Pedicle Screw Surface Coatings Improve Fixation in Non-Fusion Spinal Constructs

INTRODUCTION:
Transpedicular screw fixation has become the gold standard in the treatment of various thoracolumbar spinal conditions. However, pedicle screw loosening has been reported, especially in mechanically demanding constructs or in vertebrae with low bone mineral density. Several strategies to augment the bone-implant interface, such as pedicle screw surface coatings, have been considered for use in osteotropic patients and in non-fusion constructs to improve screw fixation strength.

METHODS:
Four types of 4.35mm x 25mm titanium alloy monaxial pedicle screws (uncoated (U), hydroxyapatite coated (HA), titanium plasma spray coated (TPS), and HA/TPS composite coated) were instrumented in the thoracolumbar spine of 6 mature Yucatan mini-pigs (18 to 24-months old). The screws were connected in mono-segmental constructs with a 5.5mm diameter, 5cm long titanium rod in a systematically varied, single-blinded fashion. After three months, the spines were harvested en-bloc. A CT of the harvested spine was performed to ensure intra-pedicular screw placement at all levels, to evaluate for radiolucent zones around the screws, and to evaluate for a fusion mass. A quantitative CT was also performed on each spine to obtain bone mineral density (BMD) data. Additionally, one screw of each type was instrumented in each animal at adjacent levels as a time zero control (5 of each type of screw).

Biomechanical Evaluation:
Five of the six specimens were prepared for non-destructive biomechanical testing. A torsional screw extraction analysis was performed to evaluate the mechanical strength of the bone (tissue)-implant interface (Figure 1). Each harvested spine (6 vertebral bodies) was potted en-bloc by seating the anterior vertebral column in a two part epoxy resin (Bondo Corp., Atlanta, GA) and affixed in a bi-axial materials testing machine (858 Mini-Bionix, MTS Corp., Eden Prairie, MN) using an angle vise. The machine actuator was fitted with a custom fabricated driver tip mounted in a drill chuck (Jacobs Chuck Manufacturing Co., Greendale, WI). For each test the angle vise was used to position the spine so that the screw to be tested was aligned with the machine actuator. The custom driver was then carefully inserted into the screw channel ensuring optimal alignment and zero axial load or torque prior to testing. The screws were extracted at a uniform rate (0.1 degrees/second) to a maximum excursion of 30 degrees. Angular displacement (degrees of rotation) and torque were sampled at 200 Hz for the duration of each test.

RESULTS:
Five screws of each type (20 screws total) underwent “time zero” biomechanical testing and ten screws of each type were tested after a 3-month survival period (40 screws total). Biomechanical data were analyzed using a custom designed Matlab processing script (The MathWorks, Inc., Natick, MA) to define the peak torque and the angle at peak torque, as well as the stiffness in the initial linear region of the torque-angular displacement curve. The script allowed the user to specify the middle of the linear region avoiding inconsistencies in identification of the toe region and yield inflection. Three data points were collected from each screw extraction analysis: peak torque (N-mm), angle at peak torque (degrees) and stiffness (N-mm/deg).

Histological Evaluation:
The sixth spine and one of the five biomechanically tested spines (8 vertebral bodies / 16 screws total) were prepared for non-decalcified histological analysis (Vet Path Services, Inc., Mason, OH). The spines were fixed in 10% buffered formalin for at least 48 hours, trimmed to the desired size and orientation along the sagittal longitudinal length of each screw, and placed on an automatic tissue processor under vacuum for dehydration. After dehydration, the tissues were infiltrated and embedded with methyl methacrylate and placed into molds. The polymerized block was then cemented to a slide using a vacuum adhesive press and ground parallel. Slides were cut from the block and ground down to a thickness of 100µm. The slides were then polished to an optical finish using a variable-speed grinding wheel (Buehler Incorporated, Lake Bluff, IL), stained with toluidine blue and examined under a light microscope. Digital photographs (1x, 100x and 200x magnification) were obtained of each slide and analyzed with image editing software (Adobe Photoshop, San Jose, CA) to evaluate the tissue-screw interface.

Statistical Analysis:
Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS Inc., Chicago, IL). Bone mineral density data were compared between the six specimens using an analysis of variance (ANOVA). A two-way ANOVA was used to compare the biomechanical data. The three dependent variables were peak torque, angle at peak torque, and stiffness; and the two independent variables were time (time zero and 3 months) and screw type. Multivariate ANOVAs with Bonferroni post-hoc comparisons were then performed to evaluate differences between screw types and time points for the three dependent variables. All data were checked for normality and equal variances, and the level of significance was set at a p value of 0.05.

DISCUSSION:
These findings suggest a loss of fixation over time for standard, uncoated titanium pedicle screws placed in a non-fusion model. Screw coatings, which promote mechanical interlocking (TPS) or direct osteoblast bonding (HA), increased screw fixation (peak torque). However, more non-HA coated screws were thought to be “loose” with a nearly zero peak extraction torque and fibrous encapsulation. Increased osseointegration with HA may result in a decreased incidence of screw loosening and improved outcomes of transpedicular spinal instrumentation in non-fusion procedures.