

Peri-Radicular Fibrosis After Lumbar Surgery: Is There Any Help?

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Abstract

Study Design: This study was based on Clinical Trial medical records from the Valencia University General Hospital (Hospital General Universitario de Valencia), Spain. The study population consisted of patients who underwent spinal surgery and who had documented follow-up visits for at least 2 years afterwards.

Objective: The primary objective of this study was to evaluate re-operation rates in spinal surgery patients treated with SuproFilm Layer Matrix as compared to similar patients given standard treatment (without SLM).

Background: Dural adhesions resulting from peridural fibrosis can cause persistent pain and may lead to re-operation. There is a need for treatments that prevent dural adhesions and minimize the impact of peridural fibrosis on the post-operative outcome of spine surgery.

Methods: Retrospective data was used from 200 patients. The study cohort (S matrix group) consisted of consecutive patients (100 patients) who were treated with SLM. Patients in the standard procedure group (100 patients in all) were operated on prior to the adoption of the use of SLM by the author's clinical team. Patients underwent spinal surgery and completed follow-up evaluations for no less than 3 years post-op. Following surgery, pain was assessed at time points of: 0 to 6 months, 6 to 12 months, and 12 to 36 months). An MRI scan was performed on patients experiencing excessive pain to assess the extent of peridural scarring and adhesions.

Results: Re-operation Rate. The difference in re-operation rate between the collagen matrix group and the standard procedure group is statistically significant ($p < 0.01$).

Conclusions: Findings in this study: Reduced pain and a lower incidence of adhesions are consistent with the SL Matrix acting as an effective adhesion barrier. It is likely that the SL Matrix may be used in other regions of the spine to prevent peridural fibrosis and associated sequelae.

Keywords: Lumbar disc surgery; Pain; Radiculopathy; Reop rate; Mechanical barrier

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Background

Peridural fibrosis is the scar tissue formed over the dura mater after a laminectomy. It has been implicated as a cause of the persistence of pain after spinal surgery and associated with an increased risk of complications during revision surgery [1,2]. The application of a mechanical barrier to cover the peridural space to block the migration

of inflammatory cells from superficial layers to the epidural space can, potentially, prevent or decrease scar formation [3]. The authors evaluated the use of SuproFilm for this purpose.

Postoperative fibrosis is one of the most important causes of Failed Back Surgery Syndrome after lumbar disc surgery [4]. Numerous natural and synthetic materials have been investigated as a means

to prevent or reduce postoperative scarring after these operations.

A retrospective clinical study was conducted. The aim was to present a new idea during lumbar discectomy, and to evaluate whether this helps to prevent or diminish postoperative fibrosis. Peridural fibrosis that develops after lumbar discectomy may be responsible for as much as 20% of all cases of Failed Back Surgery Syndrome. A variety of biological and non-biological materials have been used as a barrier against the invasion of fibrous tissue into the vertebral canal.

The purpose of this study was to evaluate the use of SL Matrix to inhibit peridural fibrosis and reduce FBSS symptoms after lumbar discectomy.

SL is a transparent, flexible, cuttable, does not stick to the glove, is easy to apply, it has its own bonding agent, which means that no suture is required. SL is an anti-adhesive membrane for the prevention of postoperative adhesions. SLM is applied directly on the wound surface forming a sticky liquid from the first day. It prevents the wound surface from starting to absorb glucosamine monomer liquid from the film thus increasing the repair and renovation of the serum layer. It has a characteristic that limits fibroblasts which cause hyperplasia. It decreases the formation of collagen and saves collagen fibre groups. It does not affect the formation of collagen and wound healing.

Observations on fibrosis

The extent of fibrosis varies from patient to patient, depending on the inflammatory response, vascular condition, and surgical approach/technique.

The development of an effective barrier for the inhibition of postsurgical fibrosis is critical to achieving an optimal clinical result.

The objective of this prospective clinical study was to investigate the potential benefits of using the SL Matrix as an adhesion barrier following spine surgery in order to avoid peri-radicular lumbar fibrosis

Material and Methods

Prospective Review of 200 patients 2010-2013

Control Group 100

DuraGen Group 100

Surgery of the lumbar spine

Follow up for a minimum of two years

Clinical follow up

1 month, 3 months, 6 months, 1-4 years

Post-operative Pain Assessment at each time point:

2 = No Pain, 3 = Mild Pain, 4 = Moderate Pain, 5 = Severe Pain

Extent of Fibrosis graded by Gad-MRI:

In a prospective study we compared postoperative results of 100 patients who had a Dural Graft matrix implanted during lumbar discectomy with the results obtained from 100 patients in whom

no material was implanted. The outcomes were evaluated using a questionnaire on activities of daily living according to the Low Back Outcome Score, pain-grading scale.

Results

Pain Outcomes: Results from the Control Group (Standard Practice)

Patients with more fibrosis, shown by the arrows, exhibited more significant symptoms **Figure 1**.

Results from the SL Group **Figure 2**.

Postsurgical fibrosis was found in 2% of the Collagen Group vs 8% in the Control G

MRI image of fibrosis after surgery **Figures 1 and 2**.

Mean postoperative pain scores for the SL Group were lower at all time points and statistically lower at 3 to 6 months.

None of the 100 patients from the SL Group required re-operation for symptoms due to fibrosis.

The difference in re-operation rate between the SL group and the standard procedure group is statistically significant ($p < 0.01$).

Discussion

There is a need for treatments that prevent dural adhesions and minimize the impact of peridural fibrosis on the post-operative outcome of spine surgery [5-7].

The development of postoperative scar tissue and adhesions is a natural consequence of healing, but can be associated with general medical and reoperation complications. Many biocompatible products have been evaluated as barriers or deterrents to adhesions [8-10].

The failed back surgery syndrome (FBSS) is a severe, long-lasting, disabling and relatively frequent (5-20%) complication of lumbosacral spine surgery [11,12]. The wrong level of surgery, inadequate surgical techniques, vertebral instability, recurrent disc herniation, and lumbo-sacral fibrosis are the most frequent causes of FBSS [13,14].

Approximately 15% of all laminectomy or discectomy patients experience persistent disabling pain in the hip, thigh, leg, or lower back. These symptoms have been linked to peridural scarring (fibrosis), spinal stenosis, retained disc fragments, and other surgical complications, such as pseudoarthrosis and infection [15]. Peridural fibrosis can bind the dura and nerve roots leading to persistent sciatic and lumbar pain, which may require re-operation [16,17].

Given the link between peridural fibrosis and costly re-operation, a considerable amount of effort has gone into the development of techniques and materials to prevent epidural adhesions. The results, after repeated surgery on recurrent disc herniations, are comparable to those after the first intervention, whereas repeated surgery for fibrosis gives only a 30-35% success rate, and 15-20% of the patients report worsening of the symptoms [18,19]. Computerized tomography (CT) with contrast medium and, in particular, Gd-DPTA enhanced MRI have allowed a

differentiation between these two pathologies permitting us to adopt different therapies [20].

In a comparison between spinal surgery patients undergoing anti-adhesion treatment with either SLG or Standard Procedure, the percentages of patients requiring re-operation were approximately 2% SLG and 8% Standard.

After a period of approximately two years of follow-up, later re-operation began to lean heavily in favour of SL.

When categorized by diagnosis (most commonly Ruptured Disc and Stenosis), the results consistently favoured the SLG vs Standard Procedure.

In addition, the SLG group consistently exhibited less pain and fewer adhesions during follow-up.

The two treatment groups were similar with regard to demographic characteristics and, in general, as regard surgical characteristics.

Diagnoses were roughly divided into a 60% of Ruptured Disc:

40% Stenosis in the SLG group while the corresponding division was about 80%:20% in the Standard group. However, this did not seem to have any effect on the superior response with SLG. Also, the SLG group had relatively more Lumbar L4-L5 cases and relatively fewer Single Level procedures than the Standard group, but this may not have been clinically important when making a comparison between the two treatment groups.

Conclusions

1. The data strongly suggest that treatment with SL Matrix was significantly more beneficial than treatment without an adhesion barrier in lumbar surgery patients. By preventing dural adhesions, the SL Matrix significantly reduced the need for re-operation to relieve recurrent pain.
2. The use of SL membrane improves the outcome of the surgical treatment of lumbar Spine Surgery.

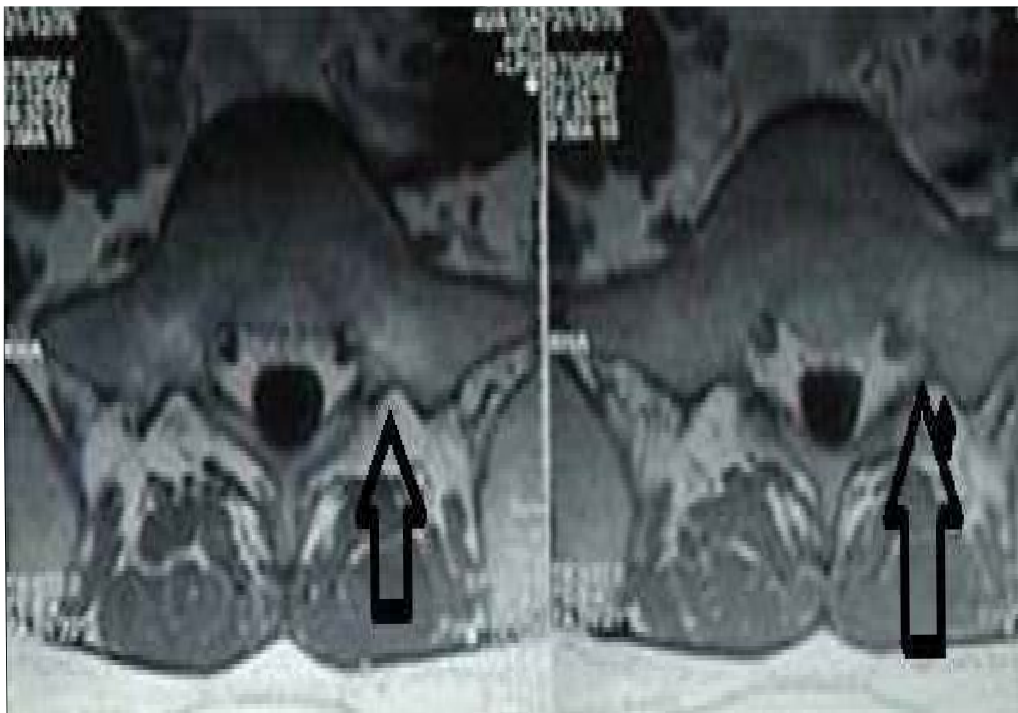


Figure 1 Probability of not requiring re-operation.

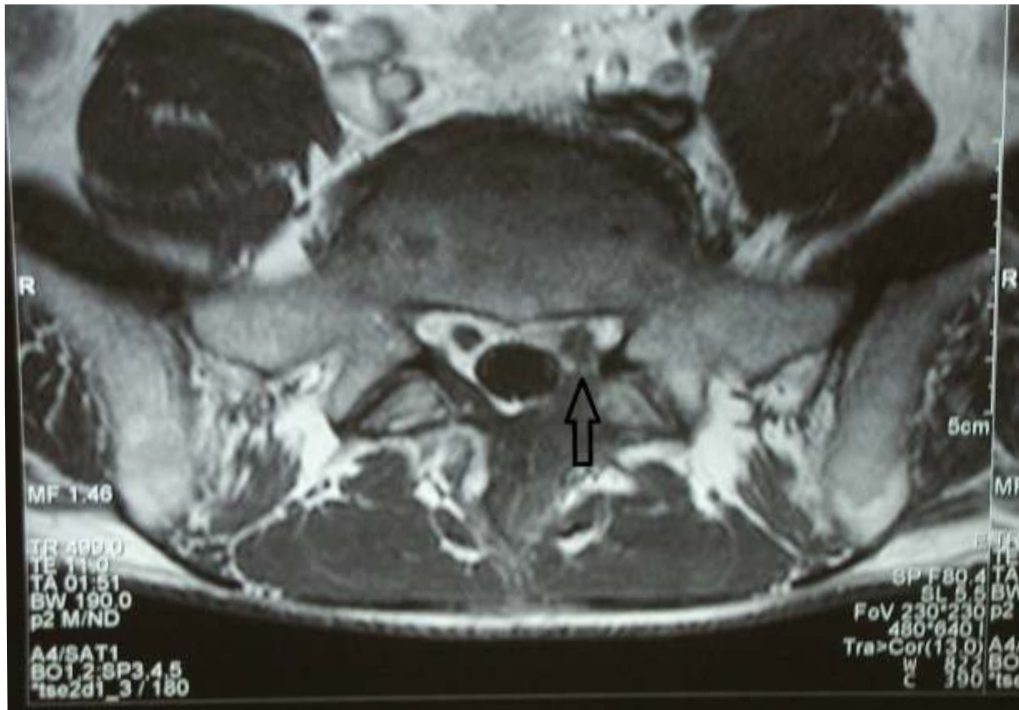


Figure 2 Patients with Duragen without fibrosis.

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