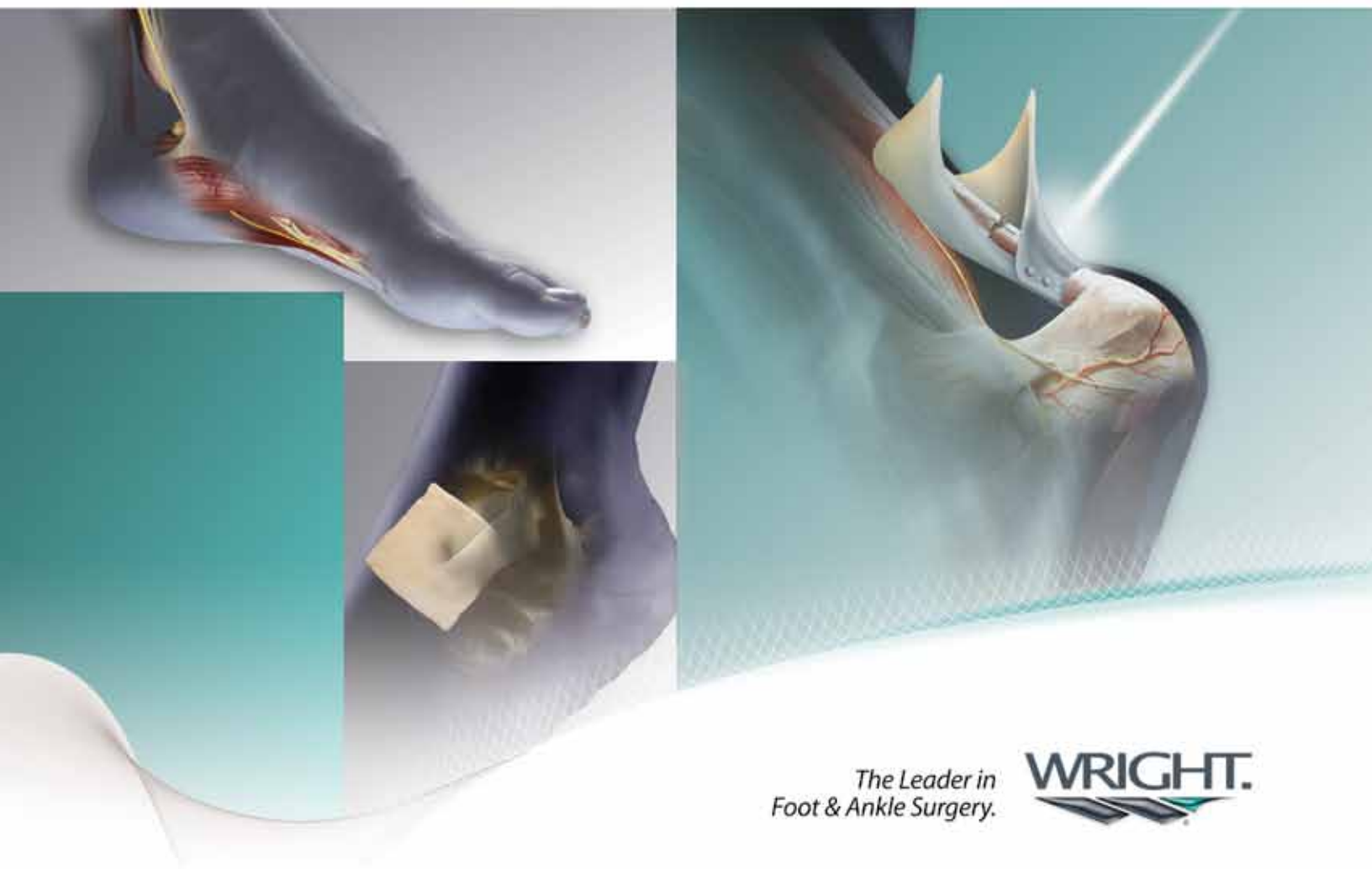


GRAFTJACKET®

Regenerative Tissue Matrix

SURGICAL TECHNIQUE



*The Leader in
Foot & Ankle Surgery.*

WRIGHT.


Achilles Tendon Reinforcement
Lateral Ankle Stabilization
Posterior Tibial Tendon Reinforcement

The potential for complications or adverse reactions with any implant can be minimized by following the instructions for use provided with the product. It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur. The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are common. The patient's mental status must also be considered. Willingness and/or ability to follow post-operative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients.

The following are suggested techniques for applying the GRAFTJACKET® Matrix. Proper surgical procedures and techniques are necessarily the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the techniques based on his or her own medical training and expertise.

GRAFTJACKET®
Regenerative Tissue Matrix
Achilles Tendon Reinforcement
surgical technique as described by
DR. JAMES E. CROUSE, FACS
Cedar Valley Medical Specialists
Waterloo, IA

Modified Bröstrom-Gould Lateral
Ankle Stabilization
surgical technique as described by
DR. STEPHEN A. BRIGIDO
Foot and Ankle Center at Coordinated Health
East Stroudsburg, PA

Posterior Tibial Tendon
Reinforcement
surgical technique as described by
DR. MARIE L. WILLIAMS
Residency Director for Barry University, Parkway
Regional Medical Center
North Miami Beach, FL

GRAFTJACKET®

REGENERATIVE TISSUE MATRIX
Achilles Tendon Reinforcement

as described by Dr. James E. Crouse, FACS

INTRODUCTION



The achilles tendon is one of the strongest tendons in the human body. It is capable of withstanding loads over 60N, yet is one of the most common major tendon injuries. Acute ruptures may go undiagnosed or misdiagnosed resulting in a chronic situation. Acute and chronic achilles tendon ruptures present unique challenges for repair and may require augmentation for successful outcome.

The GRAFTJACKET® Regenerative Tissue Matrix is a human dermal collagen template that is readily incorporated into the body. The GRAFTJACKET® Matrix undergoes a patented process that renders the material essentially acellular and is freeze-dried to prevent the formation of ice crystals to preserve the intact matrix including vascular channels. The GRAFTJACKET® Matrix provides a scaffold for remodeling to host tissue and, once implanted, is revascularized and repopulated with host cells. Coupled with excellent tensile and suture retention strength, the structural components of the GRAFTJACKET® Matrix make it an excellent scaffold to reinforce primary repairs in the foot and ankle while eliminating morbidity associated with harvesting autograft.

TECHNICAL COMMENT REGARDING GRAFT SELECTION

The GRAFTJACKET® Regenerative Tissue Matrix is available in multiple dimensions and thicknesses (from 0.5mm to 2.0mm average thickness). Selection of the appropriate graft is the responsibility of the operating surgeon based on the individual patient needs and circumstances. Graft thickness and graft strength requirements are considerations in appropriate selection. Generally, thicker grafts have increased strength.

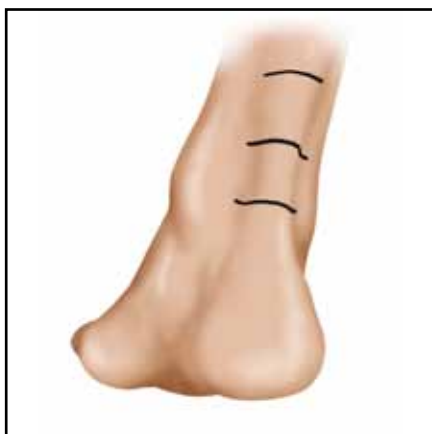


FIGURE 1 |

SURGICAL TECHNIQUE

The patient is placed in a prone position and the leg and foot are prepped and draped. A longitudinal incision is made along either the medial or lateral border of the achilles tendon centered over the defect. | **FIGURE 1**

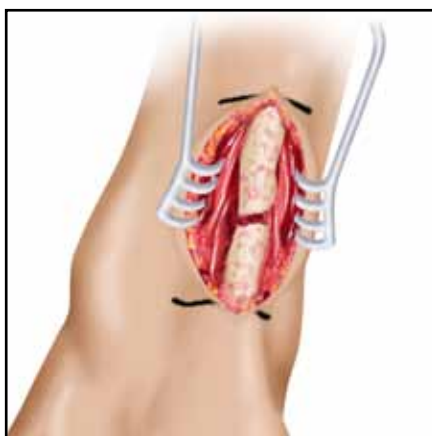


FIGURE 2 |

The skin and subcutaneous tissue are opened. While preserving to the largest extent possible, the paratenon is incised to expose the achilles tendon and the rupture. Care is taken throughout the procedure to protect the skin and the overlying vascular supply, as well as the sural nerve running along the lateral border of the achilles tendon. The paratenon is reflected as part of a full thickness flap with skin and subcutaneous tissue. | **FIGURE 2**

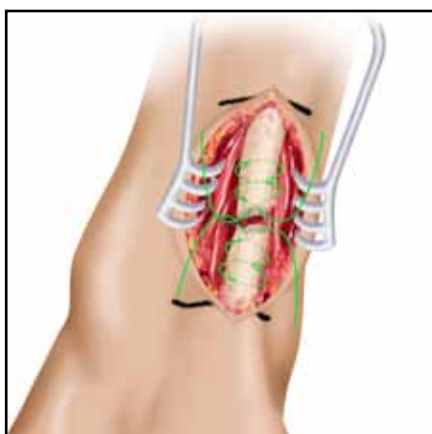


FIGURE 3 |

The tendon rupture ends are exposed and hematoma evacuated. A light debridement of the mop ends of the rupture is carried out. Heavy non-absorbable suture is placed using a Kessler or Krakow type suture to secure the proximal and distal tendon/muscle tissue. | **FIGURE 3**



FIGURE 4 |



FIGURE 5 |

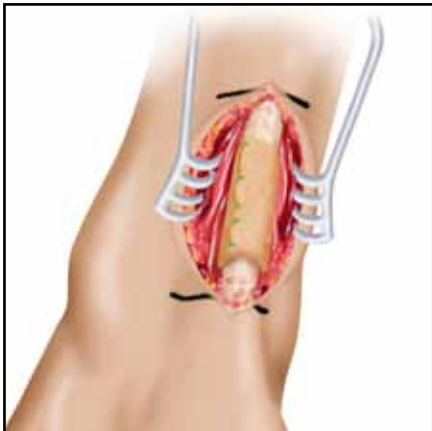


FIGURE 6 |

The foot is plantar flexed and the suture then runs circumferentially about that tendon at the rupture site. | **FIGURE 4**

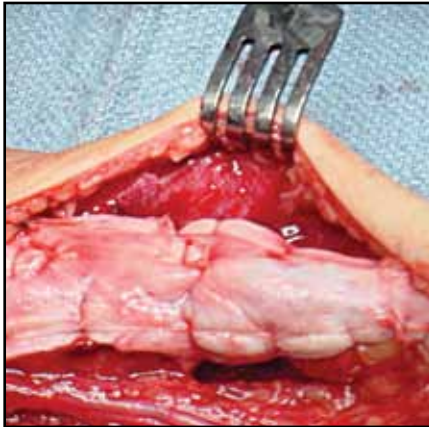
Augmentation of the achilles tendon can be accomplished either by using GRAFTJACKET® Matrix as a simple onlay or via circumferential wrapping. Regardless of the technique, the graft should be firmly anchored with suture of choice to the achilles tendon in order to properly reinforce the primary suture repair. The reticular or shiny side is placed down toward the tendon. Rehydrate the GRAFTJACKET® Matrix allowing sufficient time according to the provided instructions for use.

As an onlay, the GRAFTJACKET® Matrix is first cut to contour the tendon so that the graft is tapered distally. Interrupted #1 absorbable sutures are placed along the medial and lateral margins, as well as at the proximal and distal margins and centrally, incorporating the underlying tendon both proximal and distal to the rupture site. In cases of a proximal rupture, the suture would be placed primarily in muscular tissue, but an attempt is made to incorporate central tendinous fibers in this suture. Additional augmentation can be obtained by using any portion of the graft that was trimmed during the contouring process by placing anterior to the tendon rupture.

Wrapping circumferentially, the GRAFTJACKET® Matrix is sutured both proximally and distally using an absorbable stitch. | **FIGURE 5** The graft is then rotated around the tendon and then again onto itself. The final edge of GRAFTJACKET® Matrix is sutured upon itself and to the tendon. | **FIGURE 6**

Following the repair, an absorbable suture is used to approximate the paratenon and suture together over the graft to provide an intervening layer between the graft and skin. The subcutaneous tissue is closed and the skin is repaired according to the surgeon's preference. A bulky dressing is applied and a short-leg cast with the achilles tendon under slight tension.

CASE STUDY



INTRA-OP | reinforcing main suture repair



POST-OP | 4 months, symmetric double heel rise



POST-OP | 4 months, the patient exhibits excellent range of motion.

PATIENT PROFILE

The patient is a 29 year-old male, weighing approximately 94kg. The patient experienced a “pop” and pain behind his left ankle while playing basketball.

SURGICAL TECHNIQUE

Briefly, following exposure of the ruptured ends and evacuation of hematoma, light debridement of the ruptured tendon ends was carried out. Primary repair of the ruptured tendon was performed using #5 Ethibond in a Kessler type suture repair. A 5x10cm of GRAFTJACKET® Matrix was prepared and cut to contour to the tendon tapering distally and secured using interrupted #1 absorbable suture. A bulky dressing was applied and a short leg cast used with the achilles tendon under slight tension.

POST-OPERATIVE COURSE

The cast was taken off at 10 to 14 days and the skin clips removed. The degree of protection and length of immobilization is individualized. A walking cast or walking boot is generally applied with crutches, but weight bearing is tolerated with a walking boot. When using a walking boot, it can be removed for range of motion exercises. This was continued for 4 weeks. The patient was then given a heel lift and rehab was progressed. Normal activities are allowed when motor strength is similar to the uninvolved extremity. Stretching and rehab exercises are continued for at least one year postoperatively.

At 10 months post-op, the patient was comfortable with excellent strength in his left leg and a full range of motion. He had returned to running and sporting activities (although his wife has banned him from basketball).*

** Patient results may vary*

GRAFTJACKET®

REGENERATIVE TISSUE MATRIX
Modified Bröstrom-Gould Lateral
Ankle Stabilization

as described by Dr. Stephen A. Brigido

INTRODUCTION



Sprains of the lateral ankle are extremely common in the athletic population. While the majority of these sprains can be treated with a functional ankle-rehabilitation program, an estimated 15% to 20% require surgical intervention due to recurrent instability and reinjury. The Modified Bröstrom-Gould Technique provides for reinforcing the repair to limit inversion, the likelihood of re-injury, and correcting the subtalar component of the instability.¹

REFERENCES

1. Baumhauer, JF and O'Brien, T. Surgical Considerations in the Treatment of Ankle Instability. *J Athl Train*. 2002 Dec;37(4):458-462.
2. Barber FA, Herbert MA, Coons DA, "Tendon augmentation grafts: biomechanical failure loads and failure patterns," *Arthroscopy*. 2006; 22(5): 534-538.

TECHNICAL COMMENT REGARDING GRAFT SELECTION

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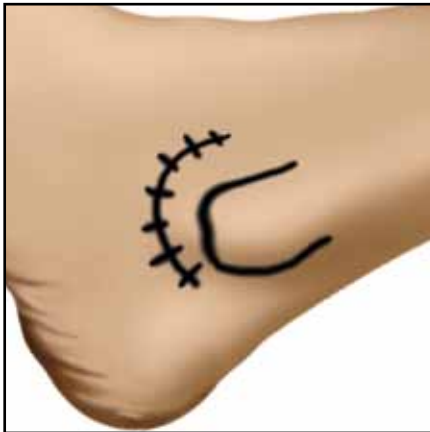


FIGURE 1 |

SURGICAL TECHNIQUE

A curvilinear skin incision is created anterior and inferior to the distal tip of the fibula. The lateral branch of the superficial peroneal nerve, the peroneal tendons, and the sural nerve are protected. | **FIGURE 1**



FIGURE 2 |

Dissection is carried to the level of the joint capsule. The anterior talofibular ligament (ATFL) is visualized as a thickening of the capsular tissue. The calcaneal-fibular ligament (CFL) is deep to the peroneal tendon complex and is also associated with attenuation or tear in chronic ankle instability. | **FIGURE 2**

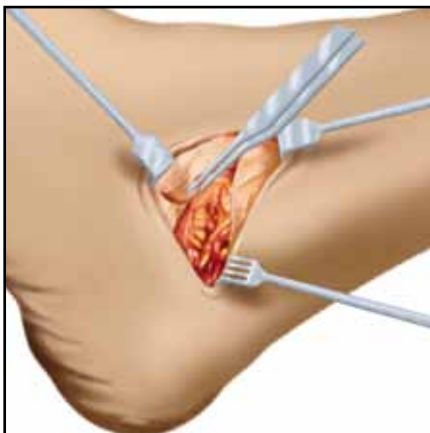


FIGURE 3 |

Leaving a 3-5mm flap of tissue along the border of the lateral malleolus, the joint capsule is divided from the anterior aspect of the joint capsule to the region immediately deep to the tendon complex. The ankle is placed in slight dorsiflexion/eversion and the ends of the CFL are prepared for reapproximation. | **FIGURE 3** Utilizing non-absorbable suture, the ends of the ligament are sutured in overlapping fashion.

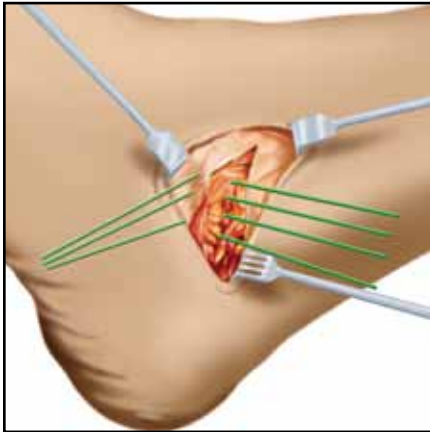


FIGURE 4 |

Attention is now directed to the ATFL with the repair again being performed with “overlapping reapproximation”. Multiple sutures are used to recreate anatomic length to the ATFL. | **FIGURE 4**

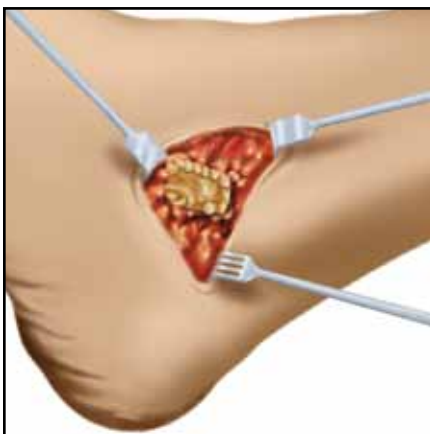


FIGURE 5 |

Rehydrate the GRAFTJACKET® Matrix allowing sufficient time according to the provided instructions for use. After primary repair is performed, the GRAFTJACKET® Matrix is cut in shape to mimic the orientation of the ATFL structure. Utilizing a tissue elevator, a periosteal flap is created along the distal fibula to allow for attachment of the proximal portion of the tissue scaffold. Utilizing absorbable suture, the tissue scaffold is affixed to the periosteal flap proximally and to the anterior-lateral joint capsule distally. | **FIGURE 5** The graft should be placed to ensure the reticular (shiny side) is toward the tendon. Range of motion is examined to assure stability. The use of the GRAFTJACKET® Matrix allows for augmentation of the repair without the need to sacrifice the proximal portion of the extensor retinaculum.

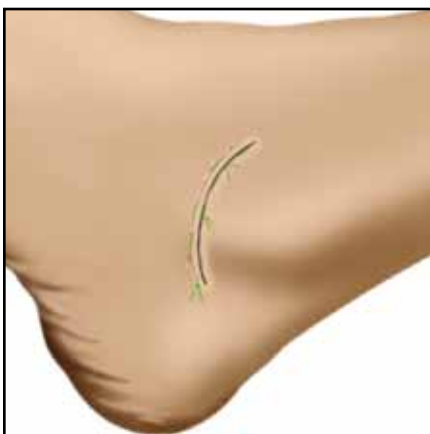
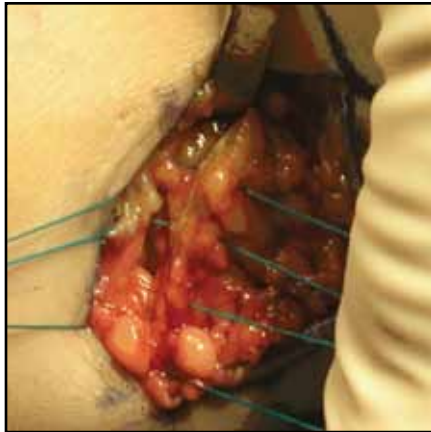


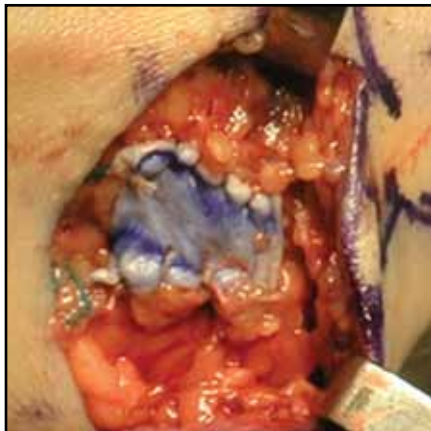
FIGURE 6 |

Subcutaneous tissue and skin closure is performed in layers with suture of choice. | **FIGURE 6** The patient is placed in a multi-layer compressive dressing postoperatively for 2 weeks. At 2 weeks, the sutures are removed and the patient is placed in an aircast and begins physical therapy with assisted progressive weight bearing and exercise. This is continued for approximately 6 weeks with the patient strengthening the lateral ankle complex throughout.

CASE STUDY



Overlapping reapproximation of the ATFL



Reinforcing the primary repair with the GRAFTJACKET® MATRIX



Patient standing on surgical extremity only at 6 weeks.

PATIENT PROFILE

The patient is a 38 year-old male 6'4" 240 lbs. with a history of chronic ankle sprains to the left lower extremity.

SURGICAL TECHNIQUE

Primary surgical repair of the CFL and ATFL were conducted as follows.

Briefly, the ankle was placed in slight dorsiflexion/eversion and the ends of the CFL were repaired using overlapping reapproximation utilizing non-absorbable sutures. Primary repair of the ATFL was conducted in a similar fashion. The GRAFTJACKET® Regenerative Tissue Matrix was used to reinforce primary repair of the ATFL.

POST-OPERATIVE COURSE

Postoperatively, the patient was placed in a multilayer dressing with kerlex, kling, and coban. The patient remained non-weight bearing for the first 2 weeks. At 2 weeks, the suture was removed and the patient was placed in an aircast for frontal plane support. Physical therapy assisted progressive weight bearing was started and continued until 6 weeks postoperatively.

GRAFTJACKET®
REGENERATIVE TISSUE MATRIX
Posterior Tibial Tendon
Reinforcement

as described by Dr. Marie L. Williams

INTRODUCTION



Rupture or dysfunction of the posterior tibial tendon (PTT) is the most common cause of acquired flat-foot disease in the adult population. Etiology of PTT dysfunction can vary but is largely attributed to traumatic, inflammatory and degenerative causes. In cases of Stage-I or Stage-II, PTT insufficiency associated with hindfoot valgus, medial foot pain, a mobile subtalar joint and weakness, reinforcement with a flexor tendon may be indicated with associated repair of the PTT.¹

REFERENCES

1. Mann RA, Thompson FM. Rupture of the posterior tibial tendon causing flat foot. Surgical treatment. *J Bone Joint Surg Am.* 1985 Apr;67(4):556-61.

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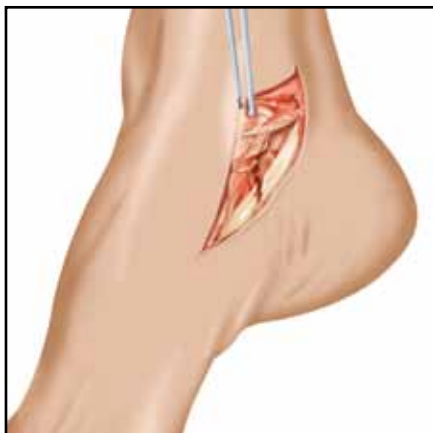


FIGURE 1 |

SURGICAL TECHNIQUE

Using a curvilinear incision, expose the retinaculum over the posterior tibial tendon (PTT). Make longitudinal cut into the compartment and expose the PTT. | **FIGURE 1**



FIGURE 2 |

After exposing the PTT, identify the tendon pathology (i.e., complete tear, longitudinal tear, etc.). Primary repair of the tendon is carried out by resection of the pathologic tendon (if needed), resection of the hypertrophied sheath and retinaculum, and suture repair of the tendon.

| **FIGURES 2 AND 3**

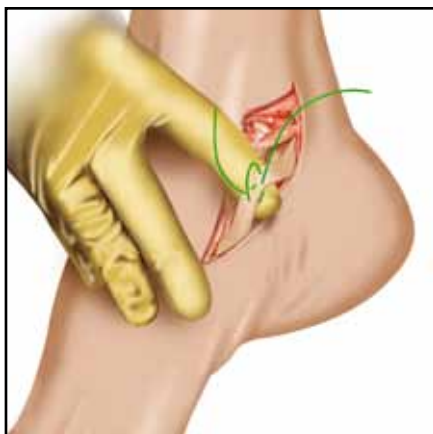


FIGURE 3 |



FIGURE 4 |

Rehydrate the GRAFTJACKET® Matrix allowing sufficient time according to the provided instructions for use. Reinforce the primary tendon repair with the GRAFTJACKET® Matrix ensuring the reticular (shiny side) is towards the tendon. Wrap the GRAFTJACKET® Matrix around the repaired PTT and use straight hemostats to temporarily secure. The width of the GRAFTJACKET® Matrix should be sufficient to cover the entire primary repair. | **FIGURE 4**



FIGURE 5 |

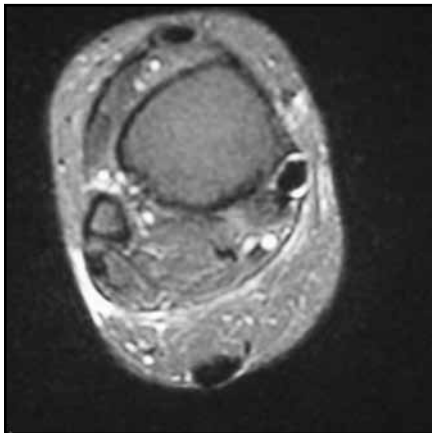
Starting on the tendon side of the hemostats, begin a running suture through the GRAFTJACKET® Matrix using 2-0 Vicryl or Ethibond Suture. Tie off to secure. | **FIGURE 5**



FIGURE 6 |

Using a scalpel, cut away excess GRAFTJACKET® Matrix ensuring that sutures are not compromised. Close in standard fashion. | **FIGURE 6**

CASE STUDY



MRI confirmation of the longitudinal tear in the posterior tibial tendon.

PATIENT PROFILE

The patient is a 54 year-old female who presented with significant pain in the right foot in the area of talonavicular articulation extending to the medial malleolus, and whose arch had collapsed significantly on the same side. The patient was non-responsive to conservative treatment which included physical therapy, bracing, orthotic management and control and anti-inflammatory medication. X-rays indicated collapse of the medial arch and degenerative changes at the talonavicular joint. There was also fluid and fullness along the course of the posterior tibial tendon. An MRI demonstrated a longitudinal tear in the posterior tibial tendon extending from the medial malleolus down to the tuberosity navicular.

SURGICAL TECHNIQUE

An incision was made extending from the medial malleolus along the course of the posterior tibial tendon to the tuberosity of the navicular. Once the sheath was opened a significant amount of fluid was present and evacuated. The posterior tibial tendon demonstrated characteristic changes associated with a degenerative process, was yellowish in color and demonstrated a longitudinal tear. As a result of the changes within the tendon, a section was removed and repaired with absorbable suture. The GRAFTJACKET® Regenerative Tissue Matrix was used to reinforce the primary repair and the entire defect area of the tendon sheath in a longitudinal direction extending from the medial malleolus to the insertion of the navicular. In addition to the primary repair of the posterior tibial tendon and augmentation using the GRAFTJACKET® Matrix, fusion of the talonavicular joint was performed. Repair of the chondral defect in the posterior medial malleolar groove was also conducted.

POST-OPERATIVE COURSE

The patient was followed post-operatively and completely healed from the surgical procedure. There was no evidence of reaction or response to the GRAFTJACKET® Matrix including no excessive swelling and no pain. The clinical outcome is consistent with the patient who presents with posterior tibial tendon dysfunction while avoiding the potential morbidity associated with flexor tendon transfers.



ORDERING information



8600-5X05
GRAFTJACKET® REGENERATIVE TISSUE MATRIX
Dimensions 5 x 5cm 1EA.
Average Thickness 1.0mm

8600-5X10
GRAFTJACKET® REGENERATIVE TISSUE MATRIX
Dimensions 5 x 10cm 1EA.
Average Thickness 1.0mm



8600-4X07
GRAFTJACKET® REGENERATIVE TISSUE MATRIX
- MAXIMUM FORCE
Dimensions 4 x 7cm 1EA.
Average Thickness 1.5mm

86MX-5X05
GRAFTJACKET® REGENERATIVE TISSUE MATRIX
- MAXIMUM FORCE
Dimensions 5 x 5cm 1EA.
Average Thickness 1.5mm



86UM-4X07
GRAFTJACKET® REGENERATIVE TISSUE MATRIX
- MAXFORCE - EXTREME
Dimensions 4 x 7cm 1EA.
Average Thickness 2.0mm



8600-2X04
GRAFTJACKET® REGENERATIVE TISSUE MATRIX
- HAND SURGERY
Dimensions 2 x 4cm 1EA.
Average Thickness 0.5mm



8600-0530
GRAFTJACKET® SLR
- REGENERATIVE TISSUE MATRIX FOR SMALL
LIGAMENT REINFORCEMENT
Dimensions 5 x 30mm 1EA.
Average Thickness 1.4mm

GRAFTJACKET® Matrix is intended to be used as a scaffold for replacement or repair of damaged or inadequate, integumental tissue and does not contain wound healing agents.

Before use, physicians should review all risk information, which can be found in the "Directions for Use" attached to the packaging of each GRAFTJACKET® Graft.



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