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Use of a Bioresorbable Polylactide Sheet (OrthoWrap™) for Reduction of Soft Tissue Attachments in Hand Surgery

INTRODUCTION

The development of postoperative uncontrolled healing has long caused clinical problems for hand surgeons in a variety of scenarios. Acute repairs of either tendons or nerves has often been associated with the development of exuberant scar tissue postoperatively that interferes with function. It has been a long sought after goal to try to minimize this scar tissue using a variety of techniques in order to improve clinical outcome after these types of surgical interventions.

The minimizing of recurrent soft-tissue attachments and scar formation is particularly critical in patients where excision of scar tissue is already being performed, and the goal is to minimize this recurrence. This occurs, for example, in neurolysis where excess scar tissue is removed encasing nerves that have either been previously repaired or sustained trauma. Tenolysis is similar in that dense scar surrounding a tendon will not allow it to perform its purported function. Once a neurolysis or tenolysis has been performed, it is exceedingly difficult to minimize the amount of recurrent scarring since the very procedure itself will generally lead to some recurrence of that clinical problem. The surgeon's goal is to use whatever means available in order to improve the outcome of that particular procedure of removing scar tissue. This can also be a problem in an acute scenario since the repair of a tendon or nerve will obviously lead to formation of scar tissue, much of this in excess. A longstanding lofty goal of the hand surgeon is to minimize tendon scarring after flexor tendon repairs.

Postoperative soft tissue attachments can have different adverse effects depending upon the clinical situation. After nerve injury, the scarring can limit nerve function by interfering with the conduction of an electrical signal enhanced by the myelin sheath.

This restrictive scar tissue can then lead to poor nerve function, be it sensory or motor. In the case of tendon injury, the limitations of scar tissue are much more obvious. A tendon can exert its function only by a motion that leads to a desired function at the joint level, and scarring would obviously limit the excursion of that tendon, hence negating its function. For all of these reasons, it is clinically desirable to utilize techniques that limit soft tissue attachments in a variety of hand surgery scenarios.

Flexor tendon surgery perhaps presents the best model to analyze differing approaches used in achieving the goal of reinforcing soft tissues and minimizing tissue attachments to the device. Authors such as Gelberman and Manske have performed many basic science and clinical studies looking at this very problem of minimizing scar formation after flexor tendon repair.¹ Chemical agents ranging from nonsteroidal anti-inflammatories, 5-fluorouracil, and a variety of hyaluronic-acid-based products have all been used in order to reduce uncontrolled healing and scar formation.^{2,3,4} Unfortunately, none of these compounds have a mechanical effect in reducing extrinsic soft tissue attachments to the device surrounding the tendon.

During the past decade, peripheral nerve surgery has used mechanical separation of the tissues to improve outcome.⁵ Long ago, it was discovered that trophic factors were largely responsible for the healing of peripheral nerves and it was soon apparent by many authors that nerves can heal simply by providing a constrained environment to allow axons to grow protected from surrounded soft tissues. This concept affirms the fact that nerve healing is intrinsic and can occur for short distances without external scar tissue formation to provide blood supply. Studies have also indicated that intrinsic healing of flexor tendons

would suffice and obviates the need for scar formation as well. Therefore, in both peripheral nerve and tendon nerve repairs, a mechanical separation with a protective sheet may very well be a good clinical solution to this problem.

More recently, general and gynecologic surgeons have utilized bioresorbable technology to mechanically separate the tissues and prevent or limit soft tissue attachments to the device in abdominal or pelvic surgery. Clinical, as well as basic science studies, have confirmed that this leads to decreased soft tissue attachment formation that minimizes complications in these surgical disciplines.^{6,7} For reasons previously outlined, it would be advantageous to use this similar principle in minimizing the attachment of soft tissues in both tendon and nerve surgery. These protective sheets perform at the tissue level and will minimize adverse soft-tissue attachment to the anatomic structure in question. Other types of protective barrier materials perform at the cellular level and are less predictable in terms of placement or positioning and have the potential side effect of interfering with the desired tissue healing.

The OrthoWrap™ Bioresorbable Protective Sheet is a polylactide resorbable device with indications for use in Orthopedics. The OrthoWrap™ sheet is made from 70:30 Poly (L-lactide-co-D,L-lactide), more commonly known as PLA. Polylactide acid (PLA), has a long track record of having minimal tissue reaction with no known side effects. It is, of course, broken down to lactic acid which is naturally produced in the body and is further broken down into separate ester chains which are further metabolized by the liver into water and carbon dioxide. Therefore, there is no long-term collection of foreign body, either at the local tissue level or even remotely. Polylactide acid belongs to a chemical family known as alpha esters. This also would include polyglycolic acid (PGA). However, comparative studies of both these esters have indicated that PGA polymers cause a greater tissue reaction than PLA. Specifically, PLA has already been used as nerve conduit material, confirming its clinical tolerance in this setting. Therefore, the use of a polylactide acid bioresorbable sheet seems to be a natural extension of its clinical application as already demonstrated in other surgical disciplines. My current indications for the use of OrthoWrap™ is in scenarios where either a tenolysis or neurolysis is performed in a tissue bed that theoretically can lead to recurrent scarring, such as an area where one would expect a great deal of bleeding postoperatively. This is particularly the case when either neurolysis or tenolysis is performed at the forearm or wrist level where surrounding soft tissues have a greater

propensity for scar tissue formation. The use of a biologically well-tolerated protective sheet that separates opposing tissues around the treated structure would be advantageous. A natural extension of this application would be in the more acute scenario. Acute repair of a peripheral nerve, particularly at the forearm or wrist level, would also be a good indication for use of a protective sheet. Exact clinical usage depends upon the particular scenario. As an example, a median nerve neurolysis in a patient who had previous nerve and multiple tendon repairs would be a good indication in order to minimize soft tissue attachments to prevent recurrent scar tissue. Once the median nerve is neurolysed, the segment of scarred nerve is measured and the corresponding portion of OrthoWrap™ is then cut. The nerve is then wrapped with the OrthoWrap™ material, essentially creating a longitudinal tunnel that the nerve sits inside of. Several resorbable sutures are used to close that tunnel and maintain the protective environment of the OrthoWrap™ material. A similar construct is created after a tenolysis, but one must ensure that adequate tendon excursion can occur within the material so that it does not limit function. Other materials utilizing a similar mechanism are now available on the market, and the concept of mechanical barrier formation in this clinical setting is only now being explored.^{8,9,10} The performance of prospective studies comparing the use of this with controls is a necessary task in order to demonstrate its clinical effectiveness.

CASE STUDIES

1. A 9-year-old girl sustained a reportedly superficial laceration to the volar distal aspect of her forearm extending to the volar wrist crease. The patient was seen by a physician family member who treated this wound with simple suturing. There was no exploration or repair of deep structures. It soon became apparent to the patient's mother that the child was restricting use of that hand and described a tingling that extended into the digits along the median nerve course. After consultation, it was decided to bring the child to surgery where indeed it was noted that the median nerve had been cut for approximately 40% of its diameter with a great deal of scar tissue encasing it.(fig. 1a & b) The flexor carpi radialis had also been divided and was surrounded by scar tissue. Surrounding tenolysis was performed, and the median nerve was then repaired in a delayed manner after appropriate neurolysis.(fig. 1c) Both the median nerve and the wrist flexor tendon were encased in the OrthoWrap™ material in order to support the soft tissues and minimize the attachment

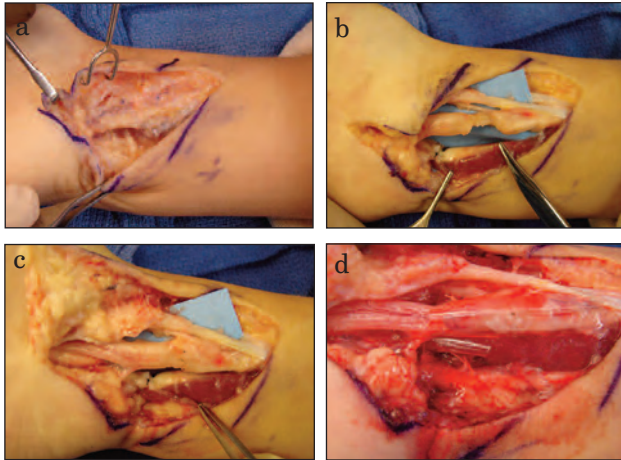


Figure 1.

of soft tissues to the device.(fig. 1d) The patient had no adverse reaction and regained digital motion very quickly. Within two months she was also noted to have early recovery of partial median nerve distribution sensation.

2. A middle-aged laborer had sustained open fractures of the radius and ulna as well as severe multiple tendon injuries and an ulnar nerve injury at the level of the distal forearm. The nerve was treated by cable sural nerve grafting at an outside institution, and the patient presented with persistent hypoesthesias in the ulnar nerve distribution as well as hypersensitivity in the area of the previous nerve repair. The patient was brought to the operating room where exploration of the previous nerve grafting was performed. It was noted that there was a great deal of scarring around the ulnar nerve but that the nerve grafts were in good continuity.(fig 2a) It was decided to perform a neurolysis and separate the nerve from the surrounding scarred tissue bed. In

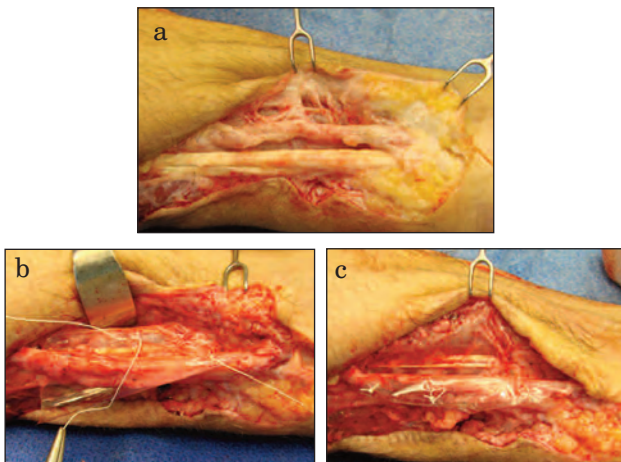


Figure 2.

order to support the soft tissues and minimize the attachment of soft tissues to the device, the nerve was encased in an OrthoWrap™ “tube” that was created during this revision surgery, and the skin directly overlying the ulnar nerve was repaired primarily.(figs. 2b & 2c) At short-term followup, it was noted that the patient had complete relief of the hyperesthesias and was being followed for recovery of improved ulnar sensation. There was no adverse tissue or skin reaction in the area of the OrthoWrap™ material placement.

3. A young female sustained accidental laceration in the volar ulnar forearm with numbness in the fourth and fifth fingers. At the time of surgical exploration, it was noted that the ulnar nerve was nearly completely divided, and a primary neurorrhaphy was

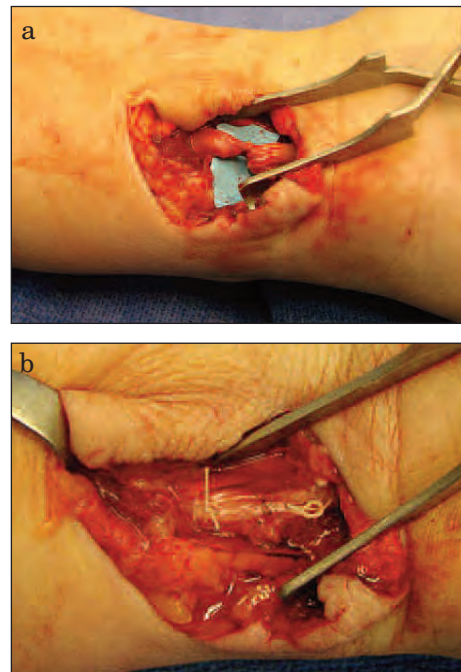


Figure 3.

performed.(fig. 3a) Due to its location in the forearm, surrounded by flexor muscles, it was decided to wrap the ulnar nerve after repair in an OrthoWrap™ sheet in order to support the soft tissues and minimize the attachment of soft tissues to the device that may inhibit healing or cause traction phenomena postoperatively.(fig 3b) The patient easily recovered digital range of motion and has had no adverse wound or tissue effects. She awaits return of sensation and hopefully some intrinsic function.

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