INTRODUCTION
Postoperative fibrosis is a natural consequence of surgical wound healing. Peridural fibrosis arises from activated fibroblasts in the disrupted epaxial muscles during wound healing from spinal surgery. Postoperative peridural adhesions may occur and result in tethering, traction and compression of the thecal sac and nerve roots. Although controversy exists about the role of peridural fibrosis and adhesion in failed-back syndrome, it is generally accepted to be a problematic clinical entity with no efficacious treatment options. Many biological products have been tested in an attempt to find the ideal barrier to prevent peridural adhesions. In this study, an ovine dorsal laminectomy model was used to evaluate and compare three bioresorbable materials that were implanted in to the laminectomy site to prevent adhesion formation on the spinal cord following surgery.

METHODS
The care and use of the sheep in this study were approved by the Colorado State University Animal Care and Use Committee. Twelve sheep were used in this study. The sheep were anesthetized in a routine manner and aseptically prepared for surgery. A three level dorsal (posterior) laminectomy was performed with an unaffected level in between each laminectomy site. In each sheep there was one control (untreated) laminectomy site and two treatment sites. Treatment and control sites were randomized. Three materials were tested as a barrier to postoperative peridural adhesion: 1. a 20 µm thin Lactosorb® (L20) bioresorbable film (specific composition: 88% PLA/12% PGA EBI, L.P., Parsippany, NJ), 2. 40 µm thin Lactosorb® (L40) bioresorbable film and 3. Mesofol® (Biomet Europe), a 40 µm thin bioresorbable anti-adhesion barrier. The sheep were kept alive for 10 weeks. On the day of sacrifice, all sheep were euthanized in a humane manner. Seven sheep were chosen for gross evaluation (scoring) of scar volume and tenacity and 5 sheep were designated for histology of the spine. Scar scoring was achieved by removing the vertebral bodies of the vertebrae en bloc and slowly elevating the spinal cord in a ventral (anterior) direction out of the spinal canal. Scar scoring was performed by two observers at the time of dissection and one at a later time by videotape taken at the time of the dissection. Scar volume scoring values were as follows: 0 = no adhesions present, 1 = <25% of original laminectomy defect affected, 2 = ≥25% and < 50% of original laminectomy defect affected, 3 = ≥50% and < 75% of original laminectomy defect affected, and 4 = ≥75% to over 100% of original laminectomy defect affected. Scar tenacity score values were as follows: 0 = no adhesions present, 1 = thin, membranous threads; easily detachable, 2 = slight adhesions; some blunt dissection required, 3 = moderate adhesions; some sharp or blunt dissection required, and 4 = tenacious adhesions; sharp dissection required.

RESULTS
Significance tests for volume and tenacity were performed overall comparisons between the treatment groups: control, L20, L40 and Mesofol®. The significance differences were assessed using a restricted maximum likelihood-based mixed-effect model that included the categorical, fixed effects of treatment, spinal level and scorer. A random animal effect was also included in the model via PROC MIXED in SAS. Scorer and spinal level did not have significant effects on scar tenacity or volume. Significant differences were found for all treatments in comparison to control with P values < 0.05 for both scar tenacity and volume. There were no significant differences when comparing treatments to each other.

DISCUSSION
Mesofol®, currently marketed in Europe, is a transparent, bioresorbable film that can be inserted between muscles, muscles and tendons or nerves to prevent the formation of postoperative adhesions. Mesofol® can take over the fascia's sliding function, improving the physiologic free gliding and thus reducing postoperative pain and preventing negative effects due to tissue conglutination. Degradation of the product is approximately 4-6 weeks in vitro and in vivo and, during in vitro testing, it was shown to be impermeable to microorganisms and larger molecules that may be involved in development of adhesions. Lactosorb®, a biore corrobor film with a specific composition of PLA (88%) and PGA (12%), has also been developed for use as an anti-adhesion barrier. This product is currently under study and not yet available for clinical use. The product was tested in two forms: 20 µm (L20) and 40 µm (L40) thin sheets. The degradation time of L20 appears to be around 4-6 weeks in vivo. In this 10 week study, evidence of L40 film was still present in several sites. The surgeon (LSK) found the handibility of L20 and Mesofol® to be very good and compatible with clinical usage. The L40 film was more difficult to handle and maneuver by comparison. The results of our study found statistically significant improvements in scar volume and tenacity with the use of all the products tested in comparison to untreated control sites. All of the products tested show good potential for use in clinical spinal surgery.

REFERENCES

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