Abstract

Study design: To evaluate the role played by the Layershield matrix (L.S.M.) in avoiding scar tissue and adhesion of the median nerve after decompression in carpal tunnel syndrome.

Objective: Prospective randomized trial to examine this technique. The idea was to investigate the potential benefits when dealing with complications (adherence of the flexor tendons and severing or scarring of the median nerve using the two-inch matrix as an adhesion barrier following mini-open carpal tunnel release).

Summary of background: The study cohort (L.S.M group) consisted of consecutive patients (200 patients) treated with L.S.M. Patients in the standard procedure group (200 patients in all) underwent operations using the same technique in carpal tunnel surgery in both groups, completing follow-up evaluations at no less than 3 to 6 months post-operation. The male to female ratio was 1:6. In twenty patients, there was bilateral involvement.

Method: All operations were conducted by the author at the Hospital General Universitario de Valencia, and the Clínica La Salud, Valencia, Spain, between 2012 and 2013. All patients complained of numbness and or sensory disturbance or weakness in the median nerve distribution of the hand. Tinel and Phalen sign tests were positive in about two-thirds of patients. EMG studies were performed in all patients and were positive, ranging from mild to severe.

Results: Numbness and paresthesia were relieved in 95% of patients in the L.S.M. group and 89% in the control group (CG). Pain was relieved in 95% DG and 90% CG. Motor weakness was relieved in 95% DG and 92% CG. Normal grip strength was evident in 93% DG and 91% had normal pinch strength.

Re-operation rate: Adherence of the flexor tendons in 3 CG patients and 8 patients due to scarring involving the median nerve, with the L.S. matrix group undergoing re-operation for the following reasons: recurrent pain (3 patients due to scarring around the median nerve). The difference in the re-operation rate between the collagen matrix group and the standard procedure group is statistically significant (p<0.01).

Conclusions: Findings in this study (reduced pain and lower incidence of adhesions) are consistent with the L.S. matrix acting as an effective adhesion barrier. By preventing median nerve adhesions, the L.S. matrix may significantly reduce the incidence of disabling pain associated with re-operation. Ultimately, the prophylactic use of the Layershield Matrix to prevent adhesions may result in improved patient outcomes.

INTRODUCTION

Carpal tunnel syndrome (CTS), or compressive median neuropathy at the transverse carpal ligament, is the mononeuropathy most commonly encountered in clinical practice. It has an estimated prevalence of 125 cases per 100,000 populations [1], although other surveys indicate that the prevalence may be as high as 1% of the population [2]. The clinical signs and symptoms include hand paresthesia, upper-extremity pain, Tinel’s sign on percussion over the median nerve at the wrist, Phalen’s sign, median distribution sensory loss, and thenar muscle weakness and atrophy. Many of these clinical features are not unique to CTS and distinguishing among the several causes of upper-extremity signs and symptoms often has
Electrodiagnostic testing, including motor and sensory nerve conduction studies and needle electromyographic (EMG) studies, plays an important role in the evaluation of patients with possible CTS. Electrodiagnostic testing has been shown to have a high degree of sensitivity and specificity in evaluation of CTS [3]. In addition, it may help to identify superimposed or alternative neuropathic conditions mimicking CTS, such as cervical radiculopathy, brachial plexopathy, proximal median neuropathy or other upper limb mononeuropathies, as well as peripheral neuropathy. When electrodiagnostic testing is normal, this may suggest that non-neuropathic conditions, such as arthritis or tendinitis, are responsible for the patient’s symptoms.

Despite the clear value of nerve conduction and EMG studies in the evaluation of patients with possible CTS, the tests may be underutilized in clinical practice. Since CTS has become an important public health problem because of its frequent occurrence in workplace settings leading to repetitive stress injury, its diagnosis and treatment have attracted the attention of organized medicine and governmental agencies. At least nine medical specialty societies have published position papers of various kinds, and three governmental agencies have issued statements on the subject [4]. There is an increasing debate related to the proper setting for electrodiagnostic testing, and some attempt has been made to limit its use in the diagnosis of CTS. Much of this debate has been based on the opinions of individuals or groups with varying degrees of expertise in the field, little on actual data. We carried out this study in order to determine the actual real-life experience of a clinical neurophysiology laboratory in the evaluation of CTS.

Surgical division of the transverse carpal ligament (TCL) has been performed since 1933 and is usually a relatively simple procedure [5]. A recent report on a microsurgical carpal tunnel release (CTR) technique, performed on an outpatient basis, documented excellent results equal to those obtained by using minimally invasive techniques such as the retinaculotome or the endoscope [6]. The reported advantage of the minimally invasive techniques is a small-sized incision, which allows for a short operating time and an early return to work for the patient.

A thorough knowledge of the anatomy of the carpal tunnel is essential in order to avoid complications and to ensure optimal patient outcome. There are many strong arguments for open (short 2-cm incision) vs. conservative treatment. Nerve conduction studies (NCS) potentially have great value in selecting patients for a specific treatment and in objectively assessing the efficacy of treatment for carpal tunnel syndrome. Release of the transverse carpal ligament can be performed safely under local anaesthetic without requiring a tourniquet (bupivacaine 0.5% without adrenaline) and bipolar diathermy. The local anaesthetic was injected into the carpal tunnel and into the subcutaneous tissue under the skin incision, from proximal to distal, in order to make infiltration more comfortable.

PURPOSE

The objective of this prospective clinical study was to investigate the potential benefits when dealing with complications (adherence of the flexor tendons and severing or scarring of the median nerve) using the Layershield Matrix (SuprofilmTM) as an adhesion barrier following mini open carpal tunnel release.

PATIENTS AND SETTING

The study cohort (LS matrix group) consisted of consecutive patients (200 patients) treated with Suprofilm. Patients in the standard procedure group (200 patients in all) underwent operations without using the matrix. Patients underwent carpal tunnel surgery (Figure 1) using the same technique in both groups and completed follow-up evaluations at no less than 12 to 24 months post-operation. The male to female ratio was 1:6. Twenty patients were found to have bilateral involvement. All operations were conducted by the author (2012-2013). All patients complained of numbness and/or sensory disturbance or weakness in the median nerve distribution of the hand. Tinel and Phalen sign tests were positive in about two-thirds of patients. EMG studies were performed in all patients and were positive, ranging from mild to severe.

STUDY DESIGN AND TECHNIQUE

To evaluate the role played by the LS matrix in avoiding scar tissue and adhesion of the median nerve after decompression in carpal tunnel syndrome (Figure 2).

RESULTS

Numbness and paresthesia were relieved in 95% of patients in the LSM group and 89% in the control group (CG). Pain was relieved in 95% DG and 90% CG. Motor weakness was relieved in 95% DG and 92% CG. Normal grip strength was evident in 93% DG and 91% had normal pinch strength.

RE-OPERATION RATE

Adherence of the flexor tendons in 3 CG patients and 8 patients due to scarring involved the median nerve, with the LS matrix group undergoing re-operation for the following reasons: recurrent pain (3 patients for scaring around the median nerve). The difference in re-operation rate between the LS matrix group and the standard procedure group is statistically significant (p<0.01). There were no infections or complications due to the LS matrix. After 8 weeks the matrix became endogenous tissue, meaning that fibrosis was over at this point.

Figure 1 Short incision for a carpal tunnel release.
DISCUSSION

Long-term persistent pain is a major determinant for the success or failure of open carpal tunnel release (OCTR). The complication of long-term persistent pain may arise from any of the following causes: hypertrophic skin scarring, intra- and perineural scarring, adherence of the nerve to the skin, subcutaneous tender nerve secondary to superficial position, adhesions between flexor tendons and the median nerve, pillar pain at the thenar and hypothenar eminences, and reflex sympathetic dystrophy (RSD) [7].

Hypertrophic scars are often the result of an incision that transverses the flexion crease at a right angle. If a painful hypertrophic scar should occur despite all attempts to prevent this, scar revision should be performed [6].

Intra- and perineural scarring sometimes produces dysesthesia, pain and hypersensitivity. Proper hemostasis is important to prevent perineural scarring [9]. If intra- and perineural scarring should develop despite the surgeon’s best efforts to prevent it, the hypersensitivity and dysesthesia respond to coverage of the nerve with a L.S matrix.

The superficial position of the median nerve and adherence of the nerve to the skin are usually consequences of an improper skin incision directly above the nerve, rather than toward the ulna. Splinting the wrist in a slightly dorsiflexed position for the first 3 to 5 postoperative days may lessen the likelihood of superficial nerve position [10]. Three common methods of insulating the nerve from the skin surface include: rotation of a hypothenar fat-pad flap; rotation of local muscle pedicle flaps, such as the pronator quadratus and abductor digitii minimi; and Z-plasty with underlying temporary silicone sheeting, or the easy way [11] is to use LS matrix to prevent scar adherence.

Tendon adhesions may result from poor hemostasis during conventional OCTR surgery or from bleeding associated with tenosynovectomy. Resection of the synovium is usually indicated only in cases of an extremely bulky synovium, such as those associated with rheumatoid arthritis, because of the propensity of tenosynovectomy to cause bleeding and scar formation with subsequent adhesions between tendons or between tendons and the median nerve [12]. Using the matrix may reduce this point.

Preoperatively, patients should be informed about the expected clinical course following carpal tunnel release. They should be specifically warned about tenderness around the incision for up to 8-12 weeks after the operation. Although night-time symptoms are often relieved immediately, other symptoms, such as persistent numbness, weakness or dumsiness are due to nerve damage. These will be very gradually resolved, and recovery may be incomplete [13]. The patient should be counseled regarding activity modification and the possible impact on his/her employment. The patient should also be instructed on the isolated tendon-gliding exercises to be initiated postoperatively.

Gentle exercise and light use of the hand is encouraged from the day after surgery. The bandage and stitches are removed about a week after surgery. The palm is tender for at least four to six weeks after the procedure. Golf and hand-related sports are usually too uncomfortable for up to six to eight weeks postop.

Patients planning to return immediately to strenuous activities may do so in a short arm cast or strong clamshell splint, 30 degrees wrist dorsiflexion, basal joint immobilized, worn for one month.

The effects of scar tissue shrinking and maturing result in adhesions which pull on the median nerve and often result in brief shooting or electrical pains with motion, particularly when the patient stretches his or her hand out to reach something at arm’s length. Sudden shooting or electrical shock pains may also occur spontaneously while the patient is inactive. Both of these are normal occurrences and improve with time [14].

The shrinking and swelling associated with scar maturation results in the feeling of a lump at the base of the palm at the proximal end of the incision. This is most noticeable when the patient leans on the hand while changing from a sitting to a standing position. This is normal and improves over time and with massages. Patients are given therapy to make their hands less tender. Grip strength is normally reduced for two to three months following surgery, but full recovery can be expected.

The mid-proximal palm is normally the most sensitive and tender to the touch during the interval from two to six weeks following surgery. The patient is given clearance to resume light activities within their own tolerance level, including driving, as soon as they feel comfortable enough to do so. They are encouraged to use common sense and avoid activities that may cause pain. They are normally seen for a follow-up visit four to six weeks after surgery.

CONCLUSIONS

Findings in this study (reduced pain and lower incidence of adhesions) are consistent with the Suprofilm Matrix acting as an effective adhesion barrier. By preventing median nerve adhesions, the collagen dural matrix may significantly reduce the incidence of disabling pain associated with re-operation. Ultimately, the prophylactic use of the L.S Matrix to prevent adhesions may result in improved patient outcomes.

REFERENCES

1. Dayican A, Unal VS, Portakal S, Utkan A, Tumoz MA. Carpal tunnel...


