INTRODUCTION

The optimal initial graft fixation technique for hamstring tendon anterior cruciate ligament (ACL) grafts remains controversial.\textsuperscript{1–10} Biomechanical studies have demonstrated that cross-pin and Endobutton-CL femoral fixation techniques provide excellent initial fixation properties.\textsuperscript{11,12} However, tibial fixation of hamstring tendon ACL grafts has been more problematic. This is primarily due to the lower bone mineral density of the proximal tibia and the fact that tibial fixation devices must resist tension applied parallel to the axis of the tibial bone tunnel.\textsuperscript{13–16} Extratunnel tibial fixation techniques that anchor to the tibial cortex can provide secure initial fixation; however, the implants are often prominent and cause local skin irritation and pain, requiring a second operation for removal.\textsuperscript{17} Intratunnel tibial fixation using interference screws eliminates the problem of prominent hardware, but the single interference screw technique has been shown to have somewhat low initial fixation strength and increased slippage under cyclical loading.\textsuperscript{13–15,17–19}

The IntraFix tibial fastener was designed with two goals in mind, one mechanical and one biological. The first goal was to achieve more rigid intratunnel fixation of soft tissue grafts and eliminate or decrease the need for supplemental tibial fixation. The second goal was to maximize bony integration of the soft tissue graft strands into the bone tunnel wall. To achieve these goals, the device was designed with an expandable, four-channel, ridged, 30-mm polyethylene sheath and a tapered Delrin expansion screw. The four channels individually capture and grip each of the four strands of the hamstring tendon graft into separate compartments and directly compress each of the graft strands against cancellous bone. We performed cyclical and single load to failure (LTF) tests comparing the plastic IntraFix and bioabsorbable interference screws in paired young to middle-aged human cadaver tibiae with human doubled gracilis and semitendinosus grafts (DGSTs) (Table 47-1). The plastic IntraFix demonstrated a mean ultimate failure load of 800 N and stiffness of 200 N/mm, which was significantly higher than interference screw fixation. In an independent biomechanical study comparing commonly used hamstring tendon graft tibial fixation devices, Kousa et al\textsuperscript{20} demonstrated that the IntraFix had the highest LTF (1309 N) and stiffness (267 N/mm) and the least amount of slippage (1.5 mm) after cyclical loading.

Following the successful clinical introduction of the nonabsorbable IntraFix tibial fastener, a Bio-IntraFix composed of PLLA/TCP was developed to satisfy the desire of some surgeons for a bioabsorbable device. Testing of the Bio-IntraFix using DGST and paired human cadaveric tibiae (mean age 63 ± 10 years) was performed with the line of force applied parallel to the axis of the tibial tunnel. Elongation was measured using a video camera system to determine displacement of contrast.
markers attached to the graft and bone. The graft–Bio-IntraFix–bone complex was cyclically loaded between 50N and 200N at a rate of 0.5 Hz for 1000 cycles (33 min, 20 sec). One thousand cycles approximates 1 week of postoperative intermittent passive motion. The mean ultimate failure load and linear stiffness for the Bio-IntraFix were 643 ± 152N and 325 ± 111 N/mm, respectively. Elongation after 1000 cycles was 2.28 ± 1.19 mm. The failure load of the Bio-IntraFix was found to be superior to that of the Delta screw (Arthrex, Naples, FL), and the stiffness was two times that of the Delta Screw. During cyclical loading, three of six Delta screws failed compared with only one of six DGST grafts fixed with the Bio-IntraFix.

The second goal of this design was to maximize the amount of contact between graft tendons and bone. Fixation outside tunnels and from suspension devices results in a loose fibrous attachment between the tunnel wall and the graft, with little if any bony ingrowth into the graft. In contrast, direct compression of tendon to bone by interference screws within the tunnel leads to bony ingrowth including Sharpey fiber formation. However, a single interference screw inserted next to a bundled four-stranded graft definitely leaves a considerable portion of the tunnel filled by the screw and some of the tendons without bony contact. In contrast, the IntraFix has the potential for more extensive bone–graft integration because each strand is pressed against bone and the entire tunnel wall is in contact with graft.

A limited histological study performed on the IntraFix in sheep demonstrated early bony integration (Fig. 47-1). Thus extrapolation of the interference screw data to this device seems justified. Further evidence of extensive bony integration when using the IntraFix and Bio-IntraFix comes from direct examination of the tibial tunnel many months after reconstruction. Fig. 47-2 shows an example of the appearance of the tibial tunnel 1 year after ACL reconstruction; it was obtained during a revision case after the sheath had been removed and the arthroscopic inserted into the tibial tunnel. It shows a firm surface, apparent integration of the sutured tendons into the bone tunnel wall, capillary ingrowth, and no loose fibrous tissue.

### TABLE 47-1 Sizing Scheme for Bio-IntraFix

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<th>Graft Diameter</th>
<th>Drill Tunnel</th>
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### SURGICAL TECHNIQUE

#### Graft Preparation

Preparation of the tendons is facilitated by the use of a graft preparation board. The two tendons are cut to a total length of 20 to 21 cm, and the opposite ends of the tendons are whipstitched for 4 to 5 cm using a #2 nonabsorbable suture. This length of tendon graft allows for 25 mm of the DGST tendon graft to be inserted into the femoral tunnel and typically results in a significant length of suture-reinforced tendon within the tibial tunnel and a short (1-cm) length of the tendons extending outside the tibial tunnel. If more of the DGST tendon graft is inserted into the femoral tunnel, or if the tibial tunnel is longer than 40 to 45 mm, then the...
total length of the two tendons should be increased accordingly. This is important because suture-reinforced tendon constructs have been shown to increase pullout strength by 30% to 40% in our laboratory biomechanical tests.

**Use with Allografts**

If a soft tissue allograft such as a tibialis tendon is used, we prefer to divide each end of the allograft in two for a distance of 5 cm and then to whipstitch each strand so that a four-stranded construct comparable to a DGST is created. The IntraFix four-chambered sheath accommodates and provides more uniform compression with a four-stranded graft preparation compared with a two-stranded graft. The graft construct is then placed on a tensioning board, cinching the whipstitched sutures and removing creep from the graft construct. Removing creep from the graft-suture construct is particularly important if supplemental fixation is required.

**Tibial Tunnel**

Our preferred method for performing endoscopic ACL reconstruction is the transtibial tunnel technique (Fig. 47-3). The transtibial technique allows a longer femoral tunnel to be drilled compared with drilling the femoral tunnel through the anteromedial portal and also allows cross-pins to be used for the femoral fixation. Another advantage of the transtibial technique is that the femoral tunnel does not have to be drilled with the knee in hyperflexion, which constrains fluid inflow and limits visualization in the notch. The disadvantage of the transtibial tunnel technique is that it provides more limited access to the sidewall of the lateral femoral condyle compared with drilling the femoral tunnel through the anteromedial portal.

The tibial tunnel must be carefully oriented in both the sagittal and coronal planes for several reasons. Due to the large cross-sectional area of four-strand hamstring tendon grafts, sagittal placement of the tibial tunnel is especially critical. The tibial tunnel position in the sagittal plane determines whether the ACL graft impinges against the roof of the intercondylar notch in full knee extension. Roof impingement is associated with effusions, loss of extension, anterior knee pain, quadriceps weakness, and increased anterior laxity. Coronal plane orientation is the primary determinant of placement of the femoral tunnel along the side wall of the intercondylar notch and, to some degree, of the length of the femoral tunnel. A more medial starting position on the tibia allows the femoral tunnel to be drilled closer to the 10- or 2-o’clock position along the sidewall. A femoral tunnel at the 10-o’clock (right knee) or 2-o’clock position (left knee) is important because a single-bundle ACL graft positioned at these locations in the intercondylar notch is more effective at resisting combined rotatory loads than one placed at the 11-o’clock position. Biomechanical studies have demonstrated little difference in coupled anterior tibial translation between this graft and a double-bundle hamstring ACL reconstruction at low degrees of flexion.

In our surgical technique, a tibial tunnel length of 35 to 45 mm is optimal because this will accommodate the entire 30-mm IntraFix or Bio-IntraFix with no chance of the device protruding into the joint. In general, setting the variable angle tibial aimer between 45 and 55 degrees will allow these tibial tunnel lengths to be achieved. The guidelines of Jackson and Gasser, Howell, and Simmons et al are used for intraarticular placement of the tibial guide pin. If necessary, the tibial guide pin position can be checked by intraoperative radiographs or fluoroscopy with the knee in maximum extension.

**Tunnel Sizing**

When using the plastic IntraFix, the diameter of the tibial tunnel should equal the diameter of the suture-reinforced end of the graft. When using the Bio-IntraFix, the tibial tunnel should be drilled 0.5 to 1.0 mm larger than the diameter of the suture-reinforced end of the graft because the Bio-IntraFix sheath does not compress or flow during screw insertion. Biomechanical testing of this oversized scheme showed no loss of fixation strength for the Bio-IntraFix compared with tunnels sized to the same diameter as the graft. Half-millimeter–sized drill bits can be used to make this sizing more precise. The tibial tunnel should be drilled with a fluted drill to prevent anterior drift of the tunnel as the proximal cortex is breached.

After drilling the tibial tunnel, it is important to clear soft tissue from around the edges of the tibial tunnel using...
Femoral Tunnel and Graft Fixation

Because the IntraFix tibial fastener can be used with any femoral fixation technique, the choice of the femoral fixation is based on the surgeon’s preference. However, we prefer cross-pins or the Endobutton-CL because these fixation techniques have been shown to be strong and stiff and to have the least amount of elongation under cyclical loading. More importantly, these two femoral fixation techniques permit equal tensioning of all four graft strands. This is an important goal because, as shown by Hamner et al., it is necessary to equally tension all four strands of a DGST graft to maximize initial graft strength and stiffness. An equally tensioned DGST graft was stronger and stiffer than a 10-mm, central-third patellar tendon autograft. However, when no attempt was made to equally tension all four graft strands, the ultimate failure load and stiffness of the DGST graft were not statistically different from that of a doubled semitendinosus tendon graft alone. Thus failure to equally tension all four graft strands of a DGST graft negated any contribution from the doubled gracilis tendon graft.

Device Insertion

Concentric device placement within the tibial tunnel is critical to the success of the technique. To achieve this, the central axis of the tibial tunnel is identified by passing a stout guide-wire or a Trailblazer (Smith & Nephew Endoscopy, Andover, MA) through the center of the tie tensioner and down the center of the four graft strands into the knee joint (Fig. 47-5). Once the central axis of the tibial tunnel is identified, the tie tensioner should be held in this orientation during all the subsequent steps to avoid divergent placement of the IntraFix sheath and screw. The surgeon can improve his or her ability to maintain this orientation by placing several fingers or the entire side of the hand holding the tensioner on the tibia during the next steps. Next, the four-quadrant dilator is inserted down the center of the four graft strands and oriented so that each graft strand sits in its own channel (Fig. 47-6). While maintaining the desired tension on the graft, the four-quadrant dilator is tapped into the tibial tunnel for a distance of 35 mm. This step compresses and separates the four tendon strands, and, in the case of smaller tunnels (7 to 8 mm), notches the bone tunnel wall to accept the sheath. It is important to keep the dilator oriented along the axis of the tibial tunnel as it is impacted because the dilator...
has a tendency to diverge, as do most tunnel dilators. Because the sheath for the IntraFix and Bio-IntraFix is 9 mm in diameter, the four-quadrant dilator also enlarges the tibial tunnel in the case of smaller tunnels, providing easier insertion of the IntraFix sheath and tapered screw. There are now two sheaths for the Bio-IntraFix and a smaller and larger dilator appropriate to each. The smaller sheath is used for 7- and 8-mm tunnels and the larger for 9- and 10-mm tunnels.

After dilating the tibial tunnel, the 30-mm Intrafix sheath is placed on the sheath inserter with the derotational tab on the sheath oriented to match the tab on the sheath inserter. The knee is positioned at the chosen flexion angle, and a final tension of 60N to 80N is applied to the DGST graft or tibialis tendon allograft using the tie tensioner. The Intrafix sheath is inserted among the four graft strands, taking care that each graft strand is positioned into a separate channel of the IntraFix sheath. The derotational tab on the sheath is oriented at the 3- or 9-o’clock position (Fig. 47-7). Orienting the derotational tab at these positions allows the IntraFix sheath to be inserted more deeply into the tibia and prevents prominence of the device. The inserter is tapped into the tunnel until the derotational tab is flush with the cortex. As stated earlier, clearing the soft tissue from the bone tunnel opening will allow for better assessment of the depth of insertion and trimming of any protruding tendon or sheath after the screw has been inserted. The sheath inserter is removed, and the 0.042-inch guidewire for the IntraFix tapered screw is inserted through the center of the sheath until a loss of resistance is felt as the tip of the guidewire enters the knee joint.

For the plastic IntraFix, a tapered screw size 1 mm larger than the tibial tunnel diameter is used. For example, an 8-mm tapered screw is used for a 7-mm tibial tunnel. Given the typical size of DGST grafts, the 7- to 9-mm tapered screw is most commonly used. The IntraFix screw is inserted into the plastic sheath until its inferior aspect is flush with or buried just below the tibial cortex (Fig. 47-8). Because the best bone quality is at or next to the tibial cortex, overly deep insertion of the screw may decrease fixation strength. The tension on the graft...
strands from the tie tensioner should prevent the sheath from rotating during screw insertion in hard bone, but some rotation of the outer sheath is acceptable because the sheath within the tunnel does not move in concert. Prominent areas of the polyethylene sheath are trimmed flush with the tibial cortex using a 15 blade and a small bone rongeur.

The technique for insertion of the Bio-IntraFix device is identical, but the sizing scheme differs from that just described (Table 47-2). Because the PLLA/TCP sheath is noncompressible and because the insertion torque is higher than with the plastic version, the tunnel should be drilled or dilated 1.0 mm larger than the graft diameter. The Bio-IntraFix sheath adds more than 1 mm to the diameter of the Bio-IntraFix screw, so in effect the fixation device in total is oversized to the tunnel diameter, which is the usual practice with interference screws and with the plastic IntraFix.
The stability and range of motion of the knee are checked. It is important to verify that the patient has full range of motion before leaving the operating room. The arthroscope is inserted into the knee, and graft tension and impingement are assessed. Our usual graft placement and tensioning technique results in the four strands of the DGST being maximally tight between 0 and 20 degrees, with the graft tension decreasing slightly as the knee is flexed to 90 degrees.

**Troubleshooting**

**Sheath Overinsertion**

As with any fixation device, potential errors can be made during the use of the IntraFix device. Overinsertion of the sheath is one such error. This problem typically occurs when a sheath smaller than the tunnel size is driven into the tunnel and the sheath’s advancement is not controlled. When this happens, the opening to the sheath cannot be seen.
and central placement of the screw cannot be assured. If the sheath is far into the tunnel, screw insertion should be abandoned until the sheath is pulled back into position or removed and another sheath is inserted. Because the ridges on the sheath are slanted to resist slippage of the graft proximally, attempts to grasp the sheath and pull it out of the tibial tunnel are often unsuccessful. Cutting the sheath or blindly grabbing it with an instrument such as a pituitary rongeur can damage the graft strands and the sutures holding them, risking rupture during tensioning. A better method involves pushing the sheath further up the tunnel, together with pulling the graft proximally with a probe inside the joint until the sheath can be seen entering the knee joint. At this point, the sheath can be grasped and...
removed through one of the portals, usually in pieces. The graft is then retensioned using the tensioner, and the standard steps noted above are repeated.

**Screw Breakage**

Screw breakage has sometimes occurred during insertion. This problem is partly due to the friction between the screw and sheath, which was never a concern with the plastic IntraFix, and in part because the tunnel may not have been enlarged above the diameter of the graft as recommended. (At the time of this writing, a newer, more robust screw and a sheath with improved properties have been produced, which will make breakage much less likely.) A third factor that can lead to screw breakage is failure to insert the screw along the central axis of the sheath and tunnel. A fourth cause is failure to seat the screwdriver fully within the screw.
When screw breakage happens, it is most often early during insertion, and it is nearly impossible to withdraw the screw tip with the driver due to a lack of purchase. Furthermore, the screw seems to bind within the sheath. The surgeon has two basic options at this point. The first approach is to revise the entire construct. In this case we use an “easy-out” device, such as those marketed to remove stripped cannulated interference screws, and core the screw out from within the sheath. Sometimes a new smaller screw can be inserted in its place and into the same sheath, but more commonly the sheath needs to be replaced. If the smallest of the screws (6 to 8 mm) was used initially, another screw of the same size is likely to suffer the same fate. A better strategy is to remove the sheath with a grasper and then to insert the larger 9-mm dilator more deeply into the tunnel among the graft strands, enlarging the tunnel further. After a new sheath is placed, a new screw should be carefully inserted along the axis of the tunnel. Blood, fatty tissue, or saline can be used to reduce insertion torque and should be tried during screw insertion in such instances, especially if the patient’s bone is hard and if additional tunnel dilation efforts did not seem to enlarge the diameter very much. The second technique, which is less commonly used, is to take the sutures from the tendon ends and tie them down onto a staple or screw distal to the tunnel. This approach can only be recommended if there is a significant length (greater than 50%) of screw within the sheath so that the sheath construct will not collapse when the sutures are tied below and migration of the device will not occur.

### Failure to Advance

A related screw insertion problem is failure of the screw to advance until it is fully seated. This has primarily been a problem with the Bio-IntraFix. The main cause is a tunnel diameter too small to accommodate the size of the IntraFix or Bio-IntraFix that was chosen. This situation, although quite rare, may be more challenging than screw breakage. The fact that the screw failed to advance almost certainly indicates that the screw has gained good purchase, at least in the distal portion of the tunnel. Therefore if the screw is no more prominent than an external fixation device such as a screw-washer, then it can probably be left in place, although it may require later removal after the graft has healed. If a much longer portion protrudes and it cannot be withdrawn with the screwdriver, then the protruding portion must be removed with a saw; the inserted portion and sheath removed; and a new, more properly sized device inserted.

### Low Bone Density

The fixation strength of any intratunnel fixation device is dependent on the local bone mineral density. If, during the insertion of the tapered screw, the surgeon subjectively feels that there was low insertion torque, or if the patient has soft bone as assessed during drilling and dilation of the tunnel, then we recommend that supplemental tibial fixation be used. Depending on the graft length, the tendons can be stapled below the tibial tunnel opening using one or two small barbed staples (Smith & Nephew Orthopaedics, Memphis, TN). Another method of backup is to tie the sutures around a small nonbarbed staple, a screw and washer, or a tibial fixation post (Smith & Nephew Endoscopy).

### Too Short a Graft

Finally, the surgeon may be faced by a graft that is not long enough and with ends that are recessed in the tunnel. If the graft is recessed to the degree that identification of the individual strands is not possible, then concentric placement of the sheath becomes much more difficult. One could try to separate the strands blindly, but then insertion of the dilator runs the risk of rupturing the sutures, with loss of ability to tension. In this case, therefore, it is probably best to tie the sutures onto a fixation post or use an interference screw as the sole means of fixation, or to use a hybrid of the two methods.

### Closure and Postoperative Dressings

A Hemovac drain can be inserted under the sartorius fascia and into the hamstring harvest site to prevent postoperative hematoma formation and decrease subcutaneous skin ecchymosis along the medial side of the knee. This is particularly useful when excessive bleeding is encountered during the hamstring tendon harvest. The sartorius fascia that was preserved during the hamstring tendon graft harvest is closed over the tibial hardware and repaired back to the tibia with a #0 absorbable suture. The subcutaneous tissue is closed in layers with fine absorbable sutures. A running #3–0 Prolene (Ethicon, Sommerville, NJ) subcuticular pull-out suture or #4–0 Monocryl produces a very cosmetic closure. A light dressing is applied over the wound, followed by a thigh-length TED antiembolism stocking (Cryocuff, Aircast, Summit, NJ) and knee immobilizer.
POSTOPERATIVE MANAGEMENT

The procedure is routinely performed as an outpatient procedure. If a Hemovac drain is used, the drain is removed when the patient is discharged from the day surgery unit. We allow unrestricted motion and weight bearing as tolerated. Early flexion performed as heel slides is encouraged because it prevents scarring of the extensor mechanism.

The weight-bearing schedule is modified if a meniscus repair, microfracture, or other associated ligamentous surgery has been performed. The patient is weaned from the knee immobilizer when quadriceps control is regained. Crutches are continued until the patient has regained a normal gait pattern. Riding a stationary bike can be started when the patient has at least 100 degrees of flexion. Closed chain strengthening exercises using a leg press machine, elliptical cross-trainer, StairMaster, and step-ups are started around 4 to 6 weeks after surgery. During the first 3 months after surgery, the hamstring donor site must be protected by avoiding sudden hamstring stretching with the hip and knee in extension. This position is commonly encountered during activities of daily living such as bending down to tie shoes or put on socks or reaching down to pick an object off the floor. We also recommend that isolated hamstring resistive exercises performed in the prone position be avoided for the first 2 to 3 months. Isolated hamstring strengthening exercises using a seated leg curl machine can usually be started after 6 to 8 weeks if tenderness is not present or is minimal at the hamstring donor site. We allow jogging and running at 3 to 4 months, side-to-side cutting at 4 to 5 months, a return to noncontact sports at 5 to 6 months, and a return to unrestricted sports at 6 to 7 months. In revision cases, we recommend that a return to unrestricted sports be delayed until 9 months.

RESULTS

We report the preliminary results of the first 84 patients operated on by Dr. Joseph H. Sklar using a DGST graft with Endobutton-CL femoral fixation and tibial fixation with the IntraFix tibial fastener. The mean age of the patients was 30 years (range 16–54 years). Of the patients, 46 were male and 38 were female. The mean diameter of the DGST graft for all patients was 8.3 mm (range 7–9.5 mm) and 7.9 mm for females. The mean KT-1000 side-to-side difference for all patients at the 12-month follow-up was 1.8 mm, with 83% having a side-to-side difference of 0 to 3 mm; 13%, 3 to 5 mm; and 4%, greater than 5 mm. At the 24-month follow-up, the mean KT-1000 side-to-side difference was 1.78 mm, with 85% having a side-to-side difference of 0 to 3 mm; 11%, 3 to 5 mm; and 4%, greater than 5 mm. For female patients, the mean KT-1000 side-to-side difference was 2.3 mm, with 80% having a side-to-side difference of 0 to 3 mm; 20%, 3 to 5 mm; and no patient had a difference greater than 5 mm. Supplemental tibial fixation was used in 17% of the male patients and 42% of the female patients. There were no postoperative infections in the group, and no patient had a loss of extension. Flexion averaged 138 degrees at 24 months. Two patients required an early manipulation under anesthesia to regain flexion. No patient has required a second operation to remove prominent hardware.

CONCLUSION

In summary, the IntraFix and Bio-IntraFix devices provide strong rigid tibial fixation that is superior to the fixation properties of interference screws and most external fixation methods. The device grips each of the graft strands in its own separate compartment and increases the amount of graft in direct contact with the cancellous bone of tunnel, potentially increasing the amount of bone–tendon healing. Successful use of the device depends on proper tunnel preparation and sizing and the concentric insertion of the device parallel to the axis of the tunnel. In cases in which doubt exists about the hardness of the bone, the IntraFix and Bio-IntraFix can be used in combination with cortical backup fixation.

References

Anterior Cruciate Ligament Reconstruction


**Suggested Readings**


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