Observations on the Use of Seprafilm® on the Brachial Plexus in 249 Operations for Neurogenic Thoracic Outlet Syndrome

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Abstract

Purpose Seprafilm® was initially used successfully as a membrane to reduce abdominal adhesions. Subsequently it was tried in a number of other areas to reduce postoperative scarring. Seprafilm® was employed in this study to see if it would reduce postoperative scarring after supraclavicular thoracic outlet decompression for neurogenic thoracic outlet syndrome (NTOS).

Material and methods There were 249 operations for primary NTOS (185) and recurrent NTOS (64). Seprafilm® was applied to the nerve roots at the end of each procedure. Diagnosis was established by careful history and extensive physical exam consisting of several provocative maneuvers. Scalene muscle block confirmed the diagnosis.

Results Success rates for primary operations, 1–2 years postoperation were 74% for scalenectomy without first rib resection and 70% for scalenectomy with first rib resection. For reoperations, success rate for scalenectomy and neurolysis after transaxillary rib resection was 78% whereas success rate for neurolysis after supraclavicular scalenectomy was 68%. Seprafilm® did not significantly improve overall results compared to our results 15 years ago, although

in reoperations there was a trend toward improvement with Seprafilm®. Observations in 10 reoperations after use of Seprafilm® revealed that there were fewer adhesions between fat pad and nerve roots, making it much easier to find the nerve roots. Recurrence was because of scar formation around individual nerve roots.

Conclusion Seprafilm® made reoperations easier by reducing scarring between scalene fat pad and brachial plexus. However, it did not prevent scar tissue forming around the individual nerve roots nor did it significantly lower the failure rate for primary operations. The trend supported the use of Seprafilm® in reoperations.

Keywords Seprafilm · Thoracic outlet syndrome · Neurogenic thoracic outlet syndrome · Brachial plexus

Introduction

Seprafilm® is a membrane composed of hyaluronic acid and methylcellulose that acts as a mechanical barrier preventing adhesions and scarring between adjacent structures. Seprafilm® is totally absorbed in body tissues in 3–4 weeks. It has been demonstrated to significantly reduce adhesions after abdominal and pelvic surgery [3–5, 9, 13, 24]. In animal studies, it has reduced peridural fibrosis at laminectomy sites [25] and prevented adhesions after tenolysis [11, 14]. It has been employed for the same purpose in several other areas including the heart [26], eye [15, 23], and ear [12]. As surgery for neurogenic thoracic outlet syndrome (NTOS) has a 30% failure rate [21], much of it because of postoperative scarring, it was thought that Seprafilm® might reduce this. This study was designed to see the effects of Seprafilm® covering the brachial plexus in 249 supraclavicular operations for NTOS.

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Material and Methods

Over 2.5 years, between March 2002 and November 2004, 249 operations for NTOS were performed on 207 patients; 42 were bilateral. There were 165 women (80%) and 42 men. Ages were 13 to 64, with three teenagers; most patients were 25 to 45 years old.

Diagnostic Tests History and physical exam were the primary diagnostic tools. Physical exam included several provocative maneuvers (see p. 76 in Sanders and Haug [20]). In addition, all patients received a chest and neck x-ray to detect rib abnormalities as well as a scalene muscle block, cervical spine magnetic resonance imaging (MRI), electromyography (EMG), and nerve conduction velocity (NCV) measurements.

Scalene muscle blocks to confirm the diagnosis were performed in all patients by injecting 4 ml of 1% procaine into the belly of a tender anterior scalene muscle (ASM). The needle was introduced 1 cm above the clavicle, aimed at the most tender point over ASM and angled about 45° cephalad to avoid pneumothorax. Needle aspiration was always performed each time the needle was moved to prevent injection into a vessel. A good block was determined by loss of tenderness over the ASM. A good response was reduction of symptoms at rest and improvement in physical findings (see p. 91–3 in Sanders and Haug [20]).

Primary Operations There were 185 primary operations performed through a supraclavicular approach, which included neurolysis of the five nerve roots of the brachial plexus plus anterior and middle scalenectomy. Once both scalenes had been removed, the relationship of the lower nerve trunk to the first rib was observed. If the rib was pressing against the lower nerve trunk, the rib was excised. If the nerve trunk had minimal contact with the rib, the rib was spared. The technique has recently been described [19]. A round 10-French drain was used in all operations.

Reoperations There were 64 reoperations on patients whose previous operation did not include Seprafilm®. In 44 reoperations, supraclavicular scalenectomy with or without rib resection had been the first operation; they were treated with supraclavicular neurolysis. In the other 20, transaxillary first rib resection was the first procedure; they were treated with supraclavicular scalenectomy and neurolysis.

There were 10 reoperations for recurrence on patients who initially received Seprafilm®, thereby allowing an opportunity to observe the amount of healing and scarring 1–3 years after inserting Seprafilm® around the brachial plexus. First rib resections had previously been performed in nine and scalenectomy alone in the tenth.

Seprafilm® At the end of each operation the five nerve roots were covered with Seprafilm®, which is a brittle clear plastic-like material when removed from its package. It is difficult to pick up. We found that the best way to manage it was to cut it into postage-stamp sized pieces while still in its paper covering. Then it was picked up with forceps, run through saline, and quickly applied to the surface of the nerve. It could be repositioned for only a few seconds before it stuck to whatever it was touching. The advantage of its adhesiveness is that it remains in place. The disadvantage is that once in place it cannot easily be repositioned. The nerves were covered with at least two layers of Seprafilm®. Seprafilm® was used off-label as a material already approved for human use by the FDA.

Indications for Surgery History and several positive physical findings compatible with NTOS were necessary to consider the diagnosis (see p. 79–81 in Sanders and Haug [20]). A positive response to a scalene muscle block was supportive but not essential. Surgery was considered when at least 3 months of conservative therapy had failed and there was some degree of disability at work, sleep, recreation, or in activities of daily living.

Postoperative Care After left neck operations, patients were given only ice chips and water by mouth for at least 24 h, until it was determined that there was no lymph leak. The drain was removed when all drainage stopped, which usually was within in 24–48 h. Most patients were discharged 2 days postoperation. Before discharge patients were instructed on neck stretching and wall climbing exercises. Physical therapy was recommended to patients who continued to have symptoms after the first post-operation month.

Statistical Methods Success rates were determined both by simple ratio of successes to total procedures and by the life-table method [7]. Statistical significance was determined by a *P* value under 0.05, calculated from the chi-square test. Follow-up to the 1–2 years postoperation level was obtained by phone or questionnaire in 91% of the patients.

Results were graded subjectively as follows: *excellent* indicated all symptoms were relieved, *good* indicated improvement in most major symptoms but minor symptoms persisted, *fair* indicated improvement in some symptoms and the patient felt the operation was still worthwhile for the improvement noted although some major symptoms were minimally improved, and *failure* indicated no significant improvement. Because statistics using life-table method consider only success or failure, the excellent, good, and fair results were all considered successful.

Table 1 Results with and without Seprafilm®.

Operation	2007 (with Seprafilm)		1989 (without Seprafilm) [21]		<i>P</i> value ^a
	No. of Patients	% Success ^b	No. of Patients	% Success ^b	
1. Scalenectomy	106	74	286	76	0.938
2. Scal and 1st rib resection ^c	79	70	249	77	0.634
Total	185				

^a *P* value compares 2007 results with those of 1989.

^b Life table method at 1–2 year follow up

^c Scalenectomy and first rib resection

Results

Etiology

A history of neck trauma was elicited in 87% of the patients, the most common being a whiplash injury in a motor vehicle accident. Other common causes were slips and falls on stairs or ice and work injuries, particularly repetitive stress injury in keyboard workers.

Signs and Symptoms

Extremity pain, paresthesia, and weakness were present in almost all patients. Other common symptoms were neck pain and occipital headache.

Physical findings present in at least 90% of the patients were scalene muscle tenderness plus reproduction of symptoms using provocative tests of neck rotation and head tilt, the upper limb tension test of Elvey [8], and abducting the arms to 90° in external rotation (see p. 79–81 in Sanders and Haug [20]).

Diagnostic Tests

Electromyography and NCV studies were usually normal or revealed nonspecific changes. They were helpful to identify other neurologic conditions at the elbow, forearm, or wrist. No patient in this series had typical ulnar neuropathy that could be attributed to NTOS. Scalene muscle blocks gave a positive response in 95% of these patients and was used to

confirm the diagnosis. Neck x-rays revealed 13 cervical ribs.

Postoperative Improvement

The overall results from 249 operations were 67 failures (27%), and 182 successes (73%). Successes included 34 (14%) fair results and 148 (59%) good to excellent results.

Results of 185 primary operations are in Table 1 and results of 64 supraclavicular reoperations are in Table 2. These tables record results with the life-table method [7], which gives results a few percentage points lower than simple success rates regardless of follow-up time. In these tables the results are compared to our results for the same operations reported in 1989 [21] and 1991 (see p. 204 in Sanders and Haug [20]). There were no statistically significant differences between the results of 15 years ago and the current results. However, the 7% increase in improvement rate with the use of Seprafilm® for reoperations, although not statistically significant, did represent a trend favoring Seprafilm®.

Observations After Use of Seprafilm®

There were no complications from using Seprafilm®. Ten supraclavicular reoperations (4%) were performed several months after the initial operation in which Seprafilm® was used. At operation through a supraclavicular incision, once the lateral edge of the sternocleidomastoid had been retracted, the scalene fat pad was exposed. In previous operations without

Table 2 Reoperations.

Operation	2007 (With Seprafilm)		1991 (Without Seprafilm) [20]		<i>P</i> value ^a
	No. of Patients	% Success ^b	No. of Patients	% Success ^b	
1. Neurolysis	44	68	37	61	0.760
2. Scalenectomy and neurolysis	20	78	59	71	0.811
Total	64				

^a *P* value compares 2007 results with those of 1991.

^b Life table method at 1–2 year follow up

Seprafilm®, multiple layers of tight scar usually covered the plexus, making dissection very difficult and identification and isolation of the nerve roots hazardous. In the 10 patients who had previously had their plexus covered with Seprafilm®, this did not occur. The nerve roots were easily identified with minimal dissection of the fat pad required. However, individual nerve roots were still surrounded by tight envelopes of scar tissue so that their neurolysis was as difficult as if Seprafilm® had not been used. Results of these 10 reoperations were good in 5, fair in 4, and no improvement in 1.

Discussion

Diagnosis

To date, objective tests have been of little use in the diagnosis of NTOS [2, 16]. Magnetic resonance imaging has yet to define clear diagnostic criteria for NTOS. It is used to rule out treatable cervical spine disease, which is always evaluated and treated before treating NTOS. Likewise, EMG and NCV studies have seldom been helpful in diagnosing NTOS [18]. They are obtained to rule out other peripheral neurologic disorders. The scalene muscle block has been the most useful test, although its results are subjective. In this series, on physical exam several provocative maneuvers were performed, and in all patients positive responses were noted on at least four maneuvers to support the diagnosis that was suggested by several symptoms. In no case was surgery performed on someone with isolated extremity pain or paresthesia on the basis of exclusion.

Reasons for Failures

Initial failure after neurolysis is usually because of a missed diagnosis or an associated diagnosis, such as cervical neck strain, cervical disc disease, or shoulder pathology (see p. 194 in Sanders and Haug [20]) [17, 22]. The primary reason for failure after the first 2 months is adherence of new scar tissue to the nerve [6]. As the scar matures it contracts, compressing the nerve and producing recurrent symptoms. This is true not only for the brachial plexus but for other nerves throughout the body.

From previous studies it was learned that most failures of surgery for thoracic outlet syndrome occur during the first 24 months postoperation [1] (see p. 196 in Sanders and Haug [20]). This time period coincides with the known observation that it takes about 18 months for scar tissue to completely mature. Because of this, it was possible to determine with a 1- to 2-year follow up that Seprafilm® did not significantly reduce the failure rate of thoracic outlet decompression compared to previous experiences.

We postulate that organized fibrin from postoperative hemorrhage was the most likely cause of this scarring. The only difference in operative technique between the current series and the operations reported 15 years ago is that in the current series more attention was paid to meticulous control of operative bleeding by liberal use of the bipolar cautery. In spite of this, postoperative bloody drainage was always obtained and ranged from 25 to 100 cc in the first 24 h, only a little less than in the earlier series. Our general observation was that drainage was usually higher when the first rib was removed than when it was not, although we have not compared the actual measurements from patients' charts as we discovered that recording of these was often inaccurate. First rib resection was not performed routinely, but only when the lower trunk of the plexus was touching the rib. By avoiding rib resection, bleeding from the intercostal muscles, which is more difficult to cauterize than scalene muscles, was eliminated as a source of postoperative hemorrhage. Unfortunately, even by avoiding rib resection, there was still enough postoperative wound hemorrhage to coat the nerve roots.

In the reoperation group, postoperative drainage was usually reduced at least half, compared to drainage after primary operations. This supports the observation that there is almost always less intraoperative bleeding with a reoperation than a primary one.

Seprafilm®

It is not unusual to find patients who initially experience good improvement after neurolysis to develop recurrent symptoms several months later. There has yet to be found a good method for preventing this phenomenon. It was our hope that Seprafilm® could reduce scarring after brachial plexus neurolysis. We observed that Seprafilm® reduced adherent scar surrounding the plexus. This was evident in the 10 patients who were reoperated upon after use of Seprafilm® at the first operation. Unfortunately, this still did not improve the success rate when compared to the results of the same procedures published in 1989 [21] and 1991 (see p. 204 in Sanders and Haug [20]).

Although the plexus was easier to find after using Seprafilm, scarring around individual nerve roots still developed and caused recurrence. In spite of this, the fact that Seprafilm® made it easier to find the plexus when reoperating was reason enough to justify its use. Significantly, we observed no complications or detrimental effects from the use of Seprafilm®. A similar experience in a different area was observed in a 2006 report on Seprafilm® in the abdomen. It noted that whereas it did not decrease the rate of bowel obstruction it did reduce by 50% the need for surgery [25].

Once in the body, Seprafilm® becomes a gel in 24–48 h and remains at the site of application for up to 7 days. It is then totally absorbed in body tissues in 3–4 weeks [5]. Currently, in place of Seprafilm®, we are trying another material, Surgiwrap®, which is absorbed over several months, providing a significantly longer barrier. As yet we do not know how well it will perform compared to Seprafilm®. Were it not for this we would continue to employ Seprafilm® for its benefits at reoperation.

Although Seprafilm® has been used in a number of different anatomical areas, to date we have not seen reports of its use in humans around peripheral nerves where muscles do not require excision or division and therefore where surgical hemorrhage is minimal. In view of our observations that Seprafilm® caused no complications or detrimental effects when placed around nerve roots of the brachial plexus, other areas such as carpal tunnel or cubital tunnel might be good areas in which to try Seprafilm®. Supporting such a trial is a study with hyaluronic acid placed over the sciatic nerve of rabbits, which demonstrated a reduction of scar tissue formation after neurolysis [10].

Conclusion

Seprafilm® made reoperations easier by reducing scarring between scalene fat pad and brachial plexus. However, it did not reduce the failure rate because it did not prevent scar tissue forming around the individual nerve roots, which probably developed because of postoperative bleeding from muscle ends, in spite of all efforts to prevent it.

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