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Mechanical evaluation of aluminum oxide roughened screws in equine third metacarpal bone

Petrisor Baia
Louisiana State University and Agricultural and Mechanical College, pbaia@vetmed.lsu.edu

MECHANICAL EVALUATION OF ALUMINUM OXIDE ROUGHENED SCREWS IN EQUINE THIRD METACARPAL BONE

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DEDICATION

To my loving wife *Jenny*, for her continuous support and encouragement

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ABSTRACT

Objectives – To compare the osseointegration of roughened and electropolished 5.5 mm cortical screws used to secure a 4.5 mm broad dynamic compression plate (DCP) in equine third metacarpal (MC3) bones.

Study Design – In vivo study

Animals – 5 Adult thoroughbred horses (2-7 years old).

Methods – For each horse one MC3 was randomly assigned to secure a 4.5 mm broad DCP with 4aluminum oxide (Al_2O_3) roughened screws on the dorsal mid diaphysis. Four regular electropolished screws used to secure a similar plate on the contralateral limb served as control. They were removed at 12 weeks and the extraction torque was recorded. A paired t-test was used for comparison and statistical significance was set at $p < 0.05$.

Results – At 12 weeks, the mean extraction torque for roughened screws was significantly greater ($p < 0.0002$) when compared to regular AO screws. The roughened screws had a mean extraction torque of 3.24± 0.56 N-m, which was twice the mean extraction torque of the AO screws (1.65 ± 0.34 N-m).

Discussion/Conclusions – Bone tissue infiltrates the pores of the roughened screws increasing the contact surface and the mechanical anchorage. In our study the screw surface roughness is 2.14± 0.48 µm. This roughness has the lowest pore size that will interact with the surrounding bone without altering the screw dimensions. We found that Al_2O_3 roughened screws have a significantly greater removal torque when compared to the electropolished AO cortical screws when removed at 12 weeks post implantation.

Clinical relevance - Information obtained from this study may help in improving the contact surface of implants and subsequent fixation and stability of bone-implant construct in equine fracture repair.

CHAPTER 1
GENERAL INTRODUCTION

1.1 Principles of Equine Long Bone Fracture Repair

The original Swiss AO (Arbeitsgemeinschaft für Osteosynthesefragen) system of plates and screws was founded in 1958 to research into the concepts of functional rehabilitation and rigid internal fixation for human fracture repair. This system is known today as the Association for the Study of Internal Fixation (ASIF). The first veterinary AO/ASIF course for veterinarians was organized in Columbus, Ohio in 1970. Since those early years it developed an equine and small animal subgroup and remains the premier in North America for operative treatment of fractures in veterinary medicine.

The treatment of equine long-bone fractures remains challenging. Postoperative complications like laminitis, angular limb deformities, surgery site infection, and implant loosening /breakage or bone failure contribute to failure of the successful surgical repair (Auer et al, 1987; Crawford et al, 1985; Nunamaker, 1996). To prevent contralateral limb laminitis or limb deformity, evenly distributed weight bearing on all limbs is essential. As a result, the goal is to immediately reestablish a functional, full weight bearing limb that is nearly painless (Bramlage, 1983). Veterinary orthopedic surgery has been dependent on implants designed for the use in humans. While the small animal veterinary orthopedic community embraced the latest concept of biological fixation, the equine group is still looking for increased strength and stability in their fixations as required by full weight bearing in the horse (Nunamaker, 2002). Complications specific to the horse have helped maintain the focus of the equine group on improving the immediate loading potential of internal fixations. Horses don't experience bone atrophy and "stress protection" associated with their implants to the extent that occurs in man and small animals (Nunamaker, 2002). Therefore, the need to move the implant away from the bone seems unnecessary and may compromise the strength of the fixation. Cyclic loading of implants, which occurs during weight bearing in the horse, has pointed out the importance of micro motion within the bone/implant composite as it relates to implant failure and fracture healing (Nunamaker, 2002). The adaptation for large-animal fractures has been difficult because of the long bone size and the need for the repair to be immediately weight bearing. Anesthetic recovery of horses can be difficult and implants must withstand extreme forces. The repaired fractures are exposed to axial cyclic loading of 1.5 times body weight during walking and up to 4 times body weight during recovery from anesthesia (Rybick, 1977).

1.2 Bone Structure and Function. Bone Healing

Bone is not an inert structure, it can renew itself. It can add and subtract new bone on its surfaces (change shape) as it grows in a process called remodeling. It may also replace itself going through a remodeling phase that involves bone activation, discrete areas of resorption followed by bone formation in these resorption spaces. Modeling and remodeling can be occurring in the same bone at the same time. Bone does not heal, incorporating the scar tissue as seen in most all other tissues: it regenerates itself. It changes its shape and structure based on its use and if fractured can resume 100% of its former strength and function. Any treatment that doesn't reconstitute the bone into its fully functional state must be considered sub-optimal (Nunamaker, 2002).

The three major components of bone are osteogenic cells, organic matrix, and mineral. The osteogenic cells include osteoblasts, osteocytes, and osteoclasts, while the organic matrix consists predominantly of collagen and proteoglycans that constitute approximately 30% of the bone mass. The mineral that makes up approximately two thirds of bone is composed of calcium phosphate crystals deposited as hydroxyapatite. Although all bone is made up of these components its structure differs based on its apparent density and porosity. Cortical bone in the horse is made up of primary and secondary osteons or haversian systems. Cortical bone has an apparent density of 1.85 g/cm3. Cancellous bone is less dense with an apparent density of 0.9 g/cm3 or less (Nunamaker, 2002). Cortical bone may have a porosity of only 5%, whereas cancellous bone may be greater than 20% (Nunamaker 2002). Osteoblasts develop through an undifferentiated lineage from stem cells. They are very active metabolically when turned on and also participate in matrix mineralization. Osteoblasts may become trapped in their own matrix production and become osteocytes. These cells have long cytoplasmic processes that extend to other osteocytes and osteoblasts to form a network that covers over 90% of the mature bone matrix. Osteoclasts are multinucleated giant cells that resorb bone. These cells form on bone surfaces and resorb bone at the junction of their brush border with the mineralized matrix. They appear mobile and their cell numbers change in response to the "need" for local resorption (Figure 1.1).

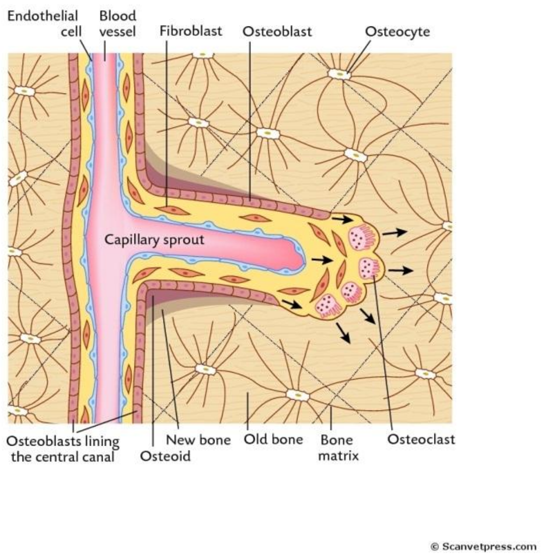


Figure 1. Cortical bone remodeling with "Cutting cone" osteoclastic resorption (Figure taken from www.scanvetpress.com)

In cancellous bone the osteoclasts form Howship lacuna or craters as they resorb bone on surfaces (Markel, 2005). In cortical bone these osteoclasts form the front of the so-called “cutting cone” that marks cortical bone remodeling (Figure 1.1).

The organic matrix of bone consists mostly of type 1 collagen. The inorganic matrix is a calcium phosphate that forms a crystalline hydroxyapatite. As the inorganic phase matures, its solubility decreases and mineralization increases changing the mechanical properties of bone making it stiffer. The calcium content also affects fatigue life of the bone with less calcium yielding longer fatigue life in vitro and possibly in vivo (Nunamaker, 2002). Morphologically, bone tissue appears to be under the control of bone cells. Modeling changes bone’s shape and seems to be related to the physical forces that the bone encounters (Wolff’s Law).

Vascularity of bone is maintained through a medullary and periosteal blood supply.The cortex is largely supplied from the medullary source (inner two thirds) with the periosteal supplying the outer one third of the cortex. Circulation is mainly centripital in nature. The afferent blood supply consists of arteries and arterioles (nutrient vessels) and the efferent supply is made up of the veins and veinules (periosteal vesseles) with the capillaries being the intermediate connection. At the microscopic level the central canal of the haversian system is the arteriole with Volkman’s canals being transverse components. Bone formation and resorption is a vascular phenomenon and does not occur without blood supply. In the dog and horse, no osteocyte is more than 0.3 mm from a blood vessel (Nunamaker 2002)

Mechanically, bone functions as a material and as a support structure for the body. As a material, the type 1 collagen of the organic matrix combined with the mineralized matrix gives bone material properties that allow for limited deformation and certain brittleness. This explains why bones bend then break. The bending is related to the collagen phase, which has a very low modulus of elasticity (stiffness), and the breaking is related to the mineral phase, that has a high modulus of elasticity, which allows little deformation (up to 2% strain) before bone failure. Composite materials are made of two or more different materials with different physical properties. Bone is a composite material (collagen and mineral) and its modulus relates to the sum of its parts. Equine cortical bone has a modulus of elasticity of 18–20 giga pascals (Gpa). Its structure has greater strength in some directions than in others. Bone is anisotropic in that it has different material properties in different directions. Long bones are usually thought to be orthotropic, being strongest in their axial direction and 20% weaker in their radial and transverse directions. Bone is strongest in compression and weakest in tension. Bending forces produce tension on the convex surface of the bone, hence bones are weak in bending. Torsion forces will resolve into tension forces as well so bones are also weak in torsion. Loading of bone determines its shape: functional requirements may lead bone to model and remodel to change its shape and internal architecture. Bone overload may create injury and fracture.

Fracture healing involves a series of overlapping processes that occur in the majority of fractures. These stages are typically referred to as the inflammatory phase(first 2-3 weeks), the reparative phase(2-12 months), and the remodeling phase (Markel, 2005). Primary bone healing (haversian remodeling) occurs under the stable conditions provided by interfragmentary compression with direct bone apposition; such conditions are produced by lag screw fixation or an axially loaded dynamic compression plate. (Schatzker, 2002). The healing is the result of a proliferation of new osteons which grow parallel to the long axis of the bone through the necrotic bone ends and then across the fracture, reestablishing bony continuity. There is no net resorption in this type of union. For every bit of necrotic bone removed new bone is laid down. The internal remodeling of the haversian system uniting the fragment ends is the only process in direct healing that results in solid union. Therefore, direct healing does not lead to faster union, but it is characterized radiologically by the virtual absence of callus formation. The mechanical environment will affect the reparative phase. Under conditions of instability, secundary (indirect) healing occurs by formation of callus. Initially, granulation tissue forms around and between the bone fragments. The fracture gap widens due to resorption of the bone ends. Finally, bone forms through a series of steps from granulation tissue through to fibrocartilage, unmineralized callus, mineralized callus, and eventually cortical bone. The greater the instability at the fracture site, the greater amount of callus that is produced before healing occurs.

The biological environment will also influence the facture healing. Local pluripotential mesenchymal cells and adequate vascular supply are both required for a successful outcome, therefor balance between accurate anatomical reduction and preservation of blood supply the bone fragments promote biological fixation.

1.3 AO Principles of Lag Screw Fixation

The lag screw was defined by Perren and Buchanan (1981) as the production of interfragmental compression by compressing the bone under the screw head against the fragment in which the screw threads are anchored. The steps for proper lag screw principle for a 5.5-mm cortical screw are as follows:

1. The fracture is reduced and held with reduction forceps.

2. The glide hole is drilled through the near cortex or fragment with a 5.5-mm drill bit protected by the drill sleeve.

3. The 4.0-mm drill sleeve is then inserted into the glide hole until it comes into contact with the far cortex or the bottom of the glide hole(parent bone).

4. The thread hole is then drilled in a coaxial direction in the trans-cortex or parent bone with a 4.0-mm drill bit.

5. The cis-cortex is countersunk with the large countersink.

6. Screw length is then measured with the large depth gauge.

7. The thread hole is then tapped with a 5.5-mm bone tap. By turning two turns clockwise and one-half turn counterclockwise, the cut bone is directed into the channels of the cutting flutes to be removed.

8. A 5.5-mm cortical screw is inserted with the large hexagonal screwdriver ensuring engagement of the transcortex.

1.4 General Consideration of Equine Fracture Repair with Internal Fixation

Internal fixation of long bone fractures by use of tension band principle has been the primary method of fixation of equine fractures for the last few decades. Oblique or transverse fracture of long bones can be stabilized by means of interfragmentary compression. Axial compression may be achieved with tension devices or by the insertion of load screws in a self-compression plate. Axial compression increases with loading, this type of fixation been referred as dynamic compression. Because a compressive force is applied on the opposite side of the compressive load, it functions as a tension band. A dynamic compressive plate applied to the tension side of the bone is called tension band plate. Under dynamic load it converts the tensile forces into axial compressive forces. The tension band acts as additional compression placed on the bone to offset eccentric loading and thus help reduce or eliminate the tensile bending stress. Therefore, bone plates are best placed on the surface of the bone with the most tensile strain. Placed on the compressive side, the resulting forces for the plate would tend to further distract the bone fragments on the side normally experiencing tensile loads (Rybicki,1977). This would also increase the risk of the plate bending. Certain equine long bones such as radius, tibia, femur and humerus are eccentrically loaded. The strain on these cortices is not in equilibrium. The metacarpus is a bone which is loaded almost axially throughout the stride. Medial and dorsal quadrants endure a bit more tension than the lateral and palmar side (Turner, 1975). The plate can be placed on the tension side, compressing the fracture gap, provided there is bony contact on the compression side. Without an intact cortex on the compression, the tension band principle cannot work because of lack of buttress (Nunamaker, 2000).

1.4.1 Bone-Screw Interface

The function of the surgical bone screw is to compress a plate to the bone or to lag bone fragments together. When the screw head engages the screw hole of the plate, continued tightening of the screw pulls the plate and the underlying bone together (Hughes, 1972),

(Figure 1.2).

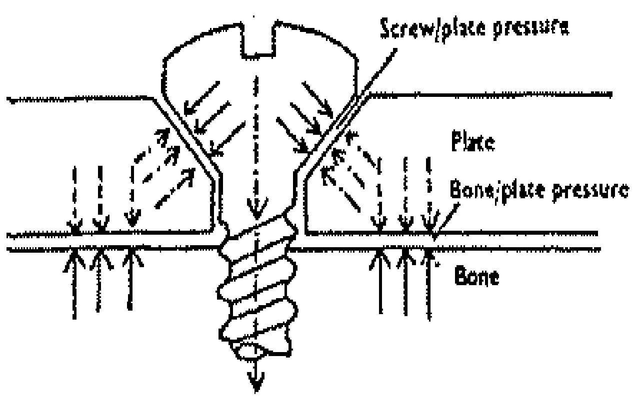


Figure 1.2 Schematic representation of compressive stresses between screw and plate countersink and between bone and plate, by the tensile stress induced in the screw. (Figure taken from Hughes et al. 1972)

A linear relationship exists between the applied screw torque and the amount of axial force generated within the screw (Nunamaker, 1976). The fatique life of a screw used with a bone plate can be enhanced by applying maximum torque to it; this increases the transverse load applied to the screw as a bending moment, since a greater part will be taken by the plate-cortical bone density. The friction produced by compressing the plate against the bone is used to resist shear. The greater the compression induced friction the greater the shear forces can be neutralized. Since a 316L stainless steel cortical bone screw and equine cortical bone have a different modulus of elasticity, the stresses and strains are concentrated at the bone-screw interface (Ling, 1986).

Histological studies have shown that immediately after its insertion, a limited area of contact between screw threads and bone exists (Uhthoff, 1973). For a cortical screw with buttress threads, the thread surface closest to screw head is perpendicular to the screw long axis. Only at the level of this horizontal thread surface of the screw do the threads firmly oppose the bone. In tightening the screw, the horizontal surface compresses the bone while the oblique under-surface of the thread, which is oriented towards the tip of the screw, is lifted away from the bone (Uhthoff, 1973), (Figure 1.3).

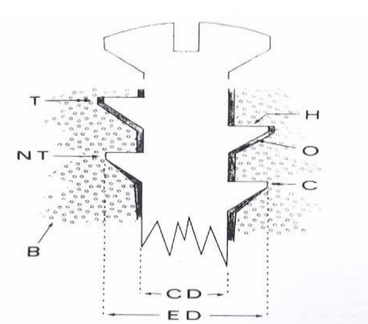


Figure1.3 Diagram showing contact between screw and bone (B)-is limited at a part of the horizontal thread surface (H). The oblique (O) undersurface is separated by a space show as dark strip. When a tap (T) has been used to cut threads into cortical bone, the thread crest of the screw does not touch the bone. CD = core diameter; ED = thread diameter (Figure taken from Uhthoff, 1973).

For AO cortical screw insertion, the thread hole (3.2 mm for the 4.5 mm and 4.0 for the 5.5 mm cortical screws) is larger than the inner core diameter of the screws (3.0 mm for the 4.5 mm and 3.9 mm for the 5.5 mm cortical screws), which results in decreased bone thread depth and less contact. The tap diameter is larger than the outer thread diameter of the screw and further decreases the contact between the screw thread and bone, with the crest of the screw threads losing contact with the bone. These spaces between the screw threads and bone can be up to 0.150 mm thick (Figure 1.3). The limited contact and the presence of spaces between screw and bone predispose to screw micromovement and bone resorption (Uhthoff, 1973).The microscopic space is invaded by migrating cells and the presence or absence of movement influences the differentiation of these cells growth. In cases of stable internal fixation these cells differentiate into osteogenic cells and produce a solid callus in 4 weeks. Osteoblast, osteoid and mineralized matrix are observed adjacent to the lamina limitans-like layer, suggesting bone is deposited directly on the surface of the implant, extending outward from the biomaterial; thus bone formation in the periprosthetic region occurs in two direction (Puelo, 1999). The bone extending away from the implant forms at a rate about 30% faster than that moving toward the biomaterial (Puelo, 1999). Biological tissue interact with the outermost atomic layers of the implant. “The primary interaction zone” is about 0.1-1 nm and much effort is being devoted to methods of modifying the surface of existing biomaterials to achieve desired biological responses.

1.4.2 Biomechanical Studies on Roughened Implants

The internal fixation maintains and protects the reduction of the fracture. This is a mechanical function of force transmission; therefore the plate must be firmly fixed by the screw onto the bone. The stability of repaired fracture with plates and screws depends on the bending stiffness of the screw and the friction between plate and bone (Cordey, 2000). The bending stiffness of the screw does not allow forces larger than 1200N to be sustained (Martin, 1980). A previous in vitro study, (Cordey, 2000) demonstrated that the difference between stainless steel and titanium plates is not due to material itself (stainless steel or titanium) but to the roughness of the undersurface. Motion is prevented by friction and depends on the axial forces of the screw that presses the plate against the bone. Slippage occurs at a lower eccentric load for a plate with a smooth contact surface compared to a plate with a rough contact surface. In that study they found that the surface roughness contributes highly to stabilization and prevention of motion between the plate and the bone (Cordey, 2000). In a more recent study, by creating a rough contact surface, the contact area was increased and appears to have changed the friction between the plate and bone (Sod, 2011). For the fixation of osteotomized equine third metacarpal bones, the constructs with plates having rough contact surface were superior to the corresponding constructs with plates having standard smooth contact surfaces in resisting cyclic fatigue under palmarodorsal four-point bending (Sod, 2011). Hutzschenreuer (1980) studied the extraction torque of cortical screws with roughened surface prepared by titanium plasma sprayed. These screws had only the tip ward half roughened. The authors reported removal torque after 16 weeks of 50% of the insertion torque for the polished screws and 50% increase of the insertion to removal torque for the rough screw (Hutzschenreuer, 1980).

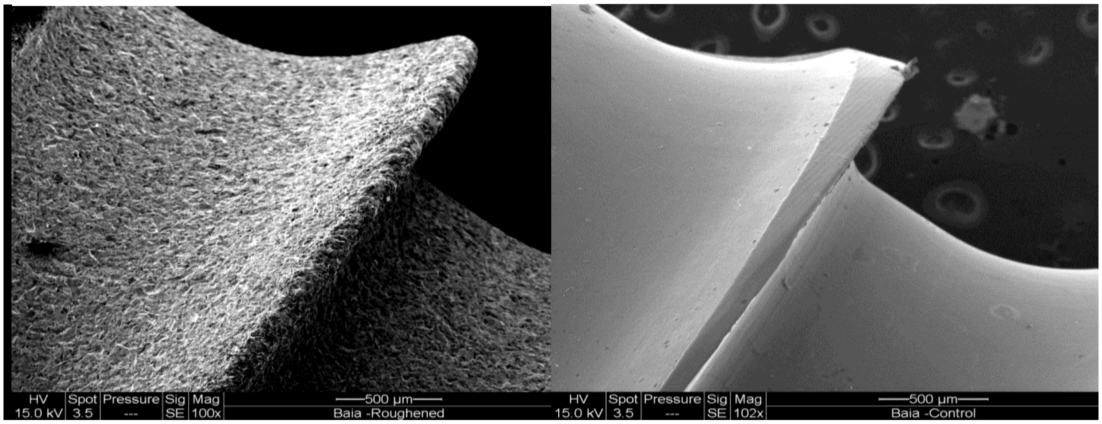
1.4.3 The 5.5 mm AO Cortical Bone Screw

The 5.5 mm cortical screw (Synthes Vet, Paoli, PA) is made of 316 L stainless steel and is fully threaded. It is not self-tapping so a tap is required to cut its threads into the bone before insertion (Nunamaker, 2000). The drill bit for the thread hole measures 4.0 mm in diameter. The thread diameter of the screw is 5.5 mm and the core has a diameter of 3.9 mm. They come in lengths from 24 to 100 mm (Synthes Vet Catalog, 2008). Electropolishing of stainless steel is considered standard, which gives it a smooth surface with a roughness average of 0.13µm. This surface is void of microdiscontinuities and as a result supports fibro-osseous integration upon implantation (Hayes, 2010).

1.4.4 The Aluminum Oxide (Al_2O_3) Roughened Screw

Aluminum oxide (alumina) is classified as an inert bioceramic with low conductivity of electricity and heat and high melting temperature (Billotte, 2006). Alumina is a quite hard material with a 9/10 hardness index on Moh's scale, second after diamond (Billotte, 2006). Because of its high hardness (between 20 and 30 MPa), alumina has been used as an abrasive and as bearings. The alumina's high hardness is accompanied by low friction and wear and inertness to the *in vivo* environment (Billotte, 2006). Alumina has been used in the area of orthopedics and dental surgery for more than 30 years (Billotte, 2006).

For the purpose of our study the screw surface roughening with aluminum oxide was made in accordance with the manufacturer's specifications (Orchid Bio-Coat) using a Trinco 20/CPH blaster and 100 mesh size. The 5.5 mm cortical bone screws (Synthes, Paoli, PA) were used for surface treatment. Subsequent to blasting, the surfaces were ultrasonically cleaned. Roughness measurements were performed by the manufacturer using a Mitotoyo Surftest 211 profilometer, and an average of five readings was performed for each surface. The mean surface roughness and standard deviation for the 100mesh Al_2O_3 was 2.14±0.48 µm. The roughness created by the 100mesh finish was typically of those commercially available finishes. Larger grit size would have created an increased roughness, but this would also begin to destroy the geometry of the implant. SEM micrographs were taken at 100X to assess the appearance of the roughness and compare it with the smooth electro polished surface of the untreated screws (Figure 1.4).



R AO

Figure 1.4 SEM picture of Al_2O_3 roughened (R) and electropolished AO cortical screws (AO).

CHAPTER 2

MECHANICAL EVALUATION OF ALUMINUM OXIDE ROUGHENED SCREWS IN EQUINE THIRD METACARPAL BONE

2.1 Introduction

The poor prognosis for survival for adult horses suffering from long bone fractures hasn't improved by much over the last decades (Saunder-Samis, 1986; Auer, 1987; Bischofberger, 2009; McClure, 1996). This in part due to lack of adequate orthopedic implants available for equine osteosynthesis. When the extreme loads concentrated on implants overcome fixation stability, breakdown injuries occur (Auer, 1987; Bischofberger, 2009; McClure, 1996). Repeated loading of the affected limb during walking and weight shifting can lead to cyclic fatigue failure of the implants. Ways to increase the stability of implant are needed (Ling, 1986). Surgical implant complications are often associated with the strength of the fixation construct relative to the mechanical demands placed on it. Catastrophic fracture construct failure may occur when it is exposed to forces that exceed the implant strength, such as during recovery, or when the rate of bone healing is slower than the implant fatigue life. Implant loosening as a result of localized implant or bony failure can result in an unstable fracture and delayed healing. (Markel, 2005).

The resistance of the bone-screw-plate construct to cyclic fatigue relies on the bone-plate friction and anchoring strength of the screw in the surrounding bone. Microfracture and resorption of the surrounding bone followed by screw loosening is most commonly the result of cyclic mechanical loading during limb use (Schatzker, 1975). A recent study reported that a common cause of implant failure in equine metacarpal/metatarsal fractures is still screw loosening, bending or breaking (Bischofberger, 2009). Ways to improve the screw behavior in this sensitive construct of bone-screw-plate can potentially add to the longevity of the implant (Zacharias, 2007; Moroni, 2001; Caja, 1996).

Osseointegration and the importance of micro-and macro- texture of screws have been addressed extensively in human orthopedic research (Thomas, 1985; Boyan, 1999; Brett, 2004; Brunette, 1988). There is currently sufficient evidence (over 95% clinical efficacy) that titanium implants with rough surfaces achieve faster bone integration, a higher percentage of bone implant contact, and a higher resistance to shear documented with higher removal torque values when compared with titanium implants with smooth surface (Nasatzky, 2003; Guehennec, 2007).While titanium implants are biologically inert and more ductile, stainless steel are preferred in equine orthopedics where implants must withstand extreme loads. Stainless steel implants have a higher yield stress and stiffness, are stronger and less expensive than corresponding titanium implants (Hayes, 2010). During implant healing, bone tissue deposits onto the pores of the roughened surface and the mechanical anchorage continues to increase even after healing of the surgical site is complete (Takeuchi, 2004). Methods to assess the anchorage of roughened screws, including insertion vs extraction torque, pull-out and push-in test on cortical bone have been done in sheep, goat and rabbit models (Nasatzzky, 2003), but not in equine model.

Recent studies looking at screw mechanical properties and bone screw interface (BSI) have found significant increase in pullout strength and resistance to cyclic fatigue failure by increasing the bone-screw interface with polymethylmethacrylate and Teflon foil (Sod, 2004; Sod, 2007). A current in vitro study has shown that plasma sprayed hydroxyapatite coated AO stainless steel screws can be placed in equine third metacarpal bone without exceeding physiologic thermal thresholds (Gudehus, 2008). This was followed by in vivo studies with placement of HA-coated screws in dorsal equine MC3 under unloaded and loaded conditions which revealed significant increase in extraction torque at 12 weeks post implantation, when compared with the electropolished cortical bone screw (Gudehus, 2009, Durham, 2011).

The present study focused on testing the strength of bone-roughened screw attachment under loaded conditions. Having an increased contact surface, roughened screws should provide superior biomechanical interlocking strength when compared with smooth cortical bone screws.

The objective of our study was to determine if Al_2O_3 roughened screws (R) would have a greater extraction torque at the end of the study when compared to the smooth cortical bone screw (AO). Our hypothesis is that roughened screws will have significantly greater mean extraction torque at 12 weeks when compared to the AO screws when used to secure a 4.5 mm broad dynamic compression plate (DCP) to equine third metacarpal bone.

2.2 Materials and Methods

Development of the aluminum oxide (Al_2O_3) roughened implant by the use of 5.5 mm AO screws (Synthes, Paoli, PA), which were grit blasted with 100 mesh Al_2O_3 particles to obtain implants with surface roughness of 2.14± 0.48 µm (Orchid Bio-Coat Inc, Southfield, MI).

After the implant threaded surface was grit blasted , the surface was ultrasonically cleaned. SEM analysis was performed on Amray 1645 SEM with an energy dispersive x-ray analysis set-up (EDAX, Orchid Bio-Coat). Roughness measurements were performed using a Mitotoyo Surftest 211 Profilometer, with an average of 5 readings been performed for each surface.

Groups:Twenty 5.5 mm x 24 mm Al_3O_2 roughened screws (R Group) and twenty 5.5 mmx 24 mm AO cortical screws (AO group) were evaluated. For each horse one metacarpus (MC3) was randomly assigned to secure a 4 hole, 4.5 mm narrow dynamic compression plate (DCP), (Synthes, Paoli, PA), with 4 roughened screws and separated plate on the contralateral MC3 using conventional AO cortical screws.The limb selection was determined by a computer generated list. Unicortical screw placement was used to limit variables arising from differences in cortical thickness and insertion technique.

- **Surgical Procedures**

Five adult Thoroughbred horses between 2 – 7 years of age, free of orthopedic disease, were used in the study. Food only was withheld 12 hours prior to surgery. An intravenous jugular catheter was placed using aseptic technique. Perioperative medications consisting of potassium-penicillin (22,000 IU/kg IV), gentamicin (6.6 mg/kg IV), and flunixin-meglumine (1.1 mg/kg IV) were administered 30 minutes prior to induction of general anesthesia. Xylazine (0.5 mg/kg IV) was administered for preanesthetic sedation. Anesthesia was induced with diazepam (0.5 mg/kg IV) and ketamine hydrochloride (2.2 mg/kg IV), and maintained on total intravenous drip anesthesia (1L guiafenesin, 500mg xylazine, and 1g ketamine) at 1.5-2 ml/kg/hr adjusted as needed based on anesthetic monitoring. Horses were placed in dorsal recumbency and the surgical sites were routinely clipped, aseptically prepared and draped. The mid-diaphyseal area was determined (midpoint between the carpometacarpal and metacarpophalangeal joints) and a incision was made in the dorsal mid diaphysis. A 4-hole x 71 mm broad DCP (Synthes, Paoli, PA) was positioned on the bone. Thread holes were drilled perpendicular to and through the dorsal cortex of the MC3 bone using a 4.0 mm drill bit (Synthes, Paoli, PA) using a drill guide in the neutral position on the plate. The depth of each hole was measured using a depth gauge and the thickness of the cis cortex recorded. Each hole was tapped using a 5.5 mm tap. A new 4.0 mm drill bit and 5.5 mm tap was used for each limb. Screws were inserted by hand using a screw driver with the final revolution performed with a digital torque wrench (DTW 265i, Checkline, Cedarhurst, NY) fitted with the shaft of an AO/ASIF screwdriver that was welded to a 3/8 inch square drive socket adapter. The digital torque wrench has an accuracy of ± 2.5% clockwise rotation and ± 3.5% counterclockwise rotation with a resolution of 0.01 Nm. Drilling, tapping and screw placement were performed under constant irrigation using 0.9% NaCl solution. Screws were numbered from 1 to 4, from proximal to distal and were all tightened through the plate in the bone to a final torque of 5.4 N-m. Incisions were closed in two layers and the limbs were bandaged prior to moving the horse into recovery.

- **Postoperative Regimen**

In the initial postoperative period (14 days), the horses were stall confined and bandages were changed every other day for seven days at which time the skin staples were removed. Unrestricted weight bearing was allowed immediately after surgery. Phenylbutazone (4.4mg/kg/day) was given for pain relief for three days following surgery. Horses were evaluated daily for lameness, general health and level of comfort. If any signs of lameness or localized infection at the surgery sites were noted, cranio-caudal and latero-medial radiographic views of the metacarpus were immediately obtained and the surgery site evaluated for any radiolucency (radiographic signs of infection) around the screws (Figure 2.1).

Figure 2.1. Lateral and dorsopalmar radiographic views of metacarpi of a horse taken at 3 months post-implantation of a 4.5 mm dynamic compression plate with 5.5 mm screws.

- **Implant Removal**

All implants were removed at 3 months post implantation under general anesthesia, in a similar manner as used for implant placement. The dorsal mid MC3s were clipped of hair, surgically prepped, and draped. Stab incisions were made directly over the screw heads. The screws were loosened one full rotation (360^o) using a calibrated digital torque wrench and the removal torque measured. The same operator performed all of the torque removal tests. The proximal stab incision was extended to facilitate plate removal and the plates were removed using a combination of periosteal elevator and osteotome as needed. Incisions were closed in one layer using skin staples. Bandages were applied prior to moving the horse into recovery and changed every other day for seven days at which time the skin staples were removed.

Calculations of values:

In order to rule out potential bone contact variability between samples, the insertion/extraction torque per screw was converted to torque per thread by calculating the scale (cortex thickness/pitch) for all 20 samples. The torque per thread was then calculated by dividing the torque applied to insert (5.4Nm) the screw by the torque recorded at extraction for every sample. . This mathematical calculation eliminates potential bone-implant contact variability.

- **Statistical analysis**

Mean $\pm$ standard deviation (SD) was calculated for the insertion and extraction torques for each screw type and each testing group. Paired samples were evaluated using t-tests for paired sample means within each testing group. Statistical significance was set at $p < 0.05$.

2.3 Results

There were no postoperative complications. All horses recovered well from surgery and resumed normal ambulation. There was mild to moderate swelling at the surgery sites after implant removal due to scar tissue formation. Radiographs did not show rarefaction/reaction around any of the screws (Figure 4.2.1). Periosteal new bone growth and cortical thickening was observed around all screws.

At 12 weeks, the mean extraction torque for the Al_2O_3 finish roughened screws was significantly ($p < 0.00005$) greater than that of AO screws. The roughened screws had a mean extraction torque of 3.24± 0.56, twice the mean extraction torque of the AO screws (1.65 ± 0.34) (Figure 2.2).

AO = standard screws group   Rough = Al_2O_3 roughened screws group

Figure 2.2 A bar chart shows screw insertion and extraction torque of two different types of 5.5 mm cortical screws placed in the metacarpi of 5 horses

There was no significant ($p = 1.00$) difference between the mean cortical bone thickness for the R group and AO group. The mean insertion torque was significantly ($p < 2.71 \times 10^{-16}$) greater than the mean extraction torque for the AO group. There was significant difference ($p<6.0 \times 10^{-7}$) between the insertion and extraction torque of the R groups as well. There was no significant difference ($p=0.07$) between the insertion torque of the AO group and the R group there was also no significant ($p = 0.78$) difference when we compared mean insertion torques for the R vs AO groups (Table 1).

Table 1 Mean $\pm$ SD of dorsal equine MC3cortex thickness, screw insertion and extraction torques per thread for 5.5 mm Al_2O_3 roughened and standard AO screws. AO = standard screws group, R = Al_2O_3 roughened screws group.

Group	Cortical Bone Thickness (mm)	Insertion Torque (N-m)	Extraction Torque (N-m)
AO	20.1 ± 1.1[1]	5.39 ± 0.23[2,4]	1.65 ± 0.75[2,5]
R	20.1 ± 0.9[1]	5.36 ± 0.35[3,4]	3.26 ± 1.32[3,5]

[1] There is no significant ($p = 1.00$) difference between the mean cortical bone thickness for the R and AO groups.

[2] The mean insertion torque is significantly ($p < 2.71 \times 10^{-16}$) greater than the mean extraction torque for the AO group.

[3] There is significant difference ($p<6.0 \times 10^{-7}$) between the insertion and extraction torque of the R group.

[4] There is no significant ($p = 0.78$) difference between mean insertion torques for the R and AO groups.

[5] The mean extraction torque for the R group was significantly ($p< 0.00005$) greater than AO group.

Implant infection was suspected on the control limb on horse # 4. Moderate increase of clear serous fluid encapsulated over the implant was noted at the time of screws and plate removal. Aerobic culture of the loose screw hole was performed at the time of implant removal and results came back negative for bacterial growth.

At the end of the study period, all incisions had healed without complications; however, all horses had a noticeable change in contour of the dorsal cannon bone consistent with periosteal reaction and soft tissue scar formation at the surgery site. These areas were not painful to palpation and no lameness was noted.

2.4 Discussion/Conclusions

Extraction torque is a mechanical testing that evaluates the strength of bone-implant attachment. In this study we found that screws with roughened surface had greater extraction torque when compared to smooth AO screws at 12 weeks post implantation. Our results are similar with recent in vivo studies where hydroxyapatite (HA) coated screws had significantly higher extraction torque at 3 months under unloaded and loaded conditions when compared to the conventional smooth screws (Gudehus et al, 2009; Durham et al, 2011). The increased extraction torque of HA-coated screws in these previous studies may have been influenced by change in surface topography (roughness), surface chemistry (HA coating), (Moroni ,1999) or both (Moroni 2003). The HA plasma sprayed coating is an additive process and it increased the screw diameter by approximately 50 μm and roughness(Gudehus, 2009). Our screws were grit blasted with 100 mesh aluminum oxide, a subtractive process which creates pits/pores into the screw surface, and not by adding material to the implant surface. It is possible that with the HA coated screws in the previous studies created a wedge effect that may have contributed to the overall increased stability and mechanical anchorage when compared to our roughened screws. It's been reported that the superior osseointegration is due to both surface texture and surface biochemical treatment (Moroni, 2002; Moroni, 2003). In our study, we attribute the superior extraction torque to surface texture since that was the only difference between the control and the studied implants. The roughened screw has an average roughness of 2.14 μm, (vs. AO screw roughness mean of 0.13 μm) which has been reported appropriate for improved bone-to-metal fixation (Wennerberg et al, 1996; Wennerberg, 2009).

The biodynamics of the implants is also influencing factor to the stability of the bone-screw interface (Billotte, 2006). The electropolished stainless steel is clasified as a biotolerant material and promotes fibrous tissue formation around it. Aluminum oxide is an inert bioceramic and promotes contact osteogenesis characterised by direct contact between implant and surounding bone. This biodynamical difference may have been contributed to the increased extraction torque recorded for the aluminum oxide screws.

Histomorphometric studies have demonstrated that implants with roughened surface support direct osseo-integration, which is highly desirable for maximal stability (Hayes et al, 2010) By contrast the 316 L stainless steel screw, the most commonly used screw in equine orthopedics, has electropolished surface, void of micro discontinuities and supports fibro-osseous integration upon implantation(Hayes et al, 2010). Histological studies in other species confirmed fibrous tissue encapsulation around standard smooth screws with both stainless steel and titanium implants. (Schatzker,1975; Caja, 1996; Moroni, 2003; Guehennec, 2007; Pierce, 2008). Histomorphometry gives a measure of the degree of bone implant contact, whereas mechanical testing gives an evaluation of the strength of bone–implant attachment. Our mechanical testing revealed stronger bone-roughened screw attachment demonstrated by the extraction torque at 12 weeks suggesting increased osseointegration; Histomorphometric evaluations of the bone screw interface needs further analysis in order to determine the degree of bone-implant contact.

Resistance of the bone-screw-plate construct to cyclic fatigue relies on bone-plate friction and the anchoring strength of the screw in the surrounding bone. A linear relationship exists between the applied screw torque and the amount of axial force generated within the screw (Nuanmaker, 1976). The magnitude of force which compresses a plate to bone depends on the tensile stress induced in the screw. This tensile strength is derived from the torque applied to the screw head (Hughes, 1972). Ideally the smallest increments of torque should induce some tension but in practice this is never reached since some of the applied torque is lost to overcome friction between screw threads and bone, and between the screw and the countersink surface of the plate (Hughes, 1972). It would be interesting in determining the torque available for conversion into tension (useful torque) from the 5.4 Nm applied torque in our study. Because of their roughened threaded surface, the screws have to overcome higher friction forces than the smooth screws. Therefore, the useful torque would probably be lower when compared to the smooth AO screws. This would translate into less compression of the plate onto the bone and increased loading and fatigue cycling when compared to the standard AO screws. The increased extraction torques for the roughened screw in our study suggests that the roughened surface of the screws provides superior interlocking into the surrounding bone even at lower useful torque.

Previous in vivo study looking at cortical screws with roughened thread surface vs polished surface reported removal torque after 16 weeks 50% of the insertion torque for the polished screws and 50% increase of the insertion to removal torque for the roughened screw(Hutzschenreuer, 1980). This was an in vivo gap osteotomy model repaired with a single plate and screws in sheep. A gap osteotomy model would not be possible in equine. Succesful fracture repair in horses necessitates anatomic reconstruction and interfragmentary compression with screws and plates.This allows the sharing of loads between the reconstructed bone and the implants. Interfragmentary compression is absolutely essential for maintaining bone contact between fragments to protect the relatively weak implants. Orthopedic implants by themselves are not able to withstand the full force of weight-bearing without failure in equine. Although not a fracture model, the significant difference in insertion-extraction torque for both smooth and rough screws demonstrate cyclic loading conditions in our study. A decrease of 25 % in extraction torque was also noted when HA screws with plate were implanted in equine cannon bone vs screws alone (Gudehus, 2009;Durham, 2011). These studies show that even without a fracture model, the plate will create loading effect on the screws.

Unstable internal fixation has been shown to lead to the development of thick fibrous tissue layer and limited bone to screw contact at the interface between the loose metallic screw and bone (Uhthoff, 1973). Shatzker (1975) stated that if the compression between the screw threads and bone decays rapidly, rigidity is lost and movement, non-union, and failure of the fixation may be the outcome. The higher surface roughness of the roughened screws as opposite to the polished surface of the conventional screws may have been beneficial to optimize initial screw stability and consequently osseointegration. Increasing fracture stiffness before the natural increase in stiffness provided by bone callus formation could have positive clinical consequences

It has been shown that aluminum oxide blasting applied to machined implants promote mesenchimal stem cell commitment to the osteoblast phenotype. Greater bone-specific gene expression was observed in tissue adjacent to Al_2O_3 implants, and associated increases in bone-implant contact and torque removal were noted, leading to the conclusion that aluminum may directly influence cell behavior to enhance osseointegration (Mendonca, 2009). Aluminum oxide roughening process is also more affordable when compared to other surface treatment techniques.

The limitations of this study include the evaluation of results at only one period of time, the fact that a nonfracture model was used and the absence of histological analysis. Future studies should address quantitative and qualitative histomorphometric evaluation of these implant in bone. This will give a better understanding of the degree of osseointegration of roughened implants in equine cortical bone.

CHAPTER 3
FINAL DISCUSSION AND CONCLUSIONS

3.1 Summary

A primary function of any roughened implant is to increase their initial mechanical fixation to the surrounding bone and maintained stability for later remodeling and oseointegration. In equine patient, the initial BSI interlocking is desired for a stable repair to be immediately weight bearing. Although not a fracture model, in our study we were able to evaluated the mechanical strength of bone-screw attachment and found that roughened screws have a significantly greater extraction torque when compared to the smooth surface AO cortical screws. The higher surface roughness of the roughened screws as opposite to the polished surface of the conventional screws may have been beneficial to optimize initial screw stability and consequently osseointegration. Increasing fracture stiffness before the natural increase in stiffness provided by bone callus formation could have positive clinical consequences in equine fracture repair. Information obtained from this study may help in improving the contact surface of implants and subsequent fixation and stability of bone- implant constructs in equine fracture repair.

Further work is needed to completly analyse the effect of surface roughening on electropolished implants. Histology and histomorphometry will will determine the type of tissue that comes in contact with the screw and the measure the degree of bone-implant contact. It would also be interesting in comparing the axial compression generated by the 5.4 Nm torque applied in our study. Because of the roughened threaded surface, the aluminum oxide screws have to overcome higher friction forces between the screw thread and bone during insertion and may generate less compression than the smooth AO cortical screws at the same insertion torque.

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VITA

Petrisor Baia was born in 1979, in Drobeta Turnu Severin, Mehedinti, Romania. He grew up in Severin, where he completed his high scool education at 'Colegiul Traian"in 1998. Pursuing his dream of being around horses he entered the University of Agricultural Sciences and Veterinary Medicine in Timisoara, Romania, and following a 6 year program graduated with a Doctor in Medicina Veterinara degree in 2004.

Upon graduation, Dr. Baia traveled to the United States and accepted an internship program in a small animal practice in Southern California before entering a one year internship in equine at Chino Valley Equine Hospital in Chino, California. In 2007 Dr. Baia entered a second private practice equine internship at Brazos Valley Equine Hospital in Stephenville, Texas. In 2008 before commencing his current position, Dr Baia completed a one year rotating internship in large animal medicine and surgery at Louisisna State University, School of Veterinary Medicine in Baton Rouge, Louisiana. Dr. Baia is currently completing his second year of a three-year large animal surgery residency at Louisiana State University School of Veterinary Medicine in Baton Rouge, Loisiana, and will be awarded the degree of Master of Science in Veterinary Medical Sciences in December 2011.