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AXIAL PULL-OUT STRENGTH OF 3.5 CORTICAL AND 4.0 CANCELLOUS BONE SCREWS PLACED IN CANINE PROXIMAL TIBIAS USING MANUAL AND POWER TAPPING

By

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Many orthopedic conditions in dogs require the placement of bone screws in the proximal tibial metaphysis. Currently, both cortical and cancellous screws are used clinically depending on the surgeon's preference; however, the ideal screw for use in the proximal tibia has not been determined.

Currently, both the manual and power tapping techniques are used during surgical procedures of the proximal tibia in dogs. However, it is unknown if the use of power tapping when placing screws in the canine proximal tibial metaphysis affects screw purchase.

Measurement of axial pull-out strength is traditionally used to evaluate and compare the holding power of screws inserted in bone. This study compares the axial pull-out strengths of 3.5 mm cortical and 4.0 mm cancellous screws inserted using manual and power tapping techniques in the proximal tibial metaphysis.

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CHAPTER I

INTRODUCTION

Fractures, controlled or traumatic, are a common occurrence in veterinary patients. Tibial fractures account for 20% of all veterinary orthopedic fractures. And finding the most efficient means of fixation, that allows the animal to regain ambulation while minimizing complications, is paramount. This is because veterinary patients are unable to use devices that are common place in human trauma patients, such as crutches, wheel chairs or prolonged bed rest. Therefore, finding the best form of rigid internal fixation is extremely important in animals.

Orthopedic screws alone or with surgical plates are a common method of fracture fixation in veterinary medicine. Also, a variety of other orthopedic conditions utilize screws such as; tibial plateau leveling osteotomy (TPLO) or tibial tuberosity advancement (TTA) for cranial cruciate rupture, or triple pelvic osteotomy (TPO) for hip dysplasia, or corrective wedge or rotational osteotomies for angular limb deformities (ALD). However, the thickness, strength and durability of each bone varies and can change with patient maturity; thereby making each bone area unique.

Finding a rapid yet reliable and rigid fixation method is necessary to optimize overall patient outcome. By decreasing anesthetic time, morbidity, infection, and arguably mortality can be minimized. The infection rate associated with tibial fracture repair has been estimated at 15% of cases.[1]

This project was undertaken to identify the optimal screw insertion method and screw type for use in the canine proximal tibial metaphysis. Chapter III will better explain the differences between orthopedic screw types as well as how previous studies have compared them. The traditional way to asses the holding power of screws inserted in bone is by measurement of axial pull-out strength. Studies using axial pull-out strength data have been performed to assess proper screw diameter and screw length in an effort to design improved implants. Currently, there are few studies comparing the axial pull-out strength of cortical versus cancellous screws in various bones, and results vary depending on the anatomic location in which the screws were tested, the bone density, and the species evaluated. This study compares the axial pull-out strengths of 3.5 mm cortical and 4.0 mm cancellous screws inserted using manual and power tapping techniques in the canine proximal tibial metaphysis.

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CHAPTER II

FRACTURE HEALING

Bone healing requires a stabile mechanical environment to ensure successful fracture repair. Primary bone healing occurs through a process of cortical remodeling and occurs with 2% strain at the fracture site.[1] Secondary bone healing occurs through the process of intramembranous and endochondral ossification and occurs with 2-10% strain at the fracture site.[1] If strain is excessive at the fracture site, then fibrous tissue forms rather than bone, and the fracture does not heal, resulting in a nonunion. A variety of orthopedic implants are used to stabilize fractures and hold strain to a minimum to allow fracture sites to heal. The most commonly used implant is the orthopedic screw.

Screws can be placed in a neutral, positional or lag fashion during orthopedic procedures. Surgical screws can be used alone or in combination with plates, tension bands or prosthetic ligaments in a variety of trauma or elective veterinary orthopedic conditions. When screws are used appropriately, they provide the stabile environment necessary for fracture healing to occur.

The most common causes of failed fracture healing are violation of orthopedic principles during fixation, owner noncompliance, uncontrolled animal behavior, adverse metabolic effects or a combination of these factors. The general types of complications that can occur with orthopedic screws are implant failure, malalignment or malpositioning of the bone, premature growth plate closure, stress protection, osteomyelitis, malunion, delayed union, nonunion, and fracture related neoplasia.[2, 3]

Veterinary orthopedics has a unique set of circumstances which requires surgical patients to bear weight on the operated limb almost immediately. The use of non weight-bearing slings and braces on orthopedic polytrauma patients is impractical. In addition, using external coaptation can dramatically increase owner expenses with regular bandage changes as well as cause superficial dermatitis, decubital ulcers, muscle atrophy and bone mineral density loss leading to a decrease in range of functional limb motion. Finding the optimal means of internal fracture fixation, that allows the animal to walk quickly after surgery, is the best option.

When orthopedic implants are placed, there is always a ‘race’ between fracture healing and implant failure because of the mobility of veterinary patients. The implants absorb forces transmitted through bone and will eventually cycle until fatigued. The surgeon must choose the appropriate fixation methods, implants and implant size to assure stability for adequate time for the bone to heal. If the bone does not heal in the time expected, the implants are at risk for failure resulting in fracture fixation failure. The objective is to have the fracture heal before the implant has cycled to its critical failure point.[2, 4]

The majority of fracture complications can be addressed and corrected once the reason for failure is discerned. Proper surgeon education as to technique and correct implant size is imperative to minimize 'surgeon error' related complications. The major cause of fracture failure was instability from improper technique in 100 dogs with diaphyseal fractures; however infection also played a major role.[5] Infection is far more common with fractures treated by internal fixation versus external coaptation and has been reported in as high as 27% of fracture repair.[5,6] Another study found that three out of 506 orthopedic surgery cases developed osteomyelitis in hospital and another 36 were infected at admission.[7] It is widely accepted that the most common cause of infection is the patients' endogenous flora, and the risk of surgical infection doubles with every hour of open surgery. This further illustrates the importance of providing rapid stabilization to minimize postoperative complications.

In controlled fracture settings, as with elective orthopedic procedures, avoiding complications with implant failure and infection are still important. Controlled osteotomies may be performed for various reasons such as; tibial plateau leveling osteotomy (TPLO) or tibial tuberosity advancement (TTA) for cranial cruciate rupture, or triple pelvic osteotomy (TPO) for hip dysplasia, or corrective wedge or rotational osteotomies for angular limb deformities (ALD). Doornick reports complications in 29% of 227 TPO cases with screw loosening accounting for 25%.[8] TPLO complications have been reported to occur in 13-28% of cases.[9-11] Major complications (necessitating additional surgery) reported with this procedure include intra-articular screw placement, screw breakage, screw loosening, and lameness induced by screw irritation to surrounding structures.[9-11]

Optimal screw purchase and holding power are equipment variables, while screw positioning and length depend on selection by the surgeon. Several varieties of screws have been designed to optimize bone-screw interface and minimize screw failure or fatigue. The weakest point of plate fixation is the screw, which leads to instability and fracture fixation failure. Therefore, optimizing screw purchase in the bone will minimize one of the more avoidable postoperative fracture complications.

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CHAPTER III

COMPARISION OF ORTHOPEDIC SCREWS

Although there are numerous screw designs, and new variations continually being developed, there are two major types of screws; cortical and cancellous. They are designed to optimize the bone-screw holding power in their respective types of bone. A hole is drilled into the bone with an appropriate size drill bit. The drill bit used should equal the inner diameter of the screw. Then threads are tapped or cut into the bone prior to screw insertion.

A screw tap is designed to be much sharper than the threads on a screw. It is a more efficient mechanism of clearing bone debris so it does not accumulate and clog screw threads during insertion. Loose bone debris retained in screw threads decreases the amount of surface area of bone-screw purchase and therefore the overall strength of the fixation. A screw hole can be tapped by manual power or with the aid of a drill. While manually tapping a surgeon may become fatigued during fracture fixation and may cause bone damage due to ‘wobble’ of the tap.[1-3] Alternatively, power tapping may cause microfractures or weaken the bone holding power.[3]

There are several definitions that need to be mentioned in this discussion of screws. Screw pitch is the distance between the threads on the screw. The lead is defined as the number of threads per unit area. Tensile strength of a screw depends on the core diameter, or the diameter of the screw between the threads. Axial pull-out strength depends on the outside diameter of the threads as well as the number of threads engaged in the cortex, and individual bone properties. Axial pull-out studies are tests that shear the bone-screw interface. Other contributing factors to screw holding power include: thread surface area, depth and pitch, triangulation of screw placement, tapping prior to insertion, pilot hole diameter, and shear strength of the holding material.[1-9]

Cortical Screws

Cortical screws have closely-spaced shallow threads and larger core-to-outer diameter ratios than cancellous screws. These threads were designed to hold firmly in dense cortical bone and optimize bone-screw surface area contact. Cortical screws are stronger than cancellous screws of the same outer diameter due to their thicker core. However, a small change in screw diameter does not guarantee a significant increase in mean pull-out strength.[10] Cortical screws are usually blunt ended, but are available in a self-tapping variety. Full-threaded screws are typically used to engage both bone cortices with plate fixation to maximize stability. The blunt end or tip should extend 2-3 mm beyond the trans cortex to minimize adjacent soft tissue damage while optimizing the cortical bone holding power.

Cancellous Screws

Cancellous screws are a variety of screw designed for optimal purchase in cancellous bone. Cancellous bone is founding the metaphyseal region of long bones, especially in young growing animals. Cancellous screws have more deeply cut and more widely spaced threads compared to cortical screws. These threads give a deeper purchase in less dense bone, again trying to optimize total bone-screw surface area. However, the screw head is more likely to break off during insertion due to the narrower base. This makes the screws less optimal for orthopedic usage, in addition to fewer lengths being available. Cancellous screws are sometimes used for lag fixation of metaphyseal fractures. Recently, cancellous screw pitch has been studied more extensively to optimize the holding power of these screws. It is thought that increasing the threads per inch and decreasing screw pitch may increase their holding power.[11] However, cadaver and clinical trials have not been conclusive.

Pull-out Studies

The accepted method for testing screw holding power is by axial pull-out strength as described by the American Society for Testing and Materials (ASTM).[12] While this does not take into account the shearing or cyclic loading of screws, for comparative experimental means it has proven useful and reliable. Both cadaver and synthetic materials have been used to test screw pull-out; however, no one perfect model has replaced the cadaver bone testing in its entirety.

Cadaver collection, handling and uniformity can also play a role in testing variability. Repeated freeze-thaw cycling of cadaver specimens leads to moisture loss which has been shown to alter mechanical properties.[13] Experimental designs must take this into account if the intent is to extract in vivo force data from in vitro models. The optimal freeze temperature for cadavers has been described as -20C.[14] In one report a non-significant trend for an increase in pull-out force over 14 days was seen in bones stored at -20C. So the authors recommended either decreasing freezer temperature to -70C or maintaining shorter durations of freezing. However, since the study was not statistically significant many authors continue storing cadaver bone at -20C or below. The individual variation in bone between animals can also influence experimental data. Specifically, in human tibia it was determined that when cortical width was less than 1.5mm, cancellous density determined ultimate pull-out strength of screws. Conversely, when cortical width was greater than 1.5mm, cortical width alone influenced the holding capacity of the screws.[15] The cortical layer thickness, rupture load and shearing tension all progressively increase from the metaphysis to the diaphysis.[16] This progressively increasing pattern corresponds to changes in the bone diameter, cortex thickness, and character of local trabeculae along the tibia. So depending on the anatomic location of the screw and age of the patient, different screws will better optimize the bone-screw interface with their threads in cadaver bone.[3]

In an effort to reduce the number of animal experiments and make mechanical testing more reliable without patient variation, synthetic bone models have been designed. There are a variety of materials that have been used but there usefulness has yet to be completely validated. In one study the use of a synthetic material showed self-tapping screws superior to cortical screws, while in the cadaver model they were identical.[17] Another study showed cortical screw pull-out force to be significantly less in polyurethane foam versus cadaver bone, but showed similar cancellous screw pull-out force in both the foam and cadaver bone model.[18]

A recent study in humans showed that cortical thickness and cancellous density account for 93% and 98% of the variance of the ultimate load of the screws in an axial pullout study.[19] When reviewing the literature comparing cortical versus cancellous screws, it becomes apparent why there is no ‘perfect screw’ for all scenarios. A study from Cooper showed cancellous screws to be superior in human tibial plateau fractures than cortical screws, but also indicated that smaller screws were stronger than larger screws.[20] This last statement seems counterintuitive since the holding power of the screw is base on the surface area of the bone-screw interface.

A study using canine cadaver tibia documented the importance of one-way pin insertion.[21] By advancing positive threaded pins, structurally similar to screws, you seat the threads into the bone. If you have to back out the pin due to length or to replace the pin, microfractures can occur and thereby decrease holding power. Kudnig found that in canine radii, a small increase in screw diameter does not significantly alter the pull-out force.[22] This was further illustrated by Robb et al. who saw no difference in pull-out strength for cortical or cancellous screws in the canine proximal and distal tibial metaphyseal bone.[23] It should be mentioned, however, that this particular study only used 5 replicas, making the statistical power low. Lastly, a canine pelvis study showed cancellous screws to be superior to cortical screws in immature bone.[8] The authors attributed this to the larger threads of cancellous screws being utlitized to contact more of the less dense juvenile bone.

Equine studies mirror some of these findings including the increase pull-out strength in diaphyseal bone versus metaphyseal bone.[24] This further illustrates the necessity for analysis for multiple anatomic locations due to the uniqueness of the bones morphology. One study showed no difference in cortical versus cancellous screw pull-out force in the diaphysis of the third metacarpal bone, but significantly stronger holding power of the cancellous screws in the metaphyseal bone.[25] However, this model was designed to portray the clinical situation of stripping a screw, therefore the optimal drill bit sizes were not used for the cortical screws. By overdrilling, only 1mm of thread purchase was attained with cortical screws and 2 mm of thread purchase with cancellous screw, showing the advantage of using cancellous screws in metaphyseal bone after a smaller cortical screw is stripped. The larger surface area provided by the cancellous threads has also been shown to increase the amount of compression in the equine distal phalanx.[26] Axial pull-out strength was not addressed in that study, and the authors cautioned the use of cancellous screws due to the weaker resistance to postoperative fatigue cycling compared to cortical screws.

There is also a large study using calf bones comparing cortical and cancellous screws inserted in metacarpal and metatarsal bones.[27] The study found no statistically significant differences in hold power in the diaphysis or proximal metaphysis of the bones between the two screw types. However, holding power was significantly greater for cancellous screws in the calf distal metaphysis. This study conformed that not all areas of bone are equal in density nor are all metaphyseal bones equal in density. This finding further cautions the use of blanket statements with regards to optimal screw choices in our surgical orthopedic patients.

The other area of debate in screw insertion technique is tapping the bone manually, with power or using self-tapping screws. The technique used to insert bone screws may also affect the strength of the fixation.[23, 28-32] Power tapping (the use of a drill to tap the screw hole) is significantly faster than manual techniques and allows screws to be inserted more quickly, thus reducing anesthesia and surgical time and potentially reducing the risk of infection.[33] Power tapping is often used when applying plates in horses and humans and in other long bones in dogs, depending on surgeon preference. Power tapping may reduce 'wobbling' during the tapping procedure, however, it may also cause microfracture formation, and induce thermal necrosis.[3, 32, 34-36] A study performed in equine bone found no difference in the holding power of manually inserted screws and power inserted screws; however, no similar study has been reported in canine bone.[32] It is unknown if the use of power tapping when placing screws in the canine proximal tibial metaphysis affects screw purchase. Thus, one of the aims of this study was to ascertain if using power tapping methods to decrease screw insertion time would have an effect on holding force.

Self-tapping screws, while shortening screw insertion time, are promising for future use in veterinary orthopedics. Their additional cost leaves their use at the discretion of the surgeon. Andrea in 2002 found no difference in pull-out strength of cortical screws with either self-tapping or non-self-tapping insertion into the equine third metacarpal bone.[33] However, a similar study in foal third metacarpal bones showed that pre-tapping the screws provided a greater axial pull-out versus using self-tapping cortical screws.[37] While worth mentioning, self-tapping screws are still a current area of research and debate in surgical orthopedics.

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CHAPTER IV

METHODOLOGY

In brief review, many orthopedic conditions in dogs require the placement of bone screws in the proximal tibial metaphysis, including collateral ligament repair, tibial plateau leveling osteotomy (TPLO), tibial tuberosity advancement (TTA), and fracture repair. Surgeons must be mindful of screw stripping, microfractures, and premature screw loosening when placing screws, particularly in the proximal tibia since the cortical bone of the proximal tibia is relatively thin compared to other bones and compared to cortical bone in the diaphyseal region of the tibia.[1-3] This region of the tibia also contains a large amount of cancellous bone. Retrospective studies have identified screw loosening and plate loosening as potential complications of TPLO and other orthopedic procedures of the proximal tibia.[4-5] Currently, both cortical and cancellous screws are used clinically depending on the surgeon's preference; however, the ideal screw for use in the proximal tibia has not been determined.

The technique used to insert bone screws may also affect the strength of the fixation.[1-6] As discussed in Chapter III, power tapping is significantly faster than manual techniques and allows screws to be inserted more quickly, thus reducing anesthesia and surgical time and potentially reducing the risk of infection. Power tapping is often used when applying plates in horses and humans and in other long bones in dogs, depending on surgeon preference. Power tapping may reduce ‘wobbling’ during the tapping procedure, however, it may also cause microfracture formation, and induce thermal necrosis.[6-10] It is unknown if the use of power tapping when placing screws in the canine proximal tibial metaphysis affects screw purchase.

Measurement of axial pull-out strength is traditionally used to evaluate and compare the holding power of screws inserted in bone.[6-7, 11-16] Studies using axial pull-out strength data have been performed to assess proper screw diameter and screw length in an effort to design improved implants.[2, 6, 14] Currently, there are few studies comparing the axial pull-out strength of cortical versus cancellous screws in various bones, and results vary depending on the anatomic location in which the screws were tested, the bone density, and the species evaluated.[3, 6, 17-26] This study compares the axial pull-out strengths of 3.5 mm cortical and 4.0 mm cancellous screws inserted using manual and power tapping techniques in the canine proximal tibial metaphysis.

Materials and Methods

Forty mature canine cadaver tibias were harvested from twenty dogs (18-33kg) euthanized for reasons unrelated to this project. Radiographs were obtained to confirm skeletal maturity before inclusion in the study. Patients that exhibited arthritis or other radiographic pathology were excluded from the study. The tibias were cleaned of soft tissues, wrapped in moistened cloths, then placed in plastic bags and frozen at -20ºC.

Prior to testing, the bones were thawed at room temperature for 24 hours. Each tibia was then potted with methylmethacryate[a] and placed in a custom fixture. Each individual tibia, independent of dog, was randomly assigned to one of four groups (n = 10 for each group) using the SAS procedure PLAN, System for Windows, Version 9.1 (SAS Institute Inc.).

Group 1- 4.0 mm cancellous screw-manual tapping

A single screw was placed from medial to lateral through each tibia. The screws were positioned perpendicular to the long axis of the bone and 1.5 cm distal to the tibial plateau using a custom jig. To insert the screws, a 2.5 mm drill hole was made and the hole was manually tapped with a 4.0 mm cancellous tap. The screws were slid into the conical shaped jig attachment and inserted into the tibia by hand until 2 mm of the screw exited the lateral cortex and 30-40 mm remained exposed on the medial cortex to allow attachment to the actuator of the testing machine. Care was taken to minimize off-axis loading during insertion.

Group 2- 4.0 mm cancellous screw-power tapping

The screws were inserted as described for Group 1, except that a power drill[b] was used to tap the hole with a 4.0 mm cancellous tap. Lavage was not utilized and the drill was used in full speed (100-200 rpm), once the cis-cortex was engaged, with a freshly charged battery to create a “worst-case” scenario.

Group 3- 3.5 mm cortical screw-manual tapping

The screws were inserted as described except that a 3.5 mm cortical tap was used. Tapping and screw insertion were performed manually.

Group 4- 3.5 mm cortical screw-power tapping

The screws were inserted as described. A 3.5 mm cortical tap was used. A drill was used as described earlier to tap the hole before manual insertion of the screw. Each tibia (with screw inserted) was then mounted to the 25 kN load cell of a MTS Bionix 858 Test System (MTS Systems Corporation, Eden Prairie, MN), a computer-controlled servohydraulic universal testing device, using a customized mounting jig (Figure 1).

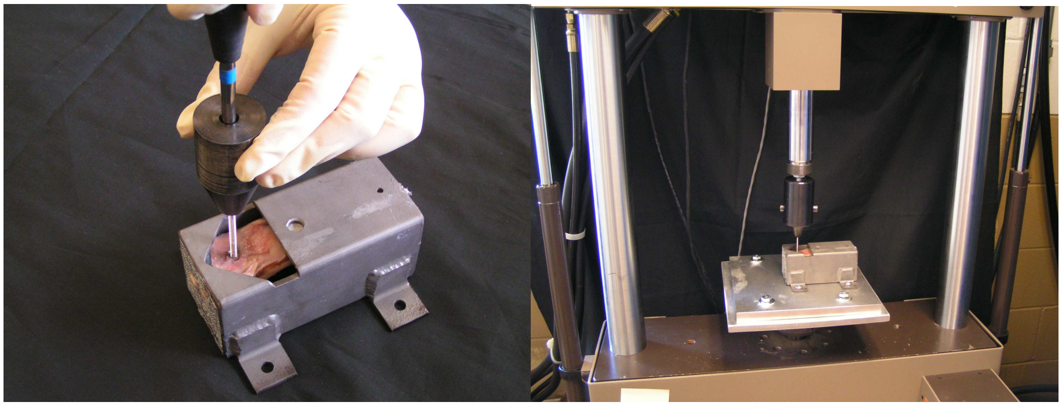

Figure 1: Custom tibial mount and jig for MTS machine

Screws were aligned vertically and attached to the MTS actuator via a conical slip for the screw head to rest in and a ball-and-socket joint attachment to minimize off-axis loads. Screws were extracted from the bone at a fixed displacement rate of 1 mm/minute according to ASTM (American Society for Testing and Materials) standards for determination of axial pull-out strength of medical bone screws.[26] Load and displacement data were continuously recorded at a sampling frequency of 10 Hz. Force was plotted against displacement for each sample, and pull out strength defined as the maximum force on this curve (Figure 2). The slope of the line was traced to ascertain stiffness before fatigue. The type of failure at the screw-bone interface was recorded for each construct.

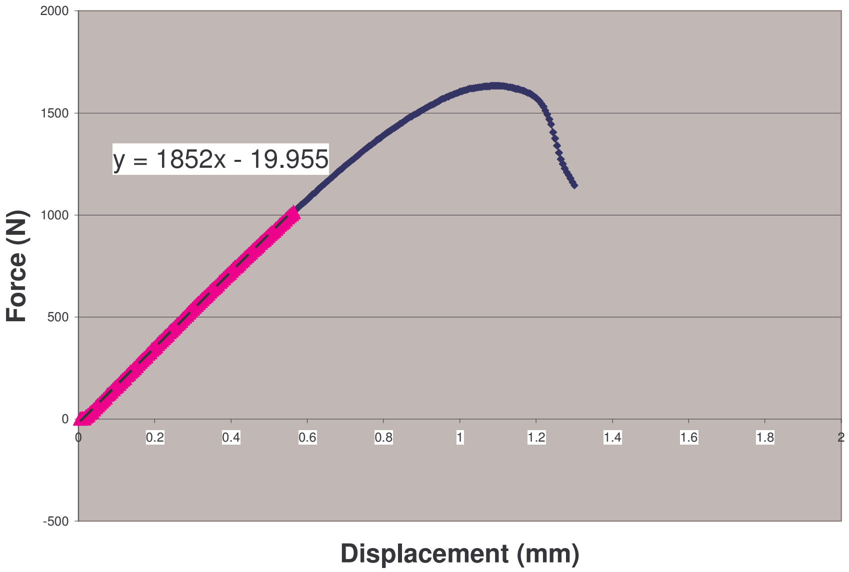

Figure 2: Example MTS recording for screw extraction

A computer generated best-fit line was drawn to the point of maximal force achieved during axial pull-out testing. Using the formula depicted, y=mx+b, 'm' represents the Newtons of stiffness used for analysis.

Following screw removal, the tibias were transected at the screw insertion site. The total diameter of each tibia at the screw insertion site was measured, as well as the width of the cis and trans cortices and the width of the medullary cavity. Measurements were obtained to the nearest 0.1 mm using a digital caliper. Briefly, caliper measurements were taken by placing the upper fine point tip in the center of the screw hole and manually dialing the caliper to extend the lower tip to the opposite point of interest, then recording the digital read out. All measurements were performed in triplicate by one individual (JLD) and their average recorded.

Failure load was analyzed using a one-way analysis of variance (ANOVA) for a completely randomized design with four groups (cortical screw power tapped, cancellous screw power tapped, cortical screw manually tapped, and cancellous screw manually tapped). ANOVA was performed using the SAS procedure GLM (SAS Institute Inc.). When significant effects were found, means were separated using the Least Significant Difference Test. The clinical importance of statistically significant differences were assessed using confidence intervals.[28] All calculations were performed using the SAS System for Windows, Version 9.1 (SAS Institute Inc.); all statistical tests used the 0.05 level of significance.

Results

The mean weight for dogs in Groups 1, 2, 3 and 4 was 25.5±5.6 kg, 24.2±5.4 kg, 25.4±6.0 kg, and 25.8±5.1 kg, respectively. The mean cortical width in tibias from Groups 1, 2, 3, and 4 was 2.9±0.3 mm, 2.9±0.7 mm, 2.7±0.3 mm, and 2.8±0.2 mm, respectively. The mean total width of cortices and medullary bone for tibias in Groups 1, 2, 3, and 4 was 10.4±2.6 mm, 9.2±1.6 mm, 11.5±2.8 mm, and 10.3±3.8 mm, respectively. There was no statistically significant difference in weight, mean cortical width (p=0.5649) or total mean width among groups (p=0.2808).

The mean axial pull-out strength for all four groups was 717.8±56.5 N (95% CI= 597.3-838.2). The mean pull-out strength for the 4.0 mm cancellous screws inserted using the manual tapping was 712.1±57.7 N (95% CI=589-835). The mean pull-out strength for the 4.0 mm cancellous screws inserted using power tapping was 770.3±55.3 N (95% CI=652-888). The mean pull-out strength for the 3.5 mm cortical screws inserted using manual tapping was 744.8±56.9 N (95% CI=623-865). The mean pull-out strength for the 3.5 mm cortical screws inserted using power tapping was 643.8±56.2 N (95% CI=524-763). There was no statistically significant difference in axial pull-out strength among groups (p=0.4813).

The mean axial pull-out force when adjusted for cortical width for Groups 1, 2, 3, and 4 was 705.5±83.4 N, 694.4±79.6 N, 751.3±82.9 N, and 798.5±81.9 N. There was no statistically significant difference in force/cortical width among groups (p=0.5318)**.** The mean axial pull-out force when adjusted for total tibial width for Groups 1,2,3, and 4 was 716.9±88.8 N, 716.1±110.6 N, 699.7±96.2 N, and 761.0±88.8 N, respectively. There was no statistically significant difference in the force/total width among groups (p=0.7428)**.**

The mean stiffness for the 4.0 mm cancellous screws inserted using the manual tapping was 8181±3290 N (95% CI=8092.0-8270.0). The mean pull-out strength for the 4.0 mm cancellous screws inserted using power tapping was 8539±3116 N (95%

CI=8460.4-8618.4). The mean pull-out strength for the 3.5 mm cortical screws inserted using manual tapping was 8704±4266 N (95% CI=8615.3-8793.3). The mean pull-out strength for the 3.5 mm cortical screws inserted using power tapping was 8476±3785 N (95% CI=8365.1-8587.1). There was no statistically significant difference axial pull-out stiffness.

Over all, there was no statistically significant difference among groups for axial pull-out strength, weight, cortical width, total width, pull-out strength when corrected for cortical width and, pull-out strength when corrected for total bone width (p>0.2808). (Table 1) All specimens failed on the bone at the screw-bone interface versus screw breakage.

Table 1: Axial pull-out strength of 3.5 mm cortical and 4.0 mm cancellous bone screws inserted in the canine proximal tibial metaphysis using manual or power tapping.

Screw type and insertion method	**Pull-out Force (N ±/- SE)**	**95% CI**	**Weight (kg ±/- SE)**	**Cortical Width (mm)**	**Total Width (mm ±/- SE)**	**Force/Cortical Width (N ±/- SE)**	**Force/Total Width (N ±/- SE)**
Cancellous- Manual tapped	712.1±57.7	589-835	25.5±5.6	2.9±0.3	10.4±2.6	705.5±83.4	716.9±88.8
Cancellous- Power tapped	770.3±55.3	652-888	24.2±5.4	2.9±0.7	9.2±1.6	694.4±79.6	716.1±110.6
Cortical- Manual tapped	744.8±56.9	623-865	25.4±6.0	2.7±0.3	11.5±2.8	751.3±82.9	699.7±96.2
Cortical- Power tapped	643.8±56.2	524-763	25.8±5.1	2.8±0.2	10.3±3.8	798.5±81.9	761±88.8

There was no statistically significant difference among groups (p>0.2808). N=newton, SE=standard error, CI=confidence interval

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Footnotes

[a] Technovit® Powder/Liquid, J-61PB, J-61LB, Jorgensen Laboratories Inc., Loveland, CO.

[b] Makita® Orthopedic Power Drill, Standard Model DC7020B, Jorgensen Laboratories Inc., Loveland, CO.

CHAPTER V

CONCLUSION

This study compared axial pull-out strengths of 3.5 mm cortical and 4.0 mm cancellous bone screws inserted into cadaveric canine proximal tibial metaphyses with and without power tapping. The canine cadaveric tibias used in this study were collected within hours of euthanasia and handled as described to minimize biomechanical artifacts due to storage. Cadaver bone has routinely been used for *in vitro* mechanical studies; and single thaw cycles with adequate thawing prior to testing have been shown to preserve mechanical properties of the bone.[1-7]

Screw pull-out strengths obtained from cadeveric bone (rather than from live bone) are a measure of the holding power of the screw achieved immediately after insertion and not that which might be achieved after some period of weight bearing, bone healing and/or bone necrosis has occurred. Therefore, these measurements do not take into account the effects of cyclic loading of the implants nor the possibility of thermal necrosis that can occur with the use of high speed drills during power tapping. Thermal necrosis is not as common in canine bone when compared to equine and human bone due differences in cortical density. Additionally, clinical screw failure often occurs early in the healing process and a measure of immediate bone purchase is clinically relevant. It is also prudent to employ cadaveric studies prior to subjecting live patients to a procedure that may be disproven *in vitro*.

Axial pull-out testing extracts the screw from the bone by traction along the screw's longitudinal axis, perpendicular to the bone surface. Axial pull-out testing at a fixed displacement rate of 1 mm/minute is recommended by the American Society for Testing and Materials (ASTM) for the determination of axial pull-out strength of medical bone screws.[8] This testing method was used in the study reported here to comply with ASTM recommendations, to ensure consistency of testing technique, and to allow direct comparison to previous studies performed in human, canine and equine bone.[9-14] Axial load to failure was measured to directly compare screw strength, although stiffness may be a better indicator for holding strength in healing bones when studying plate fixation and fatigue cycling. Every effort was made to minimize variables that might affect pull-out strength, including the use of a jig to ensure all screws were inserted perpendicular to the bone and to minimize "wobble" during drilling and tapping.

Using skeletally mature dogs within an assigned weight range was done to minimize outliers or bone size variability while minimizing cadavers used for this study. Tibias were randomly placed into test groups to further avoid variability; patient weight, cortical width, and total bone width were not significantly different among or between the groups tested in this study. This shows the computer randomization was effective in making the four separate treatment groups equal with regards to the dog size and bone anatomic measurements. Qualitative bone mineral density was beyond the scope of this study but may have been a more sensitive normalizing methodology than comparing pull-out force related to bone widths. However, the variance between confidence intervals of the four groups was smaller when analyzed relative to bone thickness. The decrease in variation of confidence intervals supports the use of this strategy for normalizing the data. It is also important to note that although measuring axial pull-out force of the screws provides useful comparative data, the actual forces applied to screws in the clinical situation are typically oblique to this axis or parallel to the bone surface. Thus, although the relative magnitudes of the forces measured in this study are of value for comparison, they may not accurately reflect the forces encountered by bone screws *in vivo*. Therefore, this experiment tests the screw in their “worst-case” scenario.

Stiffness during the pull-out trials was also not found to be different between the two groups. There is some evidence that stiffness may be another way to test for clinical holding power. However, in our stiffness calculations, the large variation within groups caused the standard deviations to widen the confidence intervals. These larger variations made useful conclusions impossible statistically. We did not perform further analysis on the stiffness since there has been shown to be a linear relationship between axial pull-out and stiffness and both are proven to assess holding strength.

This study found no difference in the axial pull-out strength of 3.5 mm cortical and 4.0 mm cancellous screws when inserted in the proximal tibial metaphysis. This finding concurs with previous studies that found no difference in axial pull-out strength between these two screw types when tested in human and canine bones and in synthetic models.[9] We also had similar total axial pull-out force in our study as previously reported by Robb et al. In one study, manually tapped cortical and cancellous screws were inserted into the proximal tibial metaphysis of dogs and pull-out strength was compared to that of commercially available bone anchors. The dogs were of similar size as those used in the study reported here. The results found no difference in axial pull-out strengths between cortical and cancellous screws; and the maximum force at extraction was similar to that found in the study reported here.[9]

However, other studies of axial pull-out strength in human and canine bone found either increased pull-out strength of cortical screws[11, 15] or increased pull-out strength of cancellous screws[13, 16-17] depending on the species tested, the bone tested, and the age of the patients tested. It has been noted that the biomechanical strength of the screw-bone interface is affected when screws are placed in juvenile or aged/osteoporitic bone; and different screw types are required to achieve adequate anchorage in bone depending on the width of the cortical and cancellous bone at the site.[12, 17-18] Specifically, in human tibia it was determined that when cortical width was less than 1.5mm, cancellous density determined ultimate pull-out strength of screws. Conversely, when cortical width was greater than 1.5mm, cortical width alone influenced the holding capacity of the screws.[13] In the study reported here, there was no difference in the cortical or cancellous width among groups. Further testing is required to determine the effect of thicker cortices or softer juvenile bone on the pull-out strengths of cortical and cancellous screws in the canine tibia.

This study also found no difference in axial pull-out strength of cortical and cancellous screws when manual tapping or power tapping was used to insert the screws into the canine proximal tibial metaphysis. This finding agrees with other studies that found no difference in pull-out strength when comparing power tapping and manual tapping in other bones in human, dogs or synthetic models.[1, 19-23] These studies in combination with our results suggest that power tapping is a viable option when inserting cortical or cancellous bone screws in the proximal tibia of dogs. Power tapping is faster, thus reducing surgical time, and may minimize the "wobble" that can occur during manual tapping, particularly if the surgeon is fatigued or when placing long screws. It is recommended to use slow speed, high torque, and lavage when using power drills to tap screw holes in live bone to reduce thermal necrosis.[10] *In vivo* studies are needed to further clarify the effect of power tapping technique (speed and torque) on the placement of screws in the proximal tibial metaphysis of live dogs. A live animal study could also clarify areas not addressed in our *in vitro* study such as intermittent loading, implant fatigue cycles, and bone healing.

The absence of statistically significant differences among the 4 groups in this study may be because there is, in fact, no difference in holding power between the two screws inserted in either manner, or because any difference that may exist was masked by the intrinsic variability of the bone. A failure to demonstrate statistical significance may also be a result of too few specimens in each group (type II error). However, the number of tibias in each group was determined by statistical analysis of previous studies to ascertain a clinically significant difference in mean axial pullout strength of approximately 15%. Power evaluation suggests 1000 tibias would be needed to be 90% certain to detect differences with 95% confidence with our standardized difference of

15%. These additional tibias would be needed to prove the small differences in means in our groups are real, if any differences exist in our pull-out force results. While this may prove to be statistically significant, with a mean pullout force in excess of 700±250N, a difference of less than 100N is not likely clinically significant. Therefore, the use of this excessive number of animals to achieve statistical significance was deemed unnecessary.

The findings reported in this study are clinically relevant to surgeons placing screws in the proximal tibial metaphysis during TPLO, fracture repair, and other orthopedic procedures in dogs. Despite the thin cortices and large volume of cancellous bone in the proximal tibia, cortical screws can be placed rather than cancellous screws. Cortical screws are less likely to suffer screw head breakage during insertion and are available in more lengths. Power tapping may also be used to insert screws in the proximal tibial metaphysis without a reduction in axial pull-out strength. This can reduce operative time and perhaps reduce the incidence of infection associate with prolonged surgical procedures. Surgeons should, however, use proper speed and torque during power tapping to minimize thermal injury to the bone. Cortical screws placed with power tapping in this surgical location in canines can be recommended, since their pull-out strength is equal to the mechanically inferior cancellous screws.

There are many future areas of study to continue to optimize these techniques. Newer screw models may prove more beneficial in the canine proximal metaphysis, such as self-tapping or cannulated screws. Also, testing other various places on the canine cadaver to ascertain differences in axial pullout strength is warranted. Once cadaver studies are verified, using these methods in vivo to better account for bone healing and thermal necrosis would be vital. Finally, using different age dogs with varying bone mineral density and healing capacity would be a worthwhile study.

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