Use of polylactide resorbable film as a barrier to postoperative peridural adhesion in an ovine dorsal laminectomy model

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Object. The purpose of this study was to evaluate the performance of a resorbable polylactide film in the sheep posterior spine in the presence of a combined laminectomy and durotomy defect.

Methods. A resorbable polylactide film was used to cover the combined defects in the eight sheep used in this study. Two surgical levels were performed in each animal, with randomly assigned control and treated sites. Each surgical level consisted of a full laminectomy followed by a needle-induced durotomy. The treated levels received a resorbable polylactide film cut to size and tucked in under the laminar defect. At 8 to 10 weeks postoperatively, results of myelography and visual dye infiltration showed complete healing of the duralotomies for all sites. In addition, evaluation of gross dissection based on volume and tenacity scores as well as histological findings indicates decreased posterior dural adhesions for sites treated with resorbable polylactide film.

Conclusions. The results of this investigation support previous studies in which the use of a resorbable polylactide film was found to be effective in reducing posterior dural adhesions in the spine with no apparent safety issues related to impaired dural healing.

KEY WORDS • peridural adhesion • laminectomy • durotomy • bioabsorbable barrier • sheep

Postoperative fibrosis is a natural consequence of surgical wound healing. The source of fibrotic tissue after spinal surgery was originally thought to be the disrupted intervertebral disc,29 but a later study by Larocca and Macnab31 revealed that fibroblasts arose from the disrupted epaxial muscles in the surgical wound. Postoperative peridural adhesion results in tethering, traction, and compression of the thecal sac and nerve roots, which cause a recurrence of hyperesthesia that typically manifests a few months after laminectomy surgery.2,6,5,21,35,37,59 Although controversy exists about the role of peridural fibrosis in failed-back syndrome,17,60 it is accepted by many to be a problematic clinical entity with no efficacious treatment options.1,3,9,16,21,39,46,56,62 The advent of magnetic resonance imaging performed with Gd-diethylenetriamine pentaacetic acid contrast material has resulted in easier identification of recurrent intervertebral disc extrusion as opposed to peridural scarring as a cause of failed-back syndrome.15,54,56 Repeated surgery for removal of scar tissue is associated with poor outcome and increased risk of injury because of the difficulty of identifying neural structures that are surrounded by scar tissue.5,15,37,46,59,62 Therefore, experimental and clinical studies have primarily focused on preventing the adhesion of scar tissue to the dura mater and nerve roots.

The ideal agent for preventing peridural adhesion and fibrosis would have the following properties: 1) prevention of scar tissue adhesion to the dural tissues; 2) prevention of the development of leptomeningeal arachnoiditis; 3) no potential to impair dural healing following tearing and CSF leakage; and 4) no capability to induce excessive inflammation around neural tissues. Previously studied materials or procedures include autografts (free and pedicled fat grafts, ligamentum flavum, and lamina replacement);1,3,9,16,21,39,46,56,62 manufactured biomaterials that provide a mechanical barrier (for example, expanded polychlorotrifluoroethylene membrane, Gelfoam, Sialastic membrane, Surgicel, Avitene, polymethyl methacrylate, TachoComb, synthetic carbohydrate polymers, and Goretx);1,3,9,16,21,39,46,56,62 topical administration of biochemcials to reduce fibroblast function and infiltration (for example, urokinase, tissue plasminogen activator, mitomycin-C, hyaluronic acid, and glucocorticoids);6,13,23,27,59 and intraoperative application of...
CO₂ laser therapy or localized administration of external-beam radiation therapy perioperatively. 4,8,20 The effectiveness and safety of each of these agents and procedures have not met with widespread acceptance. Use of free fat autografts as an interposition membrane is probably the most common practice in spinal surgery performed in humans, but some reports have shown little benefit or even detrimental results caused by herniation of the fat graft and subsequent neural impingement. 7,25,26,38,40,49 Previously, investigators have suggested that the most statistically and consistently effective antiadhesion barrier used in spinal surgery was ADCON-L. 11,14,17,28,37,42,47,48,55–57 Nevertheless, this material was removed from the market after multiple reports were published that implicated it in impaired dural healing and persistent CSF leakage in humans. These complications were caused by inadvertent or unrecognized intraoperative dural tearing despite experimental work in rats that indicated that ADCON-L would not impair dural healing. 22,33,51

Preliminary studies performed in a rat model demonstrated significant reduction of peridural scarring with the use of a polylactide resorbable film. 41 In an earlier study, Welch, et al., 61 evaluated the use of a 0.02-mm-thick polylactide resorbable membrane as a mechanical antiadhesion barrier in canine and ovine small laminotomy models. Although in the previous study good results were reported when the film was used as a barrier membrane in the ovine laminotomy model, the current study was designed to evaluate the barrier membrane in the more challenging laminectomy model. In this study we have evaluated the efficacy of the polylactide barrier film in a larger defect by performing a dorsal (posterior) laminectomy and durotomy in an ovine model. All evaluations were performed in a blinded fashion and included pre-mortem myelographic studies, postmortem gross evaluation of the tenacity and volume of peridural scar adhesion, and histological studies of the treated and control laminectomy segments.

MATERIALS AND METHODS

Animal Care

Eight sheep were used in this study, six of which were allowed a 10-week survival period and two of which had an 8-week survival period. The care and use of the sheep in this study was approved by the Colorado State University Institutional Animal Care and Use Committee.

Anesthesia and Pain Management

On the day of surgery, ear vein catheters were placed for intravenous medication and fluid administration. Anesthesia was induced with Valium (7.5 mg intravenously) and ketamine (4 mg/kg), and maintained with isoflurane (1.5–3% in 100% O₂ at 2 L/minute). The sheep were given 15 mg/kg intravenously administered atracurium intraoperatively to facilitate muscle dissection and retraction, and their respiration was controlled with a mechanical ventilator to maintain normocapnia and adequate oxygenation.

For pain management, fentanyl patches (one 10-mg and one 5-mg patch) were applied 24 hours preoperatively and maintained for 3 days. In addition, 1 g phenylbutazone was orally administered daily, beginning 1 day preoperatively and continuing for 3 days postoperatively. Prior to skin incision, 8 ml of 2% lidocaine was injected into the subcutaneous tissues along the length of the incision site and 0.75% bupivicaine (8 ml/side) was injected into the epaxial muscles bilaterally before skin closure.

Test Material

The material tested as a barrier to postoperative peridural adhesion was a 0.02-mm thin resorbable polylactide film (MacroPore Biosurgery, Inc., San Diego, CA). The specific composition of the amorphous bioresorbable copolymer film was a 70:30 ratio of poly(L-lactide-co-D,L-lactide); all implants were sterilized with e-beam radiation.

Ovine Laminectomy Model

The wool was clipped and the sheep were aseptically prepared for the dorsal (posterior) approach to the T-13 and L-2 vertebral laminae. A midline incision was made in the skin and subcutaneous tissues from T12–L3. The thoracolumbar and the fascia semispinalis, multifidus, and longissimus lumborum muscles were elevated from the dorsal spinous processes, laminae, and pedicles by using electrocautery, beginning at the caudal (inferior) aspect of T-12 and continuing to the cranial (superior) aspect of L-3 bilaterally. The dorsal spinous processes were removed from T-13 and L-2 by drilling through the base; these structures were detached with bone rongeurs. Dorsal laminectomies that extended between adjacent interarcuate spaces cranially and caudally and just medial to the articular facet joints bilaterally were performed using a compressed air drill and burr. The articular facet joints were left intact (Figs. 1–3).

Once the laminectomies were completed, the intervertebral discs of T13–L1 and L2–3 were incised and the nucleus pulposus was disrupted with an 18-gauge needle. A notch was made with bone rongeurs bilaterally in the pedicles at the middle of the laminectomy for later identification of an incision made into the dural and subarachnoid

Fig. 1. Schematic drawing of the dorsal aspect of the sheep spine from T12–L3. The defects in the bone represent the laminectomy sites. The dashed lines represent the dural defects. The facet joints remain intact.
space (durotomy) by an 18-gauge needle (Fig. 4). The durotomy was considered completed when CSF was observed leaking from the dura. The test material was then cut into an oval shape slightly larger than the laminectomy defect and inserted over the exposed spinal cord with the edges tucked beneath the vertebral laminae, resulting in direct contact of the film with the dura (Fig. 5). The control site was left untreated. Treatments were randomized among levels for all sheep. The thoracolumbar fascia, subcutaneous tissue, and skin were closed in a routine manner.

Analyses of Postoperative Healing

Myelography. At the end of the preassigned survival periods (10 weeks for six animals in the gross dissection group and 8 weeks for two animals in the histological evaluation group), the sheep were anesthetized according to the same protocol used for the surgical procedure. The wool between the external occipital protuberance and the dorsal spinous process was clipped. A cisternal CSF tap was performed using a 20-gauge, 1.5-in needle, and 30 ml of iodinated contrast mixed with 5 ml of new methylene blue dye was injected into the subarachnoid space in the cerebellomedullary cistern. New methylene blue dye was added to the contrast to allow visual observation of leakage at the dural incision site. The sheep were then placed in a sitting position to facilitate the flow of contrast material into the lumbar spine. Lateral and ventrodorsal postcontrast radiographs were obtained that included both laminectomy sites and were used to evaluate contrast leakage and a filling defect in the contrast column or lack of contrast flow in the CSF at the laminectomy sites. The sheep were killed with 20 ml pentobarbital after myelography was completed.

Postmortem Gross Observations. Immediately after the sheep were killed, a postmortem examination was performed to evaluate the gross extent of peridural fibrosis in six sheep (all from the 10-week survival period). The

Fig. 2. Schematic drawings of the cranial aspect of sheep L-2 vertebrae without laminectomy (left) and with dorsal laminectomy (right). The articular processes are not encroached on and the facet remains intact.

Fig. 3. Intraoperative photograph showing a dorsal view of the ovine laminectomy.

Fig. 4. Intraoperative photograph showing a durotomy created with an 18-gauge needle. The durotomy was considered completed when CSF was observed to leak from the incision.
spines were removed en bloc from T12–L3. The epaxial musculature was sharply dissected from the lateral and ventral aspects of the vertebrae. The musculature and postoperative fibrous tissue over the laminectomy site was left unaltered. The transverse processes were removed from the VBs with a bone rongeur and the VBs were incised with a band saw along the length of the column just ventrally (anteriorly) to the spinal canal, leaving a thin edge of bone covering the ventral (anterior) spinal cord. The remaining bone was removed with a bone rongeur to expose the spinal cord within the spinal canal. The spinal cord was slowly elevated and dissected from the spinal canal in a ventral (anterior) direction, and adhesion of the dorsal (anterior) spinal cord at the laminectomy sites was evaluated by the surgeon performing the dissection (A.S.T.) who was blinded to the treatment site (Fig. 6). The dissection was also videotaped for assessment by other evaluators (L.S.K., J.W.T., and W.C.W., who also worked in a blinded fashion). Scarring at the surgical sites was analyzed and graded by volume (extent) and the tenacity (severity) of adhesion to the dura mater.

**Histological Evaluation of Healing.** The spines of two sheep (both from the 8-week survival period) were removed en bloc from T12–L3, labeled, and frozen at −70°C before shipment for histological analysis (J.M.T.). High-resolution radiography as well as decalcified and undecalcified histological analyses were performed on the sheep spines. The surgical sites were first evaluated using high-resolution Faxitron imaging (Hewlett-Packard Co., McMinnville, OR) on special radiographic film (Ektascan M EM-1; Eastman Kodak, Rochester, NY). Using the resultant radiographs as guides, a coronal plane cut was made from the cranial to caudal direction through the most anterior aspect of the pedicle with an autopsy saw. This created a bone defect into the spinal canal. Next, the disc was cut through to the posterior margin; every attempt was made to avoid cutting into the spinal cord. On the left side, an angled cut was made with the autopsy saw on the anterior side of the transverse process; this cut extended into the canal space. Again, caution was exercised to avoid cutting the spinal cord. Finally, an osteotome was used to remove the anterior column, level by level. This left the transverse processes intact and the cord in the canal.

Using the radiograph as a guide, tissues superior and inferior to each laminectomy defect were trimmed with a band saw and discarded. In the coronal plane, each treated lamina was sectioned through the treated defect with a band saw to produce a superior and inferior block. Randomly, one half was fixed, labeled, and processed for use in histological studies of decalcified sections. The other half was fixed, labeled, and processed for use in histological studies of undecalcified sections and the corresponding microradiographic studies. Immediately after trimming, all specimens were placed in 10% neutral buffered formalin to fix them for histological studies.

Methyl methacrylate and paraffin-embedded blocks were sectioned and stained. Differential staining (H & E and Mallory–Heidenhain) and qualitative optical microscopy were performed to identify the type of tissue within the laminectomy defect according to treatment, to evaluate qualitatively the presence or absence of postoperative peridural scar adhesions according to treatment, and to determine the histological and cytological response of the host tissues to the implanted material. The small number of treated defects in each group was not amenable to statistical analysis.

**RESULTS**

**Myelography Findings**

Clinical neurological deficits were not observed in any of the sheep before termination of the study. Myelography was completed in all but one animal (Sheep No. 6), in which the contrast agent did not flow into the subarachnoid space at or past the laminectomy site. A second dose of contrast material was injected but did not result in flow into the regions of interest. It was speculated that arach-
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noiditis or fibrosis could cause the lack of flow, but this was not confirmed by performing computerized tomography scanning, which would be more sensitive to identifying minimal amounts of contrast in the subarachnoid space. Leakage of contrast material from the dural incision was not identified in any of the animals. Very subtle filling defects in the dorsal (posterior) contrast column were observed in two animals on lateral views. These were both found at control sites but were not considered radiographically significant by the evaluators.

**Observations at Gross Dissection**

All four evaluators of gross dissection (L.S.K., J.W.T., W.C.W., and A.S.T.) were blinded to the treatment and control sites. Each laminectomy site (treatment and control) was graded by the evaluators. We note that not all evaluators assigned scores to all levels and categories because of an inability to make a confident determination. The volume of scar adhesion was assigned a grade (range from 0–4: 0, no adhesions present; 1, < 25% of original laminectomy defect area affected; 2, ≥ 25% to < 50% of original laminectomy defect area affected; 3, ≥ 50% to < 75% of original laminectomy defect area affected; and 4, ≥ 75% to < 100% of original laminectomy defect area affected). Tenacity of scarring was also assigned a grade (range 0–4: 0, no adhesions present; 1, thin membranous threads, easily detachable; 2, slight adhesion, some blunt dissection required; 3, moderate adhesions, blunt dissection or some sharp dissection; and 4, tenacious adhesions, sharp dissection required). Results recorded by individual evaluators and the mean scores are presented in Tables 1 to 4. Scores for scar tenacity at the treated sites ranged from 0 to 3 (Table 1) with a mean score of 1.5, compared with scar tenacity scores at control sites that ranged from 1 to 4 with a mean score of 2.9 (Table 3). Scores for scar volume at the treated sites ranged from 0 to 3 (Table 2) with a mean score of 1.4, compared with scar volume scores at control sites that ranged from 0 to 4 with a mean score of 2.4 (Table 4). In general, there was a trend toward better agreement between the evaluators in scoring the scar tenacity than the scar volume. Nonparametric statistical analysis (sign test) was performed on the data; however, the small sample size did not yield statistical significance. Leakage of new methylene blue dye from the durotomy sites was not observed in any of the sheep.

In two animals (Sheep Nos. 3 and 6) small mounds of tissue were observed on the dura mater in one surgical site each. The spinal cords from these animals were fixed in 10% formalin and submitted for histological evaluation of these regions.

**Histological Analyses**

Transverse sections were made through the vertebral column and spinal cord at each laminectomy site in two sheep. A representative histological section for the untreated control laminectomy site is shown in Fig. 7, which provides an overall view of the laminectomy defect and the bioabsorbable film barrier. The mean scar tenacity score in six sheep is presented in Table 3.

### Table 1

Scar tenacity scores per evaluator in six sheep

<table>
<thead>
<tr>
<th>Sheep No.</th>
<th>Spinal Level</th>
<th>Tenacity Score (eval initials)</th>
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<tbody>
<tr>
<td></td>
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<td>LSK &amp; JWT</td>
</tr>
<tr>
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<td></td>
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<tr>
<td>2</td>
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<td></td>
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<tr>
<td>4</td>
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<td>2</td>
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<tr>
<td></td>
<td>thoracic</td>
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<tr>
<td>5</td>
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<tr>
<td></td>
<td>thoracic</td>
<td>3</td>
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<tr>
<td>6</td>
<td>lumbar</td>
<td>—</td>
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<tr>
<td></td>
<td>thoracic</td>
<td>3</td>
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</tbody>
</table>

* Evaluators worked in a blinded fashion. For explanation of scores see Observations at Gross Dissection. Abbreviations: eval = evaluator; — = not reported.

### Table 2

Scar volume scores per evaluator in six sheep

<table>
<thead>
<tr>
<th>Sheep No.</th>
<th>Spinal Level</th>
<th>Vol Score (eval initials)</th>
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<tr>
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<td>6</td>
<td>lumbar</td>
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<td></td>
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* Evaluators worked in a blinded fashion. For explanation of scores see Observations at Gross Dissection.

### Table 3

The mean scar tenacity score in six sheep

<table>
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<tr>
<th>Sheep No.</th>
<th>Film Implant</th>
<th>Control</th>
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<tr>
<td>6</td>
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<td>3.3</td>
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<tr>
<td>mean score</td>
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<td>2.9</td>
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the dural approximation to the scar tissue. The dura is apposed and distorted by its attachment to the fibrous scar tissue in the untreated control. A representative histological section for the polylactide film–treated site is shown in Fig. 8. The polylactide barrier was observed with the aid of polarized light in decalcified sections; it was present in a capsule between the dural and cicatricial tissue in the laminectomy defect. The dura is not directly apposed to the fibrous scar tissue.

The spinal cord tissues with soft-tissue mounds on the dura were processed and stained with H & E. The tissue mound found in Sheep No. 3 was located at the polylactide film–treated laminectomy site. On gross observation, a stiff, rigid adhesion measuring 2.5 cm × 1 to 2 mm was tethered to the spinal cord. Unlike a nerve, this was difficult to bend. The spinal cord was sampled at three locations. Photomicrographs published in a previous study revealed that polylactide polymer film can be seen with the aid of polarized light microscopy. In this case, remnants of polymer were observed with the aid of normal optical transmission microscopy and confirmed using polarized light microscopy. Histological images revealed remnants of polymer film along the length of tethered tissue (Fig. 9). The tethered tissue appeared to be a dense fibrous pan-

| Table 4  
The mean scar volume score in six sheep |
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<td>Control</td>
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<tr>
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<tr>
<td>mean score</td>
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<td>2.4</td>
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</table>

The mound of tissue from Sheep No. 6 was located at an untreated control laminectomy site; the tissue appearance resembled the dura mater. The spinal cord was sampled at two locations in axial sections. Histological studies revealed normal dura mater and normal nerve roots adjacent to the dura mater. A previous study has revealed that a “bumpiness” along the length of the spinal cord is observed as the nerve roots leave the dural sac. No polymer was found with the aid of polarized light and normal optical transmission microscopy in the submitted sample obtained in Sheep No. 6. No adhesions to the dura were

Fig. 7. Photomicrograph showing a decalcified transverse histological section cut through the untreated control laminectomy site in Sheep No. 7. The dura mater is distorted and apposed to the fibrous scar tissue at the laminectomy site (arrow). Mallory–Heidenhain stain.

Fig. 8. Photomicrograph showing a decalcified transverse histological section cut through the polylactide film–treated laminectomy site in Sheep No. 7. The dura mater is apposed to the spinal cord and there appears to be an encapsulated barrier between the spinal cord and fibrous scar tissue (arrow). Mallory–Heidenhain stain.

Fig. 9. Photomicrograph showing a section of the polylactide barrier adjacent to fibrous scar tissue. H & E, original magnification × 40.

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The use of the MacroPore polylactide film barrier in an ovine laminectomy model was shown in this and in previous studies to be efficacious as an antiadhesion barrier in spinal surgery. In addition, the polylactide film exhibits no apparent safety issues related to impairment of dural healing. In future studies, larger treatment groups are needed to investigate the statistical significance of the results. In addition, Gd-diethylenetriamine pentaacetic acid contrast material may offer additional insights by allowing us to assess peridural fibrosis in a noninvasive manner at different time points. Finally, the ovine spinal cord extends along the majority of the spinal column (ending near the L-7 vertebra); it may therefore be of interest to investigate the use of this material in the region of the cauda equina. This would allow researchers to study its effects on the nerve roots further while simulating human lumbar laminectomy.

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DISCUSSION

The MacroPore resorbable polylactide film is currently used in surgical scenarios to reinforce soft tissue, for temporary wound support, and to minimize soft-tissue attachments in the viscera. The biocompatibility of the polylactide film with both peripheral and spinal cord nervous tissue has been documented in previous studies.10,16,41,44,45,58,61

In our study we have primarily investigated the performance of the film in the presence of a large laminectomy defect combined with a dural defect. No compromised healing or CSF leaks were found in the sheep on myelographic and visual dye inspection at 8 and 10 weeks. This is significant because of concerns raised by the use of AD-CON-L (a spinal product no longer on the market); some researchers have suggested that impaired healing and persistent CSF leakage occurred after product placement in the spine. Data obtained in previous animal studies have indicated that the polylactide film is effective in reducing the volume and tenacity of peridural adhesions immediately adjacent to the dural surface.41,61 It has been postulated that the encapsulated polylactide film may act as a surgical dissection plane whereby the layer of organized fibrous tissue enveloping the material forms a controlled, identifiable dissection plane that allows adjacent tissues to be separated easily.61

Our findings indicate that in an ovine total laminectomy model the MacroPore polylactide film appears to decrease both the tenacity and volume of the peridural adhesions. This is further supported by results of histological analysis, which show decreased fibrous tissue attachments on the dural surface in the presence of the polymer barrier. These findings also corroborate what the authors of previous studies have reported to date for smaller animals as well as smaller surgical sites (laminotomies).41,61 Although our study’s results indicate a trend toward preventing dural adhesions with the use of a polylactide film barrier, the small number of animals did not yield statistical significance. It was noted that in the case in which the polymer film appeared to be totally encapsulated, intact, and tethered to the spinal cord (Sheep No. 3), the scar scores were highly favorable and histological studies revealed no inflammation.

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CONCLUSIONS

The use of the MacroPore polylactide film barrier in an ovine laminectomy model was shown in this and in previous studies to be efficacious as an antiadhesion barrier in spinal surgery. In addition, the polylactide film exhibits no apparent safety issues related to impairment of dural healing. In future studies, larger treatment groups are needed to investigate the statistical significance of the results. In addition, Gd-diethylenetriamine pentaacetic acid contrast material may offer additional insights by allowing us to assess peridural fibrosis in a noninvasive manner at different time points. Finally, the ovine spinal cord extends along the majority of the spinal column (ending near the L-7 vertebra); it may therefore be of interest to investigate the use of this material in the region of the cauda equina. This would allow researchers to study its effects on the nerve roots further while simulating human lumbar laminectomy.

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Manuscript received January 15, 2004.
Accepted in final form February 4, 2004.
Financial support for this research study was provided by MacroPore Biosurgery, Inc., San Diego, California.
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