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INTRODUCTION

Implant-associated spine infections are complicated by biofilms, as hardware often cannot be removed after placement. A biofilm is a structured community of microorganisms (e.g., bacteria) embedded in a self-produced matrix that preferentially adheres to surfaces such as implanted hardware (Figure 1A). Bacteria in biofilms can tolerate >1000x antibiotic concentrations than planktonic bacteria (Figure 1B).¹

Current issues with treating these biofilm-associated infections in the spine include:

1. Toxicity from increasing systemic antibiotic doses
2. Limited drug delivery to infection sites due to compromised vasculature²
3. Failure to achieve a sustained, high antibiotic concentration

To address this clinically unmet need, we have been developing **the Purgo Pouch**, a refillable intrawound drug delivery system (Figure 2). The Pouch comprises a temporarily implanted (<30 days) antimicrobial-filled reservoir with a permeable rate-controlling membrane. The implanted reservoir communicates externally with a refilling port. Passive diffusion of antibiotics through the rate-controlling membrane and daily refilling maintain high target concentrations of antibiotics in the site tissues. We hypothesized that tobramycin, locally delivered via the Purgo Pouch, would eliminate biofilms to a greater degree in a sheep model of spinal fusion rod-related infection than systemic antibiotics alone.

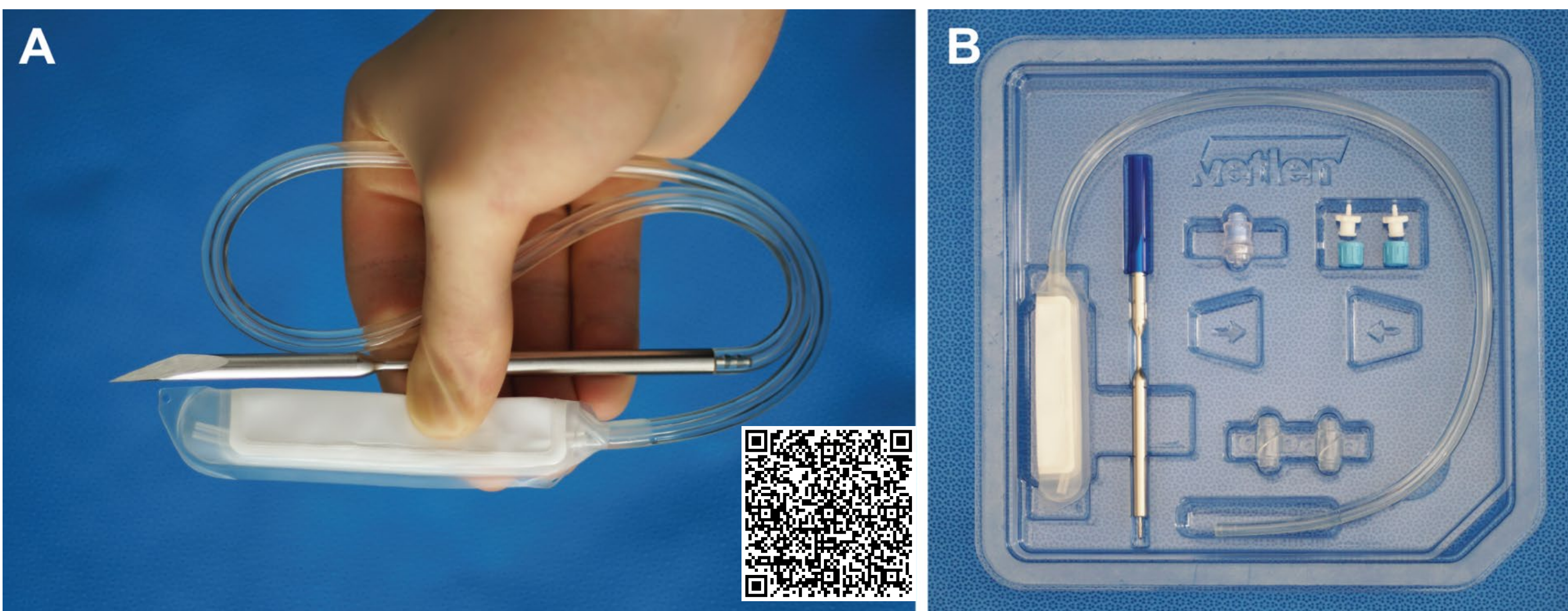


Figure 2: (A) The 10 mL pouch used in this study is in active development toward human clinical use and currently available for veterinary applications. See Purgo Pouch use in QR linked video (B) The 10 mL Vetlen Pouch, with the sterile covering peeled back to reveal the kitted components: a bendable stainless-steel trocar, Luer-lock barb fittings, needleless Luer-lock port, Luer-lock caps, and catheter tubing tissue anchors.

METHODS

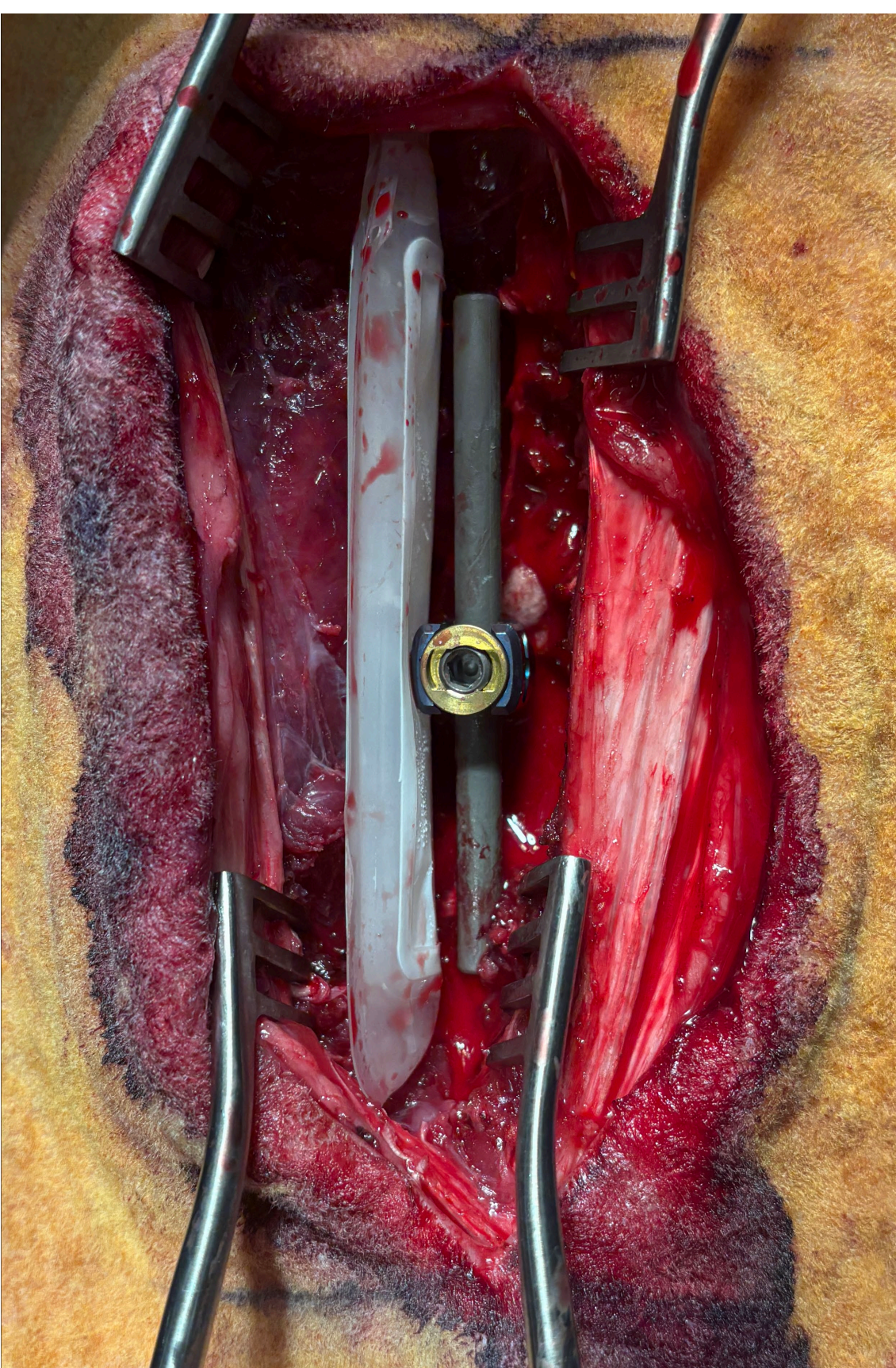


Figure 3. Established Ovine Deep Spine Infection Model. Surgically implanted spinal hardware (Right) with the Purgo Pouch (Left).

Our study objective was to compare the Purgo Pouch against a systemic antibiotic clinical standard using an established sheep spine infection model.³ This model uses a *Staphylococcus aureus* biofilm grown on a spinal fusion rod, which is then surgically implanted into the lumbar spine of sheep using a pedicle screw and locking cap (Figure 4). Sheep (age 1-3 years) were randomly assigned to 1 of 5 treatment groups (with approximately equal amounts male and female) as shown in Table 1. The implanted cap and rod, along with tissue and bone samples were collected at necropsy for histological and quantitative microbiological analysis.

TABLE 1. Study Groups

Group Name	Daily Treatment	Group Size	Duration
+ Control	None	n = 5	30 Days
- Control	None	n = 5	30 Days
Systemic Only	Systemic Rifampin (600 mg) + Levofloxacin (750 mg)	n = 5	14 or 30 Days
Pouch Only	Local Tobramycin (352 mg)	n = 5	14 or 30 Days
Pouch + Systemic	Systemic Rifampin (600 mg) + Levofloxacin (750 mg), Local Tobramycin (352 mg)	n = 5	14 or 30 Days

RESULTS

Microbiologically, there was no statistically significant difference in bioburden between the antibiotic treatment groups after 30 days of treatment (Figure 4A). However, there was a significant difference between the pouch groups and the systemic only group with the 14-day treatment duration (Figure 4B), indicating that infection was cleared faster with the Pouch.

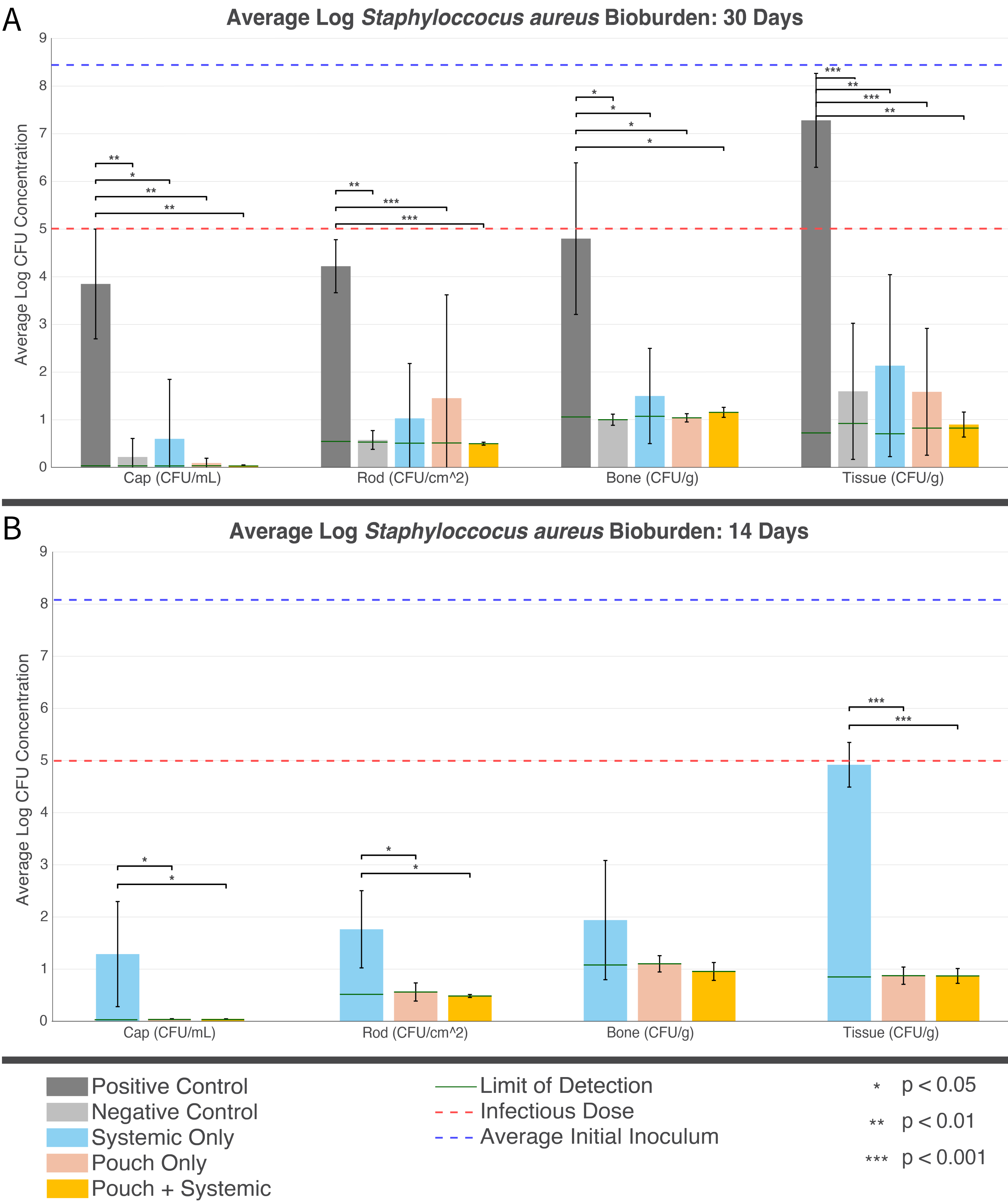


Figure 4. Average Log Bioburden of *S. aureus*. A) 30-day treatment duration showed no statistical difference between antibiotic treatment groups. B) 14-day treatment duration showed statistical difference between pouch groups and systemic only in 3 of 4 samples.

Micro-CT imaging was used to determine bone health in the facet joint, spinous process, and vertebral body (Figure 5). Average bone necrosis grading showed a statistically significant difference between the pouch groups and systemic antibiotics only (Figure 6).

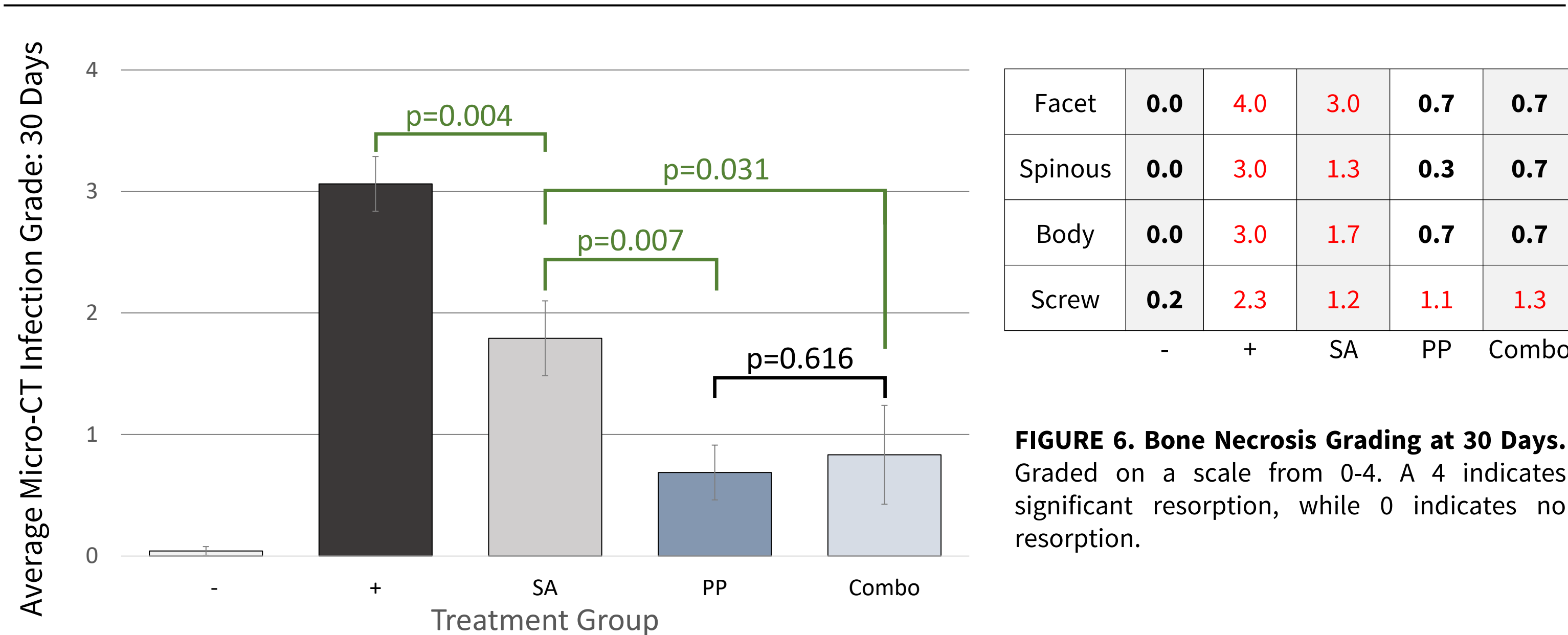
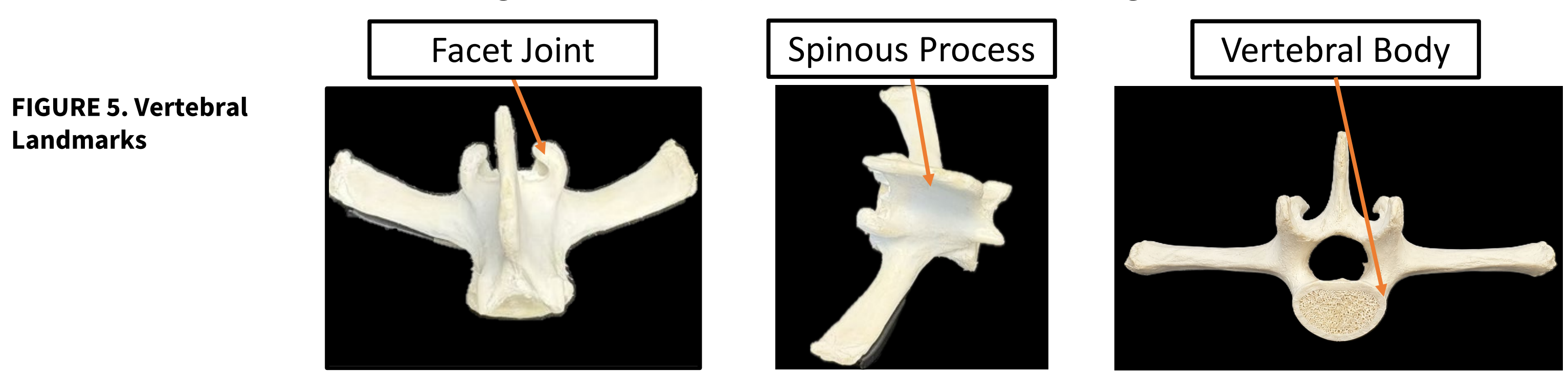


Figure 6. Bone Necrosis Grading at 30 Days. Graded on a scale from 0-4. A 4 indicates significant resorption, while 0 indicates no resorption.

RESULTS CONTINUED

This micro-CT data showed that sheep receiving systemic antibiotics only had high bone resorption (degradation) in the spinous process (Figure 7A) and especially the facet joint (Figure 7B). Sheep that received locally delivered antibiotics through the Purgo Pouch showed minimal bone resorption.

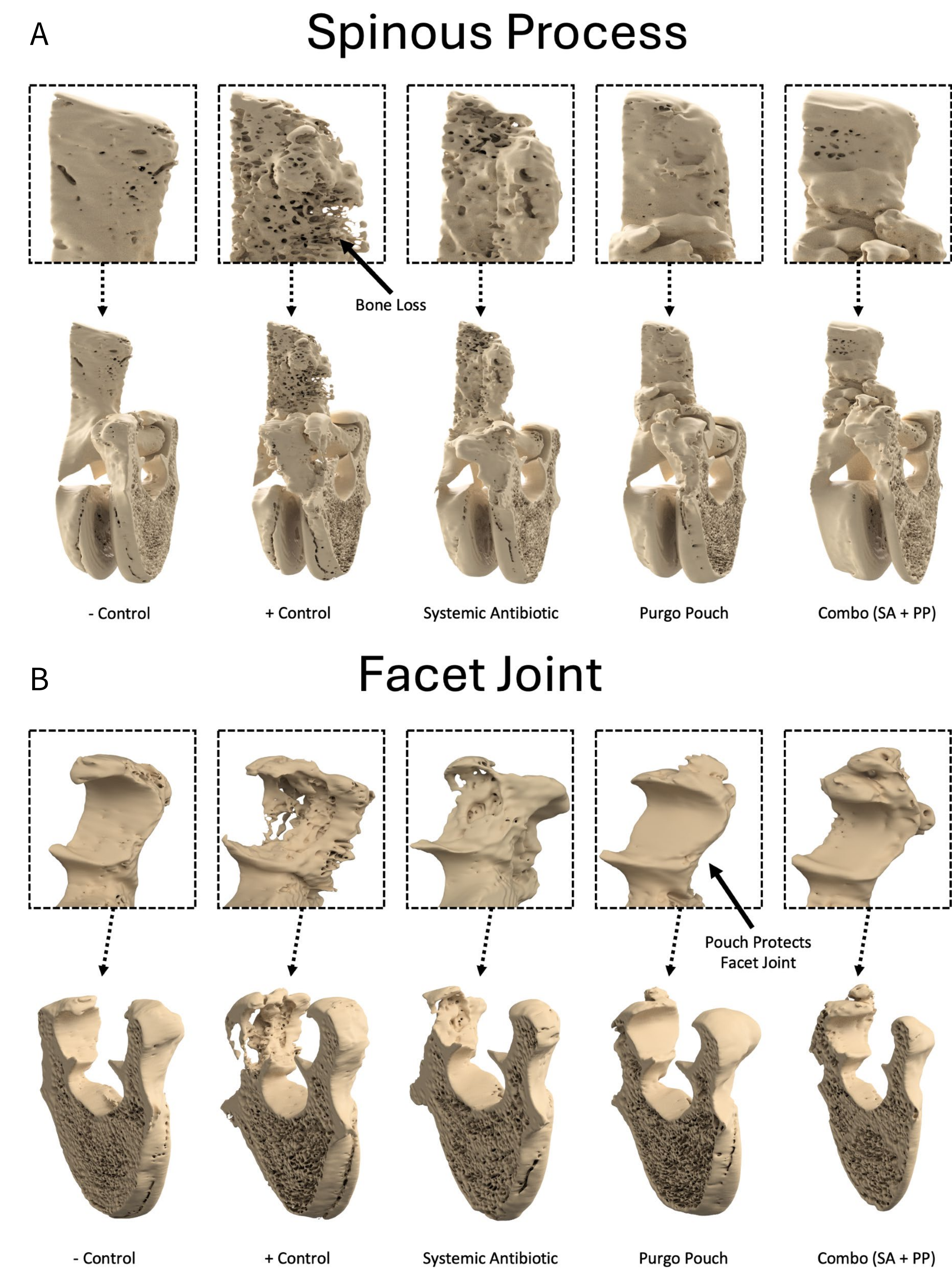


Figure 7. 3D-Renderings of Spinous Process (A) and Facet Joint (B) at 30 Days. Note that these are representative images from each treatment group. The systemic antibiotics group is most similar to the positive control in both vertebral regions, with large pockets of "moth-eaten" bone. The Purgo Pouch groups showed smooth, healthy bone similar to negative controls.

DISCUSSION

Conclusion:

- Bacteria in sheep with the Purgo Pouch were killed **sooner** than those with systemic therapy alone.
- Sheep treated with the Purgo Pouch had far **less** bone resorption.

Future Work:

- Compare the Purgo Pouch to sprinkled antibiotic powder using the same model.
- Analyze histology with the 14-day treatment groups.
- Determine release kinetics of the Pouch.

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Abstract Disclaimer: The DoD award number HT9425-24-1-1110 has supported and continues to support this work. Without this award, this work would not be possible, and the Purgo Pouch technology would not be viable. The mention of a product by name is solely for the purpose of representing Command collaborations and should not be implied as endorsement. The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of the Army, the Department of Defense (War), or the United States government. Authors DW, BK, RE, BB, and NA have financial interest in Purgo Scientific.