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Pedicle Screw Extraction from a Horse Model

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Introduction

Plasma Sprayed Hydroxyapatite (HA) pedicle screws are common on the market and can achieve a higher level of fixation than standard titanium screws[1]. These HA coated screws are an essential tool in the orthopedist's tool kit but have problems in that they can be very difficult, if not impossible, to remove[2,3]. Nanotubes on titanium implants provide a solution that allows for increased and accelerated fixation while addressing the issues associated with HA coatings. In approaching new technology, the concerns expressed by many surgeons is this: Can I remove the nanotube treated screws without complications such as breaking the screw or losing a large amount of host bone? In this study, Nanovis tested nanosurfaced screws in dense cortical and cortical-cancellous bone to answer two questions. 1) Can pedicle screws and cervical plate screws with nanoVIS Ti™ Surface Technology be safely extracted from bone? 2) Does extraction of the screws with nanoVIS Ti™ Surface Technology damage or delaminate the nanosurface?

Horses were used in this model to accommodate the largest screw surface area with nanoVIS Ti™ Surface Technology. Second, horses have denser, stronger, and more mineralized bones than humans[4]. This serves as a worst-case model for over-fixation which tested mechanical failure of the screw and the stability of the nanosurface during extraction. 13 weeks was selected as the testing duration as this is a common follow-up timeframe for orthopedic implants. This timeframe also allowed for at least two remodeling cycles while the horses were fully ambulatory, ensuring that the screws were well-integrated into the bone[5].

Methods

Adult horses were used in this study to accommodate the large pedicle screws. Two sizes of pedicle screws, 9.5 x 100 mm (typically used at the base of large posterior fixation constructs) and a commonly used size of 6.5 x 60 mm, were implanted into the cortico-cancellous bone of the ilium in the horse pelvis, Figure 1A. Holes were drilled and tapped following instructions for use. Screws were positioned such that the neck of the screw was level with the bone. An additional set of 4.0 x 20 mm cervical plate screws were posteriorly implanted into the cortical bone of the mandible of the jaw. These screws were self-tapping, and no additional preparation was performed on the bone. Horses were pastured and monitored for 13 weeks (about 3 months) before sacrifice.

Portions of the ilium or mandible containing the screws were recovered and subjected to radiographs and micro-CT imaging. The bone was then placed in a vice, ensuring not to compress the segment containing the screw during torque testing. Torque testing was performed with hand-held, Snap-On™ torque wrenches to measure the peak force in N*m generated by backing the screw out 90 degrees. Screws were then fully extracted for imaging to look for presence of the nanoVIS Ti™ surface, any associated damage, and the bone material remaining on the surface.

Results

All screws successfully achieved fixation over 13 weeks and were removed successfully without failure of the screw, the driver, or the host bone. The greater the surface area the screws had, the greater the fixation potential. The 9.5 x 100 mm screws peeked out at 11 N*m, Figure 1B. When the surface area of the screws was considered, the pedicle screws had equivalent fixation (i.e., torque per surface area), regardless of screw size, Figure 1C. The plate screws showed significantly higher fixation in the mandible based on surface area, Figure 1C.

The nanotube surface of the screws was examined after extraction to demonstrate that the nanosurface survived implantation and extraction from the host bone. Small flakes of bone were observed under SEM on the surface of the screw, Figure 1D. The nanotube structures also remained intact on the surface of the screws. Collagenous fibers and bone matrix were visible on the surface of the nanotubes, Figure 1E. No areas of bulk delamination of the surface were observed. Only on the very edges of the cutting flutes of the screws, where titanium wear is expected, were nanotubes removed to any noticeable degree.

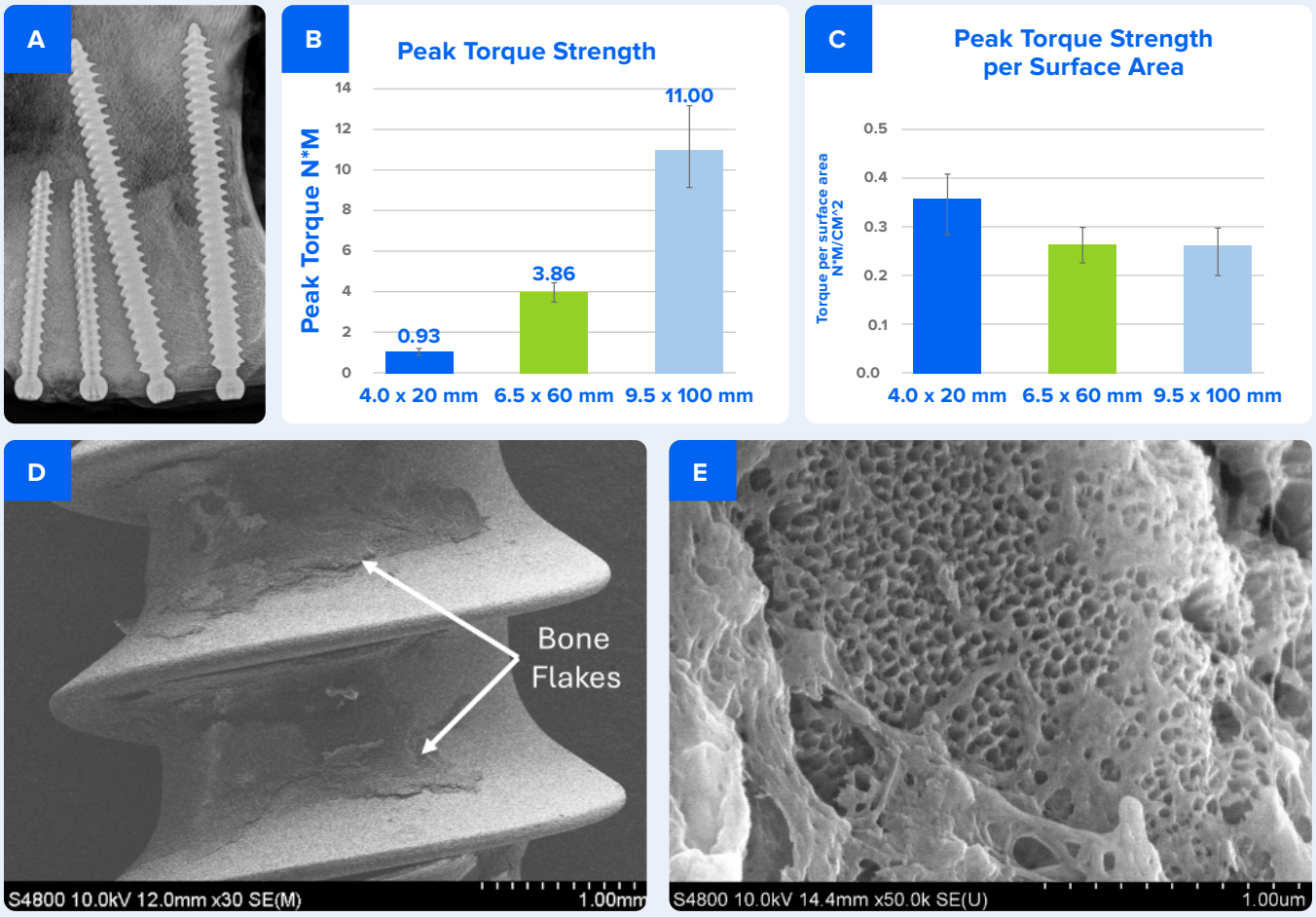

Figure 1: Peak torque extraction of pedicle screws and cervical plate screws from horse bone at 13 weeks post-implantation. (A) X-ray of pedicle screws in ilium, (B) Peak torque measurements, (C) Peak torque measurements relative to surface area, (D) Bone flakes on pedicle screw surface at 30x magnification after extraction, (E) Nanotubes present with collagen fibers and bone matrix at 50,000x magnification after extraction.

Discussion

The pedicle screws were implanted into the ilium with a cortical shell and cancellous bone. Most of the surface area of the screw was exposed to cancellous bone. The fixation torque based on surface area was statistically indistinguishable between the two sizes of pedicle screws. The plate screws were implanted entirely in cortical bone. This allowed more contact with dense bone and thus accounting for the higher fixation per unit surface area.

Pedicle screws need to achieve initial fixation with a mechanical mechanism. Micromotion, resorption of bone, poor bone quality and trauma can all change the stability of the construct over time[6]. Technology, such as the nanoVIS Ti™ surface, that can encourage the biological fixation of implants, gives patients greater odds of stable long-term fixation. HA coatings have been the go-to solution for enhanced fixation, but this technology has its draw backs, such as coating delamination and over fixation[1-3]. Excessive fixation can cause screw failures during extraction in normal patients. Conditions such as osteoporosis require strong fixation, but in cases where a construct revision with an HA coated screws is required, it can be devastating for the patient where an entire pedicle may be at risk.

Conclusion

This study demonstrated that screws with nanoVIS Ti™ Surface Technology provided a solution which drove biological fixation of the screws. The nanoVIS Ti™ surface also provided the ability to remove hardware and/or revise constructs without the concerns associated with HA coated screws. Also, the nanoVIS Ti surface is permanent and stable on the surface of the implants even under the forces of insertion and extraction.

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