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Improved Pedicle Screw Fixation in a Sheep Micromotion Model

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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. Improving the fixation strength of bone to pedicle screws is attainable with nanoVIS Ti™ Surface Technology.

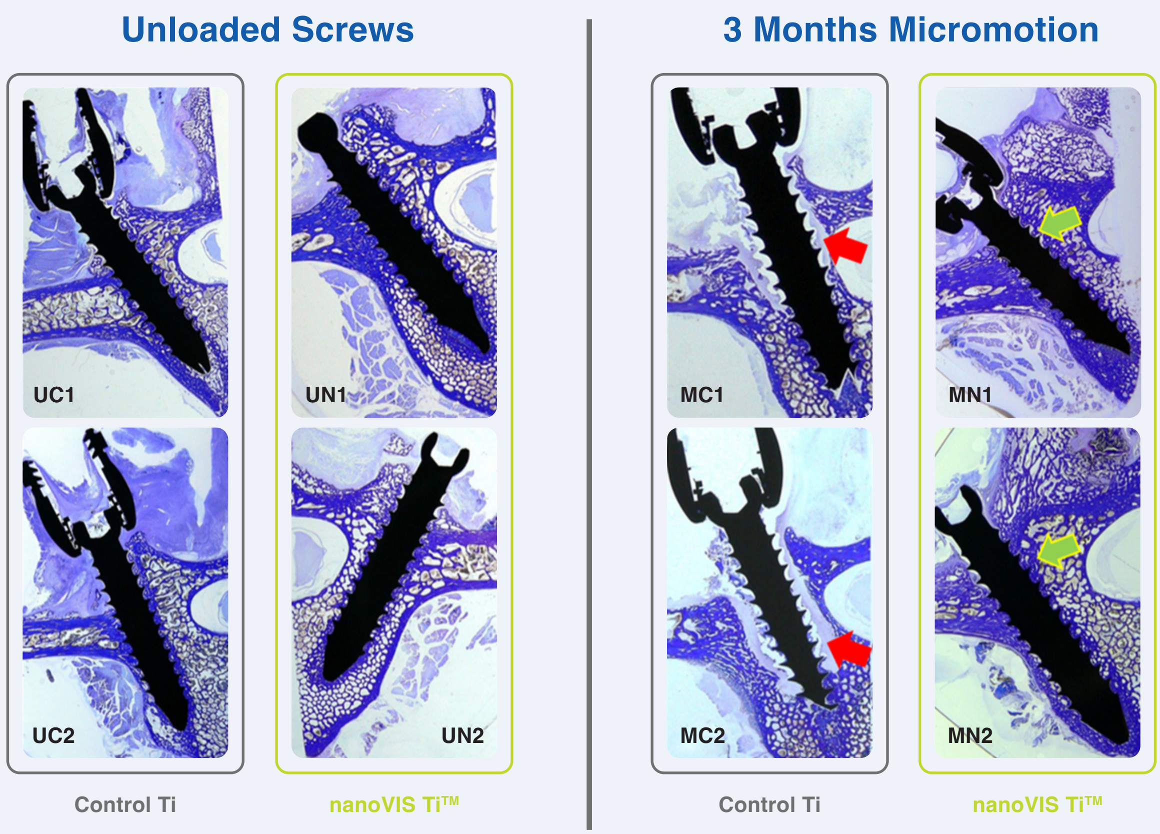
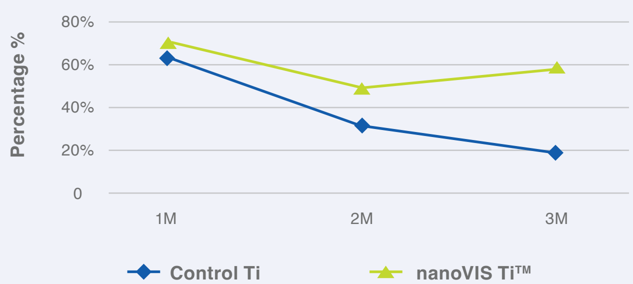


Figure 1 – Histology of control and nanoVIS Ti™ pedicle screws at 3 months for the unloaded model (left) and the micromotion loaded model (right). Unloaded screws show increased bone apposition around the whole screw, regardless of surface. UC - Unloaded control titanium; UN – Unloaded nanoVIS Ti™; MC – Micromotion control Ti; MN – Micromotion nanoVIS Ti™. 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.

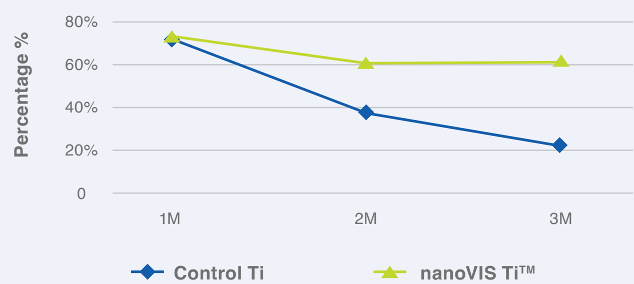
There are two fixation types with pedicle screws – mechanical fixation and biological fixation. Mechanical fixation is achieved when the screws are compressed against the bone with sufficient force to secure the construct in place. This compression damages the bone upon implantation and restricts its 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 effect of the nanoVIS Ti™ Surface Technology is done by pushing the initial immune system reaction to a healing phenotype. 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. Nanotube surfaces in literature have demonstrated this array of capabilities in vitro and in vivo[1-3]. The nanoVIS Ti™ Surface Technology is the only commercially available and FDA approved nanotechnology surface that can accelerate biologic fixation that has greater strength than the mechanical fixation achieved at implantation.

Bone to Implant Contact
After 3 Months of Micromotion



Bone Volume in Threads
After 3 Months of Micromotion



Relative Fixation Torque
After 3 Months of Micromotion

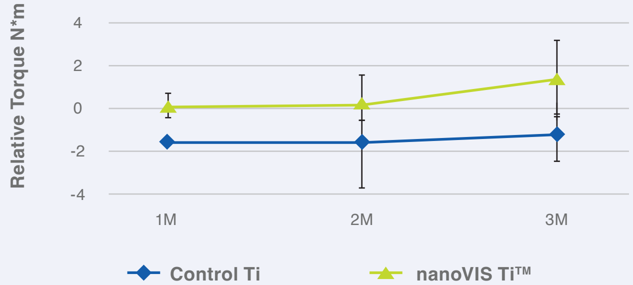


Figure 2 – The percentages of bone-to-implant contact, bone volume in threads, and relative torque removal of pedicle screws at one, two, and three months post implantation

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 animal was walking in the pasture. Animals could walk around in pasture for one, two, or 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

Screws that were not subject to micromotion, i.e., unloaded model, integrated into bone well, without consideration 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 Figure 1). Screws with 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 Figure 1). Mechanical testing of relative torque demonstrated the ability to retain mechanical fixation with the nanoVIS Ti™ Surface Technology (Figure 2). Control screws subject to micromotion progressively lost fixation over the course of three months.

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 contact and bone volume results in higher fixation after three months, even exceeding the mechanical fixation at implantation. The ability of the nanoVIS Ti™ Surface Technology to resist micromotion and improve the overall fixation of the pedicle screws, above that of Day 1 insertion torque, demonstrates the ability of the technology to improve the stability of implant-bone interfaces in the face of strong micromotion.

Conclusion

The nanoVIS Ti™ Surface Technology is capable of achieving fixation in bone that can resist the micromotion from mechanical constructs that would otherwise degrade the fixation strength between the pedicle screw and bone. The nanoVIS Ti™ Surface Technology on pedicle screws has demonstrated an ability to improve mineralization of extracellular matrix in vitro, increase bone-to-implant contact in vivo, and resist micromotion forces in vivo. Human patients are also showing dense mineralized bone around the screw shanks, visible in post-operative radiographs[4]. The nanoVIS Ti™ Surface Technology is the only commercially available surface with an FDA cleared nanotechnology designation.

References

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