Mattioli 1885 **Vol. 41/N. 3/December 2004**
ISSN 0080-3243

RIVISTA DI
Chirurgia della Mano
[A Magazine on Hand Surgery]

CHIRURGIA E RIABILITAZIONE DELLA MANO DELL'ARTO SUPERIORE E MICROCHIRURGIA
[Hand, Upper Limb Surgery and Rehabilitation and Microsurgery]
Official publication of the Italian Society of Hand Surgery

3/2004

RIVISTA DI
Chirurgia della Mano

CHIRURGIA E RIABILITAZIONE DELLA MANO DELL'ARTO SUPERIORE E MICROCHIRURGIA
Official publication of the Italian Society of Hand Surgery

Vol. 41/N. 3/December 2004

Riv. Chir. Mano – Vol. 41 (3) 2004

THE ANTI-ADHESION BARRIER MACROPORE'S SURGIWRAP* IN THE SURGICAL TREATMENT OF PERIPHERAL NERVE ENTRAPMENT SYNDROMES OF THE UPPER LIMB

C. ROSSI[1], E. MARGARITONDO[2], F. BIZZARRI[1], G. COSTANZO[1]
[1] Department of Pathology of the Locomotor System, Università degli Studi L'Aquila, Coppito (AQ), Orthopedics and Traumatology Depts "Ospedali Riuniti della Marsica"
[2] Ospedale "Sandro Pertini", Rome, Hand Surgery Dept

The anti-adhesion barrier Macropore's SurgiWrap in the surgical treatment of peripheral nerve entrapment syndromes of the upper limb*
SUMMARY

Purpose: *There are a number of nerve compression syndromes involving the upper limb, the most frequent of which are carpal tunnel syndrome, cubital tunnel syndrome and Guyon's tunnel syndrome. After surgical decompression of the nerve, symptoms often persist as a result of extra-neural fibrosis or scar adhesions. In recent years, a number of methods for treating these residual symptoms have been proposed which have had different degrees of success. The aim of this study was to evaluate the therapeutic possibilities of a self-absorbable, anti-adhesion film called "Macropore's SurgiWrap*" placed around the decompressed nerve.* **Materials and methods:** *This study was carried out between February and June 2003. Sixty patients treated with a self-absorbable film around decompressed nerves (group "A"), and sixty patients (control group "B") treated with simple surgery decompression of the nerve, without Macropore's SurgiWrap* film.* **Results:** *All patients of the group "A" resulted in a complete recovery, while two cases of the group "B" reported no significant pain relief or improvement in their sensory disturbances, (follow-up at 12 months).* **Conclusions:** *This completely self-absorbable film is made of a copolymer of lactic acid and could help prevent the formation of extraneural fibrous tissue or scar adhesions and thus the reoccurrence of symptoms and further surgical treatment. However, we believe that more detailed clinical studies are necessary to validate our findings.* **Riv Chir Mano 2004; 3: 158-162**

KEYWORDS
Macropore's SurgiWrap*, adhesions, extraneural fibrosis

Arrived: June 7, 20
Accepted: September 10, 2004
Correspondence: Dr Costantino Rossi, Via B. Davanzati, 7 – 00137 Rome – E-mail: costantinorossi@hotmail.com

INTRODUCTION

The most frequently occurring nerve compression syndromes of the upper limb are carpal tunnel syndrome, elbow cubital tunnel syndrome, and Guyon's tunnel syndrome. Usually, these nerve compression syndromes are treated surgically, by opening the anatomical tunnel that holds the compressed nerve, and proceeding with tenosynovectomy, synovectomy, cutting of the perineurium or neurolysis. The formation of extraneural fibrous tissue and scar adhesions between soft tissues may affect postsurgical

recovery and result in persisting symptoms even after nerve decompression. These symptoms are often due to the existence of an intense fibrosis or an extraneural scar that creates adhesions between the nerve and its contiguous tissues resulting in reduced nerve mobility and pain recurrence in the perineurium. To prevent the likelihood of these not-so-rare occurrences, we have considered studying the effects of the application of a self-absorbable, anti-adhesion barrier placed between the nerve and its contiguous tissues. Our study aims at evaluating the actual effectiveness of the use of anti-adhesion film Macropore's SurgiWrap*, according to its stated purposes:

1. to prevent the formation of abnormal scar tissue and the formation or recurrence of adhesions;
2. to facilitate further surgical procedures, in case of reoperation, by forming a surgical dissection plan adjacent to the anti-adhesion barrier.

SurgiWrap is a self-absorbable, biocompatible anti-adhesion film made of a copolymer of lactic acid absorbed first by hydrolysis of polymer chains and then by metabolization in CO_2 and H_2O of the lactic acid derived from part of the liver and excreted through the lungs. The product appears as a transparent film, .02 mm or .05 mm thick, available in sheets of various sizes (5x7 cm, 10x13 cm, and 13x20 cm), pliable, repositionable, and offering the possibility of securing it with suture stitches. (Fig. 1). The approximately 16-18 months needed for the complete reabsorption of the film allow the formation of a permanent physiological cleavage plan.

MATERIAL AND METHODS

This study was carried out between February and June 2003 on a group "A" of 60 patients under our treatment. Group "A" was treated in an outpatient facility and included 60 patients (52 women, 8 men), 45 affected by Carpal Tunnel Syndrome (CTS), 10 by Cubital Tunnel Syndrome (CuTS), and 5 by Guyon Tunnel Syndrome (GTS). (Tab. 1). All patients were evaluated with clinical tests, electromyography and X-ray exams of the cervical rachis in presurgical phase. No patients met the criteria of exclusion or contraindications to the use of SurgiWrap as follows: preexisting infection or inflammatory states, diabetes mellitus, presence of hypertrophic or pathological scars. All patients underwent surgical procedure under ischemia by applying a pneumatic blood pressure cuff around the top of the arm concerned. The SurgiWrap film was positioned between the nerve trunk and its surrounding tissues. Thus, in the treatment of carpal tunnel syndrome, SurgiWrap was positioned after neurolysis and tenolysis between tendons and nerve and between the latter and the subcutaneous tissue (Fig. 2). In the treatment of stenosis of the ulnar nerve in the Guyon tunnel, SurgiWrap was positioned between the flexor carpi ulnaris and the ulnar nerve and the subcutaneous. In the treatment of cubital tunnel syndrome, after release of the Osborne ligament, SurgiWrap was positioned between the ulnar nerve and the cubital tunnel floor, and between the nerve and the subcutaneous. After positioning SurgiWrap, the pneumatic pressure cuff was released and hemostasis checked. Sutures were applied with 3-0 nylon thread.

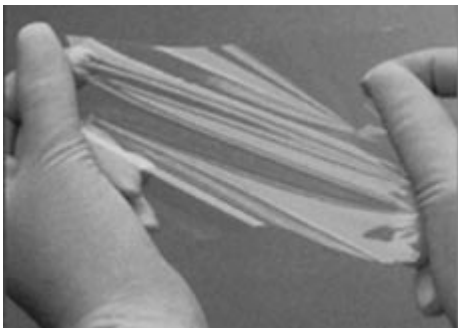

Figure 1. Macropore's SurgiWrap* film to be positioned around the nerve ligament after surgical release.

To evaluate the actual effectiveness of SurgiWrap film, in the same period of 2003 we treated a second group "B" of 60 patients affected by nerve compression syndromes of the upper limb, but without applying the anti-adhesive film (Tab. 1). This control group received the same diagnosis and treatment protocol, and the same exclusion criteria were applied.

RESULTS

All patients were submitted to postoperative checkups at 3 days, 10 days, 1 month, 2 months, 3 months, 6 months, and 1 year after surgery. A telephone checkup was also performed after 18 months. The patients in group "A" who underwent surgery with application of Macropore's SurgiWrap* did not display symptoms of either local or systemic allergic reactions. Thirty (30) days later, 80% (48 patients) showed normochromic and normotrophic surgical scars, not painful or tender to surface palpation. Furthermore, the same clinical checkup revealed the disappearance of preoperative pain and paresthetic symptoms, with negative Tinel's and Phalen's tests. One year after surgery, the patients expressed full satisfaction with the results obtained, with total recovery of working ability and barely visible surgical scar. No sign of residual symptoms due to deep adhesions or to excessive or pathological scarring processes were reported. One month after surgery, 13.4% (8 patients) showed reduced pain and paresthetic symptoms, a moderately red and hypertrophic surgical scar, painful and tender at surface palpation, negative Tinel's and Phalen's tests. The one-year checkup of these patients as well showed a complete recovery of working ability with disappearance of preoperative nerve symptoms, with a normotrophic and normochromic surgical scar. One month after surgery, 6.7% (4 patients) in group "A" complained of pains and paresthesia in the nerve area concerned, though to a lesser extent than reported at the first preoperative checkup, with Tinel's test positive and Phalen's negative. Surgical scar was reactive and hypertrophic, tender and sensitive. These patients were prescribed a 60-day therapy of one B12 complex tablet/day and application of a cortisone-based ointment on the surgical scar. The one-year checkup showed a marked improvement of the symptoms with nerve pathology defined by patients as sporadic and hardly noticeable. The surgical scar appeared raised but neither pathological nor tender. Telephone checkups revealed group "A" patients' satisfaction, with no relapse symptoms.

Figure 2. Application of the membranes around the median nerve, after its decompression at the carpal tunnel.

Table 1. *Summary of treated nerve compression syndromes of the upper limb. Group "A" with application of SurgiWrap film. Group "B" without SurgiWrap*

Group-"A"		Group-"B"	
52 Women	8 Men	47 Women	13 Men
45 CTS	(31) right (14) left	55 CTS	(41) right (14) left
10 CuTS	(7) right (3) left	3 CuTS	(3) right
5 GTS	(4) right (1) left	2 GTS	(1) right (1) left

As for the control group "B", one month after treatment, 75% (45 patients) showed a normochromic, normotrophic surgical scar, neither painful nor tender to surface palpation, disappearance of preoperative pain and paresthetic symptoms, Tinel's and Phalen's tests negative. One year after surgery, patients were satisfied with the results obtained, had total recovery of their working ability and a barely visible scar. No signs of relapse due to deep adhesions or excessive or pathological scarring processes. One month after surgery, 15% (9 patients) showed reduced pain and paresthetic symptoms, their surgical scar appeared moderately hyperchromic and hypertrophic, painful and tender at surface palpation, negative Tinel's and Phalen's tests. At the one-year after surgery final checkup these patients showed a complete recovery of their working ability, disappearance of preoperative nerve symptoms, a normotrophic and normochromic surgical scar. One month after surgery, 10% (6 patients) complained of pain and paresthesia in the nerve area concerned, to a lesser extent than reported at the first checkup, Tinel's test positive and Phalen's negative. The surgical scar was reactive and hypertrophic, tender and sensitive. This group was prescribed the same 60-day therapy of one B12 complex tablet/day and two daily applications of a cortisone-based ointment on the surgical scar. The one-year checkup showed a marked improvement of the symptoms, with patients reporting nerve pathology as acceptable and compatible with their daily working routine. The surgical scar appeared raised but neither pathological nor sensitive. During the three-month checkup, two of the six patients did not show signs of improvement, and after a further electromyography exam, they underwent a further surgical decompression of the nerve and neurolysis. In the first case of CTS the median nerve appeared trapped by excessive extraneural fibrous tissue, and in the second case of CuTS the ulnar nerve was trapped by excessive scar tissue and had limited mobility. One year after the second surgical intervention, patients showed markedly improved symptoms but were still not satisfied with the results. The 18-month telephone checkups on group B revealed the patients'

full satisfaction, except for two who reported persistence of paresthetic symptoms even after the second surgical neurolysis procedure.

DISCUSSION

Relapses of nerve compression syndromes of the upper limb are often due to postoperative formation of excessive extraneural fibrous tissue or to scar adhesions among the various tissue plans (1-4). The treatment method often employed in these cases is a further surgical release of the trapped nerve trunk, followed by protective coverage. The latter can be obtained by grafting an autologous saphenous vein (5-7), a hypothenar fat flap (8-10), or a free or pedicle flap (11-14). The industry has also created a pharmacological alternative, e.g. a self-absorbable gel, which is applied along the nerve trunk after its debridement (15, 16). Our study was therefore designed to prevent the treatment of relapse compression neuropathies by applying self-absorbable SurgiWrap film in the first place. The action of SurgiWrap film positioned during the first surgical nerve release aims at preventing the formation of adhesions between anatomical structures. Specifically, in carpal tunnel syndrome surgical interventions involving the cutting of the traverse carpal ligament with neurolysis or cutting of the perineurium, and tenolysis, one the most frequent causes of failure is the adhesion of the median nerve to soft tissues with impaired sliding of the tendon axle. The same holds true in the treatment of CuTS as well as of Guyon tunnel ulnar nerve compression, where the formation of a reactive fibrosis can decrease ulnar nerve mobility during elbow and wrist flexion and extension movements and recreate the preexisting conditions of neuralgia. No instances of specific intolerance to Macropore's SurgiWrap* film were reported 18 months after its surgical application. All patients treated with Macropore's SurgiWrap* film enjoyed excellent functional results and total absence of complications when compared to group "B". Therefore, based on the results obtained from our study, we believe SurgiWrap film to be an effective tool in the routine surgical treatment of upper limb nerve compression syndromes. However, we believe that further clinical research is needed in order to optimize the application of SurgiWrap film.

BIBLIOGRAPHY

1. Wadstroem J, Nigst H. Reoperation for carpal tunnel syndrome. A retrospective analysis of forty cases. Ann Chir Main 1986; 5: 54-8.

2. O'Malley MJ, Evanoff M, Terrono AL, et al. Factors that determine reexploration treatment of carpal tunnel syndrome. J Hand Surg 1992; 17A: 638-41.

3. Hunter JM. Recurrent carpal tunnel syndrome, epineural fibrous fixation, and traction neurophaty. Hand Clin 1991; 7:491-504.

4. Strasberg SR, Novak CB, Mackinnon SE, et al. Subjective and employment outcome following secondary carpal tunnel surgery. Ann Plast Surg 1994; 32: 485-9

5. Varatimidis SE, Vardakas DG, Goebel F, et al. Treatment of recurrent compressive neuropathy of peripheral nerves in the upper extremity with an autologous vein insulate. J Hand Surg 2001; 26A: 296-302.

6. Varatimidis SE, Riano F, Vardakas DG, et al. Recurrent compressive neuropathy of the median nerve at the wrist: treatment with autogenous saphenous vein wrapping. J Hand Surg 2002; 27B: 110-1.

7. Sotereanos DG, Giannakopoulos PN, Mitsionis GI, et al. Vein-graft wrapping for the treatment of recurrent compression of the median nerve. Microsurgery 1995; 16: 752-6.

8. Mathoulin C, Bahm J, Roukoz S. Pedicled hypothenar fat flap for median nerve coverage in

recalcitrant carpal tunnel syndrome. Hand Surg 2000; 5: 33-40.

9. Plancher KD, Idler RS, Lourie GM, et al. Recalcitrant carpal tunnel. The hypothenar fat pad flap. Hand Clin 1996; 12 : 337-49.

10. Giunta R, Frank U, Lanz U. The hypothenar fat-pad flap for reconstructive repair after scarrig of the median nerve at the wrist joint. Chir main 1998; 17: 107-12.

11. Jones NF, Shaw WW, Katz RG, et al. Circumferential wrapping of a flap around a scarred peripheral nerve for salvage of end-stage traction neuritis. J Hand Surg 1997; 22: 527-35.

12. Jones NF. Treatment of chronic pain by “wrapping” intact nerves with pedicle and free flaps. Hand Clin 1996; 12: 765-72.

13. Dahlin LB, Lekholm C, Kardum P, et al. Coverage of the median nerve with free and pedicled flaps for treatment of recurrent severe carpal tunnel syndrome. Scand J Plast Reconstr Surg Hand Surg 2002; 36: 172-6.

14. Rose EH. The use of the palmaris brevis flap in recurrent carpal tunnel syndrome. Hand Clin 1996; 12: 389- 95.

15. Boyce DE, Bantick G, Murison MS. The use of ADCON-T/N glycosaminoglycan gel in the revision of tethered scars. Br J Plast Surg 2000; 53: 403-5.

16. McCall TD, Grant GA, Britz GW, et al. Treatment of recurrent peripheral nerve entrapment problem role of scar formation and its possible treatment. Neurosurg Clin N Am 2001; 12: 329-39.

*SurgiWrap was acquired by MAST Biosurgery on May 14, 2004.

Please direct all correspondence to
MAST Biosurgery, 6749 Top Gun St., Suite C,
San Diego, CA (866) MASTBIO or visit us
@ www.mastbio.com