Use of Polylactide Resorbable Film as an Adhesion Barrier

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Abstract

The present investigation evaluates two thicknesses of a resorbable polylactide barrier film as an adhesion barrier to posterior spine scar formation. A readily contourable, thin film was placed directly over the dura. The thick film was placed above the lamina defect to act as a physical barrier inhibiting the prolapse of soft tissue into the epidural space. Through a combination of gross dissection with and without scar scores, quantitative analysis of collagen adjacent to the scar site, and histologic evaluation, the resorbable adhesion barrier membranes were found to be effective treatment for reduction of posterior adhesions. The gross dissection demonstrated that both thicknesses of resorbable polymer barrier films created a controlled dissection plane, facilitated access to the epidural space, and provided a reduction in the tissue adhered to the dura.

Postoperative fibrosis is a natural consequence of surgical intervention. Peridural fibrosis has been hypothesized as a possible cause of failed back surgery syndrome because of recurrent pain assumed to result from fibrotic scarring, and possible restriction of mobility and tethering of nerve roots. In addition to neurologic compromise, dense scar formation on the dura increases the technical challenges in subsequent spine procedures. A variety of biologic, pharmacologic, and synthetic materials have been evaluated to address the issue of scar formation in the posterior spine. Rat, rabbit, and dog models were used to evaluate these various treatment strategies.

The present study evaluates the effectiveness of resorbable films to reduce adhesions in a large animal model. These films have the potential to reduce cellular infiltration, fibrocytic activity, and vascular invasion into the epidural space from overlying muscles and bone. Resorbable films can contribute to the formation of a dissection plane consisting of organized scarring, thereby facilitating subsequent surgical intervention. Unlike a gel, the action of the barrier film is confined to the location of placement.

Previous studies have evaluated hemostatic agents, anti-inflammatory drugs, radiation treatment, gels, and mechanical barriers to reduce the severity of posterior scar formation. LaRocca and MacNab investigated the effect of Gelfoam (Pharmacia, Piscataway, NJ/Upjohn, Kalamazoo, Mich), which is a resorbable gelatin foam sponge, and various silastic membranes as mechanical barriers to peridural fibrosis in a canine laminectomy model. They concluded that the principal source of the scar originated from the posterior fibrous tissue elements of the erector spinae muscle mass. Gelfoam acted as an effective mechanical barrier for reducing the laminectomy membrane adherent to the dura. However, Gelfoam was not found to be effective in other preclinical studies.

Jacobs et al examined three treatment modalities including hemostatic agents, anti-inflammatory drugs, and mechanical barriers in a canine model. The most effective adhesion barrier was determined to be the fat graft, which was classified as a mechanical barrier. However, clinical challenges

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have been observed including seroma formation and scar dimpling.\(^4\)

Several preclinical studies examined the use of resorbable gels for the reduction of peridural fibrosis.\(^5\) Posterior hemilaminectomies were performed at all operative levels, and deep annular injuries were administered. On gross examination, the volume and tenacity of epidural scar tissue were evaluated at the posterior and anterior margins of the epidural space. Levels treated with the Adcon-L gel (Gliatech Inc, Cleveland, Ohio) demonstrated a statistically significant reduction in scar. The levels were quantified by a score of 0 to 3. Histological evaluation showed no impediment to healing from the application of the Adcon-L gel. Although the gel had been used successfully in some studies,\(^24\) in a large patient-oriented study, there was no difference between the use of Adcon-L and controls.\(^25\) There have been reported complications of spontaneous postoperative cerebrospinal fluid leaks.\(^26,27\)

Gerszten et al\(^9\) examined the effect of low-dose radiation treatment in a canine model. One-time preoperative exposure to a 700-cGy dose of external beam radiation inhibited the formation of epidural scar formation at the treated hemilaminectomy site, as compared to control sites with either no exposure to radiation or exposure to the radiation dose but without surgery. A statistically significant reduction in the extent and density of sublaminar fibrosis was observed at the treatment levels. Clinical use of this technique requires careful consideration of the potential adverse effects of radiation exposure.

Several studies have examined different mechanical barriers for the prevention of postlaminectomy scar formation; Lee and Alexander\(^7\) examined a polyactic acid (PLA) foam in a canine model. In the study, the most effective reduction in posterior scarring was observed with a thick posterior convex polyactide membrane and a marginal gap filler.

In another investigation that focused on mechanical barriers, Lawson et al\(^7\) found that mechanical isolation of the epidural space from the posterior soft tissue reduces the volume and adherence of resulting epidural scar formation. Researchers used a canine model to compare several treatment groups, including complete closure of a laminectomy defect with a nonpermeable barrier and placement of Gelfoam with an unrepaired control. Among the mechanical barriers evaluated for repair of the defect (autologous bone, PMMA, and Teflon-Proplast), autologous bone was identified as most effective in limiting the formation of adherent epidural scar tissue.

Preliminary studies in a rat model demonstrated significant reduction of the peridural scarring using a resorbable film. Massie et al\(^16\) compared the effect of several agents in their rat model: anti-adhesive gel (Adcon-L); high molecular weight hyaluronic acid gel (Healon, Pharmacia, Uppsala, Sweden); and a resorbable barrier film composed of 70/30 poly L lactide-co-D,L-lactide (70/30 D.L-PLA), 0.2-mm thick (MacroPore Biosurgery Inc, San Diego, Calif). A complete laminectomy was performed at levels L5 and L6 exposing the cauda equina. A controlled disk injury was created at disk L3-L4. The animals were sacrificed after a 3-week survival period. Biochemical analysis was used to compare the various treatment groups to normal controls (without surgery) and an untreated laminectomy group.

Following dissection, consistently sized sections of the nerve roots, dura, and attached scar tissue were excised. The samples were processed to determine the amount of collagen in the fat-free dry tissue. The amount of collagen has been related to the amount of scar tissue.\(^16\) Results demonstrated that the resorbable polymer barrier film significantly reduced the amount of total collagen in the dura. The outcome of this rat study prompted additional studies in larger animal models to further evaluate safety and efficacy of the resorbable polymer barrier film.

The current investigation evaluates two different thicknesses (0.02 mm and 0.2 mm) of the resorbable barrier film with different surgical placement techniques. The rationale for the thin film is that it is readily controllable and may be placed adjacent to the dura (inferior to the lamina) or in a laminectomy defect to prevent the regrowth of bone. The rationale for the thicker film is to act as a physical barrier to reduce the prolapse of soft tissue into the epidural space through the laminectomy defect. Because of different surgical techniques used in spinal surgery and anatomic differences between ovine and canine models, a laminotomy with

<table>
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<th>Sheep No.</th>
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<th>L5</th>
<th>L6</th>
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<td>Unoperated Normal</td>
<td>Biochemical/Gross Dissection</td>
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<td>Unoperated Normal</td>
<td>Biochemical/Gross Dissection</td>
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</table>

Abbreviation: TS=thin sheet.
no disk injury was used in an ovine model and a partial hemilaminectomy with a disk injury was used in a canine model.

All evaluations were blinded and consisted of gross dissection, quantitative evaluation of the amount of collagen adherent to the dura, or graded adhesion tenacity scale. Histologic evaluation of the two film placement strategies around the epidural space was performed in the ovine model. The goals of the histologic evaluation were to identify the type of tissue within the laminotomy defect by treatment, quantitatively evaluate the presence or absence of postoperative peridural scar adhesions by treatment, and determine the histological and cytological response to the material using a qualitative and quantitative standard technique. Cellular response was assessed to determine the type and degree of inflammatory character and presence or absence of an immune component.

**Materials and Methods**

An ovine model and a canine model were used to evaluate the implant materials. Both studies had uniform survival times of 12 weeks. In each of the studies, two resorbable polymer barrier films were evaluated: a 0.02-mm (20 μm) thin film placed adjacent to the dura (Figure 1) and a 0.2-mm (200 μm) thick film placed above the lamina (Figure 2). Both films were solid, with no pores, and were fabricated of poly L-lactide-co-D,L-lactide (Hydrosorb TS, MacroPore Biosurgery Inc, San Diego, Calif). All implants were sterilized by electron-beam sterilization.

**Ovine Unilateral Laminotomy Model**

Six sheep were used in this portion of the study, which had a 12-week survival period. Approval for the sheep surgeries was granted by the Colorado State University Animal Care and Use Committee (ACUC protocol #98-240-01). Colorado State University complies with the US Department of Agriculture regulations promulgated under the authority of Animal Welfare Act and those of the US Public Health Service Policy on Laboratory Animal Care as provided in the Health Research Extension Act. In addition, the program complies with recommendations of the American College of Laboratory Animal Medicine and the Public Health Service “Guide for the Care and Use of Laboratory Animals.” Each animal had unilateral laminotomies performed on the left side at three lumbar levels with three randomly applied treatment groups (Table 1), which allowed both intra- and intraoperative comparisons.

Animals were fasted for 24 hours before surgery. Water was not restricted during this time. Anesthesia was induced with ketalar (4 mg/kg) and diazepam (7.5 mg total). After induction, sheep were maintained on isoflurane (1.5%-3%) in 100% oxygen (2 L/min) during the surgical procedure. Muscle relaxants were not used. Uniform laminotomy windows were created on the left side of the spine measuring 5 mm×10 mm at three lumbar locations L4, L5, and L6 (Figure 3). The cortical shell was removed using Medtronic MidaS Rex (Medtronic, Dallas, Tex), a high speed cutting instrument. The laminotomy window was completed with a Kerrison rongeur. None of the sheep experienced disruption to the spinal cord or disk injury.

Treatments were randomized among levels for all sheep. The 0.02-mm film was tucked under the laminotomy edges and placed directly on the dura. The 0.2-mm film was placed over the laminotomy window and heat-sealed to the bony edges using bipolar cautery to stabilize the position of the film relative to the bone. This mode of fixation is different from the physical fixation using resorbable tacks (Figure 2). All treatments were followed by routine closure of the fascia, muscle, and skin. Pain medication after the surgical procedures included fentanyl patches at a dose of 150 μg/h administered with a continuous percutaneous patch for 3 days. Additional pain medication included phenylbutazone at a dose of 1 g administered orally once per day.
for 3 days. All animals were euthanized 12 weeks after surgery.

Gross dissection and biochemical analyses were performed on three of the six study animals. All dissections were made with the observer blinded to the treatment group; however, when the dissection approached the dura, the barrier sheets became evident. The specimens were frozen at −70°C and cut grossly with a dissection band saw to remove the right side of the spine. Care was taken not to disrupt the left side of the spinal cord and particularly the dura adjacent to the laminotomy window. The cord was frozen and mostly removed except for the dura adjacent to the bone of the posterior spinal canal.

Observations were recorded during careful dissection from posterior to anterior, outside the spinal canal. Observations were also recorded during the removal of the spinal cord dura for assessment of the tenacity of dural adhesions through the laminotomy defect; this dissection represents a different anatomic perspective from anterior to posterior.

A consistent amount of dura was obtained from each specimen adjacent to the laminotomy window (6 mm in width, medial to lateral, × 15 mm in length, cranial to caudal). Additionally, any scar tissue attached to the posterior dura and any tissues within the laminotomy window were removed to be included in the biochemical analysis.

A fourth lumbar level with no laminotomy or treatment was used as an unoperated normal in the biochemical analysis. The samples were analyzed biochemically by extracting the fat and obtaining the dry weight of the tissue. The dry tissue was then ground and an average of 2.9 mg of tissue was used for hydrolysis by hydrochloric acid to determine the total amount of collagen from the hydroxyproline content. The total amount of collagen was expressed in milligrams of fat-free dry tissue.

High-resolution radiography, as well as decalcified and undecalcified histology analyses, was performed on the remaining three of six sheep. The surgical sites were first evaluated with high-resolution Faxistron (Hewlett-Packard, McMinville, Ore) radiograph film (Ektascan M EM-1, Eastman-Kodak, Rochester, NY).

Using the resultant radiographs, the investigators prepared the specimens by making a coronal plane cut from cranial to caudal through the most anterior aspect of the pedicle with an autopsy saw. This created a bony defect into the spinal canal. Next, the disk 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. The cut extended into the canal space. 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, the cord in the canal, and the right lamina as a control.

After the dissection, high-resolution radiography was performed to localize the laminotomy defects and evaluate the presence or absence of bony exostoses, or outward projecting bony growths, adjacent to the laminotomy defect by treatment. Using this radiograph, tissues superior and inferior to each laminotomy 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 decalcified histology. The other half was fixed, labeled, and processed for undecalcified histology and corresponding microradiographs. Immediately after trimming, all specimens were placed in 10% neutral buffered formalin to fix the specimens for histological studies.

Methylmethacrylate and paraffin-embedded blocks were sectioned and stained. Differential staining and qualitative optical microscopy were performed to identify the type of tissue within the laminotomy defect by treatment, to qualitatively evaluate the presence or absence of postoperative peridural scar adhesions by treatment, and to determine the histological and cytological response of the host tissues to the implant material. The small number (N=3) of treated lamina in each group was not amenable to statistical analysis. The stains included both hematoxylin and eosin and Mallory-Heidenhain.

**Canine Hemilaminectomy Model**

A total of six purpose-bred dogs were used. Three dogs were used to study the effect of a thin (0.02 mm) resorbable polymer barrier film. Three dogs were used to study the effect of a thick (0.2 mm) resorbable polymer barrier film placed above the lamina. The study was approved by University of Pittsburgh IACUC committee (protocol #011061).

The animals were positioned prone for access to the dorsal lumbar region. Separate incisions were made for each of two operated levels. Anesthesia was induced with sodium thiopental (25 mg/kg) and maintained under isoflurane 1.5% to 3.0% in 70% nitrous oxide.

**TABLE 2**

**Canine Hemilaminectomy: Study Design**

<table>
<thead>
<tr>
<th>Dog</th>
<th>Treatment L2-L3</th>
<th>Treatment L6-L7</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
<tr>
<td>D2</td>
<td>None</td>
<td>Thin barrier film 0.02 mm</td>
</tr>
<tr>
<td>D3</td>
<td>None</td>
<td>Thick barrier film 0.2 mm</td>
</tr>
<tr>
<td>D4</td>
<td>Thin barrier film 0.02 mm</td>
<td>None</td>
</tr>
<tr>
<td>D5</td>
<td>None</td>
<td>Thin barrier film 0.02 mm</td>
</tr>
<tr>
<td>D6</td>
<td>None</td>
<td>Thick barrier film 0.2 mm</td>
</tr>
</tbody>
</table>
and 30% oxygen. Intraoperatively, the dogs received 500 mg cefazolin. Partial hemilaminectomies were performed over L2-L3 and L6-L7 on the left side using a high-speed cutting tool (Medtronic Midas Rex) and finished with Kerrison-Rongeur hand instruments; the dorsal spinous processes were left intact at all operated levels.

A disk injury was created at each level by carefully displacing the cauda equina or spinal cord and inserting a Penfield 4 probe into the intervertebral disk; the probe was manipulated to ensure disruption of the nucleus pulposus. One of three treatments was applied (Table 2). Treatment “none” had no material applied to the surgical site and is considered the control.

Treatment with a 0.02-mm thick barrier film involved placement of the film directly onto the dura and attempting to tuck excess material into the foramen over the exiting nerve root. Treatment with a 0.2-mm thick barrier film involved placement of the film over the partial hemilaminectomy defect followed by fixation with a single resorbable tack (Medtronic NT, Goleta, Calif). A 1.5-mm hole was prepared through the 0.2-mm film into the superior portion of the lamina (Figure 2), followed by insertion of the 1.5-mm diameter tack. All treatments were completed by routine closure of the fascia, muscle, and skin.

Postoperative pain medication included butorphanol 0.1 mg, three times daily for 3 days postoperative.

All animals were euthanized after 12 weeks. Gross analysis of the scarring at the operative sites was performed to evaluate both the volume of the scarring and the tenacity of the scar tissue present. The posterior (laminectomy site) and anterior (epidural space) sites were evaluated and scored separately.

**RESULTS**

**Ovine Laminotomy Model — Gross Dissection and Biochemistry**

One of the three untreated controls demonstrated a complete bony regrowth at the area of laminotomy window. All three of the posterior scars appeared extremely dense (Figure 4A). In all three instances of the untreated control, the dura tenaciously adhered to the laminotomy window (Figure 4B).

None of the three sections from the 0.02-mm film specimens demonstrated bony regrowth at the area of the laminotomy window. All three of the specimens had dense posterior scars dorsal to the barrier film and similar to that observed in the 0.2-mm film specimens. The dura was relatively easy to remove from the laminotomy window in all three specimens (Figure 5A). Once the dense posterior scar was removed, it was easier to access the epidural space because of the interface with the thin film creating a dissection plane. The 0.02-mm film was encapsulated and slightly adherent to the dura but can be easily removed (Figure 5B). A thin, organized membranous tissue was observed on the edges of the rongeured bone. The mass and dura were slightly attached posteriorly but were removed with relatively little effort and no subsequent damage to the dura.

One of the three 0.2-mm film specimens demonstrated a bony fusion at the laminotomy window. All three of the specimens had posterior scars, which appeared dense, but were relatively easy to remove from the barrier film (Figure 6A). In two of three instances, the dura was easy to remove from the hemilaminotomy window. An identifiable plane existed at the level of the resorbable polymer film and the soft tissue above and below this plane was easily displaced. The third specimen
was only slightly more difficult to remove, and it appeared as if the barrier film had shifted slightly, exposing a space for scar tissue to migrate from the dorsal region to the epidural space.

The total collagen was calculated from the dry weight and through biochemical analysis for each of the treatment groups of the three animals (Figure 7). Although the sample sizes for the study groups were too small for statistical analysis, there were notable differences among the normal, untreated, and film treatment groups. The average amount of collagen for the normal specimens was 4.5 g, whereas the average amount of collagen for the untreated group was 23.7 g.

The amount of collagen for the two groups treated with the resorbable barrier films was 12.1 g for the 0.02-mm thick film placed on the dura and 12.4 g for the 0.2-mm film placed dorsal to the lamina. There was a considerable reduction in the total collagen, ranging from 43%-50%, for both the 0.02-mm film and 0.2-mm film group samples as compared to the untreated samples. There was no difference in the total collagen measurements when comparing the two film groups.

**Ovine Laminotomy Model — Histology**

Only one hemilaminotomy defect out of nine defects in this study showed neural adhesions to the dura (14 superior, 0.2 TS). Epidural fat adjacent to the dura was consistent in all other levels. Many of the spinal cords and attached dura pulled away from the epidural fat during tissue handling and processing, especially at the treated levels. In addition to the histology, this is direct evidence that adhesions did not occur at these levels.

Representative histologic images for the untreated control specimens are shown in Figure 8. Figure 8A provides an overall view of the untreated level with fibrous scar tissue in the laminotomy defect. Figure 8B provides a higher magnification of the thick, unorganized scar within the defect. For the specimens treated with the 0.02-mm film adjacent to the dura, the overall view is illustrated in Figure 9A. Figure 9B provides a higher magnification image of the resorbable PLA film within the laminotomy defect encapsulated with fibrous tissue. Figure 10A provides an overall image of a specimen treated with the 0.2-mm barrier film placed dorsal to the lamina. A higher magnification image of the smooth, organized
fibrous tissue layer encapsulating the barrier film is shown in Figure 10B.

ASTM F981-99 standard was used to quantify the cytological response to the implanted material at the 12-week survival period in sheep. The results ranged from 0 to 1.0 for all inflammatory cells at the levels treated with the resorbable implants, using a scale ranging from 0 to 3.0. A minimal chronic inflammatory response typically consisting of macrophages and foreign body giant cells was observed adjacent to both adhesion barrier sheets. The host response did not vary with the thickness of the sheet. There was neither a humoral nor cell-mediated immune response (no plasma cells, eosinophils, and few lymphocytes).

Exostoses were observed adjacent to the left lamina, the spinous process, and the facets in four of nine sheep. The presence or absence of bony exostoses did not correlate with treatment, but correlated with the animal treated. For example, none of the three defects in sheep 15 had exostoses, regardless of treatment. One of the three defects (sheep 13, midlevel, untreated control) that had associated exostoses received no experimental adhesion barrier membrane. Sheep 14, superior level, 0.2-mm barrier film had exostoses adjacent to the membrane. Sheep 13, inferior level, 0.2-mm barrier film, had exostoses that were not adjacent to the membrane. In the level with 0.02 TS (Sheep 13, midlevel), exostoses were not found near the experimental membrane. All exostoses in this study were found above the periosteum of the bony cortex adjacent to the laminotomy, the spinous process, and the left facet joint.

**Canine Hemilaminectomy Model — Gross Dissection**

One dog displayed a classic radiculopathic syndrome characterized by hypertension of the hind limbs at 2 days postoperative. It was successfully treated with a large dose of steroids including methylprednisolone and dexamethasone for 5 days. The dog was fully ambulatory 3 days post-treatment.

For the animals treated with the 0.02-mm thick barrier film, scores of the volume of scar at the control sites (no treatment) ranged from 1 to 2 in the anterior (disk injury) and posterior (laminectomy) locations. All sites treated with the 0.02-mm barrier film had anterior (disk injury) volume scores of 1; scar volume scores at the posterior sites were nearly identical to the control sites. Similar results were observed for the scar tenacity scores. All results are shown in Table 3.

For the animals treated with the 0.2-mm thick barrier film placed over the laminectomy sites, scores of the volume of scar at the control sites (no treatment) ranged from 1 to 2 in the anterior (disk injury) location and from 2 to 3 in the posterior (laminectomy) location. All sites treated with the 0.2-mm barrier film had anterior (disk injury) volume scores of 1; scar volume scores at the posterior sites were nearly identical to the control sites. Similar results were observed for the scar tenacity scores. All results are shown in Table 4.

The most notable differences between the treated and control groups were found in the 0.02-mm film anterior tenacity scores and the 0.02-mm film...
TABLE 3
Canine Hemilaminectomy: Scar Volume Scoring Results

<table>
<thead>
<tr>
<th>Dog</th>
<th>Control Anterior</th>
<th>Control Posterior</th>
<th>0.02 Film Anterior</th>
<th>0.02 Film Posterior</th>
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TABLE 4
Canine Hemilaminectomy: Scar Tenacity Scoring Results

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anterior volume scores. These values were not significant (Wilcoxon signed ranks test, all P > 0.05).

**DISCUSSION**

The biocompatibility of PLA adjacent to dural and peripheral nerve tissues has been documented in several previous studies suggesting that the resorbable polymer material is biocompatible in the vicinity of the dura.30-34 Also, peripheral nerves have been shown to grow through tubes of resorbable PLA.30-32 The degradation of large amounts (20 g) of PLA has been shown to increase blood lactate levels by 0.2 mM/L. This represents <7% of the 3 mM/L lactate during exercise, while having no effect on pH.35,36

The mechanical properties of the film were characterized prior to implantation through in vitro aging according to ASTM standard.37 The goal of the testing was to evaluate whether the materials would be present and maintain their properties beyond the critical healing times of 6 to 12 weeks.

Earlier preclinical studies examined the concept of a physical barrier to prevent postoperative adhesions. As Lawson et al.38 state, "It is concluded that lamina repair with a solid material covering exposed dura significantly reduces the formation of posterior laminectomy scar." They further concluded that, "The idea of an absorbable material that the body will remove or degrade later has a strong attraction in spinal surgery for covering the dura.39 The early results using the 0.2-mm thick film over a complete laminectomy in rats were reported by Massie et al.16"

A summary of the quantitative analysis of scar formation directly attached to the dura is shown in Figure 11. With eight to 10 animals per study group, the results were reported to be statistically significant. The amount of collagen associated with the dura was measured to be almost three times higher in untreated laminectomy defects (3.4 mg) compared with unoperated controls (1.3 mg). Application of two gels including Adcon-L and a high molecular weight hyaluronic acid reduced the scarring significantly to 2.0 mg and 1.8 mg, respectively. Protection of the epidural space with a 0.2-mm thick barrier of the resorbable poly-L-DL-lactide (MacroPore) further reduced the amount of collagen to within normal values (1.0 mg), which was less than normal in untreated control samples (1.3 mg). The difference was not statistically significant.

The gross dissection in both the ovine and the canine studies provided valuable insight concerning the relative tenacity of the adhesions. In the canine study, the scar score results demonstrated the films to be effective in reducing the volume and tenacity of the anterior scar — adjacent to the dura — although the differences were not statistically significant in the sample sizes studied. It was further observed that once the barrier film had been reached through the dense posterior scar, a
distinguishable dissection plane was present. This controlled dissection plane is speculated to contribute to the lower scar volume and scar tenacity scores observed anterior to the film. In the ovine study, the biochemical analysis provided quantitative evidence of the adhesion reduction observed qualitatively with the gross dissection.

The two resorbable barrier treatment groups demonstrated less tissue adherence to the dura compared to the untreated control. The thin 0.02-mm barrier film was observed to be folded in all three histologic specimens (Figure 9B). It is suspected that the material is folded within the encapsulated mass removed from the laminotomy defect (Figure 5). The thick 0.2-mm barrier film placed dorsal to the lamina appeared to form a smoother, more organized layer of fibrous tissue. Both barrier films appeared to be effective in reducing scar on the anterior side adjacent to the epidural space through a mechanism of organized fibrous tissue encapsulation which created a controlled dissection plane. The total collagen was believed to be associated with the degree of scarring and these quantitative values correlate with the general observations made during careful gross dissections.

With regard to the histologic analysis, this time period permits only a glimpse of the dynamic host response to the material. In addition, the host response observed clinically may be different from what was observed in sheep, which was considered very mild. The host response was observed to be milder than experience observed upon examining resorbable sutures. Moreover, clinical experience with the specific amorphous 70/30 D,L-Pla has been favorable. Most likely, exostoses found in the ovine study were the result of surgical trauma to the periosteum that resulted in reactive bone formation and not related to the implanted membrane. In addition, the extent of bony regrowth of the laminotomy defect did not seem to correlate with treatment. A future study can involve periosteal stripping of the right lamina, without creating a defect, to further investigate this observation.

The study has several limitations including small sample sizes and technique challenges in each of the groups. The size of the spinal defects in the current study was smaller than in most of the historical literature; past studies examined complete laminectomies rather than hemilaminectomies or laminotomy windows. It is speculated that there may have been improved reductions using the 0.2-mm barrier film above the lamina with a more secure attachment mechanism in the ovine study.

In two of six sites of which 0.2-mm barrier film was used, it appeared as if the film may have translated over the hemilaminotomy window allowing scar tissue to migrate underneath into the epidural space. This was observed once in gross dissection and once upon histological examination. For the 0.02-mm thin barrier film, the implants may not have been effectively tucked underneath the lamina to create an improved barrier.

**SUMMARY**

Through a combination of gross dissection with and without scar scores, quantitative analysis of collagen adjacent to the scar site, and histologic evaluation, researchers found resorbable adhesion barrier films to be a moderately effective treatment for the reduction of posterior adhesions while posing minimal safety issues relative to host response. The gross dissection portion of the studies demonstrated that both thicknesses of resorbable polymer barrier films created a controlled dissection plane, facilitating access to the epidural space and providing a reduction in tissue adherence to the dura.

**REFERENCES**


