The Pittsburgh Flex Brace: A Dynamic Way to Treat Scoliosis

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Executive Summary

The main objective of this project was to create a brace for the treatment of adolescent idiopathic scoliosis (AIS) that is more dynamic and less restrictive than those currently on the market. One of the major issues of the current rigid, bulky braces is patient compliance. The Pittsburgh Flex Brace offers a much more comfortable, discreet design that may be worn under clothing while preventing the progression of scoliosis through the use of straps and rigid pieces.

Clinical Need

There are an estimated 6-9 million people in the United States who suffer from AIS. AIS presents itself as an abnormal curvature of the spine, through the cervical, thoracic, and lumbar regions. AIS cannot be cured. For moderate cases, the patient must wear a back brace to prevent further progression of the curve. The braces which doctors utilize to do so are the Boston Brace and Charleston Bending Brace, both of which are large, very conspicuous plastic braces. Patients are restricted in their day to day behavior due to the rigidity. In order to increase patient compliance, a new brace that is equally as effective as rigid braces but without the bulk is needed.

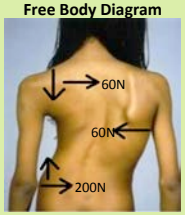
Boston brace (left) and Charleston Brace (right) are available on market but are very bulky and restrict everyday movement.

Description of Market

Although scoliosis affects people of all ages, only children who are still growing and under the age of 18 are eligible for treatment with a brace. The most commonly used braces are the ones previously stated: the Boston brace and the Charleston brace. About 30,000 children are fitted with a brace to treat scoliosis every year. The braces, which act to prevent progression of the curve, are only effective in patients who have not reached skeletal maturity. Large studies indicate that braces, when worn to full term, successfully prevent curves progression in about 80 percent of patients.

Design Requirements

Free Body Diagram



The free body diagram on the left shows the values obtained from literature searches to determine the necessary forces needed for an effective brace. The Boston brace was examined for comparison. Lumbar forces are greater than thoracic forces due to the constraints of the rib cage and patient breathing. These numbers reflect the average force the brace exerts on a standing person. The range is from 0-727N for lumbar pressure and 4-209N for thoracic pressure and are based on the patient. Based on these measurements, we designed the Pittsburgh Flex Brace to exert forces on those specific areas. This combined with flexibility of movement were the inspiration of the design.

Final Prototype

A. Stabilizing Shoulder Strap
Maintains shoulder alignment
Velcro closure for easy adjustment and removal

B. Discreet Leotard Design
Wearable for maximum patient compliance
Complete with zipper for ease of removal

C. Thoracic Corrective Strap
Customized to support thoracic curve
Clips with buckle to allow ease of removal

D. Abdomen Stabilizer
Ensures proper alignment on the abdomen
Acts as anchor for corrective straps

E. Lumbar Corrective Strap
Customized to support lumbar curve
Clips with buckle to allow ease of removal

F. Anchoring Thoracic Strap
Opposes corrective strap to bring spinal balance
Ensures optimal and corrective placement

G. Spinal Stabilizer
Double supported to ensure proper alignment of the spine
Secures orthotic placement

H. Anchoring Lumbar Strap
Opposes corrective strap to bring spinal balance
Ensures optimal and corrective placement

Evaluation Testing

Strength and Pressure Testing: We used a cable machine to simulate forces on the straps much higher than would be present in a Boston Brace, then evaluated the pressure under each strap through the use of a sphygmomanometer. This shows the capability of our brace to withstand and exert the necessary pressures required from the free body diagram, while not exerting enough pressure to incur damage on the patient. This was done with the 2nd and the final prototype. The results of the final prototype are presented below.

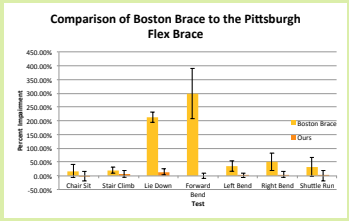
2nd Prototype: Testing 20 lbs on both straps with Sphygmomanometer applied to bottom strap

4th Prototype	0 lbs	1st Test	2nd Test	3rd Test	Notes
Bottom Strap	154 mm Hg	30 lbs: 169 mmHg	50 lbs: 176 mmHg	60 lbs: 184 mmHg	Mild Discomfort at 60 lbs
Chest Strap	160 mm Hg	30 lbs: 178 mmHg	40 lbs: 186 mmHg	50 lbs: 186 mmHg	Discomfort at 40+ lbs

Comparison of our design to Boston Brace: We had patients complete a series of tests wearing both the Pittsburgh Flex Brace and the Boston Brace to determine how restrictive our design is compared to what is currently used:

Chair Sit: Get up from sitting in chair, walk 15 ft to pick up an object, return to chair and sit
Stair Climb: Walk up and down one flight of stairs
Lie Down: Begin in standing position, lie down, and return to standing position
Left/Right/Forward Bend: Bend all the way forward, to the left, or to the right, record inches hand is from ground and farthest reach
Shuttle Run: Run 15 ft, bend down to pick up object, return to start point, drop object, run 20 ft, bend down to pick up object, return to starting point

Results: Each subject attempted each task with the Boston Brace, the Pittsburgh Flex Brace, and then with no brace and was either timed or measured. The trials with a brace worn were normalized to the task with no brace worn, and percentage changed was reported. The Boston Brace had the most impact on the lie down task and the forward bend task, while the Pittsburgh Flex Brace did not significantly impede subjects' ability to complete any of the exercises.



What Makes the Brace Novel?

- **Fully dynamic brace**: As seen in the results, the brace is fully dynamic and does not restrict a patient's breathing or every day movement.
- **Emphasis on patient compliance**: At the core of our design work was a focus on making sure patients are comfortable while receiving the same benefits of a rigid brace. As patients are often young girls, the brace must be appealing to them in order to improve the likelihood that they will wear it to the end of their treatment cycle. This is done by designing the brace in a manner that is familiar to young girls and by not adding difficult components.
- **Easy to use**: Compared to competitors the brace allows for greater independence as a patient would not need help putting this brace on and is straightforward so as not to confuse young patients.

Estimation of product costs

Bill of Materials:

Item:	Quantity:	Total Cost:
Leotard	1	$16.00
12" Zipper	1	$3.00
Nylon Straps	4	$6.00
Industrial Velcro	1	$1.50
Flexible Plastic Ruler	2	$2.00
Misc. Nylon Material	2	$0.10
Foam Comfort Pads	4	$5.00
Backpack Shoulder Strap	1	$10.00
Snap Buttons	3	$3.00
Spool of Thread	1	$3.00
Total Cost Materials		$49.60
Cost of Initial Seamstress Labor		$50.00
Cost of Seamstress Adjustments		$25.00

Total Brace Cost - $124.60

FDA Regulation

Physical Medicine Devices classification (as defined in 21 CFR Parts 890.349)
- 890.3490 TruncalOrthosis
- Class I device
- Exempt from 510(k) or PMA
- Does not require FDA clearance before US marketing
- This brace will be registered within generic category and classification name before distribution using FDA's Unified Registration and Listing System