A Comparison of the Effectiveness of Adcon-L® and Medishield® for the Prevention of Adhesions in a Rabbit Laminectomy Model

James T. Robertson, M.D., Jon P. Moseley, Ph.D., Warren E. Haggard, Ph.D., and Jill Soble-Smith
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Introduction

Dural scarring after laminectomy has long been known as a cause of post-operative pain in a high percentage of surgical cases. Although many treatment modalities have been used in an effort to prevent or reduce adhesions, most have not been effective.

This study was designed to compare the efficacy of two commercially available products for prevention of dural adhesions. Adcon®-L (Wright Medical Technologies, Inc.) is a gel derived from porcine collagen and Dextran Sulfate. Medishield® gel, also sold as Oxiplex® gel (Fziomed Inc., San Luis Obispo, CA), is comprised of carboxy methyl cellulose and polyethylene oxide.[1] Both products are indicated for use following spinal procedures such as laminectomy and nerve root decompression.

Materials and Methods

Nineteen adult New Zealand White Rabbits were utilized in the study. Each animal had three lumbar laminectomies performed with a vertebra left intact between sites. Laminectomies were approximately 10mm long by 5 mm wide. After achieving hemostasis, one site was treated with Adcon®-L, one with Medishield®, and the third was irrigated with saline. Both treatments were applied according to the instructions for use, coating the dura up to the level of the ventral lamina (approximately 0.4 – 0.5 ml). The order of application was randomized within each subject but the levels receiving each treatment were rotated according to a pre-determined schedule in order to reduce or eliminate bias. The wounds were then closed in three layers.

Four weeks +/- 3 days after surgery, the animals were euthanized by IV overdose of pentobarbital. The laminectomy sites were exposed by careful dissection and evaluated for both extent and tenacity of surgical adhesions according to the following system. The evaluator was blinded as to the treatment received by each site. The adhesion score is the sum of the extent score and the tenacity score (Maximum=6).

Six spinal cords were removed for and are undergoing histological analysis. These six were chosen randomly prior to retrieval.

Table 1. **Adhesion scoring system**

Score	Extent*	Tenacity
0	No adhesions	No adhesions
1	< 25%	thin, non-adherent
2	25%-75%	blunt dissection required
3	75%-100%	sharp dissection required

***** Extent refers to the percentage of the original laminectomy area covered with scar tissue.

Adhesion Score = Extent Score + Tenacity Score (e.g. If Extent = 15%, Tenacity =1, then AS = 2)

Results

The summary statistsics for total adhesion scores are shown in Figure 1. For Adcon-L®, 14 of 19 sites (74%) had no observable adhesions and only 2 animals (10%) exhibited scar formation of sufficient extent to be considered clinically relevant. In contrast, the Medishield® and the control groups both showed significantly higher numbers of sites with extensive scarring, with over half of the sites

yielding adhesion scores of 4 or higher. Statistical analysis (non-parametric, Friedman's test) confirm that the Adcon-L group scores were significantly lower than both the Medishield and the Saline ($p = 0.0006$). The Medishield treatment was not significantly different from the saline controls ($p = 0.65$) Representative photographs showing sites with median and maximum scores for each treatment are shown in Figures 2. through 7.

The majority of the wounds in all sites were well healed at four weeks post-surgery. However, there were four animals (20%) in which the surgically incised deep muscle immediately above the laminectomy treated with Adcon®-L failed to reattach completely at 28 days, resulting in a pocket approximately 1 cm deep as shown in Figure 8. This phenomenon was not observed in the sites treated with Medishield® or in the saline controls.

Figure 1. Percentage of Sites with Adhesion Scores of 0 to 1

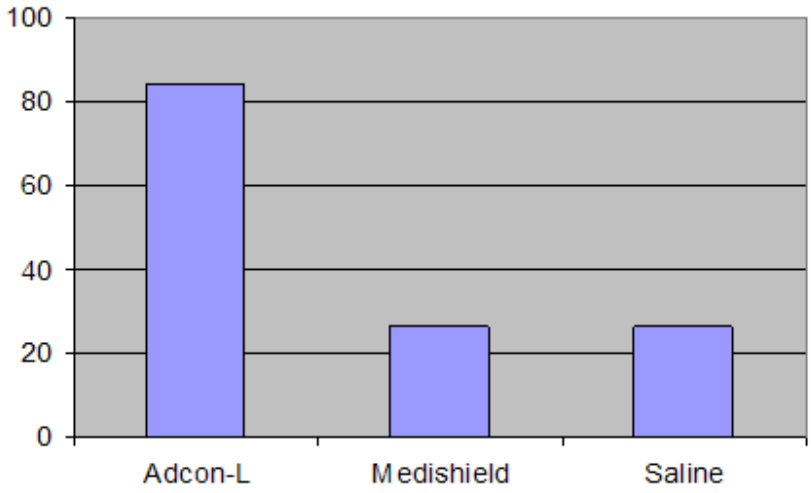
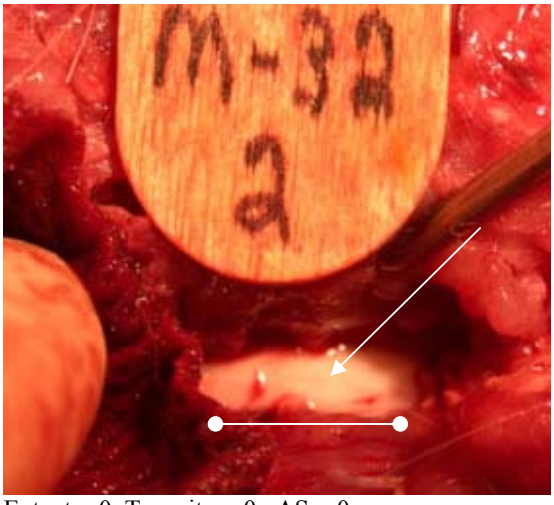


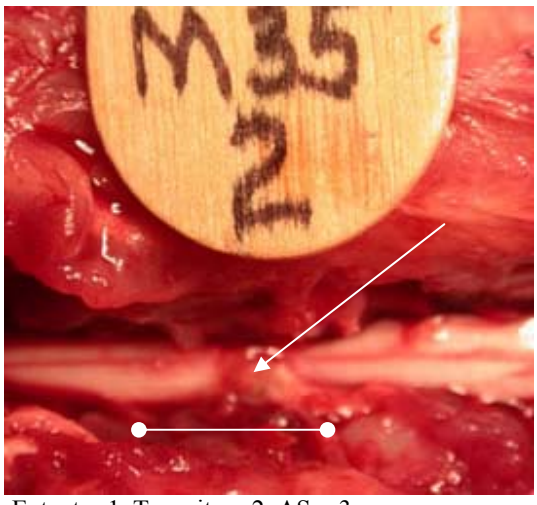
Figure 2. Adcon-L treated site Median score



Extent = 0, Tenacity = 0, AS = 0
Bar = laminectomy site (11 mm), Arrow = Cord

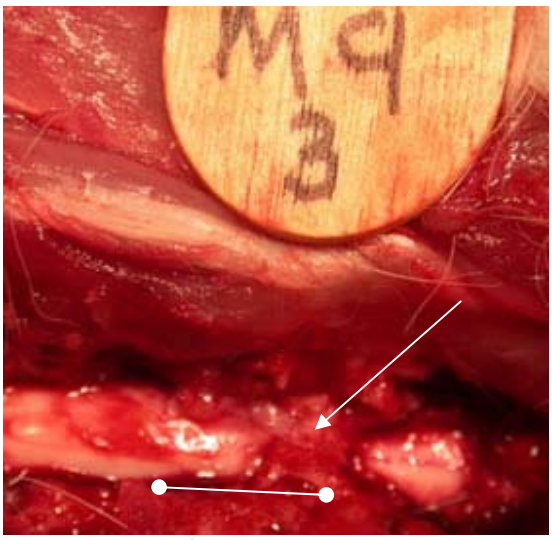
Figure 4. Medishield Treated Site Median Score

Figure 3. Adcon-L treated site highest score



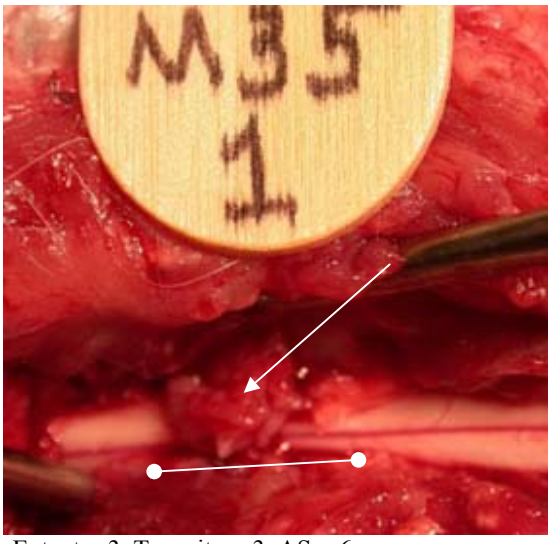
Extent = 1, Tenacity = 2, AS = 3
Bar = laminectomy site (10 mm), Arrow = Scar

Figure 5. Medishield Treated Site Highest Score



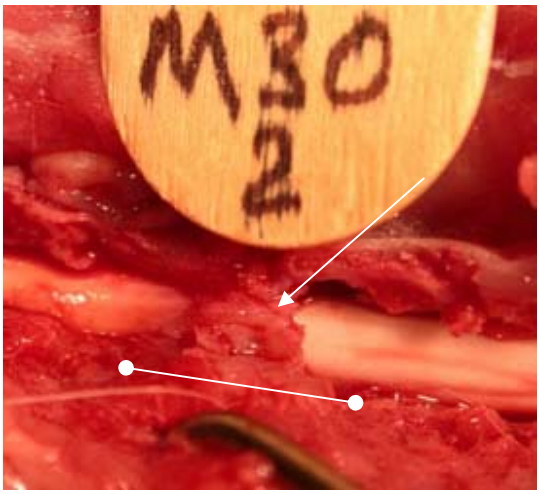
Extent = 2, Tenacity = 2, AS = 4
Bar = laminectomy site (9 mm), Arrow = Scar

Figure 6. Saline Control Median Score

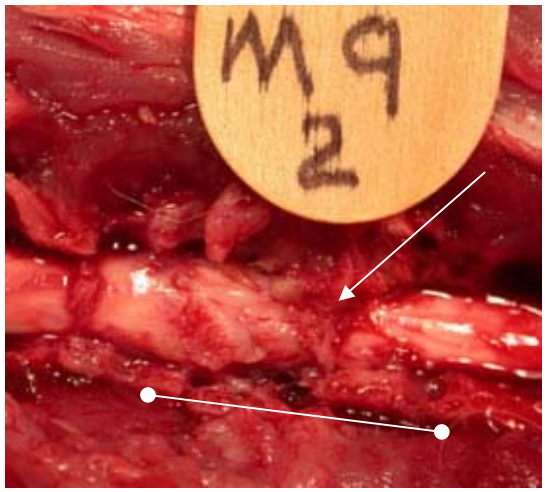


Extent = 3, Tenacity = 3, AS = 6
Bar = laminectomy site (11 mm), Arrow = Scar

Figure 7. Saline Control Highest Score



Extent = 2, Tenacity = 2, AS = 4
Bar = laminectomy site (11 mm), Arrow = Scar

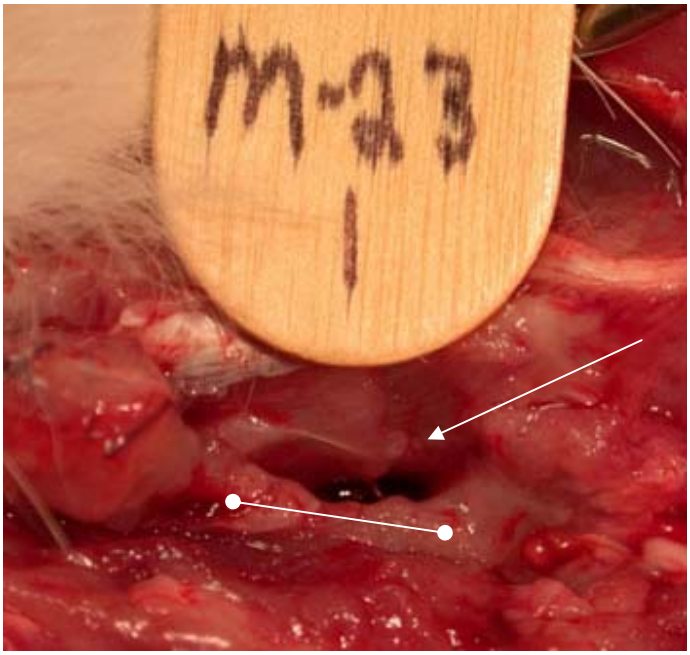


Extent = 3, Tenacity = 3, AS = 6
Bar = laminectomy site (12 mm), Arrow = Scar

Figure 8. Site Treated with Adcon-L Showing Incomplete Healing of the Deep Muscle (arrow)

Discussion and Conclusions

The results of this study clearly show that Adcon-L® is effective in reducing both the incidence rate and the severity of dural adhesions in a well established pre-clinical model. Medishield® (aka Oxiplex® gel) was not effective in this study, with a distribution of adhesion scores that was virtually identical to that found for untreated laminectomy sites. These findings are in marked contrast to recent study using a similar rabbit model by Berg et al., which reported opposite results[1]. This contradictory



Bar = 10 mm

finding may be explained in part by the differing methods of analysis. In the Berg study, the adhesions were evaluated from histological specimens which are by nature limited to a subset of the laminectomy site. It is also debatable as to whether the tenacity of an adhesion may be evaluated with any reliability by this method. While this may explain the low scores found in their study for the Medishield® product, it does not resolve the difference for the Adcon®-L material. Given the very low incidence of adhesions found in both the present study and in previous studies[2,3] for Adcon®-L, the histological analysis should at the least have resulted in a finding of equal effectiveness. There may also have been differences between the two studies in the amount of material used, but this detail was not reported by Berg.

The fact that the deep muscle layers failed to completely reattach at 28 days in 20% of the sites treated with Adcon-L® was not unexpected based on the lead author's previous experience. Apparently a portion of the gel either migrated or was inadvertently placed in contact with one of the muscle surfaces during application to the site. In essence the gel performed its intended function on an unintended tissue. While the incompletely attached muscle did not cause any functional problems with the animals in this study, this might not always be the case. It may be prudent to use deep sutures to close the muscle layers immediately above the laminectomy site to help ensure proper healing. This finding also stresses the importance of both careful placement of the gel and the need to use only enough material to completely coat the dura.

References

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2. Einhaus, S.L., Robertson, J.T., Dohan, F.C., Wujek, J.R., and Ahmad, S., *Reduction of Peridural Fibrosis After Lumbar Laminotomy and Discectomy in Dogs by a Resorbable Gel(Adcon-L),* Spine, 22, 1440-1446, 1997

3. Robertson, J.T., Maier, K., Anderson, R.W., Mule, J.L., and Palatinsky, E.A., *Prevention of epidural fibrosis with Adcon-L in presence of a durotomy during lumbar disc surgery: Experiences with a pre-clinical model,* Neurological Research, 21,S61-S66, 1999