Introduction

The DePuy Mitek RIGIDFIX ACL Cross Pin System is an innovative method for fixing bone-tendon-bone grafts during ACL reconstruction. It was developed with the following three goals in mind:

1. PROVIDES BIOABSORABLE (PLA) FIXATION AT THE GRAFT-TUNNEL INTERFACE
2. DELIVERS 360° OF BONE-TO-GRAFT CONTACT*
3. INSTRUMENTS ELIMINATE INTRAOPERATIVE MEASURING

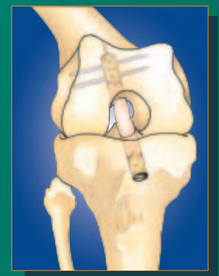
** A study of bone-to-bone grafts showed 100% circumferential ingrowth at 12 weeks. Study on file at DePuy Mitek , conducted by Steven Arnoczky et al.: The healing of cortiocancellous bone plugs fixed with DePuy Mitek BTB cross-pins or an absorbable interference fit screw (Bioscrew™) – an experimental study in dogs. Laboratory for Comparative Orthopaedics College of Veterinary Medicine, Michigan State University.*

DePuy Mitek
a Johnson & Johnson company

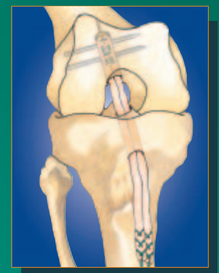
RIGIDfix®

ACL CROSS PIN SYSTEM

Bone-Tendon-Bone (BTB)



Soft-Tissue (ST)



INDICATIONS

Femoral fixation of autograft or allograft ACL graft material, either soft tissue (semitendinosus, etc.), or bone-tendon-bone (patellar tendon, etc.)

CONTRAINDICATIONS

1. Pathologic conditions of bone, such as cystic changes or severe osteopenia, that would compromise secure cross-pin fixation.
2. Pathologic conditions in the graft to be attached which would impair secure fixation with the cross pins.
3. Physical conditions that would eliminate or tend to eliminate adequate implant support or retard healing, such as blood supply limitations, infection, etc.
4. Conditions that would tend to preempt the patient's ability to recover during the healing period, such as senility, mental illness, or alcoholism.

PRECAUTIONS

1. Surgeons should not attempt clinical use of the DePuy Mitek RIGIDFIX ACL Cross Pin System before reviewing the instructions for its use and mastering the installation procedure in a skills laboratory.
2. Used stepped trocar should be discarded in a sharps container.
3. DePuy Mitek's RIGIDfiX ACL Cross Pin Instruments should be used only with the DePuy Mitek RIGIDFIX 2.7 mm BTB Cross Pin Kit and the DePuy Mitek RIGIDFIX 3.3 mm Cross Pin Kit.
4. Discard used sleeve assemblies and interlocking trocars in a sharps container.

WARNINGS

Inspect all instruments for damage before use. Do not attempt to repair a damaged instrument. Polylactic acid (PLA) implants have shown to cause some tissue reaction in a small percentage of patients. The DePuy Mitek RIGIDFIX Cross Pin Kits must never be reused. Do not re-sterilize. Discard opened and unused RIGIDFIX Cross Pins, Sleeve Assemblies, and Interlocking Trocar.

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a physician.

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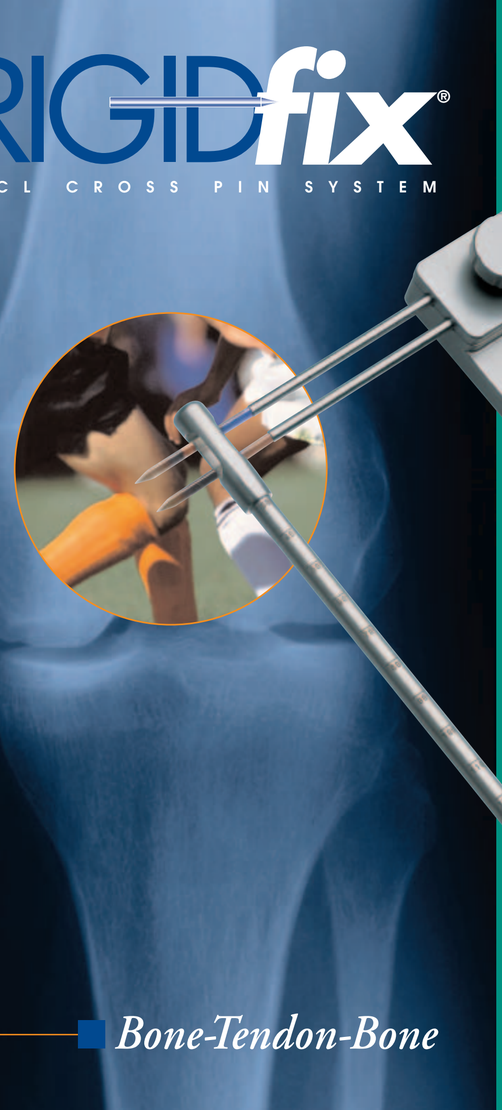
For more information, call your DePuy Mitek representative at 1-800-382-4682 or visit us at www.depuymitek.com. DePuy Mitek, Inc., 325 Paramount Drive, Raynham, MA 02767

RIGIDfix®

ACL CROSS PIN SYSTEM



Bone-Tendon-Bone

Paul H. Marks, BSC, M.D., FRCSC
Assistant Professor, University of Toronto
Toronto, Ontario, Canada

BONE-TENDON-BONE

Surgical Technique for DePuy Mitek® RIGIDFIX ACL Reconstruction

DePuy Mitek
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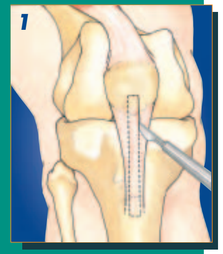
SURGICAL TECHNIQUE

RIGIDfix®
ACL CROSS PIN SYSTEM

BONE-TENDON-BONE

Paul H. Marks, BSC, M.D., FRCSC



Graft Harvesting

Make a longitudinal incision about 4 to 5cm in the mid-line or slightly medially. Take dissection down through skin and subcutaneous tissue and obtain hemostasis. The skin and subcutaneous tissue are undermined down to the underlying fascia. This allows the wound to be mobilized for access to the patellar tendon and for tibial drilling on the medial side.

Using sharp dissection, incise the paratenon in the mid-line. This is reflected for later closure after graft harvesting. Use a ruler to mark the central third (9 to 10mm) for the patellar tendon graft. Again, using sharp dissection, incise the central third of the tendon down to its bony attachments at the tibial tubercle and the inferior aspect of the patella (Fig. 1). Mark a 25mm bone plug on both the tibial side and the inferior patellar side. Then using an oscillating saw and a small blade, first take the bone plug from the tibial side. Use caution in removing the plug from the tibial defect that has been created. The soft-tissue attachments (or fat pad) are released from the posterior aspect of the patellar tendon graft.

Next, wrap a moist sponge around the tibial bone plug. With appropriate retraction, the inferior aspect of the patella can be visualized. Once again, use the oscillating saw to make cuts on the inferior patellar bone plug. Gently remove the bone plug and take the free graft to the back table for preparation. Note: to prevent injury to the underlying articular cartilage, do not use an osteotome with any force or impaction on the patellar side.

Graft Preparation

In preparing the free graft on the back table, carefully dissect off any remaining soft tissue or adipose tissue. In general, the bone plugs are sized to 10mm tubing. If a slightly smaller graft has been obtained, then 9mm sizing may be more appropriate. If a very large tendon has been encountered, an 11mm bone plug may be appropriate.

Any extra bone that is removed from the bone-patellar tendon-bone graft should be saved so that it can be placed later in the inferior patella defect and tibial tubercle defect. In general, the tibial tubercle bone plug is placed in the femoral tunnel, and, conversely, the inferior patellar bone plug is placed in the tibial tunnel. Once the bone plug for the femoral tunnel has been chosen, it should be sized very carefully to a 10mm diameter so that the femoral tunnel is completely and snugly filled.

Next, make appropriately sized drill holes in the bone plugs. One drill hole is placed in the femoral plug for application of a stay suture (Fig. 2). Two drill holes are generally placed in the tibial bone plug at perpendicular angles. The stay sutures are applied to the graft. Take the graft through a 10mm or appropriately sized tubing to make sure it passes easily in anticipation of placement in the knee. Place the prepared graft in sterile solution in a safe place on the back table.

Arthroscopy

The arthroscopic phase of the procedure is the appropriate time for dealing with all concomitant intra-articular pathology (for example, meniscal tear). Release and excise the ligamentum mucosum to improve visualization of the intracondylar region (notch). Use the shaver to excise any remnant of the anterior cruciate ligament. Make sure to protect and preserve the synovium that overlies the posterior cruciate ligament.

Notchplasty

Perform an appropriately sized notchplasty to ensure clearance of the bone-patellar tendon-bone graft. This will eliminate any impingement of the graft that could cause range-of-motion problems or injury to the graft itself. The burr and shaver can be used to perform the notchplasty. Make impingement checks to ensure complete clearance of the graft within the intercondylar region.

Tibial Tunnel

Using a tibial drill guide, choose a point above the anterior cruciate ligament tibial footprint for emergence of the guide pin. Place the guide pin up through the medial metaphysis. Enter the joint adjacent to the posterior cruciate ligament but do not impale it. After the guide has been placed, check the direction and look for any potential impingement so as to ensure an appropriate position.

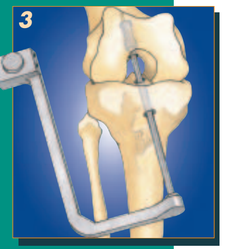
Next, use a cannulated drill system to drill the tibial tunnel. Make sure that the drill size corresponds with the prepared free graft. Clear the tunnel of any bone and soft-tissue debris. The edges should be chamfered with a rasp to eliminate any abrasion of the graft along the bone-edge surface.

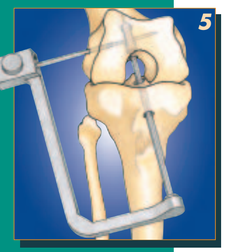
Femoral Tunnel

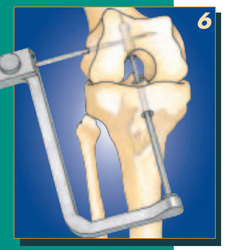
Using an offset guide, place the drill guide pin at the appropriate superior position, which corresponds to approximately 10 o'clock for the right knee and 2 o'clock for the left knee.

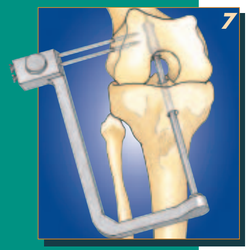
Advance the guide pin far enough so that you can feel the tip beneath the subcutaneous tissue on the lateral aspect of the thigh. This will ensure that the guide pin passes easily when the graft is positioned in the knee. Place an appropriately sized cannulated reamer over the guide wire up and through the tibial tunnel. This step should be done carefully, by hand, to pass the reamer over the posterior cruciate ligament tissue without injuring it. Once the reamer is up against the femoral bone, drill the bone to a depth of 25 to 30mm.

Next, remove the reamer and then the guide pin from the joint. Once again, clear the tunnel of any debris to permit easy passage of the graft. Now conduct impingement checks again. A 10mm dilator can be used up through the tibial tunnel and the orifice of the femoral tunnel. With extension of the knee, one can ensure that there will be complete clearance for a dilator that is appropriately sized and that corresponds to the graft size. (Caution: if you use a dilator, do not place it in the femoral tunnel and extend the knee, as this will blow out the femoral cortex.)









Femoral Fixation

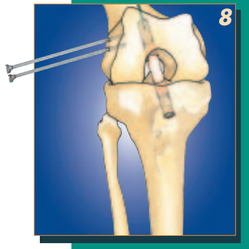
Attach the appropriately sized femoral rod (for example, a 10mm rod for a 10mm femoral tunnel) to the guide body and insert the guide into the femoral tunnel. Place the RIGIDFIX Cross Pin guide through the tibial tunnel and into the femoral tunnel so that the shoulder of the femoral rod can be easily seen at the tunnel edge. (Fig. 3) The RIGIDFIX Cross Pin guide should be relatively parallel to the floor. With large patients, take care not to damage the skin that overlies the lateral side of the femur.

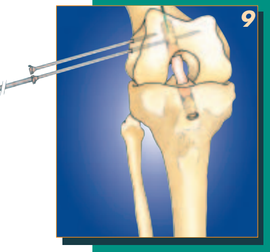
Assemble the sleeve over an interlocking trocar (Fig. 4). Drill the sleeve-trocar assembly through the bottom hole of the guide into the lateral side of the femur until the sleeve hub meets the guide (Fig. 5). Remove the trocar by pulling it from the sleeve, leaving the sleeve in the guide/femur (Fig. 6). Note: *do not* drill or spin the trocar when removing it from the sleeve. If water is flowing into the knee, there should be good flow of water out of the sleeve at this point.

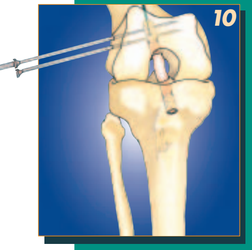
Drill the second sleeve-trocar assembly through the top hole of the guide (Fig. 7). Detach the guide plate and remove the guide body from the knee, leaving only the two sleeves in the femur.

Next, place a long guide pin through both the tibial and femoral tunnel and out through the lateral cortex. Place the stay suture of the femoral bone plug through the eyelet of the guide pin. Now, under arthroscopic visualization, pull the graft into the joint. Advance the femoral bone plug into the femoral tunnel until the bone face is flush with the opening of the femoral tunnel (Fig. 8). Then drill the longer trocar through one of the femoral sleeves (Fig. 9). Using the stepped pin insertion rod and mallet, insert a DePuy Mitek RIGIDFIX Cross Pin into the sleeve (Fig. 10). Advance until the step portion of the rod meets the sleeve hub. Repeat this procedure in the other sleeve, advancing a second DePuy Mitek RIGIDFIX Cross Pin to complete the fixation.

Using the sleeve removal tool, remove the sleeves from the femur. The graft is fixed in the femoral tunnel with two parallel pins (Fig. 11). Place tension on the graft on the tibial side and then perform appropriate tibial fixation.







Tibial Fixation

The graft on the tibial side can be fixed with appropriate interference fixation devices. If the bone plug is completely outside the tibial tunnel, then a trough and staple and/or screw fixation technique can be employed. At this point, test the notch for impingement and verify that there is full range of motion in the knee.

Rehabilitative Protocol

Follow standard postoperative protocols. Full weight bearing is permitted, and an accelerated rehabilitation protocol can be pursued. Keep patients in a knee immobilizer for their protection until they obtain quadriceps control.