Tibial stent

Designing a novel fixation device for pediatric orthopedic tibia fractures

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Abstract

In order to stabilize severe adult tibial fractures, titanium rods are inserted through the proximal face of the tibia into the intramedullary canal. This method does not work for pediatric patients as the rod would damage the growth plate distal to the epiphysis. Therefore, current pediatric procedures insert two elastic nails through drilled openings in the lateral and medial sides of the bone directly distal to the metaphysis. However, this mechanism is difficult to install and does not always lead to proper alignment. In order to create a novel device to fixate pediatric tibial fractures, three different designs were considered and a device that expands laterally through compression was deemed the best design to replace the current flexible pediatric nails for stabilization.

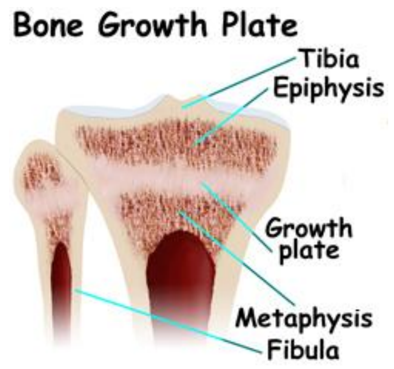
Background

Tibial Fractures

- 5% of all fractures in children
- Caused by falling, trauma, sports, abuse, or overuse
- Load bearing bone necessitates correct alignment

Growth Plate

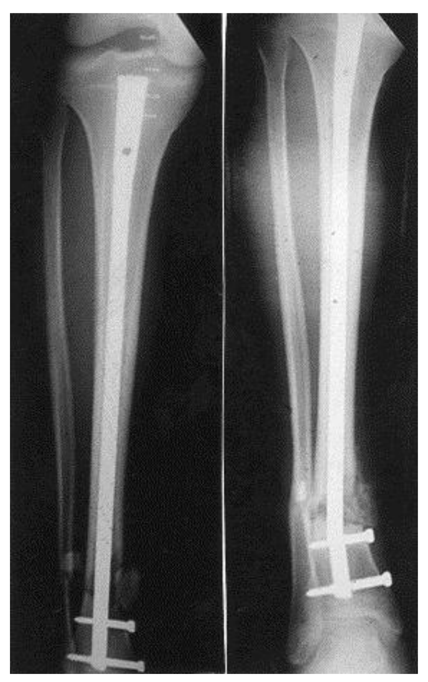
- Growth plates important for growth
- Located between epiphysis and metaphysis on distal and proximal ends of the bone
- Damage to the growth plate can lead to stunting of tibial growth



Current Practices

Adult Intramedullary Stent

- Titanium rod
- Insertion through proximal face of tibia
- Spans entirety of break
- Does not work for pediatric patients due to growth plate
- Leg is externally hard casted



Pediatric Intramedullary Stent

- 2 Flexible nails
- Insertion on lateral and medial sides of tibia
- 3 points of contact
- Limited optimization dependent on break location
- Leg is externally hard casted

Design Requirements

- Must span tibial break
- Must have enough stability to align bone
- Must be implantable at distal or proximal location
- Must have a diameter of less than 1 cm
- Must be biocompatible

Design Matrix

Criteria	Balloon Stent	Expanding Foam	Compressive Expansion
Fixation (30)	20	15	25
Client Preference (15)	10	10	15
Ease of Implantation (15)	5	10	10
Feasibility (15)	10	5	15
Safety (15)	15	5	15
Cost (10)	10	5	10
Total (100)	70	50	90

Final Design

- Flexibility allows for intramedullary insertion
- Lateral expansion achieved through buckling due to vertical compression
- Compression of wires attained by pulling on fixed, central cable

Components

A. End cap

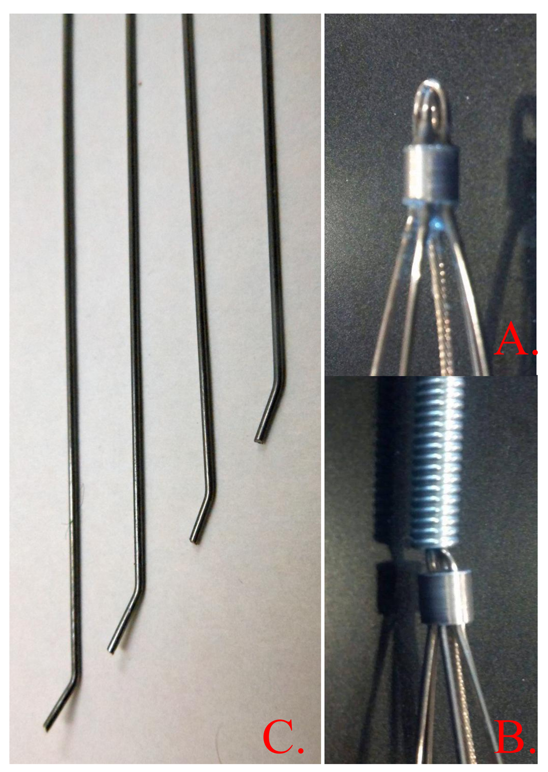
- Central hole for cable fixation
- Outer holes for wire fixation
- Distal loop for pin fixation

B. Mid Cap

- Stainless cable is able to freely slide through center hole
- Contains loop for ease of removal

C. Flexible stainless steel wire

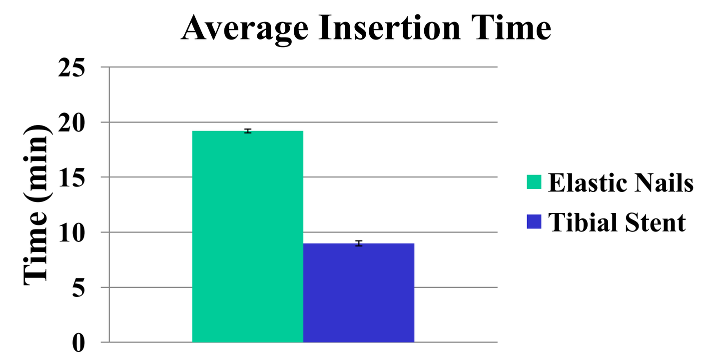
- Pre-bent ends to direct desired directional flexion



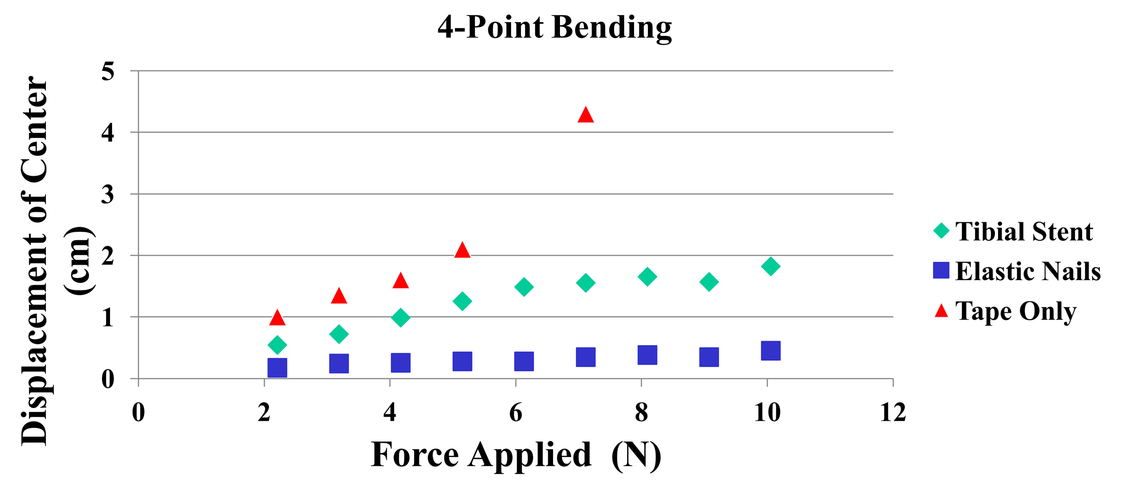
D. Final six wire prototype

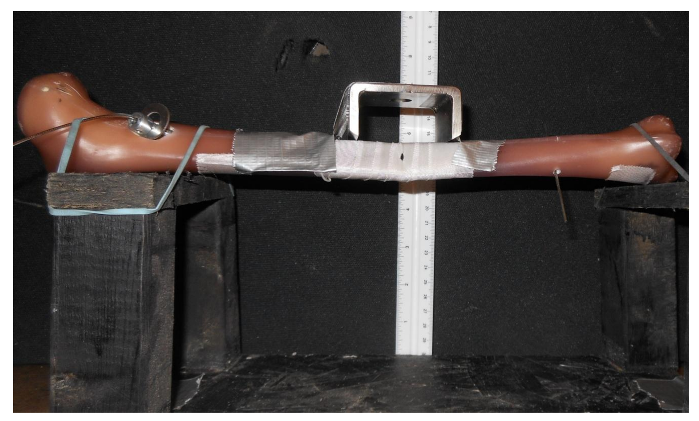
Testing

- Timed testing showed decreased insertion time compared to elastic nail system



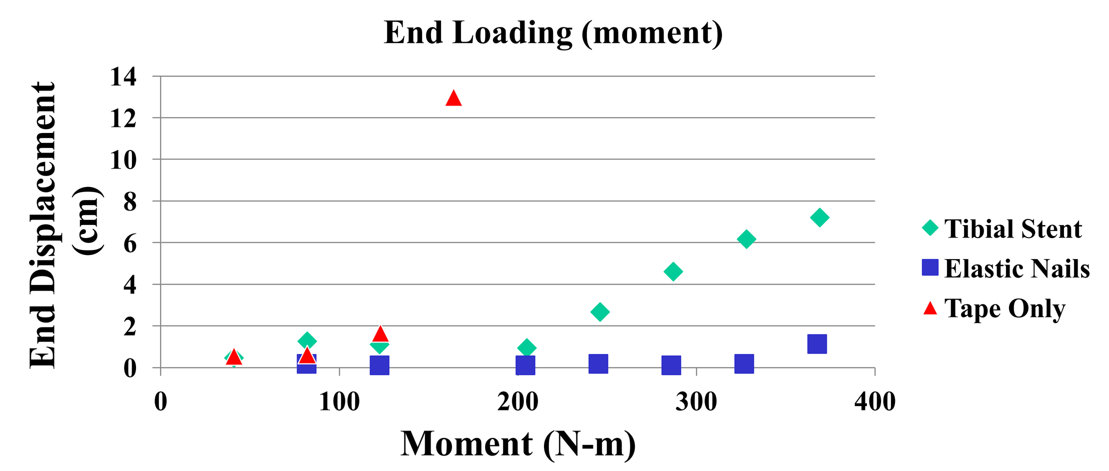
- 4-point bending test showed less lateral stability than elastic nails but more than control



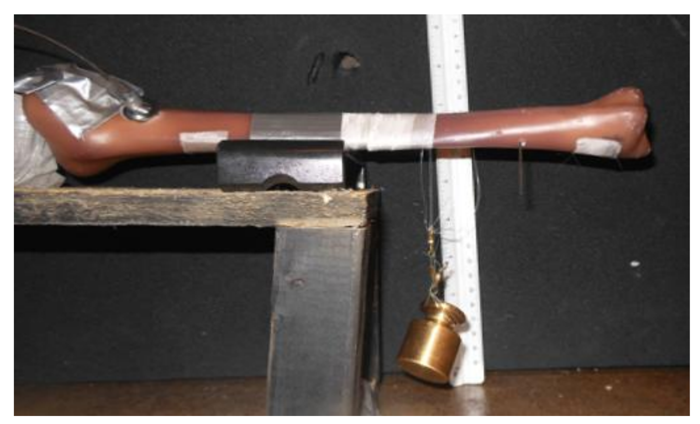


4 Point Bending Set Up

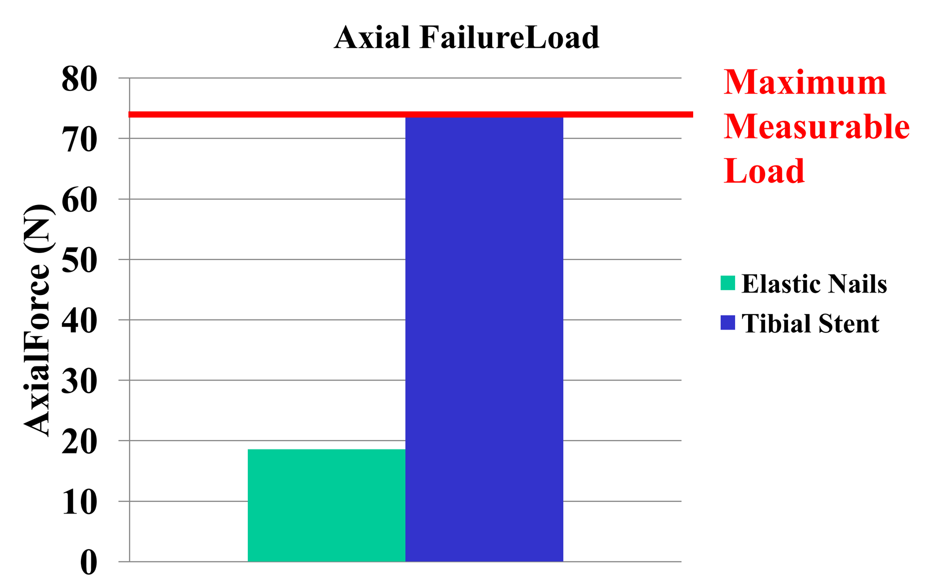
- Moment loading test showed less lateral stability than elastic nails but more than control



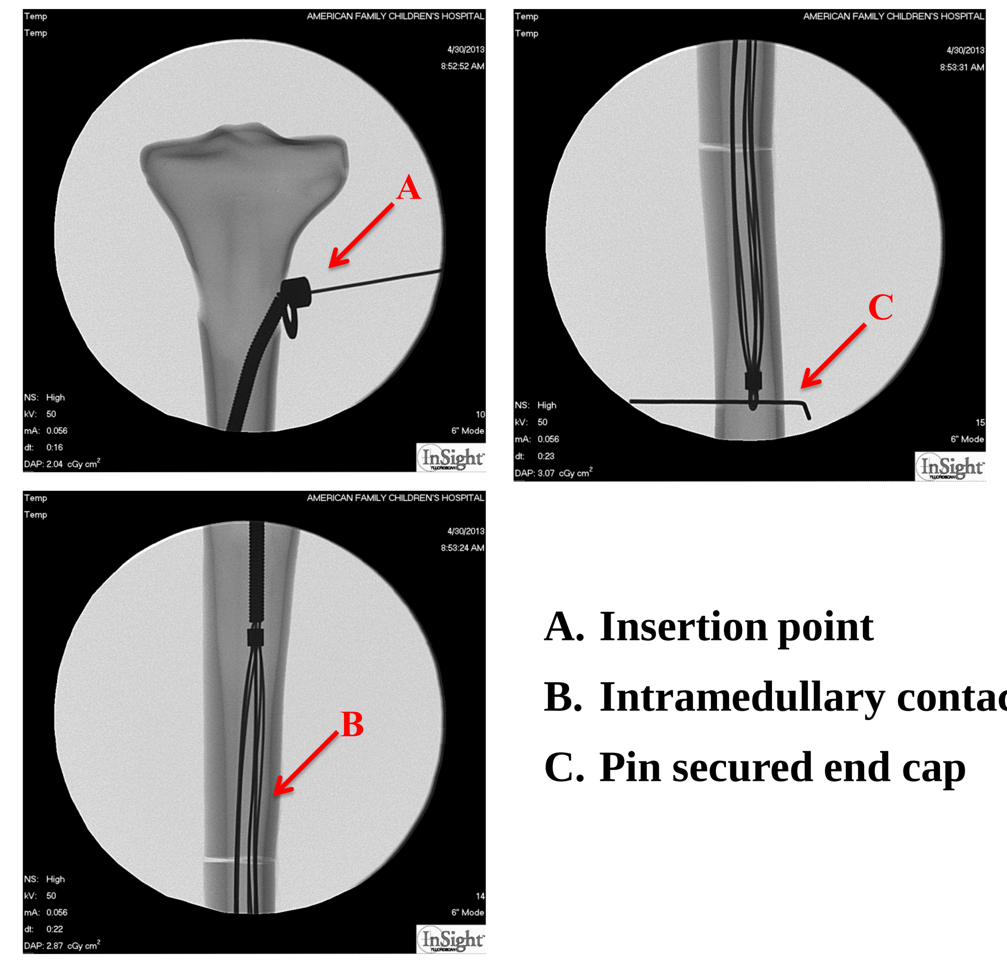
Moment Loading Set Up



- Axial loading showed more axial stability than elastic nails



X-ray Imaging



A. Insertion point

B. Intramedullary contact

C. Pin secured end cap

Marketability

- Tibia is the most frequently fractured long bone
  - Large and continuous market
- New device installation substantially faster than current
  - OR time billed at $62/min
  - New device decreases cost through decreased OR time
- Potential use in any fractured long bone (e.g. clavicle)
  - Further market expansion

Future Work

- Increase lateral stiffness
- MTS testing
- Animal testing
- Apply for patent

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