UNIVERSITY OF WISONSIN-MADISON

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

Department of Biomedical Engineering

Adviser: Tracy Puccinelli Ph.D.
Client: Dr. Matthew A. Halanski M.D.

Taylor Jaraczewski (Team Leader), Lucas Schimmelpfenning (Communicator), Kyle Jamar (BSAC), Stephen Kernien (BWIG), Cody Bindl (BWIG)

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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 be necessary for patients whose muscles weaken drastically while the casts or splints are on.[2]

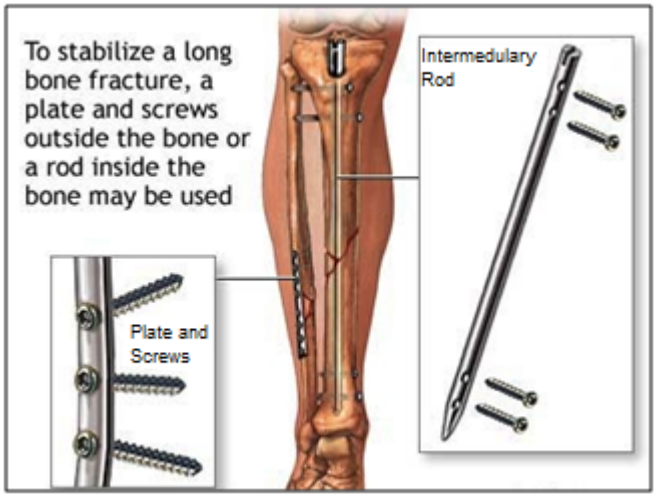


Figure 1: Currently used process to stabilize long bones in adults.[1]

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 misalignment would have to be fixed by the use of braces, casts, or even another surgery.

It is important to note the differences between a child and adult tibia. 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.

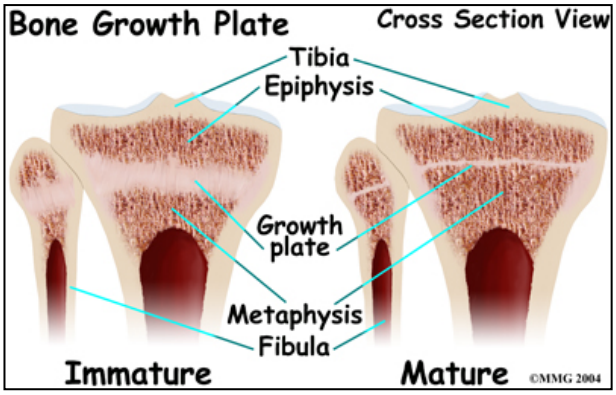


Figure 2: View of a child (immature) and adult (mature) growth plate on the proximal end of the tibia. The adult growth plate is completely calcified and thus no longer growing.[6]

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 intramedullary 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 that is drilled 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 (Fig. 3).[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]

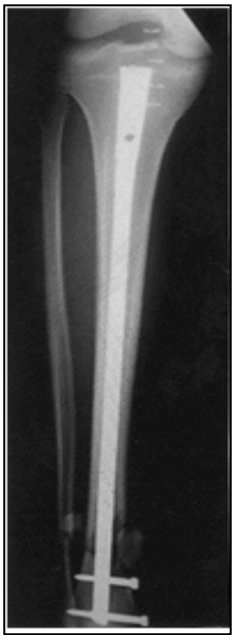
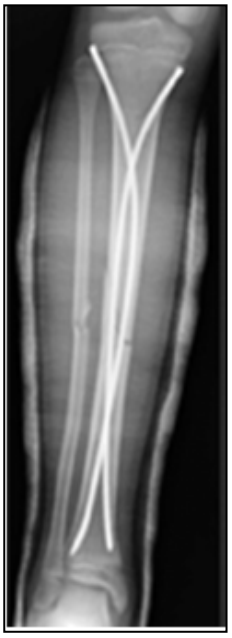


Figure 3: X-ray of adult tibial intramedullary rod with screws inserted on the distal end to provide rotational stabilization.[10]



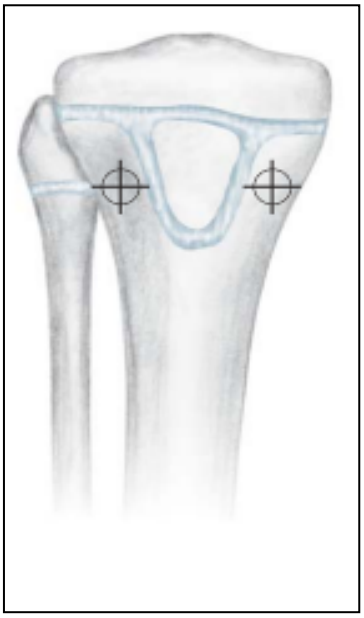


Figure 4: a) Shows two flexible nails used to immobilize a pediatric tibial fracture.[9] b) shows the lateral and medial insertion sites in the tibia where the flexible nails will be inserted.[8]

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 the 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 may 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

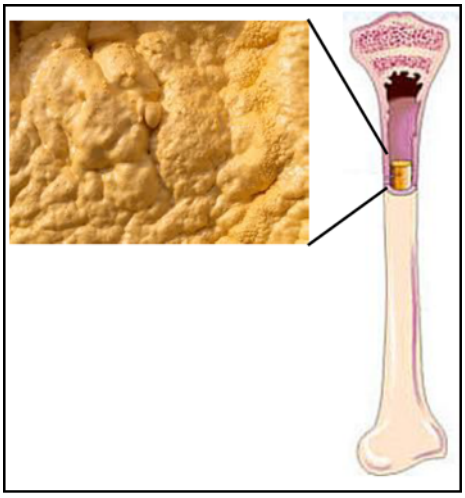


Figure 5: Diagram of Expanding Foam inserted into the intramedullary canal.

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.

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.

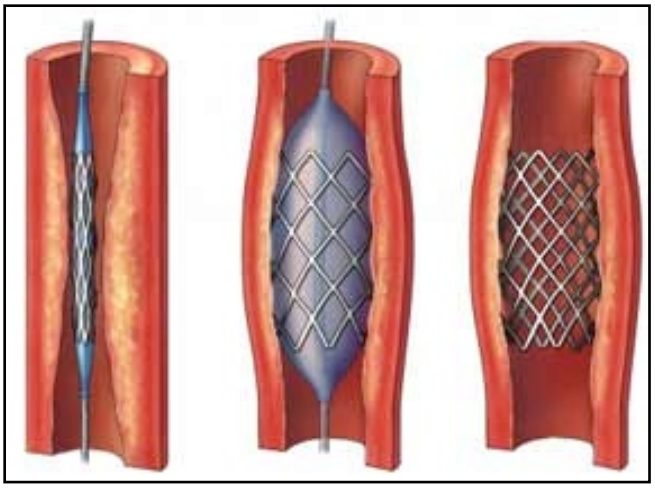


Figure 6: The general diagram of an arterial stent, which is the concept behind the Balloon Induced Tibial Stent.[11]

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.

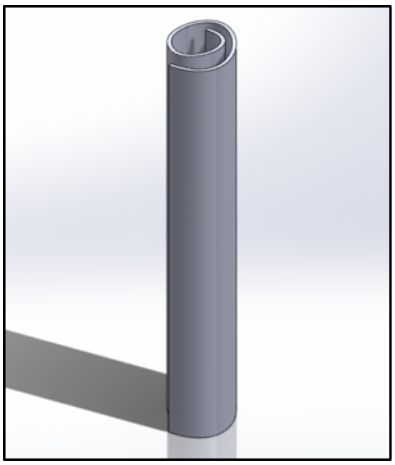


Figure 7: The basic structure of the stent which will be rolled tighter to create a smaller diameter. When released, the stent will expand to fill the canal.

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.

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

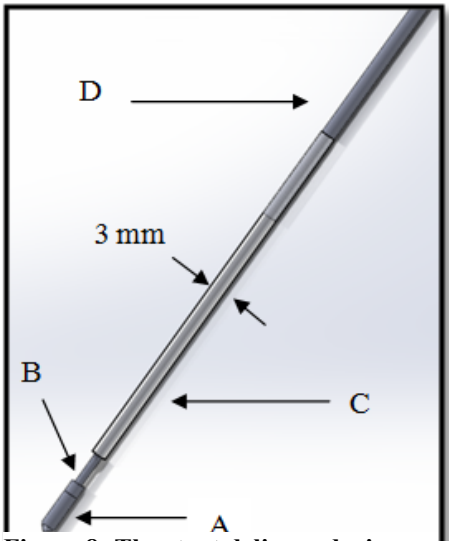


Figure 8: The stent delivery device and each component of the design. This will be placed through medial or lateral areas of the tibia to gain entrance to the intramedullary canal.

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.

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 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

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**

Table 1: 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 above. 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. Each category is weighted and each design is then scored in each category. The highest possible score is 100.

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 therefore it received a 25 in this category.

The balloon stent was given a 20 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 15 because client preference is critical in creating this device. The expanding stent design was given a 15 in this category. The expanding foam was given a ten because it would require extensive to get to a prototype stage, and even longer to be approved for clinical use.

Ease of implementation was rated on the surgeon's ability to easily control and insert the device. This category was weighted a 15 as it is an important factor in this device being used clinically. The expanding stent and expanding foam were rated the highest in this category because of its simplistic design and functionality. The balloon stent was also given a five because of its similar approach to the expanding stent in terms of delivery, but there are more components, which makes installation more difficult.

Safety was rated on the material properties and their interactions with the surrounding tissue. This category was weighted a 15 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, leading to a possible embolism in the patient. Therefore, the foam was rated a 5.

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 15 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 ten in this category because the delivery device can be made out four basic components, all of which can be made out of the same material. This would allow the device to be quickly and cheaply produced.

Final Design

After determining the expanding stent was the most viable alternative design, more in depth research and design took place. Through this research, it was determined the original expanding stent that relied upon elastic properties of coiled metal for expansion would provide insufficient expansion and bone retention. Therefore, ways to reinforce the original expanding stent were explored. Ultimately, a design that utilizes a similar installation process as the coiled stent but has a different mechanical means of expansion was developed.

This modified design consists of a three wire design with an expanding stent length of 115 mm. The cables are expanded by pulling on a galvanized steel cable which is fixed at the tip of the design with an aluminum stop sleeve. The cable passes through the center of the end cap and mid cap that serve to secure the wires in a fixed three bolt-hole pattern. At this stage, the wires are held into the end cap with epoxy; ideally a weld will be used in future prototypes. The reason for the epoxy is to prevent the wires from spinning within the end cap. The cable is then

passed through a hollow aluminum tube used to feed the stent into the bone, as well as to provide a rigid structure for longitudinal force generation on the wires. The wire will be fixed in tension by a plain ball swage which is crimped at the end of the aluminum tube. The arrangement of the wires, end cap, mid cap and cable can be seen in figure 9.

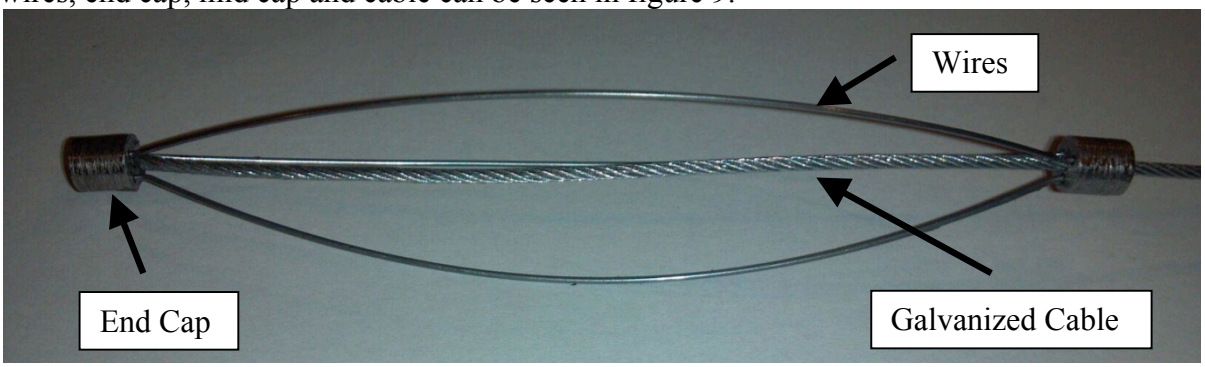
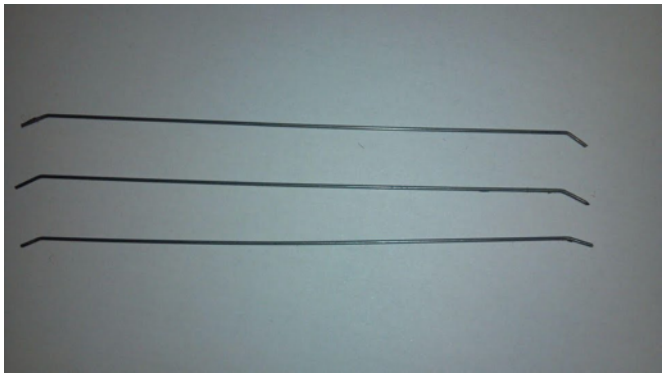


Figure 9: The arrangement of the wires and cable can be seen in the assembled prototype. The galvanized steel cable is highlighted, as is the end cap, and expandable wires.

The materials used in the prototype are an aluminum hollow tube, galvanized steel cable, steel end cap and mid cap assembly and steel piano wire. These materials are used because of their availability, but ideally either stainless steel or cobalt chromium will be used. Both stainless steel and cobalt chromium are rated for human implantation and have similar material properties to steel.

To optimize the design it will be possible to alter the number of wires by simply switching out the end cap and mid cap assembly and adding the desired number of wires. Further testing on the force generation of the deformed wires will help to optimize this portion of the design.



Fabrication

The fabrication of the prototype for the expanding wire stent consists of four main components. The first component is the wire, which is plastically deformed to fill the intramedullary canal. Three wires are present in this prototype, but this design could easily be comprised of four or more wires. The wires in the prototype are 0.3 mm in diameter and 115 mm in length. The gauge (diameter) of the wire can be varied depending on the force needed in the canal. The wires are bent at a 35 degree angle at each end, 8mm from the tip, to ensure the wire will deform in the proper direction. Figure 10 shows the wire with the bent ends.

The second component of the prototype is the end-cap and mid-cap assembly (Fig. 11), which secure the wires in the proper alignment. The caps are milled from 5/16” 1020 grade steel rod, which is lathed down to an outside diameter of 7.5 mm. A center hole is bored on a lathe with a #50 bit. Three holes are drilled

Figure 11: Close-up of the end cap assembly (same as mid cap)

around the center, evenly spaced on a mill using a 3 or 4-bolt hole pattern. A #65 bit is used which is slightly larger than the diameter of the wire. The wires are secured in these holes with epoxy to prevent them from spinning.

The third component is the galvanized steel cable used to deform the wire segments. The cable has a diameter of 2 mm and is attached through the end cap with an aluminum stop sleeve. Stainless steel stop sleeves could also be used. The stop sleeve is crimped onto the cable with a crimping tool and a vise (Fig 13). The cable is 24" long but can be cut down at any time by the surgeon. The cable passes through the mid cap and the aluminum rod and is secured on the other end with a plain ball swage and a crimping tool during the surgery. The cable, stop sleeve and plain ball swage can be seen in figure 12.

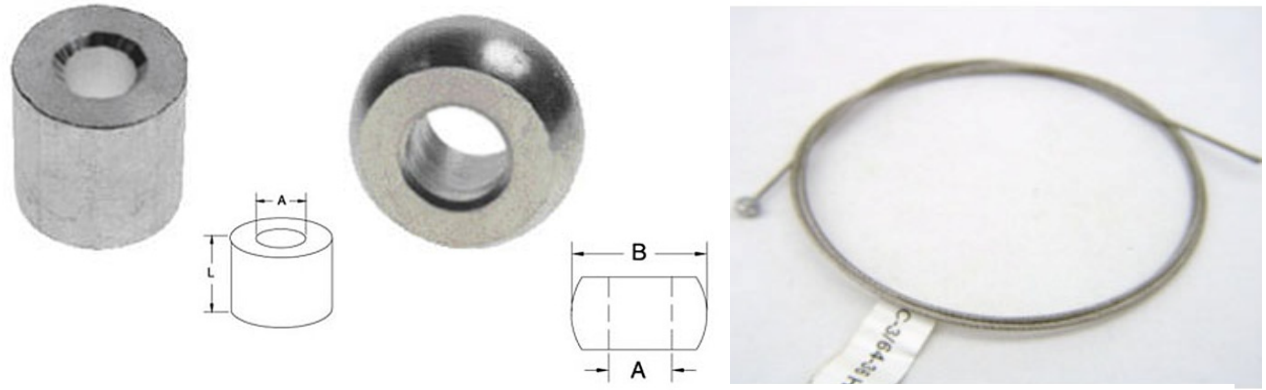


Figure 12: The stop sleeve (left), the plain ball swage (center) and steel cable (right).
http://www.uscargocontrol.com

The fourth component of the device is the aluminum tube (Fig. 14) used for insertion. This tube is crucial because this is what the wires deform against longitudinally. The outer diameter of the tube is 5 mm and the inner diameter is 3 mm. A long, tightly coiled spring could be used instead of the tube. The spring will allow for longitudinal force generation and greater flexibility for insertion. Also, the spring will decrease the likelihood of the cable binding in the tube. The aluminum tube and possible coil spring can be seen in figure 13.

Figure 13: The crimped stop sleeve holding the galvanized cable through the end cap

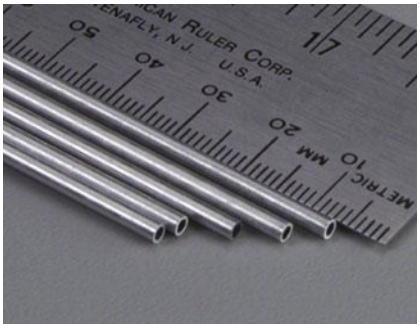


Figure 14: The aluminum tube (left) and the coil spring (right) http://www.go-ride.com/product/

Testing and Results

Proof of Concept

In order to test the viability of the prototype, the team assessed two important aspects of the design: expansion and implantation. The first aspect tested was the capability of the prototype to expand. The prototype is designed to expand horizontally due to an axial force that creates horizontal compression. During testing, an external force was applied to the device to create a 1 mm compression and the subsequent horizontal deflection was measured. This process was then repeated until a total vertical compression of 10 mm was achieved. The resulting data was plotted and a parabolic relationship between vertical compression and horizontal expansion was seen, which is shown in Figure 15. Through this test, the prototype was shown to have expansion capabilities and a relationship between compression and expansion of the device was determined.

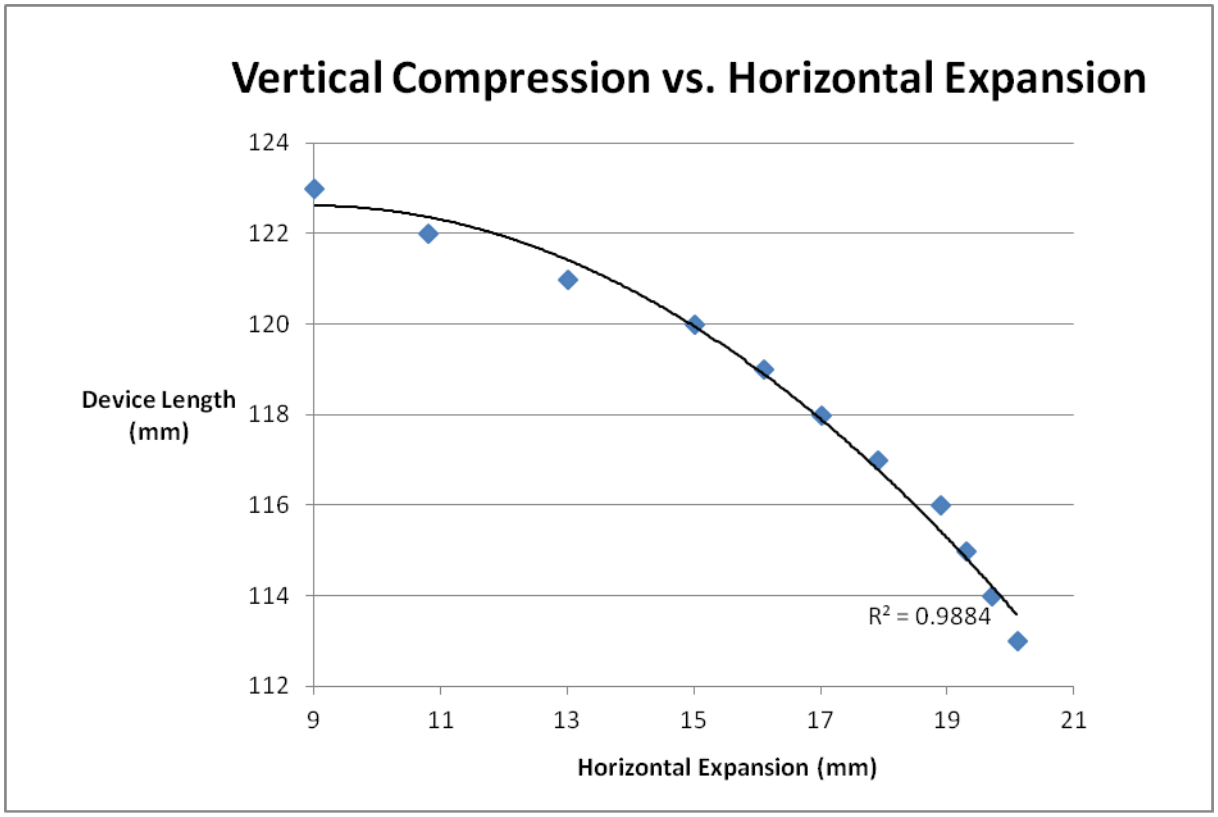


Figure 15: The relationship between vertical compression and horizontal expansion.

The second aspect tested was the capability of the prototype to be implanted into the intramedullary canal of a pediatric tibia below the growth plate. To test this, a 1 cm hole was drilled at a 45 degree angle from the horizontal plane into the canal of cortical foam Sawbone™ at the same approximate location as current pediatric tibial stent surgeries. As seen in Figures 15 and 16, the prototype was then fed into the canal while in its contracted phase. The device was

able to be both inserted and removed without damage to the prototype or the Sawbone™. This implantation was also able to be done by hand without the need of any additional tools. This test conclusively showed the design prototype has the flexibility necessary to be implanted at the sharp angle necessary to avoid pediatric growth plates during surgery.

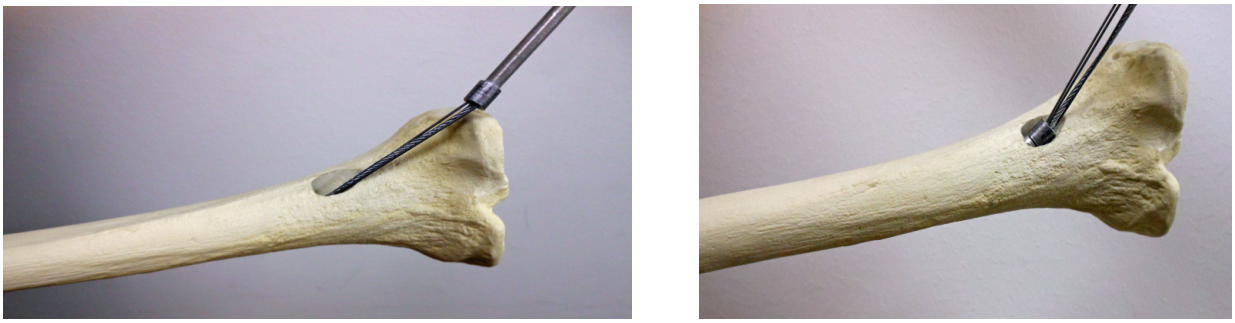


Figure 16: Device insertion into the intramedullary canal of a Sawbone™.

SolidWorks Analysis

For further testing, the team required a method that would allow them to alter the materials and minor details in the design and compare how the results would change. With these requirements in mind, SolidWorks 2012 Student Edition™ was chosen to help the team model and test variations of the chosen design. In order to help prove proof of concept, a video animation using the SolidWorks animation tool was created. This animation shows the prototype transition from its contracted to expanded states, as would happen during a surgical procedure. Below are before and after images from the SolidWorks animation (Figures 17).

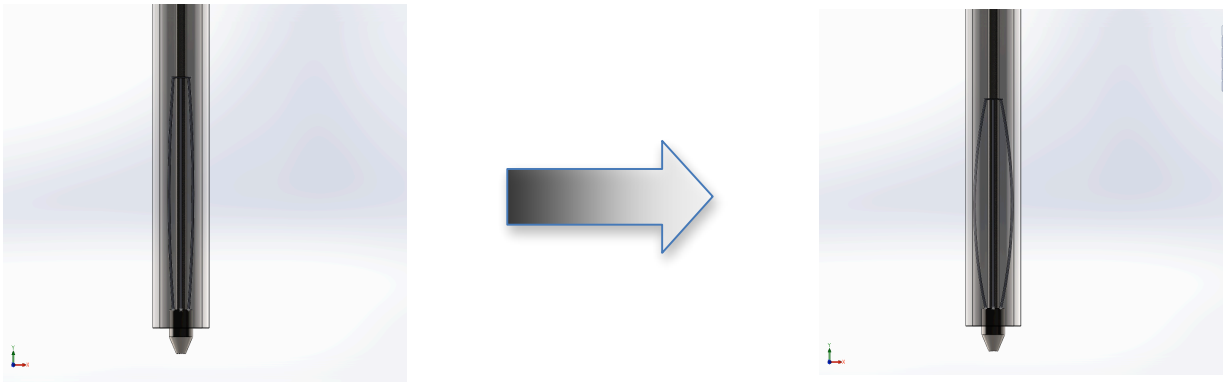


Figure 17: Before and after activation of the tibial stent device in a tube acting as the intramedullary canal.

Following creation of the animation, the simulation suite of SolidWorks was used to help model what the prototype would look like under various applied forces. Since the team plans on using stainless steel in the final prototype, 201 Annealed Stainless Steel was arbitrarily chosen from the SolidWorks material database as an adequate metal with which to run the simulations. For simplicity purposes, all simulations were run using a static linear model. While this model does not truly represent the motion of the device, after consulting the SolidWorks help website and based on the recommendation by the client's graduate student Marc Egeland, the team

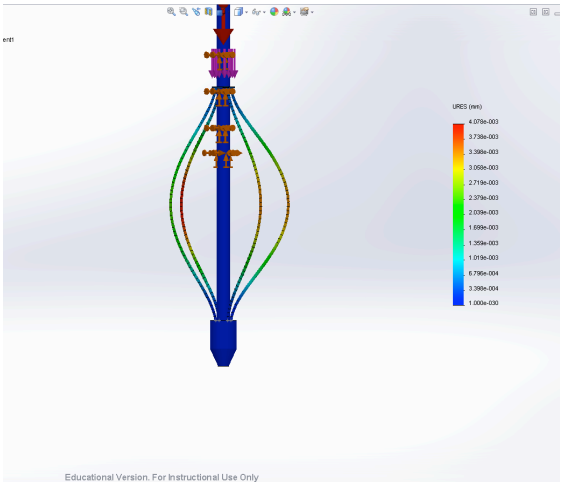


Figure 18: The initial deformation model predicted by a linear analysis performed in SolidWorks. Note that the scale is considerably off and that the actual.

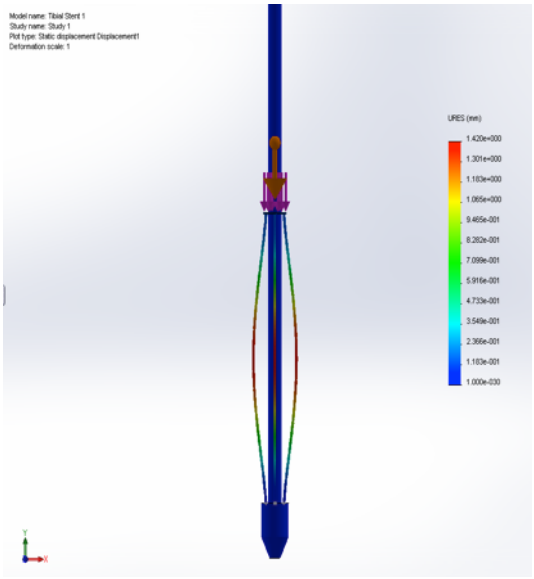


Figure 19: The results from the second linear deformation analysis performed using SolidWorks. This result more closely mimics what the team was seeing in the proof of concept tests but still is not completely accurate.

determined that it would be best to start off with a linear analysis to get baseline results. An attempt was made to run a more complicated nonlinear analysis – which would accurately reflect the prototype's force distribution and deformation – but it proved unsuccessful. Further attempts at a nonlinear analysis will be made in the future.

The first simulation performed tested a four-wire prototype and examined the amount of deformation undergone by the wires when a 25 N load is applied to the washer. The results of this analysis are shown in figure 18. It should be noted however that the figure is not to scale. While the scale bar is listed in millimeters, the red color denotes a deformation of 4.078×10^{-3} mm, and the blue denotes a deformation of 3.398×10^{-4} mm. So in actuality the deformations displayed are on the level of microns. Additionally, not all of the wires deformed the same amount, ranging from a maximum of 4.078×10^{-3} mm to a minimum of around 2.039×10^{-3} mm.

Taking these errors into account, some adjustments were made to the original model to ensure that all four wires were in the same original starting position – it was discovered that the two wires with vastly different deformation characteristics were modeled in slightly different starting positions. Another linear static study was performed on this new model with a force of 100 N. As is shown in figure 19, the two main problems of the first simulation have been resolved. In this image the deformation is to scale and all the wires deform the same amount. The maximum deformation undergone at the center of each wire is 1.42 mm and decreases down to 1.183×10^{-1} mm close to the proximal and distal ends. Plots were also generated showing the stress and strain undergone by the wires. However, a drawback of the linear model is that in the stress analysis, it predicts that the wires will snap before reaching the 1.42 mm of deformation as can be seen in figure 20 (next page). This happens because the linear model does not take into account the dynamic deformation of the wires when they are subjected to the load. It therefore calculates the stress as if 100 N were applied to a stationary object and that the wires have no give, which is not the case in our model. Because the wires are moving throughout the duration of the applied force and their movement occurs in a nonlinear manner, a nonlinear dynamic simulation needs to be performed to accurately model the stresses and strains undergone by the wires, and by

association to accurately model the forces the wires would apply to the intramedullary canal. See appendix: SolidWorks Model for the dimensions of the model used in the simulations.

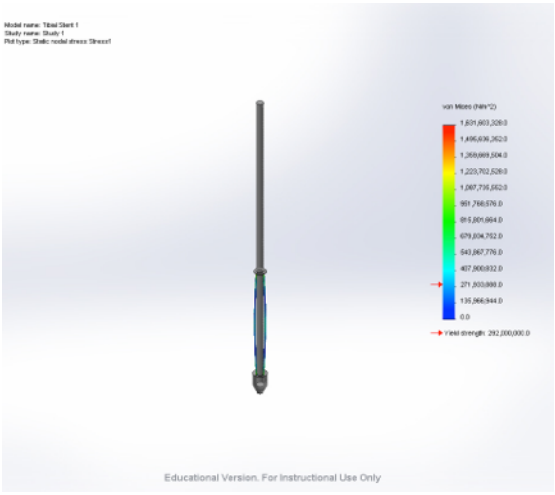


Figure 20: The stress results from the linear analysis as performed in SolidWorks. Since the wires actually undergo motion more accurately represented by a nonlinear model, these results are not correct.

Theoretical Mathematical Modeling of Force Distribution on Intramedullary Canal

As the primary objective of this design is to create a device that will supply enough radial force within the intramedullary canal for strong fixation, it is important to theoretically assess the feasibility of this with our design. To perform this analysis, the main component of the design that will be analyzed is the individual wires that will undergo buckling. It has been well established that thin tubes, rods, or plates undergoing axial compression can be modeled as beams undergoing Euler buckling, or buckling due to elastic instability.[15,16] In this investigation, each of these wires will be treated as a linearly elastic beam confined between two parallel surfaces, fixed at both ends, and undergoing an axial force (as shown in figure 21). Values will be generated using the small deformation mathematical analysis theory proposed by *Chai* (1998).

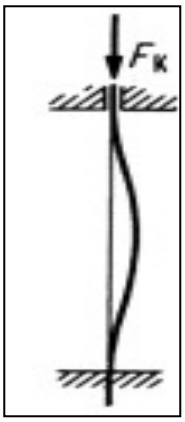


Figure 21: This image shows typical Euler buckling which has an axial force (Fx) causing elastic instability.[17]

In this model the beam begins at an initial point in contact with a parallel plate as shown. Upon application of an axial force the beam will begin to buckle and, eventually, make contact with the other parallel wall, which is called point contact (figure 22A). Further axial force will cause the beam to begin straightening on the wall, called line contact (figure 22B). The normalized resultant force on the ends of the beam (which will be identical to those on the wall of the tibia) can be determined for both point and line contact with the following equations:

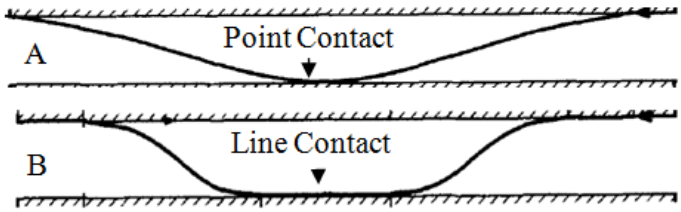


Figure 22: A) Depicts the phenomenon of point contact on the bottom surface. B) Depicts line contact on the bottom surface.[16]

Normalized Resultant Force: $\bar{R}\left(=\frac{R}{P}\frac{L_0}{h}\right)$

Point Contact: $\bar{R} = \frac{4n^2}{\left(1 - \frac{2n}{\pi\varsigma}\tan\frac{\pi\varsigma}{2n}\right)}$ *Line Contact:* $\bar{R} = 2n\varsigma$

where n is the number of buckles that occur (assumed to be 1 in this design), and ς is the normalized square root of the axial force which equals

$$\varsigma \equiv \frac{kL_0}{2\pi} \qquad k^2 \equiv \frac{P}{EI}$$

where P is the axial force, E is the elastic modulus of the material, and I is the moment of inertia of the column.

Using these equations and prototype properties (Appendix) it is possible to determine the theoretical resultant force R that will be exuded on the intramedullary canal with varying axial forces P. As can be seen by figure 23 as the axial force increases the resultant force on the intramedullary canal goes up in what seems to be a second order fashion. Further, from this plot a direct relationship between the axial force and theoretical resultant force can be described as

$R = -0.0004P^2 + 0.0874P + 0.7245$

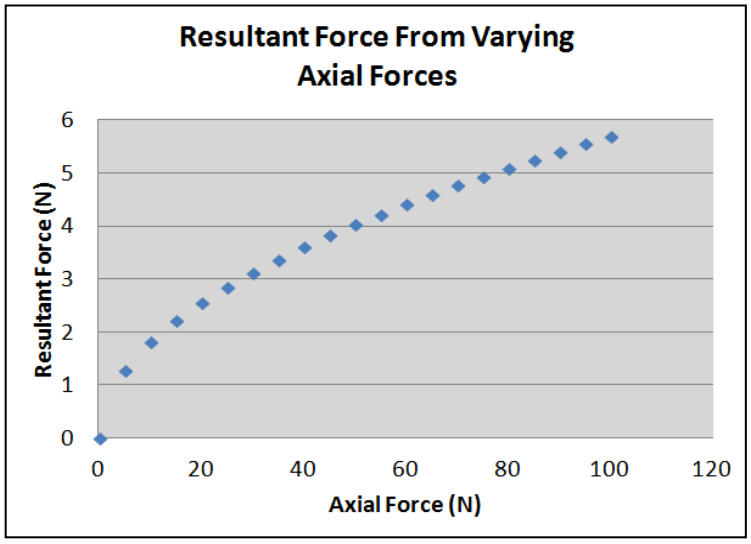


Figure 23: Theoretical resultant force with varying axial forces. The relationship appears to be of 2nd order in nature.

This relationship will prove to be useful for future work on this design as it will give insight into how to manipulate different material and mechanical properties to obtain a desired resultant force. It is important to note that no literature is currently published discussing the force needed within the intramedullary canal to obtain solid fixation. This is due to the fact that no device has been fabricated or studied which relies on an actuated system as this design does. Therefore, as previously mentioned, this mathematical analysis, in conjunction with other testing methods, simply provides a solid mathematical model to be used in future works.

Cost Analysis

The prototype was produced in house for material costs of $15 and approximate labor time of two hours to machine the necessary components. Assuming a shop rate of $75 (average rate quoted by the COE student shop for lathe and mill work) the prototype would cost $165 to produce.

Producing a prototype in-house with stainless steel or cobalt chromium would increase cost for both materials and labor. Both stainless steel and cobalt chromium are harder materials than steel and aluminum, which makes them inherently more difficult to machine. The material cost will be $30 and the machining costs will be $80 per hour. A prototype designed with these optimal materials would cost $190 to produce.

A quote from ProtoLabs Inc. projected costs of $69 for steel versions of the end cap and mid cap and $72 for stainless steel end cap and mid cap. Accounting for the rest of the labor and materials for a single prototype it would cost a minimum of $300 to have one produced by a manufacturer. These costs can be drastically decreased by mass production and the end cap and mid cap assemblies could be cast out of stainless steel with the wires and cable already in place. This would both negate the need for epoxy or welding to secure the wires and the need to a stop sleeve to secure the cable.

Future Work

Having settled on the expandable wire prototype as our final design and having already performed a proof of concept test and preliminary analysis via SolidWorks on its mechanical properties, the next step is to continue analysis of the device using SolidWorks. This involves attempting to accurately model the forces that the wires would apply to the intramedullary canal by means of a linear dynamic study. It also can involve running the simulations using different shaped wires made out of different materials to observe what effect that would have on the deformation characteristics. Other testing methods also need to be undertaken. This includes working with Marc Egeland to stress test the device while it is fixating a fracture in a tibial saw bone, and possibly animal or cadaver bones. Marc has access to an MTS machine at the Wisconsin Institutes for Medical Research and has expressed interest in working with the team in the spring semester to do force analysis using the machine. The team feels that this data would be an excellent compliment to SolidWorks simulation and modeling data, and, thus, will contact Marc in early February to begin testing.

Additionally, the team needs to determine a way to ensure that the wires will expand in a uniform, symmetric fashion when a force is applied to the device. A handful of ideas have been brought forward over the last week, ranging from pre-bending the wires, to encircling the four wires with a ring at their center, to anchoring the wires at an angle at the bottom of the device. The ideas will then be tested by modifying the current prototype accordingly and performing simple proof of concept tests in a saw bone to determine whether or not they worked.

Furthermore, different methods to manufacture the device will be looked into, as the team plans on attending a conference of medical device manufactures in the spring. The current prototype, while good for proof of concept testing, needs to be further refined using micro machining methods that are not directly available to the team. Once a method of manufacturing has been determined, the team must look into what type of material to make the final prototype

out of, as that will affect both its final cost and its ability to clear FDA regulations should it get to that point.

Finally, the client has expressed an interest in patenting the device, should testing prove that it is a suitable replacement to the current Titanium nails. Therefore, the team will do further research on other patents in the area and begin preliminary talks with the Wisconsin Alumni Research Foundation about the feasibility of patenting the device.

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.

Timeline

Task	September			October				November					Dec
	14	21	28	5	12	19	26	2	9	16	23	30	7
Project R&D													
Determine Preliminary Final Design				X									
Prototyping					X	X	X		X	X	X	X	X
Testing													X
Deliverables													
Progress Reports	X	X	X	X	X	X	X	X	X	X	X	X	X
Midsemester						X							
Final Poster											X	X	X
Tong Presentation													X
Meetings													
Client	X		X			X					X		X
Team		X	X	X	X	X	X	X	X	X	X		X
Advisor	X	X	X	X	X	X	X		X	X	X	X	X
Website													
Update	X	X	X	X	X	X	X	X	X	X	X	X	X

Conclusion

This paper reports the beginning stages and fabrication of a device to stabilize pediatric tibial fractures. Current methods use elastic nails which, while functional, are difficult to use and manipulate once inserted into the intramedullary canal of the tibia. The device highlighted in this paper will be placed within the intramedullary canal in a comparable fashion to the currently used system; however, to create fixation an externally located cable will be used to actuate the opening of a medley of wires. When initiated, these wires will undergo Euler buckling and, eventually, contact the inner wall of the intramedullary canal, which will provide the stabilization. This paper also presents two different methods to determine properties of this device such as the resultant force against the wall, deformation of wires and stress within the wires under a range of loads. Finally, the paper concludes by highlighting future plans to create a fully functional and biologically compatible device for tibial fixation.

References:

1. Howarth WR, Gottschalk HP, Hosalkar HS. Tibial tubercle fractures in children with intra-articular involvement: Surgical tips for Technical ease. *J ChildOrthop*. 2011 Dec; 5(6): 465-70.
2. Foster PA, Barton SB, Jones SC, Morrison RJ, Britten S. The treatment of complex tibial shaft fractures by the Ilizarov method. *J Bone Joint Surg Br*. 2012 Dec; 94(12): 1678-83.
3. Mashru, R. P., Herman, M. J., & Pizzutillo, P. D. (2005). Tibial shaft fractures in children and adolescents. *American Academy of Orthopaedic Surgeons*, *13*(5), 345-352. Retrieved from http://www.jaaos.org/content/13/5/345.abstract
4. He B, Wang J. Plate fixation of paediatric fractures of the distal tibia and fibula. *Acta Orthop Belg.* 2012 Oct; 78(5): 660-2.
5. Eralp L, Kocaoğlu M, Polat G, Baş A, Dirican A, Azam ME. A comparison of external fixation alone or combined with intramedullary nailing in the treatment of segmental tibial defects. *Acta Orthop Belg.* 2012 Oct; 78(5): 652-9.
6. http://www.eorthopod.com/content/blounts-disease-in-children-and-adolescents
7. Wheeless, Clifford, MD. 2012. Tibial Fractures: Techniques of IM Nailing. *Wheeless' Textbook of Orthopaedics.* <http://www.wheelessonline.com/ortho/tibial_fractures_technique_of_im_nailing>
8. Odéhouri-Koudou, T; Gouli, J; Yao Kreh, J; Tembély, S; Ouattara, O; et al. *Elastic stable intramedullary nailing in paediatric traumatology at Yopougon Teaching Hospital*. African Journal of Paediatric Surgery: AJPS 8. 2 (May 2011): 155-8.
9. Synthes. 1998. *The Titanium Elastic Nail System: Technique Guide.* Adapted from <http://www.rcsed.ac.uk/fellows/lvanrensburg/classification/surgtech/ao/manuals/Synthes%20TENS%20nails.pdf> on September 30, 2012.
10. Ruiz, A. Kealey, W. Implant failure in tibial nailing. *Failure.* 1999. <http://www.injuryjournal.com/article/S0020-1383(00)00002-4/abstract>
11. http://www.beliefnet.com/healthandhealing/getcontent.aspx?cid=14867
12. http://www.medtronic.com/patients/coronary-artery-disease/therapy/balloon-angioplasty-and-stenting/index.htm
13. R. Pearce. Sheet metal forming. Adam Hilger, 1991.
14. Betts, A. 2008. Expandable Blade Device for Stabilizing Long Bone Fractures. U.S. Patent 8,157,804 B2, filed August 09, 2007, and issued on April 17, 2012.
15. Chai, Herzl. Lateral confinement as a means for enhancing load bearing and energy absorption in axially compressed tubes. *Thin-Walled Structures* 46.1 (2008): 54-64.
16. Chai, Herzl. The post-buckling response of a bi-laterally constrained column. *Journal of the Mechanics and Physics of Solids* 46.7 (1998): 1155-1181.
17. Affolter, Ch, et al. Collapse of a high storage rack. *Engineering Failure Analysis* 16.6 (2009): 1846-1855.

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 intramedullary 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 diaphysial 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

Appendix Table 1. Test data showing device length and horizontal expansion

Device length(mm)	Horizontal expansion (mm)
123	9
122	10.8
121	13
120	15
119	16.1
118	17
117	17.9
116	18.9
115	19.3
114	19.7
113	20.1

Table 2. Test data from buckling testing

		P (N)	k	c	Resultant Line Force
		0.000	0.000	0.000	0.000
		5.000	88.753	0.636	1.272
		10.000	125.516	0.899	1.799
		15.000	153.725	1.102	2.203
Length (m)=	0.045	20.000	177.507	1.272	2.544
n=	1	25.000	198.459	1.422	2.844
E (Pa) =	2.07E+11	30.000	217.401	1.558	3.116
Moment of Inertia=	3.07E-15	35.000	234.819	1.683	3.365
height(m)=	0.009	40.000	251.033	1.799	3.598
radius (m) =	0.00025	45.000	266.260	1.908	3.816
		50.000	280.663	2.011	4.022
		55.000	294.362	2.109	4.219
		60.000	307.451	2.203	4.406
		65.000	320.005	2.293	4.586
		70.000	332.085	2.380	4.759
		75.000	343.740	2.463	4.926
		80.000	355.014	2.544	5.088
		85.000	365.940	2.622	5.244
		90.000	376.549	2.698	5.396
		95.000	386.867	2.772	5.544

		100.000	396.917	2.844	5.688

Appendix: SolidWorks Model