A NOVEL FIXATION DEVICE FOR PEDIATRIC ORTHOPAEDIC TIBIA FRACTURES

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Abstract

Pediatric complete tibia fractures are common and are currently managed non-operatively by casts; however, a surgically implanted device would provide more structural stability and expedite bone healing. Elastic nails are now used to surgically fix such fractures, but do they not provide rotational fixation or sufficient stabilization of non-medial fractures. A previous design team's device addressed this problem, but failed to provide adequate rotational fixation. Axial rotation within the bone could lead to device failure, unnecessary pain, and extra corrective surgery. This semester's goal is to improve the pre-existing device's strength and axial fixation. The device must provide stability but be flexible enough for 45-degree implantation into the intramedullary canal of the tibia without disturbing the epiphyseal growth plates. The new design is a segmented center rod with a threaded mid cap and laterally restricted end cap. When the center rod is rotated, the mid cap moves down towards the end cap compressing the surrounding biaxial braided cylinder made of metal ribbon. This braid expands under compression, pushing against the canal wall, and stabilizing the fracture. Future work includes strengthening the joints of the center rod, fabrication, assembly, and experimentally determining the bending and rotational stiffness of the device.

Background

Motivation & Current Devices

Problem Motivation

- 5% of pediatric bone fractures are tibia fractures (**Figure 1**)
- 5% of pediatric tibia fractures cannot be addressed by casting alone
- Weight bearing bone requires proper healing for development[2,3]
- Epiphyseal growth plates at proximal and distal ends of tibia[4]

Figure 1. X-ray of pediatric complete tibia fracture.[1]

Current Devices

Elastic Nails (Figure 2):

- Two bent titanium nails inserted into the side of the bone[5]

Figure 2. Elastic nails implanted in pediatric femur. The location of implantation is similar for the tibia. Implantation avoids growth plates.[4]

- Most common technique for pediatric tibia fractures
  - Avoids growth plates[5]
- *Problems: Surface contact restricted to mid-point of bone*
  No rotational fixation[6]

BME 400/402 Design (Figure 3):

- Converts tensile force (red) to radial force (blue):

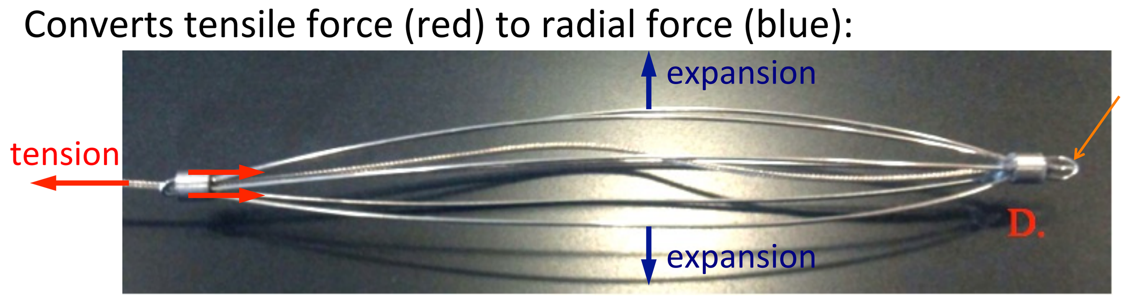


Figure 3. Device consisting of a galvanized steel cable attached to an end cap and threaded through a mid cap. Bowed wires run from the mid to end cap that provide radial force once tensile force is applied to the center cable.[7]

- Center cable held in tension by extender with a cable lock at the end[7]
- *Problems: Insufficient axial fixation*[7]
  Extraneous material
  Not rigid enough to use without a cast

Problem Statement

- Device must provide structure and stability for complete pediatric tibia fractures
- Avoid epiphyseal growth plates
- **This semester**:
  - Increase rigidity compared to previous device
  - Increase axial fixation compared to previous device

Design Specifications

- Limit axial rotation
- Rigid to stabilize fracture
- Implanted in the intramedullary canal avoiding growth plates (45˚ angle)
- Implanted for 6-9 months
- Visible on x-ray for implantation procedure
- Biocompatible and complies with FDA implant guidelines

Final Design

Braided Cylinder:

- Stainless steel biaxial braid between two caps
- Axial compression ➔ Radial expansion
- 🡅 Surface area results in 🡅 axial fixation

Car Jack Centerpiece:

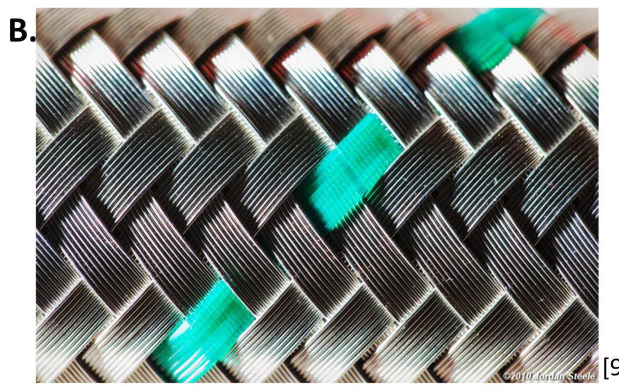
- Several jointed threaded stainless steel segments
- Makes rod flexible for 45˚ insertion
- Mid cap threaded, end cap free sliding

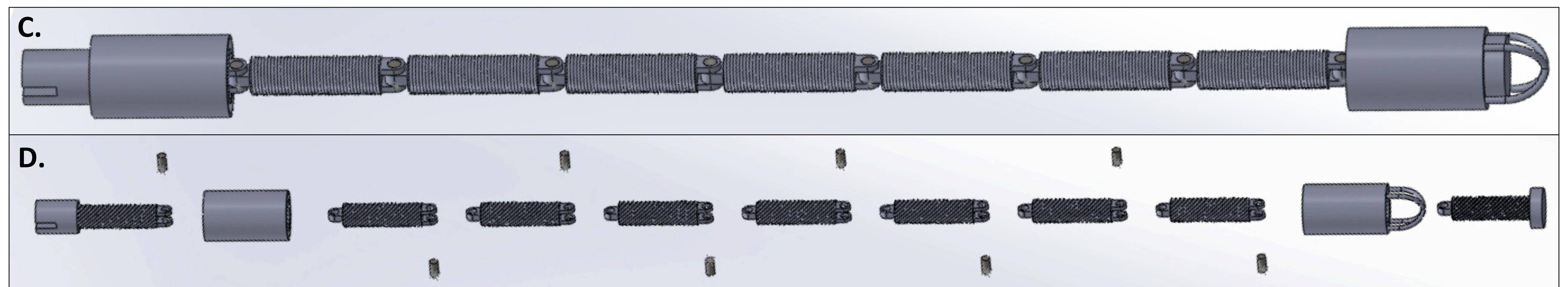
Operation:

- When centerpiece is rotated:
  - Braid prevents mid cap from rotating
  - Mid cap advances toward end cap
  - Compression causes braid expansion

A.

B.





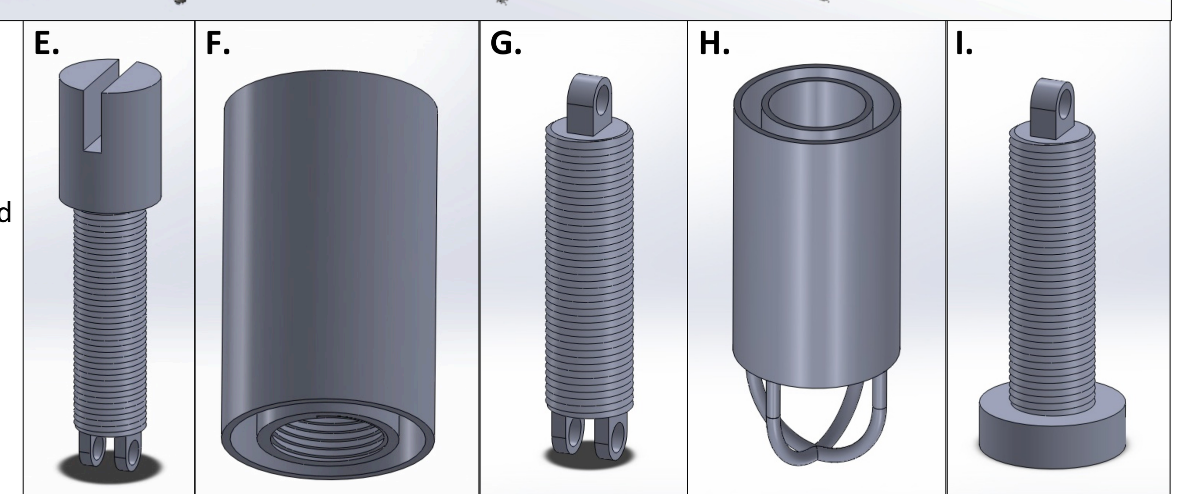
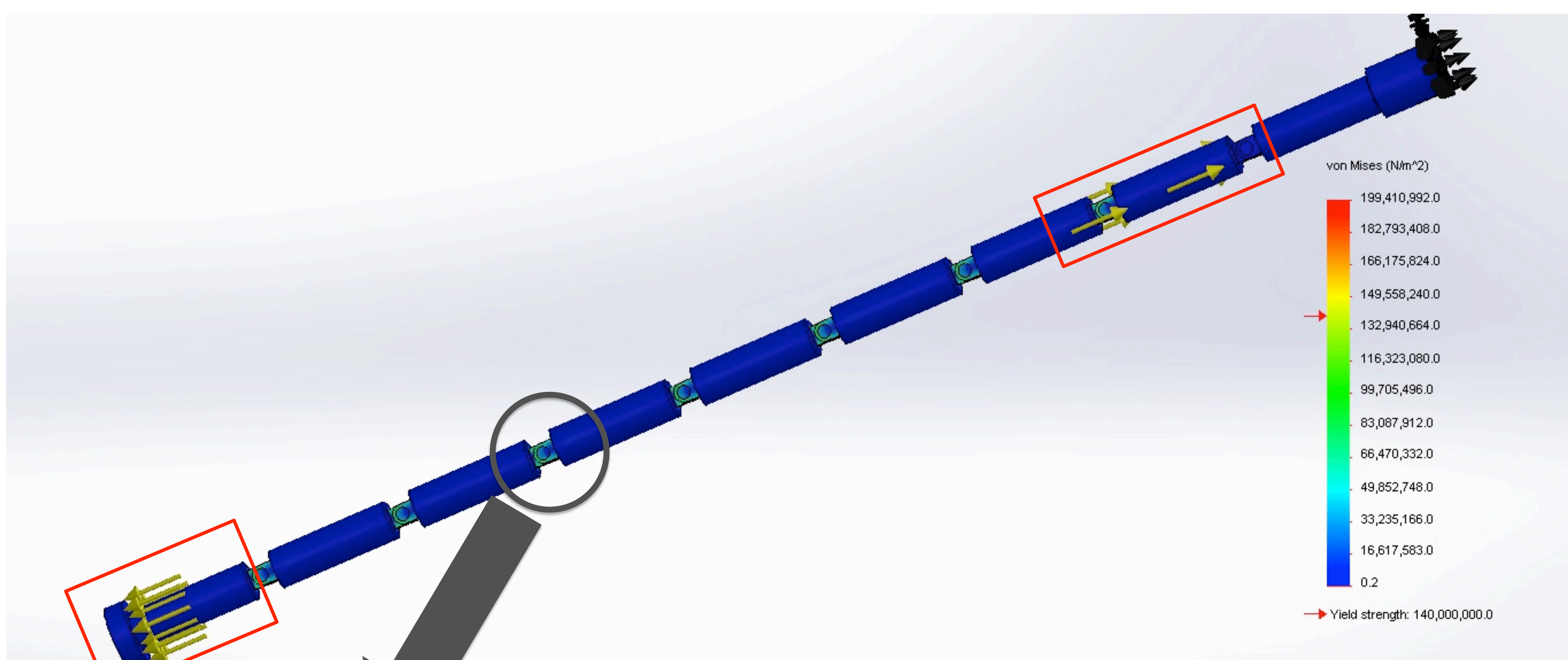


Figure 4.
A. Stainless steel biaxial braid surrounding centerpiece
B. Magnified image of stainless steel biaxial braid
C. Assembly of segmented centerpiece
D. Exploded view of segmented centerpiece
E. Top centerpiece segment
F. Threaded mid cap
G. Centerpiece segment
H. End cap
I. Bottom centerpiece segment

Simulation & Results



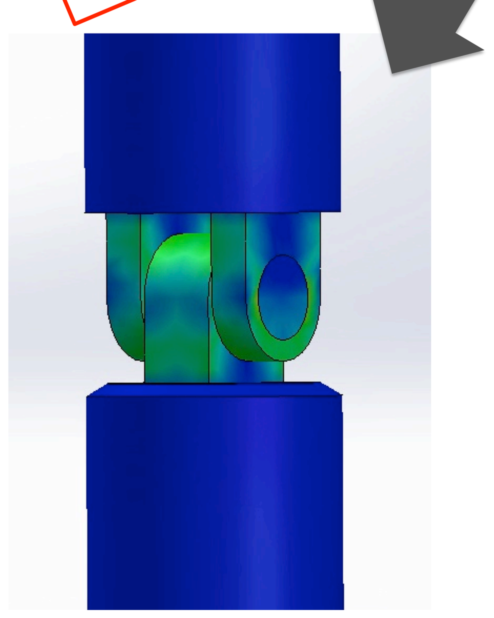


Figure 5. Von Mises stress simulation plot of mid and end cap loading configuration on simplified centerpiece (above) & magnified view of single joint (left). The majority of stresses within the centerpiece are concentrated at the joints. Thus, the expected mode of failure is pin pull-through.

Simulation Results:

Value	304 Stainless Steel	Titanium
Yield Strength	206.807 MPa	140 MPa
Maximum Displacement	123.792 µm	182.494 µm
Maximum Load	30.1884 N	28.8156 N
Factor of Safety	1.0	1.0

Table 1. Von Mises stress simulation results for the segmented centerpiece made of both stainless steel 304 and titanium. Neither of these two materials is strong enough to withstand the forces we would like to apply for this design. Stainless steel 304 has almost identical material properties as surgical grade stainless steel (309).

Conclusion: Current joint design not strong enough for this device

Materials and Expenses

Material	From	Price
TechFlex Flexo-Braided Stainless Steel	Wirecare.com	$47.15
Proof-of-Concept Parts	Home Depot	$9.70
Final Total	$56.85	

Table 2. Expenses for project

Future Work

- Optimize joints ➔ increase maximum load and factor of safety
- Design method to rotate centerpiece that also avoids growth plates
- Order centerpiece and caps from fabrication firm
- Fabricate metal ribbon braided cylinder ➔ customize expansion properties
- Testing:
  - Centerpiece tensile strength test ➔ confirm SolidWorks predicted failure load
    - Use same loading configuration as simulation
  - Determine apparent bending stiffness and rotational stiffness of implanted device

3-Point Bend Testing

Bending stiffness:

$$k = P/d$$

Goals:

- Increase in bending stiffness from previous semester's device (t-test: $p < 0.05$)
- Bending stiffness ≥ 15N/µm (stiffness of intact bone)

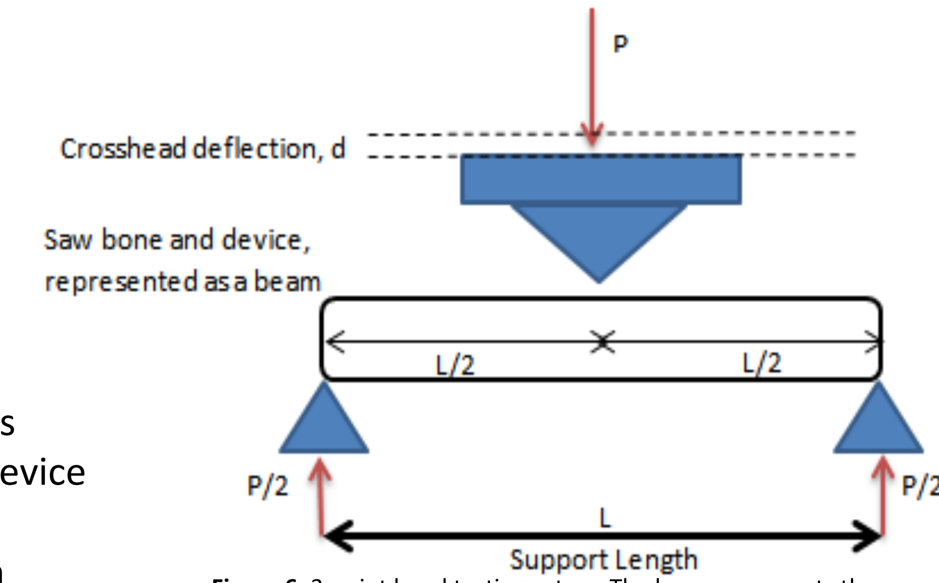


Figure 6. 3-point bend testing setup. The beam represents the device implanted inside of a Sawbone model. It is supported at both ends and a load is applied by the MTS machine at the midpoint. Displacement is also measured by the MTS machine.

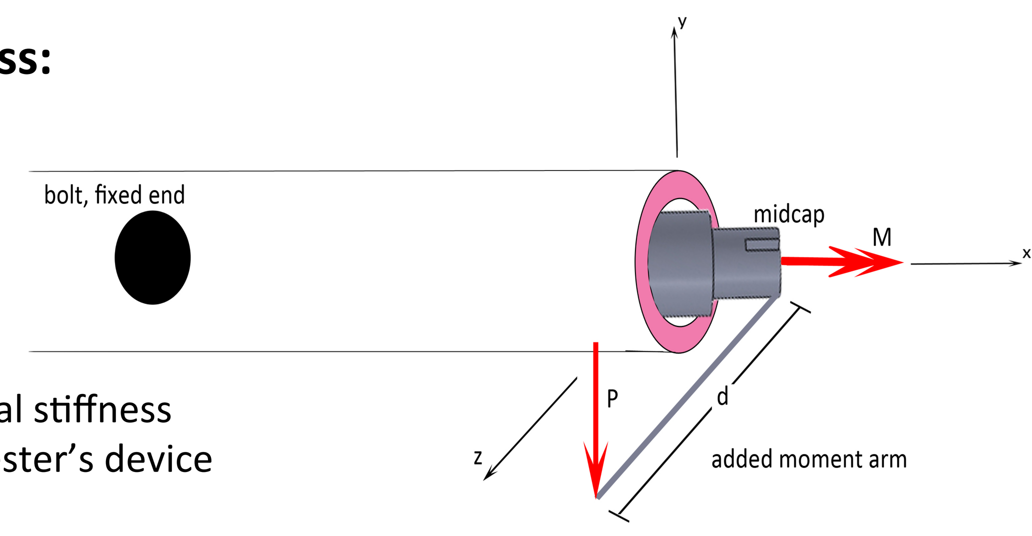
Rotational Testing

Rotational stiffness:

$$k = M/\theta$$

Goal:

- Increase in rotational stiffness from previous semester's device (t-test: $p < 0.05$)



- Osseointegration testing of braid
- Cadaver and animal testing of implant

Figure 7. Rotational testing setup of device implanted in Sawbone model. A moment arm is added to the device contacting both the mid cap and centerpiece. The MTS machine applies a load at the end of this moment arm and measures the displacement.

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