Intramedullary Nail:
A proposed design to increase nail fastening success rate

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Abstract:

Intramedullary nails (IN) present one method of repairing long bone fractures. This project specifically deals with INs used in canines. Upon insertion into the intramedullary space the nail is fastened with 2 proximal and 2 distal screws. Holes must be drilled into the bone such that they align with the 4 holes in the nail. Currently, a jig assembly is used to guide the bone drill to these holes during surgery. Sometimes this assembly fails to align the drill correctly, resulting in misplaced screws and an insecure nail. The assembly appears to fail at the extension-nail interface. A re-designed nail-extension unit has been developed to address this issue. Initial results suggest that replacing the extension-nail interface with a stress-raiser reduces the movement that occurred about the old connection.

I. Problem Statement

To improve the intramedullary nail in an effort to decrease misalignments that lead to the inability to secure the nail to the bone.

II. Background Information

If not properly healed a severe long bone fracture can seriously complicate or even threaten an animal's life. If bone fragments are misaligned, the animal may need a surgical procedure for proper healing to occur. One method of repair uses an intramedullary nail (IN) to secure bone fragments in correct alignment. The IN is inserted into the marrow of the bone, spanning the fracture. It is then attached to a jig containing drill guides which are aligned with the pre-drilled screw holes in the nail. Using the drill guide a surgeon drills into the bone such that screws or bolts can fasten the IN and bone fragments in place. This procedure realigns the bone and provides support during healing.

This system is a very effective method to treat clean fractures where sufficient space is available on proximal and distal fragments to secure the nail. The effectiveness of the procedure is limited if the nail fails to fasten securely to the bone. A study that was done on this surgical procedure involving 126 dogs concluded that 86% of the surgeries had excellent results, 11% had good results, and 3% had fair or poor results. According to this same study, 4% of the screws that were inserted did not pass through the nail holes due to misalignment [1]. Another study demonstrated the overall bending strength of the nails. According to this study, the 8mm nails are significantly resistant to bending [2]. This, along with visual observation of the device under stress, suggests that the misalignment of the jig's drill guides with the nail holes is due to movement at connections between the nail and the extension, the extension and the jig, or a combination of the two rather than bending of the nail (Figure 1). This project aims to reduce misalignments in IN surgical procedures by redesigning components of the IN.

Figure 1: The nail and extension are secured to the jig. The nail can be seen deviating from the jig holes at the extension-nail joint.

III. Surgical Materials and Procedure

As stated previously, IN are used to repair canine long bone fractures. IN and their components are constructed with stainless steel and manufactured by Innovative Animal Products in Rochester, Minnesota. This system of repairing fractures was developed in 1989 by R. Tass Dueland, DVM from the University of Wisconsin-Madison.

Figure 2: Nail head (lower left) and extension joint (upper right).

The surgical procedure requires the canine to be put under local anesthesia. Standard X-rays of the fracture site enable the surgeon to determine the appropriate length and diameter nail to use in the procedure. Nails are manufactured in 4.0, 4.7, 6.0 mm and 8.0 mm diameters and a variety of lengths [4]. After choosing the nail, the marrow of the bone can then be reamed out either through the fracture point, or through the proximal or distal ends of the bone. Reaming is done by hand and makes inserting the nail easier. The IN is then inserted such that the top of the nail does not extend past the greater trochanter, which is the protrusion of bone at the proximal end of the femur [1]. Usually the nail is inserted farther such that the head of the nail is buried within the intramedullary space. The location of the nail within the bone can be determined from markings on the extension piece that are 2mm apart (Figure 2).

The IN head has an “H” shape, depicted in Figure 2. The head allows the nail to connect to the attachments that are used to insert the nail and attach the jig. The first attachment is an extension piece. Extension pieces come in two sizes: short for the femur and longer for the tibia to prevent interference with the femoral condyles or patella. During insertion of the nail the extension piece is connected to a handle with which the surgeon forces the nail in the intramedullary space.

All connections are fastened in place with threaded male and female components. The extension piece and nail head fit together with their interlocking “H” ends, Figure 2. The “H” head provides alignment of the holes relative to the position of the extension piece. It also prevents independent rotation about the long axis of the two pieces once they are connected. The units are secured via an allen screw which is tightened with an allen key from the opposing end of the extension. The extension unit secures to the jig via a compression fit. The jig is the L-shaped piece that lies outside the bone and directs the screws into the holes in the nail. Compression between the extension and jig is achieved using a hand-turned fastener that passes through the jig and threads into the top of the extension unit. Alignment is achieved at the extension-jig interface via

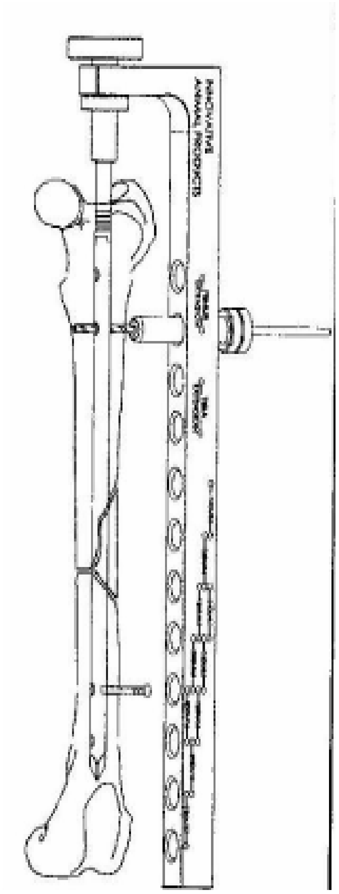


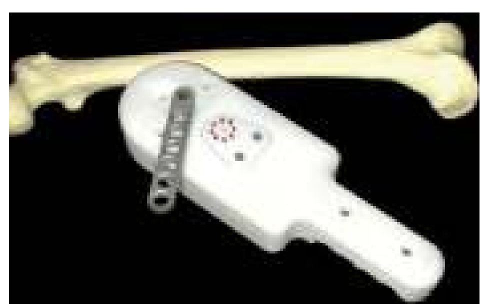
Figure 3: Nail, extension, and jig shown connected. A drill is shown drilling a hole using the jig through the bone and hole in the IN [4].

interconnecting male and female holes. All of these components are displayed in Figure 3.

After the nail is aligned in the bone fragments and the fracture reduced, the handle is removed and the jig is attached (Figure 3). The jig is positioned such that tissues will not interfere with its position. At the doctor's discretion, holes are drilled such that screws or bolts are placed through either the proximal or distal holes first. Placing the proximal screws first may shorten the lever arm such that the nail is better aligned distally with the guide holes on the jig. Holes are first marked with a center punch-like piece to indent curved surfaces of the bone. This prevents the drill bit from slipping on the bones curved surfaces. The holes are drilled with a power drill with the drill bit passing through various components that fit with the jig's drill guide holes. If the drill holes line up with the hole in the nail, a screw or bolt (surgeons' discretion) is inserted and secured. Screws thread into the bone along the screws entire length. Bolts are threaded near the bolt head and will only thread into the bone approximately 2mm. Bolts are a stronger fastening method but have a tighter tolerance within the nail than the screws. Once the nail is secured the jig and extension piece are removed, the tissues and muscles are returned to their position, and the incision is stitched closed.

Current Products

A prototype has been developed at the Virginia Polytechnic Institute and State University to target holes in the nail and drill holes in the bone. This device (depicted in Figure 4) is called a Magnetic Targeting Device. It works by locating the predrilled holes in the nail, which contain magnets, with a sensor able to distinguish the magnetic forces. The sensor



light switches from red to green when the strongest magnetic force is discovered (i.e. when the sensor has located the hole). It is currently being tested on humans but could potentially affect canine surgery in the future [11]. However, it is unclear as to how the device enables one to drill holes that are aligned about all axes.

IV. Client Information

R. Tass Dueland is a doctor of veterinary medicine who works with the University of Wisconsin-Madison's Veterinary School. In 1989 he developed the intramedullary rod, with his colleagues, as an alternative for healing canine long bone fractures [12]. In association with DVM Dueland, Professor Ray Vanderby is overseeing the project. They present the task of improving the intramedullary nail design and reducing misalignments.

Client Design Requirements

After evaluating the issues the client presented and viewing the surgical procedure, some design requirements were established. First, the design must maintain the integrity of the nail. Any design should also be easily implemented into current surgical procedures to reduce the amount of new material the surgeon must learn. Since the nail will be implanted into the animal's bone, any materials used must be biocompatible and easily sterilized. Finally, the designs should attempt to reduce misalignments at the distal holes of the nail and make locating the holes easier.

V. Initial Design Ideas

Prior to developing initial design ideas the primary causation of misalignment needed to be discovered. Upon visual inspection of the nail, extension and jig in their connected configuration it was determined that the primary movement of the nail occurs at the nail-extension interface. For this reason all design alternatives attempt to address this junction in an effort to remove the primary source of deviation. The force that causes this movement was quantified during testing and these results are summarized later in the paper.

Design Alternative 1: Additional Parallel Rods

Design one incorporates two rods protruding from the extension piece that run down the long axis of the nail. Currently the extension has only the single threaded allen screw entering no more than a centimeter or two into the nail. If a longer screw could be threaded into the nail the movement at this joint may be reduced. However, the proximal holes in the nail restrain the length for that screw. Placing different rods along the sides of the nail may achieve the same effect without interfering with the proximal holes.

Figure 5 depicts the design as it would be seen from the jig (holes aligned with jig holes). The threaded screw diameter and the diameter of the proximal holes in the nail will likely need to be reduced so the two rods can be added. The two rods will run along the long axis of the nail, parallel to the threaded screw hole, and will miss the proximal nail holes off to the side as shown. This design would allow the additional rods to be as long as required. A new nail and new extension piece will have to be made (Figure 5). Atop the new extension piece will be the same mechanical attachment to the jig as in the current design.

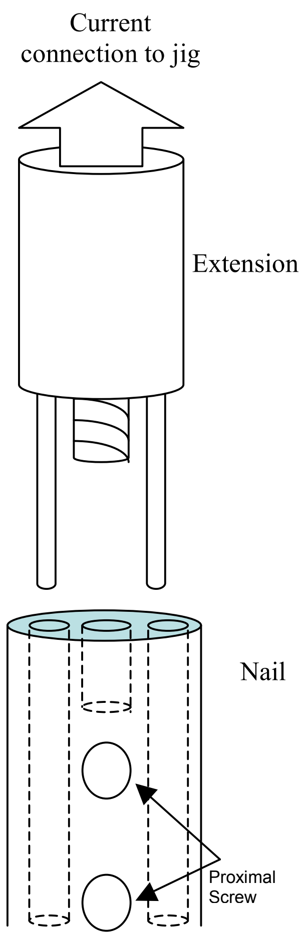


Figure 5: Design 1 alternative extension - nail connection.

This design addresses the nail-extension interface, where the most movement seemed to be occurring. Misalignment of the nails was due to the movement of the nail from left to right when viewing the nail from the jig, as in Figure 1. The additional rods running down both sides of the nail may provide a solution to the problem by changing the mechanics of the connection. With this design, the nail's rotation will be prevented at the threaded screw and the two additional rods. This mechanical change may ultimately limit the amount of movement that occurs in the distal end of the nail.

Some issues arise while analyzing this design alternative. The nail's integrity may be compromised with the addition of the two holes into the top of the rod that extend past the proximal screw holes. In developmental studies of first generation IN, nails and screws failed such that bone fracture or screw hole deformation occurred when using larger screws to secure the nail. Using smaller nails or bolts remedied the problem [6]. Reducing the integrity of the rod around these nail holes may increase the occurrence of nail failure. Tests could be performed to determine if using a smaller screw and hence smaller hole in the nail will affect failure rate. It is also unknown what the length of the additional rods will have to be in order to restrain movement along that axis. It could be a distance that does not progress past the proximal screw holes, and ultimately doesn't affect the integrity of the nail. Another problem that may limit the effectiveness of the design is the movement in the direction toward and away from the jig. Although the rod would have to display substantial movement in that direction to actually miss the holes, the new design could increase that displacement. While the new design will undoubtedly restrain movement in other directions, it is unseen whether or not movement toward and away from the rod will be affected.

Design Alternative 2: Conical Connection

Design alternative two also addresses the junction of the extension unit to the nail as this seems to be the primary source of movement. The design is depicted in Figure 6. The concept retains the use of the threaded allen screw currently used to attach the extension to the nail. The "H" shaped head is entirely abandoned. The head of the nail assumes a conical shape that will fit within the machined out conical shape of the extension. With the units held together the allen screw passes through the extension piece and threads into the nail, similar to what is shown in Figure 2.

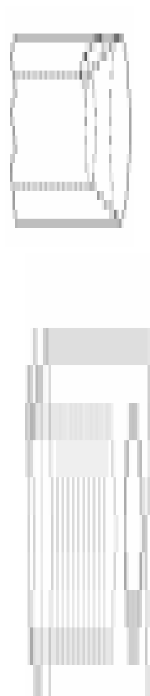


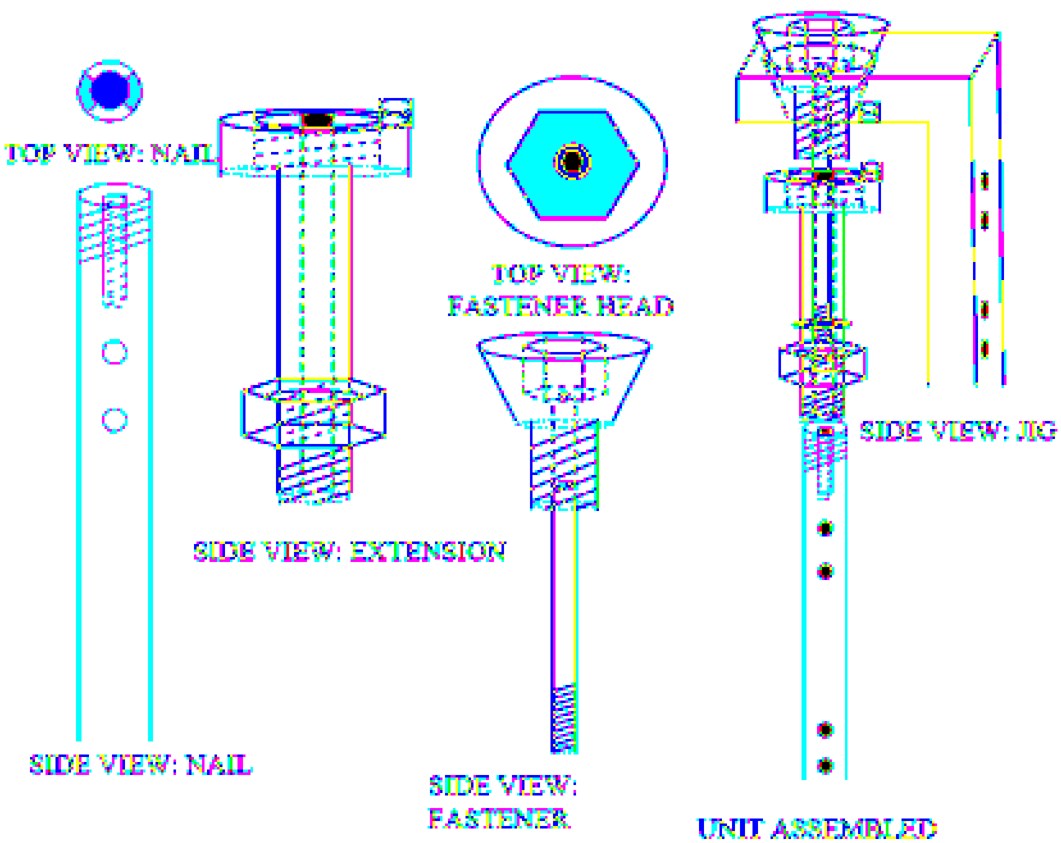
Figure 6: Nail head (bottom) shown how it would fit within the extension (top).

To maintain alignment about the long axis, a notch will protrude from the conical shape and fit within a hollowed out notch of the extension. This will allow the unit to attach to the jig such that the orientation of the holes is known and rotation about the long axis will not occur.

The conical shape should distribute forces better than the current extension nail interface. The new junction also provides opposing forces along the conical shape instead of relying strictly on the screw to compress the extension and nail together. The current design can essentially pivot slightly along its edge. The conical shape can provide an opposing couple moment via its proximal and distal edges. Testing is needed to determine the magnitude of a moment this opposing couple can withstand before movement occurs.

Some issues may arise in further development of this design. The small diameter of the nail may make this design difficult to apply. The screw may have to be reduced in size to develop a sufficient conical shape. In addition, the force required to hold these units together sufficiently should be quantified in order to determine the necessary thread count of the screw.

Design Alternative 3: Double Sided Screw
There will be four parts in this design for the intramedullary nail device: the jig, the nail, the extension piece, and the fastener - all seen in Figure 7. The nail is attached to the extension piece, which can then be either attached to a long handle used to insert the nail into the bone marrow or to the jig used to guide the drill. The insertion handle is only attached when the surgeon is inserting the nail into the intramedullary space. The jig will have the same design except the connection between the extension piece and the fastener will be conical instead of cylindrical. This can be seen in the side view of the jig in Figure 7. The fastener, which secures the jig to the extension piece, has two different components. One is the conical piece with threading on the bottom which will be used to secure the fastener to the extension and the second is a long, slender screw. This long screw will pass through the fastener and extension to thread into the nail compressing the fastener, jig, extension and nail together. The long screw is tightened via a smaller allen key within the head of the fastener which



can be seen in the fastener's top view in Figure 7. The fastener is also secured to the jig and the extension via compression achieved by threading the fastener into the extension. This connection is then tightened using the large hexagonal allen head on the fastener, shown in the top view of the fastener in Figure 7. The extension will have a flat top except for the cylindrical protrusion that fits into the indentation in the jig. This feature allows the holes in the nail to align with the guide holes in the jig about the long axis. In addition, the extension will have a threaded outer diameter at its distal end, seen in the side view of the extension in Figure 7. The head of the nail will also have a threaded outer diameter segment. This will allow a nut to fit over the two units at the joint for increased stability. The bottom of the extension will be “H” shaped, as in the current units, to align the holes in the nail with the holes in the jig.

This design has advantages over the current design of the intramedullary nail. The long screw that spans from the fastener to the nail will allow all the units to share a common structural piece, reducing the amount of torque between the different pieces of the structure. The nut on the exterior of the nail and extension interface provides an additional layer of support so that movement may also be decreased.

Despite these advantages, there are some drawbacks to this system. The nut that connects the extension to the nail will interfere with inserting the nail completely into the intramedullary space. The nut may also interfere with the compression achieved by the long screw. Finally, the long screw itself is more susceptible to fracture during tightening because of its length and small diameter. These disadvantages are important to keep in mind while determining which design to pursue.

VI. Proceeding from Midsemester

The project took a new direction since the original three designs were compared. To accommodate this, a new design matrix was drafted. After carefully considering the design alternatives, it was decided to pursue the newest concept - the stress raiser design.

Table 1: Design Matrix **Scale: 1 (worst)- 10**

	Simplicity (1-5)	Integration into process (1-10)	Cleaning (1-5)	Cost (1-5)	Potential to reduce Misalignment (1-10)	TOTAL (5-35)
Extra Bars	4	9	5	3	7	28
Conical Connection	3	8	5	3	7	26
Double-sided Screw	4	7	5	2	7	25
Stress Raiser	4	9	5	3	9	32

This decision was made by utilizing the design matrix displayed in Table 1. Certain categories have been weighted more heavily based on their importance. The two categories rated highest are the “Integration into Process” and “Potential to reduce misalignment” categories. It was decided that these should be rated higher as they affect the surgical procedure and its success. Developing a device that requires a radically different surgical procedure is not practical. The potential to reduce Misalignment of the device was rated on a higher scale because successfully securing the nail is imperative as surgical procedures are expensive, time consuming, and potentially damaging to an animal's health. The highest score a design could achieve with this scale is 35 points.

Upon comparison, the Stress Raiser Design was clearly the best overall. Most importantly, it scored highest in the "potential to reduce Misalignment" category, which was the major concern with the three original designs.

VII. Final Design

Concept
The final design aims to decrease misalignments between the jig and the nail holes in the most efficient and economical method. During initial brainstorming, eliminating the extension-nail interface was discussed briefly and abandoned. The idea was abandoned because it was not clear to the team how one could have the nail imbedded into the bone yet still have a jig attached to the nail without an extension. After the mid-point of the semester it became clear to the team that the three initial design alternatives above did not seem to adequately address the nail-extension interface. A re-examination of the possibility to eliminate the nail-extension interface led to the final design and prototype.

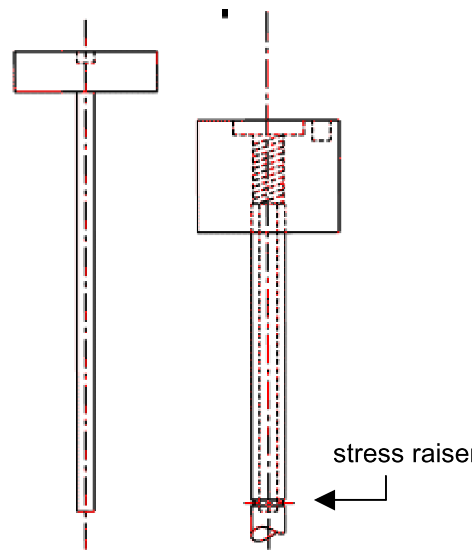


Figure 8: The push rod (left) and the nail and nail head (right) are depicted side by side.

The final design eliminates the nail-extension interface and is composed of one long nail welded to a unit which can attach to the jig, (Figure 8). Further design details can be found in Appendix B. A stress raiser is machined into the nail at the location where the extension-nail interface existed on the current IN set. A stress-raiser is based on the concept that stress concentrations occur around features machined into a material. One can use these stress factors as an advantage by incorporating a known breaking point. The nail is inserted into the intramedullary space in the same fashion and secured via the screws.

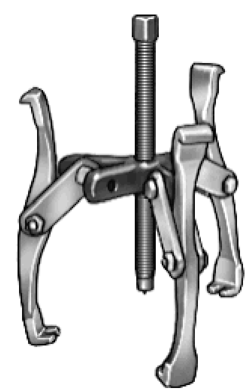


Figure 9: The mechanical puller used to apply tension across the stress raiser. [9]

After the nail is fastened the jig would be removed and the push rod would be inserted into the hole drilled down the center of the nail. The push rod applies a tension force across the stress raiser via a mechanical puller. In testing the prototype a mechanical puller similar to the one in Figure 9 was used. The three external jaws grip the nail head while the center threaded unit is tightened, applying force to the top of the push rod. This action compresses the push rod into the nail at the end of the hole in the nail while pulling on the nail head, effectively creating a tension across the stress raiser. The mechanical puller, also called an external jaw puller, has a load capacity of 1 ton or 8.9 KN. Further information on the puller can be found Appendix C. The unit will break with less load than one might expect due to stress concentrations. However, the solid material in place of the previous extension-nail interface will be more resistant to transverse loading than the current threaded connection. Stress concentrations are dependent on the unit's geometry.

Stress Raisers

Stress concentration factors, K_t, are experimentally determined for common shapes and configurations among materials. Figure 10b depicts experimentally determined concentration factors as a function of selected geometrical ratios. This figure is specifically concerned with tubes under tension with a fillet [8]. The fillet of radius, r, in Figure 10b is comparable to the indent of radius, r, in the IN prototype. Figure 10a depicts the geometrical shape of the IN prototype where: t=0.5mm, h=0.9mm, d_i=3.18mm, r=0.5mm, and P is the applied tension force.

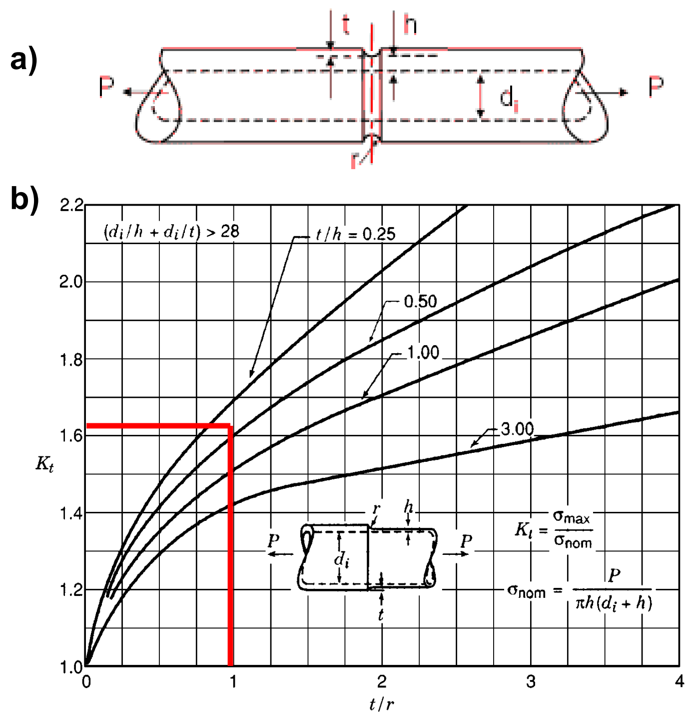


Figure 10: A. Geometry of prototype stress raiser. B. Graphical relationship between depth of stress raiser (t), radius of cut (r), and thickness of tube at the stress raiser (h) [8].

From these specifications it can be seen that t/r = 1.0 and t/h~0.5. To determine K_t one operates on the t/h=0.5 relationship. The IN prototype has a concentration factor of 1.6 based on the stress raiser's and surrounding dimensions. The equations in figure 10b can be rearranged to determine the required tension force necessary to fracture the IN at the stress raiser.

$$P = \frac{\sigma_{max} \pi h(d_i + h)}{K_t}$$

Equation 0: This equation can be used to determine the force required to fracture a tube in tension at its stress raiser.

It was determined that the current nail is likely made from 316L stainless steel [10]. 316L stainless steel has a yield point at about 485 MPa. Using equation 1 it was determined a tension force of approximately P = 3.5KN would be needed to fracture the stress raiser. The mechanical puller purchased to apply this tension force has a capacity of 8.9KN.

Three IN prototypes were manufactured with the specifications in Appendix B. The majority of machining was performed on a lathe using carbide cutters. The off-center hole in the nail head was located and drilled using a CNC end mill.

VIII. Testing

In order to evaluate the effectiveness of the new prototype, it was necessary to perform tests that would quantitatively compare it to the current intramedullary nail model. The goal of the prototype was to reduce the movement about the nail/extension interface which resulted in misalignment of the nail with the drill guide. This movement is a result of transverse forces being applied to the nail. Therefore, it was important to test whether or not the prototype could withstand larger forces than the current nail before it deviated from alignment. In addition, two of the nails were fractured to ensure the concept of stress raisers became reality.

Procedure: Force Tests

This test was conducted by attaching each nail to the jig and then securing the jig tightly to a table top. The drill guide sleeve was then inserted into the jig such that it lined up with the most distal hole. A force gauge was placed on the nail 19.5 cm from the extension/jig interface. Then, a force was applied to the force gauge, which pulled the nail down until the hole in the drill guide sleeve could be seen

Figure 11: Testing setup. The force guage pulls down on the nail until the entire hole in the drill guide sleeve can be seen. The picture depicts the point at which the force would be recorded.

almost entirely above the side of the nail (Figure 11) At this point, the reading on the force gauge was recorded. This process was repeated 3 times per nail so that an average force could be computed. All test data is supplied in detail in Appendix D.

The deviation force was calculated for each of the three prototypes. For comparison, the current nail model with similar dimensions to the prototype (i.e. 6mm diameter, 16 cm nail with the short extension piece) was also tested. The forces are graphically represented in Figure 12.

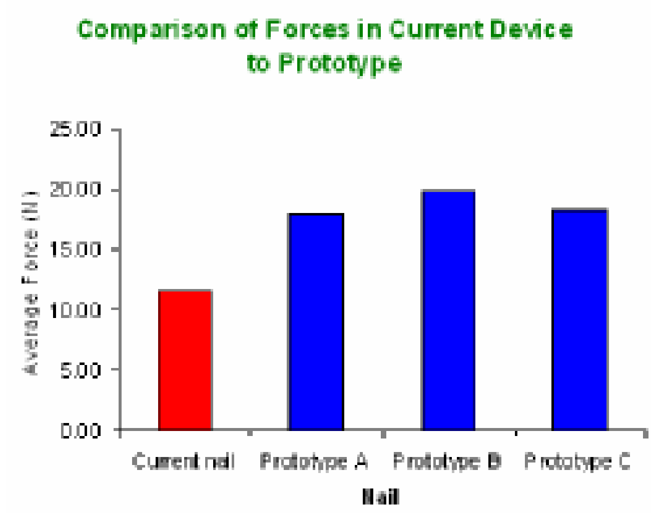


Figure 12: Graphical representation of average forces that cause misalignment . The force fore each prototype is approximately 1.5 times that for the current nail.

Knowing the distance from the jig that the force was applied and the magnitude of the force allows for the calculation of the moment about the extension/jig interface that is necessary to cause misalignment. If one assumes this moment to be constant, one can graphically represent the possible force and distance combinations that will cause the screws to miss the nail (Figure13).

Results and Discussion: Force tests

The graphical data shows that each of the three prototypes successfully increased the force that can be applied to the nail before it will be misaligned with the drill guide. This force was more than one and a half times the force applied to the current nail model. Prototypes A, B, and C required forces of 17.94 N, 18.77 N, and 18.33 N while the current nail only required a force of 11.56 N. Because the force is increased in the prototypes, the moment

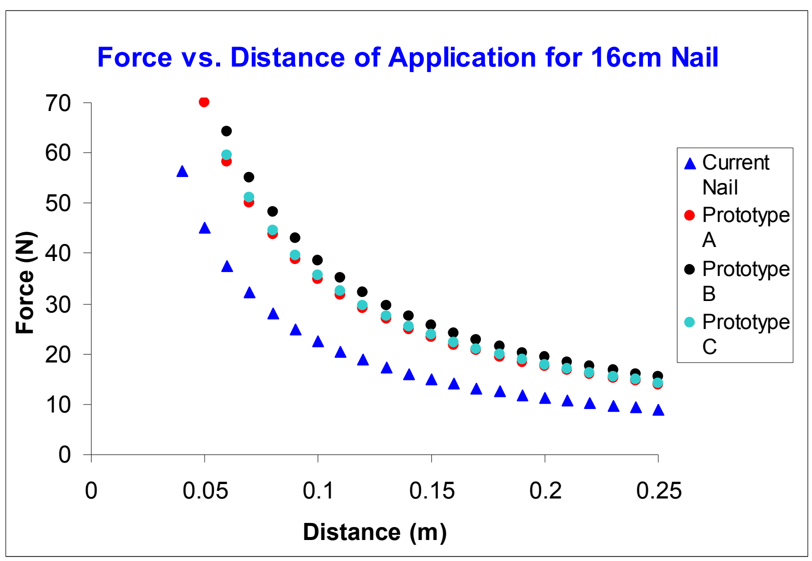


Figure 13: Graphical representation of relationship between magnitude and application point of force. Above line will cause misalignment.

it can withstand before deviation is also much greater (Prototype A 3.5 Nm, Prototype B 3.86 Nm, Prototype C 3.59 Nm, vs. Current nail 2.25 Nm). Therefore, any combination of force and application distance will be less likely to cause misalignment in the prototypes than in the current nail.

Because our sample size was only 3 nails and the stress raiser depth was not uniform between them, this data should not be considered representative of fact. Many more tests would be required with more consistently machined nails and a larger sample size. The data is, however, an encouraging preliminary representation of the capabilities of the prototype from which to base further research.

Fracture

As stated earlier, a mechanical puller similar to that in Figure 9 was used to force the push rod into the IN prototype while simultaneously pulling on the top of the nail, thus applying a tension, P, across the stress raiser. To achieve fracture, the mechanical puller was attached to the nail head in the manner shown in figure 14a. The push rod was forced down by tightening the “T” handle.

Upon turning the “T” handle approximately 10 times, 180 degrees each time, the push rod top became compressed against the nail head. No fracture had occurred at this point. It was observed that there was considerable deformation of the push rod. It was also visually observed that the IN prototype was experiencing considerable deformation about the stress raiser. Suspecting that the IN was close to fracture, the unit was fractured by applying a bending moment via hand. The push rod can be seen protruding from the fracture in figure 14b.

The first attempt at fracture was with a welded push rod assembly (top and rod). This unit experienced greater bending deformation than the second push rod assembly which was not welded. This is likely due to unequal hardening of the push rod during welding. It is recommended that the push rod is not welded to the top unit if further work is to be done.

This leads one to believe that fracture presents a feasible method of eliminating the extension-nail

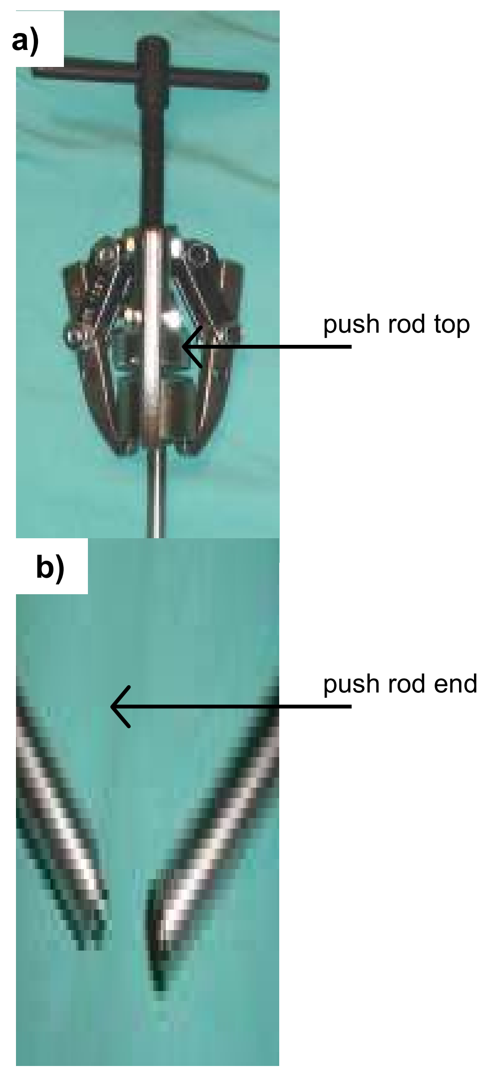


Figure 14: a) The mechanical puller is positioned on the nail head and the push rod top. b) The push rod end can be seen protruding from the fracture point after fracture occurred.

interface. Though initially unsuccessful, many options remain available that should remedy the issue. These will be discussed in the future work section.

IX. Ethical Issues

Anytime a device is to be used on or by living things, it must not expose the animal or person to unwarranted risks. This device must be thoroughly tested to ensure its safety before it is used in canines. In particular, tests must be conducted to verify the assumption that minimal force will be transferred to the animal's bone after the stress raiser breaks. Ideally, as the surgeon attempted to break the nail, the force pressing on the nail would not transfer into the bone of the patient at all. If the force did in fact transfer to the bone, it could potentially shatter the bone, which would seriously exacerbate the original injury. It would be unethical to implement this device in veterinary surgeries without proper testing in applicable situations. Bones from the different species in which the device would be used must be obtained, and within the different species, different sized bones would also have to be found. Once the bones are obtained, research must be conducted to find conclusive evidence that the procedure with the newly implemented device is safe for the patient as well as the surgical staff.

X. Future Work

Although the prototype did not function as expected, minor modifications will likely resolve the problem and yield a fully functional prototype. The first modification that should be made is to the diameter of the inner hole in the nail where the push-rod is inserted to place the force on the nail. Increasing the diameter will ultimately increase the stress concentration factor in Equation 1, which would decrease the amount of force required to fracture the nail at the stress raiser. Not only does it decrease the amount of force required, but increasing the hole's diameter also allows for the use of a thicker, stronger push rod. The new push rod will be less likely to deform during the force application and thus, will transfer more of this force to the nail. After the modifications have been made, more testing will need to be done on the nail to find the force and moment required to cause misalignment of the nail. It is important to ensure that the bending strength of the nail is not compromised by the modification.

Using a different material for the push-rod would also result in a more effective design. Mechanical properties of the push-rod are important because it directly influences the amount of force applied by the puller and the distance that the puller will have to apply the force. Using a stiffer material (one with a higher elastic modulus) will decrease the amount of force that needs to be applied by the puller because not as much force is lost against the interior walls of the nail when bending occurs. A stiffer material will also be more resistant to bending and longitudinal deformation. The push-rod was made out of the 440 stainless steel, one of the stiffest stainless steels available, E=200 GPa [10]. Research suggests that there is no steel that is substantially stiffer than 440. Nickel is slightly stiffer (E=207 GPa). Stiffer materials exist but are uncommon engineering materials such as Tungsten, Molybdenum, Osmium, and Ruthenium, which makes them difficult to obtain and apply to the design since little is known about their properties.

XI. Conclusion

The current prototype showed notable improvement by increasing the force necessary to cause misalignment but, unfortunately, it did not correctly fracture at the stress raiser. Testing results suggested that the new stress raiser design was considerably more resilient to transverse loading than the current system which uses an extension piece. If the force is applied to the distal end of the nail, a force about one and a half times that in the current nail design would be required to deviate the nail enough to cause misalignment. Regarding the moment needed to misalign the nail, the new design requires 3.5 to 3.86 Nm to deviate the nail, which is appreciably greater than the 2.25 Nm needed for the current nail. Thus, surgeons securing the nail can be more confident that moments and forces inflicted on the nail during surgery will not change the alignment of the nail to the extent that would cause them to miss the screw hole and incorrectly secure the nail.

Although the nail did not fracture at the stress raiser as effectively as intended, the testing helped clarify how the prototype could be altered in order to produce the desired results. Breaking the nail required only a small amount of outside force in addition to the force being applied by the push-rod and puller system. Since only a minimal additional force was needed, it is clear that minor alterations in the design dimensions and other slight modifications will result in a fully functioning prototype. Also, when the nail did fracture, it fractured cleanly and in the correct spot. These facts suggest that the design is likely to function correctly and effectively once the alterations have been made.

Appendix A: Product Design Specification (PDS)

Title

Improving Intramedullary Rod Surgical Equipment, September 15, 2005
Team Members/Roles

- Erik Yusko/Team Leader
- Danielle Ebben/Communications
- Tony Wampole/BSAC
- Anna Moeller/BSAC
- Jon Sass/BWIG

Abstract

When longer bones such as the humerus and the femur suffer sever fractures they need assistance to heal properly. One method of repair is an intramedullary nail (IN). The nail is inserted through the proximal end of the bone and into the bone marrow. The nail is anchored in place by 4 pins, 2 proximal and 2 distal. During the surgical procedure the head of the IN is attached to an extension piece and a drill jig. The jig allows the surgeon to guide the drill through the bone at the precise locations of the holes located in the IN. However, some flex exists in the rod or the attachment to the jig. This causes the drill to sometimes miss the holes located in the IN, more often the distal holes. A new mechanism to attach the IN to the drill guide is needed to ensure surgeons can confidently drill through the bone to the holes located in the IN.

Problem Statement

Develop a drill guide and IN that can attach securely without play, with the end goal of consistently allowing surgeons to use the drill guide to drill through the bone without missing the IN holes.

Client Requirements:

- Develop a mechanism to lock the IN in place without play.
- Consistent drilling into the IN holes without missing.

1. Physical and Operational Characteristics

a. Performance requirements: The device must be able to accurately and consistently fit each screw through the holes in the rod. The nail must not move with respect to the jig when the forces required to get the rod in place are applied. The jig should withstand multiple uses. The nail is only used once but it must have compressive strength since it must help support the weight of the animal. It must not break or wear away during the life of the canine.

b. Safety: The rod must be a safe and comfortable option for canine fracture repair. It must be strong enough to prevent further injury and it must consist of materials that are not harmful in any way if implanted in a living organism. For the safety of the animal, only qualified veterinarians who understand the correct operation of the device should use it. The equipment should only be used after being thoroughly sterilized.

c. Accuracy and Reliability: Current devices were estimated to fail 10% of the time. The new design should reduce the failure rate, and attempt to eliminate it.

d. Life in Service: The rod itself must withstand at least 12 years of compressive forces without any service, as it will be implanted in the canine. The jig may be used several times a week for several years with little to no maintenance necessary.

e. *Shelf Life:* The product would be used for multiple surgeries over the course of its time, but will likely contain only mechanical components which will not expire. The device will be autoclaved with the surgical tools and stored in a sterile environment until its next use.

f. *Operating Environment:* Any device will be operated under standard surgical room conditions. A doctor may be able to operate the device without assistance but will likely acquire help from an assisting physician or nurse. The time of operation may vary on the surgery but should fall in the time span of 1-2 hours. While in use the device is likely to encounter different biological contaminates, especially blood.

g. *Ergonomics:* The device should interface with the current nails, and surgical procedures. Thus, one or two people should be able to operate it without difficulty. The design will likely have low acceptable torques, because it should provide accurate aiming of the drill.

h. *Size:* The current jig used is approximately 18" x 6" x 3". Any additional components on the existing device should not increase this size significantly. Any size increase is restrained only by the ability of two people to operate it simply. The device has to be portable, and should be kept as small as possible to ensure efficient operation.

i. Weight: The intramedullary nail should weigh no more than the current version. The extension can weigh more but must still be able to be used comfortably by the surgeon, so no more than 3 lbs. The optimum weight is less than 1lb.

j. *Materials:* The nail cannot react with the internal environment of the canine. It also needs to be made with a material that can withstand weight, such as stainless steel. The extension can be made out of other materials as long as it is durable and lightweight. Materials like wood or rough metal should not be used.

k. Aesthetics, Appearance, and Finish: The appearance does not need to be pleasing, just practical and not difficult to use.

2. Production Characteristics

a. *Quantity*: Only one prototype needs to be completed until further testing is done on it.

b. *Target Product Cost*: The cost of the product has not been determined. It will depend on how effective the prototype is at solving the problems and the amount of materials needed to make a working product.

3. Miscellaneous

a. *Standards and Specifications*: As with medicine, all veterinary instruments must meet FDA approval. Due to the variance in animal size, a standard system is difficult to create.

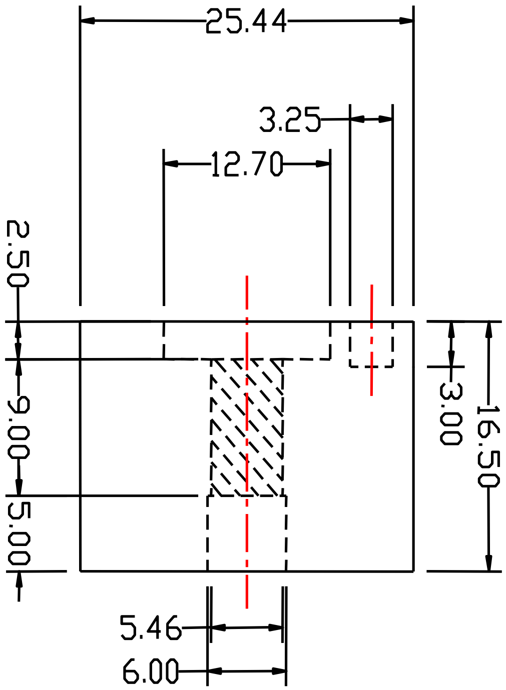
b. *Customer*: The customer does not expect a complete and usable prototype to be created. The customer is more concerned with knowing whether a solution can be found, and creating a prototype that will test if the solution is effective.

c. *Patient-related concerns*: In the future, if such an improved intramedullary rod system is to be adapted to humans, any issues or complications which may arise through the transition should be predicted and tested.

d. *Competition*: A device, the Ti Cannulated Humeral Nail, which rectifies the aforementioned problem, has recently been realeased. The product, however, is only intended for human use. It is possible that a veterinary counterpart could be adapted from this system by the same counterpart.

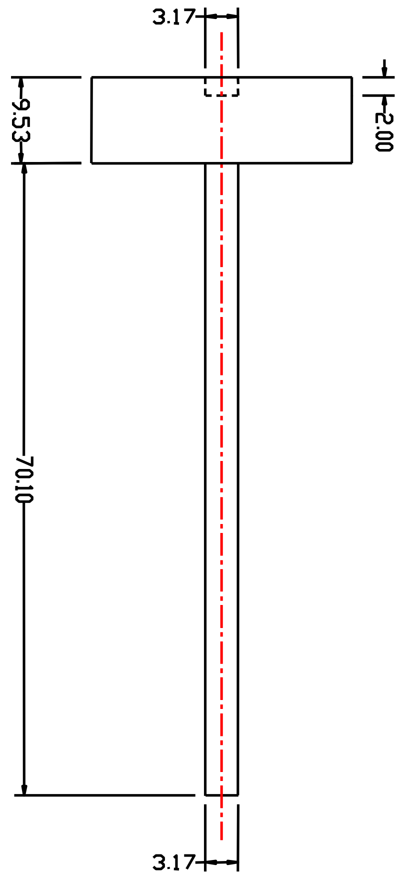
Appendix B: Final Design Specifications

Note: All dimensions in millimeters.



SIDE VIEW of Nail Head

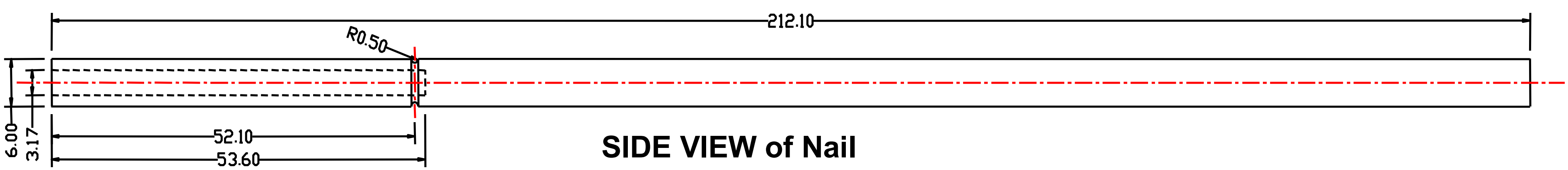
- Threads in the center are 28 threads/inch (Ultra Fine Threads)



SIDE VIEW of Push rod

In assembled configuration the nail is inserted into the 6.0 mm hole in the Nail head and welded.

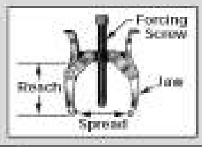
The prototype was designed to test a 6.0mm Ø nail that was 160mm in length.



SIDE VIEW of Nail

Appendix C: Mechanical Puller Specifications

About External and Internal Jaw-Style Pullers

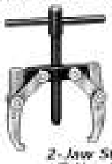


Jaw-style pullers remove gears, bearings, wheels, and pulleys. When clearance permits, you should use a three-jaw puller for better stability and an even pulling force.

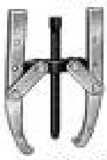
The listed capacity of the puller serves as a guideline. Normally, if you can grip and reach an object your puller will have enough power to pull it. When in doubt, go with the next larger puller size.

Mechanical Pullers

External Jaw Pullers



2-Jaw Style T-Handle



2-Jaw Style (Gripping Tips at One End)

Combination 2/3-Jaw Style (Gripping Tips at Both Ends)

Combination 2/3-Jaw Style

Pullers are made of forged steel for strength and have an alloy steel hex-head or T-handle forcing screw. Jaws have an extra hole in them (unless noted), allowing you to adjust the reach for the best grip. *Combination* and *dual-grip 2/3-jaw pullers* can be used as a two-jaw and a three-jaw puller for added grip versatility.

Replacement jaws are sold individually. All have grip-style tips on both ends (unless noted), giving you two different sizes on one jaw. For replacement forcing screws, see page 2559.

Pullers

Spread	Reach	Style	Cap., tons	Forcing Screw Size	Jaw Tip Size, Wd. × Thick.		Each
2-Jaw Style							
3¼"	2⅛"	Gripping Tips at One End	1	5/16"-24 × 3⅞"	1/4" × 9/64"	6340K71★	$27.43
4"	3¼"	Gripping Tips at Both Ends	2	3/8"-24 × 4⅞"	1/4" × 3/16"; 1/2" × 1/8"	6340K21	26.29
6"	3¼"	Gripping Tips at Both Ends	5	9/16"-20 × 6 15/16"	3/8" × 5/16"; 3/4" × 1/4"	6340K31◆	34.68
6"	5½"	Gripping Tips at Both Ends	5	9/16"-20 × 6 15/16"	3/8" × 5/16"; 3/4" × 1/4"	6340K22	38.60
9"	5"	Gripping Tips at Both Ends	7	11/16"-18 × 9"	1" × 5/16"; 1" × 11/32"	6340K32◆	62.14
9½"	8¾"	Gripping Tips at One End	7	11/16"-18 × 9"	1" × 11/32"	6340K23	62.78
12"	11"	Gripping Tips at One End	13	13/16"-16 × 12"	1" × 9/16"	6340K24	115.83
15½"	15¼"	Gripping Tips at One End	13	13/16"-16 × 12"	1" × 9/16"	6340K25	123.63
16"	18¾"	Gripping Tips at One End	17½	1"-14 × 13½"	1 9/32" × 13/16"	6340K27	231.20
20"	22¼"	Gripping Tips at One End	25	1¼"-12 × 16⅝"	1½" × 1 1/16"	6340K79	385.87
3-Jaw Style							
3¼"	2⅛"	Gripping Tips at One End	1	5/16"-24 × 3⅞"	1/4" × 9/64"	6340K72★	39.22
14"	[illegible]	Gripping Tips at One End	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
16"	18¾"	Gripping Tips at One End	17½	1"-14 × 13½"	1 9/32" × 13/16"	6340K43	346.91
20"	22¼"	Gripping Tips at One End	25	1¼"-12 × 16⅝"	1½" × 1 1/16"	6340K84	535.56
Combination 2/3-Jaw Style							
4¾"	3¼"	Gripping Tips at Both Ends	2	3/8"-24 × 4⅞"	1/4" × 3/16"; 1/2" × 1/8"	6340K41	36.90
7"	3¼"	Gripping Tips at Both Ends	5	9/16"-20 × 6 15/16"	3/8" × 5/16"; 3/4" × 1/4"	6340K51◆	50.41
7"	5½"	Gripping Tips at Both Ends	5	9/16"-20 × 6 15/16"	3/8" × 5/16"; 3/4" × 1/4"	6340K53	52.30
10½"	5"	Gripping Tips at Both Ends	7	11/16"-18 × 9"	1" × 5/16"; 1" × 11/32"	6340K52◆	83.63
11"	8¾"	Gripping Tips at One End	7	11/16"-18 × 9"	1" × 11/32"	6340K54	83.72
12"	11"	Gripping Tips at One End	13	13/16"-16 × 12"	1" × 9/16"	6340K55	177.90
17"	15¼"	Gripping Tips at One End	13	13/16"-16 × 12"	1" × 9/16"	6340K56	188.46
Combination 2/3-Jaw Style Set*—Furnished with six jaws*							
10½"	5"	Gripping Tips at Both Ends	7	11/16"-18 × 9"	1" × 5/16"; 1" × 11/32"		
11"	8¾"	Gripping Tips at One End	7	11/16"-18 × 9"	1" × 11/32"	6293K12	146.08

★ Has a T-handle. ◆ Jaws do not have an extra adjustment hole.

Replacement Jaws

For Pullers	Reach	Cap., tons	Jaw Tip Size, Wd. × Thick.		Each
6340K21; K41	3¼"	2	1/4" × 3/16"; 1/2" × 1/8"	6340K2	$9.12
6340K31; K51	3¼"	5	3/8" × 5/16"; 3/4" × 1/4"	6340K3	11.19
6340K22; K53	5½"	5	3/8" × 5/16"; 3/4" × 1/4"	6340K4	12.47
6340K32; K52	5"	7	1" × 5/16"; 1" × 11/32"	6340K5	21.03
6340K23; K54	8¾"	7	1" × 11/32"	6340K6■	18.89

■ Grip at one end only.

T-Handle Locking External Jaw Pullers and Sets

2-Jaw Style

3-Jaw Style

These pullers have an outside cage that locks the jaws in place during setup and a T-handle to open and close the jaws. The outside cage design also keeps the jaws in alignment and the puller in place when tightening the forcing screw. Jaws have tapered tips for access to tight spots. Jaws and T-handle are made of drop-forged steel. Cage assembly is die cut steel with black powder-coated finish. Forcing screw has a hardened tip.

Also Available: Replacement parts. Please ask for 6169K9 and specify forcing screw, pin, jaw head or jaw, puller capacity, and style (2- or 3-jaw).

Pullers and Sets

Spread	Reach	Cap., tons	Forcing Screw Size	Jaw Tip Size, Wd. × Thick.		Each
2-Jaw Style						
3¼"	2¼"	1	5/16"-24 × 5½"	.31" × .16"	6169K2	$53.64
5"	4"	2	9/16"-16 × 9 11/16"	.62" × .18"	6169K31	90.16
7"	6"	6	5/8"-14 × 12¾"	.75" × .24"	6169K13	124.59
12"	8"	12	3/4"-14 × 16¼"	.87" × .26"	6169K17	154.92
15"	9 41/64"	14	3/4"-14 × 19¼"	1.00" × .36"	6169K15	167.21
18"	12"	25	1⅛"-14 × 26"	1.25" × .38"	6169K23	360.00
25"	14"	35	1¼"-14 × 31½"	1.43" × .46"	6169K25	465.45
3-Jaw Style						
4½"	3"	2	3/8"-24 × 7"	.31" × .16"	6169K1	68.85
5"	4"	5	9/16"-16 × 9 11/16"	.62" × .18"	6169K32	105.74
7"	6"	10	5/8"-14 × 12¾"	.75" × .24"	6169K14	140.16
12"	8"	17	3/4"-14 × 16¼"	.87" × .26"	6169K18	177.05
15"	9 41/64"	20	3/4"-14 × 19¼"	1.00" × .36"	6169K16	197.54
18"	12"	30	1⅛"-14 × 26"	1.25" × .38"	6169K24	424.59
25"	14"	40	1¼"-14 × 31½"	1.43" × .46"	6169K26	595.45

External Puller Set—Capacity is 5-20 tons. Contains one each of 6169K13, K14, K16, and K32.
6169K63 .... **Per Set** $548.33

Internal/External Puller Set—Contains a 5-ton puller (6169K32), 3 internal jaws, 3 additional long jaws, and a 2½-lb. slide hammer. Set comes in a plastic case.
6169K66 .... **Per Set** $282.50

Accessories

2½-lb. Slide Hammer—Fits 6169K13, K14, K31, and K32.
6169K68 .... **Each** $85.00

Appendix D: Test Results and Analysis

i. Calibration of Force Gauge

Table D-1: Known applied force and Force gauge output

Force (N)	Force gauge output
1.23	1
2.41	2
5.56	4
9.2	6
10.83	7

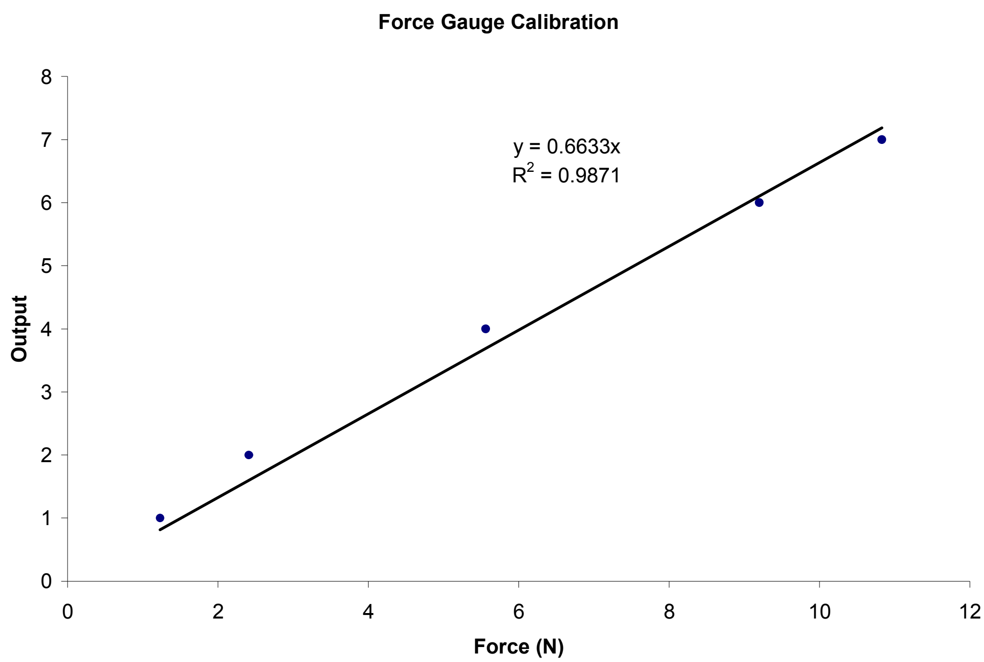


Figure D-1: Force Gauge Calibration Curve

ii. Testing of Current Nails

Table D-2: Current Nail test Data

nail	23 cm w/ long extension	23cm w/ small extension	16cm nail w/ long extension	16cm nail w/ small extension
output 1	2.000	3.000	4.000	8.000
output 2	2.000	3.000	4.000	7.000
output 3	2.000	3.000	4.000	8.000
average	2.000	3.000	4.000	7.667
force (N)	3.015	4.523	6.030	11.558
Moment arm about e/n interface	20.000	20.000	13.500	13.500
Moment arm about abutment	28.000	24.000	21.500	17.000
moment arm about jig	31.000	27.000	24.500	19.500
Moment about e/n inter	0.603	0.905	0.814	1.560
moment about abutment	0.844	1.085	1.297	1.965
moment about jig	0.935	1.221	1.477	2.254

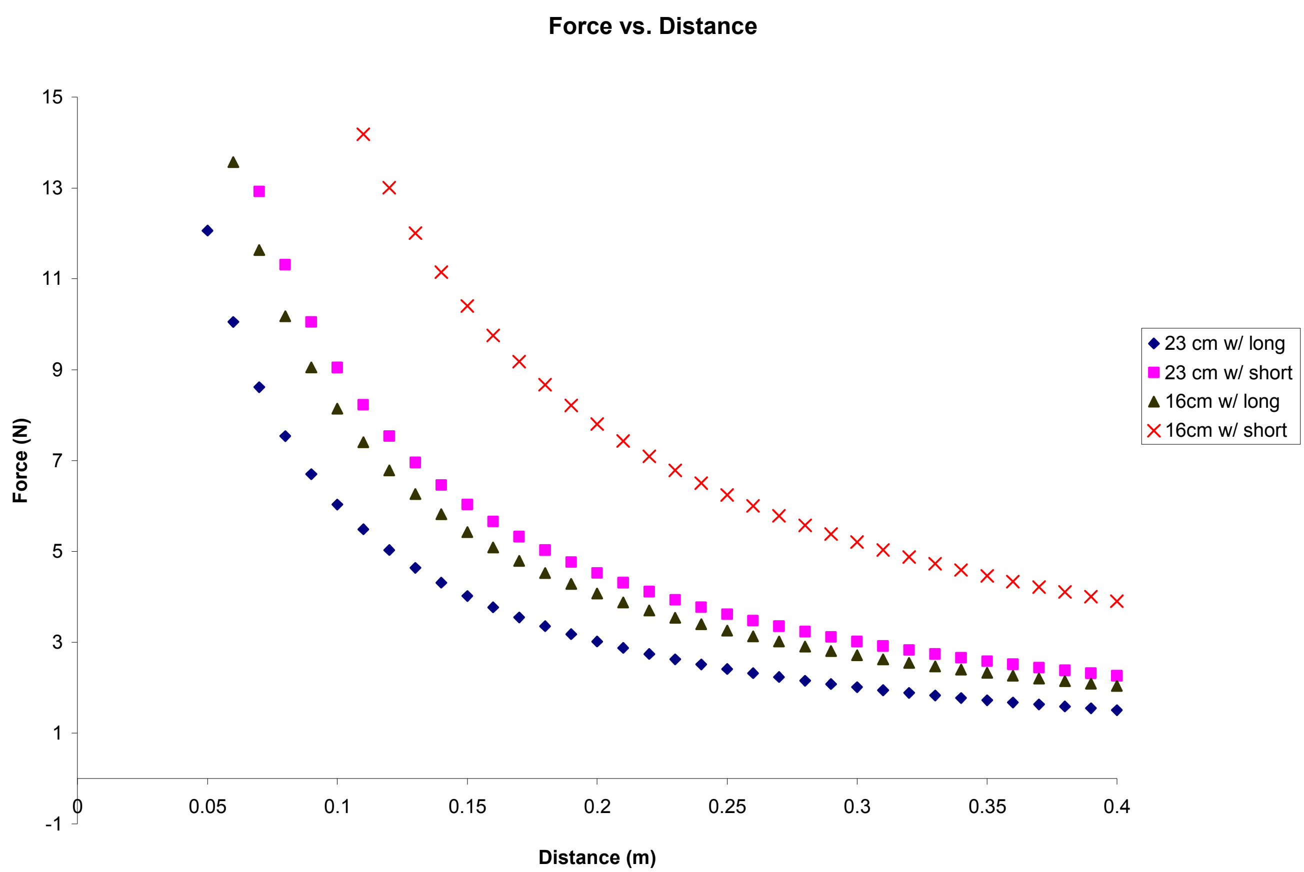


Figure D-2: Graphical representation of Force and Distance of force application relationship for four different current nails. Any points above line will cause misalignment.

iii. Testing Prototype

Table D-3: Prototype Testing Data

	Nail A	Nail B	Nail C		
			original cut	second cut	third cut
raiser depth (mm)	0.6	0.465	0.325	0.56	0.625
Force Test 1 raw	14	17	13	22	17
Force Test 2 raw	16	18	16	18	16
Force Test 3 raw	17	17	17	22	15
Average value raw	11.90	13.12	11.58	15.64	12.16
Average Force (N)	17.94	19.77	17.46	23.58	18.33
Moment arm abt jig (m)	0.195	0.195	0.195	0.195	0.195
Moment abt Jig (Nm)	3.50	3.86	3.40	4.60	3.57

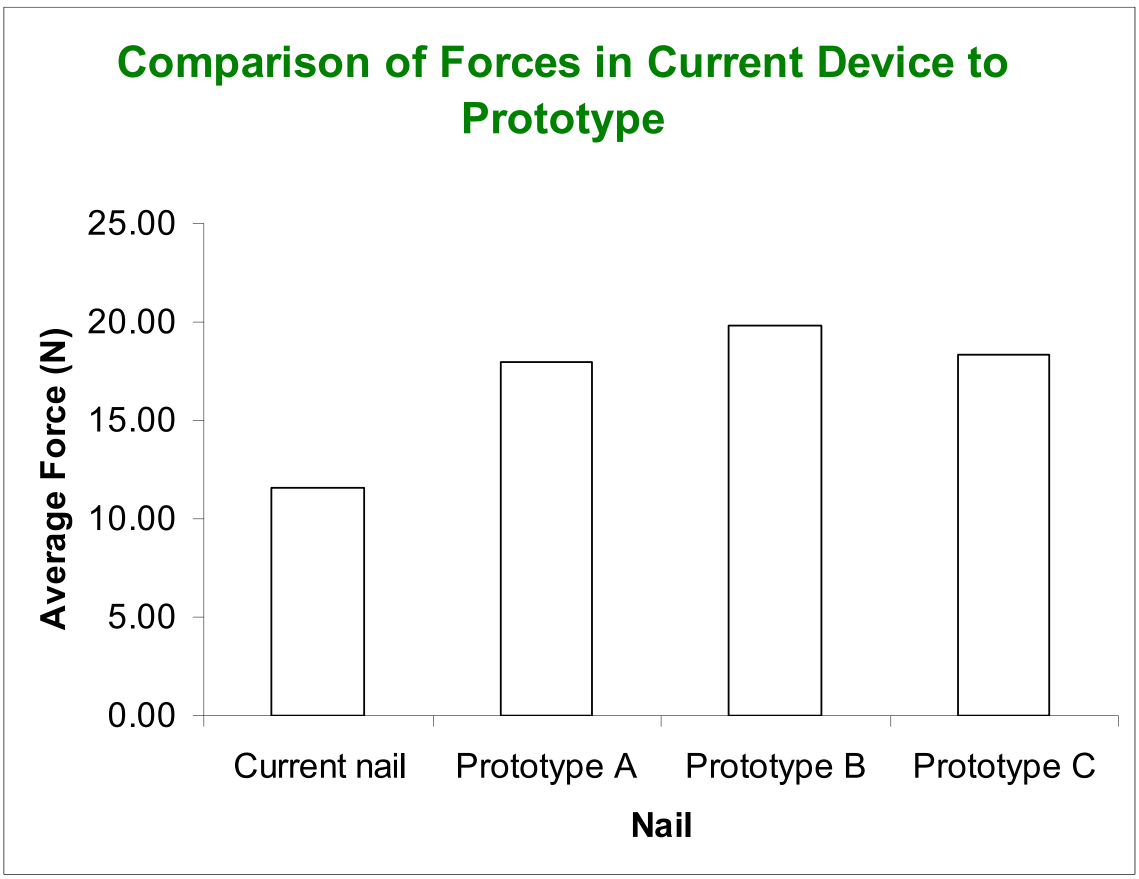


Figure D-3: Graphical comparison of force to misalign nail between prototypes and current nail of similar dimensions.

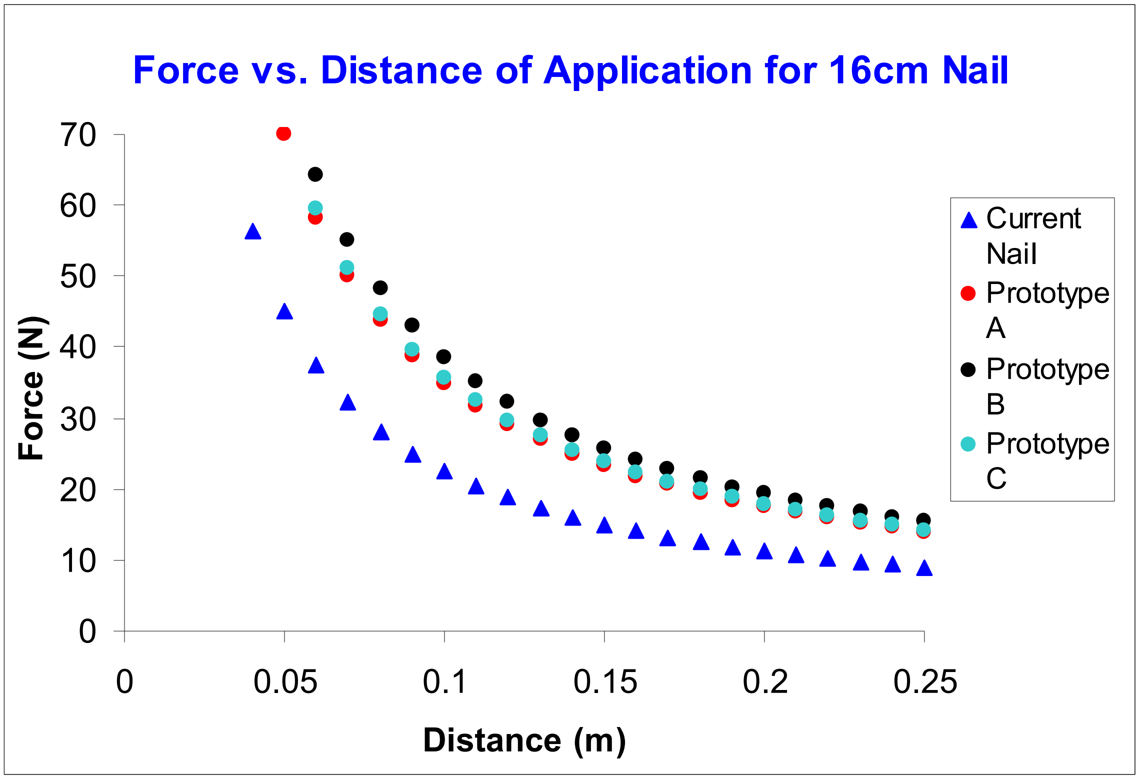


Figure D-4: Force and Distance relationship for the current nail and our 3 prototypes.

Appendix E: Bill of Materials

Part	From	Part Number	Quantity	Cost each	Cost
316 Stainless Steel Metric Rod, 6mm Diameter, 1 meter length	McMaster-Carr	1335T25	1	24.36	24.36
316 Stainless Steel Machinable Rod, 1” Diameter, 1’ length	McMaster-Carr	9298K161	1	32.93	32.93
External Jaw Puller, 3-1/4” Spread, 2-1/8” Reach, 3-Jaw, T-Handle	McMaster-Carr	6340K72	1	39.22	39.22
440C Stainless Steel, Precision Ground Rod, 1/8” Diameter 1’ length	McMaster-Carr	9094K311	1	7.64	7.64
				Total	104.15

Appendix F: References

[1] R. Dueland, K. Johnson, S. Roe, M. Engen, A. Lesser. “Interlocking Nail Treatment of Diaphyseal Long-Bone Fracture in Dogs.” *JAVMA* 214 (1999): 53-64.

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