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

Final Report

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Abstract

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

Background

Bone fractures occur while under stress or force, and result in loss of function due to the anatomical disconnect of the bone structure. Breaks of many types require proper fixation and realignment to ensure that the patient recovers load-bearing capability and full range of motion. The general process to full recovery involves fracture reduction and realignment, immobilization, and potentially physical therapy. Realigning bone fractures is crucial for successful healing because without proper alignment the bones may skew during healing leading to the need for corrective surgeries and longer rehabilitation time. After alignment is complete, the fractured bones must be immobilized for callus formation.[1] Several methods to correct the incurred bone fractures include splinting, casting, surgery, or combinations of the three.[2]

Tibia fractures account for 5 percent of all pediatric bone fractures, and due to the anatomy of the tibia during growth and development, these fractures are more difficult to treat in children than many other orthopedic fractures.[3] In addition to bearing force during walking, running, and standing, the tibia also plays a major role in growth and development as well as overall structure and stability.[3,4] Epiphyseal growth plates reside at the proximal and distal ends of the tibia. As shown in **Figure 1**, the adult epiphyseal growth plate hardens to form an epiphyseal line making the bone stronger, while in pediatric tibias it is not fused and more susceptible to fracture.[6] The growth plates are comprised of four different zones: resting, proliferative, hypertrophic, and spongiosa.[7] All of these zones are essential for proper bone growth. Any disturbance to these growth plates prior to fusion could result in uneven growth, requiring corrective surgeries. While fractures in adults are usually aligned and fixated by means of castings and splints, pediatric tibia fractures require more inventive methods for stabilization and immobilization.

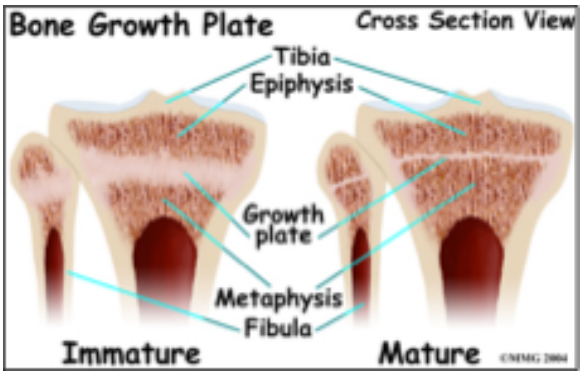


Figure 1: Diagram showing location of epiphyseal growth plates in a pediatric tibia and fusion of the growth plate in the adult tibia[5]

Management of tibia fractures also has an economic impact. In 2005, the health industry had average associated costs for operative management by intramedullary nailing of $3,365, for operative management by non-intramedullary nailing of $5,041, and for casting alone of $5,017. Societally, on average it costs $12,449 for operative management by intramedullary nailing, $15,571 for operative management by non-intramedullary nailing and $17,343 for casting alone.[8] The average time of healing for closed tibia fractures is between eight and twelve weeks, depending on wound severity and risk of infection.[9] Another component of the economic impact of tibia fractures is leaves-of-absence from work in adults, or parents missing work to care for injured children. By designing a novel fixation device to stabilize these fractures during healing, we hope to minimize hospital visits and time off work, expedite healing, and help reintegrate patients suffering from tibia fractures back into society as quickly as possible.

Problem Statement

Tibia fractures are common in children, and these injuries are currently managed nonoperatively using casts; however, a surgically implanted device would provide more structural stability and aid the healing of the fracture. Adult patients with this injury typically have a rigid intramedullary device implanted into their tibia bone. Unfortunately, these implants cannot be used in pediatric patients due to the presence of growth plates at the insertion site. A previous design team produced a working device that can enter the medullary canal through a hole in the side of the bone and then expand outward to stabilize the fracture, held in place by static friction against the canal wall. This device is flexible enough to fit into the canal, yet rigid enough to maintain fracture reduction, can be secured in place with screws, and can be removed from the canal when desired; however, the device is not fully fixated against the walls of the bone canal, and the friction force of the device is not sufficient to prevent axial rotation within the canal. This rotation can lead to device failure resulting in unnecessary pain for the patient and extra surgery to correct the issue. Last semester, our team designed a theoretical device consisting of a threaded segmented centerpiece inside of a metal biaxial braid. When the centerpiece is rotated, the braid experiences a compressive load, which causes it to expand radially. This radial expansion would ultimately provide the force to stabilize the fracture; however, the that design is not ideal, and the client has recommended improvements for it.

The goal of this semester is to improve the design from last semester by optimizing the centerpiece design and the braid/cap interface, which will give us the ability to build and test a prototype, and to develop a novel tool that can rotate the centerpiece when the implant is placed into a bone.

Current Devices

Intra-medullary Devices

Intramedullary rods are used for the stabilization and fixation of adult tibia fractures. To access the intramedullary canal of the tibia, an incision is made above the patellar tendon. A titanium intramedullary rod is inserted after a guide wire is placed inside the canal. Once the rod is in place, locking screws are inserted through the proximal and distal ends to secure it in place.[10] An implanted intramedullary rod is shown in **Figure 2**. Due to the epiphyseal growth plates, intramedullary rods cannot be used in pediatric tibia fractures. In a mature tibia, these epiphyseal growth plates are fused, and therefore are not an issue.

Figure 2: Rigid intra-medullary device implanted in fractured adult femur (A) aiding in alignment for proper healing (B)[11]

Elastic Nails

Elastic nails are a method of fixing fractures that avoids the epiphyseal growth plates in pediatric patients.[12] Approximately 5 percent of pediatric tibia fractures are currently treated using elastic nails because casting alone is insufficient to facilitate proper healing. As shown in **Figure 3**, two titanium nails, approximately 2.5 to 4 mm in diameter, are inserted from medial and lateral entry points at the proximal tibia in the distal metaphysis.[6] The traction forces are transformed into compression forces at the fracture by the two bent nails crossing each other and each providing three points of fixation within the medullary canal.[13] This leads to a total of six points of fixation for the fracture.

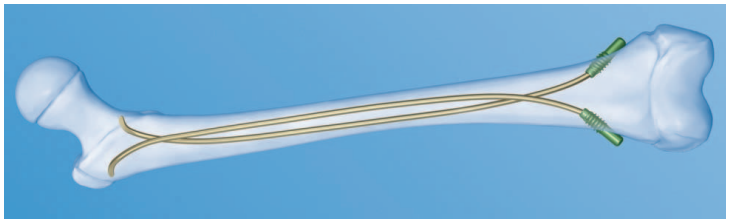


Figure 3: Diagram showing location of elastic nails in a femur. The locations are similar in the tibia. Elastic nails avoid contact with the growth plates.[6]

Although this method is currently used in pediatric tibia fractures, it works best for medial fractures because the elastic nails have a point of contact with the canal near this region; however, fractures at the distal and proximal ends of the bone are not optimally stabilized by elastic nails. This method has been proven to work effectively regardless of the type of fracture; however, it lacks support and fixation for non-midline fractures and allows for rotation within the tibia canal.[13]

Design Requirements

There are a number of important design requirements that must be considered in order to effectively optimize the previously designed tibial stent. Most importantly, the optimizations should improve the stent's ability to provide support and stability throughout the fractured area in the bone. This is important to ensure consistent alignment of the bone for the duration of the healing process, which can take anywhere between two and nine months. Complications could lead to improper healing and additional surgery. To accomplish this fixation, the modification must limit axial rotation of the device within the medullary canal.

Consistent with previous semester's work on this project, the device must be implantable at a location of the tibia that avoids the growth plates. Considering the fact that current devices used in pediatric tibia fractures use the same point of entry, this will keep some aspects of the surgical procedure consistent. The modified stent must be flexible enough to enter the medullary canal through a 8 mm diameter hole drilled at a 45˚ angle yet rigid enough to stabilize the fracture point. Preferably, the device's rigidity will be sufficient to be used in conjunction with minimal post-operative casting or elimination of post-operative casting. This would lead to a shorter recovery time, and enable the patients to return to daily life sooner.

Finally, all materials and components must be biocompatible and comply with all FDA guidelines regarding surgical implants.

Fall 2013 Design

Braided Cylinder

A stainless steel biaxial braided cylinder was used last semester to provide the primary means of fracture stabilization and axial fixation of the device. When placed under a compressive load, this braided cylinder expands radially between the top and bottom cap. In this previous design, the ends of the braided cylinder slide into a concentric circular recess on the underside of both the top and bottom cap and are fixed by a weld. This connection between the bottom cap and braid allows the rotational restriction of the bottom cap (provided by the screw) to also prevent rotation of braided cylinder. When a compressive load is applied so that the braided cylinder expands to the diameter of the intramedullary canal, the braid will begin to apply radial force against the bone leading to increased pressure at the fracture point.

Carjack Centerpiece

A viable centerpiece was designed to work specifically with the braided cylinder. The 3mm diameter segmented carjack centerpiece consists of several small, threaded, stainless steel segments that are connected together by joints; a small pin holds each of these joints together (**Figure 4a** & **b**). These joints allow each segment to bend at least 45˚ from the axis of the device, and the length of the segments allows each segment to sequentially enter the canal. This system allows the centerpiece to enter the canal through a hole 8 mm in diameter drilled into the bone at a 45˚ angle, yet maintain enough rigidity, once inside the canal, to support the device. The first and last segments of the centerpiece have slight modifications to facilitate the operation of the device. The top segment of the centerpiece has a built-in screw head so that it can be twisted using a standard flathead screwdriver (**Figure 4c**). Conversely, the bottom segment has an end plate that holds the bottom cap in place on the centerpiece (**Figure 4d**).

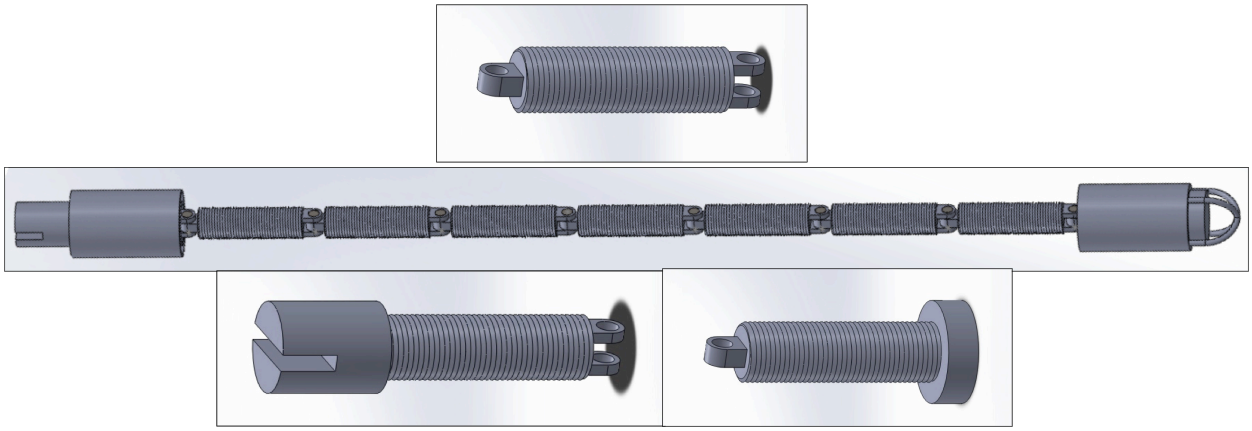


Figure 4: SolidWorks renderings of a) general threaded centerpiece segment; b) assembly of centerpiece segments with joints with top and bottom caps on the ends of the assembly; c) top segment of centerpiece allowing for twisting by screwdriver; d) bottom segment of centerpiece with endplate to hold the bottom cap on the centerpiece.

For this centerpiece to work, the top and bottom cap are independently designed. The bottom cap is not threaded and exhibits free lateral motion along the centerpiece restricted only by the end plate incorporated on the final threaded segment (**Figure 5a**). It also has two hooks that protrude over the end plate. When implanted, a screw is inserted through the bone passing through the hooks. This fixes the lateral position of the device and also prevents the bottom cap from rotating. In contrast to the bottom

cap, the top cap is threaded to match the segments of the centerpiece and is the main source of the compressive force on the braid (**Figure 5b**).

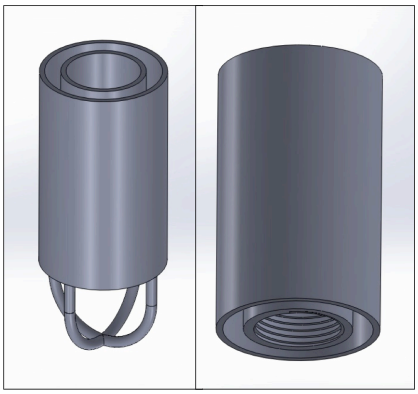


Figure 5: SolidWorks renderings of a) free sliding bottom cap with hooks for fixation; b) threaded top cap that supplies compressive load when centerpiece is twisted by moving down the centerpiece toward the end cap.

When the centerpiece is twisted, the rotational restriction of the top cap causes it to move down the threaded segments toward the bottom cap. This compresses the braided cylinder and induces its radial expansion. Once the braid contacts the canal wall, as more force is applied by twisting the centerpiece, the braid corrects any buckling that may have occurred and establishes uniform contact. As force continues to be applied, it is translated directly into a pressure pushing outward in all directions on the intramedullary canal wall at the fracture point thereby stabilizing the fracture.

While this design was a good start to accomplishing the desired goal while concurring with the necessary design requirements, it does introduce a number of complication, the first of which deals with the maximum tensile stress the centerpiece can handle before failure. Because the centerpiece has such a small diameter it does not allow for the joint design to be very big. The small amount of material that makes up the joints does not allow the design to have optimum strength, ultimately hindering the efforts to stabilize the fracture. This centerpiece is also somewhat complex. It is made up of several rather small pieces, which is never ideal when implementing something into the human body. Lastly, this design requires the user to spin the centerpiece itself in order to active the device and expand the braided cylinder. This will introduce an excessive amount of torsional strain on the jointed segments and possibly contribute to the mode of failure of the device.

Design Alternatives – Centerpiece Optimization

K-wire Centerpiece

Due to concerns regarding the reliability and functionality of the carjack centerpiece design, further alternatives were developed to specifically address issues with this first design. The first of these optimizations utilizes a Kirschner wire (K-wire) as the centerpiece to drive the caps together and provide the compressive load on the braid. A K-wire is a threaded rod made of stainless steel 309 that has a diameter specifically selected to lend the rod a certain degree of flexibility (**Figure 6**). These rods are typically used to temporarily stabilize fractures by

Figure 6: Kirschner wire typically used in surgical applications. This K-wire is only partially threaded; the K-wire used as a centerpiece for this design would be fully threaded.[14]

holding the bone fragments together. Diameters of K-wires typically range from 0.7 mm to 1.6 mm, and the flexibility of each wire is inversely related to its diameter.[15] For this design the caps would simply be attached to the K-wire, which would be flexible enough to maneuver through the hole 8 mm in diameter drilled into the proximal end of the bone at a 45˚ angle; however, to address the torsional loading concerns of the previous carjack design, the method of operation and the connection of the caps to the K-wire were altered. Rather than rotationally fixing the bottom cap and twisting the centerpiece to drive the top cap downward as in the carjack design, the bottom cap in this design would be fixed to the K-wire, and the top cap would be free sliding. A nut above this free-sliding top cap would supply the downward motion when it is twisted, thereby pushing the top cap downward and supplying the compressive force to expand the braid and apply pressure to the fracture point.

This design has a major advantage over the other designs in that the centerpiece is comprised of one solid piece, which would inevitably increase the torsional and tensile strength of the overall device relative to other options; however, the fact that the K-wire is one solid piece also poses a potential disadvantage since the added overall rigidity may make the device more difficult to implant and remove during surgery.

Threaded Segments on Wire

The final design combines elements of both the carjack and K-wire designs with the goal of creating a design that integrates the advantages of each. This design would use the same threaded segments of the carjack design except rather than connecting the segments with joints, the segments would be drilled along the cylindrical axis and then strung along a stainless steel wire like beads on a string. These segments would then be welded into position on the wire to prevent translocation along the wire during device operation (**Figure 7**). To supply the compressive force, this design would utilize the same method for attaching the caps to the centerpiece as the K-wire design. A fixed bottom cap and a free-sliding top cap would be driven together by twisting a nut above the free-sliding top cap. This would supply the compressive force on the braid leading to expansion.

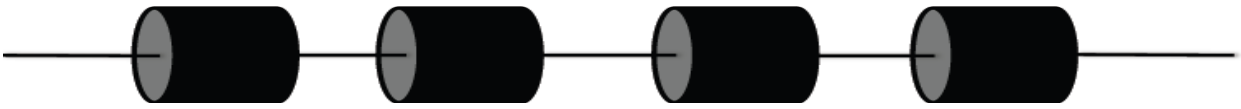


Figure 7: Schematic representation of threaded segments design. The threaded segments from the carjack design are strung along a stainless steel wire.

This design successfully combines the advantages of the first two designs. The threaded segments facilitate easy insertion and removal compared to the solid K-wire design, and the solid wire at the center of the device provides more tensile strength compared to the jointed segments; however, this device relies on the ability to twist the nut in order to deliver the compressive load, and as the braid begins to apply pressure to the intramedullary canal wall at the fracture point, friction in the threads of the nut will make twisting the nut more difficult. Flexible stainless steel wire has very little resistance to torsional loading and tends to curl in the center when loaded in excess. This fact may impede the ability of this optimized design to successfully integrate into the mechanism of operation for the current design.

Design Matrix – Centerpiece Optimization

A design matrix is an unbiased method to determine the best design idea moving forward in the design process given the current knowledge and understanding of the problem and background gained from research. Typically three competing designs are assessed based on a number of different important parameters of the design stated in the product design specifications. The parameters are weighed out of 100 based on importance to the design with the highest weight going to the most important parameters. Once the parameters and their respective weights are determined, each of the three designs is given a score from 1-5. 1 indicates a design that does not meet the parameter or meets the parameter poorly. Conversely, a score of 5 indicates a design that meets the parameter exceptionally or is the perfect or ideal design for the specified parameter. Once all designs are scored for each of the parameters, the final score for the design is computed by taking the sum of the scores normalized to the weight of each parameter. The design with the highest score out of a possible of 100 points will be deemed the winner and the likely design moving forward. If there are two designs with close final scores, more parameters may be considered in order to determine if there is a clear design winner.

To evaluate the carjack design, K-wire design, and threaded segment design, a design matrix was generated using weighted parameters (**Table 1**). Each design was given a score between 1 and 5 with 1 indicating "poor," 2 indicating "average," 3 indicating "good," 4 indicating "great," and 5 indicating "exceptional." Following design scoring, the scores for each category were weighted leading to a maximum possible score of 100.

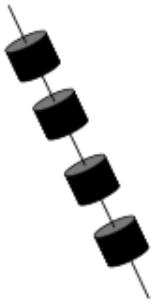
Parameters (Weight)	Last Semester's Design 		K-Wire 		Piano Wire with Segmented Threads 	
Tensile Strength (30)	2	12	5	30	3	18
Ease of Implantation and Removal (25)	4	20	2	10	5	25
Client Preference (20)	2	8	5	20	3	12
Fabrication (15)	2	6	5	15	4	12
Cost (10)	1	2	5	10	4	8
Total (100)	**48**		**85**		**75**	

Table 1: Design matrix for centerpiece optimization. Designs evaluated in the matrix are the design from last semester, which is the base for the optimizations, the K-wire centerpiece design, and the segmented threads on a wire centerpiece design.

The parameters considered in this matrix are tensile strength, ease of insertion and removal, client preference, fabrication, and cost. Tensile strength was given the highest weight because the tensile strength of the centerpiece may be the determinant in how much pressure can be applied to the canal, which is directly related to the efficacy of the device. The second parameter was ease of insertion and removal. It is critical that this device be relatively simple to use in the operating room and that potential complications are minimized since this is a medical implant. The next parameter is client preference and, while we recognize that the client has a great deal of experience in the field and we take this into consideration, it should not have an overwhelming influence on the outcome of the design matrix. Finally, the last two categories are ease of fabrication and cost. Because our client has provided a very generous budget for this project, all components of the device will be purchased from an independent manufacturing firm and, while the production cost of the device is relevant for scale-up, it is not a major concern for this project.

Carjack Centerpiece

The tensile strength of the carjack centerpiece design is thought to be very low due to the information garnered from SolidWorks simulations last semester (unpublished data) and the segmented nature of the design. This device is predicted to be easily implanted into the canal if designed correctly due to the joints allowing bending of the device for entry; however, it does not have the same degree of freedom as the segmented threads design because the joints are unidirectional. The client is apprehensive of this design due to its innate complexity and the fact that the centerpiece is not one solid piece. Additionally, since the device is small and complex, the ease of fabrication is low and the cost is high, so this design is weighted low for both of these parameters.

K-wire Centerpiece

The tensile strength of the K-wire design is very high due to the fact that the device is one solid stainless steel piece; however, implanting and removing the device could be quite challenging as well due to the K-wire's limited flexibility. Because this design results in the centerpiece of the device being one solid piece, our client highly approves of this design. Finally, because the device is commercially available, fabrication is a non-issue, and the cost is relatively low compared to fabrication costs for the other two designs.

Segmented Threads on Wire

The tensile strength of the segmented threads design is between that of the K-wire, because the wire is flexible and thinner, and that of the carjack centerpiece, because the wire is all one piece rather than jointed segments. This device is predicted to be the easiest out of all three to implant and remove from the bone canal because the wire facilitates bending between the segments in any direction thereby easing insertion and removal. While the client prefers this design to the carjack centerpiece, because it has a component that is all one piece, he also has concerns about the complexity of the design and would prefer something simpler. Finally this device is relatively easy to fabricate once the segments are created and the projected cost is relatively low because of the wire is commercially available.

Summary

Ultimately, the K-wire design was the highest scoring design in this matrix due to its high tensile and torsional strength and the client's strong preference for this design as well as its low cost and ease of fabrication. The only category in which the K-wire design did not have the highest score was the ease of insertion and removal; however, by selecting the diameter of the K-wire carefully, concerns regarding the balance between flexibility and strength will be minimized.

Design Alternatives – Braid/Cap Interface Optimization

The braid interface with the caps is a key component to the success of the design, and different modes of connection must be evaluated when developing ideas as how to best approach fabrication of the prototype. Failure at this juncture could result in complications for the patient and may be economically taxing for the manufacturer.

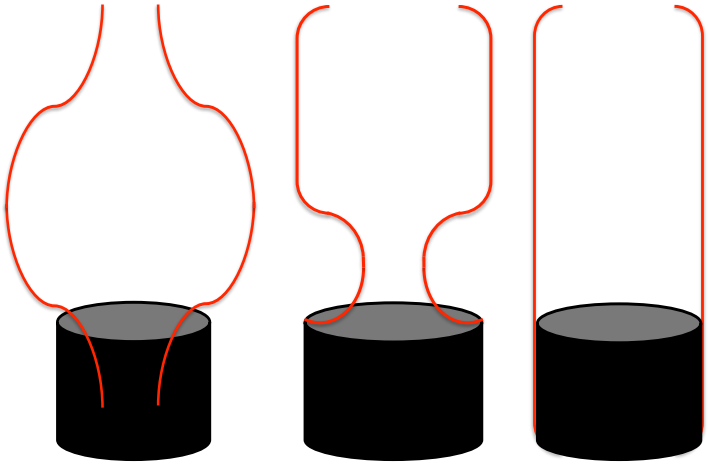


Figure 8: Design alternatives for braid/cap interface. a) braid welded to a groove in the cap. b) braid welded to the underside of the cap. c) braid welded to the side of the cap.

The first design is the most complex. A circular groove is cut out to half the height of the cap. The inner and outer diameters of the groove are concentric with the outer circumference of the cap. These grooves are where the ends of the braided cylinder are placed before being welded to the caps (**Figure 8a**). This design was originally developed last semester. The second design has the ends of the braided cylinder pulled outward and slightly inverted. Each end of the braid is then laid flat on the underside of a cap and welded down (**Figure 8b**). For the third and final approach the end of the braided cylinder encompasses the cap and is welded directly to the side of the cap (**Figure 8c**). This is the simplest design of the three. For this design, the braided cylinder is directed nearly straight up the cap.

Design Matrix – Braid/Cap Interface Optimization

The development of the braid cap interface design matrix follows the same procedure and has the same purpose as previous design matrix. The designs were given a score from 1 to 5 and then normalized to the weight of each parameter with a possible maximum score of 100.

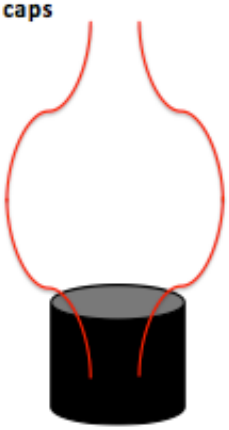
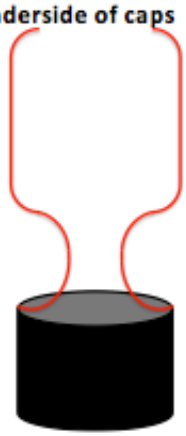
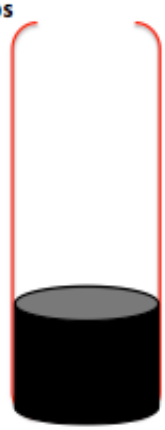
Parameters (Weight)	Braid welded inside caps		Braid welded to underside of caps		Braid welded to side of caps	
						
Risk of inversion (40)	2	16	5	40	4	32
Stress on Weld (40)	5	40	4	32	2	16
Fabrication (10)	1	2	3	6	4	8
Cost (10)	2	4	5	10	5	10
Total (100)	**62**		**88**		**66**	

Table 2: Design matrix for braid/cap interface optimization. Designs evaluated in the matrix are welding the braid into a groove in the cap, welding the braid to the underside of the cap, and welding the braid to the side of the cap.

In the design matrix, the first parameter considered was the risk of inversion, or the chance of the cap pulling through and inverting the braid under large loads. Stress on the weld was the next parameter considered. Both of these parameters were given a weight of 40 because these are properties that influence the strength and reliability of the finished product, while the other two parameters for this design matrix, ease of fabrication and cost, are manufacturing properties and are less important for the functionality of the design. Fabrication and cost were given an equal weight of 10.

Fix in Groove of Cap

In this first design, the risk of inversion is believed to be high, due to the outward curvature of the braided cylinder near the cap, thereby facilitating movement of the caps towards one another. For this reason, the risk of inversion for this design was given a low score. This design's strength is in the stress put on the weld, so it was given an exceptional grading. The stress on the weld of this design is very low compared to the other designs because all the force being applied to the braided cylinder is being transferred through the cap rather than the weld. Although this is very effective for removing stress from the weld point, the removal of material may compromise the strength of the cap. The presence of the groove in the cap also complicates the fabrication of the caps and makes welding the braided cylinder to the cap more difficult. As a result of this more complex fabrication procedure, the manufacturing cost of the caps in this design is more expensive relative to the other designs. This is the reason why both fabrication and cost were each given low scores.

Fix to Underside of Cap

This second design has the lowest risk of inversion due to the inward bending of the braid near the cap. The braid has a high stress concentration at this curve, but this curve will prevent the caps from pulling through and inverting the braid. The stress on the weld is also low for this design. The majority of the force being applied to the braided cylinder is travelling through the cap at the braid/cap interface. The force that is not directly relayed from the cap to the braid is distributed along the braid surface and causes a small stress at the weld. This stress is larger than in the grooved design, but smaller than the third design where the braid is fastened to the side of the cap. Fabrication of this design is considerably easier than the first design. The cap is not as complex to fabricate without the groove, present in the first design; however there is still a small amount of space to weld the braid to the cap. Finally, cost of this design is relatively low relative to the budget for this project.

Fix to Side of Cap

As stated above, the braided cylinder in the third design is directed nearly straight up the cap. With no inward bend similar to the second design there is a higher likelihood that the cap will invert the braid; however, there is no outward bend to promote the caps inversion as in the first design. The major disadvantage of this design is the high stress put on the weld. All the force being applied by the braided cylinder is being transferred through the weld. Because the caps are very small and welding will be difficult it is not expected that the weld will have the same strength as the stainless steel caps. The fabrication of this design would be the easiest because there is more area on the cap to weld the braid, and the welding points are more accessible to the welder compared to the other two designs. Finally the cost of this design will be the same as for the second design, and thus it received the same score.

Summary

In conclusion, the second design (braid welded to underside of the cap) scored highest in the design matrix mainly due to its inherent resistance to inversion and relatively low stress applied to the weld.

Final Design

The final design consists of a K-wire centerpiece (threaded stainless steel) with a bottom cap fixed to one end of the K-wire and a top cap that is not threaded facilitating free lateral motion. Both the top cap and bottom cap are welded (underside of the caps) to the ends of the braided cylinder (**Figure 9**). A threaded nut is placed above the top cap to push the top cap towards the bottom cap generating a compressive force on the stainless steel biaxial braided cylinder. This causes the braided cylinder to expand outward, providing a radial force. This radial force will generate a pressure inside the intramedullary canal, which will stabilize the fracture until healing is complete.

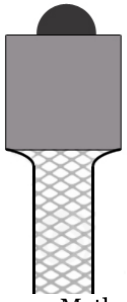


Figure 9: Method of attaching braided cylinder to each cap

Materials & Expenses

Braided Cylinder

For this device, a stainless steel biaxial braided sleeve was obtained from Techflex (Model: Flexo SS). Of the two braids obtained, this braid had the most natural rigidity and, due to thicker wires, was overall sturdier than the other braid. These braids are typically used to protect hoses or form conduits of multiple hoses in automotive and aerospace applications. For this design, the expansive properties of the braid under axial compression are the basis for the success or failure of the device.

Kirschner Wire

Kirschner wires (K-wires) are sterilized, sharpened, smooth stainless steel pins widely used in orthopedics. They come in different sizes and are used to hold bone fragments together or to provide an anchor for skeletal traction. The K-wires are often driven into the bone through the skin using a drill. This device uses a threaded K-wire as its centerpiece, which the threaded nut screws down in order to compress the braided cylinder.

Top and Bottom Caps

The top and bottom caps are free-sliding and were fabricated out of stainless steel stock by Caspersen Machining in Deforest. There were two sets of caps, one for each sized K-wire (5/64" and 3/32"). For both the top cap and bottom caps (see **Appendix**: *Solidworks of Top and Bottom Caps*) the holes matched the diameter of the K-wires. The diameter of the holes for the 5/64" caps is 0.078125" and the diameter of the holes for 3/32" caps are 0.09375". The outer diameter for all caps (5/64" and 3/32" & top and bottom caps) is 0.23622" (6 mm) and the height of all caps is 0.3937" (10 mm). The bottom caps are fixed at the bottom end of the K-wire as a threaded nut, described below, restricts the top cap movement. A nail is inserted through the bone and through the hooks of the bottom cap to avoid lateral movement up and down the bone canal and to fix the device in place when the surgeon screws down the nut and expands the braid, effectively activating the device.

Threaded Nut

A threaded nut with a thread count corresponding to the different K-wires sizes (5/64" and 3/32") were used to be screwed down the K-wire and push the two caps together. The threaded nut sizes were 2-56 and 3-48 for the smaller and larger diameter K-wires, respectively.

Auger

A hand auger was the tool selected to apply the necessary torque from outside the bone to drive the threaded nut down the K-wire inside the bone canal. This tool is commonly in plumbing to unclog drains. The surgeon will be able to turn the auger hand clockwise, which will result in rotation of the drive shaft and external hex broach to turn down the threaded nut to activate the device.

Drive Shaft

The hollow flexible shafts from Suhner Manufacturing Inc. are extremely rugged, high-longevity components that permit continuous work operations at both low and high-speed ranges, up to 50,000 rpm. This is far above any speed possible when

spinning the hand auger. These hollow shafts have been used in orthopedic equipment before due to the high flexibility and very smooth rotation. The specific drive shaft that we obtained from Suhner Manufacturing Inc. has 4 high-tension wires per layer with an outside diameter (**Figure 10A**) of 8 mm and inside diameter (**Figure 10B**) of 3.20 mm.

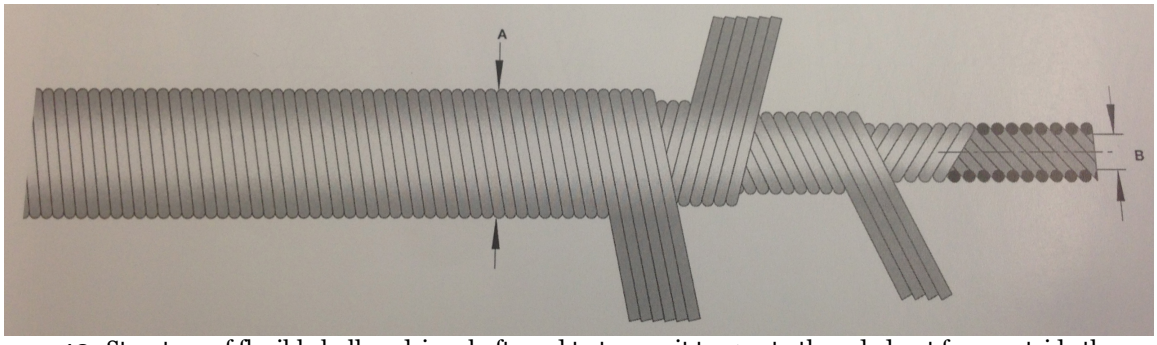


Figure 10: Structure of flexible hollow drive shaft used to transmit torque to threaded nut from outside the canal. Measurement A shows the outer diameter, while measurement B shows the inner diameter of the shaft. (Image provided by Suhner Transmission Expert)

The flexible shaft will be used to transmit mechanical rotary power from the drill or auger outside the bone to the device inside the bone. This transmitted torque moves the threaded nut down the K-wire, which in turn expands the metal biaxial braid. The drive shaft is a great substitution for complex drive units, such as gears or universal joints and becomes especially helpful when dealing with a limited workspace. Approximately 1 foot of this drive shaft was connected to the auger and the external hex broach.

External Hexagonal Broach

The external hex broached piece (**Figure 11**) is made of M2 metal that goes around the threaded nuts, and serves as a socket adapter to twist the threaded nuts down the K-wire. M2 metal is high-speed steel commonly used for twist drills, reamers, broaching tools, and taps. Some key measurements to consider are the across flats diameter of 0.185" for the hole, which is slightly bigger than the threaded nuts across diameter. Also the overall length of the external hex broach is 0.472" (12 mm), which is short enough to fit in the canal of the smallest of child tibias, which have a diameter in the middle of the bone of approximately 0.3937" (10 mm). Using trigonometry, we calculated that the length of the broach needed to be shorter than 0.5568" (14.142 mm) for an angle of entry into the bone of 45˚. In addition this broach has a diameter of 0.315" (8 mm), which is just small enough to fit inside the drilled hole into the proximal end of the tibia made during surgery to insert the device.

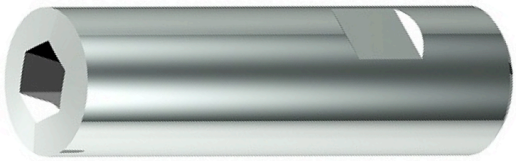


Figure 11: Image of external hexagonal broach used as socket adaptor for this design. (Image provided by Polygon Solutions)

Expenses

The expenses for this semester are outlined in **Table 3**.

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

Table 3: Expenses for the Tibial Stent design project (both Fall 2013 and Spring 2014).

Fabrication of Prototype

Validation of Braid Efficacy

Before fabrication of the prototype could begin it was necessary to confirm the effectiveness of the braid. In order to do this, a much larger device was used in testing. This 'proof of concept' used the compression of a braided cylinder to apply stability at the fracture point on a larger scale. The device was placed inside a PVC tube that was cut halfway along its length at a 45° angle in order to model the bone fracture. A cantilever and four point bend test were then conducted on the bone with both the device deactivated and activated. It was observed that the activated proof of concept device lowered the deflection angle in the cantilever and four point bend test by 6.33° and 0.49° respectively. This confirmed the use of the braid to be effective at stabilizing individual components and justified beginning fabrication of a prototype.

Fabrication of Prototype

The first part of fabrication involved attaching the two ends of the 150 mm biaxial braided cylinder to both the top and bottom cap. Silver soldering was tested as a way to attach the pieces together and create a strong enough interface to handle the necessary compressive load. Due to the small scale of the device, this technique was unsuccessful. The small size of the pieces being soldered made it extremely difficult to concentrate the heat in the desired area. As a result, the heat transferred too far down the braid causing the silver solder to rush down toward the middle of the braid and stiffen the individual wires, ultimately hindering the biaxial braided cylinder from expanding properly. On top of that, the extra material present around the interface of the cap and braid from soldering increased the overall diameter of the device beyond the maximal 8 mm for insertion into the canal. These complications led to a change in the design of the caps. Instead of having a uniform diameter of 8 mm for the entire 10 mm length of the caps, the diameter was cut to 3.75 mm half way down to allow space for the solder (see **Appendix**: *Redesign of Top and Bottom Caps*). In order to compensate for the inability to solder the individual pieces, a JB Weld concrete adhesive was used for the prototype. It is important to note, however, that the JB Weld adhesive is not biocompatible and, therefore, will have to be replaced by a biocompatible low-temperature weld in the future.

Once the biaxial braided cylinder was attached to the caps, the K-wire was then slid through the top cap and fixed to the end cap. For many of the same reasons previously mentioned, the same JB weld adhesive used in the connection of the braided

cylinder to the caps was used also used for this connection. The final prototype is shown in **Figure 12**.

Figure 12: Completed prototype of design. The center threaded K-wire is attached to the bottom cap with JB Weld through the free-sliding top cap. The braid is attached with JB Weld to each cap. Another layer of braid was used to repair a braid rupture in the middle of the device due to damage sustained prior to fabrication. This repair braid was attached using heat shrink tubing. The threaded nut is above the top cap ready to compress the braid when driven by the drive shaft assembly.

Sawbone Model Preparation

In order to accurately test the prototype a pediatric Sawbone tibia analog was also prepared in the student shop. First, the Sawbone was cut at half of the length of the tibia shaft at a 45° angle in order to model one of the more common bone fractures, known as an oblique fracture.[16] Next, the 8 mm 45° hole for insertion into the side of the bone was drilled at the proximal end. Due to the irregular cross section of the bone, a wooden saddle was developed and utilized along with an angle plate to hold the bone in place during drilling.

Assembly of Drive Shaft

The length of the flexible hollow drive shaft received from Suhner was too long for use with this device at a length of 6 meters. For efficiency, the drive shaft was shortened to approximately 1 foot. This was done by silver soldering all the way around the outside of the diameter of the shaft to ensure that the high-tension wires of the drive shaft did not unravel during cutting. A cut was then made with a dremel in the middle of the soldered zone. After cutting of a suitable section of the drive shaft, the external hexagonal broach was fastened to one end using a substantial amount of JB Weld adhesive. The assembled drive shaft is shown in **Figure 13**.

Figure 13: Drive shaft assembly for applying torque to nut above top cap on device from outside intramedullary canal. Consists of a manual auger (left), a segment of flexible hollow drive shaft (center), and the small external hexagonal broach serving as a socket adaptor used to engage the nut (right).

Device Use Protocol

When the pediatric patient comes in to the hospital with a completely fractured tibia the surgeon can decide whether or not casting will be enough to support the bone during the healing of the bone. If not, the device can be used to support the bone temporarily as the patient recovers. To begin surgery, the surgeon would make an

incision near the proximal end of the tibia and gain access to the side of the bone, just beneath the growth plates. A drill will then be used to make a hole 8mm in diameter made at approximately a 45° angle to allow for device entry. Before the device is inserted, the canal is reamed out and all bodily material (blood, fat bone marrow, etc.) is removed. The device is then inserted bottom cap first through the canal and forced down the canal until the entire K-wire is inside the canal. Next the drive shaft is inserted through the drilled hole, external hex broach end first. The external hex broach then goes around the K-wire and down towards the threaded nut. The broach is then rotated until the entire nut is inside the broach. The surgeon can then spin the auger clockwise to move down the threaded nut, which moves down the top free-sliding cap towards the bottom cap. As the caps come closer together the braided cylinder expands, providing a radial force on the intramedullary canal walls to align the two fractured bone pieces and provide bending strength and resistance to rotation to the tibia. In order to remove the device from the tibia, the drive shaft is inserted back through the drilled hole (the hole may need to be re-drilled depending on the healing at the drilled hole site) and over the K-wire and threaded nut again. The auger will then be turned counter-clockwise to screw the threaded nuts up and allowing the top cap to move up the K-wire, decreasing the diameter of the braided cylinder. The braided cylinder will no longer be pushing against the canal wall and will be at a narrower diameter that will allow for easy removal.

Testing Protocols

The goal for testing of the prototype was to assess its ability to stabilize the fracture in bending and torsional loading scenarios. Thus, the prototype was tested using both cantilever bend testing and rotational stiffness testing. The tests were conducted using both the prototype and elastic nails, the currently used device that this device is attempting to replace, to stabilize the fracture. Importantly, the drive shaft was too large to fit into the hole drilled at the proximal end of the bone, so the device and drive shaft were inserted from the distal end, where a hole the diameter of the canal already exists on the model. The actual prototype was confirmed to fit through the 45° insertion hole at the proximal end, but the drive shaft had to be used through the bottom of the Sawbone.

Cantilever Bending

Testing using the 'proof of concept' device previously showed that the braid stabilizes a pure bending moment at the fracture point. To expand on this result, cantilever bend testing was conducted on the final prototype to observe the efficiency of the device at stabilizing both bending moments and shear forces at the fracture point. For this testing, the bone, with either elastic nails or the prototype inserted to stabilize the fracture, was C-clamped to a level surface with the fracture point unsupported (**Figure 14**). Next, the baseline configuration of the bone was documented by taking an image of the setup and then a known load was applied to the unsupported end of the bone. Another image was taken to document the position of the bone under loading, and then the process was repeated three times for each of 10 different weights to facilitate statistical analysis of deflection under each different applied weight.

Figure 14: Cantilever bend testing setup.

Rotation

One of the main design objectives for this semester was to increase the axial fixation of tibia fractures. For this reason, the rotational fixation of the device was tested. In order to evaluate the extent to which the device would provide axial fixation within the intramedullary canal, the bone was C-clamped to a level surface with the fracture point unsupported. Next, a moment arm was attached to apply a torque at the free end of the bone (**Figure 15**). The amount of force required to rotate the bone to 90˚ was measured using a force gauge at the end of the moment arm. This test was repeated five times to facilitate statistical analysis.

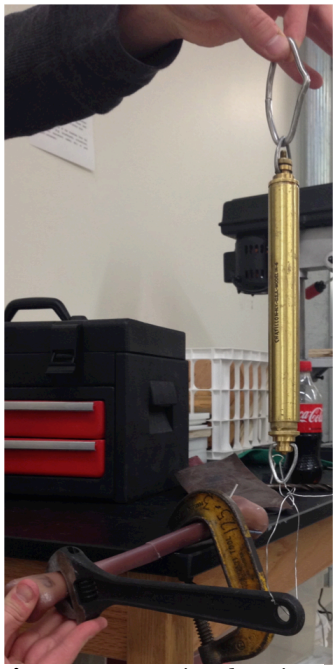


Figure 15: Rotational testing setup.

Data Analysis

Cantilever Bending

The angle at the fracture point was measured for each replicate and control using ImageJ. Then the difference between the control and loaded state was calculated giving the bend deflection angle for each replicate. The mean, standard deviation, and standard error of the deflection angle were computed for each weight applied. Independently, the moment at the fracture point was calculated, and then this moment was normalize to the deflection angle to yield the bending stiffness for each replicate. The mean bending stiffness, standard deviation, and standard error were then calculated for both elastic nails and the braid design. Finally, we used a t-test to compare the mean bending stiffness of elastic nails to that of the braid device ($\alpha = 0.1\%$).

Rotation

First, the moments applied at the central axis of the SawBone for each trial were computed from the measured force values. Then each moment value was normalized to the 90˚ that the SawBone was twisted to give the rotational stiffness for each replicate. Finally, the mean rotational stiffness, standard deviation, and standard error were calculated from the values from each trial. This analysis was not possible for elastic nails because the values were too low to measure using the smallest force gauge (6 lb) from the COE student shop. As a result, no further statistical analysis was performed.

Cantilever Testing Results

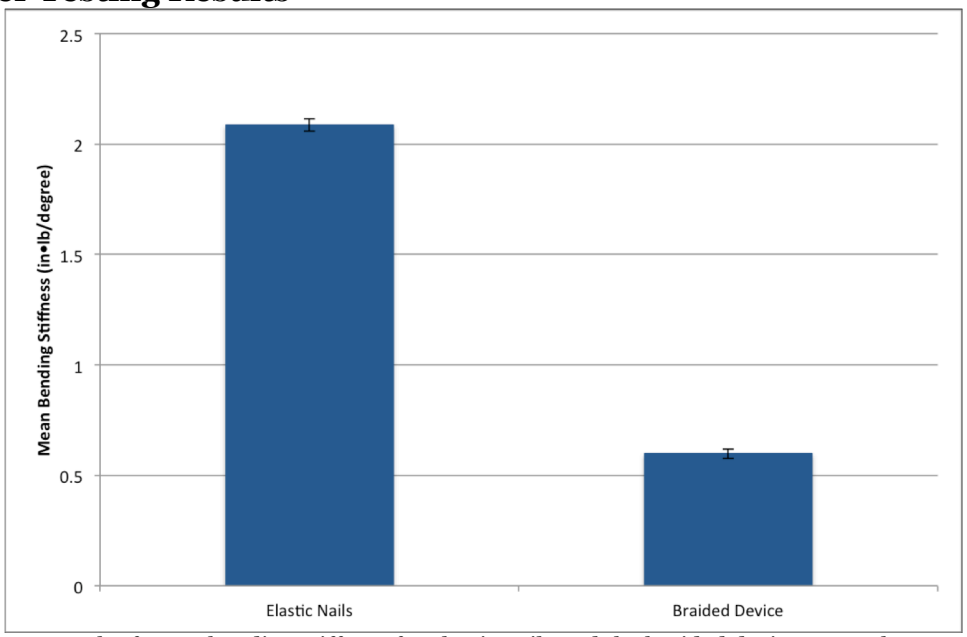


Figure 16: Bar graph of mean bending stiffness for elastic nails and the braided device. Error bars represent +/- 1 standard error of the mean. n = 30 for elastic nails, and n = 15 for the braided device. The difference between the two means is statistically significant by a t-test ($p < 0.001$).

The mean bending stiffness of elastic nails inserted into a fractured Sawbone model was 2.09 ± 0.155 in•lb/degree (n = 30), and the mean bending stiffness of the braid device designed this semester in the same bone model was 0.60 ± 0.07 in•lb/degree (n = 15) (**Figure 16**). The difference between the mean bending stiffness for elastic nails and the braid device is statistically significant ($p < 0.001$).

Discussion

Because the difference between the bending stiffness of elastic nails and the braid device is statistically significant, the elastic nails give the fracture greater resistance to bending than the current form of the braided device. This is likely largely due to the fact that elastic nails are solid pieces that fill a large portion of the intramedullary canal along the length of the tibial shaft, while the braid, which is what actually supports the fracture in the braid design, is much thinner than the nails leading to less space taken up in the canal. Additionally, the current braid being used with the device plastically deforms easily under compressive load, so the device could not be activated to its full potential. This further reduced the bending stiffness of the braid device; however, these

data show that the braid device does have an influence on the bending stiffness at the fracture point.

Rotational Testing Results

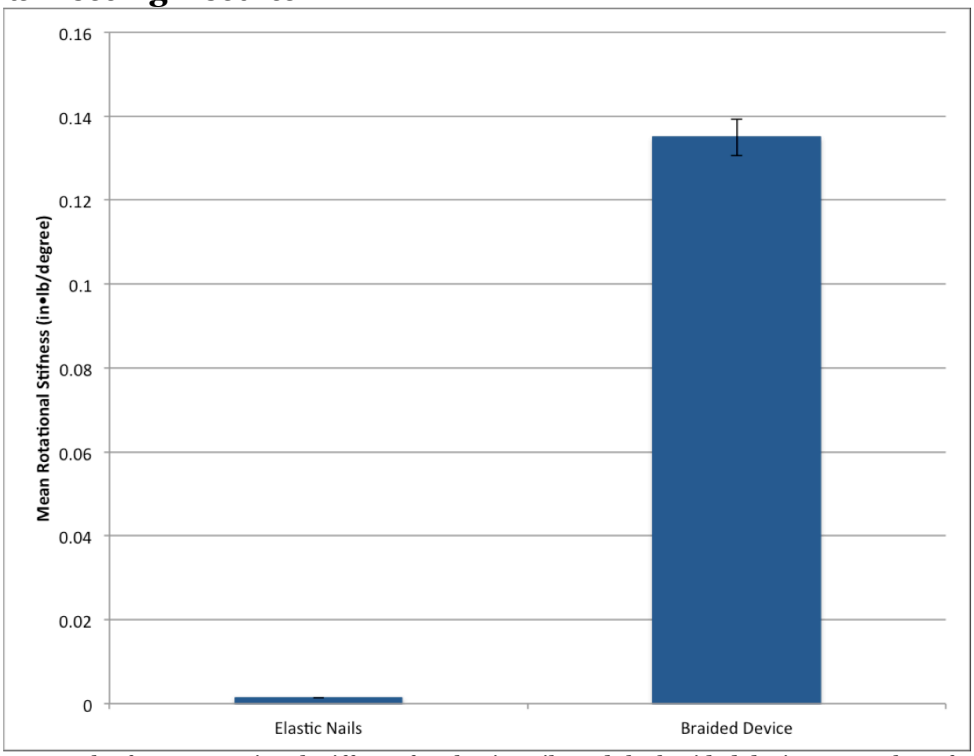


Figure 17: Bar graph of mean rotational stiffness for elastic nails and the braided device. Error bars for the braided device represent +/- 1 standard error of the mean. n = 5 for the braided device, n is not defined for elastic nails because the value shown represents the maximal value that could be measured using the force gauge.

The mean rotational stiffness of the braided device inserted into a fractured Sawbone model was 0.135 ± 0.00981 in•lb/degree (n = 5). The rotational stiffness of elastic nails inserted into the same model was not accurately measurable using a 6 lb force gauge, the smallest gauge available; however, the maximum force value measured resulted in a rotational stiffness of 0.0014 in•lb/degree, which is roughly two orders of magnitude lower than the rotational stiffness of the braided device (**Figure 17**).

Discussion

Although the rotational stiffness of the Sawbone with elastic nails inserted was not accurately measured, the data show that the braid device has a greater rotational stiffness than the elastic nails when inserted into a fractured Sawbone model. Given that the maximum observed rotational stiffness of the elastic nails in the Sawbone was two orders of magnitude less than the rotational stiffness of the braided device, and the standard error of rotational stiffness of the braided device is relatively small, we have reasonable confidence in this conclusion. The greater rotational stiffness of the braided design is likely due to increased surface area contact between the intramedullary canal wall and the device in this design compared to elastic nails. This causes greater friction force within the canal that resists torsional loads applied to the Sawbone with the braid device inserted.

Future Work

The first, and perhaps the most obvious, next step will be to obtain a hollow flexible drive shaft that has a narrower diameter that will be able to enter through the drilled hole made in surgery and be inserted down the canal where it can then activate the device. This will require a request for a custom flexible drive shaft from Suhner Manufacturing Inc., which is a possibility. A smaller drive shaft was not obtained this semester due to time constraints and that the drive shaft was given as a gift (free of charge). We accepted the drive shaft and used it as described in the testing section.

In order to improve the device's fabrication process, threaded nuts would be custom ordered to be 4 times the original height. This would increase the strength of the nuts, which may translate to an overall increase in the strength of the entire device, and would also make it easier for the surgeon to tell when the drive shaft has actually engaged the nut. The client has emphasized simpler designs and surgical procedures will result in better outcomes for the patients.

In addition, the team has discussed the possibility of using a biaxial braided cylinder made of metal ribbon instead of layers of metal wire. This would be done to increase bending stiffness and decrease the chances of buckling and fix any osseointegration problems that may arise during animal testing. The metal ribbon would not have as many holes in the mesh, which translates to less unsupported length resulting in lower probability of buckling and plastic deformation.

In addition the device needs to undergo osseointegration testing. This will be to ensure that the bone has not grown into the device when attempting removal of the device. The device will need to be proven to promote effective healing of the fracture with fewer malunions and nonunions than elastic nails before clinical trials can be considered. This would require the use of cadaver bones and animal testing. Dr. Ploeg of the UW – Madison Department of Mechanical Engineering informed the team that the best animal bone option to model a human pediatric tibia would be an onvine tibia due to the similar size and shape. In order to expand the use of the device in other long bones, the size of the device should be changed and further testing may also be needed on bigger bones. FDA approval would then need to be obtained to conduct human testing and eventually commercialize the design if it proves to be more effective in providing fixation to the bone than elastic nails.

After confirmation of the possibility of commercialization, the amount of casting required to help the device support the fracture will need to be determined. Ideally there would be no casting required, but this is likely unrealistic. Instead the goal is to use minimal casting. Casting is very uncomfortable and limits a patient's movement significantly, hindering everyday activities. The ultimate goal of this device is to minimize patient discomfort and return patients to normal activities as quickly as possible following injury by surgically implanting a device that can promote rapid healing of the fracture.

Acknowledgements

The team would like to acknowledge the advisor for this project, Dr. Paul Thompson, for his insight and guidance, as well the client for this project, Dr. Matthew Halanski and his assistants, Sarah Sund and Tana Sloan-Barsch. Also, the team would like to acknowledge Dr. Heidi Ploeg for her assistance with formulating a testing protocol. Finally, the team would like to acknowledge all parties involve in fabrication of the prototype for this project including Ray Farino of Suhner Transmission Expert, Bob Caspersen and Russell Rought from Caspersen Machining, and Tom, Tanner, Kyle, and Mark from the COE Student Shop.

References

[1] Merloz, P. (2011). Macroscopic and microscopic process of long bone fracture healing. *Osteoporos Int* 22:1999-2001.

[2] Srivastava, A.K., Mehlman, C.T., Wall, E.J., Do, T.T. (2008). Elastic stable intramedullary nailing of tibial shaft fractures in children. *J Pediatr Orthop* 28:152-158.

[3] He B, Wang J. (2012) Plate fixation of paediatric fractures of the distal tibia and fibula. *Acta Orthop Belg*. 78(5): 660-2.

[4]Rockwood, C.A.,Wilkins, K.E., Beaty, J.H., Kasser, J.R. Rockwood and Wilkins' fractures in children.5thed.Philadelphia:LippincoRWilliams&Wilkins,2001.

[5] A Patient's Guide to Blount's Disease in Children and Adolescents. (n.d.). A Patient's Guide to Blount's Disease in Children and Adolescents. Retrieved September 20, 2013, from http://www.orthopediatrics.com/docs/Guides/blounts.html

[6] Synthes. (1998). The Titanium Elastic Nail System: Technique Guide. Adapted from <http://www.rcsed.ac.uk/fellows/lvanrensburg/classification/surgtech/ao/manuals/Synthe s%20TENS%20nails.pdf>

[7] Brighton, C.T. (nd). Normal Bone Formation: Epiphyseal Bone Formation. http://cal.vet.upenn.edu/projects/saortho/chapter_02/02mast.htm

[8] Busse, Jason W., Mohit Bhandari, Sheila Sprague, Ana P. Johnson-Masotti, and Amiram Gafni. "An Economic Analysis of Management Strategies for Closed and Open Grade I Tibial Shaft Fractures." *Acta Orthopaedica* 76.5 (2005): 705-12.

[9] Marshu, Rakesh P., MD, Martin J. Herman, MD, and Peter D. Pizzutillo, MD. Tibial Shaft Fractures in Children and Adolescents. *Journal of American Academy of Orthopaedic Surgeons* 13.5 (2005): 345-52.

[10] Wheeless, Clifford, MD. (2012). Tibial Fractures: Techniques of IM Nailing. Wheeless‘ Textbook of Orthopaedics.

[11] Lee, Z., Chang, C., Yang, W., Hung, S. (2005). Rush pin fixation versus traction and casting for femoral fracture in children older than seven years. Med. J. 28: 9-15.

[12] Parikh, S.N., Nathan, S.T., Priola, M.J., Eismann, E.A. (2013). Elastic nailing for pediatric subtrochanteric and supracondylar femur fractures.

[13] O’Brien, T., Weisman, D.S., Ronchetti, P., Piller, C.P., Maloney, M.(2004). Flexible titanium nailing for the treatment of the unstable pediatric tibial fracture. *J Pediatr Orthop* 24:601-609.

[14] Disposable Instrument. (nd). Products – Steinman pins. http://www.disposableinstrument.com/steinman.php

[15] Delta Surgical Instruments. (nd). Kirschner wire (K-wire). http://www.deltasurgicalinstruments.com/Catalog/K-Wire.pdf

[16] Skurihin, Y. K. "Transfocal Compression Fixation of Oblique and Spiral Fractures of the Tibia." *The Journal of Trauma: Injury, Infection, and Critical Care* 17.1 (1977): 85-95.

Appendix

Product Design Specifications

Client: Dr. Matthew Halanski, MD

Advisor: Dr. Paul Thompson, PhD

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

Function:
Rigid intramedullary devices have been used in adults with complete fractures of the bone; however, this method cannot be used in pediatric patients due to the presence of epiphyseal growth plates at either end of the bone. Therefore the purpose of this project is to design and fabricate a device similar to a rigid intramedullary device which can be used in pediatric patients. A previous design team developed a device that is flexible enough to be inserted into the bone at a 45˚ angle, yet can be made rigid enough to provide adequate structural support to the bone. This semester's work will center around improving the fixation properties of this existing device specifically focusing on limiting axial rotation of the device within the medullary canal without negatively affecting radial force and flexibility properties.

Client Requirements
- No axial rotation or lateral movement after insertion in canal
- Flexible enough to be inserted into the bone at a 45˚ angle
- Rigid enough to stabilize fracture
- All components of design must be biocompatible/hemocompatible

Design Requirements
1. Physical and Operational Characteristics
    a. Performance Requirements: The device must have a narrow flexible state, and a rigid expanded state. The flexible state must be able to fit through a 8 mm hole drilled at the proximal end of the tibia at a 45˚ angle. In the expanded state, the device must be able to be fixed in the tibia bone canal and handle all mechanical forces normally experienced by a casted limb. The device must also be able to compress back to the flexible state for easy surgical removal after the fracture is healed.

    b. *Safety:* This device must be able to be sterilized easily, should be made of biocompatible materials, and should not plastically deform or fail while inside the tibial canal of the patient.

    c. *Accuracy/Reliability:* This device must be very reliable, as it will be implanted into a patient to assist with bone fracture healing.

    d. *Life in Service:* The device must to be able withstand insertion lasting anywhere from 2 to 9 months.

e. *Shelf Life:* The device should have as infinite shelf life if kept in place and not tampered with before surgical insertion.

f. *Operating Environment:* The device will be inserted inside the medullary canal of the tibia, which is normally full of fat and blood; however, this is not a concern as the canal is emptied as part of the surgical procedure. In addition, the inside of the ends of the canal are soft bone tissue, while the tissue near the midpoint of the bone is rough and hard. This device will be used primarily near the midpoint of the tibia since this is the place where complete fractures are most common.

g. *Ergonomics:* The device should be intuitive for a trained surgeon to use, and should be designed to maximize the ease of insertion. The device must also be able to be arranged with the other tools of the surgical set up to provide intuitive placement to avoid confusing the surgeon, which could lead to error or complications.

h. *Size:* The device must be cylindrical in shape, no wider than 8 mm, and 115 mm long to match the previous design.

i. *Weight Materials:* The device weight should be kept to a minimum. With the current design, total weight should not be a problem and due to its very small size, the weight of the materials will not have a significant effect on leg function and motion.

j. *Aesthetics:* There are no aesthetic requirements for this device because it is an implant. Function takes precedence to form.

2. *Production Characteristics*
    a. Quantity: There was no requested quantity of devices, we would like to be able to fabricate at mass quantities if possible.
    b. Target Product Cost: For this project we have been given a budget of $4,500 but we would like to keep the total fabrication cost of the device to under $500.
3. *Miscellaneous*
    a. Standards and Specifications: The device must comply with FDA standards and specifications for implantable medical devices.
    b. Customer: Dr. Matthew Halanski, Department of Orthopedics, UW Health is hoping this will eventually be a commercial product that other orthopaedic surgeons and their respective hospitals will use for their pediatric patients. The highest priority is the safety of the patients, both the surgeon and the patient must be comfortable using the device to help heal bone fractures in pediatric patients. Inability to convince the patient that the device is reliable would result in target patient rejection of the design.

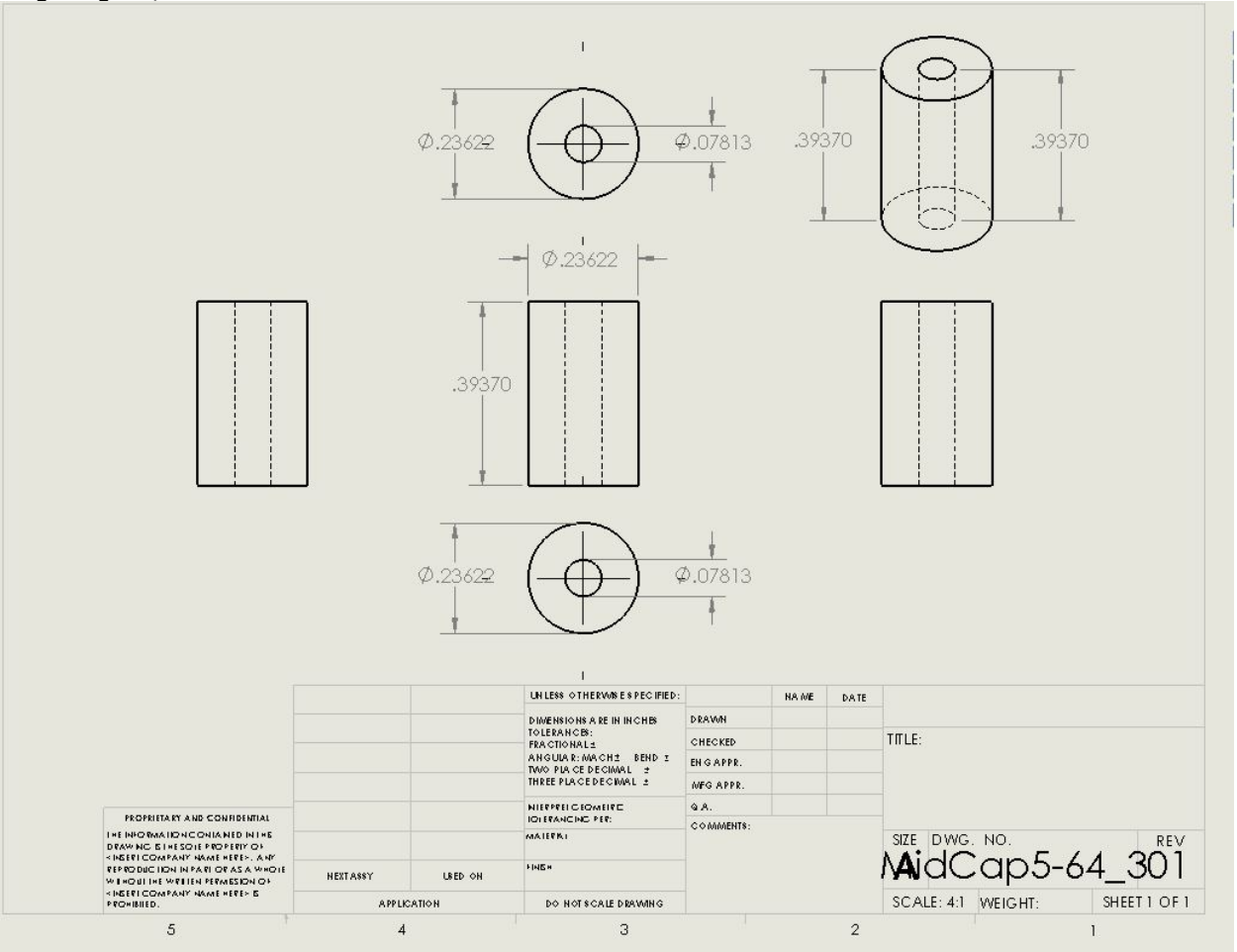
c. Patient Related Concerns: There have not been any patient-related concerns that have been brought to our attention.
d. Competition: Current designs include elastic nails, which have few points of contact with the bone and hence little fixation is seen anywhere other than points at the top, middle and bottom of bone. In addition, adult patients may undergo surgery in which an intramedullary rod is implanted through the top of the bone, through the growth plate, and then screwed in place once in the tibial canal.

Semester Timeline

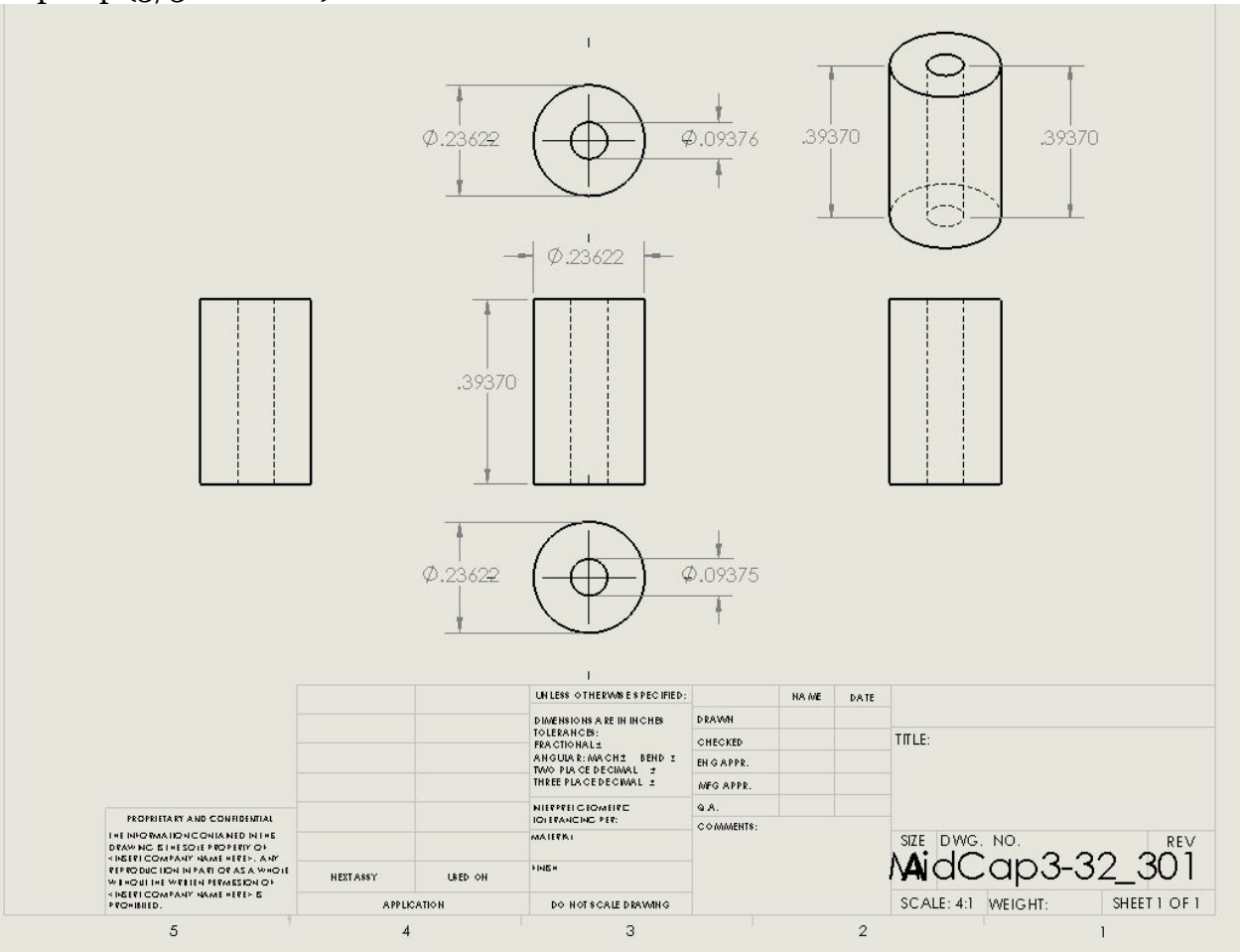
Task	January	February				March					April				May	
	31	7	14	21	28	7	14	21	28	31	4	11	18	25	2	9
Groundwork																
Set Meeting Time	X	X														
Brainstorming	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
ECB 2005 Access	X	X	X	X												
Testing																
Cast Material					X	X	X									
Braided Structure					X	X	X									
Prototyping																
Order Materials						X	X	X								
Build Prototype							X	X	X	X	X	X	X	X	X	
Test Prototype								X	X	X	X	X	X	X	X	
Deliverables																
Progress Reports	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Notebooks	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
PDS	X	X	X	X												
Midsemester Presentation				X												
Midsemester Report				X	X											
Final Poster														X	X	
Final Report														X	X	
Meetings																
Advisor Meeting	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Team Meeting	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Client Meeting			X			X			X				X			
Website																
Update	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

Solidworks of Top and Bottom Caps

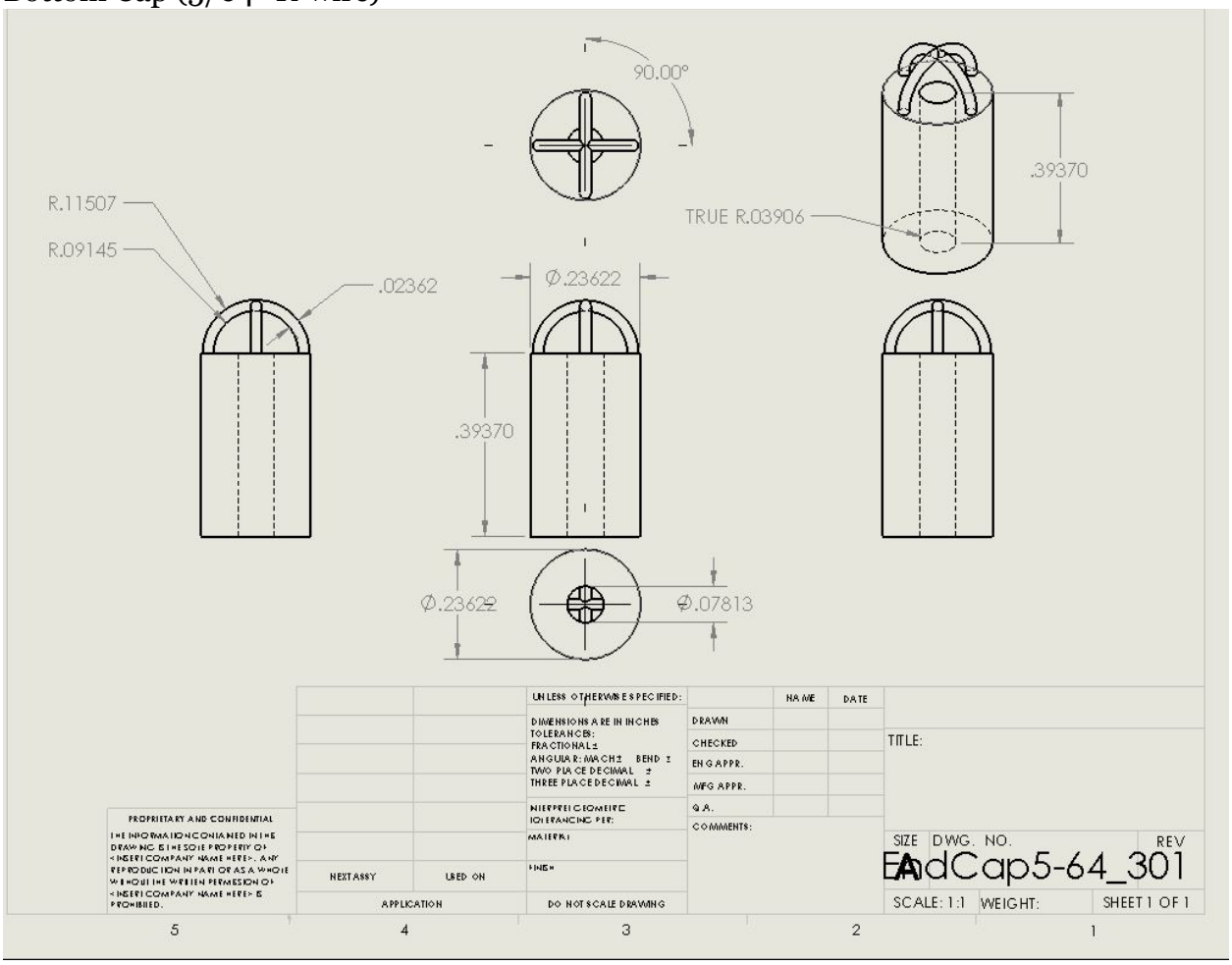
Top Cap (5/64” K-wire)



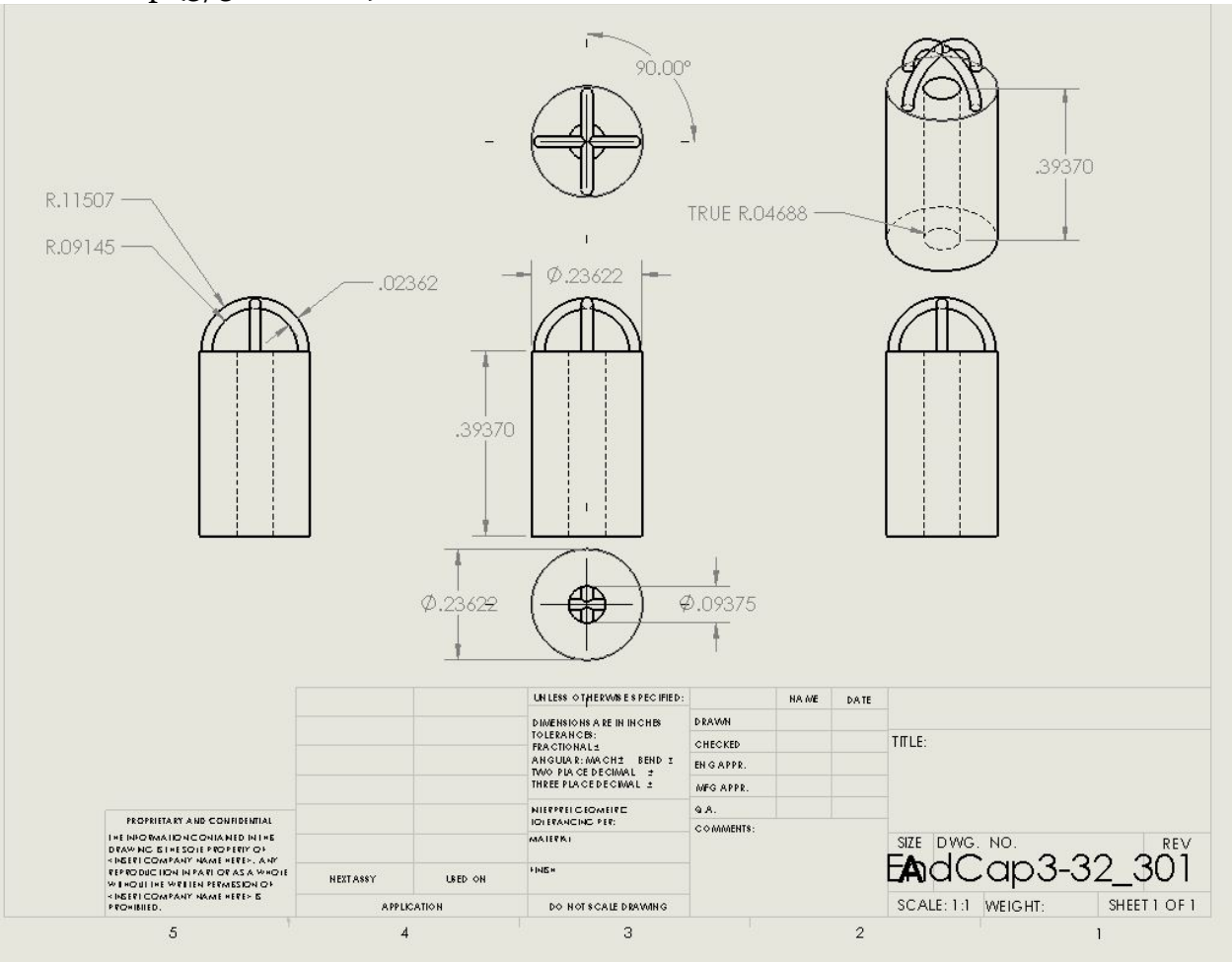
Top Cap (3/32” K-wire)



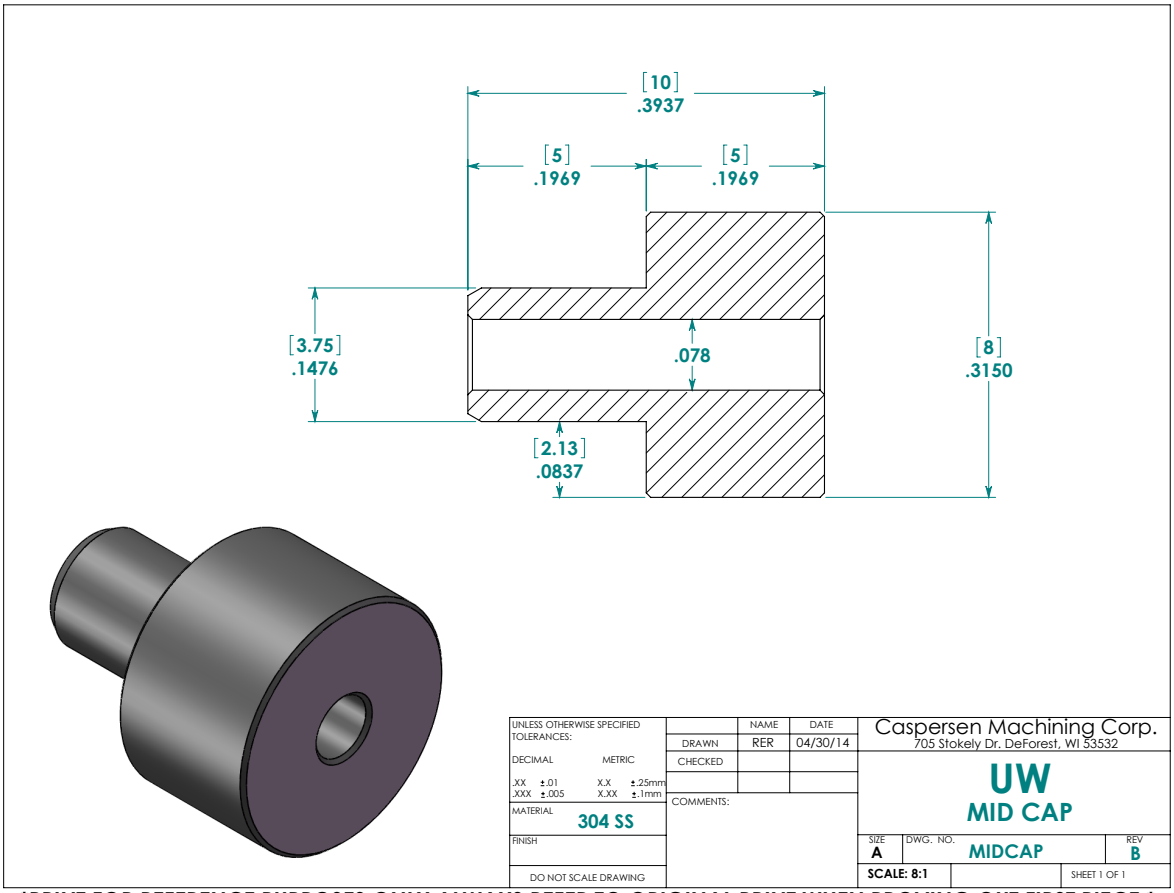
Bottom Cap (5/64” K-wire)



Bottom Cap (3/32” K-wire)



Redesign of Top and Bottom Caps



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