NANOVIS®

Improved Pedicle Screw Fixation in a Sheep Micromotion Model

Authors:

David Detwiler, PhD
Sabrina Huang, PhD
Chang Yao, PhD
Alan Kraft, BSNE
James McCarthy, BSE
Kreigh Williams, BS

Volume 4 V2

NANOVIS®

Improved Pedicle Screw Fixation in a Sheep Micromotion Model

Authors: David Detwiler, PhD; Sabrina Huang, PhD; Chang Yao, PhD
Alan Kraft, BSNE; James McCarthy, BSE, Kreigh Williams, BS

Introduction

Pedicle screw constructs are placed in the spine to limit mobility and provide decompression and spine stabilization when interbody fusion is the objective. Consequently, pedicle screws are subject to forces and cyclic loading of those forces for the lifetime of the patient. In general, the fixation strength of pedicle screws in bone are strongest immediately after implantation and may decrease over time due to various factors, including micromotion, poor bone quality, and underlying health conditions. The challenge is the limited amount of time before the pedicle screws lose fixation and fail to support the construct.

There are two fixation types with pedicle screws – mechanical fixation and biological fixation. Mechanical fixation is achieved when the screws are compressed against the bone with sufficient force to secure the construct in place. This compression damages the bone upon implantation and restricts its vascular supply. The body resorbs the damaged bone and generates new bone tissue, resulting in a diminishing fixation strength of the screws during this remodeling process. Additionally, the screws are subject to micromotion forces that further compromise the integrity of the bone-screw interface, leading to the loss of fixation. The implant's surface can play a critical role in mechanical fixation by driving higher quality implant integration.

Biological fixation is the ability of the surface to recruit the host tissue to the surface and encourage the adhesion, proliferation, and differentiation of cells to create new bone tissue that has high bone-to-implant contact. This improved bone-to-implant contact provides robust and long-term fixation. The biologic fixation is done by pushing the initial immune system reaction to a healing phenotype sooner. The pro-healing macrophages then secrete growth factors that actively recruit the host vasculature to the surface and lay the foundation to create new bone that is strong and has better implant contact. Ideally, the biologic fixation is stronger than the initial mechanical fixation. Titanium nanotube surfaces in literature have demonstrated this array of capabilities in vitro and in vivo[1-3]. In this study, the biological fixation of pedicle screws with and without the nanoVIS Ti™ Surface Technology was investigated using a sheep micromotion model.

Methods

Two surfaces on pedicle screws were tested: control as machined titanium alloy and nanoVIS Ti™ Surface Technology. Two implantation models were performed: unloaded and micromotion loaded pedicle screws. Pedicle screws were placed into the sheep spine at thoracic levels T10-T13 and lumbar levels L1-L6. Micromotion loaded screws were placed bilaterally with connecting rods to induce the micromotion forces. No rods were placed in the unloaded screws to minimize pedicle screw forces. No attempt at interbody fusion was made to ensure a normal disc space with normal movement while the sheep was walking in the pasture for three months before sacrifice. Sheep spine segments were recovered for torque testing for fixation strength and histology. Individual torque measurements were compared to the insertion torque at implantation to provide a relative torque measurement. Hard tissue histology was stained with Toluidine Blue with the bone showing as blue.

Results

Figure 1 shows representative histology images of unloaded screws and micromotion loaded screws after 3 months. Screws that were not subject to micromotion, i.e., in the unloaded model, integrated into bone well regardless of the surface. The micromotion loaded model induced tissue damage around the control screws resulting in a halo of fibrous connective tissue around the implant. Over the course of three months, the connective tissue translated from the neck of the screw towards the tip (red arrows). Screws with the nanoVIS Ti™ Surface Technology demonstrated an ability to resist micromotion, had limited fibrous tissue halo around the screw, and instead were encased in a dense bone tissue (green arrows). Mechanical testing of relative torque demonstrated the ability to retain mechanical fixation with the nanoVIS Ti™ Surface Technology, as shown in Figure 2. Control screws subject to micromotion progressively lost fixation over the course of three months.

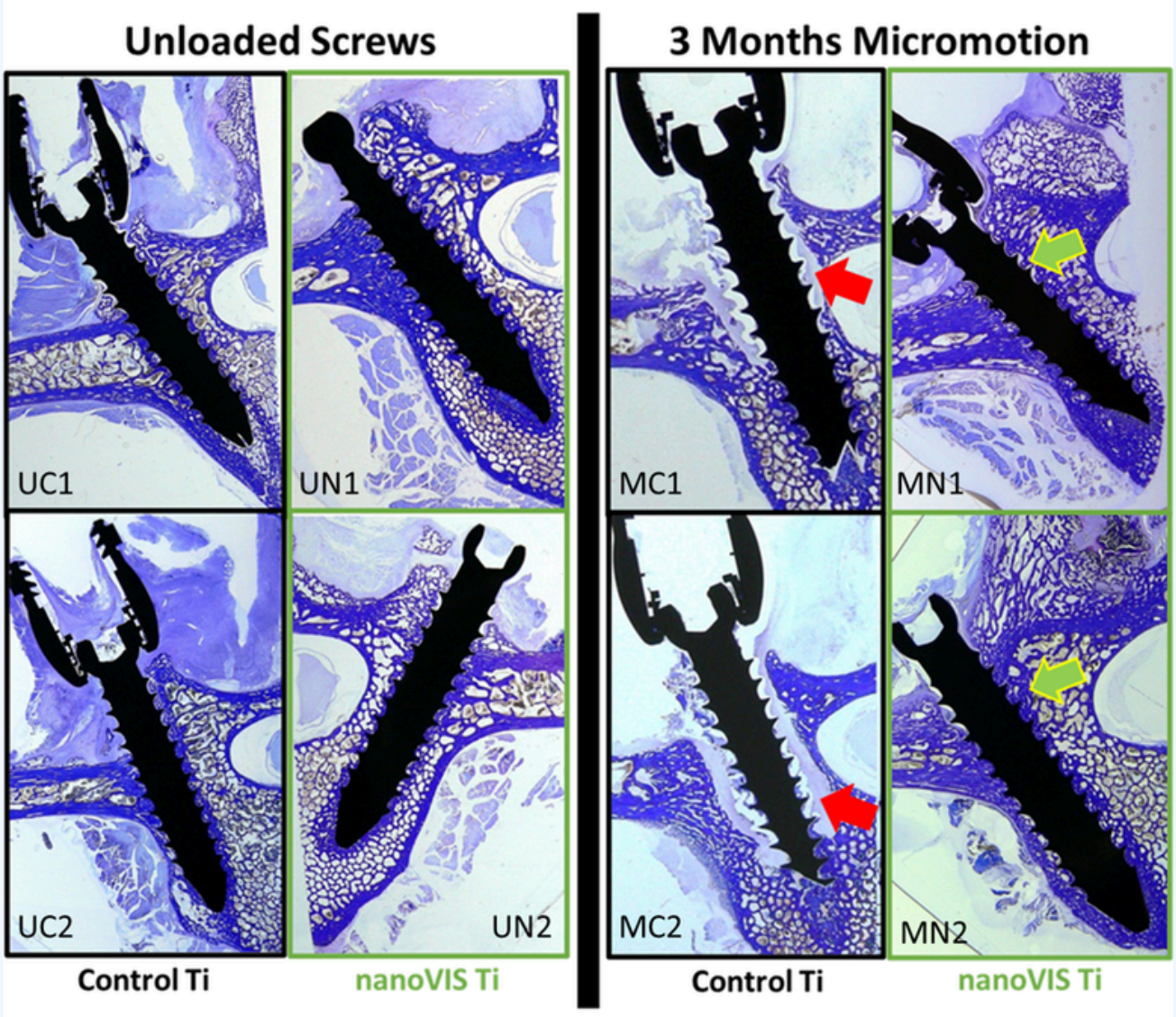

Figure 1: Histology of control and nanoVIS Ti™ pedicle screws at 3 months for the unloaded model (left) and the micromotion loaded model (right). Unloaded screws show increased bone apposition around the whole screw, regardless of surface. UC - Unloaded control titanium; UN – Unloaded nanoVIS Ti™; MC – Micromotion control titanium; MN – Micromotion nanoVIS Ti™. The numbers 1 and 2 indicate Samples 1 and 2, respectively, within each group. Red arrows show fibrous tissue associated with excessive micromotion on control screws. Green arrows show denser, i.e., more compact, bone around the nanoVIS Ti™ pedicle screws that were exposed to excessive micromotion.

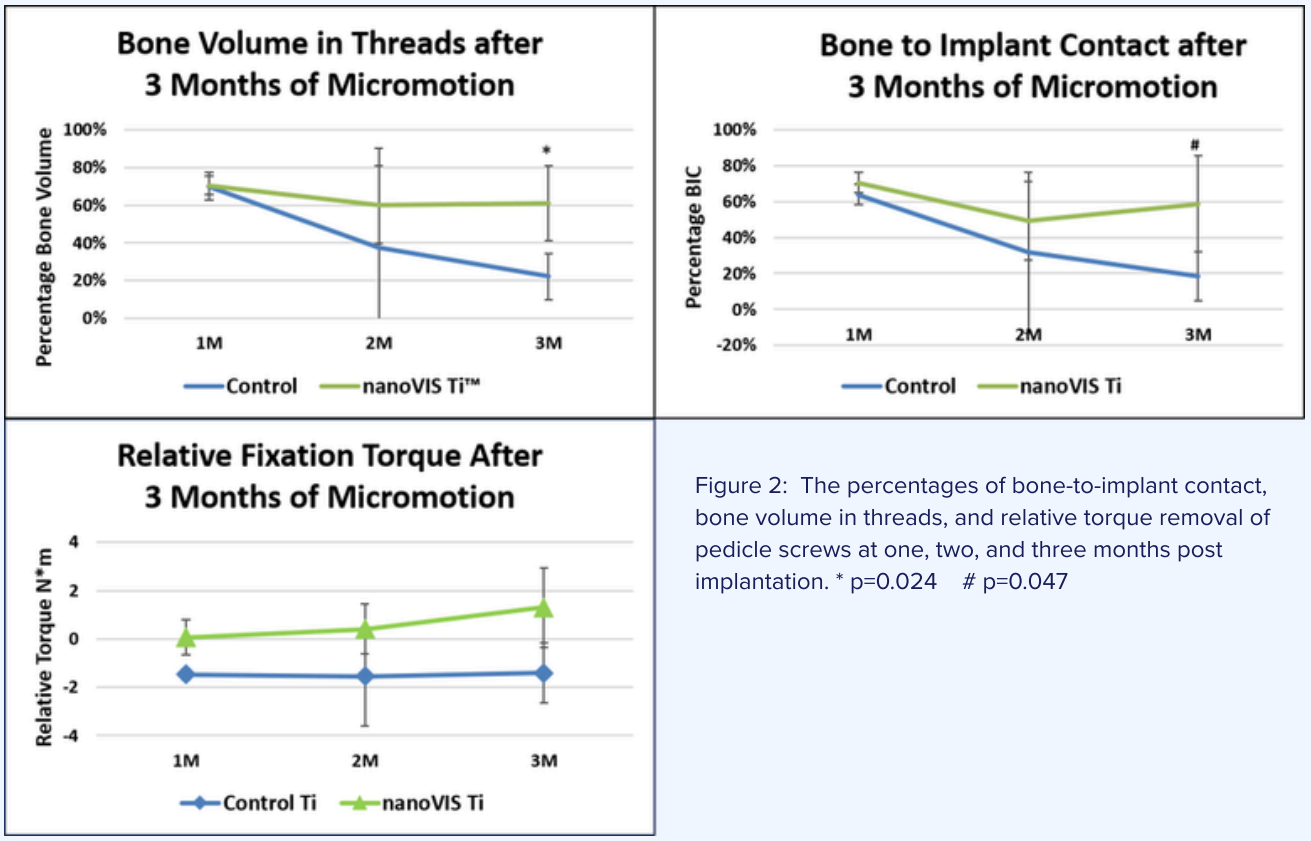

Figure 2: The percentages of bone-to-implant contact, bone volume in threads, and relative torque removal of pedicle screws at one, two, and three months post implantation. * p=0.024 # p=0.047

Discussion

The bone-to-implant contact and the bone volume between screw threads demonstrates an ability to support, grow and maintain quality bone even under heavy micromotion conditions. The increased bone-to-implant contact and bone volume results in greater fixation after three months, exceeding the initial mechanical fixation at implantation. The findings of this study also align with previous in vitro findings of enhanced extracellular matrix mineralization[4]. The ability of the nanoVIS Ti™ Surface Technology to resist micromotion and improve the overall fixation of the pedicle screws, above that of insertion torque, demonstrates the ability of the technology to improve the stability of implant-bone interfaces in the face of strong micromotion.

Conclusion

The evaluation of nanoscale surface technology in a micromotion model is important for demonstrating its potential to establish biological fixation at the bone implant interface to maintain segment stability as micromotion disrupts mechanical fixation of traditional screws. In this study, the screws with the nanoVIS Ti™ Surface Technology demonstrated an ability to increase bone-to-implant contact and provide greater resistance to micromotion forces compared with control titanium pedicle screws in a 3-month sheep micromotion model.

References

1. Ding, X. et al. The effects of hierarchical micro/nanosurfaces decorated with TiO2 nanotubes on the bioactivity of titanium implants in vitro and in vivo. International Journal of Nanomedicine **10**, 19 (2015).

2. Khosravi, N., Maeda, A., DaCosta, R. S. & Davies, J. E. Nanosurfaces modulate the mechanism of peri-implant endosseous healing by regulating neovascular morphogenesis. Commun Biol **1**, 72, doi:10.1038/s42003-018-0074-y (2018).

3. Park, J., Bauer, S., Schmuki, P. & von der Mark, K. Narrow window in nanoscale dependent activation of endothelial cell growth and differentiation on TiO2 nanotube surfaces. Nano Lett **9**, 3157-3164, doi:10.1021/nl9013502 (2009).

4. Detwiler, D. et al. nanoVIS Ti™ Surface Technology Increases Mineralization of Extracellular Matrix Produced by Osteoblasts and Mesenchymal Stem Cells. https://www.calameo.com/nanovistechnology/read/00813842807687a4cc055, (2026).