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Biomechanics of Intratunnel Anterior Cruciate Ligament Graft Fixation

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In 1983 Lambert [1] first introduced the technique of intratunnel anterior cruciate ligament (ACL) graft fixation by securing a vascularized bone-patellar tendon-bone ACL graft with 6.5-mm AO cancellous screws. Kurosaka and colleagues [2] demonstrated that fixation of a 10-mm bone-patellar tendon-bone ACL graft in human cadaveric knees with a custom-designed headless 9.0-mm fully threaded interference screw had better strength and stiffness than fixation with a 6.5-mm AO cancellous screw, staple fixation, or tying sutures over a button. Because of the many biomechanical studies demonstrating superior initial fixation properties and clinical outcomes studies demonstrating a high rate of success, interference screw fixation of bone-patellar tendon-bone grafts now is considered the standard against which all ACL graft-fixation techniques are compared [3,4]. Based on the success of interference screw fixation of bone-patellar tendon-bone ACL grafts, Pinczewski [5] in 1996 introduced the use of blunt, threaded metal interference screws to fix four-strand hamstring tendon ACL grafts, and in 1997 Fu [6] described quadrupled hamstring tendon grafts (QHTGs) for ACL reconstruction secured with a bioabsorbable interference screw.

Rigid initial graft fixation minimizes elongation and prevents failure at the graft-attachment sites, maintaining knee ligament stability during cyclical loading of the knee before biologic fixation of the ACL graft. The advantages of early joint motion, early weight bearing, and closed-chain exercises following ACL

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reconstruction have been well documented. These activities place greater demands on initial ACL graft fixation. One of the still unanswered questions regarding ACL graft fixation is, "How strong and stiff do the initial graft-fixation methods need to be to allow use of an accelerated ACL rehabilitation program?"

In the late 1960s Morrison [7,8], using force plate and gait analysis, estimated that the forces experienced by the ACL during activities of daily living ranged from 27 newtons (N) to 445 N. Noyes and colleagues [9] estimated that the ACL is loaded to approximately 454 N during activities of daily living. In vitro mechanical studies have demonstrated that the initial strength and stiffness of bone-patellar tendon-bone grafts and QHTGs far exceed the estimated loads on the ACL [9–11]. The forces placed on the ACL with rehabilitation exercises performed in the early postoperative period or during activities of daily living are unknown. The initial tensile properties of all current ACL graft-fixation methods are inferior to those of the ACL grafts themselves [12]. Therefore, the mechanical fixation of the ACL graft in the bone tunnels is the weak link in the early postoperative period.

This article discusses some of the limitations of in vitro biomechanical studies and reviews variables that influence the tensile properties of intratunnel fixation methods for bone-tendon-bone and soft tissue grafts.

LIMITATIONS OF BIOMECHANICAL STUDIES

Although in vitro biomechanical studies most commonly are used to evaluate initial ACL graft-fixation properties [13,14], these investigations have inherent limitations. First, the differing research models and biomechanical testing protocols make it difficult to compare the results of one study with those of another. Ideally, young human specimens are used for biomechanical testing; but the material properties of cortical and cancellous bone and of tendons and ligaments can vary greatly from specimen to specimen. Because of the lack of availability of human cadaveric specimens in the age range of patients typically undergoing ACL reconstruction, specimens from older donors often are used, or the same specimen is tested multiple times. Brown and colleagues [15] evaluated the initial fixation strength of bone-patellar tendon-bone grafts fixed with metal interference screws in the distal femur of bovine cadavers, of young human cadavers (mean age, 41 years; range. 33–52 years), and of elderly human cadavers (mean age, 73 years; range, 68–81 years). There was no significant difference in the failure load of the bovine (799 $\pm$ 261 N) and young human specimens (655 $\pm$ 186 N); however, the failure load of the elderly human specimens (382 $\pm$ 118 N) was significantly lower than that of the young human and bovine specimens. The authors concluded that elderly human cadavers are not appropriate models for ACL reconstruction fixation studies. Beynnon and Amis [13] have suggested testing male specimens below 65 years of age and female specimens below 50 years of age to minimize this problem. Performing multiple tests in the same specimen introduces carry-over effects that may affect the fixation properties of subsequent techniques tested after the first fixation method has been tested.

Animal models have the advantages of eliminating the potential variability introduced because of the large differences in bone mineral density (BMD) that exists in human specimens, and their availability eliminates the need to perform multiple tests using the same specimen. Because human and animal specimens differ in BMD and in the tensile properties of bone, the results of biomechanical tests performed using animal models cannot be compared directly with studies performed using human specimens. Aerssens and colleagues [16] have shown that human female femoral specimens (age range, 30–60 years) demonstrate lower BMD and failure stress than specimens from dogs, pigs, cows, or sheep. In this study the pig femur came closest to matching the BMD and failure stress of the human femur. Nagarkatti and colleagues [17] found significantly greater load to failure with both central quadriceps tendon and QHTG in porcine tibia tunnels (mean BMD, 1.42 g/cm^2) than in cadavers (mean age, 71 years; mean BMD, 0.30 g/cm^2) with an 8-mm bioabsorbable interference screw in a single load-to-failure test. Nurmi and colleagues [18] found a significant difference in bone mineral density of porcine tibias (210 $\pm$ 45 mg/cm^3) compared with those from young women (129 $\pm$ 30 mg/cm^3) and young men (134 $\pm$ 34 mg/cm^3). Because of the higher BMD and tensile properties of animal specimens, biomechanical tests performed in animal models tend to overestimate initial fixation properties (Table 1) [19–21]. This overestimation is particularly true for devices such as interference screws and cross-pins that rely on cancellous bone for fixation strength.

The in vitro biomechanical studies fail to account for the progressive healing of the ACL graft to the bone tunnel walls, which shifts the weak link from the ACL graft fixation–bone tunnel interface to the bone–ligament interface and eventually to the intra-articular part of the ACL graft [22]. Although the healing response does not affect graft-fixation properties in the early postoperative period, bony or soft tissue healing in the bone tunnels alters graft-fixation properties over time. There are few studies documenting the time frame for healing to occur at the ACL graft-fixation sites. Based on the studies of Clancy and colleagues [22] and Walton [23], the bone blocks of bone-tendon-bone grafts seem to heal to the bone tunnel wall by 6 weeks. In a dog model, Rodeo and colleagues [24] demonstrated the formation of Sharpey's fibers connecting the periphery of a soft tissue graft to the bone tunnel wall at 6 weeks. Mechanical fixation was not achieved until 12 weeks, however. In a sheep model with transverse femoral fixation, bone plug fixation was stronger than graft strength at 1 month after implantation, whereas soft tissue tendon incorporation was weaker than the graft until 2 months [25]. Soft tissue grafts take longer than bone-tendon-bone grafts to re-establish mechanical strength at the graft–tunnel interface.

Two types of biomechanical tests are used commonly to evaluate the mechanical behavior of ACL ligament-fixation techniques [13,14]. Single-cycle load-to-failure tests, the most prevalent, attempt to simulate the response of the graft-fixation technique to a sudden mechanical overload event such as a slip or fall. The load–displacement curve can be analyzed to determine the ultimate failure load, yield load, linear stiffness, and displacement at failure.

Table 1
Biomechanical studies with similar methodology that tested bone-patella tendon-bone grafts in a bone tunnel fixed with an interference screw[a]

Construct[b]	Substrate[c]	Failure (N)[d]	Failure Mode[e]
9 × 20-mm metal interference screw, endoscopic on the femur [19]	Bovine	1198 (93)	Bone plug site: failure of interference screw fit fixation or ligament avulsion
7 × 20-mm metal interference screw, endoscopic on the femur [19]	Bovine	1161 (93)	Bone plug site: failure of interference screw fit fixation or ligament avulsion
7 × 25-mm bioabsorbable interference screw, endoscopic [20]	Bovine	1151 (472)	Bone-screw interface, interligamentous failures[f]
7 × 25-mm bioabsorbable interference screw, outside-in [20]	Bovine	1017 (409)	Bone-screw interface, interligamentous failures
7 × 20-mm metal interference screw, outside-in [21]	Bovine	768.4 (163.3)	Attachment site failure or midsubstance ligament failure
9 × 20-mm metal interference screw, outside-in [21]	Bovine	728.2 (252.6)	Attachment site failure or midsubstance ligament failure
7 × 20-mm metal interference screw, endoscopic in either 0 or 10° of divergence [38]	Porcine	607 (46)	Not reported
7 × 25-mm metal interference screw, endoscopic [3]	Human (mean age, 69.5 years)	588 (282)	Bone plug fractured, femoral screw pullout, bone tendon rupture
9 × 20-mm bioabsorbable interference screw, outside-in [46]	Bovine	564.5 (272.3)	Bone plug pullout on the tibial side
9 × 25-mm metal interference screw [3]	Human (mean age, 69.5 years)	423 (175)	Pullout around the femoral or tibial screw
Interference screw, endoscopic [30]	Human (mean age, 79 years)	256 (130)	Bone block pullout, bone block fracture
Interference screw, outside-in [30]	Human (mean age, 79 years)	235 (124)	Bone block pullout, bone block fracture

[a]This table demonstrates that the maximum failure loads of bovine and porcine specimens exceed those of many human specimens.
[b]Construct describes the type of interference screw and the manner of insertion.
[c]Substrate is the type of bone that was used in the investigation.
[d]Failure is the maximum load at failure in Newtons (N).
[e]Failure mode describes the type of failure observed at the maximum failure load. The studies are listed in order of descending maximum load at failure.
[f]Interligamentous or midsubstance failures of the graft are rare in human studies because the maximum load at failure of the graft-fixation construct is below that of the ligament.

Single load-to-failure testing identifies the weak link in the fixation system. The mode and site of the fixation failure is well defined, and an upper limit of the strength of the graft-fixation construct is established. Because failure testing attempts to replicate traumatic loading conditions, a high rate of elongation (typically 100%/s) is used.

The second testing method is cyclic loading of the bone–ACL graft-fixation complex that evaluates the resistance to elongation or slippage under repetitive submaximal failure loads over time. Cyclic testing attempts to approximate the loading conditions associated with rehabilitation exercises or activities of daily living in the early postoperative period before biologic fixation of the graft. A load-control test often is performed with the upper and lower loads controlled, and the displacement of the ACL graft relative to the bone is measured. The difference in the distance between markers on the bone and ACL graft at the beginning and the end of the test represents the elongation or slippage of the ACL graft with respect to the bone. Unfortunately, there is little agreement on the force limits or the number of cycles that should be performed, making it difficult to compare data from one study to another. Beynnon and Amis [13] have recommended force limits between 150 N and −150 N and 1000 load cycles. One thousand cycles approximates 1 week of flexion-extension loading of the knee [14]. The number of cycles is limited by technical issues, such as keeping the specimen moist during testing and the thawing of the freeze clamps that grip soft tissue ACL grafts.

Despite these limitations, in vitro biomechanical laboratory testing can provide useful information on the performance of ACL ligament-fixation techniques. In summary, single load-to-failure testing evaluates the initial strength and stiffness of the bone–ACL graft-fixation complex, and cyclic testing provides information on slippage and progressive elongation at the graft fixation sites that occur as a result of rehabilitation exercises or activities of daily living in the early postoperative period before biologic healing has occurred.

BONE MINERAL DENSITY

Because intratunnel fixation methods depend on the graft-fixation device generating friction between the bone tunnel wall and the ACL replacement graft, BMD is an important variable influencing initial fixation strength and stiffness and resistance to slippage during cyclic loading. In humans BMD decreases with age, and the BMD of females is less than that of males. Cassim and colleagues [26] found that the fixation strength of bone-patellar tendon-bone grafts fixed with metal interference screws in human specimens with a mean age of 79 years resulted in a 42% decrease in failure load compared with specimens with a mean age of 35 years. The BMD of the proximal tibia is significantly lower than that of the distal femur [27]. Tibial fixation devices must resist shear forces applied parallel to the axis of the tibial bone tunnel that has a lower BMD. For these reasons, tibial fixation is the weak link in ACL graft fixation.

Although BMD is a critical factor, there are other variables that correlate with initial fixation properties. In a bone-patella tendon-bone model, Brown and colleagues [15] found that insertion torque, an indirect measure of BMD, was correlated linearly with pull-out force but with weak significance. Using elderly human cadaveric knees, Brand and colleagues [27] found that BMD measured using dual-energy X-ray absorptiometry and screw insertion torque explained 77% of the ultimate failure load observed in QHTG fixed with bioabsorbable interference screws in the distal femur and proximal tibia of human specimens. The R^2 value for the relationship between ultimate failure load and BMD was 0.65, indicating that BMD explained 65% of the ultimate failure load. This study found that a BMD of 0.6 g/cm^2 or higher resulted in better initial fixation properties. Using the proximal tibia of human cadaveric specimens (mean age, 40 ± 11 years; range, 17–54 years) and doubled tibialis tendons fixed with a tapered bioabsorbable screw, Jarvinen and colleagues [28] found that insertion torque was linearly correlated to fixation strength (R^2 = 0.54) and in their study was the variable most strongly predictive of fixation strength. Unfortunately, despite the correlation, insertion torque was a poor predictor of cyclic loading failure or single load-to-failure. The remainder of this article is aimed toward explicating the role and importance of secondary factors that influence the biomechanical properties of intratunnel graft fixation.

BONE-PATELLA TENDON-BONE FIXATION

The fixation properties of interference screw fixation of bone-tendon-bone grafts depend on the generation of friction generated by compression of the bone block into the bone tunnel wall and engagement of the interference screw threads. As illustrated in Fig. 1, factors that influence the initial tensile properties of interference screw fixation of bone-tendon-bone ACL grafts include

1. Screw diameter
2. Gap size
3. Screw length
4. Screw divergence

There is overlap between the effects of screw diameter and gap size on initial fixation properties. Kohn and Rose [29], using human cadaveric knees (mean age, 30 years), reported that tibial fixation using 9-mm screws was significantly stronger than tibial fixation using 7-mm screws. Based on their findings, they recommended against the using 7-mm screws for tibial fixation. With elderly human cadaveric specimens, two groups found no significant difference in the fixation strength of bone-patellar tendon-bone grafts fixed in the distal femur using retrograde or endoscopically inserted 7-mm screws and 9-mm screws inserted using a rear-entry or an antegrade technique [15,30]. The influence of screw diameter on initial fixation properties is probably most relevant when there is a significant size discrepancy between the bone block and the bone tunnel wall; this difference often is referred to as "gap size."

After studying various fixation methods, Kurosaka and colleagues [2] hypothesized that the gap size between the bone block and bone tunnel was a critical factor in interference screw fixation. Butler and colleagues [31], in

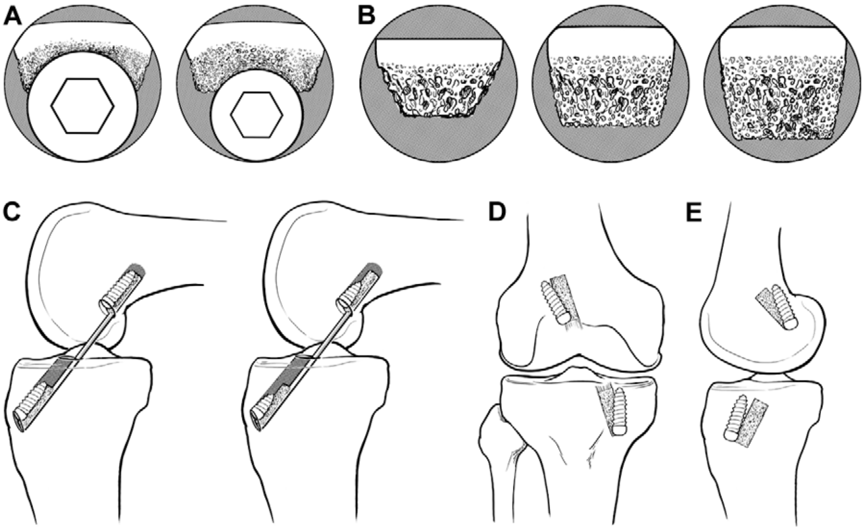

Fig. 1. Factors that influence the initial tensile properties of interference screw fixation of bone-tendon-bone ACL grafts. (*A*) Screw diameter: effect of a larger screw on bone plug. (*B*) Gap size: increase in gap size decreases strength of construct. (*C*) Screw length: lateral view of graft with longer (*left panel*) and shorter (*right panel*) interference screws. In bone-tendon-bone grafts screw length does not affect screw pullout significantly. (*D*) Screw divergence: anteroposterior view of the knee showing screw divergence from the tunnel. (*E*) Screw divergence, lateral view.

a porcine study, found that, with a gap size of 3 to 4 mm, increasing the screw diameter size from 7 mm to 9 mm significantly increased the load at which failure occurred. With a similar porcine experimental model, Reznik and colleagues [32] demonstrated that gap size significantly influenced the ultimate failure load of bone-tendon-bone grafts fixed in 10-mm bone tunnels with 7-mm screws. When the gap between the bone block and bone tunnel wall was 4 mm or more, increasing the screw diameter to 9 mm increased the failure load by 97%. When the gap was larger than 4 mm and a 9-mm screw was used, however, the results were inferior to using a 7-mm screw with a gap of less than 4 mm. It was demonstrated in an elderly human model that a cylindrical bone plug improves fixation by 19.9% (845. 8 N versus 691.7 N) compared with a bone plug with a trapezoidal cross section. Although gap size was not measured, it will be smaller with a cylindrical bone plug than with a trapezoidal bone plug [33]. In what may be the best investigation of the topic using human and bovine tissue, the authors found that, although screw diameter or gap size alone was not significant, interference (defined as the screw's outer thread diameter minus the tunnel–bone block gap) was significantly related to load at failure in the pooled specimens and in the bovine model [15]. A number of authors have suggested using larger screws as the gap size increases [34].

Screw length probably does not have a large influence on the initial fixation properties of bone-patella tendon-bone grafts fixed with interference screws. Brown and colleagues [30] found no significant difference in fixation strength between 7 × 20-mm and 7 × 30-mm screws or between 9 × 20-mm and 9 × 30-mm screws fixed in the distal femur of human specimens. Black and colleagues [35] compared 9 × 12.5-mm, 9 × 15-mm, and 9 × 20-mm interference screws in a porcine tibia model. No significant differences in insertion torque, failure load, stiffness, or displacement to failure was found among the different-length screws. Pomeroy and colleagues [36] also found no significant effect of screw length on fixation strength for a given screw diameter. Fixation strength is not improved by using an interference screw longer than the bone plug.

Divergence of the interference screw from the bone block and the axis of the bone tunnel can occur with both rear-entry and endoscopic techniques. The incidence of screw divergence is more common with the endoscopic technique (femur > tibia) [37]. Using a porcine model, Jomha and colleagues [38] reported no significant difference in femoral fixation strength with endoscopically inserted interference screws with divergence up to 10°, but there was a significant decrease with screw divergence of 20° or greater. Pierz and colleagues [39], using porcine tibias, demonstrated that interference screws inserted to simulate a rear-entry femoral fixation technique or fixation of a tibial bone block resulted in a significant decrease in fixation strength with divergence between 0° and 15° compared with 15° to 30° of divergence. Interference screws inserted to simulate an endoscopic technique resulted in a significant decrease in fixation strength only at 30° of screw divergence. These authors concluded that optimal interference screw fixation occurs when the screw is placed parallel to the bone block and bone tunnel. Because of the creation of a wedge effect, screw divergence has less effect on endoscopically inserted femoral screws. Based on clinical studies, screw divergence of less than 30° does not seem to have a significant effect on the clinical outcome [40]. Because of the in-line direction of pull, however, minor degrees of divergence have a greater effect on the fixation strength of femoral screws inserted through a rear-entry technique and tibial fixation screws.

Metal interference screws can distort MRI images, lacerate the graft during insertion, and complicate revision ACL surgery. Bioabsorbable interference screws have been proposed as a method to eliminate potential complications [41]. Several biomechanical studies have compared the initial fixation strength of bioabsorbable interference screws and conventional metal interference screws in animal and human cadaveric models. These studies showed that most bioabsorbable interference screws provide fixation strength similar to that of metal interference screws and concluded that the use of these screws may allow an accelerated postoperative rehabilitation program [42–48].

Concerns with bioabsorbable interference screws have focused largely on the issues of screw breakage and biocompatibility. Screw breakage has been addressed largely by designing screws and screwdrivers that allow the insertion torque to be distributed along the entire length of the screw and by decreasing the insertion torque by notching the bone tunnel wall. To prevent screw breakage, it is important that the screwdriver be engaged fully during insertion of the screw.

In summary, based on a review of the literature, gap size is probably the most important factor influencing the initial fixation properties of interference screw fixation of bone-tendon-bone grafts. Gap size also is the one factor that can be measured easily intraoperatively and controlled by the surgeon. Improvements in initial graft fixation can be achieved by increasing the diameter of the screw to compensate for the gap size. Increasing screw length seems to offer minimal improvements in initial graft fixation properties.

Guidelines and Recommendations for Intratunnel Fixation of Bone-Tendon-Bone Grafts

Femoral fixation: two-incision technique

The authors recommend using metal screws 7 and 8 mm in diameter with a length of 20 to 25 mm. Bioabsorbable screws can be used, but the higher insertion torque generated by the insertion of the screw against the hard cortex of distal femur may result in a higher incidence of screw breakage compared with bioabsorbable screws inserted using an endoscopic technique. When the gap between the bone block and bone tunnel wall is greater than 4 mm, suture/post or plastic button fixation should be considered in addition to intratunnel fixation.

Femoral fixation: endoscopic technique

The authors recommend using metal or bioabsorbable screws 8 or 9 mm in diameter, with a length of 20 to 25 mm. For bioabsorbable screws, one should review and use the manufacturer's guidelines regarding tapping or notching the bone tunnel wall to minimize the risk of screw breakage. The authors prefer using the EndoButton CL (Closed Loop; Smith and Nephew, Andover, Massachusetts) to avoid graft–tunnel mismatch in long grafts when the gap size is greater than 4 mm and when blowout of the posterior wall of the femoral tunnel occurs.

Tibial fixation

The authors recommend using screws 8 or 9 mm in diameter with a length of 20 to 25 mm. For gap sizes greater than 4 mm, one should consider suture/post or button as hybrid fixation. In soft bone or when low insertion torque is encountered, one should consider backing up the interference screw fixation by tying sutures around a fixation post.

SOFT TISSUE GRAFTS

Interference screw fixation of soft tissue grafts depends on many of the same factors as fixation for bone-patella tendon-bone grafts; but the relative importance of each of these factors differs [49]. As in bone-tendon-bone grafts, the initial fixation properties depend on the fixation device generating friction between the soft tissue graft and the bone tunnel wall. Friction is generated by compression of the soft tissue graft against the bone tunnel wall. Because the soft tissue graft is more compressible than the bone blocks of bone-tendon-bone grafts, a screw of a given diameter generates compression between the screw and bone tunnel wall. The amount of friction contributed by engagement of the screw threads in the bone tunnel wall and soft tissue graft also is significantly lower because of the lack of engagement of the screw threads into the soft tissue graft. As illustrated in Fig. 2, factors that may contribute to the initial fixation properties of soft tissue grafts with interference screws are

1. Screw geometry (length and diameter)
2. Tendon fit
3. Tunnel impaction or dilation
4. Screw placement (concentric versus eccentric)

Unlike interference screw fixation of bone-tendon-bone grafts, screw length seems to have a greater effect on the initial fixation properties of soft tissue grafts fixed with interference screws. Because of the lower BMD of the proximal tibia, screw length has a greater influence on tibial fixation properties [27]. Screw length may have a more significant effect on the fixation properties of soft tissue grafts because the area over which friction is generated between

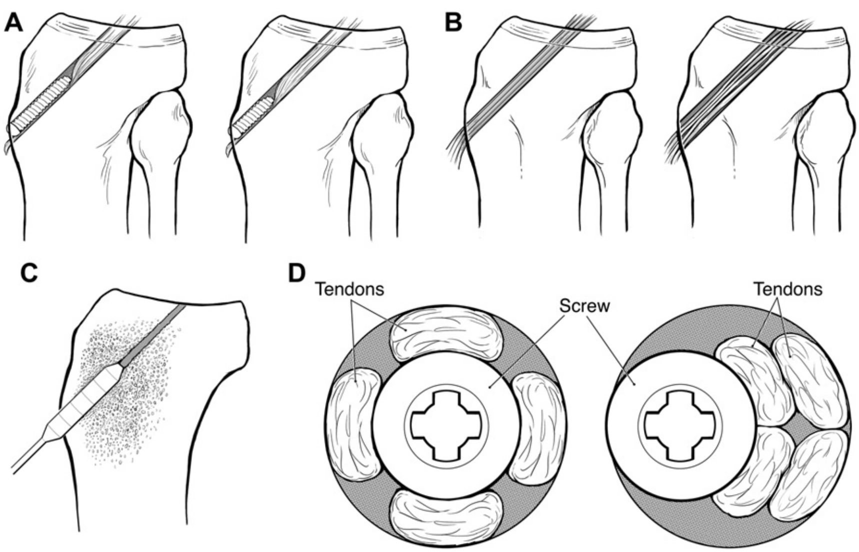

Fig. 2. Factors that contribute to the initial fixation properties of soft tissue grafts with interference screws. (*A*) Screw geometry (length and diameter): length and diameter of screw can affect construct strength. (*B*) Tendon fit: more precise fit to 0.5 mm allows improved strength with screw insertion. (*C*) Tunnel impaction or dilation: impaction drilling or serial dilation does not seem to significantly improve graft mechanics. (*D*) Screw placement (concentric versus eccentric): concentric or eccentric screw placement does not affect construct strength.

the bone tunnel wall and soft tissue graft is determined by the screw length, rather than by the length of a bone block, which is typically 20 to 25 mm. In a bovine proximal tibia model, Weiler and colleagues [50] found that 23-mm screws had lower pull-out strengths than 28-mm screws with equivalent diameters. This study also found that increasing screw length had a greater influence on failure load than increasing the screw diameter. Using human tibias (age range, 24–45 years), Selby and colleagues [51] demonstrated significantly higher ultimate failure loads for screws 35 mm long than for screws 28 mm long. Placing the screw so that it engaged the cortex of the tibia allowed significantly less slippage than screw insertion that engaged only cancellous bone [52]. Based on their findings, the authors recommend that the screw head be placed to engage the tibial cortex.

Few studies have examined the influence of screw diameter on the initial fixation properties of soft tissue ACL grafts fixed with interference screws. Using human hamstring tendons grafts and bovine proximal tibias, Weiler and colleagues [50] found that increasing the diameter of a 23-mm length bioabsorbable interference screw from 7 mm to 8 mm increased the mean pull-out force from 367 N to 479 N.

The fit of the soft tissue graft in the bone tunnel seems to have a significant influence on the initial fixation properties of interference screw fixation of soft tissue grafts. Using a human cadaveric model, Steenlage and colleagues [53] demonstrated that QHTGs fixed in the distal femur with a bioabsorbable screw had a significantly higher ultimate failure load if the bone tunnel was sized within 0.5 mm of the graft diameter rather than within 1 mm of the graft diameter.

Because BMD has such a significant effect on the initial tensile properties of interference screw fixation of soft tissue grafts, compaction drilling or bone tunnel dilation has been proposed as a method of creating increased bone density along the bone tunnel walls. It has been speculated that this approach will improve initial fixation properties. Using human male cadaveric knees, Rittmeister and colleagues [54] found that serial dilation failed to improve the initial fixation strength of QHTGs fixed in the tibia with metal interferences screws. Nurmi and colleagues [55] investigated the effects of compaction drilling versus conventional or extraction drilling on the initial fixation strength of QHTGs fixed with bioabsorbable screws in the proximal tibia of human specimens (mean age, 41 $\pm$ 11 years; range, 17–49 years). The biomechanical testing protocol consisted of cyclic loading followed by a single load-to-failure test. They found no significant difference in initial stiffness or displacement between the two drilling methods during cyclic testing or in the single load-to-failure test and detected no significant differences between the two drilling methods in yield load, displacement at yield load, or stiffness.

In a second biomechanical study, Nurmi and colleagues [56] investigated the effect of tunnel compaction by serial dilators compared with conventional drilling on the initial fixation strength of doubled anterior tibial tendons fixed in the proximal tibia of human specimens (mean age, 40 $\pm$ 11 years; range, 17–54 years) using bioabsorbable interference screws. The specimens were tested under cyclic loading followed by a single load-to-failure test. Although no significant difference in stiffness or displacement between the two techniques was demonstrated during cyclic testing, the number of failures during cyclic loading of the extraction drilling group was twice that of the serially dilated group. In the subsequent single load-to-failure test, there was no significant difference in failure load or stiffness between the two groups. A limitation of this study was the size of the tibial bone tunnel was not matched to the size of the soft tissue grafts: a bone tunnel 10 mm in diameter was created in all specimens.

The only study to demonstrate a beneficial effect of tunnel dilation on the fixation strength of soft tissue ACL grafts was performed by Cain and colleagues [57] using paired human cadaveric knees (average age, 42 years; range, 29–47 years). QHTGs were fixed with bioabsorbable screws in 0.5-mm size-matched femoral and tibial tunnels. The tibial tunnel was created using smooth tunnel dilators in one knee of the pair, and extraction drilling was used in the opposite knee of the pair. The femur-hamstring ACL graft-tibia complex was tested to failure using anterior tibial translation with the knee positioned in 20° of flexion, as previously described by Steiner and colleagues [3]. This method of testing attempts to mimic the Lachman test. All specimens failed by the graft pulling out of the tibial tunnel, but the ultimate failure load was significantly higher for the dilated tibial tunnels. Testing methodology makes it difficult to compare the results of this study with earlier studies; however, based on the literature, the benefits of compaction drilling or serial dilation probably do not justify the extra cost and operating time.

Although there is general agreement that interference screws should be inserted on the cancellous side of bone-tendon-bone grafts, controversy exists regarding placement of tibial interference screws used to fix multiple-stranded hamstring tendon grafts. Soft tissue grafts may be fixed by inserting the screw on the side (eccentrically) or down the center (concentrically) of the graft strands. Concentric screw placement maximizes contact between the graft strands and the bone tunnel wall, providing a greater surface area for healing. Simonian and colleagues [58] were unable to detect a significant difference in initial fixation properties between eccentric versus concentric interference screw position against a model of human hamstring tendon grafts fixed in a polyurethane foam. Shino and Pflaster [59] investigated the effect of eccentric versus concentric screw placement on the initial fixation properties of QHTGs fixed in the proximal tibia of paired human cadaveric knees (average age, 51 years; range, 49–54 years). There were no significant differences in stiffness, yield load, ultimate failure load, or slippage between the two screw positions.

As with bone-patellar tendon-bone grafts, QHTGs in elderly human bone tunnels, bioabsorbable interference screws provide initial biomechanical fixation properties similar to those of a metal interference screw [60]. In the laboratory, two separate investigations have noted an association between a metal interference screw applied against a soft tissue graft and graft laceration or damage. Brand and colleagues [60], using human QHTG in elderly cadaver bone, noted a greater rate of graft laceration in the group in which a metal screw was used than in the group in which a bioabsorbable screw of comparable dimensions was used. Another group compared the effect of a single insertion of a metal screw versus the use two separate bioabsorbable screws, a poly-D,L-lactide and a poly-D,L-lactide with tricalcium phosphate. After the screws had been inserted, the soft tissue grafts were tested to failure. The metal screw damaged the tendon more extensively, resulting in a significantly smaller load at failure and stiffness than seen in the tendons damaged by bioabsorbable screws [61].

Guidelines and Recommendations for Intratunnel Fixation of Soft Tissue Grafts

Unlike bone-tendon-bone grafts, in which the bone tunnel size and dimensions of the bone blocks are standardized, there are large variations in the diameter and length of soft tissue grafts. These variations make it difficult to arrive at definitive recommendations regarding selection of interference screw fixation. Nevertheless, the authors' interpretation of the literature has led to the following conclusions:

1. Because of the lower BMD, and because the line of applied force is parallel to the axis of the tibial tunnel, tibial fixation is weaker, less stiff, and more likely to slip under cyclic loading than fixation using the femoral fixation site.
2. Screw length has a more significant effect on the initial fixation properties of interference screw fixation of soft tissue ACL grafts than of bone-tendon-bone ACL grafts.
3. In biomechanical testing longer screws result in higher ultimate failure loads and stiffness and less slippage.
4. Fixation properties are improved by having the screw head engage the tibial cortex.
5. The effect of screw diameter on initial fixation properties is unclear, making it difficult to establish clear guidelines for screw sizing.
6. Matching the size of the bone tunnel to within 0.5 mm of the measured size of the graft may improve initial fixation properties.
7. Compaction drilling or serial dilation does not seem to improve initial fixation properties significantly.

ALTERNATIVE INTRATUNNEL TIBIAL FIXATION TECHNIQUES

The stimulus for the development of alternative intratunnel tibial fixation techniques for soft tissue ACL grafts arose from the desire to decrease slippage and the high rate of fixation failure reported with interference screws under cyclic loading conditions; to eliminate or reduce the need for supplemental tibial fixation; and to improve soft tissue-to-bone healing at the graft-fixation sites [49,52,62]. The IntraFix (DePuy Mitek, Norwood, Massachusetts) was designed to capture individually each of the four strands of a soft tissue graft in a separate compartment using a plastic sheath and to achieve direct compression of each of the graft strands against the bone tunnel wall by the insertion of a tapered screw into the central chamber of the plastic sheath [62]. In a porcine tibia model using human hamstring tendon grafts, Kousa and colleagues [63] demonstrated that the IntraFix had the highest load failure load (1309 ± 302 N) and stiffness (267 ± 36 N/mm) and the least amount of slippage (1.5 mm) after cyclic loading when compared with two cortical fixation techniques and three other interference screw fixation techniques. When used to fix a QHTG in a human tibial tunnel, the IntraFix device had a load at failure (796 ± 193 N versus 647 ± 269 N) and stiffness (49 ± 21.9 N/mm versus 64.5 ± 22 N/mm) similar to that of a bioabsorbable interference screw 35 mm in length [64].

The GTS System (Graft Tunnel Solution; Smith & Nephew Endoscopy, Andover, Massachusetts) is a intratunnel tibial fixation technique that positions a poly-L-lactic, tapered, fine-pitch screw concentrically within the four-strand soft tissue graft [65]. The screw features a tapered design and shorter thread distance, which enhances compression of the soft tissue graft in cancellous bone. The graft sleeve is a three-lumen, woven, nonabsorbable polypropylene mesh graft sleeve that organizes the four-strand soft tissue graft in the tibial tunnel. The graft sleeve prevents graft twisting during screw insertion, which helps maintain equal tension in the four graft strands, maximizes bone–tendon contact that enhances healing, and provides better compression of each ligament strand against the bone tunnel wall while protecting the graft strands from screw damage. Cyclic testing followed by single load-to-failure testing of the graft sleeve, tapered screw, and IntraFix has been performed using human doubled gracilis and semitendinosus tendon grafts in the proximal tibia of calf bone (2 years or younger) with BMD similar to that of the proximal tibia in young humans. There was no significant difference in slippage, ultimate failure load, or stiffness between the two devices.

HYBRID FIXATION

Although intratunnel fixation of soft tissue grafts has improved with longer tibial screws and precise sizing of grafts to tunnel diameters, concerns persist that initial fixation strength that is less than the strength of the native ACL bone construct allows graft-tunnel motion that may contribute to knee laxity. In particular, older women and other patients who have lower BMC are candidates for hybrid fixation that combines improved structural properties with the biomechanical and biologic advantages of joint-line interference-fit fixation to augment intratunnel devices [66]. The EndoPearl (Linvatec, Largo, Forida) linked with #5 Ethibond sutures (Ethicon, Somerville, New Jersey) against the tip of a bioabsorbable interference screw significantly improved femoral fixation when compared with a bioabsorbable interference screw in a femoral tunnel of a calf model as measured by maximum load-to-failure (658.9 ± 118.1 N versus 385.9 ± 185.6 N) and stiffness (41.7 ± 11 N/mm versus 25.7 ± 8.5 N/mm) [67]. Hammond and colleagues [66] evaluated femoral fixation of quadrupled flexor tendons in porcine bone using a bioabsorbable screw, EndoButton

CL, and hybrid fixation using an EndoButton CL and bioabsorbable screw. The hybrid fixation group demonstrated greater yield and ultimate failure loads and greater stiffness under displacement-controlled cyclic loads. In a similar study, Oh and colleagues [68] demonstrated that the addition of an interference screw to suspensory fixation using an EndoButton CL increased ultimate failure load and stiffness and decreased slippage. Although hybrid fixation has improved initial graft-fixation tensile properties in biomechanical studies, there have been no clinical studies demonstrating that it results in improved clinical results.

CLINICAL STUDIES

Ma and colleagues [69] compared fixation techniques with patients reconstructed with QHTG in a prospective, nonrandomized study. Fifteen patients in each group were fixed with either a bioabsorbable interference screw in the femoral or tibial bone tunnel or femoral fixation with an EndoButton and tibial fixation with a screw post. There were no significant differences in International Knee Documentation Committee (IKDC) knee scores (85 $\pm$ 11 versus 81 $\pm$ 17) or side-to-side KT differences (3.2 $\pm$ 2.6 mm versus 2.4 $\pm$ 1.8 mm). There was more tunnel widening (as measured in the femoral tunnel in the sagittal plane) in the group of patients in which the bioabsorbable screw was used than in the group of patients fixed with extracortical fixation. All other measurements of tunnel width were not significantly different between groups [69]. A prospective, nonrandomized clinical trial of patients who had QHTGs and bone-patellar tendon-bone grafts fixed with metal interference screws with a 5-year follow-up found only that the bone-patellar tendon-bone group had a greater rate of arthritis. There were no significant differences in KT 2000 maximum manual testing, the percentage of patients who had a normal Lachman's test, the number of patients who had an A or B IKDC knee score, or the return to level I or II activities (Table 2) [70]. The same group of patients was followed up again at a mean of 7 years postoperatively. There was a greater rate of arthritis on radiographic review by the IKDC criteria in the bone-patellar tendon-bone group (45%) than in the QHTG group (14%). The number of patients in the bone-patellar tendon-bone group with loss of extension increased significantly between the 5-year and 7-year follow-ups, but there was not a significant difference between the bone-patellar tendon-bone and QHTG groups in the number of patients who had extension loss (see Table 2) [71]. A prospective, randomized investigation from Slovenia compared 64 patients randomly assigned to receive bone-patellar tendon-bone grafts or QHTGs. Interference fixation was provided with a metal screw in the femoral socket and a bioabsorbable screw of similar dimensions in the tibial tunnel. These investigators also found a greater rate of arthritis in the bone-patellar tendon-bone group: 50% had at least grade B arthritis by the IKDC scoring sheet, compared with 17% in the QHTG group. There were no differences in KT 2000 maximum manual testing, the percentage of patients

Table 2
Clinical studies comparing quadrupled hamstring tendon grafts (QHTG) and bone-patella tendon-bone (BPTB) grafts, each fixed with interference fixation of both the tibial and femoral portions of the graft

Graft	KT 2000[a] < 3 mm	Normal Lachman's Test	IKDC A or B Knee	Graft Rupture[b]	Return to Activities	Comments
QHTG [70]	72	84	89	7/90	60 (Level I or II)	5-year follow-up with metal interference screw
BPTB [70]	82	90	90	3/90	69 (Level I or II)	5-year follow-up with metal interference screw
QHTG [71]	80	82	89	9/61	55 (Level I or II)	7-year follow-up with metal interference screw
BPTB [71]	74	76	85	4/59	52 (Level I or II)	7-year follow-up with metal interference screw
QHTG [72]	85	79	97	1/28	82 (Preinjury level)	5-year follow-up with metal screw in femur and bioabsorbable screw in tibia
BPTB [72]	81	85	97	1/26	88 (Preinjury level)	5-year follow-up with metal screw in femur and bioabsorbable screw in tibia

Abbreviation: IKDC, International Knee Documentation Committee.

[a]KT 2000, Lachman's test, and IKDC results are expressed as a percentage of the total number of patients in that group.

[b]Graft ruptures are the number patients with graft rupture as a numerator and the number of patients in each group as the denominator.

who had a normal Lachman's test, the number of patients who had an A or B IKDC knee score, or return to preinjury activities (see Table 2) [72].

FUTURE DIRECTIONS

The ideal ACL graft-fixation method would provide immediate rigid fixation that is strong enough, stiff enough, and able to resist slippage so that permanent elongation does not develop with the stresses of rehabilitation and activities of daily living. The fixation method should be low profile and should not require later removal because of local irritation and pain. Ideally, the device should be replaced by cancellous bone and result in the development of a normal histologic ligament-to-bone attachment site.

Future improvements in intratunnel ACL graft fixation will depend on better understanding of the in vivo forces experienced by the ACL with rehabilitation exercises and activities in the early postoperative period and of the biology of fixation-site healing. Osteoconductive or osteoinductive materials that will stimulate the development of normal osseous tissue are under development currently. Bone cement that will provide immediate rigid fixation and eventually be replaced by bone may be developed. On-going basic science research is directed at promoting and accelerating healing of soft tissue to bone. Ultrasound, bone morphogenetic proteins, and biologic growth factors currently are being investigated as possible methods to promote and accelerate tendon-to-bone healing.

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