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ORIGINAL STUDY

Median nerve biodegradable wrapping : Clinical outcome of 10 patients

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Nerve wrap protectors are bioabsorbable synthetic materials made of collagen or extracellular matrix that provide a non-constricting encasement for injured peripheral nerves. They are designed to be used as an interface between the nerve and the surrounding tissue. After hydrated, they transform into a soft, pliable, nonfriable, easy to handle porous conduit. The wall of the nerve wrap has a longitudinal slit that allows to be placed around the injured nerve.

This article presents the surgical technique for median nerve neurolysis and nerve coverage using a collagen or an extracellular matrix nerve wrap protector in 10 patients with recurrent or persistent carpal tunnel syndrome. All patients had a mean of three previous open carpal tunnel operations, which were not successful. The mean follow-up was 3 years. Under axillary nerve block anaesthesia with the use of pneumatic tourniquet, a standard open carpal tunnel approach was done incorporating the previous incision. Scar tissue was excised in a healthy bed and the median nerve was thoroughly released with external neurolysis. An appropriate length of nerve wrap protector was cut longitudinally according to the length of nerve release. The nerve wrap was loosely sutured with separate polypropylene sutures No. 7-0. A volar splint was applied for a mean of 2 weeks followed by progressive passive and active range of motion rehabilitation exercises of the wrist and fingers.

At the last follow-up, all patients showed improvement of clinical symptoms, static two-point discrimination test and median nerve conduction studies, and absence of Tinel sign. Differences in outcome and complications with respect to the nerve wrap materials used were not observed.

Keywords : median nerve ; carpal tunnel syndrome ; scar tissue ; neurolysis ; nerve wrapping.

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INTRODUCTION

Carpal tunnel surgery is a very common procedure performed for the treatment of patients with

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carpal tunnel syndrome ; the rates of success of carpal tunnel surgery range from 60% to 94% (*3,8,10, 13,21,42*). However, treatment related complications and failures may occur in 3% to 32% of the cases (*3,8,10,13,21,42*). Most common causes of failure are incomplete release of the flexor retinaculum, traction neuropathy, real recurrent carpal tunnel syndrome because of post-operative perineural fibrosis, and installed nerve lesions at the time of operation (*33*). In these cases, a reoperation for nerve decompression and release of nerve-tissue adhesions is necessary (*11*).

Many surgical techniques have been described for the treatment of recurrent carpal tunnel syndrome. Some surgeons recommend simple external neurolysis of the median nerve (*7*), while others support the role of supplementary techniques to prevent the nerve from scarring including autologous vein graft wrapping, hypothenar fat pad flap, reverse radial artery fascial flap, posterior interosseous artery flap, synovial flap, muscle flaps and free flaps such as the free anterolateral thigh flap with vascularized lateral femoral cutaneous nerve (*1,2,5,12,15,16,32,34,3 6,37,39*). The disadvantages of autologous tissue techniques include donor site morbidity, risk of surgical complications, and probably, in patients with multiple previous operations and/or excessive scarring, limited availability of autologous material for coverage (*1,2,5,12,15,16,32,34,36,37,39*). In this setting, synthetic materials for nerve wrapping could be beneficial for nerve protection from tissue adhesions.

Collagen nerve wrap (NeuraWrap™ Nerve protector, Integra LifeSciences Corp., Plainsboro, NJ) is a biodegradable synthetic material of type I collagen matrix derived from bovine deep flexor tendons that provides a non-constricting encasement for injured peripheral nerves. The collagen nerve wrap is designed to be used as an interface between the nerve and the surrounding tissue, and as a coverage of vein grafts during bypass vascular surgery to prevent overdistension of these grafts. After hydrated, it transforms into a soft, pliable, nonfriable, easy to handle porous collagen conduit. The wall of the nerve wrap has a longitudinal slit that allows to be cut for easy placement around the injured nerve. The extracellular matrix nerve wrap protector (AxoGuard® Nerve Protector, AxoGen Inc., Alachua, Fl) is an implant that provides nonconstricting protection for peripheral nerves. It is designed to be an interface between the nerve and the surrounding tissue. It is comprised of an extracellular matrix derived from a porcine small intestinal submucosa and is fully remodeled during the healing process ; it is revascularized, gradually remodeled and incorporated into the patient's tissue. When hydrated, it is easy to handle, soft, pliable, nonfriable, and porous. It is flexible to accommodate movement of the joint and associated tendons, and has sufficient mechanical strength to hold sutures. It can be trimmed to the appropriate dimensions for covering the damaged portion of the nerve. It can be sutured around the nerve along the longitudinal slit to enclose the nerve, and/or secured with stay sutures through the epineurium.

In this article, we describe the surgical technique for median nerve neurolysis and coverage using a nerve wrap protector in 10 patients with recurrent or persistent carpal tunnel syndrome, and discuss the current techniques and materials for nerve protection after nerve release.

MATERIALS AND METHODS

We present 10 patients with recurrent (nine patients) or persistent (one patient) carpal tunnel syndrome treated with revision surgery and median nerve protection with a nerve wrap material at the authors' institutions from 2009 to 2013. There were eight women and two men with a mean age of 59 years (range, 34 to 70 years). Three patients had a history of wrist fracture. The dominant hand was involved in eight patients. All patients had a mean of three previous open carpal tunnel operations (range, 2-4 operations) within the previous 1.5 years, which, however, were not successful. The mean follow-up was 3 years (range, 0.5 to 5 years) ; no patient was lost to follow-up. All patients gave written informed consent for their data to be included in this study. This study was approved by the Institutional Review Board/Ethics Committee of the authors' institution.

Clinical symptoms at presentation included pain at the wrist, hyperesthesia and numbness at the ipsilateral index and middle fingers, which, according to the patients were evident after the initial surgery. Clinical examination at presentation showed a positive Tinel sign over the carpal tunnel and a > 8 mm static two-point discrimination test

at the ipsilateral index and middle fingers. Skin scarring at the wrist was obvious in one patient with four previous operations. Median nerve conduction studies confirmed the clinical diagnosis of recurrent carpal tunnel syndrome in all patients, demonstrating impaired median nerve conduction across the carpal tunnel manifested by delayed latencies and slowed conduction velocities.

Clinical symptoms, Tinel sign, static two-point discrimination test and median nerve conduction studies were evaluated ; clinical symptoms were determined by a 0-10 point visual pain scale from 0 (no symptoms) to 10 (severe and constant symptoms). Complications were recorded.

Surgical technique

Under axillary nerve block anaesthesia with the use of pneumatic tourniquet, a standard open carpal tunnel approach was done incorporating the previous incision. The incision was extended proximally and distally to expose the compressed nerve. Extensive scarring and compression of the median nerve was observed in all patients. Scar tissue was excised in a healthy bed and the median nerve was thoroughly released with external neurolysis (Fig. 1). Next, an appropriate length of the nerve wrap protector was selected and cut longitudinally according to the length of nerve release. The collagen nerve wrap (NeuraWrap™ Nerve protector, Integra LifeSciences Corp., Plainsboro, NJ) was used in five patients (Fig. 2) and the extracellular nerve wrap protector (AxoGuard® Nerve Protector, AxoGen Inc., Alachua, Fl) was used in the other five (Fig. 3). The nerve wrap was rinsed with saline to soften and be easier to handle, and was circumferentially wrapped around the median nerve with care not to be tight and potentially constrict the nerve. Then, the nerve wrap was loosely sutured with separate polypropylene sutures No. 7-0 (Prolene, Ethicon Inc, Somerville, NJ) across the longitudinal cut (Figs. 3 and 4). The tourniquet was then released, and meticulous hemostasis was done. Skin closure was done with separate nylon No. 4-0 sutures, and a volar splint was applied. The skin sutures were removed 10 days after the operation and the volar splint was discontinued at a mean of 2 weeks (range, 1-3 weeks), followed by progressive passive and active range of motion rehabilitation exercises of the wrist and fingers.

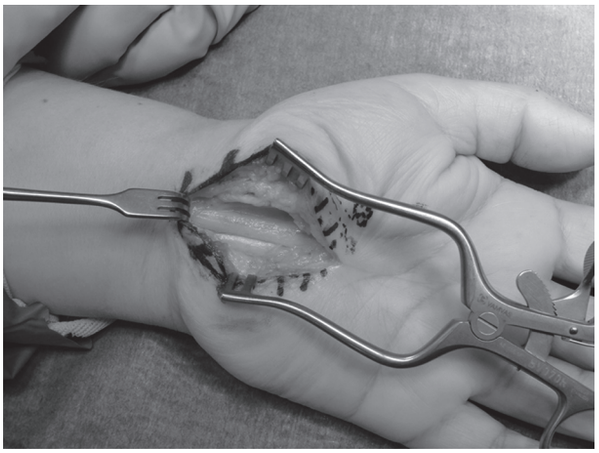

Fig. 1. — Intraoperative photograph shows complete scar tissue excision and external neurolysis.

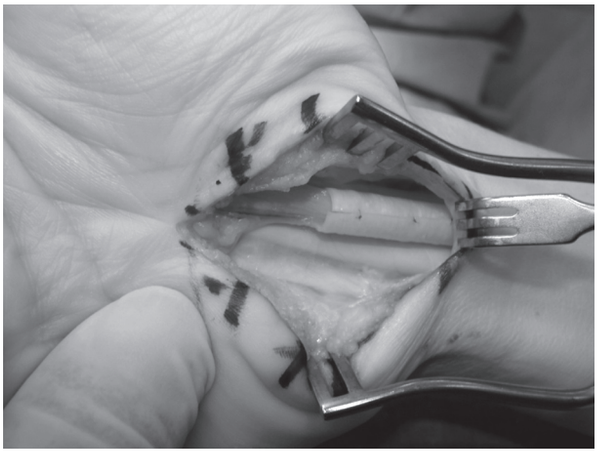

Fig. 2. — Intraoperative photograph shows median nerve wrapping with the collagen nerve wrap.

RESULTS

At the last follow-up, all patients showed improvement of pain at the wrist, hyperesthesia and numbness at the index and middle fingers. Tinel sign was absent and the static two-point discrimination test at the index and middle fingers was 3-9 mm. Median nerve conduction studies performed for the purpose of this study were improved compared to preoperative values. There were no differences with respect to the clinical symptoms, Tinel sign, static two-point discrimination test and median nerve conduction studies between the two groups of patients (Table I). Complications related to the nerve wrap materials were not observed.

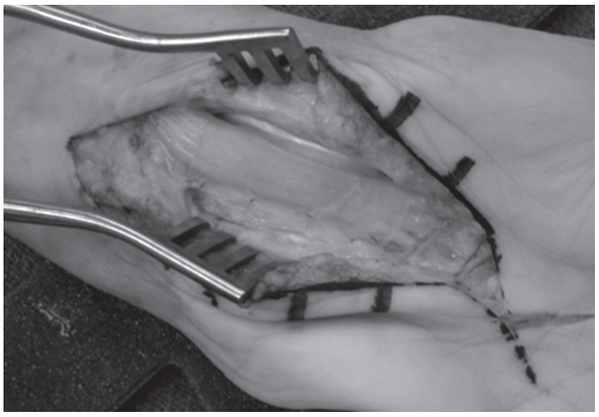

Fig. 3. — Intraoperative photograph shows median nerve wrapping with the extracellular matrix nerve wrap.

DISCUSSION

Although open carpal tunnel surgery is considered a relatively straight procedure, failures and complications may occur in up to 32% of the cases (*3,8,10,13,21,42*). Failures are usually due to insufficient release of the transverse carpal ligament or flexor retinaculum, followed by median nerve traction neuropathy, post-operative perineural fibrosis and installed nerve lesions at the time of operation (*1,17,18,24,25,33,35*). Scar tissue formation after the primary operation leads to recurrence of symptoms, in addition to deteriorated nerve compression and disruption of the nerve's vascular supply (*35*). In this setting, the surgical treatment of recurrent or persistent carpal tunnel syndrome is demanding, in order to remove the scar tissue and, if possible, to re-vascularize the median nerve so that the functionality of the nerve to be restored without any further recurrent symptoms (*6,7,28*). In this article, we presented two materials to protect the median nerve after neurolysis and scar tissue excision from previous failed open carpal tunnel operations. Our results showed complete resolution of symptoms without any implant-related complications or evidence of recurrence until the period of this writing. Because of the small sample size, we did not perform a statistical analysis to compare the two groups of patients to avoid a statistical error. However, direct comparison of the two groups did not show any differences in outcome with respect to the nerve wrap material used.

Carpal tunnel syndrome is most commonly idiopathic (*41*). The biomechanics of the carpal tunnel and transverse carpal ligament, and the exact pathophysiology of the syndrome leading to increase in pressure within the carpal tunnel that is responsible for median nerve neuropathy remains unknown (*9,20, 23,41*). Werthel *et al* (*41*) in an animal study showed that a shear injury of the subsynovial connective tissue induced similar noninflammatory thickening to what is observed in carpal tunnel syndrome, suggesting that this could be a pathway leading to idiopathic carpal tunnel syndrome (*41*). The anatomical characteristics of the transverse carpal ligament have also been clarified (*9*). Goitz *et al* (*9*) described that the thickness of the transverse carpal ligament varies along the path of the median nerve, with the thickest portions distal ulnarly and proximal radially. Moreover, the biomechanical role of the

Table I. — Details of preoperative and postoperative clinical symptoms, Tinel sign, static two-point discrimination, and median nerve conduction studies between the two groups of patients

Variables	Collagen nerve wrap		Extracellular matrix nerve wrap	
	Preoperative	*Postoperative*	*Preoperative*	*Postoperative*
Clinical symptoms	7-9 points	1-2 points	6-10 points	1-3 points
Tinel sign	Positive	Negative	Positive	Negative
Static two-point discrimination	10-15 mm	3-9 mm	8-14 mm	5-9 mm
Median nerve conduction studies	Delayed latencies and slowed conduction velocities	Improved	Delayed latencies and slowed conduction velocities	Improved
Complications		None		None

transverse carpal ligament in the compliant characteristics of the carpal tunnel is important (*20,23*) ; transection of the transverse carpal ligament leads to a nine times increase of carpal arch compliance (*20*), increase in carpal arch width and carpal tunnel volume, and changes in muscle and tendon mechanics compared to the intact carpal tunnel (*23*).

In cases of revision carpal tunnel surgery, some surgeons highlighted the importance of normal nerve excursion rather than soft tissue coverage following extensive neurolysis for median nerve adhesions (*6,7,28*). These authors do not recommend a vascularized flap coverage, and reported complete pain relief in 75% of their patients at a mean of 27.5 months follow-up (*7*). Other surgeons believe that soft tissue coverage of the median nerve is necessary for revascularization and prevention of re-formation of adhesions and scar tissue, and functional deficits from recurrent carpal tunnel syndrome (*26,27,29,30,38*). Several local muscle flaps such as the abductor digiti minimi, palmaris brevis, pronator quadratus and lumbrical muscles have been described to protect the nerve from scarring (*26,27,29,30,38*). The hypothenar fat pad flap for median nerve coverage has also been described (*4*) with an excellent pain relief (*34*) and a failure rate of less than 4.5% (*22*). Pedicle or free flaps such as the groin, lateral arm or posterior interosseous flap and the free anterolateral thigh flap with vascularized lateral femoral cutaneous nerve have also been described (*2,14,38*). However, the outcome was not always favorable (*2,14,38*) ; the surgical technique required for the dissection, transfer and positioning of muscle flaps is demanding, difficult to learn and is associated with a donor site morbidity. In addition, median nerve coverage with muscle tissue does not always prevent perineural fibrosis (*2,14,38*).

Median nerve wrapping techniques have also been described with variable results (*18,39*). Varitimidis *et al* (*39*) reported significant relief of symptoms in 15 patients with recurrent carpal tunnel syndrome at a mean of 43 months using an autologous saphenous vein wrapping technique. However, harvesting vein or muscle grafts is also associated with donor site morbidity and often results in bulky reconstructions, causing skin closure difficulties and therefore putting the graft and the reconstruction itself at risk, due to nerve bed ischemia. To avoid donor site morbidity and nerve adhesions, synthetic and biodegradable materials such as polyglycolic acid, polycaprolactine and silastic tubes have been used as alternatives for median nerve coverage and protection (*14,19,31,40*).

Synthetic nerve wrap protectors have also been reported (*3,19,40*). In the early 1960's, Kline *et al* (*14*) used a biodegradable nerve wrap tube for repair of peripheral nerve defects in chimpanzees. Subsequently, the efficacy of these tubes has been shown as conduits for nerve gaps as well as for protection of injured nerves (*19,31,40*). In 2011, Bilasy *et al* (*3*) reported the use of the Canaletto implant (Eurymed, Nimes, France) in 21 cases of revision surgery for carpal tunnel syndrome. Their surgical technique involved longitudinal incision of the "neoretinaculum", extrafascicular neurolysis of the median nerve without flexor synovectomy, and implant application with its siliconized deep surface in contact with the nerve and its edges sutured to the edges of the retinaculum. The goal was to prevent contraction of the two edges of the flexor retinaculum after incision, prevent perineural fibrosis and create a gliding plane for the median nerve. The results of the study were important. However, the ideal nerve wrap material to protect from formation of nerve scar tissue and adhesions, minimize inflammatory and immunologic reaction and improve the nerve's excursion and gliding has not been yet confirmed (*3, 14,19,31,40*).

In peripheral nerve surgery using the collagen or extracellular nerve wrap protector or similar products, extension of the previous incision is usually necessary for complete external neurolysis of the nerve with preservation of the nerve blood supply. Aiming for a biodegradable material for optimum nerve protection and coverage, we used the collagen and the extracellular porcine matrix nerve wrap in our patients with recurrent and persistent carpal tunnel syndrome after median nerve neurolysis. An appropriate length of nerve wrap is selected and cut longitudinally according to the length of nerve release. The nerve wrap should be loosely sutured across the longitudinal cut with separate No. 7-0 nylon sutures to avoid nerve constriction. Extensive tenosynovectomy should be avoided. Before wound

closure, meticulous hemostasis is required. By using this technique and a nerve wrap protector, all our patients experienced complete resolution of symptoms without evidence of recurrence at the last follow-up, and without any differences in outcome with respect to the nerve wrap material used.

Nerve wrap protectors are biodegradable materials designed to interpose between the nerve and surrounding tissue, isolating the former during the healing process. Through their pores they allow diffusion of supportive nutrients for the injured nerve, therefore, contributing to the nerve's revascularization process (*16*). They remain in place during the active phase of tissue healing and then they gradually and completely absorbed after tissue response has resolved. In this way, they protect the nerve from scar tissue formation and fibrosis, and prevent long-term nerve irritation that may necessitate reoperation and removal of a non-degradable implant. The indications for a biodegradable nerve wrap protector are recurrent carpal tunnel and cubital tunnel syndrome, nerve coverage of transected and microsurgically repaired peripheral nerves, and repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. The contraindications include active infection, patient's allergy to bovine and porcine products, and poor soft tissue bed that may require a muscle flap. The advantages of the collagen nerve wrap are lack of donor site morbidity, off-the-shelf availability and ease to use, availability in sterile packages in a variety of sizes for single-use only, and controlled rate of resorption. The disadvantages include cost, and limited preclinical and clinical data. Possible complications that may occur with any material used in nerve repair surgery include infection, acute or chronic inflammation, and allergic reaction ; initial application of surgical graft materials may be associated with transient, mild, localized inflammation. If any of these conditions occur and cannot be resolved, careful removal of the implant should be considered.

In conclusion, this article presented the technique of median nerve wrap with a biodegradable bovine collagen or porcine extracellular matrix nerve wrap material for nerve protection after scar tissue excision and neurolysis in 10 patients with recurrent carpal tunnel syndrome and advanced median nerve compression. By using these implants, there is no donor site morbidity, nor any implant-related complications. We recommend the use of these materials in revision nerve surgery for optimum nerve tissue healing.

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