

Safety and Functionality Assessment of Antimicrobial Surface-Modified Spinal Stabilization Devices

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Introduction: Bacterial infection of spinal instrumentation is a significant challenge in spinal fusion surgery (1). With the advent of antimicrobial surfaces, there's an impetus to ensure that these enhancements do not inadvertently compromise the core functionality of the of spinal instrumentation. Previous *in vitro* research has demonstrated a model of bacterial infection in the operating room setting and highlighted the substantial decrease in colonization on materials covalently bound with antimicrobial technologies (2). However, limited *in vivo* studies have been performed exploring this potential solution to the bacterial infection issue using antimicrobial surfaces, especially in spinal fusion surgery. This study was centered around two primary objectives: Firstly, to ascertain that the antimicrobial surface integration did not detract from the device's primary role in spinal stabilization. Secondly, to collate and analyze data to confirm that the incorporation of the antimicrobial surface did not introduce safety concerns that would not be present in devices devoid of this modification. This study aimed to assess the efficacy and safety of a novel antimicrobial pedicle screw system in comparison to a standard pedicle screw system through a two-level posterior lumbar fusion (PLF) in an ovine model. It was hypothesized that incorporation of an antimicrobial surface would not detrimentally affect the primary function of the device as a spinal stabilization tool.

Methods: Twelve sheep underwent PLF surgeries at the L2-L3 and L4-L5 levels, encompassing two non-contiguous functional spinal unit (FSU) fusions. Animal use approval was granted by the Colorado State University Animal Care and Use Committee (IACUC #1463). Animals were categorized into two groups: Group A (control) received the standard pedicle screw system, while Group B (treatment) was implanted with the antimicrobial pedicle screw system. Across both categories, 24 fusion levels were analyzed. Group identification remained blinded until post-surgical procedures were finalized. Radiographic evaluation was conducted post-operation and subsequently at 4, 12, and 26-week intervals, ensuring implant positioning throughout the study's duration. Furthermore, CT examinations were performed at specified intervals. At the 26-week mark, all 12 animals were humanely euthanized. Ex vivo assessments included a manual palpation scored by three independent evaluators. The manual palpation score consisted of score 1 meaning no stability of FSU; score 2 minimal stability (some motion); score 3 moderate stability (minimal motion); and score 4 meaning a complete fusion of FSU (no motion). Additionally, biomechanical pedicle screw pull-out testing, MicroCT analysis, and histological evaluation were performed.

Results: A posterior lumbar fusion procedure was uniformly executed across all animals, with no difference in the surgical placement between Control and Treatment pedicle screw systems. No adverse events were linked to the Antimicrobial Pedicle Screw System tested. Lumbar CT scans demonstrated a 100% fusion rate in the Control group at 26 weeks post-operation, while the Treatment group registered a 92% fusion rate. Only one Treatment FSU did not successfully fuse by the 26-week mark. Fusion rates, as measured by CT fusion scores, were comparable between the Control and Treatment groups at 26 weeks ($P=0.3185$). No infections or complications were evident at the surgical sites during dissection. Manual palpation scores indicated equivalency between both groups. The Treatment and Control groups demonstrated functionally equivalent manual palpation scores of 3.9 ± 0.4 and 4.0 ± 0.0 , (mean \pm std. dev.) respectively. No statistically significant differences were measured in biomechanical pull-out stiffness, ultimate failure load, or yield load for either group. MicroCT assessment revealed that fusion occurred on the dorsal (posterior) side of the vertebral bodies in the spinous process region of all FSUs with little fusion mass extending into the intertransverse process space. Semi-quantitative microCT PLF scoring revealed similar fusion outcomes between groups. Specifically, the Treatment group demonstrated 22 of 24 (92%) PLF locations fused while the Control group demonstrated 24 of 24 (100%) PLF locations fused. Both unfused PLF locations of the treatment group occurred in a single animal. No statistically significant differences were measured in microCT bone volume or bone mineral density between groups. Histopathological analysis displayed a minimal host tissue response surrounding the pedicle screws in all samples. Both groups exhibited minimal inflammation, no moderate or heavy fibrosis, and no significant presence of giant cells. The tissue response between the screw surface and the host bone varied in density and structure, but generally displayed minimal to no reaction when normalized against control samples (Figure 1). There were no indications of implant degradation or particulate debris driving any fibrosis. The fusion masses in the intertransverse spaces showed no significant disparities between control and treatment animals. Histomorphometry analyses of the pedicle screw and intertransverse regions of interest (ROI) did not show significant differences in bone area, fibrous tissue area, and void space area.

Discussion: In the present study, the PLF procedure was executed with uniformity across all animal subjects. Both the Antimicrobial Pedicle Screw System and the control counterpart were implanted without any observable differentiation, suggesting that the integration of the test system did not mandate any alterations to the conventional surgical approach. Importantly, throughout the study's duration, all animals exhibited a favorable post-operative course, devoid of complications. The data analyzed in this study, taken together, indicate that the modified antimicrobial surface did not introduce additional safety concerns when compared to identical devices without such a surface.

Significance/clinical relevance: Introducing antimicrobial surfaces on medical devices is paramount in reducing the risk of post-operative infections, which can be a significant concern in surgeries, especially spinal fusion surgeries. This study offers comprehensive insights into the performance and safety profile of antimicrobial pedicle screw systems in comparison to standard systems. Additionally, this antimicrobial surface technology could promote safer surgical practices and potentially reduce hospital stay durations and associated costs.

References:

1. DeMourant T, Rajkovic CJ, Tracz JA, Perdomo-Pantoja A, Judy BF, Hernandez VN, et al. A novel rodent model of chronic spinal implant-associated infection. *Spine J.* 2023 Sep [cited 2023 Aug 15];23(9):1389–99. Available from: <http://www.thespinejournalonline.com/article/S1529943023002292/fulltext>
2. Zhao W, Libera M, Prysak M, Katz J, De Stefano L. An in vitro model of microbial contamination in the operating room. *J Biomed Mater Res - Part B Appl Biomater.* 2022;110(11):2472–9.

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