

THE RELEVANCE OF THREADED EXTERNAL  
SKELETAL FIXATION PIN INSERTION SPEED IN  
CANINE BONE WITH AND WITHOUT PREDRILLING

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SKELETAL FIXATION PIN INSERTION SPEED IN  
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**Abstract:** External skeletal fixation is a useful tool for the veterinary surgeon in the management of various orthopedic conditions. Appropriate insertion of fixation pins is paramount to its successful application as premature pin loosening is the most common complication. Low speed insertion and predrilling have been recommended based on previous reports. Unlike predrilling, the true effect of insertion speed has been poorly evaluated. The effect of insertion speed (rpm) and pilot hole predrilling for placement of threaded external skeletal fixation pins on temperature and morphologic damage in cortical bone was evaluated. The null hypothesis states insertion speed and predrilling will have no significant effect on temperature and morphologic damage. Fixation pins were inserted into cadaveric canine femurs at speeds of 700rpm and 150rpm, with and without predrilling. Temperature was measured at each cortex 0.5mm and 3.0mm from each insertion site. Samples were examined grossly and by scanning electron microscopy and scored using visual analog scales for evidence of morphologic damage. Data were analyzed for maximum temperature, temperature increase, sites above thermal osteonecrosis thresholds, microcracks, thread quality and gross damage. Predrilling had a significant effect on maximum temperature, temperature increase, thermocouple sites exceeding osteonecrosis thresholds, microcracks, thread quality and gross damage. Speed of insertion had no significant effect on any of the measured parameters following predrilling but had a significant effect on thread quality without predrilling. Our results fail to reject the null hypothesis concerning insertion speed which has no significant effect on thermal damage and minimal effect on morphologic damage which is negated by predrilling. Our results reject the null hypothesis concerning predrilling and support the practice of predrilling fixation pin insertion sites. Linear advancement of the pin is a function of thread pitch and angular velocity. Previous reports have stated the importance of linear velocity being consistent with the angular velocity to avoid damage to the pin-bone interface. Based on those reports in combination with our findings, permitting the pin to advance at the appropriate linear velocity is more important than maintaining a low insertional rpm.

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## CHAPTER I

### INTRODUCTION

External skeletal fixation (ESF) has been utilized in veterinary surgery for fracture stabilization since 1934 (1). Since then, applications for ESF have grown to include stabilization of corrective osteotomies, arthrodeses, tenorrhaphies, and more (2, 3, 4). In the realm of fracture stabilization, our collective understanding of the importance of the biological aspects of osteosynthesis has grown tremendously in recent years. Concurrently, great improvements in the design and strength of ESF components (clamps, connector bars, and fixation pins) eliminated or, at least, significantly ameliorated those limitations that often resulted historically in ESF repairs that failed prior to achieving osteosynthesis. These advancements have led to much greater success and popularity of ESF techniques amongst veterinary surgeons in the past three decades (2). One particular aspect of ESF implant design that has remained unchanged is the trocar tip design of veterinary external fixation pins. External skeletal fixation pins were originally trocar-tipped Steinmann pins. Despite the universal recognition of the improved bone-pin interface and holding power of threaded pins, the trocar tip design has persisted, despite being, at best, an ineffective design for drilling through bone. Because the cutting edge of a trocar tip inefficiently cuts through bone and does not remove the bone debris created by drilling as it passes through bone, the pin tip tends to create significant frictional heat. The amount of heat generated may result in thermal necrosis of the bone adjacent to the pin tract. Thermal necrosis of the bone results in the necrotic bone being replaced with fibrous tissue, and the end result is a more elastic transition zone between bone and pin with eventual loosening of the pin-bone interface and

failure of fixation. Slow-speed insertion of ESF pins, based on low rpm, was initially recommended to avoid thermal osteonecrosis during pin insertion and stemmed from limited evidence that pointed towards a benefit over high speed pin insertion (5). In the 1990s, the concept of predrilling a pilot hole was proposed, and generally accepted, as a superior method for enhancing the longevity of the pin-bone interface. Various reports have stated significant benefits of predrilling of pin insertion sites, including elimination of thermal osteonecrosis (6-8). Despite the general acceptance that predrilling a pilot hole prior to pin insertion should be the standard of care for ESF pin application, the notion persists that low speed insertion is still required to avoid thermal necrosis. To the authors' knowledge, the potential benefit of low over high speed insertion on cortical bone temperature following predrilling of insertion sites for positive-profile fixation pins has not been objectively evaluated. The objective of this investigation is to determine the effect of speed of insertion with and without predrilling on heat generation and mechanical damage. Our null hypothesis states that insertional speed and predrilling will have no significant effect on cortical temperature or morphologic damage.

## CHAPTER II

### REVIEW OF THE LITERATURE

External skeletal fixation was first introduced in 1840 by Jean-Francois Malgaigne. It was not until 1934 that ESF was reported in veterinary medicine by Otto Stader (1). Since that time, considerable advancements have occurred in both design and application of ESF pins. The earliest commercial systems for veterinary external skeletal fixation included the Stader, Angell Memorial Animal Hospital, and Kirschner-Ehmer (K-E) systems (1). Advancements in component and construct design have led to greater success in application of external skeletal fixation using more modern systems. Although the K-E system has been the only of the early systems to persist, it has largely been supplanted by the Securos and IMEX systems. While different in design, the IMEX and Securos systems made substantial improvements in clamp design. The clamps of the newer systems provide the freedom of adding pins and clamps after the proximal and distal pins are connected to the connecting bar during the application process, unlike the K-E system. In addition, the IMEX and Securos clamps are designed to accept pins of varying sizes while providing a secure pin-clamp interface. Similarly, connecting bars of the IMEX system have improved stiffness of the constructs. Connecting bars composed of titanium, carbon fiber, and aluminum are available from IMEX which provide exceptional strength due to increased diameter without the weight associated with stainless steel bars. The carbon fiber rods are also radio-opaque which allows better radiographic assessment of bone healing. As a result of these advancements, both the Securos and IMEX systems were found to provide biomechanical

advantages over the K-E system in an investigation by White, Bronson, and Welch (9). These mechanical advantages allow rigid fixation without the need for more complex constructs.

## PIN DESIGN

The success of external skeletal fixation has been greatly improved through advancements in pin design. Original ESF pins were Steinmann pins which were trocar-tipped, non-threaded pins.

While the trocar tip has remained the industry standard, smooth pins were replaced with threaded pins. Threaded pins were observed to have improved pullout strength by Bennett, Egger, Histan, and Ellis in 1987 (10) and again by Sandman, et al. in 2002 (11). The first threaded pins were negative-profile pins which involved cutting of the threads into the pin. This resulted in marked weakening of the pin, concentration of stresses at the thread-nonthread junction, and subsequent pin breakage. In an attempt to avoid pin breakage at the thread-nonthread junction, Ellis pins were employed. These were negative-profile end-threaded pins intended to place the thread-nonthread junction within the medullary canal of the bone, thereby protecting the point of stress concentration. This failed to prevent subsequent pin breakage as evidenced by Palmer and Aron in 1990 (12). Because of this complication, negative-profile pins were soon replaced by positive-profile ESF pins. The threads of these implants were rolled onto the shaft of the pin, eliminating the reduction in shaft diameter that occurred with manufacturing of their negative-profile counterparts. Although stress concentration still occurred at the thread-nonthread junction, maintenance of the pin diameter increased the strength of the ESF pin exponentially by a factor of radius to the fourth power. This eliminated the loss of strength at the thread-shaft junction while maintaining the improvement in pin pullout strength as compared to nonthreaded pins (13). The most recent advancement in pin design has been the advent of a tapered run-out thread design. These pins involve addition of shaft diameter to the positive-profile ESF pin while providing a gradual taper of the threads to the smooth shaft to avoid the stress concentration at that junction.

Griffin, et al. demonstrated improved biomechanical performance of the tapered run-out design as compared to positive-profile pins of the same size (14).

Despite these marked improvements in pin design, the trocar tip has remained. This tip is a poor design for drilling of cortical bone. Trocar tips do not provide a pathway for the elimination of debris. This results in increased friction and subsequent heat generation as demonstrated by Matthews, et al. in 1984 using various pin tip designs inserted into cadaveric human femora and tibiae (6).

## PIN INSERTION

Previous investigations have sought to determine the appropriate insertion technique of ESF pins (5-7). Egger, et al. in 1986 compared insertion of pins into canine tibiae using various methods (5). These methods included hand insertion, low speed power, high speed power, low speed power using a threaded pin, and low speed power following predrilling. Heat generation, histologic evidence of necrosis, and pull-out strength of the pins were compared. Based on those results, low speed power insertion was recommended. The report did not compare high speed insertion following predrilling and only utilized threaded pins under low speed insertion without predrilling with the remainder of the insertions using non-threaded pins. Matthews, et al. in 1984 compared various insertion methods and pin tip designs in terms of heat generation using human femora and tibiae (6). The authors noted significant benefit of predrilling. While they stated they were surprised to not find more significant differences in regard to insertion speed, their results did indicate significantly higher temperatures with high speed insertion at 0.5mm from the fixation pin. That study utilized smooth pins and did not control pressure applied to the pin or linear advancement during insertion which has been shown to considerably effect heat generation when drilling bone (15-17).

Other reports have similarly supported the benefit of predrilling pilot holes prior to ESF pin insertion. The most notable study was performed by Clary and Roe in 1996, who evaluated temperature of the pin as it exited the *trans*-cortex along with histologic damage and pull-out strength following insertion through pilot holes of various diameters. Their findings supported the concept of predrilling to reduce heat generation and damage at the pin-bone interface. They also determined optimal pilot hole size to be 0.1mm smaller than the core diameter of the fixation pin (7). That investigation utilized ESF pins with a 3.2mm shaft diameter. The appropriate size difference between pilot hole and ESF pin is actually a function of pin size. As bone can only withstand a 2% strain for osteoblastic differentiation, the size of the pilot revolves around the size of the fixation pin. In practical terms, however, this most commonly translates to a pilot hole 0.1mm smaller than the ESF pin.

Since that time, the importance of predrilling has become widely accepted. Predrilling has therefore become standard practice for ESF pin insertion. The concept of low speed power insertion has become similarly entrenched in the veterinary literature despite a paucity of evidence in support of its practice. These reports include a number of review articles discussing the proper application of external skeletal fixation (8, 18-20). The proposed need for low speed power insertion is stated in a number of veterinary surgical textbooks as well (2, 3, 4).

#### THERMAL OSTEONECROSIS

Previous reports have established the thresholds at which osteonecrosis occurs. Bonfield and Li in 1968 reported weakening of the collagen-hydroxyapatite bonds and an irreversible change in structure with stress application using bovine bone at 50°C (21). The most widely accepted threshold for thermal osteonecrosis was determined by Eriksson and Albrektsson in 1983 (22). That *in vivo* study utilized rabbits with thermal chambers inserted into the tibia to evaluate the effect of three temperature and duration combinations: 50°C for 1 minute, 47°C for 5 minutes and

47°C for 1 minute. The authors reported consistent changes to occur at 50°C. Histologic evidence of osteonecrosis was noted when 47°C was applied for one minute, leading to that temperature and duration being accepted as the threshold of thermal osteonecrosis.

## MORPHOLOGIC DAMAGE

Morphologic damage of bone has been evaluated using various methods. These methods include traditional histologic techniques, bulk staining procedures and electron microscopy (8). Scoring of the damage has included the application of counting and calculating the microcrack density, measuring the length of the longest crack, subjectively grading the amount of microcracking, and using visual analog scales for subjective scoring of the damage (7, 23-25). As evidenced by the above descriptions, evaluation of microcracks has been the most commonly used assessment of morphologic bone damage. Yet, thread quality also plays an important role in maintaining security at the pin-bone interface. The amount of surface contact area between the osseous and metal thread surfaces contributes substantially to the security of that interface (26, 27). Surface contact area between the pin and cortical bone is critical to improved pullout strength (7). The use of threaded pins increases the surface contact area. Avoiding stripping of the cortical threads through proper insertion is critical to maintaining the improvement in surface contact as evidenced by Clary and Roe (7).

Gross morphologic damage to the *trans*-cortical surface has been shown to occur when inserting positive-profile pins (24). McDonald et al. (28) documented that the *trans*-cortex provides 1.62 times the holding power for pullout strength as compared to the *cis*-cortex, demonstrating the importance of avoiding *trans*-cortical fractures. While Anderson et al. failed to detect a significant difference in pullout strength between predrilled and non-predrilled insertion sites, they did detect a subjective decrease in severity of *trans*-cortical damage following predrilling (24).

## CHAPTER III

### METHODOLOGY

Ten femurs from healthy adult dogs, euthanized for reasons unrelated to this study, were harvested. Femurs were dissected free of any soft tissue attachments, wrapped in saline-soaked towels, and frozen at -20°C until time of the study. Orthogonal radiographs were obtained prior to freezing to confirm a lack of radiographic pathology.

#### PIN INSERTION AND TEMPERATURE MEASUREMENT

The femurs were allowed to thaw to room temperature for 24 hours prior to performance of the study. A 6.35mm hole was drilled in the lateromedial direction at the proximal and distal extents of the femur for horizontal mounting on threaded positioning bolts. These bolts were located within a metallic warm water bath. The position of the femur was maintained using nuts on both the lateral and medial surface at each end. Femurs were positioned such that all drilling and pin insertion was performed in a lateromedial direction. Two 0.7mm holes were drilled 0.5 and 3.0mm proximal and distal to the outer diameter of each planned ESF pin insertion site for placement of thermocouples. The proximal holes were drilled through only the lateral cortex. The distal holes continued through the medial cortex. All femurs were placed in a warm water bath at 38°C before being transferred to the testing container. After fixturing a femur and inserting thermocouples, the testing container was filled with water warmed to 38°C to just above the level of the lateral cortex. Once the temperature of the femur stabilized at 38 (+/-0.3)°C at each of the thermocouple positions, the water was drained from the container immediately before beginning



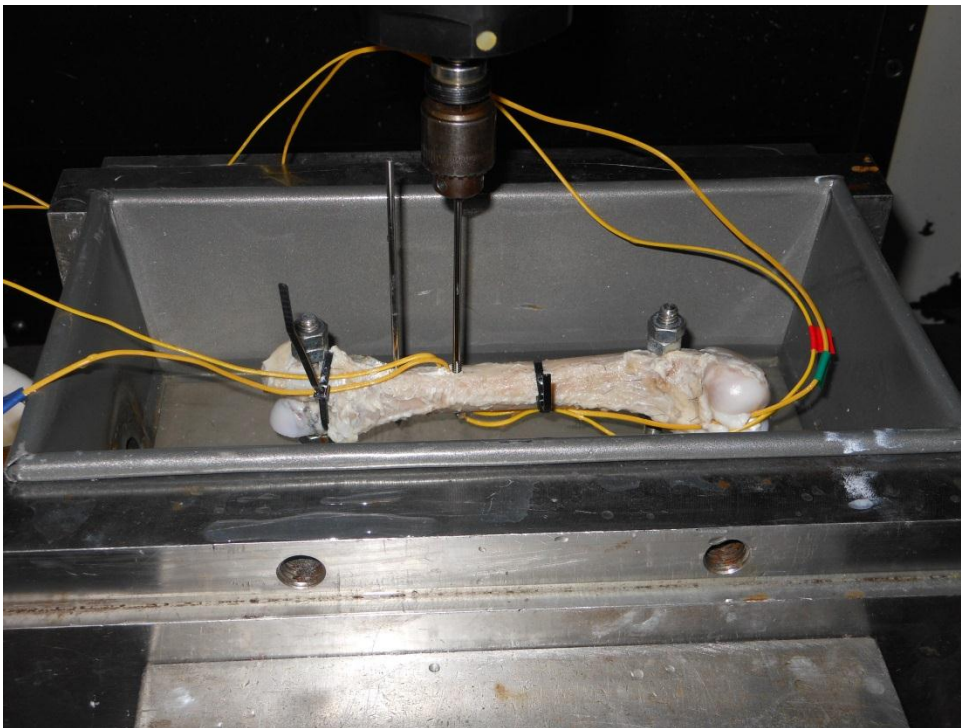
the ESF pin placement. The testing container was refilled with warm water as previously described to return the instrumented femur to proper temperature and drained again immediately prior to the pin placement process. Temperature of the femur was confirmed to be 38°C before each pin insertion. This series of steps was repeated for each pin placed.

For each femur, four pin insertion sites were evaluated according to the following treatments: predrilled and non-predrilled for both high (H; 700rpm) and low (L; 150rpm) insertion speeds. This resulted in a sample size of n=10 for each of the insertion methods. Positive-profile fixation pins (2.4mm shaft diameter, 3.2mm thread diameter)<sup>a</sup> were utilized for the purposes of this study based on the diameter of the femurs (per standard ESF application guidelines) (7). Four sites were utilized along the diaphysis of each femur with locations assigned by random draw for each treatment. The distance between each of the sites was 2cm between the centers. All drilling and pin insertion was performed by a CNC milling machine<sup>b</sup> to maintain consistent mechanical parameters including revolutions per minute (rpm), positioning, and feed rate (Figure 1).



**Figure 1:** Image of the CNC milling machine used for drilling of insertion and thermocouple sites and insertion of fixation pins.

Feed rate was calculated based on thread pitch and insertional rpm (mm of linear advancement/revolution X rpm = mm of linear advancement/minute). A 2.3mm drill bit<sup>c</sup>, according to standard ESF application guidelines (5), was utilized for predrilling the insertion site. Starting with the most proximal pin insertion site, four type K thermocouples<sup>d</sup> with heat sink paste<sup>e</sup> were inserted into the previously drilled measurement sites, the two lateral sites proximally and the two medial sites distally. The thermocouples were connected to a four-channel datalogging thermometer.<sup>d</sup> A fixation pin was loaded into the CNC machine and inserted according to the above described parameters based on random assignment. (Figure 2)



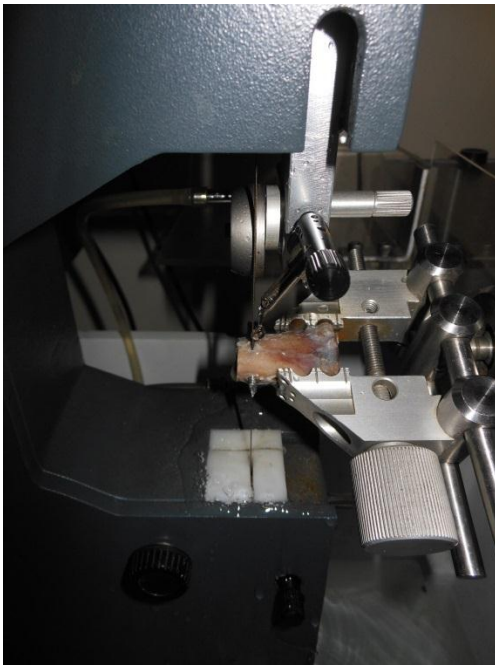
**Figure 2:** Image of instrumented bone following insertion of the second of four fixation pins.

The tip of the fixation pin extended through the medial cortex only to the extent that allowed 360° of threads to engage the outer edge of the far cortex, i.e., the trocar tip passed fully through the trans-cortex. Temperature measurements were recorded each second, for a data acquisition rate of 1Hz, from each of the four thermocouples until a maximum temperature had been reached and all

of the thermocouple readings had subsequently decreased below 37°C. The thermocouples were removed and transferred distally to the next insertion site. The same procedure was followed for the remaining insertion sites using a new fixation pin. The temperature data was transferred to a spreadsheet after completion of all four pin insertions in each femur.

#### MORPHOLOGIC DAMAGE

Following completion of the above described procedures, each femur was sectioned transversely no less than 3mm proximal and distal to each pin. Digital photographs of the trans-cortical surface were obtained for evaluation of gross damage. Fixation pins were transected 2mm above the cis-cortical surface. The samples were then sectioned through the center of the longitudinal axis of the fixation pin using a variable-speed diamond band saw at 200m/min band speed with a kerf of 0.1mm.<sup>f</sup> (Figure 3)



**Figure 3:** Diamond band saw sectioning through the fixation pin and insertion site.

Fixation pins were gently lifted from the bone. Samples were dehydrated in a graded series of 50%, 75% and 100% ethanol solutions before being critical-point dried using hexamethyldisilazane (HMDS). The samples were then sputter-coated with gold-palladium. Images of each cortical thread surface were obtained by scanning electron microscopy<sup>g</sup> at 85X and 150X magnifications. A total of six images were obtained from each sample (three from each cortex.) The samples were scored on 10cm visual analog scales (VAS) for microcrack density (from none to most possible) (25), which were modified to include other parameters important to pin-bone interface security, namely thread quality (excellent to could not be worse) and gross trans-cortical damage (none to could not be worse) with lower scores being better. The sum of those scores was reported as the total morphologic score.

## STATISTICAL ANALYSIS

Statistical analysis was performed for temperature and morphologic findings. Temperature data were analyzed for mean maximum temperature, mean change in cortical temperature, and proportion of sites that reached 47° and 50° Celsius (21, 22). Each of the morphologic VAS scores and the total morphologic score were statistically analyzed. SAS Version 9.3 (SAS Institute, Cary, NC) was used for statistical analyses. Analysis of variance procedures was used to assess the effects of insertion speeds and predrilling on temperature and morphologic damage. The experiment was designed as a two factor (speed and predrill status) factorial in a randomized complete block design. Individual bones were considered blocks. The simple effects of predrilling given speed and speed given predrilling were assessed with planned contrasts. Means and standard errors are reported, and significance was set at a 0.05 level.

## CHAPTER IV

### RESULTS

Ten femurs from five adult, mixed breed dogs were utilized for this study. Mean body weight was 20.4kg (range 15.5-25.5kg). Mean femoral diameter at the narrowest point measured 14.6mm (range 12-16mm). No gross or radiographic pathology was present in any of the specimens.

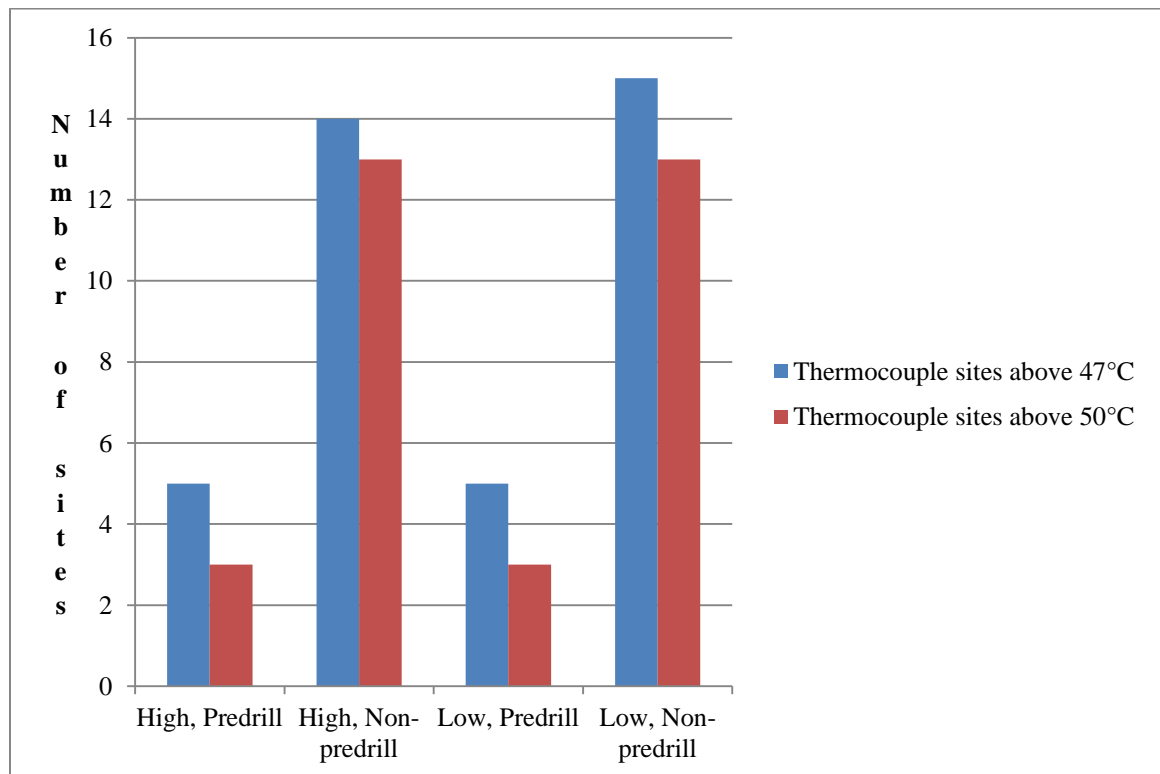
#### TEMPERATURE MEASUREMENT

All temperature data are summarized in Table 1. When all four thermocouple recordings were included, a significant difference in maximum temperature was detected between the predrilled and non-predrilled methods for high speed insertion ( $p=0.004$ ). No significant difference existed for maximum temperature reached between drilled and non-predrilled methods for low speed insertion ( $p=0.107$ ). No significant difference was detected between the high and low speed insertion for the predrilled group ( $p=0.9698$ ) nor the non-predrilled sites ( $p=0.177$ ). When only the temperatures 0.5mm from the pin insertion site were analyzed, a significant difference was detected between the predrilled and non-predrilled sites at both high ( $p<0.0001$ ) and low ( $p=0.0012$ ) speed insertion. No significant difference was present between high and low speed insertion for predrilled ( $p=0.8891$ ) or non-predrilled ( $p=0.0743$ ) sites at that distance.

When all four thermocouple recordings were included, a significant difference in cortical temperature increase was present between the predrilled and non-predrilled methods for both high ( $p=0.004$ ) and low ( $p=0.011$ ) speed insertions. No significant difference was noted between high and low speed insertion within the predrilled ( $p=0.955$ ) and non-predrilled ( $p=0.321$ ) groups for

increase in cortical temperature. When analyzing only the temperatures 0.5mm from the insertion site, significant differences were again present between the predrilled and non-predrilled sites at both high ( $p<0.0001$ ) and low ( $p=0.0005$ ) speeds. However, no significant difference was present between high and low speed insertion for predrilled ( $p=0.9536$ ) nor non-predrilled ( $p=0.0954$ ) sites.

The numbers of thermocouple sites among the 40 measured for each of the insertion methods reaching thermal osteonecrosis thresholds of 47°C and 50°C are illustrated in Figure 4.



**Figure 4:** Total number of thermocouple sites exceeding the thermal osteonecrosis thresholds among 40 possible for each of the fixation pin insertion methods. Significant differences following statistical analysis are listed in Table 1.

Significantly more non-predrilled insertion sites than predrilled sites reached 47°C for high speed ( $p=0.001$ ) and low speed ( $p=0.002$ ) insertion. Similarly, significantly more non-predrilled sites

than predrilled sites reached 50°C for high speed ( $p=0.004$ ) and low speed ( $p=0.004$ ) insertion. No significant difference was present between low and high speed insertion within the predrilled ( $p=0.474$ ) and non-predrilled ( $p=0.633$ ) groups for 47°C. Nor did a significant difference exist between high and low speed insertion within the predrilled ( $p=0.803$ ) and non-predrilled ( $p=0.803$ ) groups for 50°C.

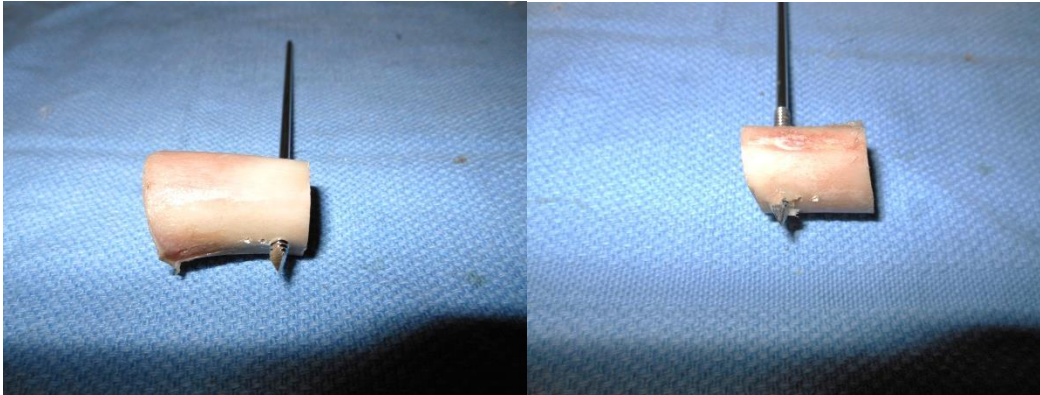
**Table 1:** Values shown are mean (standard error) in °Celsius for temperature. Unless otherwise stated, mean values include recordings from all four thermocouples. Threshold values are proportions following arcsine transformation. \* indicates significance difference between predrilled and non-predrilled methods.

		700rpm	150rpm	
Maximum temperature	Predrilled	42.5 (0.78)	42.6 (0.97)	$p=0.9698$
	Non-predrilled	48.4 (1.92)	45.8 (1.46)	$p=0.1768$
		$p=0.0039^*$	$p=0.1072$	
Max. temperature at 0.5mm	Predrilled	45.0 (0.75)	45.2 (1.01)	$p=0.8891$
	Non-predrilled	56.5 (2.43)	52.5 (1.72)	$p=0.0743$
		$p<0.0001^*$	$p=0.0012^*$	
Increase	Predrilled	3.6 (0.66)	3.7 (0.71)	$p=0.9554$
	Non-predrilled	9.8 (1.81)	8.1 (1.37)	$p=0.3211$
		$p=0.0004^*$	$p=0.0108^*$	
Increase at 0.5mm	Predrilled	7.1 (0.75)	7.2 (0.91)	$p=0.9536$
	Non-predrilled	18.6 (2.42)	14.9 (1.68)	$p=0.0954$
		$p<0.0001^*$	$p=0.0005^*$	
Above 47°C	Predrilled	0.125 (0.067)	0.150 (0.055)	$p=0.4743$
	Non-predrilled	0.375 (0.067)	0.400 (0.055)	$p=0.6325$
		$p=0.0012^*$	$p=0.0022^*$	
Above 50°C	Predrilled	0.075 (0.053)	0.075 (0.038)	$p=0.8031$
	Non-predrilled	0.325 (0.651)	0.350 (0.067)	$p=0.8031$
		$p=0.0004^*$	$p=0.0004^*$	

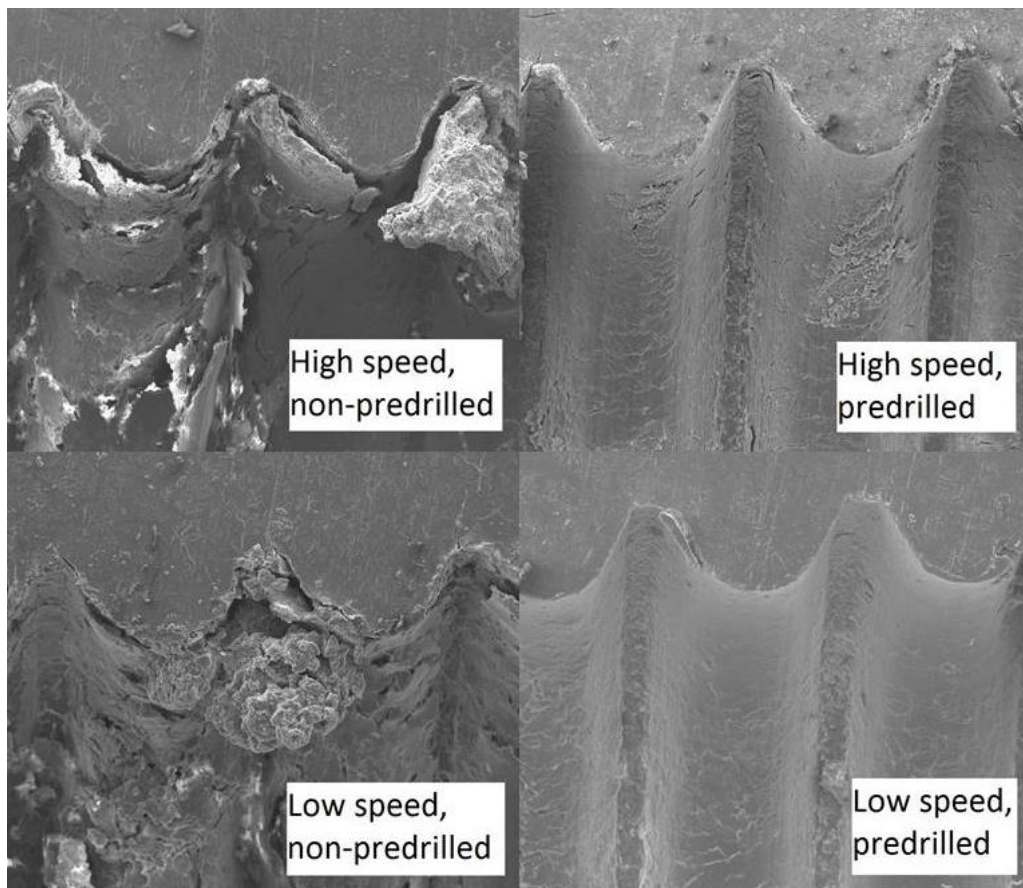
## MORPHOLOGIC DAMAGE

Results of gross and scanning electron microscopic morphologic evaluation (Figures 5 & 6) are summarized in Table 2.





**Figure 5:** Digital photographs representative of the gross trans-cortical damage of predrilled (left) and non-predrilled (right) sites.



**Figure 6:** Representative scanning electron micrographs of each insertion method from the same femur.



Results are reported as mean values of the VAS scores. Significant differences were detected for microcracks, thread quality, gross damage and total morphologic scores for predrilled versus non-predrilled sites at both high and low insertion speeds ( $p \leq 0.0002$ , see Table 2). A significant difference was present between high and low speed insertion for thread quality ( $p = 0.0026$ ) and total morphologic score ( $p = 0.0242$ ) at non-predrilled sites only. No significant difference was present between low and high speed insertion following predrilling for any of the morphologic scores.

**Table 2:** Values are mean VAS scores (standard error). \* indicates significance difference between predrilled and non-predrilled methods. † indicates significant difference between high and low speed insertion.

		700rpm	150rpm	
Microcrack	Predrilled	1.4 (0.33)	0.9 (0.28)	$p = 0.5167$
	Non-predrilled	5.025 (0.57)	3.965 (0.77)	$p = 0.1652$
		$p < 0.0001^*$	$p = 0.0002^*$	
Thread quality	Predrilled	1.2 (0.27)	0.9 (0.20)	$p = 0.6980$
	Non-predrilled	7.0 (0.57)	4.6 (0.84)	$p = 0.0026^\dagger$
		$p < 0.0001^*$	$p < 0.0001^*$	
Gross damage	Predrilled	0.8 (0.19)	0.6 (0.12)	$p = 0.6636$
	Non-predrilled	8.2 (0.35)	7.9 (0.47)	$p = 0.5184$
		$p < 0.0001^*$	$p < 0.0001^*$	
Total morphology	Predrilled	3.3 (0.59)	2.4 (0.50)	$p = 0.5467$
	Non-predrilled	20.2 (1.11)	16.5 (1.83)	$p = 0.0242^\dagger$
		$p < 0.0001^*$	$p < 0.0001^*$	

## CHAPTER V

### DISCUSSION AND CONCLUSIONS

The highest concentration of stress to the fixator-bone construct is at the pin-bone interface (2, 29). Thermal and mechanical damage at that interface are both functions of insertional technique and can lead to premature pin loosening (29-32). Avoiding thermal osteonecrosis and mechanical damage is essential to avoiding premature pin loosening (18). Despite the universal acceptance of threaded pins and predrilling, low-speed insertion continues to be recommended as a critical part of ESF pin placement (2, 5, 18, 31, 32). The primary aim of this investigation was to define the relevance of pin insertion speed when inserting positive profile threaded pins through predrilled pilot holes in canine bone. We fail to reject the null hypothesis concerning insertion speed as our results suggest that insertion speed of a threaded pin does not play a role in the generation of excessive heat or morphological damage when predrilled pilot holes are used. We reject the null hypothesis concerning predrilling as our results support the benefit of predrilling regarding thermal and morphologic damage.

When using a threaded pin placed in a pilot hole the linear velocity, or rate of advancement of the pin (feed rate), is determined by the thread pitch at any given rpm, or angular velocity, as previously described. A threaded fixation pin will advance at the appropriate rate provided the surgeon permits it to do so. The surgeon must allow the pin to advance at that determined rate to allow proper interface between the threads of the fixation pin and the cortical bone. Applying pressure to alter the rate of pin advancement to a linear velocity inconsistent with the angular

velocity based on thread pitch can cause damage, or “stripping,” of the cortical bone (28, 33). The results of our study revealed that insertion speed had no effect on cortical temperature and very minimal effect on morphologic parameters when maintaining the appropriate feed rate. Instead of focusing on maintaining low rpm, the insertion speed of threaded ESF pins should be that speed at which the surgeon can most easily permit the pin to advance at the appropriate rate.

The morphologic characteristics are important to the security of the pin-bone interface (2, 7, 8, 18). Microcracks, poor thread quality, and gross damage can all lead to premature loosening of the pin-bone interface. These parameters were scored individually on visual analog scales and cumulatively as the total morphologic score. Scanning electron microscopy was used to evaluate the thread surfaces after sectioning and removal of the fixation pin. Some damage could have developed during processing of the samples despite using a diamond band saw to reduce that damage. Nevertheless, all samples were prepared in the same manner, thereby permitting comparison between treatment methods. Predrilling improved each of the individual scores and, subsequently, the total score, regardless of insertion speed. Low speed insertion significantly improved only the thread quality and only for non-predrilled sites. As no effect of insertion speed was present for the other individual parameters, the improvement in total morphologic score was a mathematical result of the improvement in thread quality. These results support the practice of predrilling and the irrelevance of insertion speed of a threaded ESF pin following predrilling.

Another aspect impacting the longevity of the pin-bone interface is the generation of heat during insertion. The trocar tip of a fixation pin does not allow a path for removal of bone debris during insertion when predrilling is not performed. The accumulation of bone chips leads to increased frictional heat generation (19, 20). Certainly, excessive heat leads to osteonecrosis, increased osteoclastic activity and replacement of necrotic bone by granulation tissue. This results in a loose pin-bone interface and premature failure. Therefore, thermal osteonecrosis, even within 0.5mm of the fixation pin, could potentially lead to premature pin loosening (29). In an effort to

avoid excessive heat generation, early recommendations included hand insertion of fixation pins (34). Unfortunately, the lack of heat generation is offset by pin wobble during hand insertion which leads to an excessively large pin track and subsequent premature pin loosening (19, 20, 35). As an alternative, low speed power insertion was recommended to reduce thermal and mechanical damage. This recommendation was based on a previous report evaluating various insertional techniques on the pin-bone interface using trocar-tipped fixation pins (5). That report revealed that low speed power insertion following predrilling did not result in temperatures capable of producing thermal osteonecrosis and temperatures generated by low speed insertion were no higher than those created with hand insertion. While that study also found excessively high temperatures with high speed insertion, predrilling was not performed in conjunction with high speed insertion. Further, only the low speed power insertion method utilized threaded pins, making it difficult to directly compare the findings of that study to the techniques we employed (5).

Predrilling has been previously reported to significantly reduce heat generation during ESF pin insertion (6, 7). One paper demonstrated a clear benefit to predrilling in human cadaveric bone with higher temperatures reported during high speed insertion, but used non-threaded fixation pins and did not control pressure applied to nor feed rate of the fixation pin during insertion (6). Another study clearly documented an advantage of predrilling on both thermal and mechanical characteristics of the pin-bone interface using only low speed insertion. However, only the temperature of the tip of the pin as it exited the far cortex, not the temperature generated in the adjacent bone, was measured (7). What has not previously been compared is the difference in temperatures in the bone adjacent to the pin for high and low speed insertion when predrilling and positive-profile pins are employed.

Multiple studies have evaluated the threshold for thermal osteonecrosis. Results have varied from 47-55°C (21, 22). Cortical temperature in excess of 47°C for 1 minute has become accepted as

the threshold for osteonecrosis as changes in bone occurred at that temperature and duration. The same report illustrated consistent bone resorption at 50°C (22). An additional report describes irreversible bone changes due to weakening of the collagen-hydroxyapatite bonds at 50°C (21).

The proportion of thermocouple sites that exceeded both 47°C and 50°C were analyzed in our study. The duration of temperature elevation could not be evaluated as the procedures were performed on cadaveric bones. A warm water bath was utilized to bring the femurs to 38°C prior to each pin insertion to more closely resemble the clinical scenario. Once the water was drained for pin insertion, the femurs were exposed to room air. With this exposure, the temperature of the femur dropped rapidly and to a significant degree from what we chose to represent normal body temperature for a dog (38° C). Leaving the femur submerged in the warm water bath would have also altered the temperature measurements falsely due to direct exposure of the thermocouples to water. Nonetheless, direct comparisons can be drawn between the treatments as all were performed under the same conditions. Our results indicate that predrilling, but not low speed insertion of threaded fixation pins, significantly reduced both the maximum cortical temperature and the proportion of thermocouple sites that exceeded osteonecrosis thresholds.

We evaluated not only the maximum temperature reached, but also the change in temperature with insertion of fixation pins by the four methods. Because the bones would rapidly cool when the water was drained, the change in temperature provided a consistent method of evaluating the amount of heat generated during pin insertion. Temperatures were recorded by the datalogging thermometer every second. The change in temperature was the difference between the lowest temperature recorded prior to and the highest temperature recorded following pin insertion. No significant difference was present for the change in cortical temperature between high and low speed insertion for the two predrilling states. Non-predrilled sites had a significantly greater increase in cortical temperature than predrilled sites for both insertion speeds. This emphasizes

not only the importance of predrilling, but also the insignificant effect of insertion speed on heat generation for threaded ESF pins.

Very little temperature elevation was present 3mm from the insertion site, regardless of insertion method as has been reported previously (6). For that reason, we also reported the statistical analysis using only the temperatures recorded 0.5mm from the fixation pin. This resulted in changes in the mean maximum temperatures of 2.49 to 8.06°C and the finding of a significant difference between predrilled and non-predrilled sites at a low insertion speed.

This study has certain limitations primarily revolving around its *ex vivo* nature. First, the effect of circulation and surrounding soft tissues would alter the maximum temperatures reached. Bringing the bones to a stable 38°C was intended to reduce the effect of this variable. Although temperature values may have differed between our model versus an *in vitro* model, all of the insertion methods were tested under the same conditions which allowed us to make direct comparisons between techniques. The change in temperature was evaluated in addition to the maximum temperature reached to provide another means of consistent comparison between the treatment methods. Insertion of pins using a CNC milling machine, while providing a standardized testing scenario, does not resemble the clinical situation wherein a surgeon uses feel to permit appropriate advancement of the ESF pin. By controlling the feed rate, or linear advancement, we were able to eliminate that confounding variable which can have considerable effect on the pin-bone interface. Finally, evidence of thermal osteonecrosis could not be evaluated histopathologically on cadaveric bones but previous reports have established the temperature values we used as thresholds for the development of thermal osteonecrosis (21, 22).

## CONCLUSIONS

Predrilling has a significant beneficial effect at the pin-bone interface for both thermal and morphologic parameters and should continue to be standard practice. Speed of insertion of

threaded ESF pins has no effect on cortical temperature and only very minimal effect on morphologic characteristics, which is negated by predrilling. Based on these results, we recommend insertion of threaded fixation pins following predrilling at a speed which allows the surgeon to permit the pin to advance at a linear velocity consistent with the given thread pitch and angular velocity.

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## APPENDICES

### FOOTNOTES

a: Small INTERFACE® Fixation Half-pin; IMEX Veterinary, Inc., Longview, TX, USA

b: Haas VCP-D milling machine; Haas Automation, Inc., Oxnard, CA, USA

c: 2.3mm twist drill; Precision Twist Drill Company, Crystal Lake, IL, USA

d: Extech SDL200 4-channel datalogging thermometer and type K thermocouples, FLIR Commercial Systems, Inc., Nashua, NH, USA

e: Techspray® Silicone-free Heat Sink Compound, Techspray, L. P., Amarillo, TX, USA

f: Exakt 300, Exakt Technologies, Inc., Oklahoma City, OK, USA

g: FEI Quanta 600FEG Scanning Electron Microscope, FEI, Inc., Hillsboro, Oregon, USA

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