



VersaWrap[®]

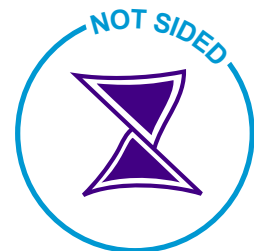
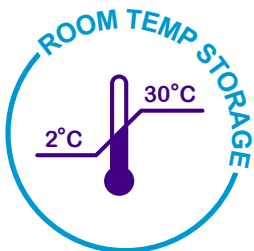
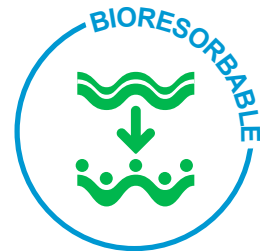
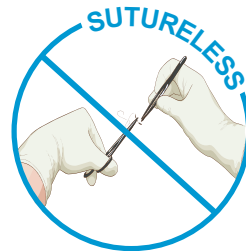
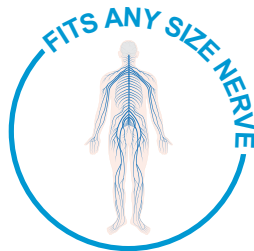


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VersaWrap® is an FDA-cleared medical device implant (not tissue) comprising hyaluronic acid (HA) and alginate that provides a gelatinous encasement for peripheral nerves, tendons, and surrounding tissues such as ligaments and skeletal muscles. VersaWrap® allows tissues to glide and to remain untethered, thereby reducing reoperations and improving patient outcomes.

The VersaWrap® Advantage



Surgical Technique

VersaWrap® consists of a bioresorbable hydrogel sheet and a wetting solution. The sheet is transparent, flexible, ultrathin, non-sided, and can be cut to the desired size before or during implantation procedures.

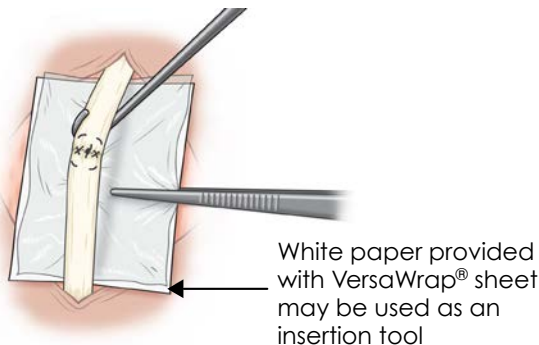
1. Cut sheet to size, as needed



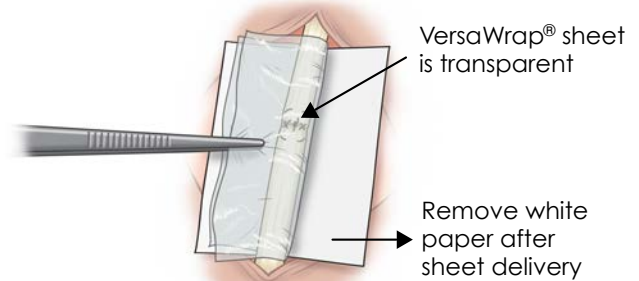
2. Implant sheet wet or dry



3. Lift repair for sheet placement

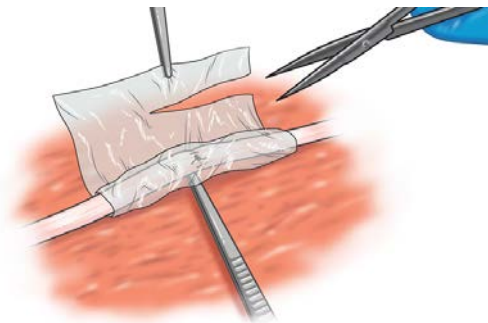


4. Wrap sheet to cover tissues

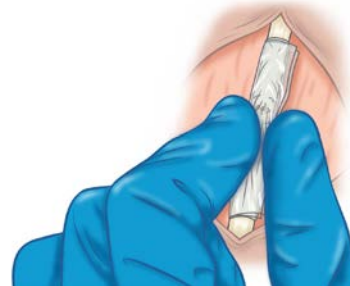


Once the sheet is positioned, the wetting solution is delivered to the sheet surface, rendering the sheet into an ultrathin gelatinous layer. VersaWrap® does not need to be sutured in place. VersaWrap® remains in place until healing is complete and then is bioresorbed.

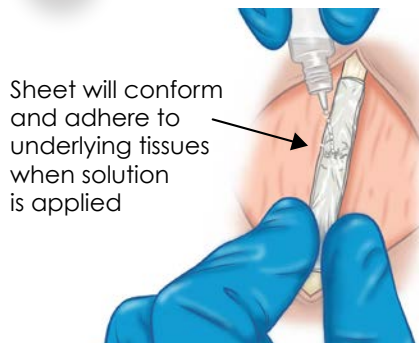
5. Cut sheet to size, as needed



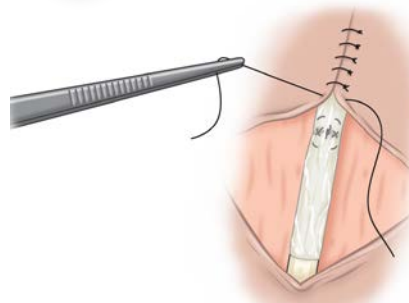
6. Ensure sheet contacts tissues



7. Apply VersaWrap solution

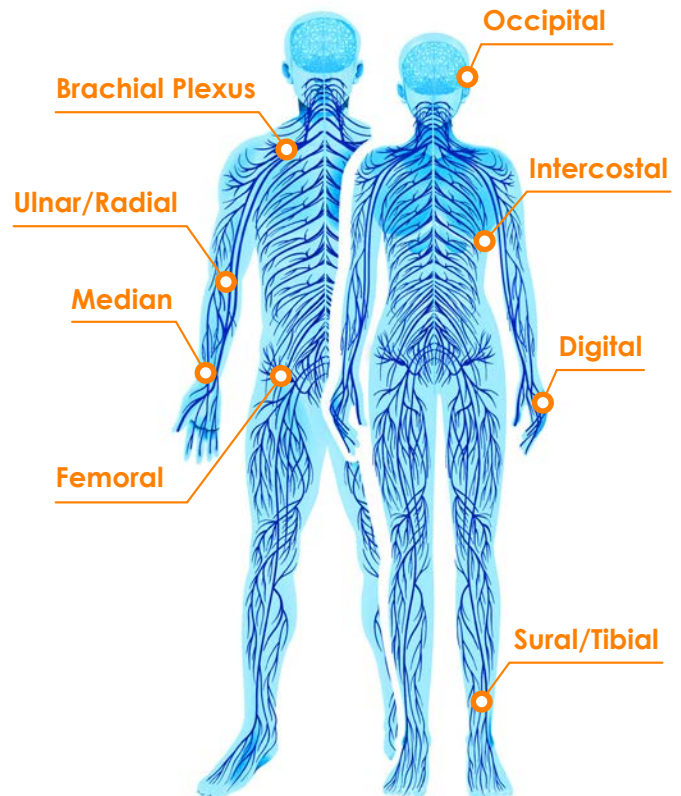
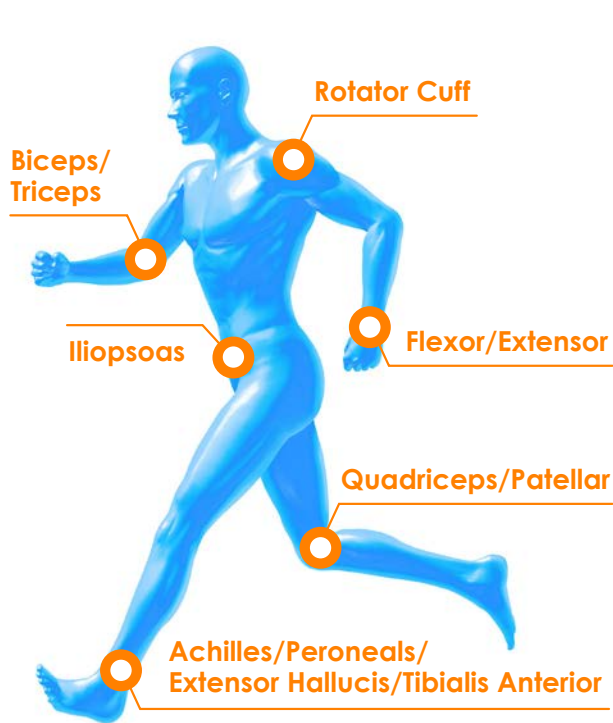


8. Close patient / continue procedure

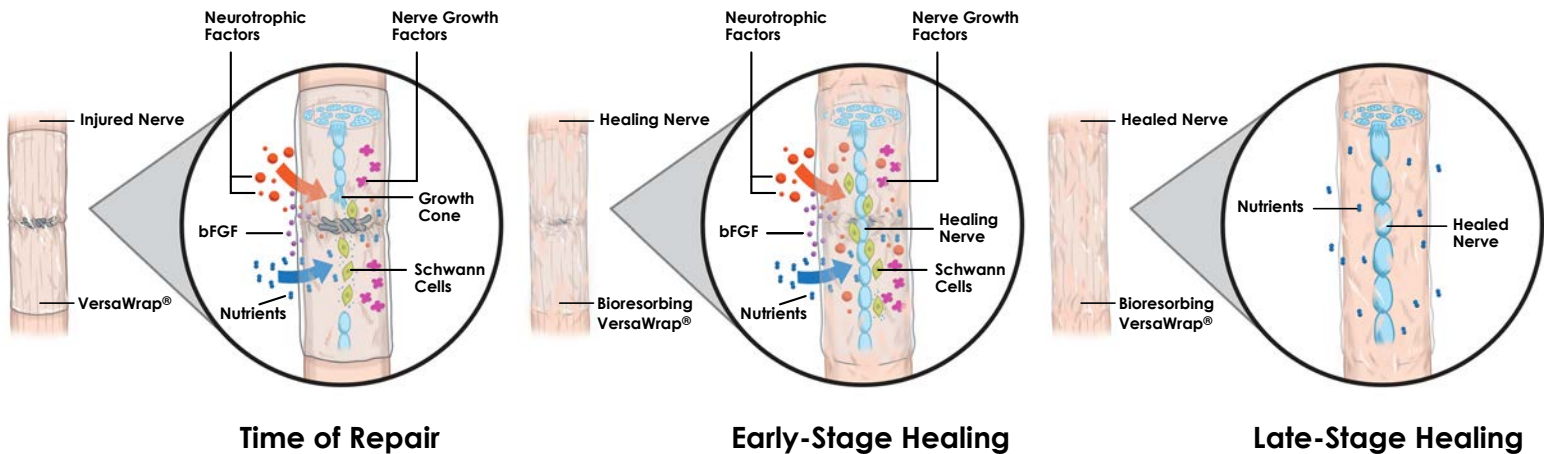


VersaWrap® Procedures

- Tenolysis/Neurolysis
- Crush injuries
- Stretch injuries
- Compression injuries
- Over direct suture repair
- Partially severed tendons/nerves
- Completely severed tendons/nerves following primary repair
- Tendon/nerve injuries and/or repairs that require separation/protection from surrounding soft tissues
- Reattachment or lengthening

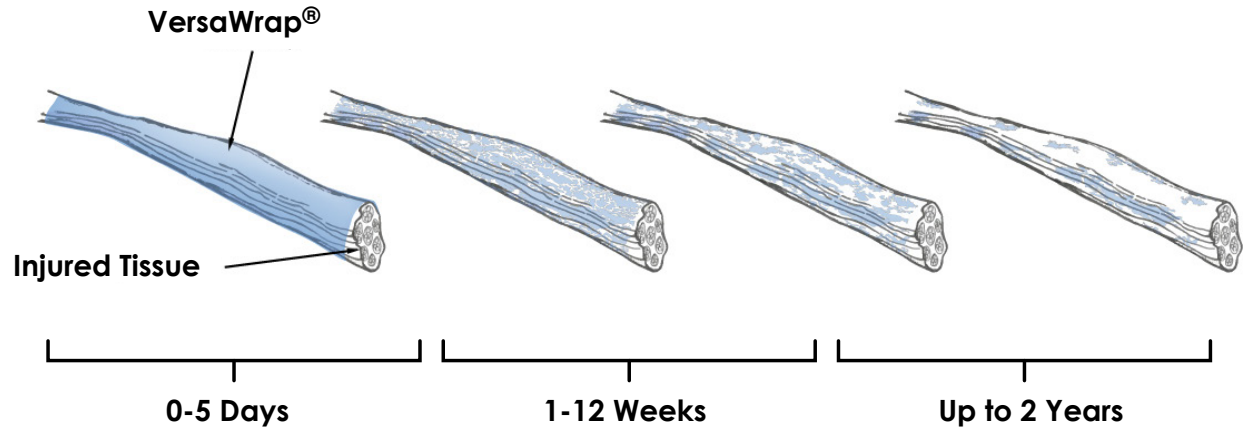


VersaWrap® Permeability



VersaWrap® is nano-porous with migration of biomolecules via passive diffusion¹. Water immobilized within the hydrogel allows rapid exchange of oxygen, nutrients, water soluble drugs and growth factors. Prior to bioresorption VersaWrap® is easily permeable to macromolecules up to 3.6 nm Stokes radius (i.e. small molecules required to support healing and regeneration) while large molecules, proteins, and cells such as fibroblasts are too large to diffuse during initial healing stages. This protection provides an optimal microenvironment for healing nerve by reducing the invasion of scar tissue forming fibroblasts to the injury site until late-stage healing.

VersaWrap® Bioresorption



VersaWrap® bioresorbs slowly throughout the healing period, over months to years². Complete bioresorption timepoint may vary, dependent on device placement and postoperative therapy. High fluid turnover rate and physical movement can increase bioresorption rate³. As VersaWrap® bioresorbs, the device is not replaced, seamlessly allowing protected and surrounding tissues to return to a pre-injured state.

² GLP data on file at Alafair (TR-011, Biocompatibility)

³ GLP data of file at Alafair (TR-054, Preclinical)

Preclinical Effectiveness^{4,5}

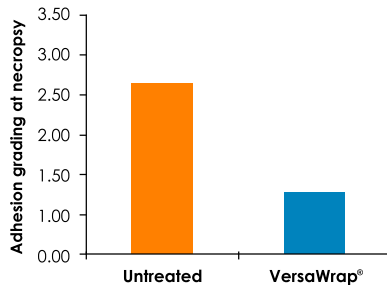


Fig 1: VersaWrap®-treated tendons had less scarring (N=10)⁴

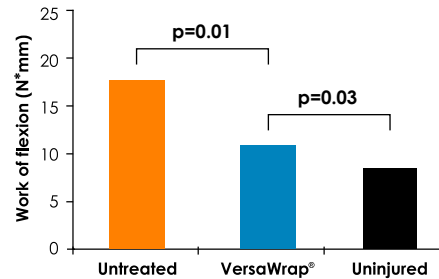


Fig 2: VersaWrap® decreased work of flexion (N=6)⁵

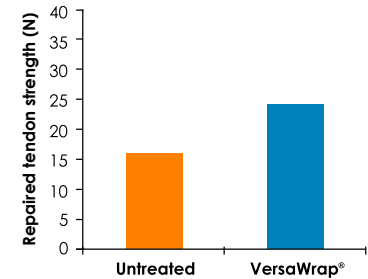


Fig 3: VersaWrap® did not reduce repaired tendon strength (N=10)⁴

VersaWrap®-treated animals had significantly less scarring as evidenced histologically (Fig 1). VersaWrap® significantly reduced the energy required to flex the repaired digit (Fig 2), demonstrating less unwanted extrinsic (tendon-to-surrounding tissue) scarring and an improved overall recovery. Furthermore, the strength of the healed tendon was preserved, demonstrating that VersaWrap® does not interrupt desired intrinsic (tendon-to-tendon) healing (Fig 3).

Preclinical results

Endpoint	Results
Scarring Fig. 1	No tissue attachments were observed to VersaWrap® or VersaWrap® - protected areas.
Work of flexion Fig. 2	The energy required to flex the digit was significantly reduced with the application of VersaWrap®. These results demonstrate a reduction in unwanted extrinsic healing that often tethers tendons to surrounding tissue.
Repaired tendon strength Fig. 3	The significant improvement in repaired tendon with the application of VersaWrap® demonstrates that VersaWrap® protects desired intrinsic tendon-to-tendon healing.

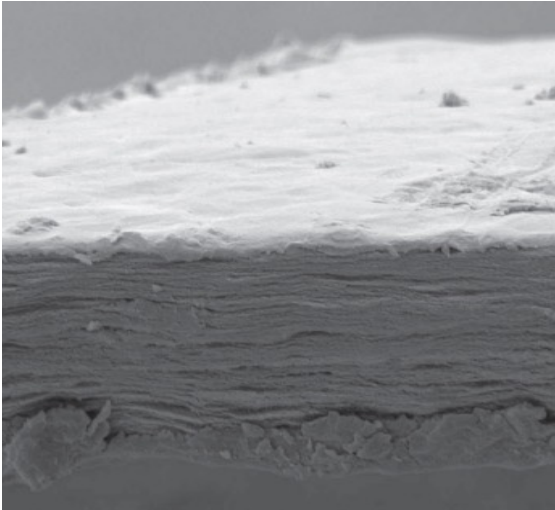
⁴ Data on file at Alafair, 279-11, GLP study

⁵ Data on file at Alafair, 279-04, Non-GLP pilot study

VersaWrap® is Safe

VersaWrap® is comprised of hydrophilic polysaccharides, hyaluronic acid (HA) and alginate. The human body uses HA as the predominant healing material for tissues and organs. VersaWrap® HA is fermentation sourced with no animal products or byproducts. VersaWrap® alginate is harvested from deep ocean seaweed and is widely used in wound healing products. VersaWrap® meets or surpasses standard biocompatibility requirements⁶.

A.



B.

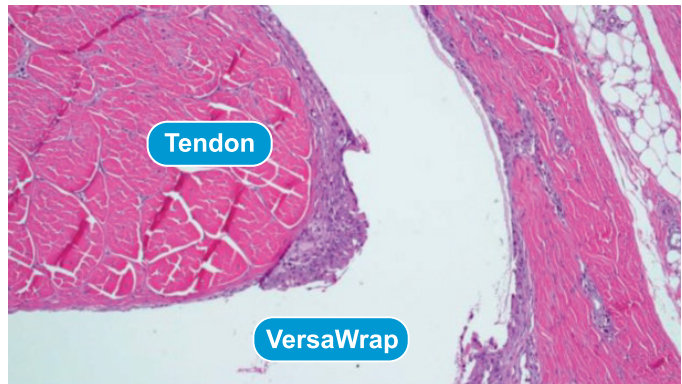


Figure: A) Cross-sectional microscopy image of VersaWrap Sheet (1000x); **B)** VersaWrap® remains in place to protect target tissues from unwanted postoperative tethering to surrounding tissues. Note the lack of foreign body reaction to VersaWrap. Inflammatory cells are absent and the implant has not been encapsulated.

VersaWrap® applied in cubital tunnel release with transposition of ulnar nerve

Type of Injury

Recurrent cubital tunnel

Patient

This patient is a 68-year-old male with a history of two previous cubital tunnel releases who presented with persistent symptoms related to ulnar nerve compression at the elbow.

Treatment

Patient underwent repeat cubital tunnel release with submuscular transposition of the ulnar nerve. VersaWrap® was used to wrap the ulnar nerve to reduce postoperative scarring.

Result

In this case, the surgeon stated that VersaWrap® protected the nerve from tethering to surrounding tissues. At six (6) weeks follow-up, the patient was improved with positive postoperative outcomes.



Figure: Application of VersaWrap® around ulnar nerve

VersaWrap® applied in flexor tendon repair with common digital nerve contusion

Type of Injury

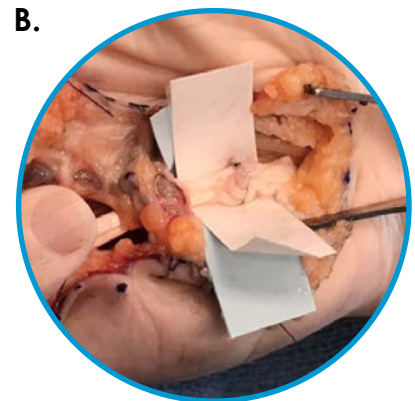
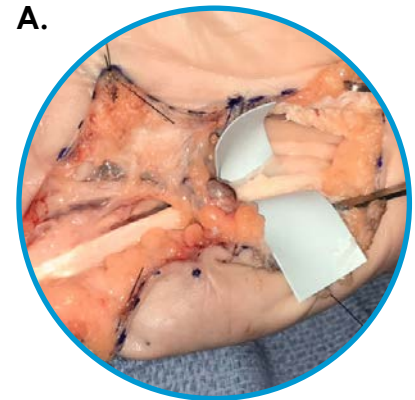
Traumatic injury on right, dominant hand leading to a ruptured FDP with an organized hematoma around common digital nerves

Patient

The patient is an otherwise healthy 73-year-old male who was walking a dog when the dog leash yanked suddenly, causing immediate pain in the patient's dominant right hand. At the time of the injury, the patient was away on vacation and sought first aid from a local clinic. Upon returning home, he saw his primary care physician 23 days post-injury and was subsequently referred to a hand surgeon. Pre-operative assessment revealed the patient had a swollen and slightly bruised small finger with absent flexor digitorum profundus (FDP) function. Sensation was present throughout all fingers.

Treatment

Surgical exploration was conducted at 26 days post-injury and the small finger FDP was found ruptured in the palm, at the transverse carpal ligament level. A small organized hematoma was found in the palm, around the common

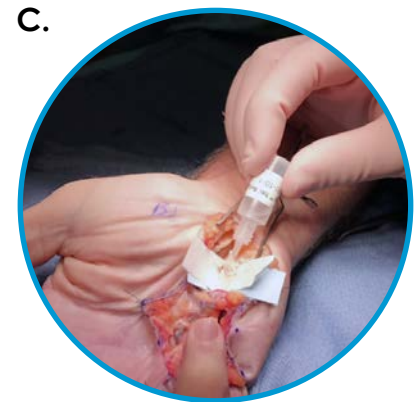


digital nerves to the small finger. The small finger FDP was repaired and VersaWrap® was wrapped around the tenorrhaphy site. Neurolysis of the digital nerves to the small finger was conducted, debriding the hematoma. Postoperatively, a routine flexor tendon rehabilitation protocol was followed along with supervised hand therapy.

Result

In this case, the surgeon stated that at five months follow-up, the patient had excellent active motion. The patient is able to make a full composite fist with no flexion contractures. The soft tissue envelope is in excellent condition with normal sensation in the digital nerves to the injured small finger. In this patient's case, VersaWrap® allowed for complete restoration of tendon function without the need for tenolysis or additional procedures despite the late presentation for definitive care.

Figure: A) Small finger FDP rupture in the palm; transverse carpal ligament is opened to allow access to tendon in canal; nerve and vessel cross over tendon (hematoma has already been washed away); **B)** Application of VersaWrap® sheet around tendon repair; **C)** Application of VersaWrap® solution on sheet.



VersaWrap® applied in Zone 2 concomitant flexor tendon and digital nerve repairs of the hand

Type of Injury

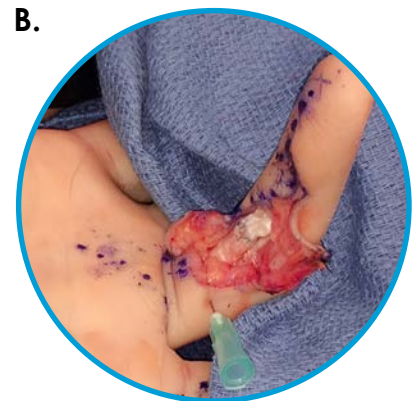
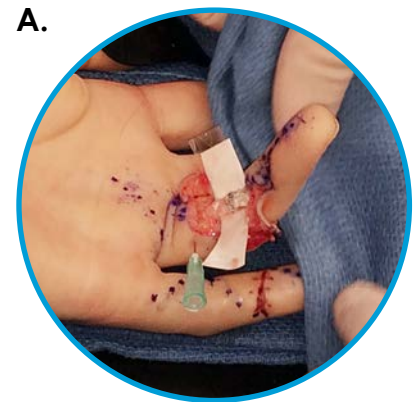
Laceration on volar aspects of small and ring fingers of non-dominant hand leading to FDP, FDS, and digital nerve lacerations of the small and ring finger

Patient

The patient is a healthy 34-year-old male who sustained a volar aspect laceration across the small finger at the DIP joint level and across the ring finger at the PIP joint level of the left, non-dominant hand. The lacerations resulted from a spinning piece of sheet metal. Immediate wound care was provided at a local ER. The patient was referred to a hand surgeon for definitive care.

Treatment

Pre-operative assessment presented with numbness along the ulnar border of both the small finger and ring finger, and absent flexor digitorum profundus (FDP) tendon function to both the small finger and ring finger. Surgical exploration was performed at 9 days post-injury and the small finger FDP and ring finger FDP were both found to be lacerated. One of the two slips of the ring finger flexor digitorum superficialis (FDS) was also lacerated. The ulnar digital nerves of both fingers



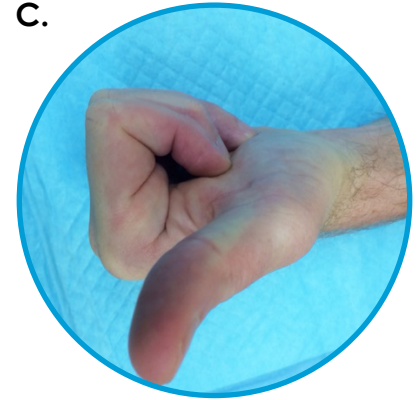
were also lacerated. FDP of both small and ring fingers were repaired. The FDS of the ring finger was repaired. Each tenorrhaphy site was treated with VersaWrap®. Adjacent ulnar digital nerves were repaired for both digits. Postoperatively a routine flexor tendon rehabilitation protocol was followed.

Result

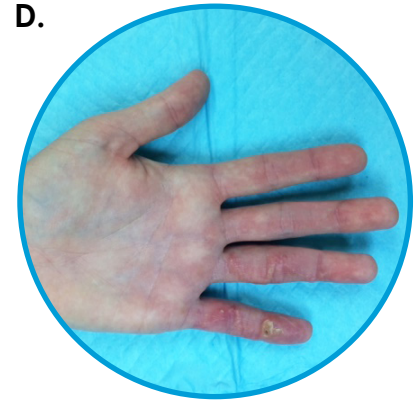
In this case, the surgeon stated that VersaWrap® allowed for complete restoration of tendon function with no deleterious effects to adjacent nerve healing. At three months follow-up, patient had excellent range of motion of all digits. The scars were remodeled very well with excellent soft tissue envelopes in both digits. The patient showed independent glide between FDS and FDP with mild residual stiffness. Tinel's sign over the repaired digital nerves was out to the DIP flexion crease level.

Figure: Small finger FDP and FDS repair with **A)** application of VersaWrap® sheet around tendon repair and **B)** application of VersaWrap® solution on sheet; three months follow-up with **C)** full fist and **D)** full extension.

C.



D.



VersaWrap® applied in Zone 2 multiple flexor tendon repairs of the hand

Type of Injury

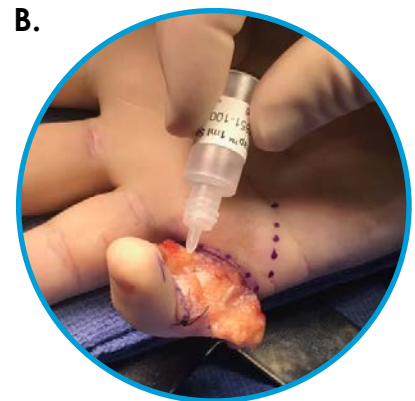
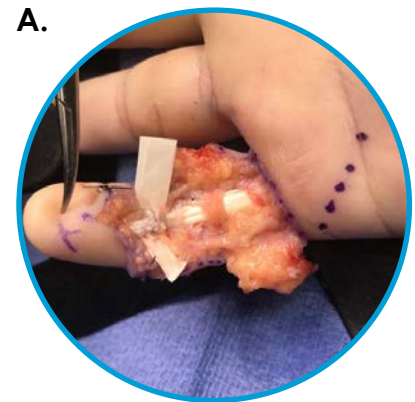
Laceration on volar aspects of small and ring fingers of right, dominant hand leading to FDP and FDS lacerations with contused common digital nerves

Patient

The patient is a healthy 23-year-old male who sustained an accidental self-inflicted knife wound to the right, dominant hand. Immediate wound care was provided at a local ER. The patient subsequently saw his primary care physician and was then referred to a hand surgeon for definitive care. Pre-operative assessment was conducted at 14 days post-injury. Patient presented with absent sensation along ulnar border of small finger and absent flexor tendon function to the small finger.

Treatment

Surgical exploration was performed at 17 days post-injury, and the small finger flexor digitorum profundus (FDP) and flexor digitorum superficialis (FDS) were found to be lacerated. The digital nerves of the small finger had contusions but were not completely lacerated. The small finger FDP and both slips of FDS were repaired. Each tenorrhaphy site was

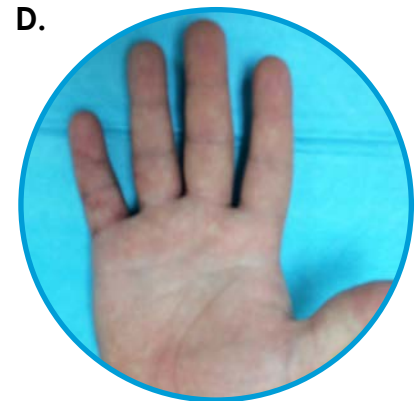


treated with VersaWrap®. Postoperatively, a routine flexor tendon rehabilitation protocol was followed along with supervised hand therapy.

Result

In this case, the surgeon stated that VersaWrap® allowed for complete restoration of tendon function with no deleterious effects to adjacent nerve healing. At three months follow-up, the patient had excellent range of motion of all digits. The patient was able to make a full composite fist with no flexion contractures. The soft tissue envelope was in excellent condition with normal sensation in the digital nerves to the injured small finger. Sensation was equal in all digits with a 5 mm 2-point discrimination, including the small finger with the nerve contusion.

Figure: Small finger FDP and FDS repair with **A)** application of VersaWrap® sheet around tendon repair and **B)** application of VersaWrap® solution on sheet; three months follow-up with **C)** full fist and **D)** full extension.



VersaWrap® applied in peroneal tendon dislocation reconstruction

Type of Injury

Peroneal Tendon Dislocation

Patient

This patient is a 44-year-old active female who had a twisting injury while skiing 3 months prior to surgery. She experienced lateral ankle pain and snapping of the peroneal tendons during activity.

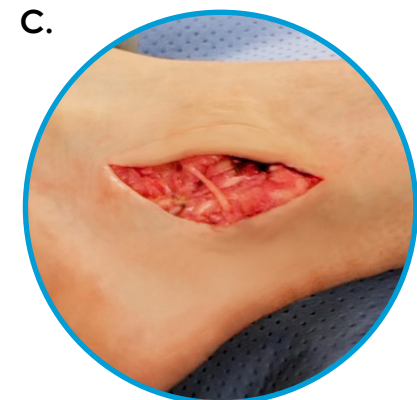
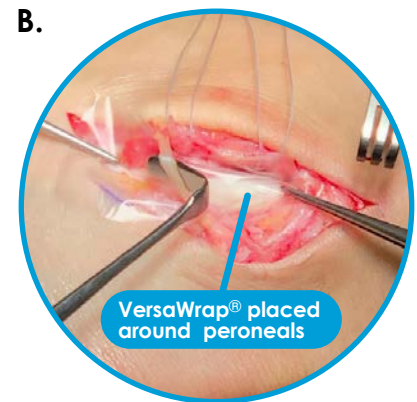
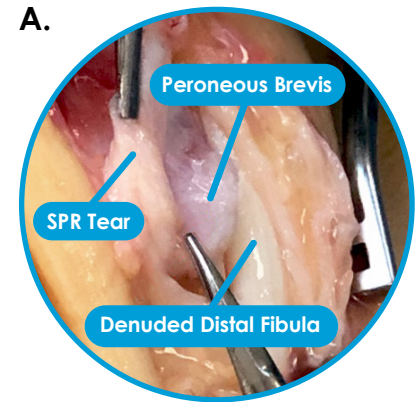
Treatment

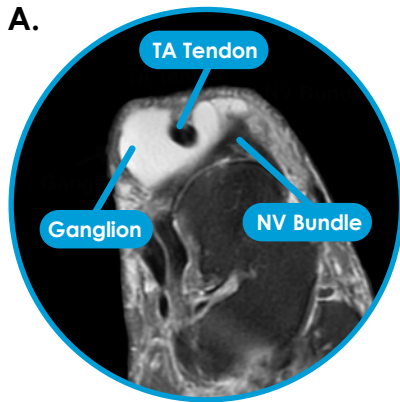
Peroneal tendoscopy was performed followed by an open repair which revealed a denuded distal fibula. VersaWrap® was placed around the peroneal tendons prior to the final repair of the SPR.

Result

In this case, the final repair allowed for gliding of the tendons with a restoration of a normal SPR. The surgeon stated that at 3 months postoperative, the patient was pain-free and returned to sports activity with full excursion of her tendon unit.

Figure: **A)** Superior peroneal retinacular tear (SPR) with a split tear of the peroneus brevis; **B)** Application of VersaWrap® around peroneals; **C)** VersaWrap® conformed to peroneals after application of VersaWrap® solution.





VersaWrap® applied in anterior ankle ganglion cyst excision

Type of Injury

Anterior ankle ganglion cyst

Patient

The patient is a 67-year-old male with 2 years of anterior ankle pain and swelling. He developed tibialis anterior synovitis and compression of his anterior neurovascular bundle (NV) at the level of the ankle causing pain and numbness.

Treatment

Operative findings included a multiloculated cyst with invasion of the tendon sheath and nerve. VersaWrap® was placed around the tendon and next to the neurovascular bundle.

Result

In this case, the surgeon stated that at 6 months, the patient had full tendon function and no nerve symptoms with all numbness resolved.

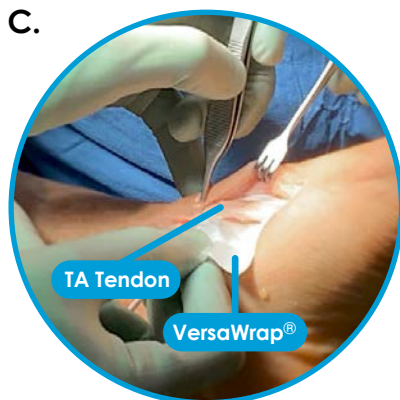
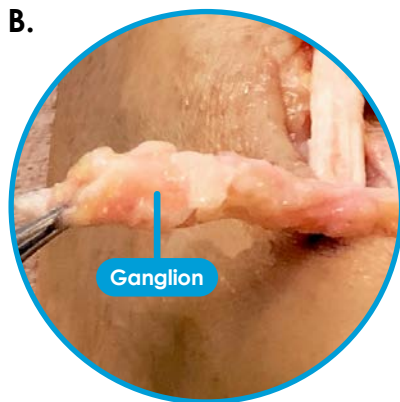


Figure: **A)** Axial T2 MRI demonstrates a complex cyst encapsulating the Tibialis Anterior tendon (TA) with abutment to the anterior tibial artery and nerve; **B)** Operative findings of Ganglion Cyst adjacent to Tibialis Anterior tendon and neurovascular bundle; **C)** Application of VersaWrap® around the Tibialis Anterior tendon.



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www.alafairbiosciences.com

VersaWrap® Product Features

Composition: Hyaluronic acid (HA) and alginate

Appearance: Flat, dry sheet with clear solution

Color: Translucent

Size: 1 x 2 inch (25 x 50 mm), 2 x 2 inch (50 x 50 mm), 1 mL

Storage conditions: 2°C-30°C

VersaWrap® Ordering Information

Catalog Number: VTP-2201, VTP-1201

For order inquiries: 800.206.5586 or
sales@alafairbiosciences.com

Always refer to the package insert, product label, and/or user instructions before using any Alafair product. Surgeons must rely on their own clinical judgement when deciding which treatments and procedures to use with patients. Products may not be available in all markets. Product availability is subject to the regulatory or medical practices that govern individual markets. Please contact your Alafair representative if you have questions about the availability of Alafair products in your area.

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