Designing a Novel Fixation Device for Pediatric Orthopaedic Tibia Fractures

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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**

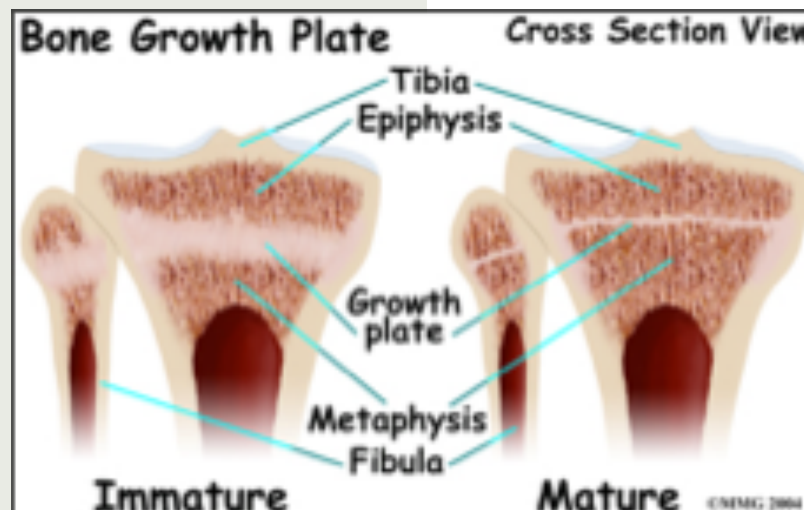
Background

- 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

[2]

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



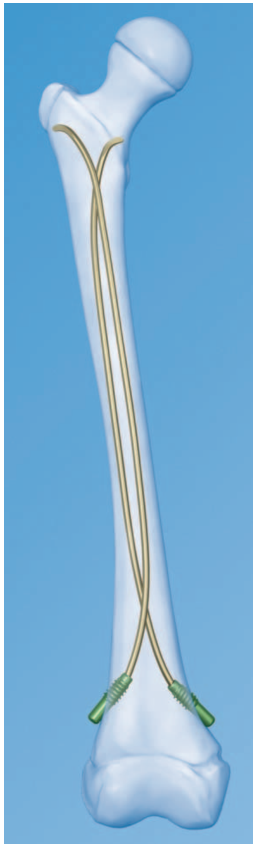
[3]

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



[6]

[7]

Product Design Specifications

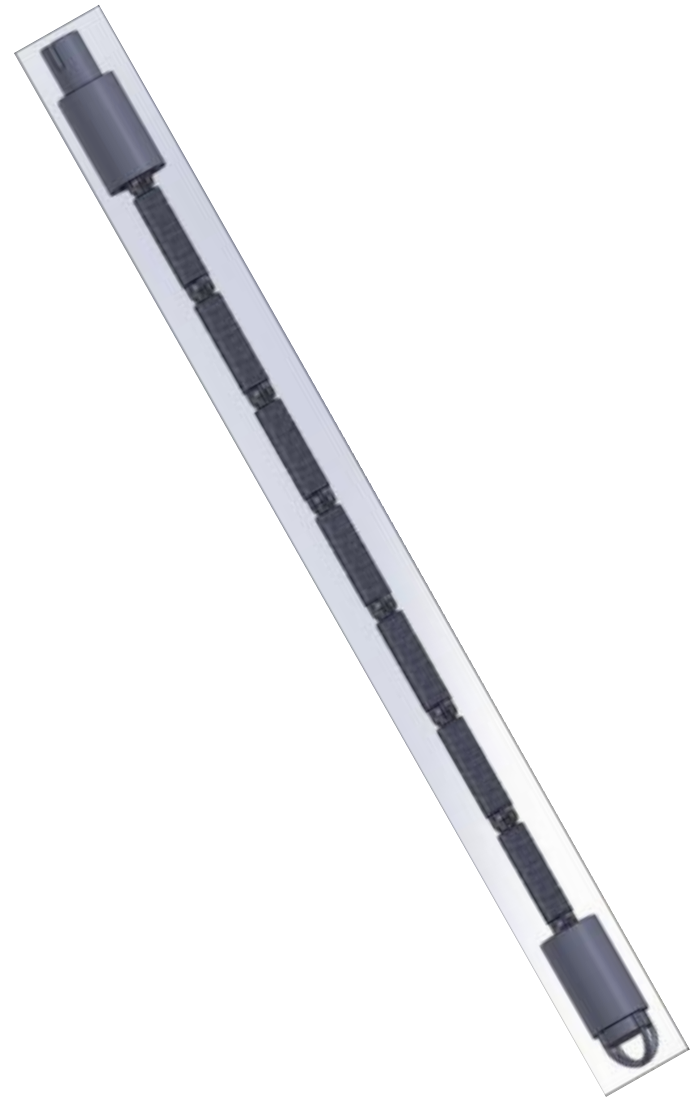
- *Function*
  - Improve stability of pediatric tibia fracture for healing
- *Design Requirements*
  - *Performance*
    - Flexible to enter bone (7mm at 45° angle)
    - Bending stiffness of fiberglass cast
    - Can be removed after 2-9 months
  - *Size*
    - Fits in tibial intramedullary canal
  - *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 → Radial Expansion
  - ↑ Surface Area results in ↑ axial fixation

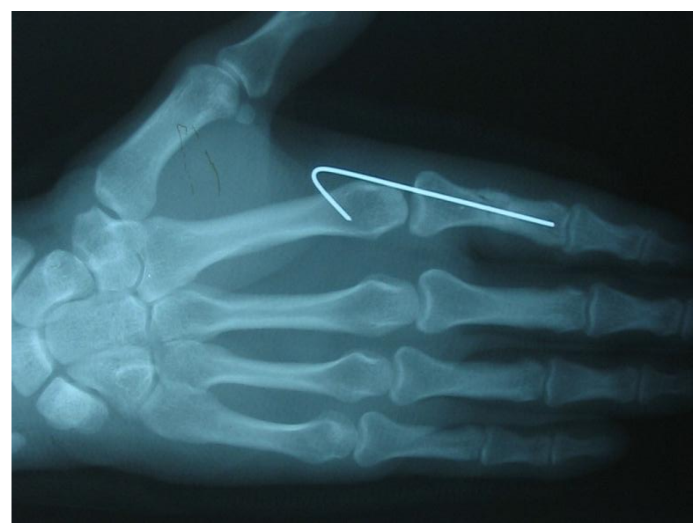
Car Jack – Design 1

- *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



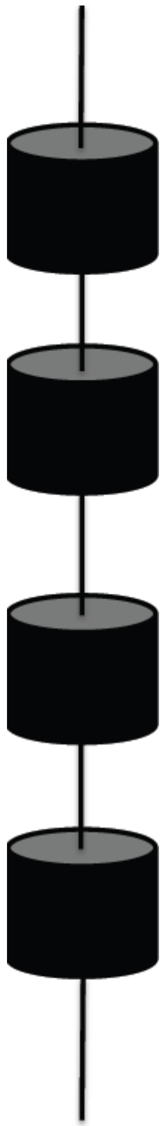
K-Wire – Design 2

- *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

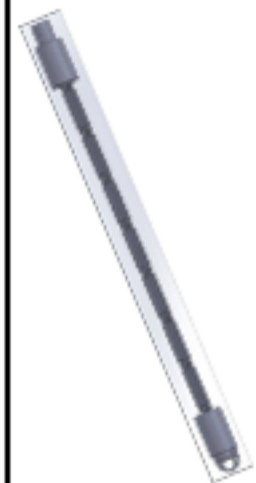
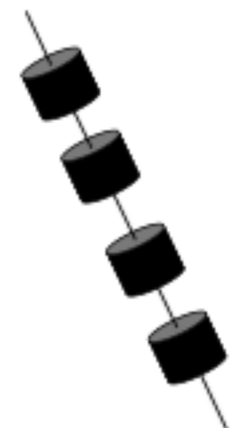


Segmented Threads – Design 3

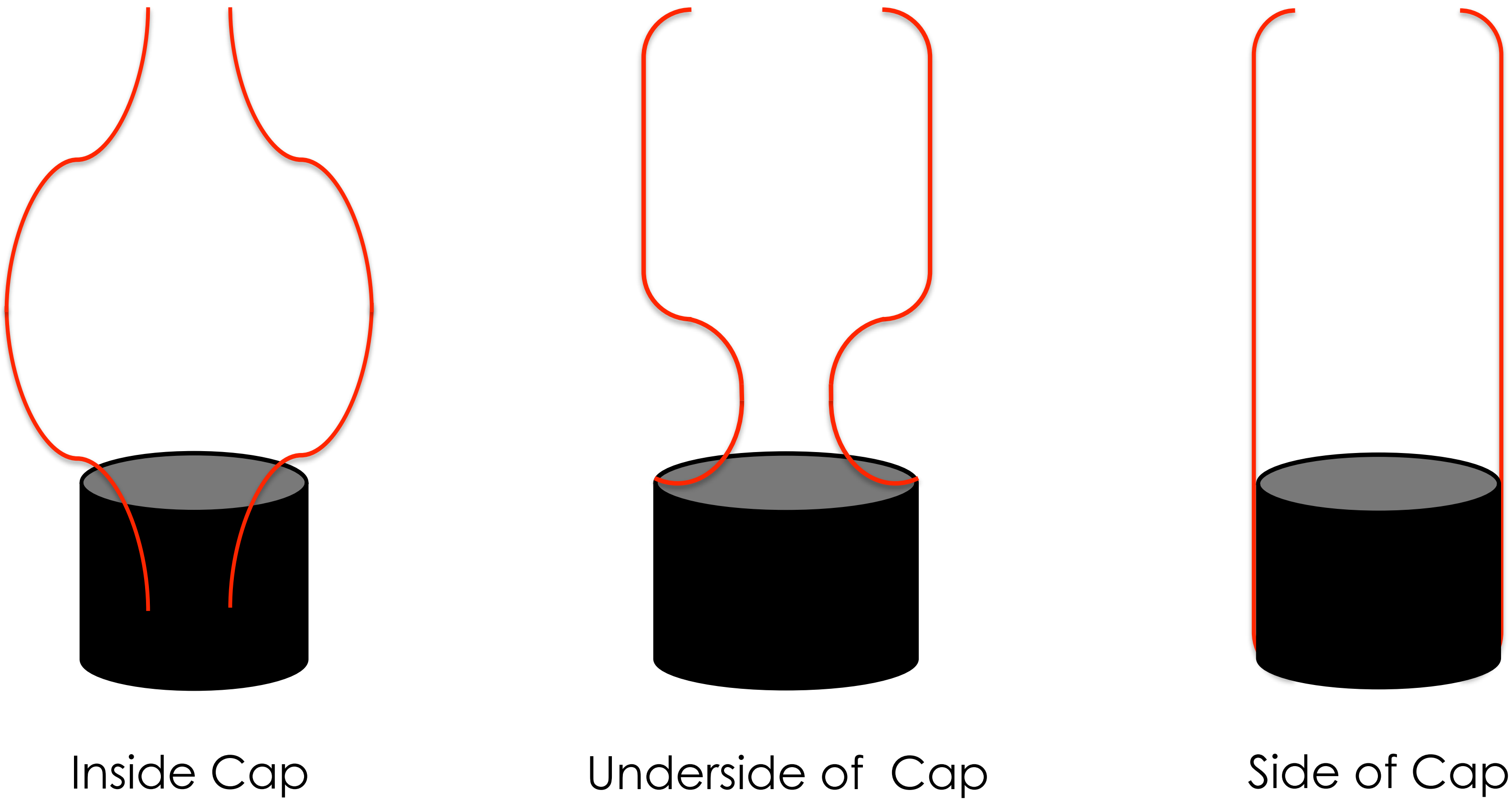
- Segmented threaded stainless steel pieces welded to a wire
- A nut would screw down free-sliding top cap from segment to segment
- *Pro:*
  - One piece
- *Con:*
  - Torsional rigidity



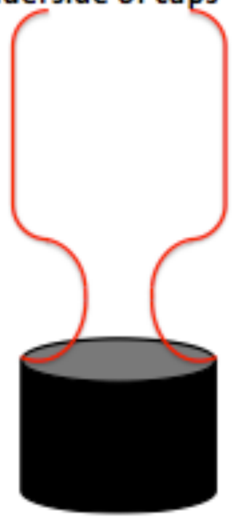
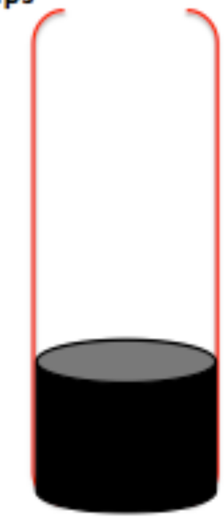
Design Matrix – Centerpiece

Parameters (Weight)	Last Semester's Design		K-Wire		Piano Wire with Segmented Threads	
						
Tensile Strength (30)	2	12	5	30	3	18
Ease of Implantation and Removal (25)	4	20	2	10	5	25
Client Preference (20)	2	8	5	20	3	12
Fabrication (15)	2	6	5	15	4	12
Cost (10)	1	2	5	10	4	8
Total (100)	**48**		**85**		**75**	

Optimization of Braid/Cap

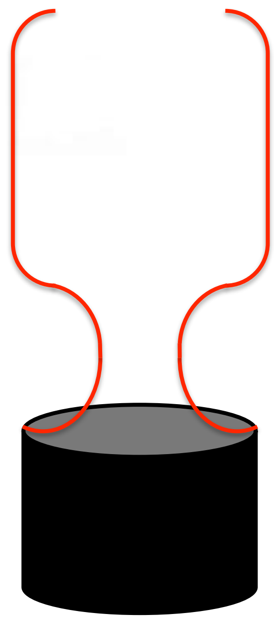


Design Matrix – Braid/Cap

<u>**Parameters (Weight)**</u>	**Braid welded inside caps** 		**Braid welded to underside of caps** 		**Braid welded to side of caps** 	
Risk of inversion (40)	2	16	5	40	4	32
Stress on Weld (40)	5	40	4	32	2	16
Fabrication (10)	1	2	3	6	4	8
Cost (10)	2	4	5	10	5	10
Total (100)	**62**		**88**		**66**	

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

- Dr. Matthew Halanski, MD
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- Dr. Paul Thompson, PhD

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Questions

References

[1] Mashru, R. P., Herman, M. J., & Pizzutillo, P. D. (2005). Tibial shaft fractures in children and adolescents. American Academy of Orthopaedic Surgeons, 13(5), 345-352.

[2] http://radiopaedia.org/images/25340

[3] http://www.orthopediatrics.com/docs/Guides/blounts.html

[4] Synthes. 1998. The Titanium Elastic Nail System: Technique Guide. Adapted from <http://www.rcsed.ac.uk/fellows/lvanrensburg/classification/surgtech/ao/manuals/Synthe s%20TENS%20nails.pdf>

[5] He B, Wang J. Plate fixation of paediatric fractures of the distal tibia and fibula. *Acta Orthop Belg.* 2012 Oct; 78(5): 660-2.

[6] http://www.synthes.com/MediaBin/International%20DATA/036.000.207.pdf

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[8] Wheeless, Clifford, MD. 2012. Tibial Fractures: Techniques of IM Nailing. Wheeless' Textbook of Orthopaedics.

[9] Lee, Z., Chang, C., Yang, W., Hung, S. (2005). Rush pin fixation versus traction and casting for femoral fracture in children older than seven years. Med. J. 28: 9-15.