A NOVEL FIXATION DEVICE FOR PEDIATRIC ORTHOPAEDIC TIBIA FRACTURES

UW BME Design

TEAM: Evan Lange, Karl Kabarowski, Tyler Max, Sarah Dicker

CLIENT: Matthew Halanski, MD, School of Medicine and Public Health, Department of Orthopedics and Rehabilitation – University of Wisconsin - Madison

ADVISOR: Professor Paul Thompson, PhD, Department of Biomedical Engineering – University of Wisconsin - Madison

THE UNIVERSITY of WISCONSIN MADISON

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, expedite bone healing, and limit uncomfortable casting for the patient. Elastic nails are now used to surgically fix such fractures, but do they not provide rotational fixation or sufficient stabilization of non-medial fractures. Insufficient stabilization and/or axial rotation within the bone could lead to device failure, unnecessary pain, and corrective surgery. This semester's goal is to design a device than will incorporate a metal biaxial braid to provide bending and rotational stiffness for the fractured bone. The device must be flexible for 45˚ insertion into the intramedullary canal of the tibia without disturbing the epiphyseal growth plates. A nut above a free-sliding top cap is twisted down a threaded K-wire centerpiece with the use of a flexible drive shaft, which moves the top cap toward the bottom cap and compresses the surrounding metal biaxial braid. This braid then expands, pushing against the canal wall and stabilizing the fracture. Our data show that this new device has a higher rotational stiffness, but a lower bending stiffness compared to elastic nails. Future work includes improving the mechanical properties of the braid by altering the braid structure and eliminating the use of non-biocompatible components during fabrication to advance this device toward a clinical setting.

Background

Motivation & Current Devices

Problem Motivation

- ~3,100 pediatric bone fractures occur each year[2]
- 15% of pediatric bone fractures are tibia fractures[2]
- 5% of pediatric tibia fractures cannot be addressed by casting
- Weight bearing bone requires proper healing for development[3,4]
- Epiphyseal growth plates at proximal and distal ends of tibia[5]

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

Current Devices

Elastic Nails:

- 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.[5]

- Most common technique for pediatric tibia fractures
  - Avoids growth plates[6]
- *Problems: Surface contact restricted to mid-point of bone*
  - *No rotational fixation*[7]

Previous Semester Progress

Braided Cylinder:

- Stainless steel biaxial braid
- Axial compression → Radial expansion
- ↑ surface area results in ↑ axial fixation

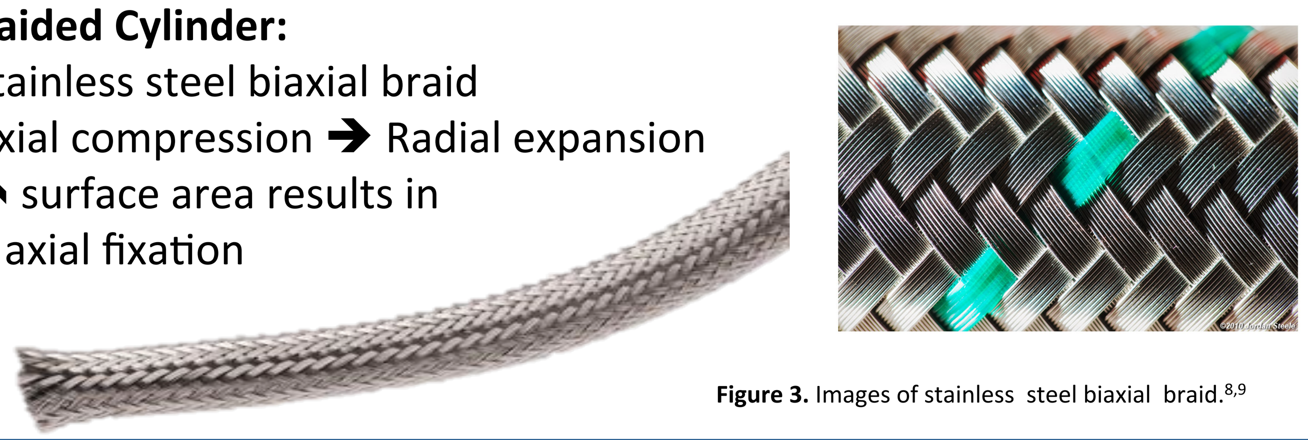


Figure 3. Images of stainless steel biaxial braid.[8,9]

Problem Statement

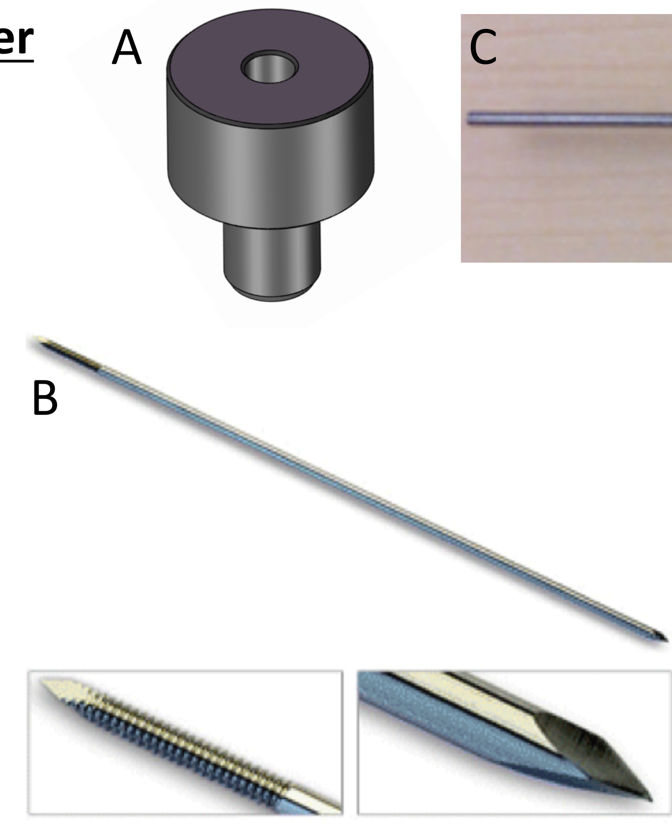
- Device must provide structure and stability for complete pediatric tibia fractures
- Avoid epiphyseal growth plates
- **This semester**:
  - Design device to implement metal biaxial braid in bone
  - Increase axial fixation compared to elastic nails

Design Specifications

- Limit axial rotation
- Rigid to stabilize fracture
- Implanted in the intramedullary canal avoiding growth plates (45˚ angle, 8 mm)
- Implanted for 6-9 months
- Visible on x-ray for implantation procedure
- Biocompatible and complies with FDA implant guidelines

Final Design

- **Flexible device to implement braided cylinder**
- Centerpiece
  - Threaded Kirschner wire (K-wire)
- Braid Connection
  - Free-sliding top cap
  - Fixed bottom cap (fixed with nail)
- Metal biaxial braid
- Method of Compression
  - Threaded nut above top cap
- **Device to drive nut for compression**
  - External hex broach
  - Manual auger
  - Flexible hollow drive shaft



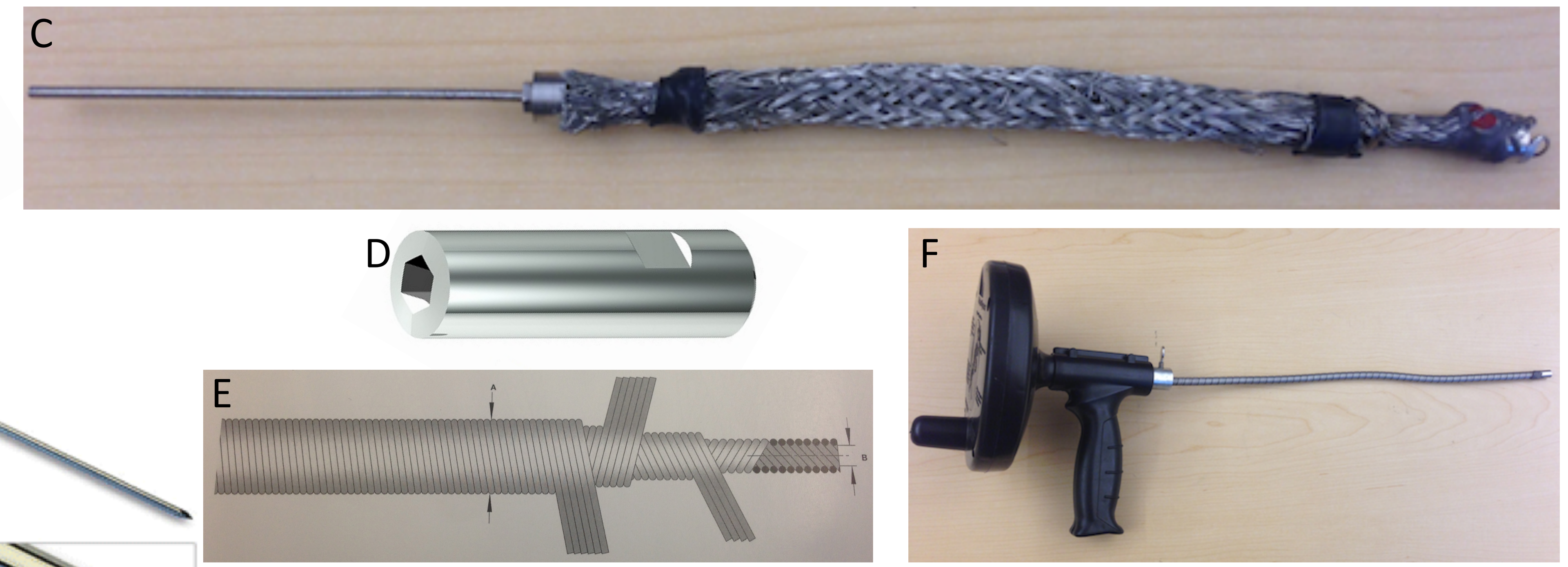


Figure 4. Final Design Components –
A) Top cap, bottom cap has hooked wires for lateral fixation; B) K-wire used as centerpiece for device[10]; C) Assembled prototype with top and bottom caps along K-wire centerpiece attached to biaxial braided cylinder, small hexagonal nut above top cap, all stainless steel; D) External hexagonal broach used to fit nut above top cap; E) Flexible hollow drive shaft used to transfer torque to nut and compress device[11]; F) Assembled drive shaft consisting of manual auger connected to flexible drive shaft with hexagonal broach on tip.

Testing & Results

Cantilever Bend Testing

Bending stiffness:

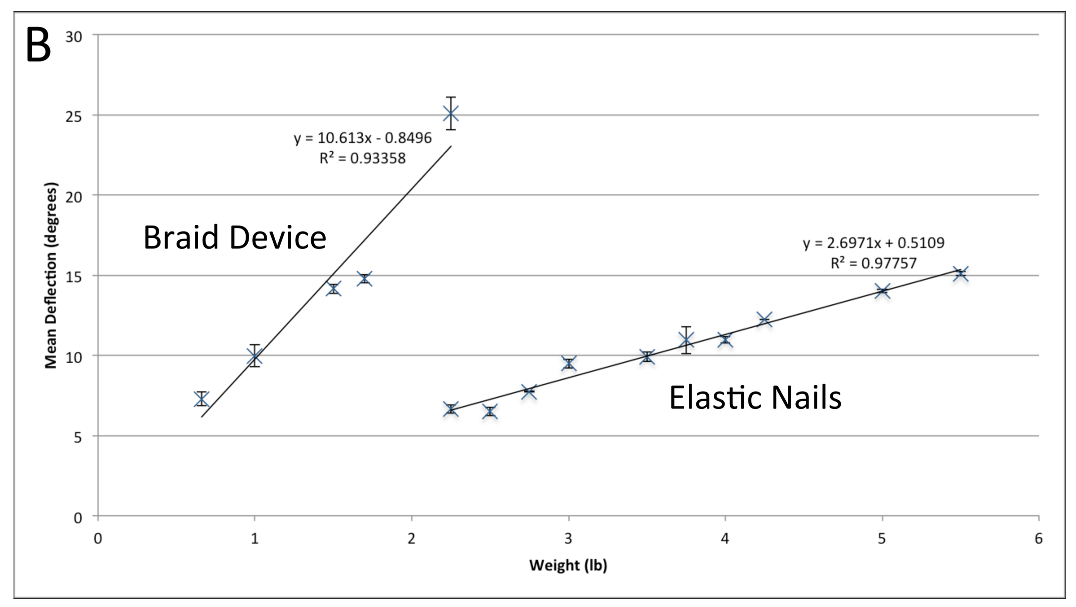
$$k = M/\theta$$

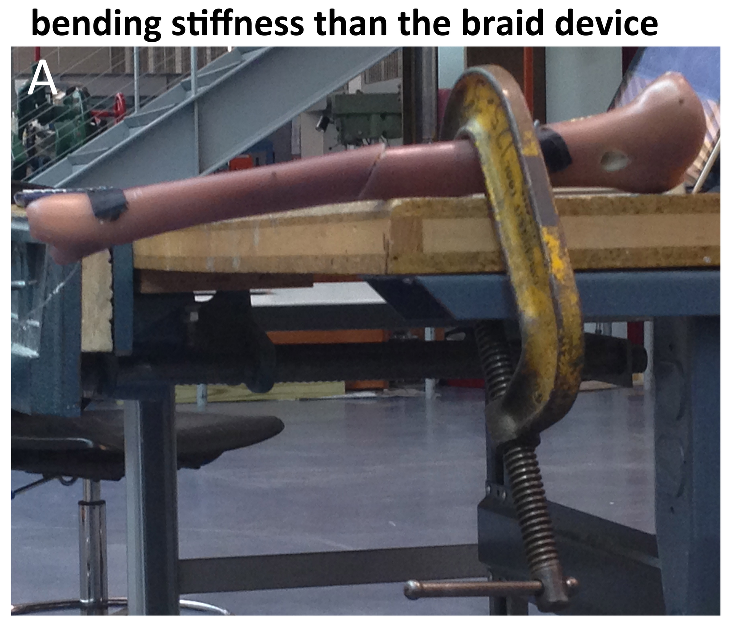
M = moment
θ = deflection angle

Approach:

- Cantilever loading –
  - Determine moment at fracture for various loads
  - Measure deflection angle of fracture point when loaded using ImageJ
  - Compute bending stiffness (moment/deflection)

Conclusion: Elastic nails have a greater bending stiffness than the braid device





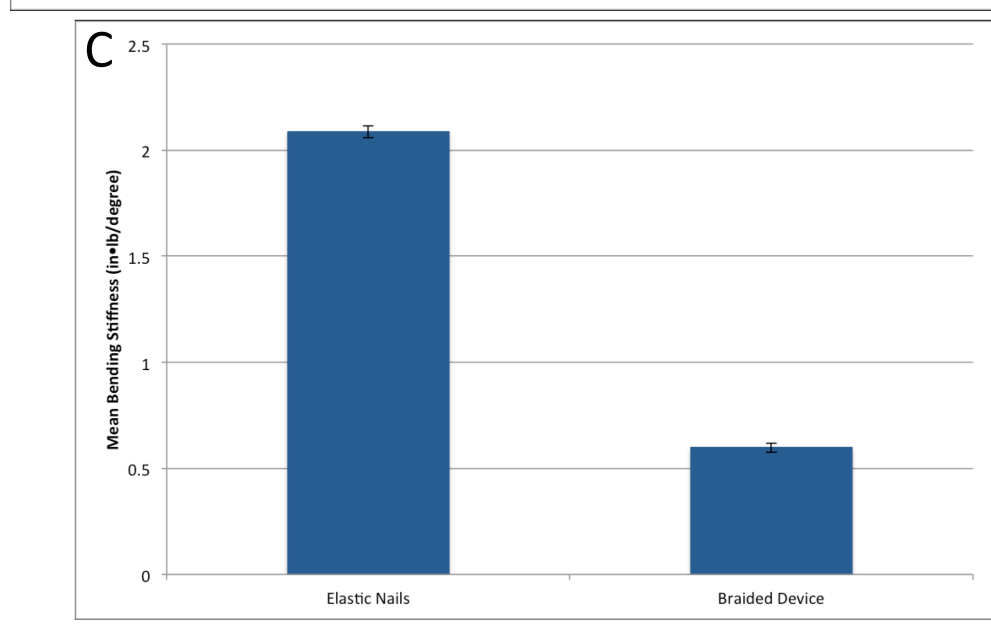


Figure 5. Cantilever Bend Testing and Results –
A) Image of cantilever bend testing setup. Sawbone model of fractured bone with braid device inserted is secured with a C-clamp. Loads are applied vertically at the free end of the bone.; B) Plot of mean deflection angle (degrees; n = 3) versus load applied (lb) for elastic nails and braid device. The linear regression of the elastic nails data has a much lower slope on the plot indicating greater resistance to bending compared to the braid device. Error bars: +/- 1 SEM; C) Bar graph of mean bending stiffness (in·lb/degree) for elastic nails (n = 30) and the braid device (n = 15). Elastic nails have a higher bending stiffness than the braid device. This difference is statistically significant (p < 0.01), confirmed by a t-test. Error bars: +/- 1 SEM

Rotational Testing

Rotational stiffness:

$$k = M/\theta$$

M = moment
θ = deflection angle

Approach:

- Impede rotation
  - Apply moment until 90˚ deflection
  - Measure force with gauge
  - Compute rotational stiffness (moment/deflection)

Conclusion: The braid device has a greater rotational stiffness than elastic nails

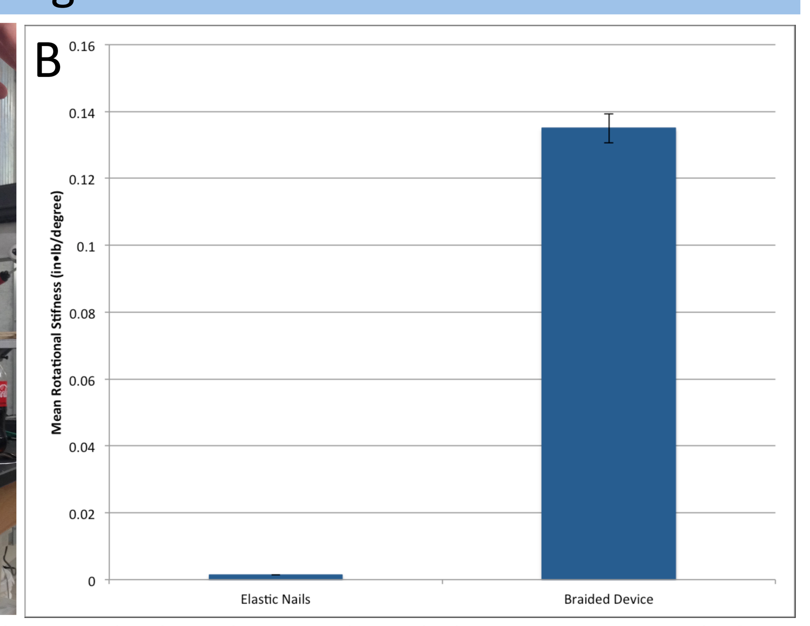


Figure 6. Rotational Testing and Results –
A) Image of rotational testing setup. Sawbone model of fractured bone with braid device inserted is secured with a C-clamp. Load is applied via a moment arm at the free end of the bone. Measure the amount of force required to deflect 90˚; B) Bar graph of mean rotational stiffness (in·lb/degree) for elastic nails and the braid device (n = 5). The force required to rotate elastic nails was not measurable using the available force gauge. The braid device has a mean rotational stiffness that is at least an order of magnitude greater than the elastic nails. Error bars: +/- 1 SEM

Materials and Expenses

Material	Provider	Price
Proof of Concept Pieces	Home Depot	$9.70
Metal Biaxial Braid	Wirecare.com	$47.15
Top and Bottom Caps	Caspersen	$669.00
External Hex Broach	Polygon Solutions	$391.61
Threaded Nuts	Ace Hardware	$6.00
Drive Shaft	Suhner Manufacturing Inc.	$0.00
K-wires	Client: Dr. Halanski	$0.00
Total		$1,123.46
Remaining Budget		$3,876.54

Table 1. Expenses for project

Future Work

- Modifications to drive shaft to be used in 45-degree hole
- Optimize braid
  - Length
  - Material (ribbon)
  - Braiding pattern
- Find biocompatible method to connect braid to caps
- Special order longer nuts for broach
- Improve machining of overall device
- Osseointegration/Animal (goat) testing
- Determine amount of casting required for use with this device

Figure 7. Chinese finger trap; inspiration for using ribbon as material; predict increased overall braid strength with ribbon design.[12]

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[8] adapted from http://www.techflex.com
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[12] http://chinesefingertrap.co.uk/