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Epidural fibrosis arises in most operated columns and involves the replacement of normal epidural fat by postoperative fibrotic tissue

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Abstract

Peridural fibrosis is a major obstacle for a successful spinal surgery. The most common surgical method used for the treatment of spinal disorder is Lumbar discectomy. After the initial surgical intervention, approximately 20% of patients will undergo revision surgery within 5 years. The common attributes of surgical failure after performing lumbar discectomy are peridural, epidural and perineural scarring. On economic evaluation of a method of adhesion prevention, which is defunct in market has demonstrated that for every 1 guilder of investment in the product (ata cost of 1000 NG per operation) approximately 1.8 guilder of saving is achieved.

Keywords: Peridural fibrosis; Lumbar fibrosis; Collagen; Leukotriene

Introduction

The phenomenal elongation of lumbar nerve roots is determined by ambulation. When to these neuro-dynamic phenomena is opposed the rigid fixation of the root Nervous system or from the dura by dense scarring fibrosis; the result is pain, due to the traction to which these structures are subjected. From here the daily activity of the patient is going to trigger a pain which pathophysiological factors seem to involve mechanical and Biochemical: to the mechanical aggression that involves the compression and stretching of Neural elements, provoking the axonal transport disorder and the ischemia of the Nerve fibers, the release of Phospholipase and from the nucleus pulpous is added in the Area of the discectomy, which has a direct inflammatory effect on contact with the root [1-3].

Defining the Clinical Problem

Spinal and dura mater also activates the Arachidonic acid cascade, giving rise to Mass production of Prostaglandins E1 and E2 Y leukotriene B exacerbating the Regional inflammatory process [4]. According to the multicenter study [5] in patients submitted laminectomy and/or primary lumbar discectomy, the relationship between the amount of epidural fibrosis (quantified by MRI) and relapse of the root pain, stating that patients with extensive fibrosis have 3.4 times more likely to present recurrence of pain [6]. The estimated percentage of unsatisfactory clinical outcomes after lumbar surgery oscillates between 5% to 15% [7]. These patients embodies the so-called "Failed Surgical Surgery Syndrome (FSSS)" and has been suggested that fibrosis is a significant etiological factor in up to 30% of these patients [8]. When the cause is fibrosis then the root pain usually reappears between 6-8 weeks. After the intervention, the patient remains pain-free during this period of time [9]. Our experience and that of other authors [10,11] shows that fibrosis and adhesions significantly increase the technical difficulties in re-interventions and the risk of producing iatrogenic lesions. All this has been modified since the use of matrix of collagen [12-14]. Till the date it was suggested that [15] interventions to treat exclusively, epidural fibrosis have clearly unfavorable results and are relatively contraindicated.

The consequence of FSSS motivated by fibrosis epidural in an operated patient who had pain, and returned to work and other daily activities, to provoke really disabling situations. Thanks to the use of the collagen matrix our point of view is aggressive in the treatment of this pathology: Posterior approach starting from the side against side and in principle performing a root release to later terminate with Circumferential Arthrodesis/PLIF. For all of the foregoing, the prevention or inhibition of fibrosis and postoperative adhesions is an essential goal for the success of spinal surgery, not only in order to reduce symptoms, but also to improve the probability of success of reoperations. A wide variety of synthetic materials such as silastic, methacrylate, foams and synthetic membranes, and the natural ones such as free fat grafts, and even bone grafts, has been examined in animal models for their power to inhibit the formation of scar tissue after surgery [16-19].

However, our first impression after evaluating the results is that:

1 - The physical barrier can really be an effective instrument to improve the chances of success of lumbar spine surgery.

2- Does not need learning curve and neither produce neither adverse reactions nor present contraindications in primary surgery?

3- In case of dural puncture allows its sealing to be the regenerating matrix of dura mater.

4- The base collagen of this product has hemostatic action.

5-The cost of using the product in our clinical trial is less.

Possible Methods of Scar Formation Prevention

Epidural fibrosis arises in most operated columns and involves the replacement of normal epidural fat by postoperative fibrotic tissue. In the immediate post-surgery period, a large amount of changes in the epidural soft tissue is observed, which may show mass effect on neural structures, with an appearance similar to preoperative HD. These changes in the anterior epidural space gradually decrease in the following months. It is therefore important to know the natural history and sequence of morphological changes experienced by the epidural scar over time. In our study, we found a progressive decrease in the amount of scarring during the first 12 months after surgery, with a slightly greater variation in the interval of 4 to 12 months than between

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the 1st and 4th month. However, only the decrease in the amount of scar in the interval between the first month and twelve months after surgery was statistically significant. The exact pathogenic role of epidural fibrosis in the development of SFCC has yet to be established. The CT/MRI demonstration of epidural fibrosis has been associated with an unfavorable surgical outcome and recurrence of symptoms. However, other authors do not find any relation between epidural and sciatic fibrosis, and similar findings have been reported regarding epidural scarring in symptomatic and asymptomatic patients. Our study did not show statistically significant differences in the presence or quantity of epidural fibrosis among patients with good clinical outcome and those who obtained little benefit from the intervention (Fisher's exact test, p=0.356). Our results support the thesis that the role of epidural scarring as a cause of poor clinical outcome has been overestimated. To date, epidural fibrosis has not been shown to occur more frequently in symptomatic patients or surgical resection of the scar leads to clinical improvement.

Bioresorbable Interpositional Membranes

In inter position membrane various other substances may be utilized for prevention of adhesion formation. To reduce scar formation Gelatin foam (such as Gelfoam® sponge, Upjohn Company Inc., Kalamazoo, Mich.), or polylactic acid (PLA) are used by placing them over the dura. There is some controversy concerning the preference of gelatin foams or sponges versus fat; however, neither is optimal since gelatin foams or sponges may move out of position, like fat, following the surgery. Moreover fat and gelatin foams or sponge may adhere to the dura, irrespective that they may form a barrier between the visceral tissue and the dura. In the clinical setting, utilization of these substances as an interpositional membrane has had no true advantage over control [20] or overuse of free fat graft[21].

It has been observed that in an inflammatory setup such as in bacterial peritonitis some membranes seem to increase adhesion formation [19]. Collagen based membranes (DuraGen [Integra Neurosciences, Plainsboro, NJ, USA]) are currently the most commonly used membranes since they act to prevent scar formation. This is because they limit the fibroblast migration through the dense collagen. The risk of adhering to the nerves and becoming a tether is the major drawback of this membrane. According to histological analysis this results because the membranes tend to undergo both fibroblast infiltration and neovascularization of the DuraGen [22]. Perhaps this finding is due to the potential of the membrane itself becoming a focus for scar formation.

Hyaluronate gel and membranes

Hyaluronic acid and its derivatives have been recommended as a possible scar modifying and adhesion preventing substance. Hyaluronic acid derived interpositional membrane or use of a film forming liquid containing a high concentration of hyaluronic acid may alter the propensity of fibroblasts to form a scar. This has been presumed because scarring has not been detected when injuries occur within the womb. It has also been hypothesized that liquid containing hyaluronic acid may help in reducing scarring around nerve roots, emanating from the spinal cord and also prevent adhesions at the posterior aspect of the cord at the site of the laminectomy [23]. It appears that in this model the effect of hyaluronate is reduction of post-laminectomy radicular pain by reduction of scar formation [24]. Unfortunately, there is a lack of sufficient amount of clinical data which affirms the success of the currently used hyaluronate-based sheet on dural adhesions. It has been observed that Seprafilm does not reduce the incidence of small bowel obstruction significantly in patients who have undergone gastrectomy for gastric cancer [25]. According to one meta-analysis the complication rate might increase in abdominal surgery when Seprafilm is used: "Our systematic review and meta-analysis showed that Seprafilm could decrease abdominal adhesions after general surgery, which may benefit patients, but could not reduce postoperative intestinal obstruction. At the same time, Seprafilm did increase abdominal abscesses and anastomotic leaks" [26]. While this conclusion has been contested by Genzyme's consultants it might indicate that there is an inherent problem with the use of bioresorbable membranes in adhesion prevention since the effects of bioresoption may affect proper tissue healing.

Disadvantages of resorbable adhesion prevention devices

A painful reminder of the potential danger which is inherent in the use of bioresorbable materials as either gels or membranes is the failure of the Adcon-L gel (Gliatech, Cleveland). The gel had shown promises in reducing post-laminectomy symptoms, but due to severe complications in the prevention of tissue healing and leakage in dura matter, it had been taken off the market [27,28]. Considering the risk of placing a resorbable device beside the dura, the un-resorbable devices might gain advantage. The use of an un-resorbable membrane has been shown to prevent adhesions similar to the use of gels [29], PRECLUDE® SPINAL Membrane, Gore Ltd.).

Un-resorbable Membranes

According to the SILASTIC sheet, un-resorbable membranes have successfully remained in use. This implant has shown result by creating a controlled dissection plane which facilitates access to the epidural space. It has also shortened the operative time by approximately 24.8% and diminished intraoperative blood loss by 37.9% when compared with patients undergoing standard cranioplasty [30,31].

Rationale for Development of the SpineShield Device

A spacing device is used to prevent dural adhesions, but it has been observed that it reduces spinal adhesion in patients as well. This spinal adhesion is casually connected to radicular pain post-surgery. The uses of bio-resorbable devices have shown increased complications and thus pursuit for a safer device was required. The use of Teflon reported various cases of hematoma formation and infection; hence it was advised to remove the device as soon as possible to avoid the risk of infection [32]. It was concluded that a successful anti-adhesion device should be inert and easily retrievable after a short time.

After further analysis, it was observed that if the device is displaced into the spinal canal, there would a risk that it might compress the nerves. Hence, during development it was conjectured that a successful device should be shapable and should act as roofing for the spinal canal [33]. The device should allow reconstruction of the ligamentum flavum as this is important in preventing adhesions. Ligament-reconstruction device had another added advantage of prevention of post-laminectomy spinal instability. There is better stability if the inter-spinous ligament is restored after spinal instrumentation [34].

Thus, it appears that the required specifications for a successful adhesion prevention device are: un-resorbable, shapable device supporting spinal ligament reconstruction and retrievable to prevent long-term complications. The SpineShield device, possess all of these properties (Table 1).

Name	Manufacturer	Material	Resorbable	Solid	Easily Retrievable	Shapable	Ligament reconstruction
Preclude Spinal Membrane	GORE: Creative Technologies Worldwide	Teflon	no	yes	no	no	possibly
Oxiplex	fzioMed	carboxymethylcellulose and polyethylene oxide	yes	no	no	no	no
Sepra film: Adhesion barrier	Genzyme	hyaluronate	yes	yes	no	no	No, not authorized for epidural placement
Gynecare: interceed	Johnson and Jhonson Getaway	oxidized regenerated cellulose	yes	no	no	no	no
Silastic: silicone elastomers	Dow corning	Dacron polyester backed silicone	no	yes	no	yes	yes
Tutoplast Processed Allografts	IOP inc	Allograft risk of prion disease	unknown	yes	no	yes	??
DuraGen Dural Graft Matrix	Integra	Collagen	yes	yes	no	Soft and pliable	??

Table 1: Current competitors on the global market.

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