Tibial Stent

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Function: The client, Dr. Matthew Halanski has asked us to create a device to use for intramedullary stabilization after pediatric tibial fractures. When fully mature adults sustain a tibial fracture the stabilization technique used is to place titanium rods inside of the tibial intrameduallary canal. This process requires the orthopedic surgeon to hammer the rod through the proximal portion of the tibia. These rods can then be rotationally stabilized by inserting screws into the side of tibia at an orthogonal angle to the rods. In children this procedure is not recommended due to the presence of the diaphyseal growth plate. Instead, pediatric patients undergo a procedure in which a small hole is drilled into the medial or lateral segment of the tibia to enable the stabilization device to bypass the growth plate. Currently, the stabilization device used is the combination of two 4 mm in diameter flexible nails being worked into the medullary canal through the strategically placed hole. For most fractures this technique works appropriately; however, for tibial fractures the procedure is not as effective. Therefore, Dr. Halanski has asked that we create a device to supplant the currently used nails.

Client Requirements

- Stabilize the fracture, regardless of the tibial anatomical position
- Allow for rotational stability
- Have a total diameter of no more than 7mm (the anatomical diameter of the intramedullary canal)
- Use the same or similar procedure currently used to allow for the bypass of the growth plate
- Be biocompatible

Physical and Operational Characteristics

- *Performance requirements:*
  - Should give full rigid and rotational support
  - Should be fairly easy to use
  - High durability
- *Safety:*
  - Biocompatible
  - Avoid dislodging contents of medullary canal
- *Accuracy and Reliability*
  - Fit into medullary canal
  - High Durability
- *Life in Service:*
  - Should be able to be kept in for the remainder of patients life or biodegrade

- *Shelf Life:*
  - Should be able to be kept in medical storage for 1-2 years
  - Should be able to adjust by cutting and not lose function
- *Operating Environment:*
  - Will be placed into medullary canal of pediatric patient tibias following fracture
- *Ergonomics:*
  - Should be fairly easy to insert into canal, thus should be mildly flexible
  - If expandable, should be easy to expand
  - Should not impede patient movement more than currently used methods
- *Size:*
  - Needs to be less than 7-8 mm in diameter
  - Length will depend on patient age
- Weight:
  - Needs to be light enough to not drastically impede patient movement
- *Materials:*
  - Biocompatible
- *Aesthetics, appearance, and finish:*
  - Should be coated to enhance durability

- **Production Characteristics**
  - *Quantity:*
    - At least one
  - *Target Product Cost:*
    - N/A at this point, for future production will want to be comparable to currently used methods
- **Miscellaneous**
  - *Standards and Specifications:*
    - There is nothing on the market for this problem, so no specifications
  - *Customer:*
    - Primary consumers are surgeons and hospital personal
  - *Patient-related concerns*:
    - Not impede movement more than currently used methods
    - Biocompatible
    - Rigid
  - *Competition:*
    - Bone plates which stabilize externally
    - Intramedullary flexible nails