Designing a Novel Fixation Device for Pediatric Orthopaedic Tibia Fractures

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Overview

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Problem Statement

- Tibia fractures are common in children

- **Need for a surgically implanted device, which would provide more structural stability and aid in healing of the fracture**

- Last semester, we designed a new device, which uses compressive force on a metal biaxial braid to provide pressure inside the canal for stabilization.
  - The centerpiece of the device failed
  - Client had recommended improvements

- **This semester’s focus:**
  - Optimizing previous semester’s design
    - Centerpiece
    - Braid/cap interface
Background

• 5% of pediatric fractures occur at tibia[1]

• Tibia is a load bearing bone
  • Correct alignment is essential

• Many bone fractures can be set with a cast or a splint

• Misalignment of tibia may require surgery followed by serial casting to repair the injury
Background

- Differences in child and adult tibia
  - Epiphyseal growth plates at proximal and distal ends of bone
  - Involved in growth spurt during puberty

- Growth plates must be avoided in all surgical procedures for pediatric patients
  - May lead to growth complications and more surgery if disturbed

[3]
Current Device: Elastic Nails

Made of titanium

2 elastic nails = six areas of contact meant to provide constant pressure and stabilization for fractured tibia\(^4\)

- Avoids growth plate
- Optimal function with mid-bone fracture
- No rotational fixation
Product Design Specifications

• **Function**
  • Improve stability of pediatric tibia fracture for healing

• **Design Requirements**
  • **Performance**
    • Flexible to enter bone (7mm at 45° angle)
    • Bending stiffness of fiberglass cast
    • Can be removed after 2-9 months
  • **Size**
    • Fits in tibial intramedullary canal
  • **Safety**
    • Biocompatible
      • Surgical grade metals
    • Easily sterilized
  • **Standards and Specifications**
    • FDA guidelines for implants
Previous Work – Braided Cylinder

- *Braided Cylinder*
  - Stainless steel biaxial braid
  - Axial Compression $\rightarrow$ Radial Expansion
  - $\uparrow$ Surface Area results in $\uparrow$ axial fixation
Car Jack – Design 1

- **Car Jack Centerpiece**
  - Several jointed threaded stainless steel segments
  - Make rod flexible for 45° insertion
  - Mid cap advances toward end cap

- **Pro:**
  - Easy to implant

- **Cons:**
  - Torsional strain
  - Complex
K-Wire – Design 2

- Centerpiece is K-Wire
  - Flexible threaded stainless steel rod
  - Currently used in surgical applications
- Caps not threaded
  - Use nut above top-cap to provide compressive force
  - Bottom cap fixed to K-wire
- *Pro:*
  - One rigid piece
- *Con:*
  - More difficult to implant
Segmented Threads – Design 3

- Segmented threaded stainless steel pieces welded to a wire
- A nut would screw down free-sliding top cap from segment to segment

Pro:
- One piece

Con:
- Torsional rigidity
### Design Matrix – Centerpiece

<table>
<thead>
<tr>
<th>Parameters (Weight)</th>
<th>Last Semester’s Design</th>
<th>K-Wire</th>
<th>Piano Wire with Segmented Threads</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tensile Strength (30)</td>
<td>2</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>Ease of Implantation and Removal (25)</td>
<td>4</td>
<td>20</td>
<td>2</td>
</tr>
<tr>
<td>Client Preference (20)</td>
<td>2</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>Fabrication (15)</td>
<td>2</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Cost (10)</td>
<td>1</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Total (100)</td>
<td>48</td>
<td>85</td>
<td></td>
</tr>
</tbody>
</table>
Optimization of Braid/Cap

Inside Cap

Underside of Cap

Side of Cap
## Design Matrix – Braid/Cap

<table>
<thead>
<tr>
<th>Parameters (Weight)</th>
<th>Braid welded inside caps</th>
<th>Braid welded to underside of caps</th>
<th>Braid welded to side of caps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of inversion (40)</td>
<td>2 16 5 40 4 32</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stress on Weld (40)</td>
<td>5 40 4 32 2 16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fabrication (10)</td>
<td>1 2 3 6 4 8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost (10)</td>
<td>2 4 5 10 5 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (100)</td>
<td>62</td>
<td>88</td>
<td>66</td>
</tr>
</tbody>
</table>
Final Design

- K-wire centerpiece
- Braid welded under cap
- Top cap not threaded
- Nut on K-wire above top cap to provide compressive force
- Bottom cap fixed to K-wire
Future Work

• Preliminary testing of braided cylinder
• K-wire 3-point bend test – stress-strain curve
• 6-ply fiberglass cast 3-point bend test – bending stiffness
• Design tool to twist nut during surgical implantation and removal
• Order Materials & Fabrication
• Test prototype – 3-point bend test
  • Bending stiffness – match or exceed 6-ply fiberglass cast
  • Compare to elastic nails
  • Mode of failure
Acknowledgements

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• Dr. Paul Thompson, PhD
References


