An Interspinous Implant to Improve Dynamic Motion in the Lumbar Spine Region

Rachel Bordin, Allen Kim, Gina Lu, Bryce Pardoe, Eric Volk

Department of Biomedical Engineering
Carnegie Mellon University, Pittsburgh, Pennsylvania
Professor Conrad Zapanta | Mentor Boyle Cheng, PhD

Problem and Clinical Need

- Lumbar spinal stenosis affects 8-11 percent of the population in the United States, with an estimated 24 million affected by 2021.
- While minor back pain can be eliminated using physical therapy and pain medication, more severe forms of back pain require surgery.
- Current procedures are able to relieve the pain through a decompression and fixation procedure, but fail to maintain dynamic motion of the spine.

Potential consumer base is 6 million people, but realistically target market is 500-800 thousand people.
- Customers are hospitals and the end users are patients with lumbar spinal stenosis.

What is Novel?

- The device takes the best features of interspinous fusion, interspinous spacers, and facet replacement systems.
- The device is a semi-interspinous device that provides the stabilization of a facet replacement system and the minimally invasive surgical procedures of an interspinous device.

Simulation

- A static simulation was performed to determine factor of safety and evaluate modes of failures.
- Simulations were performed to determine FoS in:
  - Flexion: 13.5
  - Extension: 13.6
  - Torsion: 7.0

Production Costs

- Material selection:
  - Titanium alloy Ti6Al7Nb primary structure
  - Cobalt-Chrome alloy CoCrMo articulating surfaces
- Costs include raw materials, machining, plating, and pedicle screws.
- Estimates for machining and plating estimated with approximate quotes for production given a batch size of 500-1000.
- Price comparison: average spinal implant cost - $13,000.

<table>
<thead>
<tr>
<th>ITEM</th>
<th>COST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium Alloy</td>
<td>$50/kilogram(kg) * 0.0518kg = $2.59</td>
</tr>
<tr>
<td>Titanium Machining</td>
<td>$2,200/unit</td>
</tr>
<tr>
<td>Cobalt-Chrome Plating</td>
<td>$150/unit</td>
</tr>
<tr>
<td>Pedicle Screws</td>
<td>2 * $600 = $1,200/unit</td>
</tr>
<tr>
<td>TOTAL COST PER UNIT</td>
<td>~ $3,550/unit</td>
</tr>
</tbody>
</table>

Acknowledgements

- We would like to thank Professor Conrad Zapanta and Mentor Boyle Cheng, PhD, for their constant support and helpful guidance.

References