UNIVERSITY OF WISONSIN-MADISON

Tibial Stent: Designing a Novel Fixation Device for Pediatric Orthopaedic Tibia Fractures

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Abstract
This report presents an ongoing design to create a device to stabilize pediatric tibial fractures. In adults, tibia fractures are stabilized by inserting a titanium rod through the proximal face of the tibia into the intramedullary canal; however, this procedure can devastate pediatric bone growth and development due to the presence of a growth plate directly distal to the epiphysis. Current methods insert two elastic nails through drilled openings in the lateral and medial sides of the bone directly distal to the metaphysis. However, this mechanism does not always lead to proper stabilization, which can result in surgical complexities. Three different alternative designs are discussed in this paper. These designs include the concept of stabilization by filling the canal with a biodegradable foam product as well as two separate tibial stents. After comparing all of the designs with a design matrix the team concluded that an elastically expandable stent will be the best option to fully stabilize fractures. This report concludes by offering the future steps that will be taken to fabricate and test this design in hopes of creating an efficient and effective tibial stent.

Background

When a fracture is incurred a number of general steps are followed to optimize conditions for effective healing. First, the bone must be reduced, which involves realigning the segments of the bone into their respective anatomical location. This procedure is critical for proper alignment and healing of the bone; however, can also be painful. Therefore, anesthesia is typically administered. The next step is immobilization to prevent the pieces of the bone from shifting during the healing process. Immobilization can use casts or splints to hold the bones in place and generally is in place for two to eight weeks depending on the severity and location of the break. Traction is the use of tension to prevent the bones from shortening. In certain fractures involving long bones, traction is used to counteract the large muscles that tend to pull the bone out of place. Severe cases may also require surgery with implants to keep the bones aligned during the healing process. These situations use plates and screws along with the casts to immobilize the bone (Fig.1). Finally, physical therapy may occur for patients whose muscles weaken drastically while the casts or splints are on.[2]

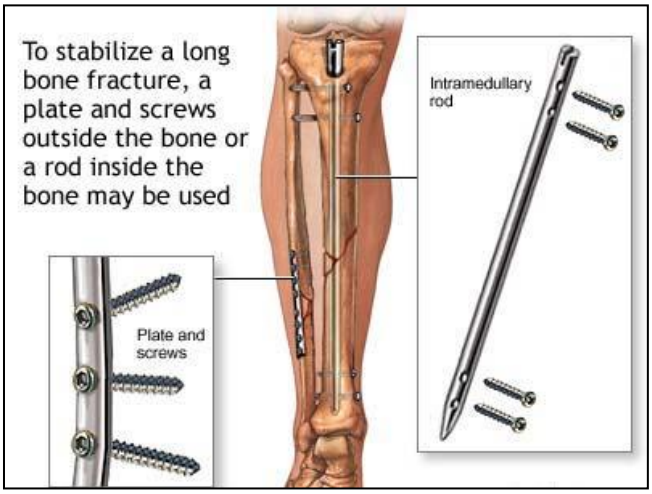

Figure 1: Currently used process to stabilize long bones in adults.[1]

Approximately five percent of all fractures in children are fractures of the tibia.[3] Some of the causes of the fractures are falling, trauma, sports, abuse and even overuse.[4] While many bone fractures can be simply set with a cast or a splint, the tibia may require surgery followed by serial casting to repair the injury. Since it is a load bearing bone, correct alignment of the tibia is essential. Misalignment can lead to severe pain when any force is placed on the

bone as well as disturbance to the patient's gait.[5] This would have to be fixed by the use of braces, casts, or even another surgery.

It is important to note the differences between children's and adult's tibias. The most notable fact is the two epiphyseal plates, or growth plates, located at the proximal and distal ends of the bone (Fig. 2). These two locations are the source of bone growth in the tibia and must be avoided in any procedure, until a person is fully grown. Damage to the growth plate can lead to stunting of the tibia, which in turn can cause uneven growth of a child's legs. This inherently can create problems, and once again may lead to more surgery.

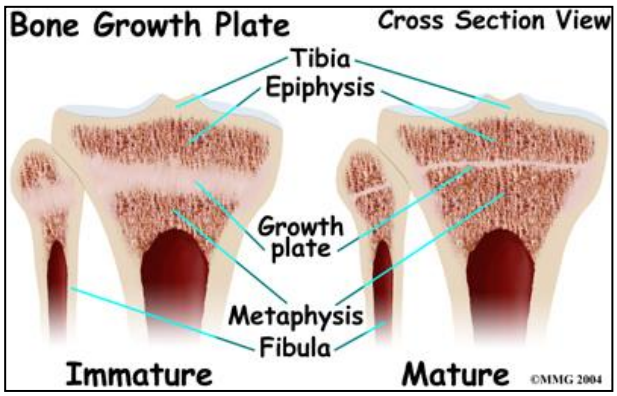

Figure 2: View of a child (immature) and adult (mature) growth plate on the proximal end of the tibia. The adult growth plate is completely calcified and thus no longer growing.[6]

Client Information:

Our client is Dr. Matthew Halanski, a pediatric orthopedic surgeon who currently works for the American Family Children's Hospital as well as the Veterans Hospital – Wm. S. Middleton Memorial.

Problem Motivation

The client's request for a mechanism to stabilize tibial fractures stems from a need for a new implant that will better secure the bones during the healing process. The goal is to create an expandable implant to be placed in the intermedulary canal that will align the bone as well as provide some structural support. The implant will need to be designed to incorporate locking screws for axial stability. Ideally the device will also be removable after a six week healing period, though this is not necessary. Along with the implant, a system for implantation of the device will have to be developed as well. To avoid the growth plate the implant will need to be inserted through a small, eccentric hole located just under the growth plate.

Current Practices

Currently two separate techniques for reduction and immobilization are used to fix severely fractured tibias. Which method used depends on whether the patient is an adult or a child. For adults solid titanium rods are placed within the tibial intramedullary canal. To install the rods an incision is made below the patella and a hole is drilled into the intramedullary canal of the tibia. Debris and intramedullary tissue are then reamed out of the canal. Reaming also ensures a consistent diameter for the rod to fit down the canal. Once reaming is complete, the rod

is forced down the canal of the tibia, realigning the broken pieces of the bone. After insertion, the rod is rotationally fixed and is further stabilized by lateral screws installed at proximal and distal locations of the intramedullary rod.[7]

This method of tibial fixation works well for adult patients; however, the insertion point of the intramedullary rod through the proximal face of the tibia would damage the tibial growth plate in pediatric patients. For this reason a separate method for pediatric patients has been established. This method utilizes two smaller diameter (2.5-4 mm) flexible nails rather than one solid intramedullary rod. These nails are inserted through medial and lateral entry points roughly two centimeters distal to the physis. The nails cross within the intramedullary canal and each has a three point contact: distal, medial, and at the insertion point.[8,9]

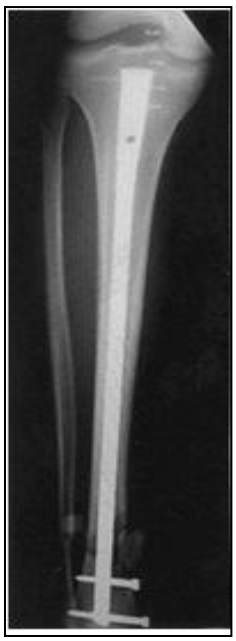

Figure 3: X-ray of adult tibial intramedullary rod with screws inserted on the distal end to provide rotational stabilization.[10]

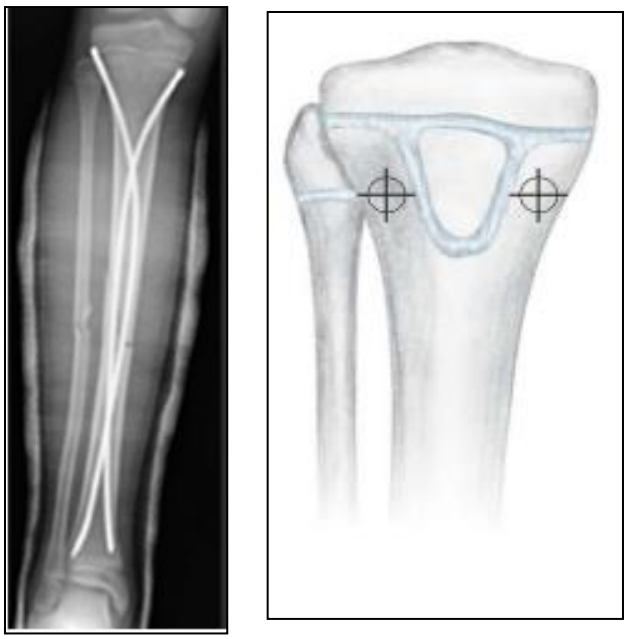

Figure 4: a) Shows two flexible nails used to immobilize a pediatric tibial fracture.[9] b) shows the lateral and medial insertion sites in the tibia where the flexible nails will be inserted.[8]

The combined six areas of contact are meant to provide a constant pressure and stabilization for the broken tibia. However, the flexible nail technique works best only if the fracture is in the middle third of the tibia.[9] This area is where the nails cross and the location of two of the six points of contact. However, if the fracture is not within this range then the flexible nails do not provide the optimum stabilization of the fracture. Furthermore, the flexible nail system does not provide a means for rotational fixation. If improperly inserted or aligned, the spring like characteristics of the flexible nails will cause improper alignment of the tibial fracture. Due to these drawbacks of using the flexible nail systems and the inability to use adult intramedullary nails, the team will attempt to produce a novel tibial stent for fracture fixation.

Design Requirements

To create an effective tibial stent a number of design requirements must be met. First, the stent must span the vertical distance in which the tibia has been broken. Furthermore, the stent

must be able to provide support and stability laterally throughout this entire span. This is important to ensure consistent alignment of the bone for the duration of the healing process, which can take up to six weeks. If this alignment is displaced then the physician must realign the tibia, otherwise improper healing may occur. This process would lengthen the healing time for the patient as well as add to medical costs.

Additionally, the stent should be implantable at either a distal or proximal location of the tibia to avoid the growth plates. This insertion area is important for multiple reasons. First, a preexisting surgical procedure for the implantation of pediatric intramedullary nails has already been characterized as an effective method for bypassing the growth plates. By keeping this installation location consistent with current practices physicians will have no change in difficulty for the installation of the design. Because the same installation procedure will be used the stent will be applied at a sharp angle and, therefore, must be somewhat flexible during the installation process. Finally, a distal or proximal insertion point is important as most breaks occur in the middle of the bone. By establishing this area as the installation location there is a diminished chance of needing to move the location from one patient to the next depending upon the break point. A consistent installation procedure can therefore be established.

The stent itself should expand within the intramedullary canal to create a secure fit once installed. This expansion should have a maximum diameter of 1 cm. This diameter is considered to be largest diameter seen for the intramedullary canal for pediatric patients. Finally, all materials and components must be biocompatible. This device will be in a patient for a minimum of six weeks and potential could be left in permanently. A permanent implant would eliminate the need for a second surgery for stent removal. However, if left in it is important for the device to be perpetually nontoxic and create no adverse affects to the body such as an immune system response.

Design Alternatives

Expanding Foam

One method for obtaining fixation within the intramedullary canal of a fractured tibia is to pump in expanding foam. Expanding foam offers one major advantage to other design choices as it has the ability to conform perfectly to the inner canal of the bone, which varies between patients. In theory the foam would fill every gap in the canal, which would limit rotational movement and offer complete and rigid stabilization. Further, proper characterization of the foam chemistry would allow the surgeon to have complete control over the final expanded volume of the foam prior to starting the surgery. The foam can be handled in a small package in a liquid form which would make it very easy to insert into the canal. By changing the hole diameter entering the canal it would be possible to control the rate at which the foam expands to ensure even expansion.

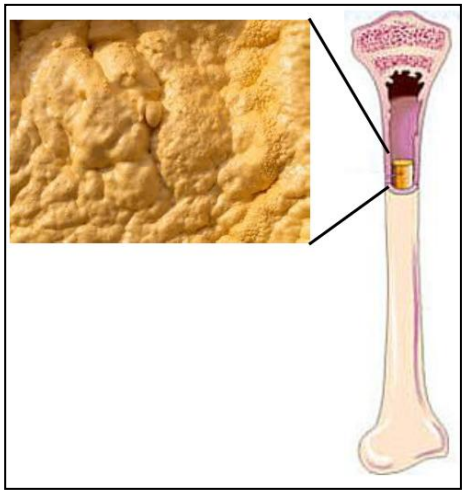

Figure 5: Diagram of Expanding Foam inserted into the intramedullary canal.

Though the expanding foam would offer the ability to fully stabilize all portions of the canal it would also offer several challenges. The foam will be difficult to control after entering the canal, and without a sealed bag surrounding the foam it may leak through the fracture point. The foam would also likely push the surrounding tissue and fluid out of the fracture point, which can be detrimental to the patient. Longitudinal stability may be limited by the strength of the hardened foam.

Balloon Induced Stent

The team's second design option, the balloon induced stent, takes inspiration from an arterial stent. As can be seen in figure 6 a typical arterial stent consists of two main components, the catheter with attached balloon and the stent itself. The stent is initially in its collapsed form over the deflated balloon. Once the catheter reaches the desired location, the balloon is inflated, locking the stent in its expanded position. After expanding the stent, the balloon can be deflated and the catheter withdrawn, leaving the stent in place.

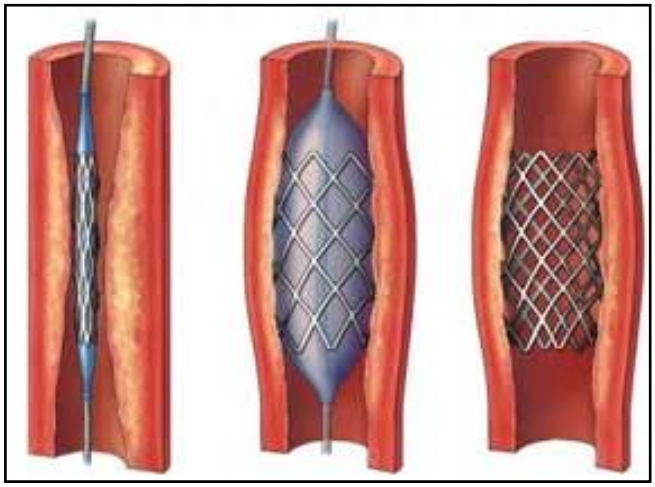

Figure 6: The general diagram of an arterial stent, which is the concept behind the Balloon Induced Tibial Stent.[11]

Mechanically, the concept would function in a nearly identical fashion, just on a larger scale, and as arterial stents are used in more than 2 million procedures every year, it is a proven design concept.[12] To accommodate the intramedullary canal, the stent would need to expand up to 1 centimeter in diameter while also being long enough to fixate a fracture throughout the length of the tibia. A similar balloon mechanism would be used to expand the stent once it is positioned by the fracture, with the balloon then being withdrawn as in the arterial stent. The stent itself would be machined out of stainless steel or titanium, in a similar webbed fashion as the arterial stent. Because the stent would be webbed, and bone has the propensity to grow into various metals used in implants, bone in-growth is a concern. To decrease this likelihood, the stent would be polished down and placed inside a biocompatible sleeve. Despite this modification, it is likely that bone in-growth would occur to some degree, which would make the stent extremely difficult to remove in the event of a failed procedure or after the fracture is fully healed. Another concern with the design is a lack of lateral force exerted on the intramedullary canal. If the bone were to move around at all once the stent was in place, it could cause the stent to collapse back into the compressed form, resulting in a loss of fixation at the fracture point.

Expanding Stent

As previously mentioned one of the primary concerns of the balloon inducible stent is its inability to provide a rigid profile for stability. The expanding stent is a response to this concern in an otherwise innovative and applicable design. In contrast to the balloon inducible stent which is elastically stable in the unexpanded position, the expanding stent will have the elastic propensity to expand. Thus, when placed inside of the intramedullary canal the expanding stent

will provide a constant lateral force on the inner surface of the conical shaped canal. This sustained force will be the basis for stabilization of the fracture.

For this design two separate components must be fabricated: the stent delivery device and the stent itself. To create the stent a sheet of metal will be annealed to maintain a spiral formation (Fig. 7). Before placing inside of the intramedullary canal the stent will be rolled tighter which will give it a smaller diameter. This action will create a loading effect due to the elastic propensity the spiraled metal will have to retain the previously defined diameter .The basis for this design will be the metallic phenomena referred to as a spring back force. Spring back is defined as the tendency for bending moments in manipulated metal to cause a shape change in metal after external loads are removed.[13] The maximum diameter of this spiraled sheet metal will be 1 cm, which is larger than the interior diameter of the canal. This size discrepancy will ensure that the stent maintains a constant stress on the inside of the canal when the stent is released from the loaded state.

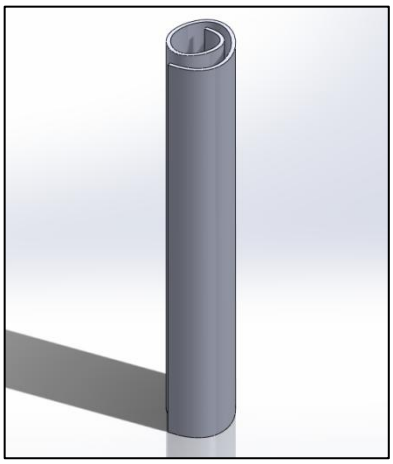

Figure 7: The basic structure of the stent which will be rolled tighter to create a smaller diameter. When released, the stent will expand to fill the canal.

The stent delivery device will be designed to act identical to the currently used elastic nails, that is, when the delivery device and stent are combined as one single component a small hole will be drilled into the lateral or medial surface of the tibia directly distal to the growth plate and the delivery device will be manipulated down the canal. This device (Fig. 8) will be comprised of a number of different segments that will act to optimize the act of introducing the stent and, potentially, removing the delivery device. To facilitate the introduction of the delivery device the tip of the device (A) will be formed as a mildly pointed leading edge to cut through any interior adipose tissue. Moving up the device, the next section is a short rod segment (B) approximately 3 mm in diameter. Sitting between the leading edge and the larger diameter upper rod, this segment will be the housing location of the stent. When placed, the stent will be wrapped around this segment of the delivery device. To transiently maintain the closed conformation of the stent, a plastic sheath (C) with a diameter slightly larger than the entire device will be slid over the attached stent. It is imperative that this sheath be moderately fixated to the tip of the device (A) to ensure that it does not release the contained stent. Further, once the stent is in an optimum position the sheath will be removed to allow the stent to expand; therefore, it is critical that the sheath be able to be controlled from outside of the intramedullary canal. The final portion of the device is the large upper rod (D) which will be used primarily for guiding and manipulating the device into the canal.

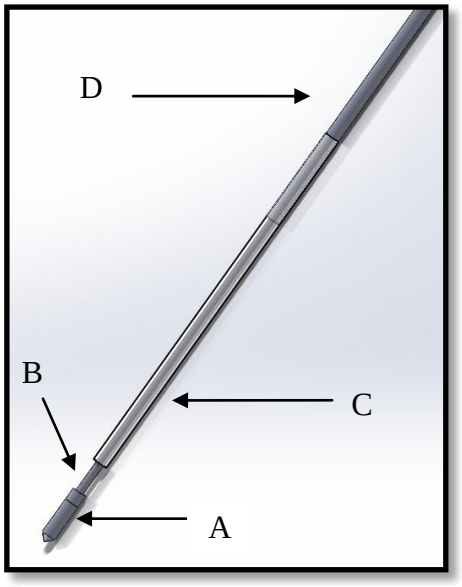

Figure 8: The stent delivery device and each component of the design. This will be placed through medial or lateral areas of the tibia to gain entrance to the intramedullary canal.

The expanding stent design has all of the advantages that the balloon induced stent has; however, it addresses the foreseeable problem of rigidity of the balloon induced stent. Further, because of the simplistic premise and design a vast amount of potential modifications can easily be implemented and tested. Despite these advantages some potential drawbacks to arise. The shape of the intramedullary canal is not perfectly conical and can mildly vary between people; therefore, it will be difficult to fully optimize the expanded shape of the stent itself. Another potential difficulty will be the small size of the stent itself. The fully expanded diameter of the stent when inside of the canal will not be much larger than 10-15 mm. Fabricating a spiraled sheet of metal at this size scale may prove to be difficult. Further, though the design will have some amount of natural lateral force due to the spring back it is not necessarily true that this lateral force will have a magnitude large enough to maintain stabilization.

Design Matrix

Parameters	Total Weight	Balloon Stent	Expanding Stent	Expanding Foam
Fixation	10	2	3	1
Client Preference	5	2	3	1
Ease of Implantation	5	3	3	2
Safety	5	3	3	1
Feasibility	5	2	3	1
Cost	3	2	3	1
Total	99	76	99	38

Figure 9: Design Matrix used to compare all of the alternative designs.

To assess the value of each of the three designs for a tibia fixation device, a comparison of the proposals was conducted with a design matrix, shown in Table 1 below. The matrix provided a quantitative analysis of which design would prove most beneficial. The categories used for analysis were fixation, client preference, ease of implantation, safety, feasibility and cost. All of the potential designs were rated against one another out of a maximum score of 3 for each category. The best design in each category received a three and the weakest design received a one. Each category was then multiplied by a weighted factor, as designated by the total weight category. The highest possible score was a 99.

Fixation was weighted the highest out of the six categories as it is one of the main design requirements, and one of the main problems with the current elastic nails. The foam scored the lowest in this category because it lacked longitudinal stability. The expanding stent appears to offer the most lateral and longitudinal stability and it received a three in this category. The balloon stent was given a two because although it offers longitudinal stability it lacks the constant orthogonal force present in the expanding stent.

Client preference was rated in a conference with the client Dr. Matthew Halanski. Each design was proposed and the decision was made based on overall appeal. This category was

weighted by five because client preference is critical in creating this device. The expanding stent design was given a three in this category. The expanding foam was given a one because it would require extensive research.

Ease of implementation was rated on the surgeon's ability to easily control and insert the device. This category was weighted a five as it is an important factor in this device being used clinically. The expanding stent was again rated the highest in this category because of its simplistic design and functionality. The balloon stent was also given a three because of its similar approach to the expanding stent in terms of delivery. The expanding foam is simple to get into the canal, but can be unpredictable once in the cavity. The foam design received a two in this category.

Safety was rated on the material properties and their interactions with the surrounding tissue. This category was weighted a five because it is another important factor in implementing this device clinically. The expanding stent and balloon stent both received a three in this category because the stent material can be made out of safe metallic materials. Expanding foam currently on the market is considered to be toxic for human consumption, and the foam would force potentially hazardous materials already present in the canal out of the fracture point which could cause and embolism. The foam was rated a 1.

Feasibility was scored on each devices potential to be prototyped and possibly manufactured in a one year period of time. This category was also rated five as it is a major contributing factor to the devices completeness. The expanding stent scored the highest in this category because it has the most simplistic design, and could easily be manufactured. The foam scored the lowest as it would require a new polymer to be created, as well as a delivery device.

Cost was scored based on predicted manufacturing costs. This was weighted the lowest because medical products are often very expensive and as this is simply a proof of concept design it is possible to take cost into account once a successful prototype has been fabricated. The expanding stent received a three in this category because the delivery device can be made out of one piece of stock material, as well as the expanding stent itself. This would allow the device to be quickly and cheaply produced.

Future Work

Having selected the expanding stent concept as the final design the team now must finish building the initial prototype, with the primary challenge being the design and fabrication of the spring component. After meeting with professors who can provide advice on what type of material to use, calculations must be performed to determine how much force should be exerted on the interior of the intramedullary canal to achieve adequate fixation. Once the material is chosen and the force values determined, the team can begin fabricating the spring component, likely by annealing the metal until the desired stiffness and shape is attained.

Following fabrication of the initial prototype, the team will perform mechanical testing on both the device and the current titanium rod method (in adults) by using saw bones provided by the client and the MTS machine located in the Engineering Centers Building. By comparing these tests results, the team can determine if the expanding stent design has the ability to fixate fractures better than the existing method. Finally, based on the results, the prototype will undergo further revisions to meet the client's needs and to perfect the design.

Ethical Considerations

To ensure that this design maintained high ethical standing, a number of different precautions were followed. One of the primary considerations was to ensure that no products are currently on the market and no patents have been filed that have a similar design. After a thorough search only one patent currently filed has somewhat similar properties. This patent is called the Expandable Blade Device for Stabilizing Long Bone Fractures (US 8,157,804 B2).[14] This design stabilizes long bones by inserting through either the distal or proximal face of the bone and releases and expanding blade which stabilizes the device. However, the device presented in this paper differs from the Expandable Blade Device as it is used for pediatric fractures (inserted through the medial and lateral sides) and relies on an expanding piece of sheet metal instead of a blade.

Another important ethical aspect to consider is the effect the expandable stent will have on patients. This is a multi-faceted consideration as the device must be biocompatible to ensure minimal host response, comfortable while within the intramedullary canal, and not cause any excess damage to the patient. Along with the biocompatibility of the stent it is also critical that all components of the delivery device also not create any immune response or difficulties. Some potential problems that could occur with the delivery device are the release of micro-particles due to excessive manipulation of the device while inserting into the canal, fracture of the device, and tearing of the sheath. All of these scenarios are avoidable if the correct materials are chosen.

Finally, because Dr. Halanski is putting a significant amount of time and capital into this design it is important that all materials that are used have been well studied in the realm of orthopedics. Using a polymer of metal/metal coat that has not been thoroughly studied could lead to difficulties with government agencies such as the FDA, which could result in an inability to patent.

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Appendix

PDS

Tibial Stent

Taylor Jaraczewski, Cody Bindl, Stephen Kernien, Kyle Jamar Lucas Schimmelpfenning

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