# Improving Fixation of a Previously Designed Pediatric Tibial Stent

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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.**
- A previous design team produced a working device, which is held in place by static friction against the canal wall.
  - not fully fixated against the walls of the bone canal, and the friction force of the device is not sufficient to prevent axial rotation within the canal.
- Previous semester's work:
  - Designed pediatric tibial stent
- **This semester's focus:**
  - **Improving fixation of previous semester's design**

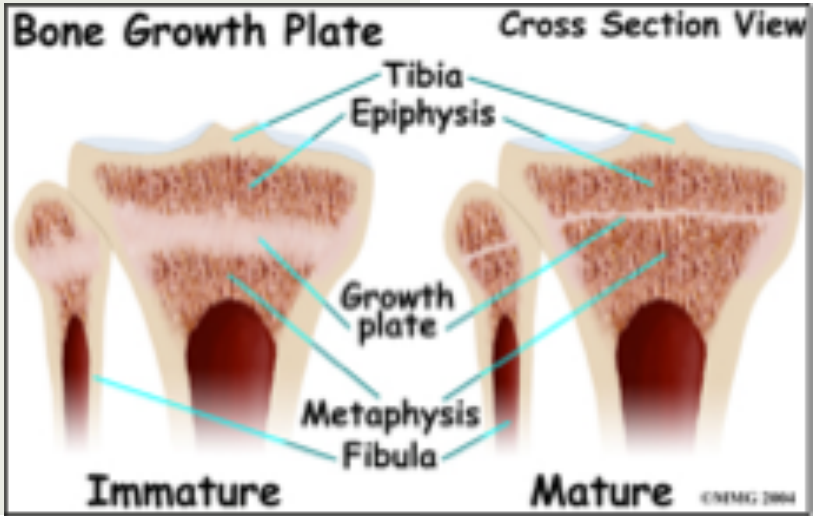
# Background

- 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; however, the 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 Devices: Rigid Intramedullary Device

Titanium rod

- Rod is rotationally fixed and is further stabilized by lateral screws installed at proximal and distal locations[8]
- Inserted into the bone at the top passing through the epiphyseal growth plate
  - Cannot be used for pediatric patients


[9]

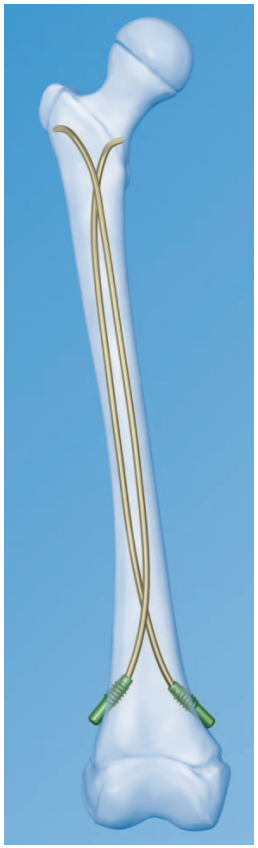
# Current Devices: Elastic Nails

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

- Diameter of elastic nails = 2.5 – 4 mm[5]

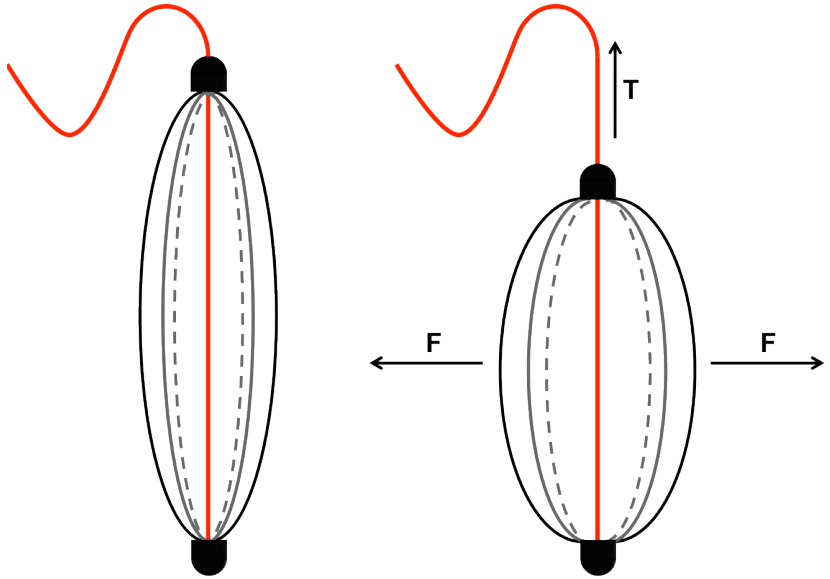


[6]

[7]

# 400/402 Design Overview

- Center cable is galvanized steel; outer wires are stainless steel
- End cap and mid-cap
- Fixed at bottom with nail
- Converts tensile force into radial force which stabilizes fracture
- Increases points of contact compared to elastic nails

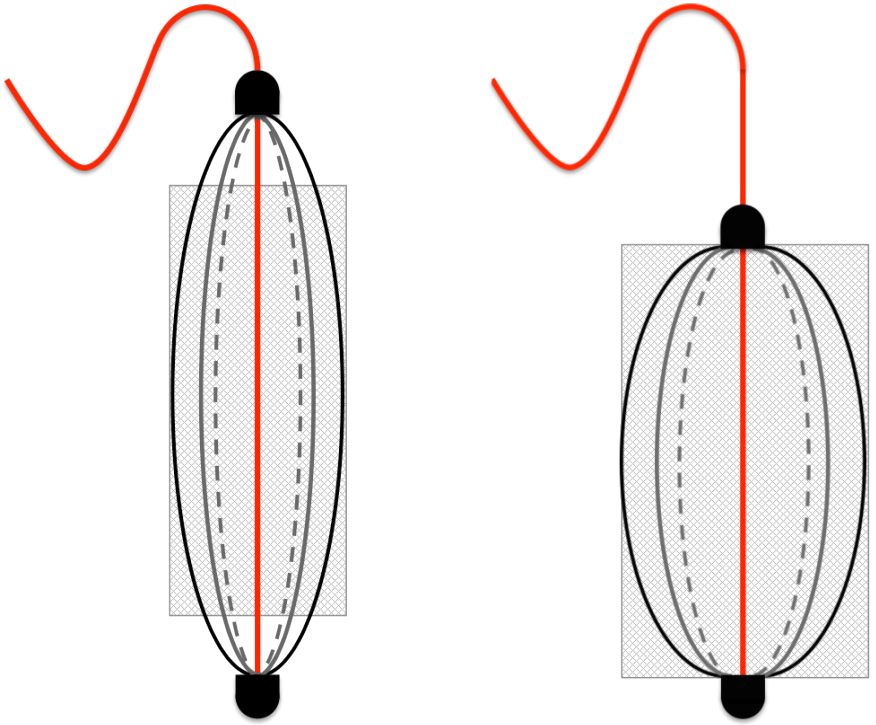



# Product Design Specifications

- *Function*
  - Improve fixation by limiting axial rotation
- *Design Requirements*
  - *Performance*
    - Flexible to enter bone (45° angle)
    - Rigid to stabilize fracture
    - Can be removed after 2-9 months
  - *Size*
    - Match dimensions of previous semester's design
  - *Safety*
    - Biocompatible
      - Surgical grade metals
    - Easily sterilized
  - *Standards and Specifications*
    - FDA guidelines for implants

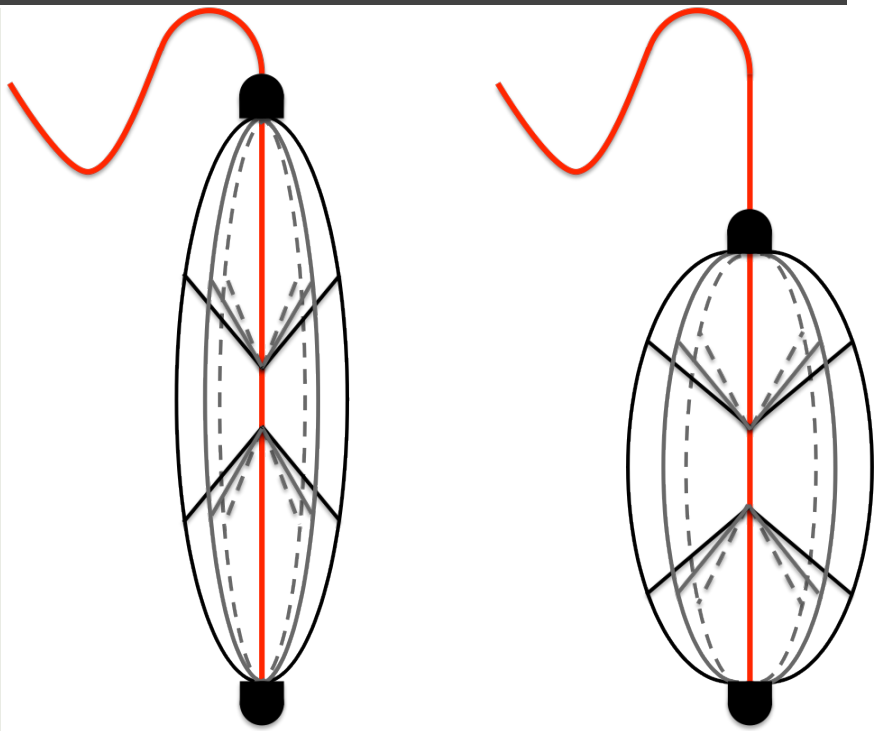
# Design Alternative 1: Mesh Cylinder

- Based on arterial stent
- Weave stainless steel wires through mesh to hold in place and prevent buckling
- When device is expanded, mesh also expands
- Provides increased surface contact with interior of medullary canal



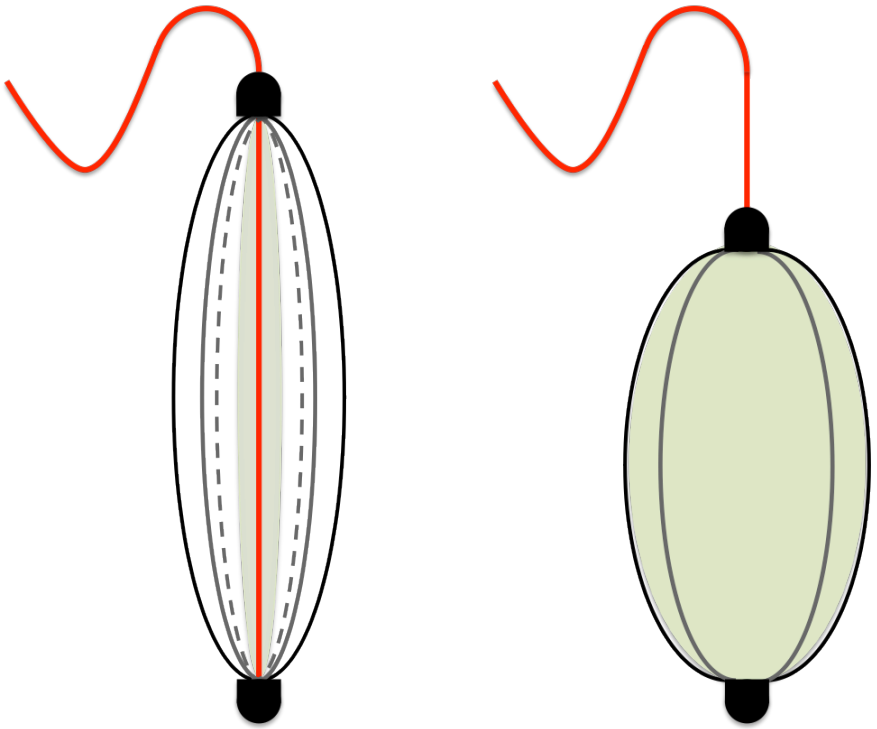
# Design Alternative 2: 2-sided Umbrella

- Based on folding umbrella design
- Rigid wire attached to galvanized steel cable
  - Prevents displacement and buckling of wires
- Used to increase radial force as device is expanded

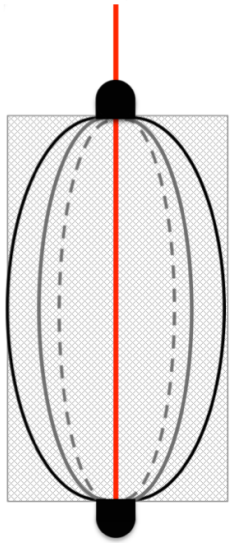
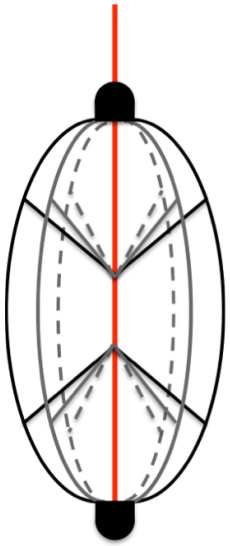
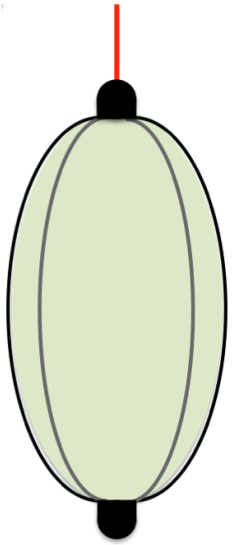


# Design Alternative 3: Air Balloon

- Inflatable bladder within device attached at end and mid-caps
- After device is expanded, bladder inflated with compressed air
- Prevents buckling of wires and adds to radial force of the device



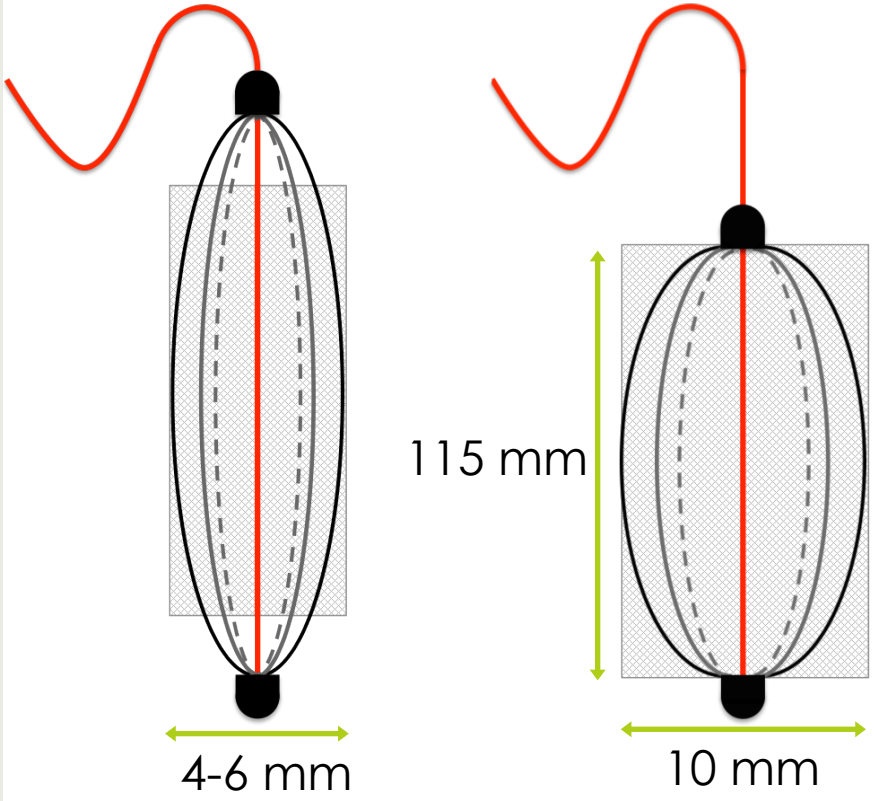
# Design Matrix

| **Parameters (weight)** | **Design 1: Mesh Cylinder**  | | **Design 2: 2-Sided Umbrella**  | | **Design 3: Inflated Air Bag**  | |
|---|---|---|---|---|---|---|
| Fixation (30) | 4 | 24 | 3 | 18 | 3 | 18 |
| Radial Force (20) | 3 | 12 | 4 | 16 | 3 | 12 |
| Ease of Entry (20) | 3 | 12 | 2 | 8 | 4 | 16 |
| Safety/Biocompatibility (15) | 5 | 15 | 4 | 12 | 2 | 6 |
| Feasibility/Fabrication (10) | 4 | 8 | 2 | 4 | 2 | 4 |
| Total Fabrication Cost (5) | 2 | 2 | 3 | 3 | 2 | 2 |
| Total (100) | **73** | | 61 | | 62 | |

# Design Selection:

Mesh Cylinder Design

- Easiest to fabricate
- No biocompatability concerns – all metal
- Longest canal-device interface due to surface area increase
- Made with surgical grade stainless steel or tantalum mesh – biocompatible



# Future Work

- Obtain previous semester's device
- Order materials for mesh cylinder
- Fabricate mesh cylinder prototype
- Integrate prototype with existing device
- Test integrated device
  - MTS testing of integrated device
  - Static friction testing of integrated device

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  - Kyle Jamar
  - Stephen Kernien
  - Lucas Schimmelpfenning
  - Cody Bindl


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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

[7] Adapted from http://www.tradeindia.com/fp580819/Titanium-Elastic-Nail.html

[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.