The University of Pennsylvania Orthopaedic Journal
15: 21–27, 2002

Graft Fixation Alternatives in Anterior Cruciate Ligament Reconstruction

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Abstract: Reconstruction of the anterior cruciate ligament is a frequently performed procedure with outstanding results. Results are dependent upon an early postoperative physical therapy program that stresses early motion. Early rehabilitation demands rigid intraoperative mechanical fixation of the graft since therapy begins prior to biologic incorporation of the graft in the bone tunnels. Regardless of the graft substitute chosen, many methods of fixation are available. The "best" fixation technique depends upon several factors including graft choice and surgeon comfort. We review current methods available for graft fixation in anterior cruciate ligament surgery.

Introduction

Anterior cruciate ligament reconstruction has become commonplace in the United States. The popularity of this procedure is based upon its ability to allow an individual to return to his/her preinjury level of activity that would otherwise not be possible. A critical component during reconstruction of a ligamentously unstable knee is an early rehabilitation protocol which stresses immediate full range of motion, strengthening, neuromuscular coordination, and early weightbearing. This protocol demands rigid fixation of the graft substitute in order to withstand the stresses of early rehabilitation.

Noyes has estimated 454 N as the critical graft substitute strength required to endure daily activities, which are recreated during rehabilitation [1]. However, good and excellent clinical results have been reported in reconstructions using fixation techniques shown to provide less strength [2,3]. The native ACL provides 2160 N of strength and 242 N/mm of stiffness [4]. Current graft substitutes provide adequate strength and stiffness at time zero; 2977 N and 455 N/mm for patellar tendon [5], 4140 N and 807 N/mm for quadrupled hamstring tendon [6], and 2353 N and 326 N/mm for quadriceps tendon [7]. Although laboratory studies demonstrate favorable strength and stiffness of these graft substitutes as compared to the native ACL, current graft fixation methods demonstrate inferior strength and stiffness. Therefore the linkage of the graft substitute to the bone, the fixation method, is the weak link in the immediate postoperative period, rather than the graft substitute itself. As initial biologic incorporation of the graft into the tunnel occurs, the rigidity of the construct may vary.

The graft and fixation links must provide rigid mechanical fixation from time zero until biologic incorporation of the graft into the bone tunnels. During this interval, the intraarticular portion of the graft as well as the portion within the bony tunnels undergoes tremendous biological activity and remains susceptible to injury. The knee must be protected while simultaneously achieving advances in range-of-motion, coordination, and strength. It is not clear when the graft becomes fully integrated into the bone tunnels, or even when it is safe to allow return to full activity, however Sharpey's fibers have been identified as early as 6 weeks in histological bone in bone models [8,9]. Therefore, a time interval of unknown duration exists between time zero (when graft fixation is the weakest link) and adequate biologic incorporation of the graft into the tunnel (when the graft substitute tissue becomes the weakest link of the construct). The duration of this period is unknown, but is longer for soft-tissue grafts than for grafts with bone plugs. During this interval, laboratory pullout studies demonstrate avulsion of the graft from the tunnel. However, as biologic incorporation is allowed to proceed, increasing failure strength is demonstrated with increasing time indicating histologic incorporation and a shift of the weak link from the graft-fixation-tunnel interface to the bone/ligament interface, then to the interstitial portion of the graft [10,11]. Current laboratory investigations of fixation strength and stiffness indicate current fixation methods provide inferior strength and stiffness to native ligaments and ligament substitutes, and do not provide abundant room for error above estimated requirements (454 N) with respect to rehabilitation.

During the postoperative period, the maximum loads to the graft substitute construct are provided by rehabilitation. These loads should be less than or equal to the graft fixation strength achieved in the operating room, at time zero. In cases where the surgeon is concerned about poor fixation, the rehabilitation program should be customized to the fixation. For example, in cases of ACL revision, bone mineral density may be poor and the tunnels may be wide (tunnel

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lysis), necessitating less than ideal fixation. These patients must undergo a less aggressive rehabilitation protocol due to inferior fixation.

Fixation methods available today involve securing soft tissue or bone plugs within a bone tunnel via fixation within the tunnel or distally, on the cortex. Many such methods and implants are available to optimize graft fixation. Although laboratory studies demonstrate significant differences between various methods, excellent clinical results may be demonstrated with a wide range of options [2,12–18]. Therefore, the techniques that are employed depend greatly on surgeon ability/knowledge and graft selection.

The ideal fixation technique provides rigid fixation (abundant strength and stiffness) at the anatomic footprint of the native ACL at the articular surface, provides no inflammatory response, facilitates biologic incorporation of the graft into the tunnel, and does not hinder future procedures or investigative techniques. Without a perfect fixation option, an exploration of advantages and disadvantages of available options is warranted.

Biomechanics

An evaluation of biomechanical properties of various fixation methods is hindered by several factors. First, we are only able to measure certain parameters in the lab. Such parameters include ultimate failure load (strength), yield point, stiffness, displacement to failure, and mode of failure. Although there are many studies documenting these properties at time zero, limited information is available regarding how these variables change during the important process of biologic incorporation. Certainly these properties relate to clinical situations, but the strength of this correlation is unknown. The laboratory does not recreate the operating room situation in that the articular surfaces and bone tunnels may be accessed more freely in laboratory specimen than the living knee. Also, the study methods utilized for these biomechanical studies are performed in different institutions with different equipment and different testing protocols, and few single studies compare many fixation methods under similar conditions. For these reasons, comparing fixation techniques across different studies with different study methods is difficult.

Two biomechanical properties are almost uniformly determined in laboratory studies and deserve discussion. Stiffness (N/mm) is the amount of force required to displace the graft a certain distance. It provides an objective evaluation of the amount of slippage (or stretch) that occurs in response to a particular force prior to frank failure of the construct. This property is important because inferior stiffness leads to a large amount of slippage that may allow increased translation; resulting in a clinical failure with a positive Lachman, anterior drawer, and pivot shift, although the graft may remain structurally intact, but non-functional. This has been compared to a chain secured to posts by bungee cords at either end of the chain. As force is applied to the chain, the bungee cords displace under tensile load although the chain does not change in length, and no component actually fails.

Strength (N) is the amount of force a construct can withstand before ultimate failure. Our current graft fixation methods are less stiff and strong than our graft substitutes and the native ACL, again pinpointing a weak link in the system at time zero [4,19,20].

Graft Incorporation

Graft fixation is the weak link of the construct until histologic anchoring of the graft in the bone tunnel. The time required for completion of this process in humans is unclear, however the issue has been studied extensively in animal models as well as some human specimens [8–11,21–23].

Several animal studies have examined incorporation of grafts with a bone plug in a bone tunnel. In sheep, graft bone integrates with surrounding bone at 6 weeks [8]. Clancy demonstrated histologically incorporated bone-patellar tendon-bone grafts in the bone tunnel at 8 weeks in Rhesus monkey. After 3 months, all testing resulted in interstitial failure of the reconstructed grafts [21].

Other studies have investigated healing of a soft-tissue graft in a bone tunnel. In sheep and human specimens, incorporation of the graft involves neochondrification, neoossification, and Sharpey's fibers, which have been identified as early as 6 weeks. Intra-articularly, neovascularization, ligamentization, and junctional ossification occurs. Scranton noted the process appears to be complete at 26 weeks, and recommends protecting the knee of the athlete for at least 4 months. Also, he noted secure fixation with physiological function enhances biologic incorporation [8]. Earlier incorporation has been identified as well. In a dog model, Rodeo showed that a soft-tissue graft had healed in a bone tunnel by 16 weeks. At that time, failures occurred at the graft or clamp in pullout studies, whereas failure was at the fixation site at 2, 4, and 8 weeks, with mixed failures occurring at 12 weeks. Serial histological analysis revealed progressive reestablishment of collagen-fiber continuity between bone and tendon, this biologic fixation occurs by formation of Sharpey-like fibers. Based on this study, he recommended protection of ligament in bone tunnel for at least 8 weeks [22]. In a rabbit model, soft-tissue graft healing in a bone tunnel occurred within 3 weeks [23].

Several studies have compared healing of a bone plug to a soft-tissue graft in a bone tunnel. In adult beagle dogs, a bone plug was shown to incorporate at 3 weeks, whereas a soft-tissue graft required 6 weeks. At 3 weeks, the ultimate load to failure was less with a soft-tissue graft, and did not differ significantly from the bone plug at 6 and 12 weeks [9]. In goats, failure occurred by pullout of grafts from tunnel at 3 weeks, but midsubstance failures occurred at 6 weeks. At 6 weeks, histological evidence of complete healing of bone plug occurred; however, soft-tissue graft incorporation had not yet occurred [11].

Although the time required for biologic incorporation has not been pinned down, it appears grafts with bone plugs achieve histologic incorporation earlier than soft-tissue grafts [9,11]. Adequate biologic fixation occurs by about 6 weeks with bone plugs, and may require up to 4 months with soft-tissue grafts. This has important implications with respect to postoperative therapy regimens, such that patients who have received graft substitutes with bone plugs may be allowed to advance to higher level activities earlier than those with soft-tissue grafts. Once biologic incorporation of the graft in the tunnel has occurred, the rigidity of the ligament substitute depends upon the intraarticular portion of the graft itself [10].

Regarding metal versus bioabsorbable screws, Walton demonstrated no difference in healing of bone plugs in the tunnel between biodegradable and metal screws. Both graft bone plugs integrated with surrounding bone at 6 weeks [10].

Soft Tissue versus Bone Plug Graft

The gold standard for fixation of a graft with a bone plug (bone-patellar tendon-bone, quadriceps tendon, Achilles tendon) is an interference screw as described by Lambert [25] and Kurosoka [20]. Interference screws may provide the advantage of rigid aperture fixation (fixation at the native ligament footprint adjacent to the articular surface) which increases knee stability and graft isometry, and avoids suture stretch and graft-tunnel motion [26]. Early fixation techniques for soft-tissue grafts were limited to distal, indirect fixation techniques (suspensory fixation) which are hindered by inferior stiffness, windshield-wipering (anterior/posterior), and bungee cord effects (superior/inferior) which may lead to delayed biological incorporation and tunnel enlargement. In cases where distal (suspensory) fixation is employed, a complete fill of the tunnel with the graft may prevent this graft/tunnel motion. Newer interference screws have been created specifically for soft-tissue grafts. These screws have blunted threads in order to decrease the risk of soft-tissue graft laceration, and have been shown to provide similar fixation to interference screws with bone plugs.

The method of fixation of interference screws with soft-tissue grafts is compression of the soft tissue in the bony tunnel. The compressive stiffness of the screw is important. The screw should have compressive stiffness less than adjacent host bone but greater than the soft tissue. The use of interference screws with soft-tissue grafts means the theoretical problems with distal fixation (fixation distant from the articular surface) may be avoided. Because of improved fixation techniques for soft tissues, soft-tissue graft substitutes have recently gained popularity in ligament reconstruction.

Femoral versus Tibial Fixation

Fixation of the graft in the femoral tunnel provides greater strength than fixation in the tibial tunnel [24]. The reasons for this are biomechanical and include a greater bone mineral density of the distal femur as well as an angle of stress relative to fixation that is mechanically stronger in the femur than the tibia. Several studies indicate improved fixation in bone with increased bone mineral density [27,28]. The higher the bone mineral density, the higher the compressive stiffness. The distal femur has been demonstrated to have a greater bone mineral density than the proximal tibia [28].

The angle at which force is applied to the tibial fixation is in line with the intraosseous portion of the graft whereas the force is oblique, and sometimes perpendicular in the femoral bone tunnel. Therefore the same stress applied to each end of the graft exposes the tibial fixation to more force than the femoral fixation. For these reasons, the same fixation technique provides greater strength and stiffness in the femur than in the tibia. The weak link in the system at time zero, immediately after surgery, is the tibial fixation point.

Interference Screws

Interference screws as described by Lambert [25] and then Kurosaka are the gold standard method of fixation for grafts with bone plugs. They combine aperture fixation with rigid strength and stiffness, providing the most secure fixation when using a bone-patellar tendon-bone graft [29]. These features lend to increased knee stability and graft isometry.

Aperture fixation has benefits over distal fixation including avoidance of suture stretch, graft-tunnel pistoning and windshield-wipering. These deleterious effects of other fixation methods allow the possibility of delayed incorporation of the graft in the tunnel at the normal anatomic site, as well as tunnel enlargement, with the possibility of clinical failure in the presence of an intact construct.

Recently, bioabsorbable screws have been used due to several potential advantages. Theoretically, after graft healing and degradation of the implant, no evidence of fixation remains in the bone, and the old fixation site is replaced with new bone. Bioabsorbable screws provide the possibility for this scenario, which is not possible with metallic screws [10]. Based on MRI findings, Lajtai demonstrated this result in 28 patients at an average of 5.2 years out from surgery [30]. Bioabsorbable screws do not cause distortion on MRI and may not require removal in cases of arthroplasty or revision. Also, you can drill through bioabsorbable screws in revision cases, effectively using the old screw to assist with fixation. Although lower fixation strengths have been reported with bioabsorbable interference screws [31], the majority of the literature indicates comparable strength and stiffness in side-by-side comparisons of metal and bioabsorbable interference screws [10,27,31–40]. Clinically, bioabsorbable screws have provided good results [13–15,30].

The literature is mixed regarding complete dissolution of the bioabsorbable implant. Lajtai reported complete absorption and replacement with new bone by MRI at 5 years in 28 patients [30], Fink reported complete screw degradation by CT scan at 12 months [13], and Lajtai noted complete absorption by MRI in 6 months [15,16]. However, some bioabsorbable screws remain evident on scans up to 24 months [41]. These studies have investigated bioabsorbable screws with different compositions. The time required for degradation and its inflammatory potential is dictated by the chemical composition of each screw, and at this point the perfect composition has not yet been agreed upon. Accordingly, it is important that the surgeon know the chemical composition of the selected screw, along with its attendant degradation and inflammatory properties.

Three potential disadvantages are screw breakage during insertion [15,36,37]: an inflammatory response described with bioabsorbable implants [42] and inadequate fixation after partial degradation prior to biologic incorporation. However, more bone plug fractures have been seen with metal interference screws [39], and similar cysts have been seen with metallic fixation as those reported with bioabsorbable screws [43]. Abate demonstrated unhindered fixation with a biodegradable screw after 28 days of degradation [38].

Regardless of fixation of a bone plug or soft-tissue graft, interference screw geometry has strength and stiffness implications. Investigating tibial fixation of a soft-tissue graft in a bone tunnel in young cadaveric knees, a 35-mm screw was found to have significantly improved strength and stiffness over a 28-mm length screw [44]. Some investigators have suggested increasing screw length provides a greater improvement in fixation of soft-tissue grafts over increasing screw diameter; whereas in bone plugs, increasing screw diameter provides a greater improvement over increasing screw length. This may be due to bone plug length which is limited versus soft-tissue length which is unlimited within the tunnel. Also, the ability of screw threads to interdigitate in the graft, or "grab" the graft is greater with cancellous bone than soft-tissue grafts [26]. Whereas the interference screw works by compression with a soft-tissue graft, both compression and interdigitation are employed with a bone plug. In fact, in porcine knees, no significant difference was noted in fixation strength of a bone plug when the screw length was downsized from 20 to 15 and 12.5 mm [45].

Several investigators have demonstrated fixation strength and stiffness is increased with larger diameter screws (9.0 vs. 6.5 mm [20] and 9 vs. 7 mm in 10-mm drill holes [24]) in the femur and tibia when using a graft with a bone plug. With a soft-tissue graft, screw diameter should approximate that of the osseous tunnel to ensure adequate strength [46]. When using a soft-tissue graft, Weiler has recommended a screw diameter 1 mm larger than the graft diameter, especially at the tibial site, and/or a longer screw, 28 mm versus 23 mm, in a hamstring graft. This is based on significantly greater pullout strength with a screw diameter of graft + 1 versus screw diameter = graft diameter with a semitendinosus tendon graft [26].

Because of concern for graft laceration, the sharp threads of metallic interference screws used for bone plug fixation were blunted in subsequent models, allowing for use with soft-tissue grafts [27].

Gap size (tunnel − graft diameter) has also found to be a significant factor when considering interference screw fixation [29]. In a comparative study of soft-tissue graft fixation with biodegradable interference screw, sizing tunnels to 0.5-mm increments improved load to failure compared with tunnels sized using 1-mm increments [47].

Another issue regarding fixation with interference screws is screw divergence. Optimal interference fixation occurs when screws are placed parallel to the bone plug or soft-tissue graft, thus allowing maximal surface area contact between screw and graft. Several laboratory studies indicate that screw divergence of 15–30° dramatically decreases the fixation strength of the construct [29,48]. In order to prevent divergence, notching the anterior edge of the femoral tunnel prior to screw insertion, flexing the knee 100–120°, and placing the screwdriver through the tibial tunnel may be helpful [46,49]. Due to the inherent inferior fixation strength of the tibia, and the in-line direction of pull in the tibial tunnel compared to the wedge effect in the femoral tunnel, avoidance of screw divergence is more critical on the tibial side than the femoral side [29]. Although laboratory significance has been demonstrated, screw divergence has not been correlated with laxity clinically [29,50,51].

Other factors relating to interference screws include bone mineral density, tunnel dilation, and insertion torque. Insertion torque has been positively correlated with pullout strength in the laboratory [26,27,28]. Insertion torque may be altered by increasing screw diameter, decreasing gap size, and performing tunnel dilation. Underdrilling by 2 mm and dilating the final 2-mm diameter compresses the adjacent cancellous bone, increasing the relative bone mineral density and compressive stiffness, with subsequent increased fixation strength [44,52].

Bone Plug Fixation in the Femur

The gold standard for fixation of a bone plug in the femur is an interference screw. This method of fixation has laboratory and clinical results which are proven and are sufficient for early, aggressive rehabilitation.

Several transfixion fixation systems are available. These techniques employ a metallic or bioabsorbable device that is placed perpendicular to the long axis of the femur and through the graft in the bone tunnel. This is predominantly used with a soft-tissue graft that is passed over the transfixion pin within the tunnel. In the laboratory, this method provides adequate strength and stiffness [17]. A clinical comparison of 2-year results following ACL reconstruction with bone–patellar tendon–bone and interference screw fixation versus transcondylar fixation demonstrated equivalent clinical results [53].

Distal fixation with a screw/washer or post has been performed with two incision techniques, and an endobutton may be used with a one incision technique. In cases of femoral tunnel blow out, an interference screw will usually not be adequate. In this situation, an endobutton, mitek anchor, screw/washer, or a post may provide distal fixation at the lateral femoral cortex.

Bone Plug Fixation in the Tibia

Historically, tibial fixation is the weak link of the graft substitute construct, with bone plugs and with soft-tissue grafts. In an effort to solve this problem, many fixation techniques have been developed.

Staples have been used to secure the graft in a shallow trough to the anteromedial tibial cortex either directly or through a suture linkage. This method has demonstrated favorable strength and stiffness when compared with interference fixation, however a high incidence of bone plug breakage (27%) was noted [54]. Screws may be used as a post, and linked with suture to the graft. A spiked washer may be used to secure the graft as it exits the tunnel on the proximal medial tibia. Depending upon soft-tissue coverage, prominent hardware may be an issue postoperatively. This method may be added to other techniques as hybrid fixation in the presence of concerns of inadequate bone quality or bone plug fracture [55].

Amidst concerns of adequate tibial fixation, interference screw fixation has proven to achieve adequate fixation for aggressive rehabilitation and provides excellent clinical results [2,12,13,15,16]. In cases of poor bone stock, revision with wide tunnels, etc., distal fixation may be added for augmentation. The standard interference screw for tibial bone plug fixation is approximately 9 × 20 mm. While the tibial screw is advanced, countertension must be applied to the graft to prevent advancement of the graft into the tunnel. Also, graft laceration has been described with metal interference screws suggesting the screw should approximate the bone plug rather than the tendinous portion [56].

Soft Tissue Fixation in the Femur

Cross pin femoral fixation has been shown to provide good clinical results at 2 years [17], yet fixation is achieved distal in the tunnel and allows for graft tunnel motion [19].

Fixation at the lateral femoral cortex may be achieved with an endobutton with favorable strength and stiffness. The endobutton with endotape linkage was found to provide similar strength and stiffness when compared to transfixion devices and bioabsorbable screws [19] and interference screws with bone plugs [57]. The endobutton with a continuous loop (eliminating the knot) demonstrated an impressive failure load and stiffness to 1430 ± 115 N and 155 ± 24 N/mm [58]. This fixation method, however, has been criticized due to the creation of a greater graft length and suspensory type of fixation, subject to graft tunnel motion [12]. In fact, 3 mm of motion within the tunnel has been demonstrated under physiologic cyclic loads with the endobutton [59]. Simonian noted tunnel expansion following endobutton fixation as compared to a normal tunnel diameter with a spiked washer on the femur, yet no difference was noted clinically [18]. Fu has recommended underdrilling the femoral tunnel, then dilating the tunnel to the desired diameter in 0.5-mm increments before endobutton fixation, potentially diminishing graft motion [46]. Although the natural history of tunnel expansion is unknown, its presence is of obvious concern to surgeons. With the association of longitudinal motion to tunnel enlargement [60,61], concern continues with suspensory types of fixation.

A screw and post or spiked washer may be used for fixation at the lateral femoral cortex with a 2-incision technique, again subject to all the concerns of distal fixation.

Interference screw fixation of soft-tissue grafts in the femur allows anatomic fixation close to the joint line, allowing optimal knee stability and graft isometry. However some reports indicated failure loads lower than that required during daily activities, yet clinical reports comparing transtibial hamstring and patellar tendon graft interference screw fixation in the femur demonstrated no significant difference in outcome [62].

An endopearl or cortical disk may be combined with an interference screw to augment fixation, significantly increasing max load to failure and stiffness. This method prevents the graft from slipping away from the screw toward the joint [63,64].

Soft Tissue Fixation in the Tibia

Tibial fixation of soft-tissue grafts can be achieved with a staple configuration. The "belt buckle" technique (tendon graft looped over a second staple) has been shown to provide greater fixation than a single staple [65]. Chaimsky has described a technique in which the proximal staple is driven into the tibial tunnel roof, collapsing the roof onto the tibial tunnel. This provides the theoretical advantage of fracture callus to increase stiffness of the fixation [66]. Staples, however, provide distal rather than aperture fixation with all the inherent disadvantages.

A screw can be used with a metal or spiked washer to secure soft-tissue grafts to the medial cortex. A washer directly on the graft is preferred over linkage with suture in order to avoid the relatively elastic suture and has been found to provide adequate strength. These methods yield strengths in the range of 800–900 N [55,65].

Some suggest initial strength of transtibial hamstring tendon interference fit fixation may not allow for an accelerated postoperative rehabilitation [65]. However, when combined with a distal technique, interference fixation provides the benefit of aperture fixation and the strength of distal fixation.

Conclusion

Graft fixation continues to be the weak link early in the rehabilitative process. This fixation strength guides the postoperative regimen in that rehabilitation and reintroduction of activities should correlate with fixation strength achieved in the operating room. Although clinical results are good with most fixation techniques, significant differences continue to be demonstrated in the laboratory. The clinical relevance of these differences is not completely known. In general, aperture fixation provides advantages over distal fixation. Interference screws are the only methods providing fixation close to the articular surface. Some other methods have demonstrated improved strength and stiffness, but distal fixation should always arouse concern for graft-tunnel motion. Ultimately, the fixation choice depends upon surgeon comfort, however knowledge of available options should be present.

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