

Intramedullary Nail:

Proposed Redesigns for Extension – Nail Connection

BME 200/300

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Abstract:

Intramedullary nails are one method of repairing long bone fractures. The nail is inserted into the intramedullary space of the two fragments, and the fracture is reduced. The nail and fragments are secured via two proximal and two distal screws or bolts. In order to drill holes for the screws or bolts that align with pre-drilled holes existing in the nail a jig which guides the drill to the correct location is attached to the nail. This project specifically discusses the intramedullary nails used in canine fracture repairs.

However, the jig apparatus sometimes fails to align the drill with the holes in the nail. A study performed by our client and others, stated that approximately 4% of the distal screws failed to properly engage the nail. When this happens the nail is improperly secured and the success of the surgery and recovery of the animal are in jeopardy.

Our client, R.T. Dueland, has requested we examine methods to decrease misalignment rates. It was determined that the primary source of movement between the nail and the jig occurred at the extension and nail interface. This paper proposes several design alternatives that address this junction to decrease movement of the nail relative to the jig.

I. Introduction and Project Motivation

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 alignment. The IN is inserted into the marrow of the bone, spanning the fracture. It is then attached to a jig containing drill guides. 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 (65% bending stiffness compared to intact femur) [2]. This, along with visual observation of the



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.

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 both rather than bending of the nail, figure 1. This project aims at reducing misalignments in IN surgical procedures used to repair canine fractures via redesigning components of the IN components.

II. 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.

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 [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 nail head does not extend past the greater trochanter [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.



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

The IN head has an “H” shape, depicted in figure 2. The head allows necessary attachments to the nail that are used to insert the nail and to 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.

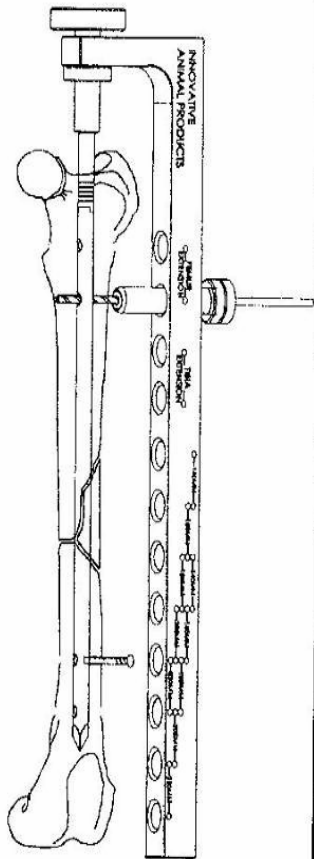


Figure 3: Nail, extension, and jig shown connected. A drill is shown drilling a hole using the jig through the bone and hole in the IN [4].

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. Compression is achieved using a top component turned by hand that fits within the jig and threads into the top of the extension unit. Alignment is achieved at the extension jig interface via interconnecting male and female holes.

After the nail is aligned in the bone fragments and the fracture reduced, the handle is removed and the jig 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 returned to their position, and the incision stitched closed.

III. Client Information

R. Tass Dueland is a doctor of veterinary medicine who works with the University of Wisconsin – Madison veterinary school. He developed the intramedullary rod for canine repair and has conducted research in small animal orthopedics. He presents this project to further improve the intramedullary nail design and reduce misalignments.

IV. Client Design Requirements

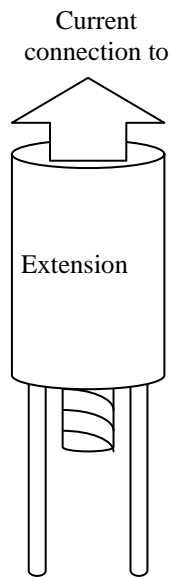
After evaluating the problem the client would like addressed and viewing the surgical procedure some design requirements have been established. First and most important is that any design must maintain the nails integrity. Designs cannot be manufactured that will fracture once implanted. Any design must also be easily implemented into known surgical procedures. As the nail will be implanted into the animal's bone any materials used must be biocompatible and easily sterilized. Finally the design should attempt to reduce misalignments at the distal holes of the nail.

V. Design Alternatives:

Design alternative One:

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 with out interfering with the proximal holes.

Figure 4 depicts the design as it would be seen from the jig (holes aligned with jig holes). The threaded screw diameter and the proximal holes in the nail will likely need to be decreased so the two rods can be added. The two rods will run 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 4. Atop the new extension piece will be the same mechanical attachment to the jig as in the current design.



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 4. The additional rods running down both sides of the nail may provide a solution to the problem by changing the mechanics of the connection. Now the nails 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.

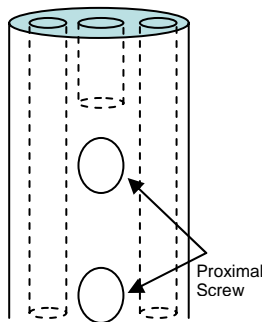


Figure 4: Design 1 alternative extension - nail connection.

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 preformed 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 Two:

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 5. 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 figure 2.

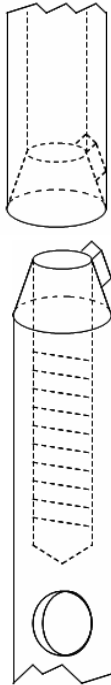


Figure 5: Nail head (bottom) shown how it would fit within the extension (top).

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 Three:

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 6. The nail is attached to the extension piece which can then be either attached to the insertion handle or to the jig using the fastener. 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 6.

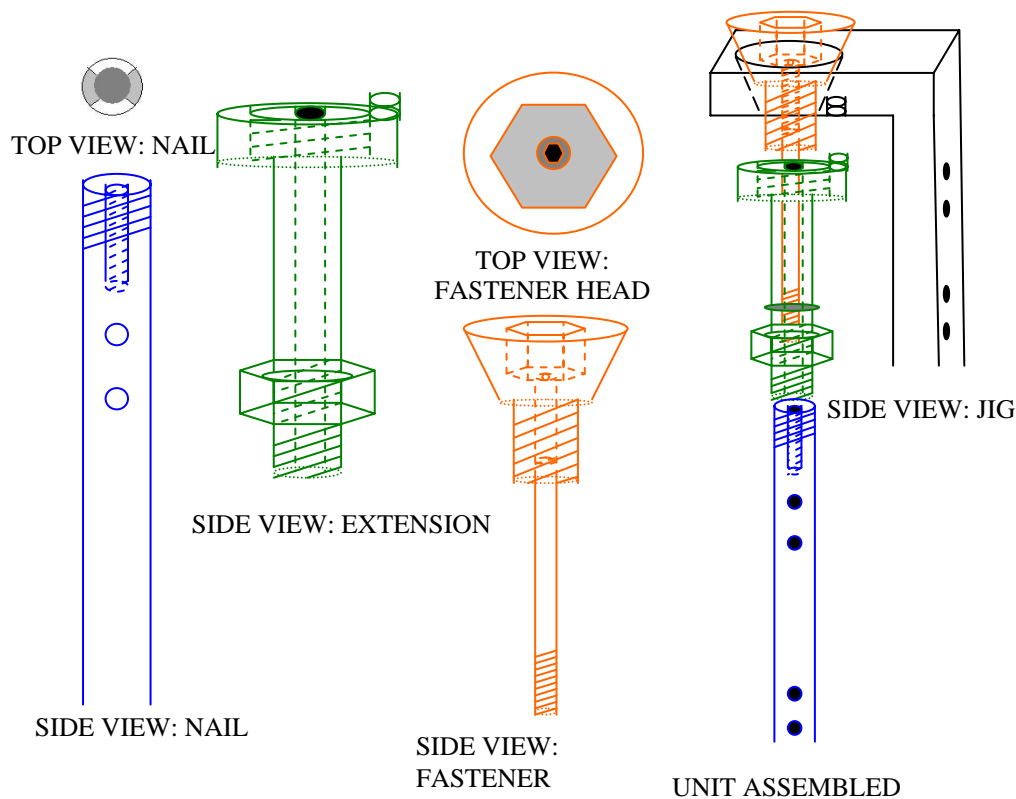


Figure 6: Units of design 3.

The fastener, which secures the jig to the extension piece, has two different components. One is the conical piece with threading on the bottom 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 6. The fastener is also secured to the jig and the extension via compression achieved by threading the fastener into the unit is tightened using the hexagonal allen head of the fastener, top view of fastener in figure 6.

The extension will have a flat top except for the cylindrical protrusion that fits into the indentation in the jig. This feature allows alignment of the holes in the nail with the guide holes in the jig about the long axis. The extension will also have a threaded outer diameter at its distal end, seen in the side view of the extension in figure 6. 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 many 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. The "H" head is a proven method to

maintain rotational alignment about the long axis of the nail. The bolt on the exterior of the nail and extension interface provides an additional layer of support so that movement may be decreased.

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. The long screw itself is more susceptible to fracture during tightening as it is long and slender.

VI. Design Matrix:

After carefully considering the design alternatives, a design matrix was constructed to evaluate designs and aid in deciding how to proceed for the remainder of the semester.

Best-10, worst-1

Table 2: Design Matrix

	Simplicity (1-5)	Integration into process (1-10)	Cleaning (1-5)	Cost (1-5)	Potential effectiveness (1-10)	TOTAL (5-35)
Extra Bars	4	9	5	3	7	28
Conical Connection	3	8	5	3	8	27
Double- sided Screw	4	7	5	2	7	25

Certain categories have been weighted more heavily based on their importance. The two categories rated highest are the “Integration into Process” and “Potential Effectiveness” 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 effectiveness of the device was rated on a higher scale merely because the success 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.

After evaluation, we have learned that all three designs have a relatively close score. Because these scores are close, it may not be wise to eliminate two designs out right. It has been decided to pursue the second design, but may incorporate elements from other designs. The leading factor to this decision was mainly based on its potential to address the problem in a simple and effective way in comparison to the other two designs.

VII. Ethics

The intramedullary nail system discussed here is used solely in canines. Although ethics relating to human medicine are a much more serious issue, this does not mean that they can be completely ignored in veterinary medicine. Confidence is required that any new design developed does not negatively affect the animal. As this team is comprised of engineering undergraduate students with minimal background in surgical techniques, it would not be wise to develop a design requiring a new surgical procedure without close discussion with our client and other doctors of veterinary medicine. This method presents a safe way to ensure that any design will not threaten an animal's health.

VIII. Conclusion

Now, that the problem has been identified and several design alternatives developed the next step is to decide which design will be developed into a working prototype. Focus will be limited to designs that most effectively address the extension and nail interface. Currently design alternative one and two seem to address this issue with limited manipulation of the current surgical instruments and procedures. The decision between the two designs will require further analysis of forces involved and the manufacturing of such units. Quantitative measurements of the force required to deviate the distal holes from the drill guide holes must be carried out to determine if any improvement is made using the new design.

Once the design has been finalized with any changes testing will be done to determine if deviation still occurs. It may be possible to build and test multiple prototypes. This will only be pursued if the necessary time is available and will not compromise the quality of our main prototype.

Appendix A: PDS

Product Design Specifications

Title

Improving Intramedullary Rod Surgical Equipement, 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 into the proximal end of the bone through 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 hills. 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 to 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 with out 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 modular aiming device when the forces required to get the rod in place are applied. The modular aiming device 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 modular aiming device 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 contaminants, 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 device 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 released. 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: References

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