

STATAK™ SOFT TISSUE ATTACHMENT DEVICE

Surgical
Techniques

Common Foot
Procedures

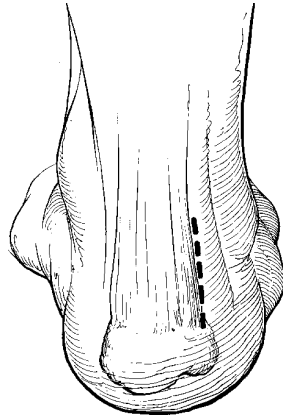


HAGLUND'S PROCEDURE (RETROCALCANEAL EXOSTECTOMY)

1 INCISION

Make a lateral incision into the most lateral aspect of the calcaneal tendon over the most lateral aspect of the prominent bone. Try not to reflect more than 15 to 20 percent of the insertion.

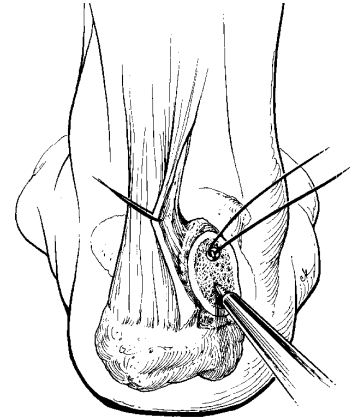
Reflect the tendon medially.



2 RESECTION AND ANCHOR PLACEMENT

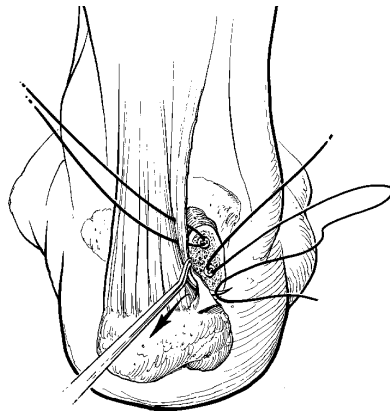
Resect the appropriate amount of bone. Then rasp the bone and flush the area.

Drive in two 2.5mm *Statak* Soft Tissue Anchors with USP #0 polyester braided sutures at the site where the tendon will be reattached. Pull back the drill to expose the sutures of the embedded anchors. Discard the suture-retaining tube and disposable metal driver.



3 TENDON ATTACHMENT

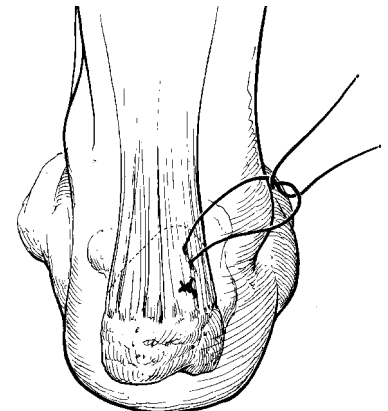
Use a ligature bypass needle (Mayo or Martin) to pass the sutures to the superior side of the tendon.



4 SUTURE TYING

Reapproximate the tendon down to bone and hand tie the sutures. Use four or five knots to ensure that the nonabsorbable suture does not unravel.

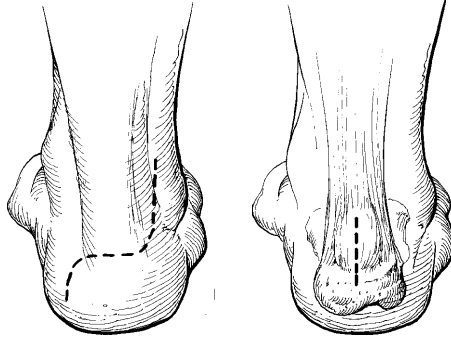
Close in the usual manner.



ACHILLES INSERTIONAL SPUR FORMATION

1 INCISIONS

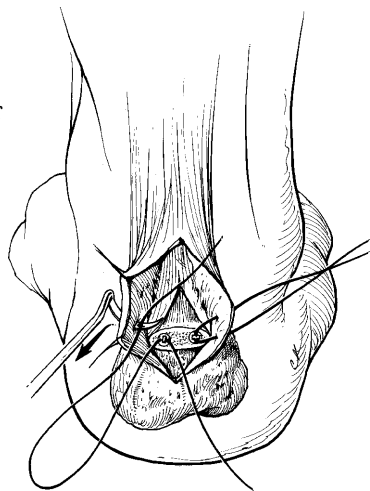
Use a 25-gauge needle and lateral radiographs to locate the most prominent aspect of the posterior part of the heel. Then make a lazy S incision over this point.



Make proximal and distal flaps, and suture them out of the way to maintain exposure. Use a 25-gauge needle to locate the most prominent aspect of the spur. Then make a linear incision from proximal to distal through the achilles tendon.

3 TENDON ATTACHMENT

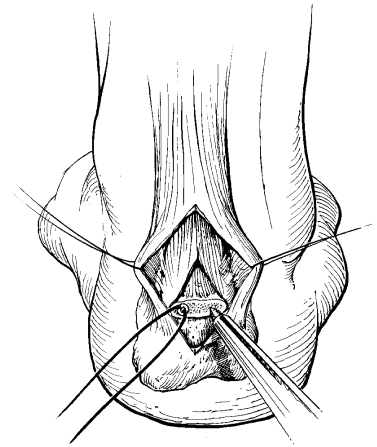
Use a ligature bypass needle (Mayo or Martin) to pass the sutures to the superior side of the tendon.



2 RESECTION AND ANCHOR PLACEMENT

Reflect the achilles tendon medially and laterally. Resect the spur with as little disruption of the tendon insertion as possible. Rasp and flush the area.

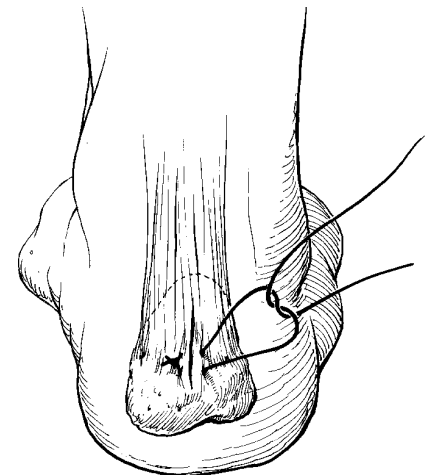
Drive in two or three *Statak Soft Tissue Anchors* at the site where the tendon will be reattached. Approximate the anchors to maintain optimal alignment. Pull back the drill to expose the sutures of the embedded anchors. Discard the suture-retaining tube and disposable metal driver.



4 SUTURE TYING

Reapproximate the tendon down to bone and hand tie the sutures. Use four or five knots to ensure that the nonabsorbable suture does not unravel.

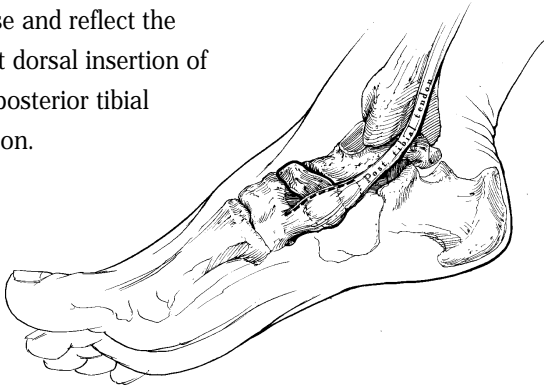
Release the flaps and close in the usual manner.



MODIFIED KIDNER PROCEDURE

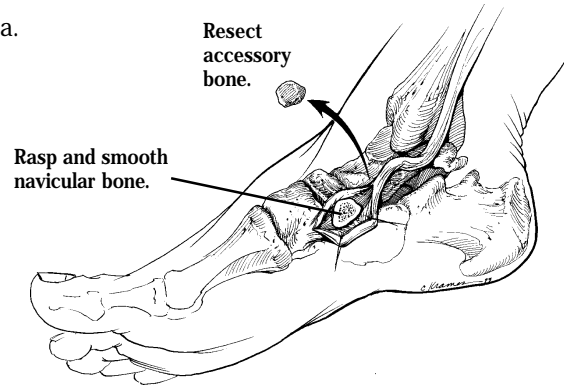
1 INCISION

Incise and reflect the most dorsal insertion of the posterior tibial tendon.



2 RESECTION AND RASPING

Resect the navicular tuberosity or the accessory bone. Rasp, smooth, and flush the area.



3 ANCHOR PLACEMENT

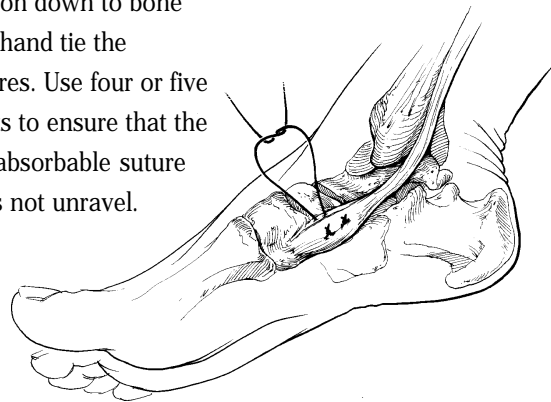
Approximate two *Statak* Soft Tissue Anchors inferiorly and one dorsally in the navicular bone, and drive them in. Pull back the drill to expose the sutures of the embedded anchors. Discard the suture-retaining tube and disposable metal driver.

Use a ligature bypass needle (Mayo or Martin) to pass the sutures through the posterior tibial tendon.



4 SUTURE TYING

Reapproximate the tendon down to bone and hand tie the sutures. Use four or five knots to ensure that the nonabsorbable suture does not unravel.



Close in the usual manner.

STATAK™ SOFT TISSUE ATTACHMENT DEVICE

U.S. Patents 4,632,100; 5,411,506

Issued: November 1993

DESCRIPTION

The soft tissue attachment device consists of a suture anchor with an attached suture assembled to a driver. This device is designed to permit precise and efficient reattachment of soft tissue to bone. Attachment is secured by anchoring the suture within the cortical or cancellous bone. Each of the two free ends of the anchored suture is then "loaded" through the eyelet of a curved free needle. The needle/suture assembly is then passed through the free end of the soft tissue and the suture is tied to approximate the soft tissue to the bone.

The suture anchor is a self-drilling, self-tapping threaded device. A double-strand, braided suture is looped through the eyelet of the anchor. The suture strands are 13 inches (32.5cm) in length. A driver delivers the suture anchor to the desired depth of the bone. The driver is then removed and discarded. This results in two sutures of equal length emerging from a single bone orifice.

MATERIAL

- Suture Anchor—*Titanium*® Ti-6Al-4V Alloy
- Driver—Stainless steel
- Suture—Braided polyester, nonabsorbable (USP Sizes #0 and #2)
- Suture retaining cap—Rubber

INDICATIONS AND USAGE

This device is indicated for use in soft tissue to bone fixation except anterior or posterior cruciate ligament repair or reconstruction. Various size anchors are provided for utility, corresponding to the anatomic size requirements.

Shoulder

- Bankart lesion repairs
- SLAP lesion repairs
- Acromio-clavicular separation repairs
- Rotator cuff tear repairs
- Capsular shift or capsulolabral reconstructions
- Biceps tenodesis
- Deltoid repairs

Foot and Ankle

- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Hallus valgus reconstructions

Elbow, Wrist, and Hand

- Scapholunate ligament reconstructions
- Ulnar or radial collateral ligament reconstructions
- Tennis elbow repair
- Biceps tendon reattachment

Knee

- Extra-capsular repairs:
 - Medial collateral ligament
 - Lateral collateral ligament
 - Posterior oblique ligament
- Iliotibial band tenodesis
- Patellar tendon repairs

Pelvis

- Bladder neck suspension procedures

INFORMATION FOR USE

1. Insert the *Statak* Soft Tissue Attachment Assembly into the Jacob's Chuck of the drill. Secure the metal driver shaft within the jaws of the Jacob's Chuck.
Note: The driver should be inserted to a depth of approximately 0.5 inch.
2. Expose the tissue reattachment site utilizing accepted surgical technique. Place the drill point of the *Statak* assembly through the cannula (where applicable) at the desired point of implantation and begin to apply pressure to the drill.
3. While continually applying pressure to the assembly at the implantation site, begin drilling. When the shoulder of the driver contacts the bone cortex and no longer advances, turn the driver 2 to 5 more turns then stop drilling. The anchor will automatically disassociate from the driver assembly.
Note: Do not allow the drill point or threads of the suture anchor to contact adjacent soft tissues while drilling. Soft tissues will occlude the threads and decrease bony purchase. It is advised that a soft tissue cannula be used when drilling in deep soft tissue holes or wherever soft tissues can contact the rotating threads of the assembly.

4. Pull drill with driver in place away from site. The suture will disengage from the cap, and the driver may be discarded.
5. Trim excess suture after hand tying.

CONTRAINDICATIONS

1. Moderate-to-severe osteopenia in which screw fixation may be tenuous.
2. Use in any bone with a diameter smaller than the length of the suture anchor plus countersink.

WARNINGS

1. Immediate range of motion should be avoided to allow biological bony/soft tissue healing.
2. Do not use where prehealing suture tension will exceed 20 lb for Size No. 2; 14 lb for Size No. 0, as suture may fail.
3. Do not attempt to implant this device within cartilage epiphyseal growth plates or bone apophyses.
4. This device is not approved in the U.S. for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

PRECAUTIONS

1. As in common proper drilling techniques, protect all soft tissue from the rotating driver and suture anchor device.
2. Saline irrigation and predrilling of a pilot hole are recommended when inserting the suture anchor into thick cortical bone. The pilot hole should be made 0.5mm smaller than the suture anchor size inserted.
3. If desired, the suture anchor can be removed by threading the driver back over the suture strands. If a knot has already been tied and the free ends cut, then it is recommended that a sturdy pair of needle holders be utilized to "pull out" the suture from its lodging within the metal anchor. The disposable driver can then be placed on to the anchor, and the device can be unscrewed. If the anchor has been countersunk beyond the length of the neck of the disposable driver, then cortical bone should be removed with a small curette until the disposable driver fits on to the suture anchor. The anchor can then be unscrewed.
4. As in all suture techniques, the suture is intended to approximate soft tissue to bone for a length of time appropriate for biological attachment of the soft tissue to bone. The suture anchor assembly is not intended to provide indefinite biomechanical integrity.

ADVERSE EFFECTS

Breakage of the suture or suture anchor can occur. Loss of fixation or pull-out of the anchor during suturing has been reported.

In addition to the obvious risks that any orthopaedic implant may fail, loosen, or fracture, the following risk of adverse tissue responses and possible complications must be explained to, and discussed with, the patient.

1. A variety of metals, polymers, chemicals, and other materials utilized with orthopaedic implants have been known to cause cancer and other adverse body reactions. In addition, any factor that causes chronic damage to tissues may be oncogenic. Cancer can metastasize from soft tissue sites (lung, breast, digestive system, and others) to bone - including areas adjacent to implants - or it can be seeded to these locations during operative and diagnostic procedures (such as biopsies). Paget's disease has been reported to progress to cancer; patients suffering from this disease who are candidates for implantations in the affected areas should be warned accordingly.
2. Metal sensitivity has been reported following exposure to orthopaedic implants. The most common metallic sensitizers (nickel, cobalt, chromium) are present in orthopaedic grade stainless steel and cobalt-chrome alloys. Titanium and its alloys (such as *Titanium* Ti-6Al-4V Alloy) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

STERILIZATION

The *Statak* Soft Tissue Anchor is supplied sterile. Resterilization by any method is not recommended.

*Developed in cooperation with E. Marlowe Goble, MD.

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