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What is This?

## Current Concepts

# Graft Fixation in Cruciate Ligament Reconstruction

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#### ABSTRACT

Cruciate ligament reconstruction has progressed dramatically in the last 20 years. Anatomic placement of ligament substitutes has fostered rehabilitation efforts that stress immediate and full range of motion, immediate weightbearing, neuromuscular strength and coordination, and early return to athletic competition (3 months). This has placed extreme importance on secure graft fixation at the time of ligament reconstruction. Current ligament substitutes require a bony or soft tissue component to be fixed within a bone tunnel or on the periosteum at a distance from the normal ligament attachment site. Fixation devices have progressed from metal to biodegradable and from far to nearnormal native ligament attachment sites. Ideally, the biomechanical properties of the entire graft construct would approach those of the native ligament and facilitate biologic incorporation of the graft. Fixation should be done at the normal anatomic attachment site of the native ligament (aperture fixation) and, over time, allow the biologic return of the histologic transition zone from ligament to fibrocartilage, to calcified fibrocartilage, to bone. The purpose of this article is to review current fixation devices and techniques in cruciate ligament surgery.

The importance of secure graft fixation in ligament reconstruction has changed dramatically in the last 20 year-

§ Address correspondence and reprint requests to Darren L. Johnson, MD, Chairman of Orthopaedic Surgery, University of Kentucky School of Medicine, Kentucky Clinic, K-439, 740 Limestone, Lexington, KY 40536. s.Current rehabilitation protocols after knee ligament surgery stress immediate full range of motion, return of neuromuscular function, proprioception, and early weightbearing forces up the kinetic chain. In the early postoperative period, graft fixation is the weak link within the entire system. No commonly used graft fixation has ultimate failure strength or stiffness comparable with the native cruciate ligament (Table 1). Fixation methods must be rigid and stiff to allow current rehabilitation principles. Current fixation techniques involve soft tissue and bone within a bone tunnel or periosteal fixation away from joint surfaces.

Bone-patellar tendon-bone, quadrupled hamstring tendon, or quadriceps tendon-bone are the most commonly used ligamentous substitutes in cruciate ligament reconstruction. Using these ligament substitutes with current fixation devices, we have been unable to reproduce the normal transition zones of insertion of the ACL and PCL. Given that anatomic structure dictates function, the mechanical profile of the ligament substitute has not been reproduced. Variables that we are able to measure in the basic science laboratory at time zero of ligament reconstruction include data on ultimate failure load, yield point, stiffness, displacement to failure, and mode of failure. Correlation of these results with clinical outcome has not been reported.

Our purpose is to review all current information with regard to ligament substitute fixation of bone and soft tissue grafts. It is important for the surgeon to be aware of the difference in fixation techniques with the associated biologic consequences. Different graft substitutes may require different fixation techniques that have direct biologic implications. Knowledge of these fixation techniques will allow the clinician to make necessary intraoperative and postoperative decisions in cruciate ligament reconstruction.

One author has commercial affiliation with a product named in this study.

TABLE 1 Ultimate Load to Failure and Stiffness of Current Graft Selections in Cruciate Ligament Surgery

Graft Selection (ref.)	Ultimate Strength to Failure (N)	Stiffness (N/mm)
Native ACL <sup>98</sup>	2160	242
Native PCL <sup>72</sup>	1867	
Patellar tendon <sup>25</sup>	2977	455
Quadrupled hamstring tendon (semitendinosis and gracilis) <sup>35</sup>	4140	807
Quadriceps tendon <sup>85</sup>	2353	326

#### IDEAL GRAFT FIXATION

#### Strength

Because there is only one means of graft fixation that approaches the strength of the native ACL, the question is, "How much strength is required of a cruciate ligament reconstruction for activities of daily living and a progressive rehabilitation program?"

Noyes et al.<sup>69</sup> have estimated the strength required for activities of daily living to be 454 N based on the failure strength of the ACL. They state that, "It seems reasonable to assume that under normal conditions biological tissues are subjected to forces ranging from one-tenth to not more than one-fifth of their breaking loads." The same group concludes "For the posterior cruciate ligament (PCL) these force levels would be increased."

Morrison,<sup>64–66</sup> a bioengineer, writing in the late 1960s and early 1970s in a series of three articles relating force plate and gait analysis data, made calculations and conclusions regarding the forces in the ACL and PCL; these are shown in Table 2. Markolf et al.<sup>58</sup> used a cadaveric model that ignored muscle forces and examined the forces on the ACL, a patellar tendon graft, and an overtensioned (45 N) patellar tendon graft. The patellar tendon graft experienced higher forces than the native ACL (peak force, 297 N) and overtensioning the graft increased the forces experienced by the graft (up to 497 N). In a similar study by Markolf et al.,<sup>59</sup> the PCL forces were examined in the intact PCL and a patellar tendon graft was used to reconstruct the PCL. The forces in the PCL study were much lower, generally less than 100 N. The higher forces developed in some grafts in hyperextension and hyperflexion, leading the authors to recommend avoiding these motions after reconstruction.

TABLE 2
Estimations of Forces Present in the Cruciate Ligaments in
Activities of Daily Living <sup>64–66</sup>

Activities	ACL (N)	PCL (N)
Level walking	169	352
Ascending stairs	67	641
Descending stairs	445	262
Descending ramp	93	449
Ascending ramp	27	1215

There is evidence that less than 454 N is sufficient for activities of daily living. In a clinical study, Shelbourne and  $\text{Gray}^{79}$  reported use of a button for both the tibial and femoral fixation of a patellar tendon reconstruction, which has a failure strength of 248 N.<sup>43</sup> Excellent clinical and objective knee stability was maintained with an accelerated rehabilitation program in their series of patients.

#### **Biomechanical Properties**

Stiffness is the slope of the linear region of the loadelongation curve and is usually reported in units such as newtons per millimeter (N/mm). As a graft and its fixation device are loaded with a tensile force, displacement in the graft and fixation device occurs equal to an amount described by its stiffness. Present graft fixation alternatives are less stiff than the native ACL and graft choices. This can be compared with a chain secured to posts by bungee cords at either end of the chain. As force is applied to the chain, the bungee cords, not the chain, will displace under tensile load. Mechanically, the majority of tendon fixation constructs are less stiff than the interference screw against a bone plug, which has been considered the standard for fixation (see Tables 4, 7, 8, and 9). Thus, given that ultimate failure strength is comparable between the two given fixation choices, tendon constructs may displace or slip more before they fail, creating laxity in the graft reconstruction.

Many tendon fixation devices are "indirect." They rely on linkage material to connect the tendon to the fixation device. A biomechanical study compared strain that was induced by cyclic loading in a patellar tendon graft and a quadrupled hamstring tendon graft and found that the



Tensile Loading on Graft

**Figure 1.** A schematic diagram demonstrating the bungee effect or longitudinal graft-tunnel motion.

tape-tissue interface (5.4%) had notably more strain than the tape (2.9%) or the tissue (1.1%) alone.<sup>52</sup> If strain or laxity is in line with the linkage, it is referred to as the bungee cord effect<sup>32</sup> (Fig. 1). These shearing forces may be responsible for tunnel expansion, also known as the windshield-wiper effect.

In the native cruciate ligament, the point of fixation is at the joint surface. However, most tendon fixation constructs are placed at a distance from the joint surface with a staple, screw and suture, or soft tissue washer. When interference fixation is placed closer to the joint surface, there is increased knee stability at a variety of flexion angles and also improved graft isometry (Fig. 2) (Ref. 41; C. Morgan, unpublished data, 1994).

#### **Biologic Properties**

It has been stated that bone plug incorporation occurs before tendon incorporation in a bone tunnel,<sup>76</sup> but basic science on this matter is not definite. In a study by Clancy et al.,<sup>23</sup> bone plug-patellar tendon-bone plug in a bone tunnel was histologically incorporated at 8 weeks after surgery in a rhesus monkey, when it was first histologically examined. After 3 months, all biomechanical testing resulted in interstitial failure of the reconstructed grafts, with no bony avulsions occurring, thus implying bone plug incorporation in the bone tunnel.

In a dog extraarticular tendon model, the tendon graft pulled out of the bone tunnel until 12 weeks postoperatively, indicating that the tendon was not healed in the bone tunnel. The graft was an extraarticular, long digital extensor tendon and was left attached distally under tension; it was not an intraarticular free graft.<sup>73</sup> However,



**Figure 2.** A schematic representation of a transtibial ACL reconstruction using a quadrupled hamstring tendon graft and direct biodegradable interference screw fixation placed at joint surfaces.

tendon graft incorporation has been shown to occur sooner. A rabbit model with a free semitendinosus graft intraarticularly placed through bone tunnels and fixed with suture suggested that the graft healed in the tunnel within 3 weeks.<sup>34</sup> In a similar ACL reconstruction study with a sheep model fixed with biodegradable interference screws directly against the free autologous Achilles tendon graft, intraligamentous failure was demonstrated by 6 weeks.<sup>92</sup> Evidence of bone plug incorporation before soft tissue healing in a bone tunnel is not definite based on animal studies. Weightbearing and rehabilitative exercises increase stress that the new, reconstructed ligament will have to respond to and react. These activities occur at the time when the weak link of the reconstruction is the fixation of the graft. In our laboratory experience, even low cyclic loads, up to 110 N, cause shear forces in the bone tunnel on the graft.<sup>12</sup> Strength and stiffness in the fixation is the key to diminishing this graft-bone tunnel motion as healing progresses.

#### FEMORAL AND TIBIAL FIXATION

There are two key differences that need to be considered between femoral and tibial fixation, that of bone density and the angle at which force is applied to the graft attachment. The bone quality and geometry of the tibia is different from that of the femur.<sup>11</sup> The Dual Photon Absorptometry (DEXA) of the tibial metaphysis has been determined to be less than the femoral metaphysis in the same knee of elderly cadavers<sup>11</sup> and in young women.<sup>89</sup> The line of force on the graft is directly in line with the tibial tunnel. The line of force on the graft is obliquely orientated to the femoral tunnel in the weightbearing position, which is extension. Based on radiographic studies, the femoral tunnel does not become colinear with the ligament graft until approximately 100° of knee flexion.<sup>57</sup>

Kohn and Rose<sup>46</sup> have found a lower ultimate load of tibial failure when using interference fixation for bone plug fixation.

#### STUDY METHODS

Study methods of present biomechanical studies vary extensively from institution to institution, making comparative statements of fixation methods and devices difficult (Table 3). Variables that we are able to measure in the basic science laboratory at time zero of ligament reconstruction include data on ultimate failure load, yield point, stiffness, displacement to failure, and mode of failure. Stiffness, an important descriptive variable that predicts the displacement or slippage of a device before it fails, has not been reported in all biomechanical studies. Another variable, bone mineral density, with direct clinical applications is varied throughout present studies. Bone mineral density is correlated with the results of tendon interference fixation and may be important in other forms of fixation as well.<sup>11</sup> The results of animal studies, which have a higher and more consistent bone mineral density, have yielded higher failure values using interference fix-

Biomechanical Study Methods for Fixation Devices					
Comparison of "Pull-out" Studies using Human Tissue	Fixation Devices	Construct	Rate of Applied Force	Grafts	
Brown et al., older cadavers (unpublished)	Semifix, bone mulch, interference fixation, endobutton, press-fit	Anterior drawer to knee at 20°	1 mm/sec	Quadrupled semitendinosis and gracilis tendon patellar tendon	
Brown et al., <sup>14</sup> older cadaver knees	Interference screws, compared rear entry to endoscopic	Femur only, in line with the tunnel	1 mm/sec	Patellar tendon	
Caborn et al., <sup>19</sup> older cadavers	BioScrew, metal interference screw	Femur only, in line with the tunnel	20 mm/min	Patellar tendon	
Caborn et al., <sup>18</sup> older cadavers	BioScrew, titanium interference screw	Femur only, in line with the tunnel	20 mm/min	Quadrupled ST/G	
Gerich et al., <sup>33</sup> cadavers (ages 18–65)	Interference screws, staples	Tibia only, "axial to tibia"	60 mm/min	Patellar tendon bone plug	
Johnson and vanDyk, <sup>44</sup> cadavers (ages 47–70)	Interference screw compared biodegradable screw to metal screw	Femoral preparation only, in line with the tunnel	4.2 mm/sec	Patellar tendon	
Kohn and Rose, <sup>46</sup> cadavers, median age, 30 (22–60)	Interference screw, influence of screw diameter, compared tibia to femur	Tibia preparation Femoral preparation, in line with the tunnel	200 mm/min	Patellar tendon	
Kurosaka et al., <sup>48</sup> cadavers, mean age, 59	Button, staples, interference fixation, 6.5 mm AO screw	Anterior drawer to knee at 45°	30 mm/sec	Patellar tendon, semitendnosis	
Magen et al., <sup>56</sup> cadavers (ages $18-67$ )	Tibial fixation	Tibia preparation, in line with the tunnel	5% graft length/sec	Quadrupled hamstring	
Matthews et al., <sup>62</sup> cadavers (ages 25–40)	Interference screw, suture and post with #2 and #5 suture	Tibia preparation, femoral preparation, graft tensioned perpendicularly to bone preparation	51 cm/min	Patellar tendon	
Pena et al., <sup>70</sup> cadavers (ages $32-57$ )	Interference screw, BioScrew and metal screw	Femoral preparation, in line with the tunnel	50 mm/min	Patellar tendon	
Rowden et al., <sup>74</sup> young cadavers (mean age, 26)	Interference screw compared with EndoButton/suture and post	Anterior drawer to knee at 60°	500 mm/min	Patellar tendon, quadrupled semitendinosis	
Steiner et al., <sup>87</sup> cadavers (mean age, 70)	Suture and post, post and washer, interference screw	Anterior drawer to knee at 20°	1 mm/sec	Patellar tendon, doubled and quadrupled hamstring	
Weiler et al., <sup>97</sup> cadaver (mean age, 41)	Button, screw and washer, RCI screw, bone plug	Anterior drawer to knee at 30°	1 mm/sec	Hamstring, hamstring with bone plug	

TABLE 3 Biomechanical Study Methods for Fixation Devices

ation than comparable human studies.<sup>56</sup> The bone mineral density of elderly cadavers may be as little as half that of a young healthy person who sustains cruciate ligament damage as a teenager. Because of the scarcity of specimens, the same specimen is often tested multiple times. Techniques vary from the clinical situation to the laboratory. For instance, the interference screw is often placed under direct visualization, minimizing the possibility of divergence, which certainly occurs in vivo.<sup>51</sup> If a device is tested in line with the tunnel, the worst-case scenario, the failure load may be less than if the device is loaded at an angle to the tunnel that will increase the shear forces. Because of viscoelastic properties of the graft-bone construct, the rate the graft is loaded will affect the stiffness. Rehabilitation and ambulation stresses are examples of cyclic loading and are not accounted for with static testing at time zero fixation of the graft

#### BONE PLUG GRAFT FIXATION—TIBIAL FIXATION

#### Staples

Although there are alternative means of fixation in graft tunnel-length mismatch, this mismatch is considered the primary indication for staple fixation of a bone plug. Another method of fixation for graft tunnel-length mismatch include a longer femoral tunnel with a proportionately longer interference screw to create aperture fixation. Various means of shortening the graft to match tunnel length have also been described. A set of doubled staples in a shallow trough (with an ultimate load at failure of 588 N) compared favorably with interference fixation (506 to 758 N) in failure, and the staples were significantly stiffer (86.3 N/mm) than interference fixation (49.2 to 54.9 N/mm) in a young (mean age, 44) human cadaveric model. Unfortunately, the incidence of bone block breakage (27%) was significantly greater than that of the interference screw fixation (1%).<sup>33</sup>

#### Screws Used as a Post

Steiner et al.<sup>87</sup> did a study that reported a screw used as a post, linked with suture, and combined with an interference screw against a bone plug. They found that this had a failure strength (674 N), which approximated that of the intact ACL (560 N) (Table 4). The angle at which the screw is placed determines whether the graft is tensioned as the screw is tightened or whether the graft is relaxed as the screw is tightened. Although a low-profile screw with a flatter head is available from many of the orthopaedic manufacturers, conventional screws are often removed because of pain. The post and suture can serve as a backup to tibial interference fixation that is compromised by poor bone quality or bone plug fracture.

#### Interference Fixation

Whatever fixation strength is required for activities of daily living and a progressive rehabilitation program appears to be met by the strength and stiffness of interference fixation, which, for this reason, has been described as the standard of graft fixation.<sup>87</sup> Interference fixation was first described by Lambert<sup>50</sup> in a study using a 6.5-mm cancellous screw. In 1987, Kurosaka et al.<sup>48</sup> demonstrated superior strength with a larger diameter screw (9 mm) for interference fixation. When poor bone stock exists—which may be due to revision, tunnel widening, or graft tunnellength mismatch—or additional fixation strength is needed for large or noncompliant patients, interference

fixation may be combined with other types of fixation such as a suture and post, EndoButton (Acufex, Inc., Mansfield, Massachusetts), or screw and washer.

Currently, a screw 9 mm in diameter and at least 20 mm in length is the standard used for fixation. The difference between the outside diameter of the screw and the core diameter is the most important consideration.<sup>97</sup> Kohn and Rose<sup>46</sup> showed that a 9-mm tibial interference screw disengaged from the bone tunnel at significantly more maximum tensile strength and linear load to failure compared with a 7-mm screw (Table 4). Screw length beyond 20 mm in conjunction with a bone plug does not appear to be necessary.<sup>14,39</sup>

The gap between the bone plug and bone tunnel and the interaction with screw diameter influences the fixation strength. Brown et al.<sup>15</sup> suggested that interference (screw outer diameter minus tunnel bone block gap) was correlated with failure, but gap size alone is not associated with failure. Similarly, a separate porcine biomechanical study showed that a 1- or 2-mm gap with a 7-mm screw yielded equal failure strength to a 3- or 4-mm gap with a 9-mm screw.<sup>17</sup> Alternatively, when faced with a gap or bone of poor quality, a bone shim may improve the fixation strength.

Despite the clinical success of interference fixation, complications, usually preventable, have been reported. Counter tension through the bone plug sutures can reduce graft advancement as the interference screw is placed.<sup>61</sup> Screw laceration of either the bone plug suture or of the graft itself are clinical concerns. If the sutures that are attached to the bone plug are lacerated with the threads from the screw, poor graft fixation cannot be salvaged with a suture-and-post construct. Suture laceration can be

Construct	Test Design	Failure (N)	Stiffness N/mm	Failure Mode
Suture (#5) to button <sup>48</sup>	Anterior drawer to knee at 45°	248 (40.2)	12.8 (2.0)	Button failed, suture pulled through the bone plug
Staple <sup>1</sup> patella tendon <sup>48</sup>	Anterior drawer to knee at 45°	129 (15.7)	10.8 (2.0)	Graft slipped under the staple
Doubled staples on patella tendon in a trough <sup>33</sup>	Tibia only, "axial to tibia"	588	86.3	Graft slipped under staple, 27% bone block breakage
Suture and post <sup>87</sup>	Anterior drawer to knee at 20°	396 (124)	27 (13)	Bone-tendon rupture, bone plug fracture, tibial post pull-out
6.5  mm AO interference screw <sup>48</sup>	Anterior drawer to knee at 45°	215 (39.2)	23.5 (2.9)	Grafts pulled out of the tunnel
9 mm interference $screw^{48}$	Anterior drawer to knee at 45°	476 (110.9)	57.9 (3.9)	Grafts pulled out of the tunnel
Interference screw and suture with a post <sup>87</sup>	Anterior drawer to knee at 20°	674 (206)	50 (21)	Bone plug fractured, pull-out around tibial screw and suture rupture
7 mm interference screw <sup>46</sup>	Tibia only, parallel to tunnel	461 (230-631)	47 (28–73)	Tendon tearing, slipping of the bone plug
9 mm interference screw <sup>46</sup>	Tibia only, parallel to tunnel	678 (394–947)	68 (32-84)	Tendon tearing, slipping of the bone plug
$9 \times 30 \text{ mm} \text{ interference screw}^{33}$	Tibia only, "axial to tibia"	758 (139)	49.2 (2)	Tendon tearing or bone plug slippage
$9 imes 25~\mathrm{mm}$ biodegradable screw^{12}	Tibia only, parallel to tunnel	293 (156-458)	42 (14-67)	Bone plug slipped, tendon tearing

TABLE 4 Tibial Fixation Options for Bone-Patellar Tendon-Bone Plug in a Bone Tunnel<sup>a</sup>

 $^{a}$  The standard deviations or ranges of variability are reported in parentheses following the mean.

avoided with the use of 20-gauge wire through the holes in the bone plug. Graft laceration may require another graft option.<sup>61</sup> Two cases of bone plug comminution have been reported: one was salvaged by reversing the graft and placing the fractured bone plug on the tibial side and fixing it with a suture and post, the other had to be revised to another graft choice.<sup>5</sup> Pain in the area of the tibial screw that was caused by hardware has been reported by 3% of patients, and screw removal was very successful in relieving this pain.<sup>49</sup>

#### **Biodegradable Interference Screws**

The terms "biodegradable" or "bioabsorbable" are used interchangeably to characterize materials that disintegrate after implantation and are subsequently excreted. Materials that disintegrate in the body have been used by orthopaedic surgeons over the past 3 decades and these materials allow for better available implants. In cruciate ligament surgery, several different biodegradable interference screws consisting of different polymeric raw materials are currently available (Table 5). A large number of studies have investigated their biomechanical and clinical performance.

Biodegradable implants consist mainly of the poly-alpha-hydroxy acids, polylactide and polyglycolide, including their copolymers, poly-(D,L-lactide-co-glycolide) and polyglycolide-co-trimethylencarbonate; stereopolymers, such as poly-(L-lactide), poly-(L-co-D,L-lactide) and poly-(D,Llactide) are also used (Table 5). These raw materials represent substantially different material characteristics, such as degradation kinetics, mechanical properties, and biocompatibility. Generally, it is considered reasonable to divide these materials into three different groups according to their degradation. Group one consists of slow degrading and highly crystalline poly-(L-lactide) and poly-(L-co-D,L-lactide) stereocopolymers with a low D,L amount. These materials are considered to have high mechanical properties among the poly-alpha-hydroxy acids, but their degradation can last up to several years and is incomplete because of a possible accumulation of insoluble crystalline implant remnants.<sup>6,22,27,71</sup> Group two is represented by amorphous poly-(L-co-D,L-lactide) stereocopolymers with a high D,L amount and the purous poly-(D,L-lactide). These materials degrade completely within 1 to 2 years, but their mechanical properties are lower compared with the poly-(L-lactide).<sup>84</sup> The third group consists of fast-degrading copolymers such as poly-(D,L-lactide-co-glycolide) or polyglycolide-co-trimethylencarbonate, whose strength retention lasts for only several weeks.

For many years, biodegradable implants have been thought to offer advantages over metal analogs. Metal implants can distort magnetic resonance imaging (Fig. 3) and release metal ions into the surrounding tissue.<sup>40,80</sup> Further disadvantages include the need for a second surgical procedure for implant removal and a revision surgery complicated by the presence of a metal implant. In cruciate ligament surgery, the major advantages of biodegradable interference screws is an uncompromised revision surgery. This is especially important because the number of revisions has risen dramatically within the last few years.<sup>68,88</sup> The difficulties encountered with retained metal screws in revision surgery has been described.<sup>77</sup> In case of revision after using biodegradable interference screws, surgery may be performed like a primary procedure if the material has degraded and osseous replacement has taken place with an appropriate amount of

	Auvantages and Disauvantages of Dinerent Diodegradable interference offews				
Implant (Manufacturer)	Raw material (Abbreviation)	Advantages	Disadvantages		
Biologically Quiet Interference Screw (Instrument Makar Inc., Okemos, MI)	poly-(D,L-lactide-co- glycolide) 85/15% (PDLLA-co-PGA)	Amorphous material, osseous replacement within an appropriate time <sup>62</sup>	Low initial fixation strength, fast degradation, <sup>71</sup> only one size available		
Bio-Interference Screw (Arthrex Corp., Naples, FL)	poly-(L-lactide) (PLLA)	High initial fixation strength, <sup>71</sup> different sizes available	Semicrystalline PLLA with recrystallization and possible incomplete degradation		
BioScrew (Linvatec Corp., Largo, FL)	poly-(L-lactide) (PLLA)	High initial fixation strength, high torsional strength, <sup>71</sup> different sizes available	Highly crystalline PLLA with incomplete degradation <sup>62</sup>		
Endo-Fix (Acufex Inc., Mansfield, MA)	polyglycolide-co- trimethylencarbonate 67.5/32.5% (PGA-co- TMC)	High initial fixation strength <sup>71</sup>	Low torsional strength, crystalline copolymer, fast degradation with possible adverse tissue response, <sup>20,30,71</sup> only one size available		
Phantom Absorbable Screw (DePuy Orthopaedic Technology Inc., Tracy, CA)	poly-(L-lactide) (PLLA)	High initial fixation strength	Highly crystalline PLLA with incomplete degradation		
Phusiline Interference Screw (Phusis matériaux biorésorbables, Le Versoud, France)	poly-(L-co-D,L-lactide) 98/ 2% (PLA 98)	High initial fixation strength different sizes available <sup>71</sup>	Low torsional strength, semicrystalline polymer with re-crystallization and incomplete degradation <sup>71</sup>		
Sysorb (Sulzer Orthopedics Ltd., Münsingen, Switzerland)	poly-(D,L-lactide) (PDLLA)	High initial fixation strength, high torsional strength, amorphous material, osseous replacement within an appropriate time $^{62,71}$	Possible viscoplastic deformation, only one size available		

 TABLE 5

 Advantages and Disadvantages of Different Biodegradable Interference Screws



**Figure 3.** A, a coronal section MRI of the femoral tunnel at 2 months postoperatively of a biodegradable screw (arrows). There is no artifact from the screw and it appears to be opposed to the quadrupled hamstring tendon graft. B, coronal section MRI of another patient with a biodegradable screw interference fixation at 1 year. The screws have nearly completely degraded (arrows) leaving a bright signal, but again the femoral graft is well opposed to the interference screw.

newly formed bone at the former implant site. In addition, functional loads can be assumed earlier by the healing bone while the material is degrading.<sup>22</sup> Another advantage in cruciate ligament surgery is a decreased potential of graft laceration during screw insertion, which has been described to occur when using metal screws.<sup>30,61</sup>

Several recent biomechanical studies compared the initial fixation strength of biodegradable and conventional titanium interference screws in human and animal cadaveric models for bone-tendon-bone graft fixation. These studies showed that most biodegradable screws provide similar fixation strength and concluded that the use of these screws may allow for an accelerated postoperative rehabilitation program.<sup>1, 19, 70, 75, 97</sup> While these investigations studied only the initial fixation strength, it is known that approximately 6 weeks are required for the bony

incorporation of a bone-tendon-bone graft, and little is known about the fixation properties of the biodegradable screws within this period while the material is degrading. Only a few in vivo studies have investigated changes in fixation strength of biodegradable interference screws over time. Walton and Cameron<sup>90</sup> used polyglycolide-cotrimethylencarbonate screws (Endofix, Acufex Inc.) in a sheep model and reported that the fixation strength of these screws remained comparable with that of metal screws for 12 weeks. Therin et al. (unpublished data, 1996) also investigated the in vivo biocompatibility and degradation of a poly-(L-co-D,L-lactide) screw (Phusiline, Phusls matériaux biorésorbables, St. Ismier, France) in a sheep model and reported proper bone healing measured by polychrome sequential labeling. Champion et al.<sup>21</sup> investigated the pushout loads of a poly-(L-lactide) interference screw (Phantom, DePuy Inc., Tracy, California) in a canine model over 24 weeks, and suggested that these screws withstand ACL forces during the healing stage of reconstruction. The clinical use of biodegradable interference screws for bone-tendon-bone graft fixation was first described in the middle 1990s (Refs. 3, 44; Therin et al., unpublished data, 1996). To date, several midterm studies comparing metal and biodegradable interference screws in clinical studies have reported no significant difference in clinical outcome.<sup>3,31,60</sup>

The major disadvantage of biodegradable screws is screw breakage or drive failure during insertion (Refs. 3, 43, 82, 97; C. Morgan, unpublished data, 1994). A screw's resistance to breakage may depend on several factors, including core diameter, drive diameter, and drive shape. The drive designs of some biodegradable interference screws are direct copies of their metallic counterparts. Others have specially designed drive systems that may provide a better force transmission to the screw core, thereby increasing implant resistance to breakage (Table 5). A recent report demonstrated that implant design may be more important than the mechanical properties of the polymeric raw material to improve torsional strength.<sup>97</sup> To avoid screw breakage, care should be taken to insert the screw convergent to the tunnel-bone block gap. To reduce peak screw insertion torque, especially in the dense femoral bone, the manufacturer's recommendations to use a notching device or a tap should be followed.

There are still concerns about an appropriate biocompatibility of other biodegradable materials because of reports on severe foreign-body reactions associated with the use of self-reinforced and highly crystalline polyglycolide implants.<sup>8,20,36,91</sup> Today, other materials such as polylactide and its copolymers and stereocopolymers are considered to have better biocompatibility,<sup>9,16,36,91</sup> and clinically relevant foreign-body reactions have not yet been described in the clinical reports on biodegradable interference screws. However, further studies should take into consideration that foreign-body reactions may principally accompany the use of each biodegradable implant and, to finally judge the appropriateness of such an implant, longterm studies are necessary.<sup>37</sup>

#### BONE PLUG GRAFT FIXATION— FEMORAL FIXATION

#### EndoButton

The EndoButton is used primarily with bone plug fixation in femoral tunnel blow-out. Interference fixation is preferable in routine femoral bone plug fixation. The EndoButton, a modification of the button, was designed to be used in the endoscopic ACL reconstruction for femoral fixation and now has been described for use in PCL reconstruction as well.<sup>4,81</sup> Doubling the linkage materials has significantly increased their mechanical properties (Table 6) (C. H. Brown et al., unpublished data, 1996).

#### Mitek Anchor

The Mitek Anchor (Mitek, Westwood, Massachusetts) is a four-pronged device that is linked to a graft by suture or tape in a fashion similar to that of the EndoButton. When comparing the Mitek device with the EndoButton in a patellar tendon-bone plug model, there was no significant difference in failure or stiffness (Table 7) (Brown et al., unpublished data, 1996). This device can be used similarly to the EndoButton in cases of femoral fixation salvage for femoral tunnel blow-out.

#### Press-Fit Femoral Bone Plug

Malek et al.<sup>57</sup> have reported press-fitting the femoral bone plug in an effort to avoid the complications of interference screw fixation. Brown et al. (unpublished data, 1996) compared the press-fit of the bone plug (ultimate load at failure, 350 N) with the patellar tendon bone plug with interference fixation (398 N), EndoButton (554 N), and Mitek Anchor (511 N). No statistical difference was noted in failure or stiffness (Table 7). A clinical study with press-fit fixation on the femoral side and interference screw fixation on the tibial side noted one case of femoral bone plug fracture.<sup>10</sup> Two cases of revision to an interference screw were required because of "insufficient femoral anchorage."

	TABLE	6
Linkage	Material	$Properties^{a}$

0	*	
Linkage Material	Failure load	Stiffness
Mersilene tape (Ethicon,	492 (28)	63.2 (7)
Inc., Sommerville, NJ)		
Doubled Mersilene	873(45)	163(14)
Meadox (Meadox Medical	509 (52)	37.8 (12)
Inc., Oakland, NJ)		
Doubled Meadox	1234(15)	109 (2)
Endotape (Smith and	699(51)	63.9 (6)
Nephew Endoscopy,		
Inc., Andover, MA)		
Doubled Endotape	1520 (89)	143(8)
Three #5 Ethibond	801 (59)	85.1 (10)
sutures, (Ethicon, Inc.)		

 $^{\alpha}$  From Brown et al., unpublished data, 1996. The standard deviations are reported in parentheses following the mean.

#### Interference Fixation

Two studies with human tissue compared a metal 7-mm diameter screw placed intraarticularly, as in endoscopic ACL reconstruction, with an outside-in technique using a 9-mm screw and found similar strength and stiffness (Table 7) (Ref. 87; Brown et al., unpublished data, 1996).

Although screw divergence from the bone plug is common when postoperative radiographs are evaluated critically,<sup>51</sup> it is not considered a clinical concern. Dworsky et al.<sup>28</sup> described the endoscopically placed interference screw acting as a "wedge," effectively blocking the femoral bone plug from being displaced into the joint. Furthermore, if the angle of screw divergence from the femoral bone plug is greater than 20°, there is a significant reduction of the pullout strength in biomechanical testing.<sup>45</sup> However, in the clinical situation, Fanelli et al.<sup>29</sup> showed that there was no increase in fixation failure with divergent interference screws placed endoscopically at angles greater than 20°.

#### SOFT TISSUE FIXATION—TIBIAL FIXATION

#### Staples

A single staple used with the semitendinosus tendon is neither strong nor stiff.<sup>48</sup> The tendon graft looped over a second staple, now called the "belt-buckle" technique, markedly improved fixation in a porcine model.<sup>56</sup> The failure load was 705 N with a stiffness of 174 N/mm (Table 8). Staples can frequently cause pain at the site of implantation and must be removed. Although the belt-buckle technique has been used successfully, fixation is periosteal and is at a distance from joint surfaces.

#### Screws Used as a Post

A screw can be used with a standard metal washer as a post to tie suture around or it can be used with a soft tissue washer against tendon. A screw with a soft tissue washer placed directly against a quadrupled tendon graft is slightly stronger and stiffer than the screw used as a post with suture (821 ± 219 N compared with 573 ± 109 N, respectively) (Table 8).<sup>87</sup> A screw with a soft tissue washer is the preferred method of tibial soft tissue fixation, compared with a screw linked with suture, because of its superior stiffness and avoidance of relatively elastic suture.

#### Washerplate

The washerplate, WasherLoc (Arthrotek, Biomet, Inc., Warsaw, Indiana), is a multiple-pronged washer and screw used to fix the tibial end of the quadrupled hamstring tendon graft. It is placed at the distal end of the tibial tunnel and can be recessed to diminish the prominence of the screw head. The ultimate failure load was 905 N (SD, 291 N) and the stiffness was 273 N (SD, 56 N), which is similar to that of the native ACL (Table 8).<sup>56</sup>

Construct	Test design	Failure (N)	Stiffness (N/mm)	Failure Mode
$\operatorname{EndoButton}^{b}$	Anterior drawer to knee at 20°	554 (276)	27.0 (13.5)	Tibial bone block fracture or suture breakage, tibial side fixation failure
Mitek device $^{b}$	Anterior drawer to knee at 20°	511 (350)	18.3 (8.3)	Patellar tendon failure, fracture tibial bone block, sutures tore through bone block
$\mathrm{Press-fit}^b$	Anterior drawer to knee at 20°	350 (48)	36.8 (16.3)	Tibial bone plug pulled out, fracture tibial bone block, patellar tendon failed
Interference screw from outside-in <sup>87</sup>	Anterior drawer to knee at 20°	423 (175)	46 (24)	Pull-out around the screw
Endoscopic interference screw <sup>87</sup>	Anterior drawer to knee at 20°	588 (282)	33 (14)	Bone plug fractured, femoral screw pull-out, bone tendon rupture
Interference screw outside-in <sup>14</sup>	Anterior drawer to knee at 20°	235 (124)	82.8 (30.1)	Bone block pull-out, bone block fracture
Endoscopic interference screw <sup>14</sup>	Anterior drawer to knee at 20°	256 (130)	70.2 (28.9)	Bone block pull-out, bone block fracture
Metal endoscopic interference screw <sup>19</sup>	Femur only, parallel to tunnel	558.3 (67.9)	No stiffness reported	Femoral fixation failure, fracture of bone plug, tearing of graft
BioScrew endoscopic interference screw <sup>19</sup>	Femur only, parallel to tunnel	552.5 (56.4)	No stiffness reported	Femoral fixation failure, fracture of bone plug, tearing of graft
Metal interference screw <sup>70</sup>	Femur only, parallel to tunnel	640 N (201)	No stiffness reported	Pullout and bone block fracture
BioScrew interference screw <sup>70</sup>	Femur only, parallel to tunnel	418 N (118)	No stiffness reported	Bone block pull-out
Metal interference screw <sup>44</sup>	Femur only, parallel to tunnel	436 (111–903)	No stiffness reported	Failure between the cortical and cancellous bone of the bone plug
Biodegradable interference $screw^{44}$	Femur only, parallel to tunnel	565 (248–987)	No stiffness reported	Failure between the cortical and cancellous bone of the bone plug

TABLE 7
Femoral Fixation Options for Bone-Patellar Tendon-Bone Plug in a Bone Tunnel <sup>a</sup>

 $^a$  The standards deviations or ranges of variability are reported in parentheses following the mean.  $^b$  From Brown et al., unpublished data, 1996.

Tibial Fixation Options for a Soft Tissue Graft in a Bone Tunnel <sup><math>a,b</math></sup>				
Construct	Test Design	Failure (N)	Stiffness (N/ mm)	Failure Mode
Stapled semitendinosis <sup>48</sup>	Anterior drawer to knee at 45°	137 (22.6)	8.8 (1.0)	Tendon pulled out of staple
QHT with suture and $post^{87}$	Anterior drawer to knee at 20°	573 (109)	18 (5)	Suture tendon stretches, post pull-out
QHT with screw and a soft tissue washer <sup>87</sup>	Anterior drawer to knee at 20°	821 (219)	29 (7)	Tendon stretches or tibial screw pulls out
QHT with a washerplate <sup>56</sup>	Tibia only, parallel to tunnel	905 (291)	273 (56)	No failure mode given
QHT with the RCI titanium screw <sup>c</sup>	Anterior drawer to knee at 20°	214 (78.8)	9.0 (6.7)	Tendons pulled out or slipped
QHT with the RCI titanium screw <sup>56</sup>	Tibia only, parallel to tunnel	350 (134)	248 (52)	No failure mode given
QHT with the RCI titanium screw <sup>94</sup>	Anterior drawer to knee at 30°	201 (50.6)	36.2	Failed at the tibial socket
QHT with biodegradable interference screw 1 mm graft sleeves <sup>86</sup>	Tibia only, parallel to tunnel	222 (75)	No stiffness reported	Graft slipped around tibial screw
QHT with biodegradable interference screw ½ mm graft sleeves <sup>86</sup>	Tibia only, parallel to tunnel	308 (207)	No stiffness reported	Graft slipped around tibial screw

TABLE 8 Tibiol Fivoti D  $a^{1a,b}$ 0... m

 $^a$  QHT, quadrupled hamstring graft.  $^b$  The standard deviations are reported in parentheses following the mean.  $^c$  Brown et al., unpublished data, 1996.

Biomechanically, this is the only tibial soft tissue fixation that approximates the ACL in failure and stiffness.

### SOFT TISSUE FIXATION—FEMORAL FIXATION DEVICES

#### Transfixion Fixation

The Trans-Fix (Arthrex, Naples, Florida) and the Bone Mulch Screw (Arthrotek) are examples of transfixion fixation. There was no significant difference in failure load or stiffness, Trans-Fix (523 N) versus the EndoButton with Endotape (520 N) (Smith & Nephew Endoscopy, Inc.). In paired knees, there was no difference in failure between the Bone Mulch screw (583 N) and EndoButton (628 N). The Bone Mulch Screw was slightly stiffer; 24.4 N/mm compared with 21.2 N/mm for the EndoButton (Brown et al., unpublished data, 1996). In cyclic biomechanical testing, both the Trans-Fix (238 N/mm) and the Bone Mulch Screw (257 N/mm) possessed stiffness superior to the EndoButton linked with either the Endotape (183 N/mm) or the continuous loop (179 N/mm). The Trans-Fix (1042 N) and the Bone Mulch Screw (978 N) were stronger to failure than the Endobutton linked with Endotape (644 N), but the highest level of failure was reported with the EndoButton linked with a continuous loop (1342 N) (Brown et al., unpublished data, 1999) (Table 9). In addition to a favorable failure strength and stiffness, transfixion devices may allow independent tensioning of the four strands of the quadrupled hamstring tendon. In a laboratory study, this resulted in a statistically significant increased failure strength of the quadrupled hamstring tendon graft and an 89% increase in stiffness.<sup>35</sup>

Patients who have had ACL reconstruction with transfixion devices have had outcomes similar to those reported in the literature. Two patients had the pin repositioned after migration.<sup>24</sup> One of those patients and later another patient had the pin removed because of iliotibial band irritation. This device has since been modified to address the prominence of the pin head.<sup>24</sup>

The cross-pin offers stiffness superior to the EndoButton linked with a continuous loop. In fact, stiffness of the cross-pin approaches that of the ACL. The device does require a second counter incision to deploy the cross-pin. Fixation by this device is deeper in the tunnel, allowing for the graft to move in the tunnel, which has been associated with tunnel expansion.

#### EndoButton

A biomechanical study in young human cadavers found that a hamstring tendon construct fixed with an EndoButton and a tibial post failed at 612 N  $\pm$  73 N compared with 416 N  $\pm$  66 N in the patellar tendon group with interference fixation.<sup>74</sup> The stiffness did not significantly vary between groups. It was commented in the study that either construct was only 20% to 30% of the failure strength of the native ACL (2195 N  $\pm$  427 N) (Table 9).<sup>74</sup> Direct biomechanical comparison between EndoButton linked with a continuous loop and linked with Endotape revealed similar stiffness data, but a much higher failure with the continuous loop, 1345 N versus 644 N for the Endotape

Construct	Test Design	Fail	ure (N)	Stiffness (N/mm)	Failure Mode	
QHT with Trans-Fix $^{\rm c}$	Anterior drawer to knee at 20°	523	(263)	34.2 (14.3)	Cross-pin toggled graft slipped off, tibial fixation failure	
QHT with Bone Mulch $^{c}$	Anterior drawer to knee at 20°	583	(108)	24.4 (4.17)	Tibial fixation failure, implant failure	
QHT with an EndoButton, mersilene tape <sup>c</sup>	Anterior drawer to knee at 20°	520	(50)	34.8 (22.3)	Tape broke	
QHT with EndoButton	Anterior drawer to	618	(242)	22.4 (6.9)	Tape broke, tibial fixation failure,	
and Endotape <sup>c</sup>	knee at 20°	663	(211)	18.1 (6.9)	tendon failure, implant pulled	
1		678	(179)	20.6 (7.8)	through bone	
QHT with EndoButton and three #5 suture <sup>c</sup>	Anterior drawer to knee at 20°	699	(210)	30.2 (8.5)	Implant pulled through bone, tibial fixation failure, suture failure, tendon failure	
$\operatorname{QHT}$ with EndoButton and 2 loops of Endotape <sup>c</sup>	Anterior drawer to knee at 20°	628	(359)	21.2 (5.5)	Tibial fixation failure, implant pulled through the bone, tape broke	
Semitendinosus fixed with the EndoButton and tibial post <sup>74</sup>	Anterior drawer to knee at 60°	612	(73)	47 (19)	No mode reported	
QHT with Mitek <sup><math>c</math></sup>	Anterior drawer to knee at 20°	412	(189)	20.3 (5.6)	Implant pulled through bone	
QHT with the RCI titanium screw <sup>18</sup>	Femur only, parallel to tunnel	242	(90.7)	No stiffness reported	Failed by graft slipping	
QHT with BioScrew <sup>18</sup>	Femur only, parallel to tunnel	341	(162.9)	No stiffness reported	Failed by graft slipping	
QHT BioScrew, 0.5 mm graft sleeves <sup>86</sup>	Femur only, parallel to tunnel	530	(186)	No stiffness reported	Failed by graft slipping	

TABLE 9 Femoral Fixation Options for a Soft Tissue Graft in a Bone Tunnel<sup>a,b</sup>

<sup>*a*</sup> QHT, quadrupled hamstring graft.

<sup>b</sup> The standards deviations are reported in parentheses following the mean.

<sup>c</sup> From Brown et al., unpublished data, 1996.

linked EndoButton (Brown et al., unpublished data, 1999).

Biomechanically, the EndoButton linked with tape has motion of the graft in the tunnel of up to 3 mm under physiologic cyclic loads.<sup>38</sup> This longitudinal motion or bungee effect has been associated with tunnel expansion in clinical trials.<sup>54,67</sup> The natural history of tunnel expansion is undetermined at present, but it is of obvious concern to surgeons using hamstring tendon fixation with linked devices. Extensive tunnel expansion complicates revision surgery because of bone loss and may jeopardize fixation of the graft. Despite this reservation, the Endo-Button has been a popular and clinically successful form of femoral hamstring tendon fixation.

#### Mitek Anchor

Brown et al. (unpublished data, 1996) compared the Mitek Anchor directly with the EndoButton in paired elderly human specimens with a quadrupled hamstring tendon graft. The EndoButton was significantly stronger (618 N compared with 412 N, P = 0.03), but stiffness was comparable (Table 9). The Mitek Anchor failed by pulling through the bone.

#### Interference Fixation

The use of interference screw fixation of a multiple-looped hamstring tendon graft has recently raised strong interest in soft tissue fixation in cruciate ligament reconstruction.<sup>26,32,78,82,83</sup> The direct tendon-to-bone interference screw fixation allows an anatomic fixation close to the joint line, which has been demonstrated to increase knee stability and graft isometry.<sup>41,42,63,96</sup> Additionally, an anatomic interference fit fixation may overcome biomechanical disadvantages of conventional extraarticular hamstring tendon graft fixation techniques, such as suture stretch-out, graft tunnel motion, and the so-called windshield-wiper effect.<sup>37,38,54,95,96</sup> It has been hypothesized that these biomechanical disadvantages may contribute to the creation of high shearing forces at the tunnel wall, which may also delay an osseous graft incorporation and lead to tunnel enlargement.<sup>54,67,95</sup>

Recent biomechanical studies compared biodegradable and blunt-threaded titanium interference screws (RCI, Smith & Nephew Donjoy, Carlsbad, California) for hamstring tendon interference fit fixation and found that biodegradable and titanium screws provide similar or superior fixation strength over conventional hamstring tendon fixation.<sup>18,86,94</sup> In these reports, the mean failure load of a transtibial ACL reconstruction with hamstring tendons and interference screw fixation exhibited substantially lower loads than the estimated forces in the native ACL or the graft during daily activities (Refs. 2, 58, 69, 96; Brown et al., unpublished data, 1996). Therefore, it has been advocated by some that the initial strength of transtibial hamstring tendon interference fit fixation may not allow for an accelerated postoperative rehabilitation (Refs. 56, 96; Brown et al., unpublished data, 1996). A clinical study showed an increase in anterior tibial translation measured from the time of operative fixation to later follow-up in some patients.<sup>53</sup> The authors are considering back-up fixation to the interference screw for patients with suspected lower bone mineral density or with poor screw purchase. Despite low loads found with biomechanical testing, a recent clinical report comparing transtibial hamstring and patellar tendon graft interference screw fixation found no significant difference in outcome.<sup>26</sup>

Several factors exist that influence the initial fixation strength of hamstring tendon grafts fixed with interference screws. These factors are especially important to increasing fixation strength on the tibial site, which has been considered to be the weak link of such a reconstruction. Initially, Morgan (unpublished data, 1994) introduced a bone-hamstring tendon-bone composite graft for an all-inside ACL reconstruction. In a biomechanical study of this technique, Liu et al.<sup>55</sup> found substantially lower loads and a high slippage for this bone-hamstring tendon-bone composite graft compared with a bone-patellar tendon-bone graft in a porcine knees model. Shin et al. (unpublished data, 1996) introduced the harvest of a hamstring tendon graft with a distally attached tibial bone plug, a method that has been used by Stähelin and Weiler<sup>83</sup> for the tibial fixation of a hamstring tendon graft in an all-inside technique. In another recent biomechanical study it was demonstrated that the harvest of a semitendinosus tendon graft with a distally attached bone plug provides similar fixation strength when compared with the conventional bone-tendon-bone graft fixation, given that both grafts were fixed with biodegradable interference screws.95

To enhance the direct tendon-to-bone interference fit fixation without bone blocks, a precise match of tunnel size to graft diameter is necessary; a recent biomechanical study compared 1- and 0.5-mm tunnel sizing and found that sizing the tunnels in increments of 0.5 mm increases fixation strength significantly.<sup>86</sup> In a separate biomechanical study investigating the effect of screw geometry on hamstring tendon interference fit fixation, it was demonstrated that by increasing both screw length and screw diameter, fixation strength was significantly improved. In this study the influence of screw length (23 versus 28 mm) was greater than that of thread diameter (screw diameter = graft size versus screw diameter = graft size + 1 mm).<sup>93</sup>

To further ascertain the appropriateness of this new technique for hamstring tendon graft fixation in cruciate ligament surgery, it is essential to understand tendon-tobone healing progression with interference screw fixation. In a recent animal study there was evidence that the healing under interference screw compression follows different patterns than what has been described in animal models using noncompressing extraarticular fixation techniques.<sup>7,34,73,92</sup> In this animal model, Weiler et al.<sup>92</sup> found that the healing progresses only partially via the development of a so-called fibrous interface (Fig. 4) This usually develops between the tendon graft and the bone surface. Their findings indicate that direct contact healing between the graft and the bone surface may exist if compression fixation is used and may also overcome the delayed tendon-bone healing if extraarticular fixation is used.





Figure 4. A, transversal cut of the tibial tunnel at 6 weeks after ACL reconstruction in a sheep model. An Achilles tendon split graft was directly fixed with a biodegradable poly-(D,L-lactide) interference screw. The graft is directly in contact with the surrounding bone tissue. A fibrous interface between the graft and the bone is only partially developed, suggesting a different mechanism of graft incorporation as compared with conventional extracortical fixation techniques. At the top of the figure is the indentation from the biodegradable screw in the tendon tissue (Masson Goldner's trichrome stain). B, fluorescence microscopy of a specimen at 9 weeks. There is an intensive fluorochrome activity at the interface between the graft and the bone tissue, indicating an early closure of the fibrous interface. The green stain (calcein green) was administered at 1 week, the yellow stain (tetracycline) was administered at 5 weeks.

When using biodegradable interference screw fixation for a soft tissue graft, there are concerns about a possible compromise of the graft incorporation when the screw degrades. In the model of Weiler et al.,<sup>92</sup> an intermediate degrading poly-(D,L-lactide) interference screw was used; it disintegrated macroscopically at 24 weeks. At this time, no graft pull-out from the tunnel was observed. This indicates that screw degradation may not compromise graft incorporation after all.

#### CONCLUSION

Graft fixation remains the weak link in the early postoperative period of ligament reconstruction. Technological advancements in surgical techniques have allowed for an immediate return of neuromuscular function within the extremity. Fixation must not only withstand these early physiologic forces but must also facilitate biologic incorporation of the graft construct in its entirety. The specific anatomic location of the attachment site will have profound effects on fiber recruitment patterns within the ligament substitute. Fixation of a bone plug in a bone tunnel with a metal or bioabsorbable interference screw appears to meet our current demands. Present soft tissue fixation within a bone tunnel or extratunnel may not possess the same biomechanical or biologic properties as a bone in a bone tunnel fixed with an interference screw. Devices that are linked to the graft or placed nonanatomically have been associated with motion through the graft construct and have spurred the search for direct fixation at the joint surface.

Controversy remains as to the suitability of soft tissue fixation for progressive rehabilitation. Other fixation devices are used and tested—such as transfixion femoral fixation, hybrid fixation, and tibial washerplate fixation—to more closely achieve the normal mechanical characteristics of the native ligament graft.

#### FUTURE DIRECTIONS

Ideally, the biomechanical properties of the entire graft construct would approach those of the native ligament and facilitate biologic incorporation of the graft. Fixation should be done at the normal anatomic attachment site of the native ligament (aperture fixation) and, over time, allow the biologic return of the histologic transition zone from ligament to fibrocartilage to calcified fibrocartilage to bone. The transition from ligament to bone may occur without a fibrous interzone with compressive interference fixation. Manipulating the biologic environment with gene therapy or tissue engineering may speed graft incorporation. Biodegradable screws can serve as a carrier for these substances or other growth factors to aid in graft incorporation in the bone tunnel and fill the bone defect that may be left by biodegradable screw absorption.

Diminishing individual fiber movement within the tendon graft and the elimination of linkage materials will improve future soft tissue fixation. Combination of fixation devices, for example, use of a screw and washer and a biodegradable interference screw directly against a tendon graft, or "hybrid fixation," may be useful in the intermediate future. Biodegradable bone cement that allows for immediate fixation of the graft and eventual replacement with normal osseous tissue may be developed. This biodegradable bone cement may need to be combined with current graft fixation choices until it cures and achieves maximum strength. Fixation that allows immediate and secure fixation will aid rehabilitation, hasten return of muscle tone and force, and benefit patient outlook.

Critical evaluation of patient satisfaction through out-

come-based research received recent emphasis at the 66th annual meeting of the Academy of Orthopaedic Surgeons (D. W. Jackson, unpublished data, 1999). The relationship between less stiff and less strong graft fixation that is currently available, the interplay with rehabilitative efforts, and laxity of the reconstructed knee has not been established. At present, there is not a strong clinical association between fixation that performs well in laboratory testing and objective knee stability. If this association is proven, the clinical association of laxity to clinical outcome and patient satisfaction can be investigated. Presently, there are few clinical studies directed to these issues. Comparative studies of different modes of graft fixation will be important in this effort. Longitudinal studies, although difficult and fraught with methods problems, will establish the relationship between patient satisfaction, residual laxity, and degenerative arthrosis.

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