RIGIDFIX® ST & INTRAFIX™ ST SURGICAL TECHNIQUE

SOFT TISSUE ACL RECONSTRUCTION PROCEDURE

as described by J. Emory Chapman, Jr., MD
Chief of Orthopaedic Surgery, Gaston Memorial Hospital

DePuy Mitek
a Johnson & Johnson company

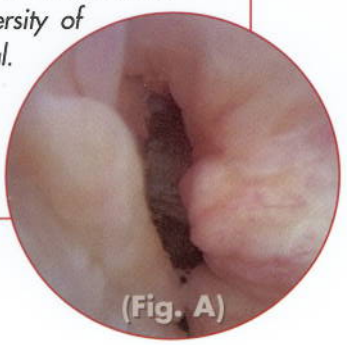
SOFT TISSUE ACL

Physician Bio

J. Emory Chapman, Jr., MD

Dr. James Emory Chapman, Jr. serves as the Chief of Orthopaedic Surgery at Gaston Memorial Hospital and, since 1999, has been a partner in Orthopaedic Specialists — both in Gastonia, North Carolina. Dr. Chapman's past experience includes Serving as Director of the Sports Medicine Service at the Letterman Army Medical Center; as an Orthopaedic Surgeon during Operation Desert Storm at the 8th Evacuation Hospital (Saudi Arabia) and at the Soto Cano Air Base (Honduras); and as a Sports Medicine Fellow at the USMA at West Point, NY.

Dr. Chapman has been named a Diplomat of both the National Board of Medical Examiners and American Board of Orthopaedic Surgery. He is a member of several professional associations, including the American Medical Association, American Academy of Orthopaedic Surgeons and Arthroscopy Association of North America — for which he serves as Chairman of the Learning Center Committee, and he holds licenses in the states of North Carolina, Georgia, California and Florida. Dr. Chapman graduated from the Medical College of Georgia in Augusta, and did his internship and residency at the University of Miami/Jackson Memorial Hospital.



(Fig. A)

Introduction

The rupture of the native anterior cruciate ligament places the knee of the otherwise active individual at risk of instability and recurrent injury with chondral and meniscal damage **(Fig. A)**. Current arthroscopic ACL reconstruction techniques vary in fixation methods, as well as graft material selection.

The two most commonly used autogenous graft materials are the semitendinosus-gracilis tendon construct and the bone-patella tendon-bone ligament. Allograft materials commonly in use are anterior tibialis tendon, Achilles tendon and bone-patella tendon-bone. Discussion has arisen as to the efficacy of using the patella bone-tendon-bone graft, not necessarily in terms of the graft itself, but in the mode of fixation. Concerns have been raised regarding the issue of screw divergence when interference screws are used on the femoral side, as well as the long-term results of this effect on the fixation of the graft. Several factors must be taken into consideration when selecting a standard ACL protocol, including graft selection, graft placement, initial graft tension, graft fixation and graft fixation site healing.

The DePuy Mitek RIGIDFIX® ACL Cross Pin System has been my preferred system for femoral fixation for the past six years. This innovative system presents a simple method for fixing either soft tissue or patella tendon grafts during ACL reconstruction. The RIGIDFIX Cross Pin System offers me:

- Bio-absorbable fixation with compression and suspension at the graft-tunnel interface
- 360° of bone-to-graft contact for more complete incorporation of the graft
- A quick and reproducible ACL surgical procedure that eliminates intra-articular graft damage from screw placement
- Eliminates the need for special portal placement needed to prevent screw divergence as is typical of other systems

RECONSTRUCTION PROCEDURE

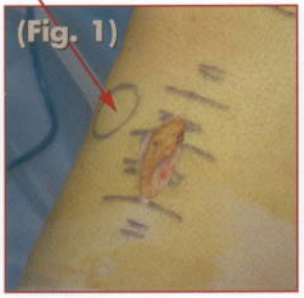
Tendon Harvest

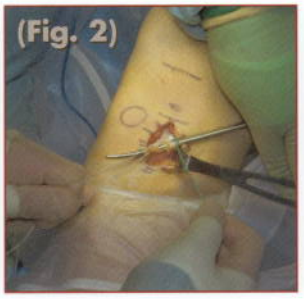
(Fig. 1) A 2cm longitudinal skin incision is made three finger breadths below the joint line and two finger breadths medial to the tibial tubercle. Electrocautery is used in order to incise the subcutaneous fat in line with the skin incision, followed by the blunt dissection of the subcutaneous fat away from the sartorius fascia overlying the tendons. The gracilis and semitendinosus tendons are palpable as two pronouncements lying deep to the insertion of the sartorius.

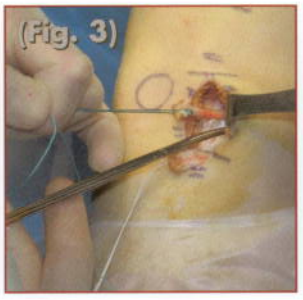
For identification purposes, the gracilis is generally narrower and located superior to the semitendinosus, which is more robust in width and appearance. Once the tendons have been identified, the skin is lengthened either superiorly or inferiorly, as needed, to aid in graft harvest. A vertical incision is made to release the pesanserinus tendon from its tibial insertion, and it is inverted to expose the gracilis and semitendinosus tendons. These coalesce into a common insertion, and a #15 blade is used to separate the two in order to facilitate tension and control of each graft limb **(Fig. 2)**. A #2 ETHIBOND® Tri-Color Pack or a #2 ORTHOCORD™ Suture is used to place a whipstitch in the end of each tendon. Sectioning the fibrous bands that attach each tendon to the medial head of the gastrocnemius is essential to discourage diversion of the tendon stripper, which might prematurely transect the tendon. The knee is flexed to 90° so that the direction of the tendons is obvious, and then the bands are sectioned with Metzenbaum scissors **(Fig. 3)**. A closed tendon stripper is advanced along the tendon parallel to the graft, while traction is provided via the whipstitch **(Fig. 4)**.

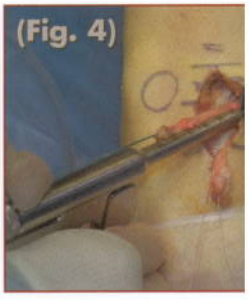
The tendon stripper is then advanced in a slow, controlled fashion without deploying trigger until it has been inserted to a depth of at least 200mm, as read off of the device's blade. At that point, the blade can be deployed and the stripper slowly advanced, while maintaining tension on the graft until it separates from its origin. If at any time, the tendon stripper does not advance in this fashion, it is best to remove the tendon stripper from the incision altogether and complete the dissection of any and all attachments to free up the tendon. I generally use a tourniquet for this part of the procedure and deflate it for the rest of the case.

Tibial tubercle

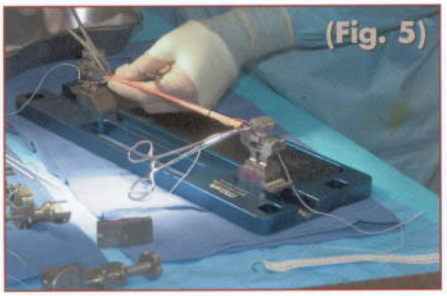








Graft Preparation



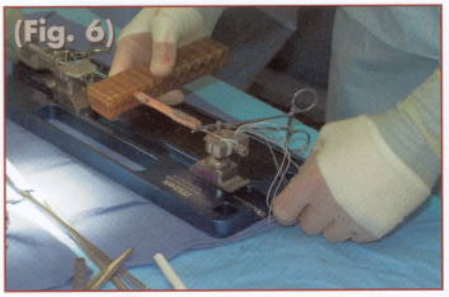
Preparation of the graft is made easier with the use of a graft preparation board. Residual muscle and fatty tissue are eliminated by gently scraping it away with a key elevator or malleable graft retractor. The end of each leg of the graft is secured for 40mm with a baseball stitch, using #2 ETHIBOND® (Tri-Color Pack) or #2 ORTHOCORD suture **(Fig. 5)**.

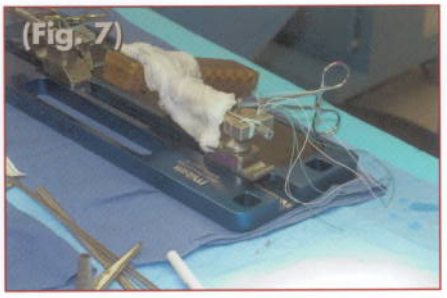
The two grafts are then looped over a #5 ETHIBOND or #2 ORTHOCORD suture to create a four-strand construct. I typically even up the ends of the graft and then snap the sutures so that they stay even while I place the graft in the graft preparation board tensioner. A whipstitch is then applied to the looped-over portion of the graft, for a distance of 30mm.

It is recommended that the semi-T be stitched to the semi-T and the gracilis to the gracilis, followed by semi-T to gracilis. The end result is a bundled graft that will subsequently be inserted into the femoral tunnel. This bundling helps to consolidate the graft so that it may be passed into a smaller tunnel, which provides a tight fit and enhances fixation, while minimizing the possibility of graft micro-motion.

At this point, the graft should be passed through a graft-sizing block **(Fig. 6)** to determine the diameter of each end of the graft. Finally, the graft is attached to the tensioning apparatus on the graft board and tensioned to the desired amount, equally distributing the applied load to each of the four graft limbs.

A circumferential mark should be made on the graft at the 30mm mark to ensure that the desired amount of graft is passed into the femoral tunnel (30mm). A damp (vs. wet) surgical sponge is placed on the graft to prevent desiccation of the graft. The femoral end of the graft can be placed into the appropriate tunnel of the graft-sizing block to prevent it from imbibing fluid and expanding **(Fig. 7)**.





Notchplasty

The remainder of the native ACL is removed, and the lateral wall of the notch is cleared with DePuy Mitek's VAPR® Radiofrequency Electrode for optimal visualization **(Fig. 8)**. With its suction tip, VAPR eliminates gas bubbles from the field and speeds the process.

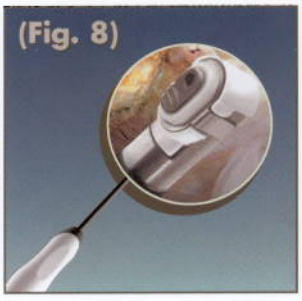
A notchplasty serves to increase the view of the posterior part of the notch and is performed, as needed, to view the over-the-top position. I typically only resect as much bone as needed to clearly visually the posterior wall. A curved curette can be used to help palpate the over-the-top position by passing it through the anterior medial portal and palpating posteriorly until the tip falls over the edge of the posterior wall **(Fig. 9)**.

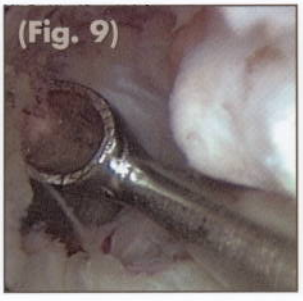
Tibial Tunnel

A tibial drill guide **(Fig. 10)** is used to establish a tibial tunnel. Setting the drill guide at a 40-45° angle ensures an adequate length tibial tunnel and easy access to position the femoral guide pin. Placement of the tunnel is confirmed by partially passing the drill pin into the joint to confirm proper direction and angle, thus recreating the normal anatomy of the native ACL.

I place my aiming guide so that the guide pin enters the joint at the posterior border of the anterior horn of the lateral meniscus and is midway between the walls of the arch **(Fig. 11)**. A common mistake is to place the tibial tunnel in an overly anterior fashion, which results in graft impingement.

Tunnel diameter is determined by sizing the graft to allow a fit that's snug enough to enhance rapid bone in-growth, but large enough to allow passage of the graft through the tunnel in an in-line fashion. Select an appropriately sized disposable fully fluted reamer **(Fig. 12)** to create the tibial tunnel, making sure to clear any debris from the tunnel. The use of a disposable fluted reamer allows for precise sizing of graft-to-tunnel diameter in each procedure.


(Fig. 8)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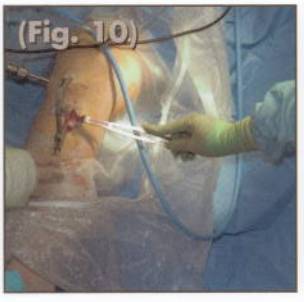
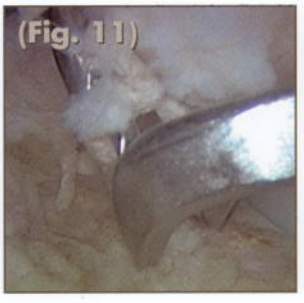
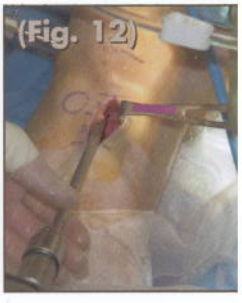
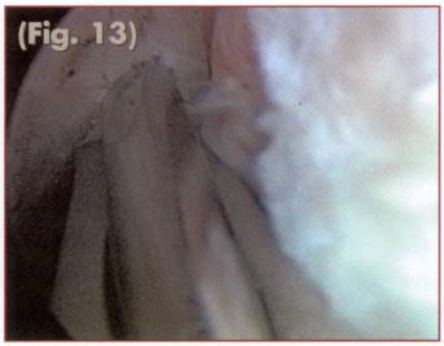

(Fig. 10)

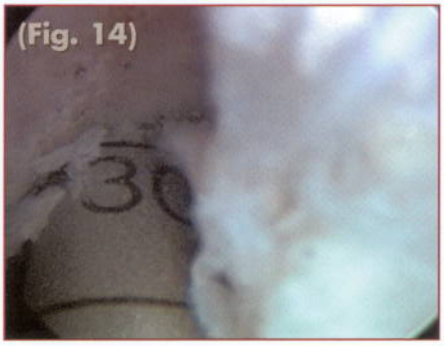

(Fig. 11)

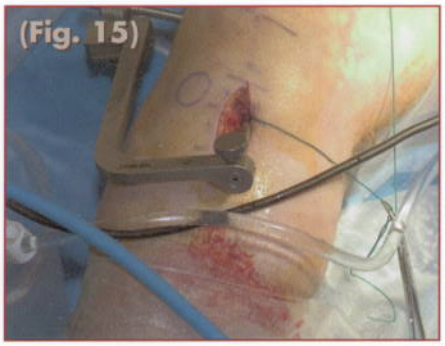

(Fig. 12)

Femoral Tunnel

Femora


(Fig. 13)


(Fig. 14)

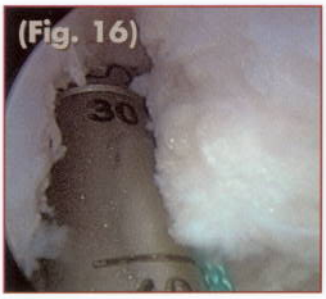

(Fig. 15)

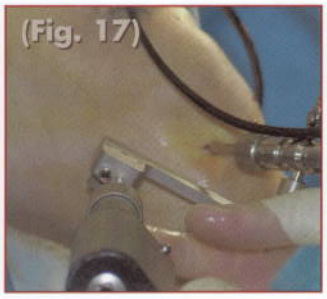
Upon completion of the tibial tunnel and removal of any residual debris within the joint, we are now ready to create a femoral tunnel. Using an appropriately angled offset guide and obtaining proper positioning on the superior aspect of the notch at approximately the 1-1:30 position, drill the guide pin through the notch and out the anterior cortex of the femur **(Fig. 13)**. Once you've removed the offset guide, select an appropriately sized disposable acorn reamer that corresponds in diameter to that of the graft. Using the RIGIDFIX system, we want to drill 25mm-30mm into the femoral tunnel **(Fig. 14)**.

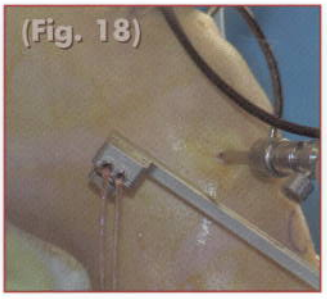
At this point, I tie a #5 ETHIBOND or #2 ORTHOCORD suture to the tibial end of the guide pin and then pull the pin out through the femoral end. Now, one end of the suture exits the anterior thigh, while the other exits the tibial tunnel. Once this has been done, the knee can be bent in different positions without fear of bending the guide pin (A bent guide pin can be difficult to remove). Leaving the suture across the joint provides an easy way to pull the graft into place later in the procedure.

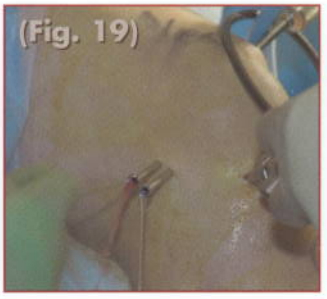
Using the DePuy Mitek RIGIDFIX Soft Tissue System, I begin by selecting a cannulated femoral rod that corresponds with the size of my femoral tunnel (i.e., a 9mm RIGIDFIX femoral rod for a 9mm femoral tunnel) and attach it to the RIGIDFIX guide frame. This construct is inserted up the femoral tunnel **(Fig. 15)** to a depth of 30mm, which corresponds to the shoulder on the femoral rod **(Fig. 16)**. Note that the extra-articular portion of the RIGIDFIX guide frame lies on the lateral side of the operative knee. If the guide pin was left traversing the knee, it must be removed from the femoral tunnel to allow the drill sleeves to be drilled into place. This may be accomplished by removing the guide pin entirely from the knee or simply sliding it down from the femoral location.

Next, the RIGIDFIX sleeves should be placed over the interlocking trocar (making sure that the teeth of the trocar are engaged in the hub of the sleeve), and then drilled through the hole in the guide into the lateral side of the femur until the sleeve hub meets the guide **(Fig. 17)**. Next, remove the trocar by disengaging the teeth from the hub of the sleeve, and slide the trocar out,

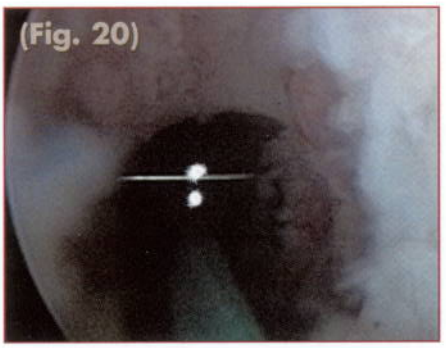

(Fig. 16)

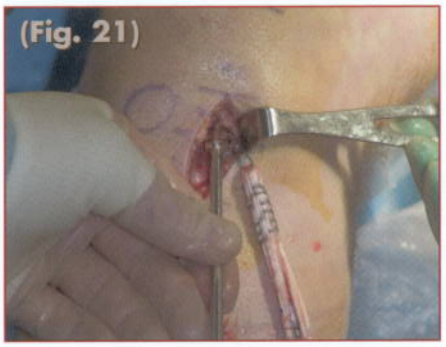

(Fig. 17)

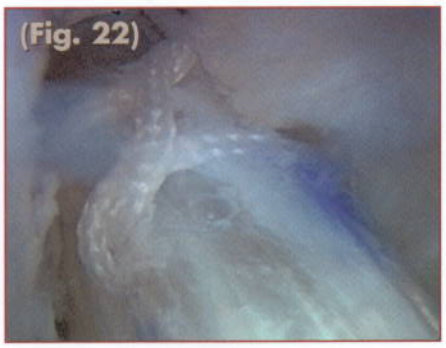

(Fig. 18)


(Fig. 19)

Fixation


(Fig. 20)


(Fig. 21)

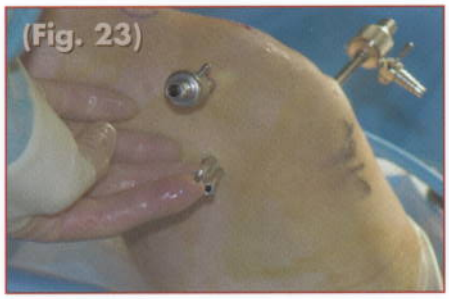

(Fig. 22)

leaving the sleeve engaged in the bone. Drill the second sleeve and trocar into the top hole of the guide in the same fashion as the first and remove the trocar from the sleeve, leaving only the sleeves extending from the lateral side of the knee. The correct sleeve placement can be confirmed by introducing fluid to the joint, at which point you should see fluid flowing out of the sleeves **(Fig. 18)**. Another option is to insert a guide pin into one of the sleeves, while visually confirming the pin crossing the femoral tunnel via arthroscopic view up the femoral tunnel **(Figs. 19 & 20)**. The guide pin may be re-inserted at this point, while the guide plate is detached and guide removed entirely from the knee, leaving only the two sleeves in the lateral femur and guide pin placed through the knee.

Prior to inserting the graft, I mark my graft on the femoral side 30mm from the tip, thus allowing me to determine full insertion into the femoral tunnel **(Fig. 21)**. Next, pull the graft up the tibial and femoral tunnels, using a basic in-line technique with either guide pin or #5 ETHIBOND suture. I look to make sure that my mark on the graft is at the edge of the femoral tunnel **(Fig. 22)**.

While maintaining tension on my #5 ETHIBOND suture that extends through the skin on the femur, I am now ready to insert my first RIGIDFIX cross pin through my superior sleeve. By placing the first RIGIDFIX pin and inserting it with the stepped pin insertion rod and mallet into the superior sleeve, I'm able to ensure that the graft is entirely and securely up the femoral tunnel. After confirming fixation via the first cross pin, by applying tension from the tibial side, I place the second RIGIDFIX cross pin **(Fig. 23)** through the inferior sleeve, while maintaining tension from the tibial side to take any laxity out of the graft's intra-tunnel portion. In each case, the stepped pin insertion rod is advanced until the stepped portion of the rod meets the sleeve hub. If the #5 ETHIBOND was left traversing the joint as described in the femoral section, then it is not necessary or desirable to replace the guide pin.

Confirming solid fixation via tension from the tibial side and making sure that my 30mm mark on the graft does not move, I now remove the sleeves with the sleeve removal tool and have completed my femoral side fixation **(Figs. 24 & 25)**.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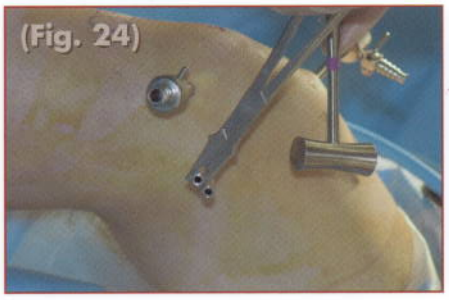
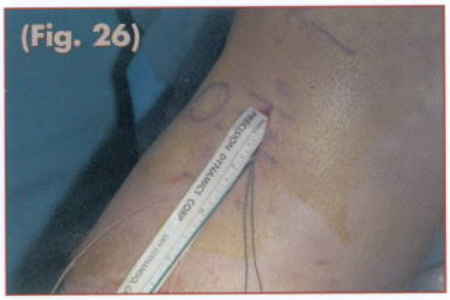

(Fig. 24)


(Fig. 25)

Tibial Fixation

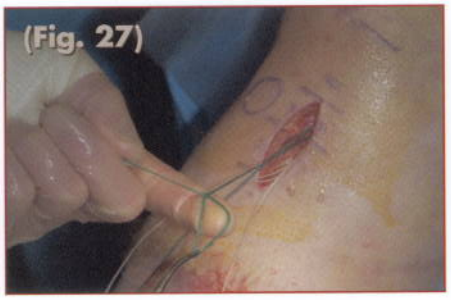

(Fig. 26)

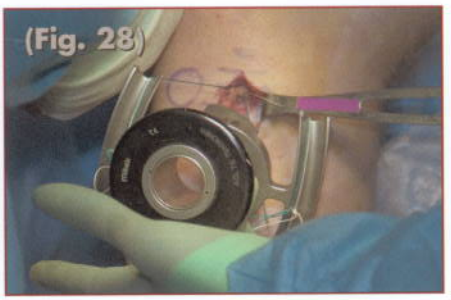
Because most soft tissue grafts have a certain amount of creep in them, I prefer to cycle the knee in extension and flexion approximately 20 times, thus minimizing any post-op loosening of the graft.

My selection for tibial fixation is the DePuy Mitek INTRAFIX™ for a couple of reasons. The INTRAFIX holds the legs of the graft in independent channels, allowing for equal compression against the tunnel walls. Because of this ability to spread the graft concentrically throughout the tibial tunnel, biological in-growth of the graft is enhanced.

The next step is to tie the loose ends of the whipstitched semitendinosus and gracilis together, forming a loop approximately 4-5" from the end of the tibial tunnel **(Fig. 26)**. This same step is used for other soft tissue grafts as well, such as an anterior tibialis allograft. I first measure the one set of sutures to a distance of 5" from the exit from the tibia. Next, I snap the sutures with the very tip of the hemostat. I then tie a knot at this point and use this knot as reference to determine the 5" mark on each of the other subsequent suture sets. I use the tip of the hemostat to help me tie knots at this precise location for each of these suture sets **(Fig. 27)**, which leaves me with four sets of sutures exiting the tibia with knots tied exactly 5" from the tibial exit. Both loops of suture are then placed over the skis of the INTRAFIX tie tensioner **(Fig. 28)** or may be held by hand if preferred. Now, by applying 20-30lbs of tension to the graft, one can see that the function of the tie tensioner equally tensions and separates each leg of the graft construct. I am able to control the amount of tension being applied to the graft, as the shaft of the tie tensioner is calibrated, indicating the amount of tension being applied. I am always impressed by the fixation that the RIGIDFIX system provides, and I have never seen a graft move in the femoral tunnel, regardless of how much tension I apply to the tie tensioner.

While the optimal amount of tension and flexion is still a topic of debate, I prefer to fix the graft with the knee in full extension, though it is acceptable to fix the graft with the knee in up to 20° of flexion. It's important not over-tension the graft while using the INTRAFIX device, as the high fixation strength

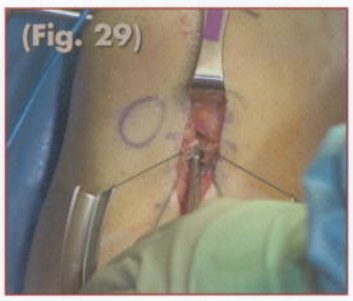

(Fig. 27)

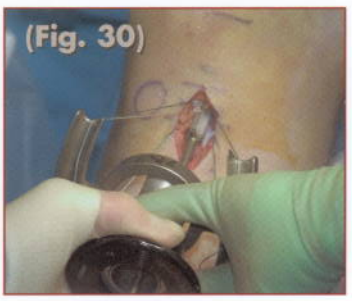

(Fig. 28)

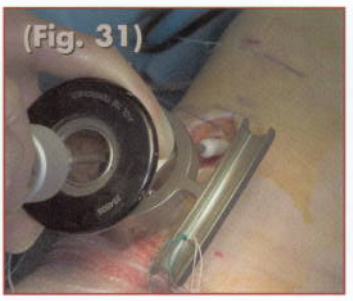
and stiffness, and lack of slippage could increase the likelihood of locking the knee at less than full extension, which makes it difficult for the patient to gain a full range of motion post-op.

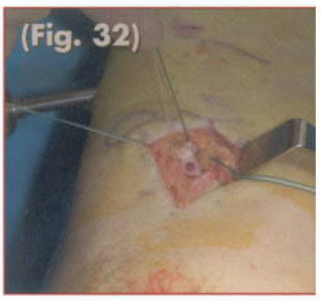
Orientation of the proper angle or axis of the tibial tunnel can be achieved by the use of a simple guidewire. Once this is accomplished, remove the guidewire and insert the INTRAFIX tibial trial to a depth of 30-35mm **(Fig. 29)**. The tie tensioner is designed to accomplish this through an opening in the device, while maintaining tension on the graft ends. By using the trial, I both compress the graft tendons and orient them concentrically along the walls of the tibial tunnel (each leg of the graft should be positioned in a channel of the trial as insertion takes place). At this point, using a mallet may be necessary to ensure that the trial reaches a depth of 30-35mm in the tibial tunnel. By pulling straight back or with the aid of a mallet, the tibial trial is removed from the tibial tunnel. While maintaining a constant and steady tension on the graft, I insert the INTRAFIX tibial sheath **(Fig. 30)**, which has been pre-loaded onto a sheath inserter. The INTRAFIX sheath comes in one length, 30mm, which will be inserted to the same depth (The INTRAFIX sheath and sheath inserter come with a pronounced tab on both the implant and instrument. Line these up so that they correspond with each other prior to insertion into the tibial tunnel). I try to keep these tabs oriented in the 12 o'clock position as the sheath is inserted into the tibial tunnel and the tab is seated against the cortical surface. The sheath inserter is removed simply by pulling straight back, leaving the INTRAFIX sheath in place among the legs of the graft. It is helpful to clear soft tissue from the superior aspect of the tibial tunnel prior to inserting the INTRAFIX sheath, which allows you to accurately gauge how deep to insert the sleeve.

The final step of implanting the INTRAFIX device is to choose a properly sized tapered screw with which to complete the fixation. The INTRAFIX tapered screws are available in 6-8mm x 30mm, 7-9mm x 30mm and 8-10mm x 30mm sizes. The recommended sizing scheme for the INTRAFIX system screws is to select a screw that is 1mm larger than the diameter of your tibial tunnel. For example, I commonly harvest an 8mm graft and drill corresponding tunnels of 8mm in both the femur and tibia; thus, selecting a 7-9mm x 30mm screw will give me optimal fixation. When inserting the INTRAFIX screw **(Fig. 31)**, it is important to note that this is not used in the same fashion as an interference screw (With an INTRAFIX screw, I let the screw engage itself within the INTRAFIX sheath, while with an interference screw, I would apply a forward force on the screw to gain purchase). I insert the INTRAFIX screw completely until the proximal end of it lies flush with the cortical surface of the tibial bone **(Fig. 32)**. In my experience, I have found the cortical bone to be of the best quality at or just below the cortical surface, and this is precisely where I would place the INTRAFIX screw. Any residual portion of the sheath should be removed or trimmed with a ronjeur, as this will not compromise the strength of the device. Finally, the stability of both the graft and the knee can be checked to confirm a full range of motion.


(Fig. 29)


(Fig. 30)


(Fig. 31)


(Fig. 32)

Post-Operative Management

To minimize pain and swelling during the immediate post-operative period, a pain pump is inserted and a polar pack is applied in the OR. Operative dressing consists of a toe-to-thigh ace wrap, which the patient may remove, along with the pain pump, after 48 hours. In the OR, the patient also is placed in a hinged Bledsoe brace locked in full extension. The patient may immediately ambulate weight-bearing with crutches, as tolerated. Patients are encouraged to remove the brace at least three times a day to work on regaining flexion; the brace is not required while sleeping.

Patients are referred to physical therapy at week one and should return to the office for suture removal eight days following surgery. As the patient gains control of the knee, the hinges of the brace can be opened up and, once adequate control is achieved, the brace may be discontinued completely.

- **Day 8-Week 3:**

  Work on regaining quad control and ROM with flexion to 120°.

- **Weeks 3-6:**

  Use the stationary bicycle for ROM. Do closed Kinetic Chain extension exercises and Hamstring curls, and double and single leg stance static balance exercises — progressing to dynamic single leg balance activities.

- **Weeks 6-12:**

  Use stationary bike for endurance and do light jogging on level surfaces.

- **Weeks 12-24:**

  Resume full jogging and progress to cutting activities.

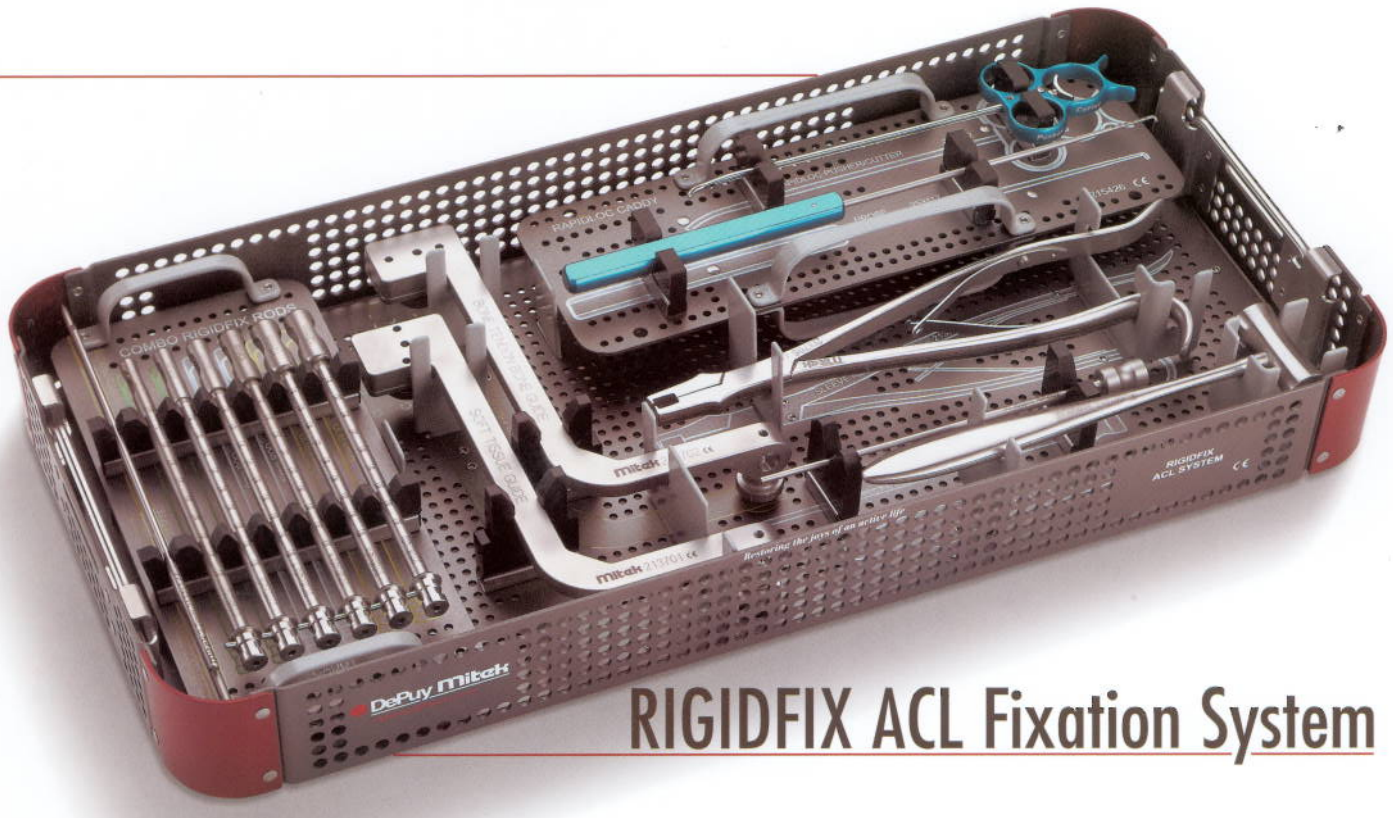
- **Week 24-on:**

  Return to contact sports.

Instruments Used

DePuy Mitek Products Used in Procedure

RIGIDFIX® ST ACL Cross Pin System	210133
ORTHOCORD™ Suture	223114
TARGET™ Tendon Stripper	232004
Graft Preparation System	280039
Graft Sizing Block	219960
VAPR® S90 Suction Electrode	225370
Tibial Drill Guide & Ratchet	219301
9mm Disposable Fully Fluted Reamer	232419
9mm Disposable Acorn Reamer	232406
ACL Disposable Kit	232300
INTRAFIX™ Tie Tensioner	254605
30mm INTRAFIX Sheath	254601
7-9mm INTRAFIX Screw	254609
6mm Offset Femoral Aimer	219356



RIGIDFIX ACL Fixation System

PROCEDURAL PERSPECTIVES

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

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