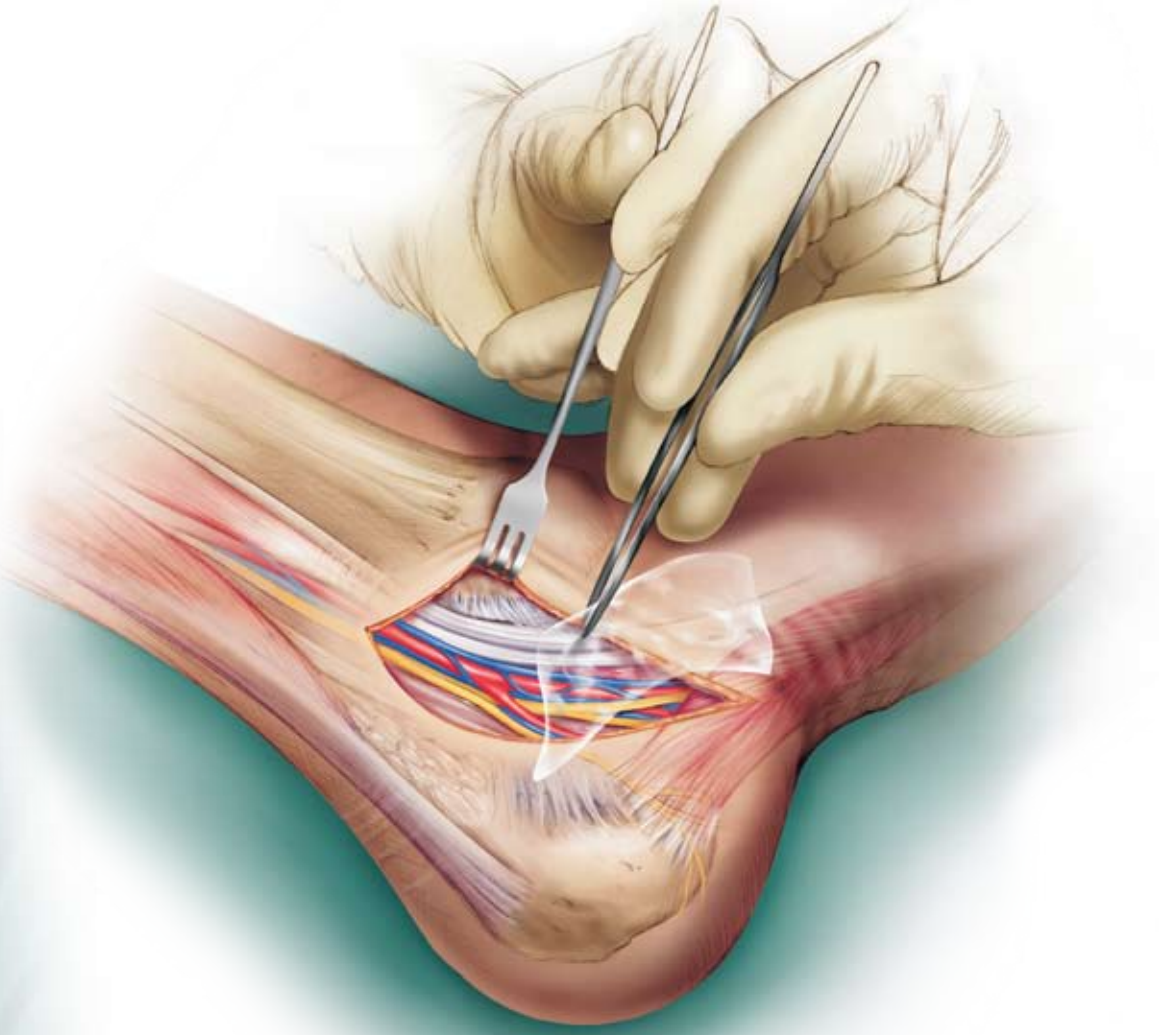
OrthoWrap™ MAST

Bioresorbable Protective Sheet



Tendon Repair – Foot & Ankle
technique guide

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Background of Tendon Repair

Tendon surgery is done most commonly when injuries involving the tendon occur. Tendon injuries that frequently require surgery are:

1. ***Acute tendon ruptures*** Repairing the ruptured tendon has numerous suture techniques with most demonstrating adequate strength to maintain the repair. Tendon allografts, autogenous tendon grafts, or tendon transfers are well described to augment the repair. The advent of biomaterials to augment the repair have been popularized to supplement the repair more recently. These techniques are especially used when gaps within the tendon are present. This graft supplementation is best documented in Achilles tendon ruptures, but it is also being used for repair of the posterior tibial tendon and other acute ruptures.

2. ***Chronic tendon injuries*** Surgical intervention for these injuries is more common in the chronic degenerative process of the posterior tibial tendon when treating posterior tibial tendon dysfunction or in chronic and recalcitrant Achilles tendinosis. The technique for repairing the chronic degenerative process usually involves excision of the degenerative tendon with some suture technique to repair the remaining tendon. Again, augmentation of the repair has been popularized with the new graft materials available.

OrthoWrap™ Bioresorbable Protective Sheet

The OrthoWrap™ Bioresorbable Protective Sheet can be utilized for the management and protection of tendon injuries where there has been no substantial loss of tendon tissue. The OrthoWrap™ sheet minimizes soft tissue attachments to the device in case of direct contact with other tissues. It can be cut with sterile scissors, shaping the material according to the preference of the surgeon for the anatomic considerations of the patient and surgical procedure. The OrthoWrap™ sheet is then sutured into place using absorbable suture. This clear sheet allows for good visualization of the tissues to ensure proper placement. However, the mechanical integrity and handling of the material is simple and allows for repositioning as often as necessary to ensure proper placement is achieved.

Discussion

Whether the tendon is repaired with suturing techniques or with suturing and graft supplementation, post-operative complications can occur. Fibrosis leading to soft tissue attachments or scar tissue between the repaired tendon and neighboring tissues are most concerning and limiting during the rehabilitation period. In addition, the period of immobilization immediately following the procedure lends itself to developing fibrosis and attachments. Scar tissue and subsequent soft tissue attachments have both been shown to limit the potential for complete recovery. At a minimum, these complications can delay the success of the rehabilitation secondary to negative effects on the tendon, muscle, joint and ligaments. Immobilization causes intra-substance fibrosis of the tendons increasing the risk of re-rupture. The muscle weakens with stiffness, more rapid fatigue and decreased metabolic capacity. Joints have stiffness and increased joint compression and lastly, ligaments have decreased strength and mass with increased stiffness.

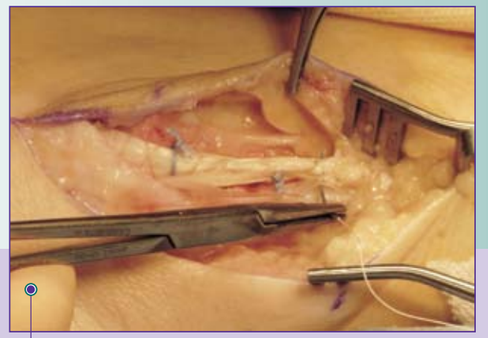
Minimizing the occurrence of fibrosis and soft tissue attachments may greatly improve the success of the tendon repair, whether the repair involved an acute rupture or a chronic degenerative process using any repair technique preferred by the surgeon. By using the OrthoWrap™ Bioresorbable Protective Sheet around the tendon as demonstrated below, it is less likely that fibrosis from adjacent bleeding bone or from surrounding soft tissues will attach to the tendon.

The OrthoWrap™ sheet is made from 70:30 Poly (L-lactide-co-D,L-lactide), more commonly known as PLA. This material has been used in other podiatric and orthopedic devices such as fixation implants. This material has a non-porous hydrophobic nature that resists attachments. The degradation of PLA weakens the OrthoWrap™ sheet, however it is impermeable throughout the critical healing period and up to 8 weeks, retaining nearly 80% of the original mechanical strength for the 0.02mm sheet and nearly 100% of the mechanical strength for the 0.05mm sheet. Loss of 50% of the mechanical strength is not seen in either size until after 20 weeks. The retention of mechanical strength is adequate since it functions during the main period of scar tissue formation. Normal tendon healing occurs over a period of months. However the inflammatory process and infiltration of fibroblasts occurs within the first two weeks; then for the next few weeks, cross linking of the collagen fibrils and scar tissue formation occurs. While this can be minimized with motion, Achilles tendon repair has documented that with the usual length of immobilization, scar tissue forms in approximately 11% of cases. The use of the OrthoWrap™ Sheet can assist in minimizing the soft tissue attachments, thus helping to alleviate the effects of the immobilization.

Step 1 Acute Achilles tendon rupture with 6 cm gap between the tendon ends.

Step 2 Augmentation of the Achilles tendon repair with graft material

Step 3 Repaired and augmented Achilles tendon repair with the OrthoWrap™ Bioresorbable Protective Sheet wrapped circumferentially around the repair to manage and protect the injured tendon while minimizing tissue attachments to the device.



Step 4 Chronic degenerative changes of the posterior tibial tendon excised and repaired with absorbable and non-absorbable suture. The OrthoWrap™ Bioresorbable Protective Sheet is being sutured around the tendon to manage and protect the injured tendon while minimizing tissue attachments to the device during the period of immobilization prior to beginning physical therapy.

Summary

The OrthoWrap™ Bioresorbable Protective Sheet has proven to be a cost effective and inert product. It can be wrapped around the various tendons in acute and chronic repairs to help manage and protect injured tendons while minimizing soft tissue attachments to the device that may impede the recovery of the patient. While early success has been observed, further investigation is required to determine the efficacy of the OrthoWrap™ sheet in tendon surgery of the foot and ankle as well as in other foot and ankle surgery procedures.

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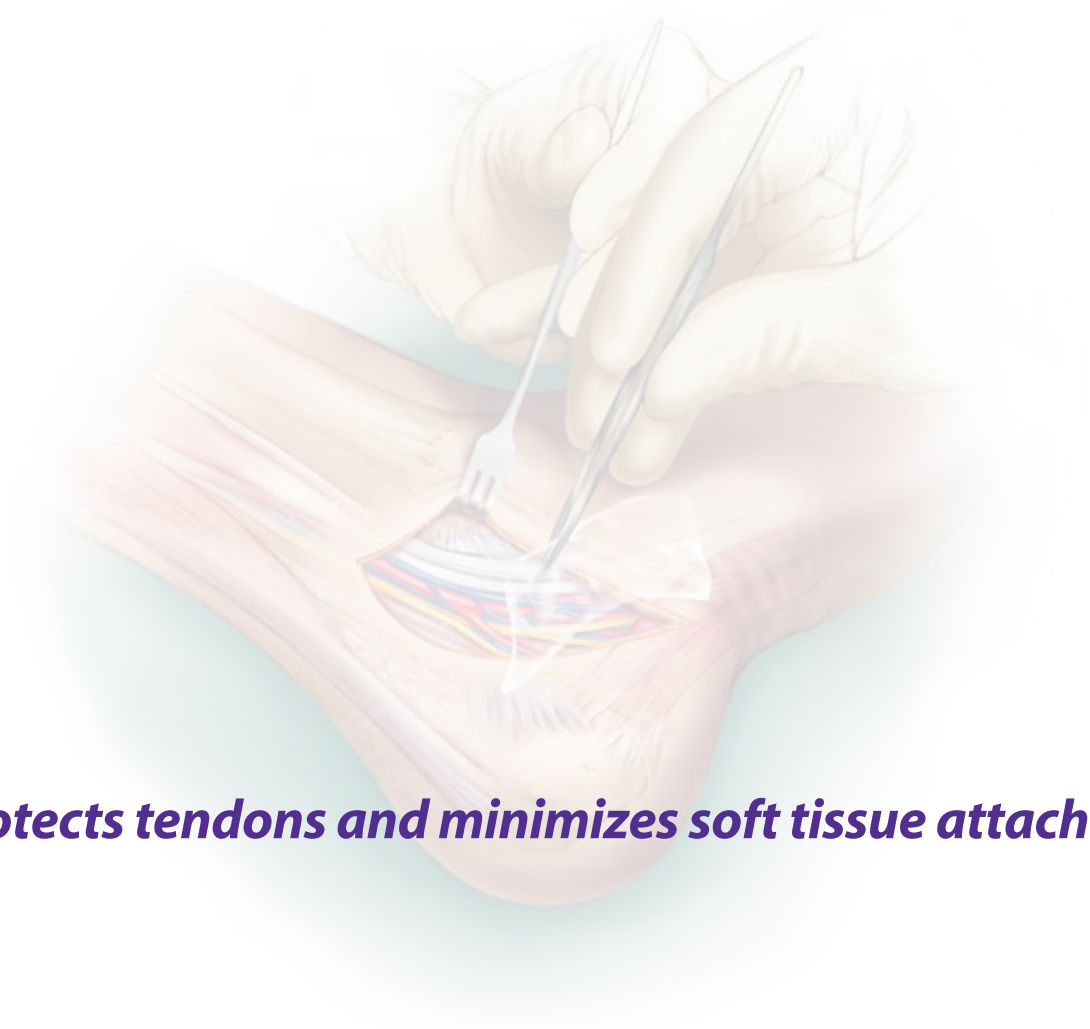

protects tendons and minimizes soft tissue attachments

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