Device Name: VersaWrap

Manufacturer: Alafair Biosciences (info@alafairbiosciences.com)

Indication for Use: VersaWrap is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. The device may also be used in the management and protection of surrounding tissues such as skeletal muscle and ligament. VersaWrap is indicated for the management of peripheral nerve (including nerve root) injuries in which there has been no substantial loss of nerve tissue.

FDA Clearances: K160364, K200311, K201631, K203600, K213163

Important Note:

- Per FDA guidance, this page must be distributed with the attached article
- Do not distribute this article with promotional material for the device
- This article describes on-label application of VersaWrap; however, the surgeon author describes the device as an adhesion barrier which is associated with an intended use that is not approved
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Research Article

Results of a Bioresorbable Hydrogel Sheet Utilized as an Adhesion Barrier in Spine Surgery

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- Adhesion barriers; Scar tissue; Spine complications; Epidural fibrosis

Abstract

Background/Intro: Scar tissue following spine surgery is expected, but hypothesized to be related to complications such as incidental durotomy, vessel injury, further increase in scar tissue formation, failed back surgery syndrome, and diminished patient outcomes. Scar tissue prevention remains elusive, but advancements in adhesion barriers have shown compelling results in minimizing complications.

Methods: A retrospective review of one orthopedic surgeon's patients that received VersaWrap (VW) during spine surgery. VW is a bioresorbable hydrogel sheet made of polysaccharides alginate and hyaluronic acid designed to separate tissues, allow gliding and prevent tethering.

Pre-operative demographics, surgical details, patient reported outcomes, complications, and reoperations were collected and analyzed for all patients. Statistical analysis was completed on the appropriate data using a paired t-test.

Results: Data for 169 patients that received posterior lumbar decompression were collected and analyzed. Patient reported outcomes showed significant improvement ($p<0.05$) in mean scores from pre-operative to 3-month follow-up for Visual Analogue Scale (VAS) neck/arm, VAS back/leg, NDI, and ODI. Four complications were reported, all peri-operative incidental durotomies that were repaired during surgery with no lasting impacts. Eleven patients underwent reoperations, unrelated to VW, but allowed for visual inspection of the VW post-operatively.

Conclusion: The use of VW during spine surgery appears to reduce potential complications from scar tissue formation, specifically in the event a reoperation occurs in the same anatomic region.

There are limitations to this study, including that it is retrospectively collected, but exploration of adhesion barriers in spine surgery applications appear promising and warrant further study.

ABBREVIATIONS

VW: VersaWrap**, VAS:** Visual Analogue Scale**, ODI:** Oswestry Disability Index**, FBSS:** Failed Back Surgery Syndrome**, EF:** Epidural Fibrosis**, CMC:** carboxymethylcellulose**, PEO:** polyethylene oxide**, EBL:** Estimated Blood Loss**, MITR:** Minimally Invasive Tubular Retractor.

INTRODUCTION

Dural tearing is a well-known complication during reoperation of posterior spine procedures [1]. This tearing is often the indirect result of scarring from the initial procedure which tethers sensitive dura and opposing neural anatomy that are normally separated tissues [1-4]. Epidural Fibrosis (EF), scar tissue in proximity to nerve root, has been reported as the 3rd most common cause of failed back surgery syndrome (FBSS) [5], with the hypothesis that dural tethering to surrounding tissues as a result of EF is likely a cause [1]. FBSS is reported in a wide range of patients (4-60%), but the etiology is complex and includes a variety of potential contributing factors [5-13]. The rate of spine surgeries continues to climb in the US, and therefore reoperations continue to increase. While the overall reoperation rates following spine surgery are difficult to quantify, it is well understood that patient success rates decline with each subsequent surgery [10, 14,15].

Diagnosis of FBSS or a new pathology, particularly in minimally invasive procedures, can lead to reoperation in the same region as the initial surgery. Although this reoperation rate is difficult to quantify in the literature, the increased risk of complications during and after reoperation in the presence of scar tissue and EF is well documented [16-20]. These complications include incidental durotomy, vessel injury, further increase in scar tissue formation, greater risk of FBSS, and diminished patient outcomes [13, 21-23].

Historically, direct treatment for EF post-formation is limited, with options such as epidural lysis and epiduroscopy. These postoperative interventions have shown some effectiveness, as confirmed by imaging [24], but often still lead to reoperation [3,25-28]. Previous studies report preventative interventions including antiepileptics, nonsteroidal anti-inflammatories, antidepressants, opioids, fat grafts, suction drains, epidural steroid injections, adhesion barriers, adhesiolysis procedures, radiofrequency ablation, and neuromodulation [1,4,29-33,1,34-

39]. Some of these efforts present compelling results in animal [37,39-41] and in limited human populations [30,33,42-44], which is encouraging for both surgeons and patients since preventative interventions are more appealing than post-formation treatment.

Of all prophylactic options, adhesion barriers are preferred as there seems to be the greatest promise for success that does not require ongoing intervention. Adhesion barriers refer to a general classification of products used to prevent tissue tethering (and, thus, EF) by mechanically separating tissues or by allowing tissues to glide against one another with reduced friction [33,37-39,42,45-48].The goal of an adhesion barrier is to prevent unwanted tethering of adjacent tissues that is initiated during the early stages of healing. Theoretically this early disruption of adhesion formation prevents permanent tethering that occurs during late stages of healing.

Adhesion barrier technologies initially included fat grafts, a practice still used today [49]. While there is some success with limiting EF adhesion, fat grafts have unintended consequences of neural compression, causing increased pain for patients. The adhesion barrier evolution has produced carboxymethylcellulose / polyethylene oxide (CMC/PEO) [33, 45], gelatin USP products [42], bacterial cellulose with mesenchymal stem cells [37], human amniotic membrane and placental-derived tissue barriers, and carbohydrate polymer gels [38,39].These products have widely been advertised to prevent adhesions, particularly for use in spine procedures, yet there is a paucity of literature to support these claims [47,50,51]. There is currently no standard of care for protection or management of nerve root during spine procedures.

VersaWrap® (Alafair Biosciences, Austin, Texas) is a new option unique from previous barrier technologies. VersaWrap® is plant-based, comprised of well-known hydrophilic polysaccharides alginate and hyaluronic acid. The device is a thin bioresorbable hydrogel sheet that transitions into a viscous gelatinous layer once implanted. This transition precludes the need for suturing or tissue glue, making device application quick and easy. Previous literature reports successful prevention of adhesions in a rat abdominal model [52], and initial clinical results for placement of the hydrogel device in recurrent cubital tunnel procedures appear promising [53].

The present study is a large, retrospective series of patients receiving VersaWrap® (hydrogel device) utilized as an adhesion barrier to prevent postoperative tethering of the nerve root to surrounding tissues such as bone, dura, and muscle in posterior approach decompression procedures.

MATERIALS AND METHODS

The study is a retrospective review of operative and medical records of patients that received posterior approach lumbar spine decompression surgery with the use of the hydrogel device by one orthopedic spine surgeon. A waiver of consent was received to collect data of adult patients receiving surgery between May 2018-March 2020 with a minimum of 3-month postoperative follow-up.

Patient charts were reviewed for baseline (pre-operative) demographics, surgical details, and postoperative outcomes. Baseline demographics included patient age at surgery, gender, BMI, and smoking status. Surgical details collected were Estimated Blood Loss (EBL), type/spine levels of surgery, operative time, and operative complications. Patient reported outcomes, including Visual Analogue Scale (VAS), and Oswestry Disability Index (ODI) were collected and statistically analyzed using a paired t-test. Reoperations were collected and analyzed at all available post-operative time points.

Product Description and Application

VersaWrap® (Figure 1) is a is a class II medical device, FDA cleared for use on tendon and peripheral nerves [54,55]. It is a bioresorbable hydrogel device made of polysaccharides alginate and hyaluronic acid designed to serve as an interface between target tissues and surrounding tissues to provide a non-constricting, protective encasement. The hydrogel sheet separates tissues, allowing tissue gliding, and preventing unwanted tethering during healing. The product is plant-based, transparent, flexible, ultrathin, non-sided, biocompatible, and can be implanted as a pre-formed sheet or as a gel, in situ.

The surgeon applied the hydrogel during posterior approach lumbar spine decompression surgery (Video 1, link to video) to manage scar tissue adhesion/tethering of the nerve root to the surrounding anatomy such as ligament, nerve, dura, bone, or other soft tissues. It is hypothesized that patients receiving the hydrogel in the initial procedure are expected to need less mechanical disruption of tissue during revision, if reoperation is needed.

Application

Lumbar application of the hydrogel occurred during decompression surgeries at various levels (L1-S1). Lumbar decompression surgery (foraminotomy, laminectomy, discectomy) was performed using the minimally invasive tubular retraction (MITR) technique. The hydrogel sheet was cut into 1 cm x 1 cm squares, advanced through the tube, and placed on the peripheral nerve root and the adjacent dura, under the lamina of the spine (Figure 2). In the event of a potential incidental

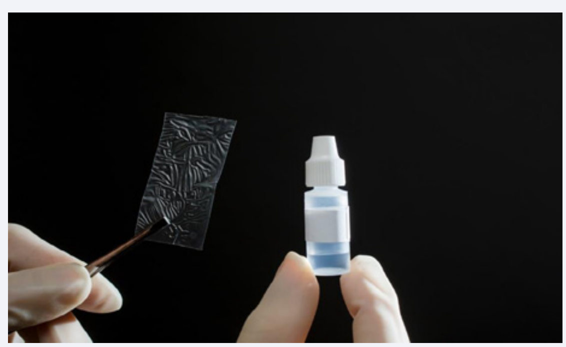

Figure 1 VersaWrap® is a class II medical device that consists of a clear hydrogel plant-based sheet and a wetting solution provided in a dropper bottle. The wetting solution is applied to the sheet to render the sheet a gelatinous tissue adherent layer that separates target tissues from surrounding tissues to prevent unwanted postoperative tethering.

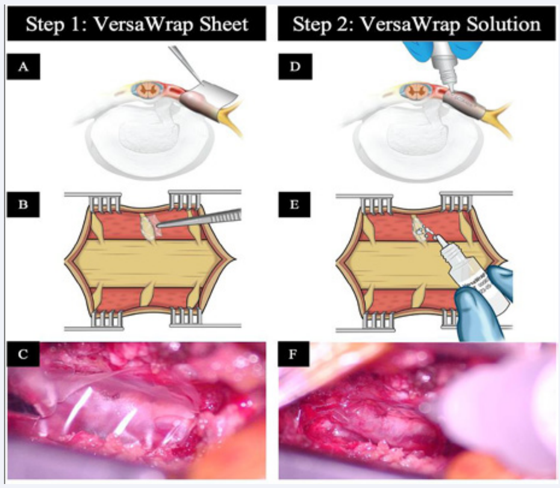

Figure 2 Application of VersaWrap on nerve root in a decompression procedure: A) side view illustration, B) top view illustration, and C) top down photograph of applying VersaWrap sheet onto nerve root tissue; D) side view illustration, E) top view illustration, and F) top down photograph of applying VersaWrap solution to the implanted VersaWrap sheet. Conformance to underlying tissues is visually observed with application of the VersaWrap solution.

durotomy during surgery, the hydrogel device was applied over the dura at the location of the durotomy.

RESULTS AND DISCUSSION

Patient Demographics

One hundred sixty nine (169) patients met the inclusion criteria for the study. Demographics of the overall study population are included in Table 1.

Patient Reported Outcomes

Patient outcomes were collected as standard of care in the surgeon's clinic. Patients reported statistically significant pain improvement in VAS back/leg ($p<0.05$), and significant functional improvement via ODI score ($p<0.05$) at all timepoints through 3-month follow-up when compared to baseline scores. (Figures 3 & 4).

Complications

There were four (4) peri-operative complications reported. The four (4) complications were reported as incidental durotomy, and the hydrogel was placed over the dura at the location of the tear. One of these patients required a reoperation (Table 2, Patient No. 22); a revision L5-S1 decompression at 17-months post-operative that was unrelated to the dural tear.

Reoperations: Opportunities for a second look

During data collection, there were eleven (11) patients that required a reoperation or secondary procedure that allowed visual confirmation of the effects of the hydrogel sheet. All reoperations were captured and evaluated for relatedness to the initial surgical indication; all reoperations were assessed by the operative surgeon and were deemed unrelated to the use of the hydrogel in the initial surgery. Reoperations occurring in the same anatomic region as the initial surgery are included in Table 2.

The Intended function of the hydrogel is to allow postoperative tissue gliding such that there is reduced dural tearing during a reoperation.

Surgeon experience during reoperation was that the anatomy where the hydrogel had been placed was easily moved without significant mechanical disruption (Figure 6). Photographs and video were captured during three (3) reoperations in patients that received the hydrogel in their initial surgery.

Patient 09 received a bilateral laminectomy at L4-5 with placement of the hydrogel device, and a reoperation at 12 months for a revision bilateral laminectomy, also at L4-5, and new bilateral laminectomy at L3-4. (Figure 5) As expected, EF was present, however, more importantly, this fibrosis did not adhere the nerve root or peripheral nerve tissues to the adjacent dura and tissues were moved with ease.

Patient 10 received an initial L5-S1 fusion in 2002, with a prior surgeon and without the use of any adhesion barrier. An L4-5 left laminectomy was completed during this study, and the hydrogel was placed per the surgeon's standard application. The

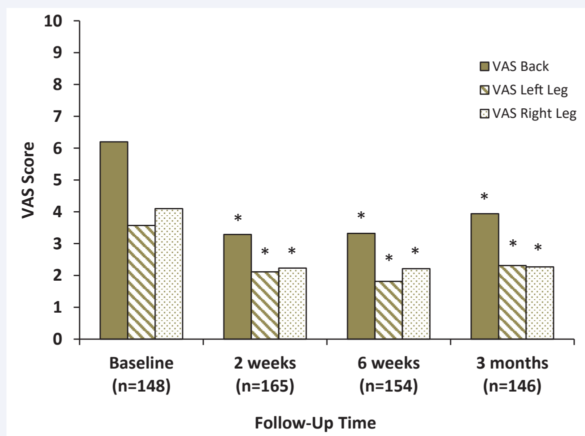

Figure 3 Lumbar Decompression VAS Score. *p<0.05 using the paired t-test to compare the change from baseline.

Table 1: Demographics.

No. Patients	Gender (% F)	Mean Follow-up months (min-max)	Mean BMI	Smokers	Mean EBL (cc)
Lumbar Decompression Patients					
169	70/169 (41.4%)	9.5 (3-26)	31.3	19/169 (11.2%)	19.9
BMI: Body Mass Index, **EBL:** Estimated Blood Loss					

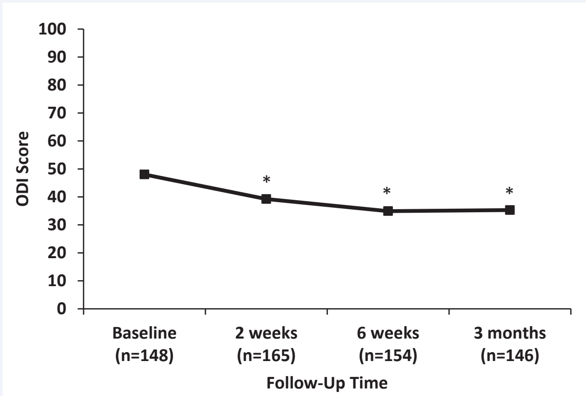

Figure 4 Lumbar Decompression ODI. *p<0.05, using the paired t-test to compare the change from baseline.

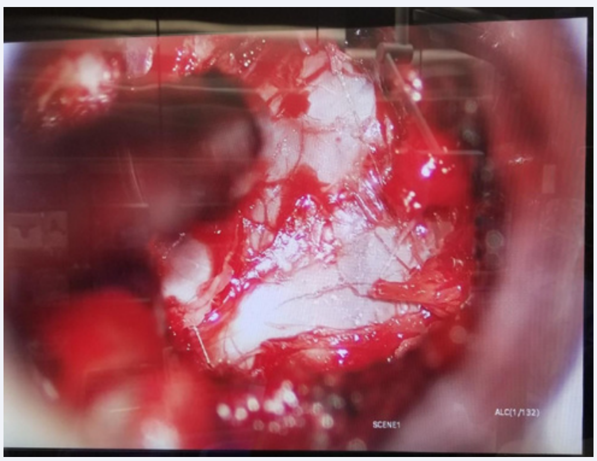

Figure 5 Reoperation L4-5 laminectomy with VW used during initial surgery.

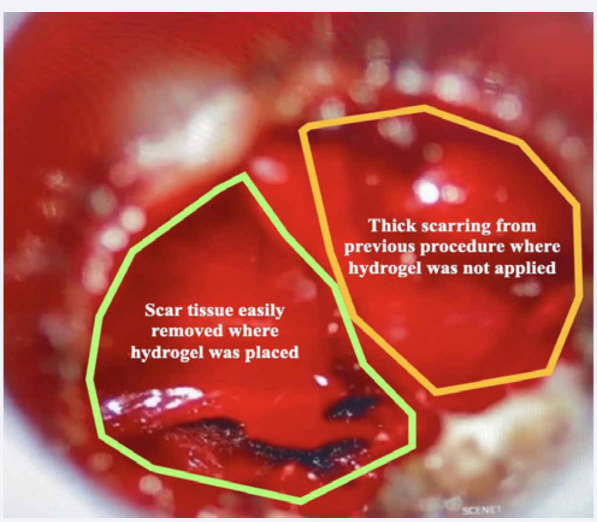

Figure 6 Reoperation VW used single side only during initial surgery.

Table 2: Reoperations.

No.	Initial surgery description (Levels)	Time to reoperation (months)	Reoperation Description
1	Lumbar decompression Left (L5-S1)	3	Revision decompression for recurrent disc herniation L5-S1 left side
2	Lumbar decompression Right (L4-L5)	6	Lumbar SCS implanted for continued pain
3	Lumbar decompression Left (L4-S1)	6	Revision decompression for recurrent disc herniation L5-S1 left side
4	Lumbar decompression Left (L4-L5)	9	Revision decompression for recurrent disc herniation L4-L5 left side
5	Lumbar decompression bilateral, right discectomy (L5-S1)	9	Lumbar SCS implanted for continued pain
6	Lumbar decompression Left (L5-S1)	10	Revision decompression for recurrent disc herniation L5-S1 left side
7	Lumbar decompression Right (L4-S1)	16	Revision decompression for recurrent disc herniation L4-S1 right side
8	Lumbar decompression Right (L5-S1)	17	Revision decompression for recurrent disc herniation L5-S1 right side
9	Lumbar decompression bilateral (L4-5)	12	Revision decompression for disc bulge and facet hypertrophy L3-L5 bilateral
10	Lumbar decompression bilateral (L4-5)	21	Revision decompression for recurrent disc herniation L4-L5 left side
11	Lumbar decompression Left (L5-S1)	23	Revision decompression for recurrent disc herniation L5-S1 right side

Abbreviations: SCS: Spinal Cord Stimulator.

video and photos were captured during the left L4-5 laminectomy reoperation at 21 months postoperative. (Figure 6 & Video 2, link to video 2) The hydrogel was previously placed on the left side where the EF did not adhere to the adjacent dura, the EF is adhered on the right side where the prior surgeon did not place any adhesion barrier.

Figure 7 and video 3 (link to video 3) represents a revision decompression for left L5-S1 recurrent disc herniation at 23 months postoperative (Patient 11). The operative surgeon indicated the presence of lightly tethered EF that was removed with ease.

Only one patient (Patient 03) experienced a complication

Figure 7 Reoperation L5-S1 decompression with hydrogel used during initial surgery.

during the reoperation. A minor focal incidental durotomy was noted when removing the scar tissue from the junction of S1 lamina and the dura. The durotomy was too small for a suture to be placed.

DISCUSSION

This 169-patient retrospective study is the first reported use of VersaWrap on nerve root in lumbar decompression procedures. The results suggest that it is safe and does not contribute to intraoperative or postoperative complication or adverse events out to 1 year postoperative.

Data from this retrospective study, using hydrogel as an adhesion barrier, indicate minimal incidence of dural tears when a secondary surgery was required. Only one patient (1/11=9%) experienced a small focal dural tear during a secondary surgery at or near the original surgical location. Other studies report an incidence of dural tears during secondary surgeries of the lumbar spine to be between 8.1% and 25% [17,56]. Dural tears reported during primary spine surgery trend lower (1%-13%) [17,57,58] as expected, given the absence of scar tissue.

Data from this study also indicate significant improvement in VAS back/leg pain for the MITR at 3-month follow-up. Given the past challenges in clinical trials utilizing the standard patient reported outcomes, such as VAS/ODI, it is understood that statistical significance does not necessarily correlate to the clinical significance of adhesion barriers. For clinical evaluation, Fransen's report of visual inspection during reoperation remains a compelling endpoint [33].

This study reports no short- or long-term complications attributed to the use of the hydrogel when used in posterior lumbar decompression procedures. Other products report short- and long-term unexpected complications such as disturbance of muscle healing [38], however we did not note any such complications in this study. Furthermore, this study follow-up timepoint extended beyond those in other reports. While efficacy remains elusive with adhesion barriers, this data indicates VersaWrap® is safe to use in these postoperative lumbar decompression procedures.

The surgeon noted during reoperations following use of the hydrogel that while some scar tissue was visible present, this tissue was easy to remove from adjacent tissues (Figures 5-7 and supplemental videos 2 & 3). The hydrogel is intended to allow opposed tissues to glide and to reduce the coefficient of friction between the nerve root and surrounding tissues, decreasing the detrimental effects of adhesions such as EF and dural tethering. The reduction of this unwanted tethering can lead to reduced complications during reoperation such as dural tearing. The prophylactic use of VersaWrap® in surgeries that carry a higher risk of reoperation should continue be explored further.

CONCLUSION

The clinical data presented here further the evidence supporting adhesion barriers during lumbar decompression surgery to mitigate the risks of scar tissue, EF, and adhesions that cause complications during reoperation. Patients receiving lumbar decompression reported significant improvement in pain and functional scores through 3-month follow-up with no reported complications related to the use of VersaWrap®. In the occurrence of reoperations, the surgeon reported less scar tissue adhesion, which reduced the need to mechanically disrupt adhesions where implanted.

There are limitations to this study, including that the data were retrospectively collected and primary endpoints for adhesion barrier studies in spine remain elusive. Adhesion barriers such as VersaWrap® should continue to be explored for more widespread use in spine surgery applications.

CONFLICT OF INTEREST

The authors have no conflict of interest that is directly related to the product in this manuscript.

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