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Pedicle Screw Extraction from a Horse Model

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Background

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 orthopedic tool kit but can be very difficult, if not impossible, to remove during revision procedures or after healing[2,3]. Nanotubes on titanium implants provide a solution that allows accelerated fixation while addressing the issues associated with HA coatings. When evaluating new technology, a common concern among surgeons is: Can nanotube-treated screws be removed without complications, such as breaking the screw or losing a large amount of host bone? In this study, Nanovis tested nanostructured screws in dense cortical and cortical-cancellous bones 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?

A horse model was used to accommodate the largest screw surface area with nanoVIS Ti™ Surface Technology. Moreover, horses have denser, stronger, and more mineralized bones than humans[4]. This serves as a worst-case model for over-fixation, allowing evaluation of the mechanical failure of the screw and the stability of the nanosurface during extraction. The testing duration was 13 weeks 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 6.5 x 60 mm (a commonly used size) , were implanted into the cortical-cancellous bone of the ilium in the horse pelvis, as shown in 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 in the horse 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 and 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 torque 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 of the screw, the greater the fixation potential. The 9.5 x 100 mm screws reached an average peak torque of 11 N·m, as shown in Figure 1B. When the surface area of the screws was considered, the pedicle screws showed equivalent fixation (i.e., torque per unit surface area) regardless of screw size, whereas the cervical plate screws showed significantly higher fixation in the mandible, as shown in 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 on the surface of the screw, as shown in Figure 1D. The nanotube structures also remained intact on the screw surface with visible collagenous fibers and bone matrix on the nanotubes, as shown in Figure 1E. No bulk delamination of the nanotube surface was observed. Noticeable removal of the nanotubes occurred only along the very edges of the cutting flutes of the screws, where titanium wear is expected.

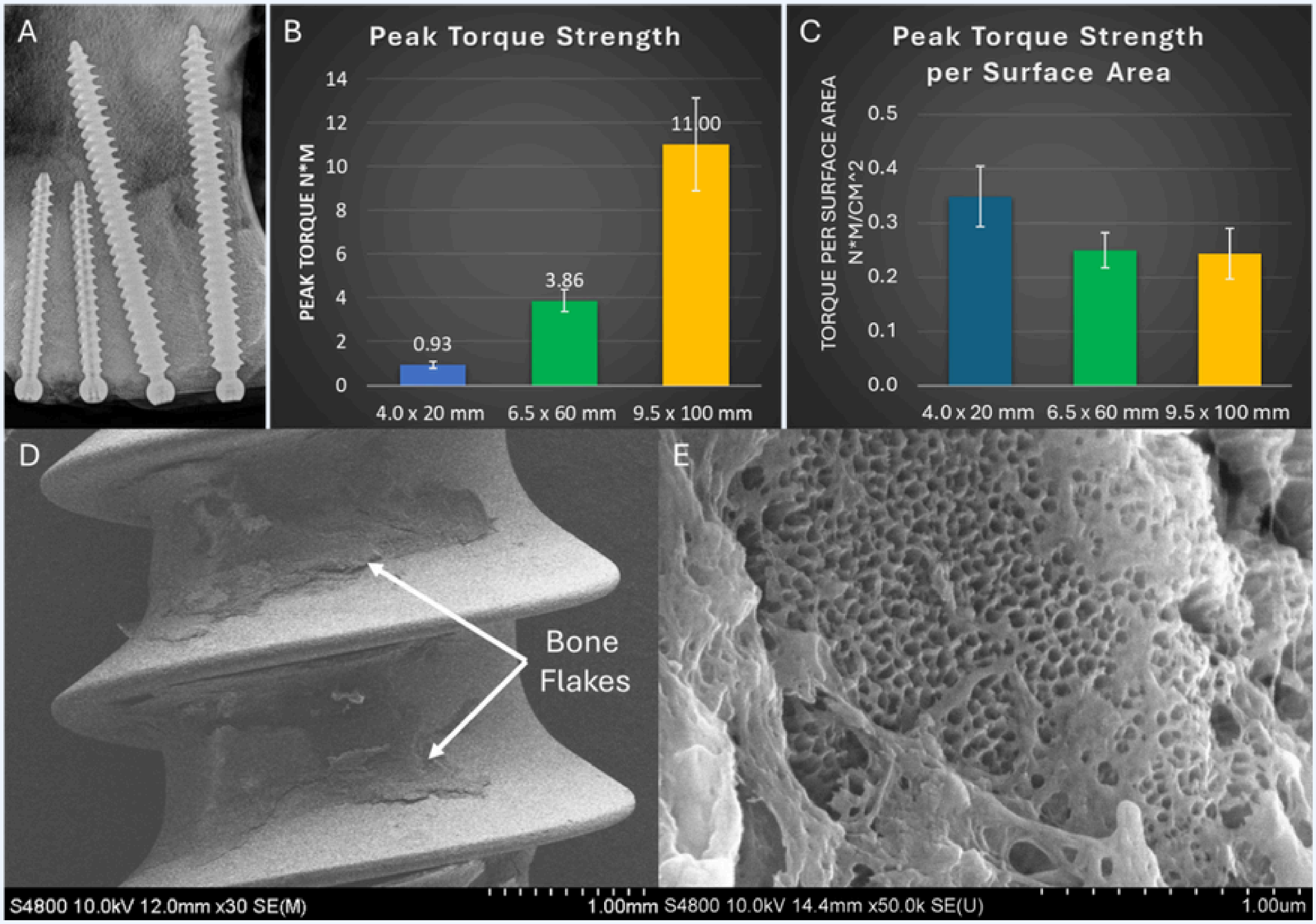

Figure 1: Peak torque extraction of pedicle screws and cervical plate screws from horse bone at 13 weeks post-implantation. (A) X-ray of pedicle screws in ilium (B) Peak torque measurements, (C) Peak torque measurements relative to surface area, (D) Bone flakes on pedicle screw surface at 30x magnification 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 through the cortical shell and into the cancellous bone. Most of the surface area of the screw was exposed to the cancellous bone. The fixation torque per unit surface area was statistically indistinguishable between the two sizes of pedicle screws. The plate screws were implanted entirely in the mandibular cortical bone, allowing greater contact with the dense bone and resulting in higher fixation per unit surface area.

Pedicle screws are required to achieve initial fixation with a mechanical mechanism. Factors such as micromotion, bone resorption, poor bone quality, and trauma can all change the stability of the construct over time[6]. The 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 standard solution for enhancing implant fixation, but this technology has several drawbacks, such as coating delamination and over fixation[1-3]. Excessive fixation can cause screw failures during extraction in patients with normal bone density. Conditions such as osteoporosis require strong fixation, but in cases where a construct revision with HA-coated screws is required, it can be devastating for the patient and put an entire pedicle at risk.

Conclusion

This study demonstrated that both pedicle and plate screws with nanoVIS Ti™ Surface Technology provided a solution that drove biological fixation of the screws. The nanoVIS Ti™ surface also provided the ability to remove hardware and/or revise constructs without delamination of the nanosurface. Also, the nanoVIS Ti™ surface remained permanent and stable on the implants, even under the forces of insertion and extraction.

References

1. Sandén, B., Olerud, C. & Larsson, S. Hydroxyapatite coating enhances fixation of loaded pedicle screws: a mechanical in vivo study in sheep. Eur Spine J **10**, 334-339, doi:10.1007/s005860100291 (2001).

2. Albrektsson, T. Hydroxyapatite-coated implants: a case against their use. J Oral Maxillofac Surg **56**, 1312-1326, doi:10.1016/s0278-2391(98)90616-4 (1998).

3. Ohe, M. et al. Pedicle screws with a thin hydroxyapatite coating for improving fixation at the bone-implant interface in the osteoporotic spine: experimental study in a porcine model. J Neurosurg Spine **28**, 679-687, doi:10.3171/2017.10.SPINE17702 (2018).

4. Gilbert, B. M. Mammalian Osteology. (Missouri Archaeological Society, 1990).

5. Marsell, R. & Einhorn, T. A. The biology of fracture healing. Injury **42**, 551-555, doi:10.1016/j.injury.2011.03.031 (2011).

6. Marie-Hardy, L., Pascal-Moussellard, H., Barnaba, A., Bonaccorsi, R. & Scemama, C. Screw Loosening in Posterior Spine Fusion: Prevalence and Risk Factors. Global Spine J **10**, 598-602, doi:10.1177/2192568219864341 (2020).