Abstract

Our team has designed a new scoliosis brace. Scoliosis is the abnormal lateral curvature of the spine that is typically found in children and adolescents. Our solution, BraceAlign, applies a three point bending force to correct the curvature of the spine. BraceAlign will be more affordable, concealable, and adjustable for users of various sizes. This design will therefore be more accessible for users in third-world countries.

Clinical Need

Idiopathic scoliosis is a condition in which the patient has a curvature of the spine in the shape of an “S” or “C.” Scoliosis can cause respiratory problems and if left untreated can increase the progression of the curvature, exarcerbating symptoms. People in underdeveloped countries are particularly burdened by scoliosis because treatment is inaccessible or too expensive. Third world countries are in need of a low-cost technology to treat scoliosis. Current treatment methods include bracing or surgery, both of which are very expensive. The “gold standard” for braces is the Boston Brace, which covers the entire torso below the chest and is very uncomfortable. Therefore, there is a crucial need for an effective low-cost for scoliosis in underdeveloped countries that has the potential to increase compliance rate.

Market

- Target market: adolescent patients with mild to moderate scoliosis in developing countries
- For mild scoliosis, curvature is generally less than 25 degrees
- For moderate scoliosis, the curvature is around 25-45 degrees
- Severe scoliosis ( >45 degrees) requires surgical intervention
- Currently, no competitive market for scoliosis braces in developing countries
- Difficult for current braces to thrive in developing countries because frequent fittings and adjustments are required

Product Design

Design Features of BraceAlign
- Applies three-point lateral bending force to the torso
  - Mechanics are similar to that of the Boston Brace, but less restricting
- Symmetrical for use on either side
- Adjustable size
- Made for comfort and minimal restriction
  - It does not enclose the whole torso of the patient and allows the user to have a large range of motion
- Concealable under clothing
- Reduced cost
- Made from low-cost materials: polypropylene and polyester webbing straps

Final Prototype
- A. Polyester webbing straps
  - Secured with rivets
  - Adjusted with metal pin buckles
- Four polypropylene plates:
  - B. Shoulder plate
  - C. Apex plate
  - D. Waist plate
  - E. Leg plate
- Silicone on leg strap

The BraceAlign Solution
- One-size-fits-all scheme
- Low cost
- Eliminates the need for frequent doctor visits
- Reduces the severity of scoliosis with less restriction, leading to higher compliance

Table 1: Manufacturing Costs

<table>
<thead>
<tr>
<th></th>
<th>Tooling Cost</th>
<th>Material Cost</th>
<th>Production Cost</th>
<th>Strap and Buckle Cost</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (10,000 Units)</td>
<td>$15,000</td>
<td>$60,000</td>
<td>$15,000</td>
<td>$43,200</td>
<td>$133,200</td>
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<tr>
<td>Per Part</td>
<td>$1.50</td>
<td>$6.00</td>
<td>$1.50</td>
<td>$4.32</td>
<td>$13.32</td>
</tr>
</tbody>
</table>

- Manufacturing costs to create 10,000 bulk units
- Plastic Injection Molding will be used to create the supporting plates
- Straps will be woven and secured with rivets
- Buckles will be created using wire forming

Testing and Results

Comfort Tests
- To compare comfort level of our brace and the Boston Brace
- Subjective scale of comfort level: 0 (uncomfortable) - 5 (most comfortable)
- 5 test subjects

Force Tests
- To test if the brace can withstand and apply adequate force to reduce spinal curvature by 50% (31N - 113N is the required force)
- Process is modeled after Newton scale
  - Attached spring to the Apex plate of the brace
  - Measured the displacement of the spring as force was applied laterally
  - Calculated spring constant and determined maximum force
  - Maximum force apex plate can apply: 160N

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References