubing handles pressurized air and is used to connect between various components	Solenoid valve connected to the inlet valve fails to open while pressurized air enters through the pressure tube	Pressure tubes burst	CO2 high pressure tubes not meant to withstand pressures supplied from air cartridges	8	4	5	160
3	Printed Circuit Board (PCB) provide electrical connection and mechanical support to electrical components	Design assembly failure	System fails to start or potential short circuit	Conductive tracks were wired incorrectly or had dropped off	7	5	4	140
4	Provide power to circuit	Battery explodes	Explosion and possible fire	Overloading of power source	10	2	5	100
6	Printed Circuit Board (PCB) provide electrical connection and mechanical support to electrical components	Poor connection from wires	System fails to start or potential short circuit	Poor soldering and connection	6	4	2	48
2	Inflatable tubes to provide compression force on the wearer's lower torso	Inflatable tubes burst from high pressure	Shrapnel released and flies into user	Over pumping of inflatable tube	6	4	2	48
5	Inflatable tubes to provide compression force on the wearer's lower torso	Air enters tube too quickly	Sudden movement might cause user further injury	Air pump inflates too quickly	9	2	2	36

Figure 22. FMEA

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