How Four Weeks of Implantation Affect the Strength and Stiffness of a Tendon Graft in a Bone Tunnel

A Study of Two Fixation Devices in an Extraarticular Model in Ovine

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Background: For a tendon graft to function as an anterior cruciate ligament, the tendon must heal to the bone tunnel. We studied the effect of 4 weeks of implantation on the strength and stiffness of a tendon in a bone tunnel using two different fixation devices in an ovine model.

Hypothesis: The type of fixation device in anterior cruciate ligament reconstruction may affect early healing, which can be measured as the strength and stiffness of a tendon in a bone tunnel.

Study Design: Controlled laboratory study.

Methods: An extraarticular tendon graft reconstruction was performed in ovine tibias. The graft was fixed with either a bioresorbable interference screw or a WasherLoc. After 4 weeks of implantation the strength and stiffness of the complex and the tendon graft-bone tunnel interface were determined by incrementally loading specimens to failure.

Results: For the interference screw, the strength deteriorated 63% and the stiffness deteriorated 40%. For the WasherLoc, the strength was similar and the stiffness improved 136%.

Conclusions: The type of fixation device determines whether the strength and stiffness of a tendon in a bone tunnel increases or decreases after implantation.

Clinical Relevance: The pace of rehabilitation may need to be adjusted based on the type of fixation device used to secure a soft tissue graft.

The development of a strong, stiff attachment of a tendon graft to the bone tunnel is important to the success of an ACL reconstruction. The healing of a tendon graft to the bone tunnel is slower 3 weeks after implantation than healing with a bone plug, suggesting that the device chosen for soft tissue fixation may need to be stronger and stiffer than the device chosen for bone-tendon-bone fixation.[19]

The identification of factors that improve the early strength and stiffness of a tendon graft healing to a bone tunnel may allow earlier and more aggressive rehabilitation and earlier return to work or sport than has heretofore been possible.[16, 17] Two factors that may determine the strength and stiffness of the tendon-fixation device-bone complex after implantation are the tendon graft-tunnel interface and the fixation device. We found no studies that determined whether a fixation device affects the healing of a tendon graft to the bone tunnel, and whether the fixation device contributes strength and stiffness after implantation.

Because there is no known method for determining the strength and stiffness of a complex after implantation in humans, a study of how the first few weeks of implantation affect the strength and stiffness of the complex must be performed in an animal model. The most common model for evaluating the healing of a tendon graft in a bone tunnel is placing an extensor tendon in an extraarticular tunnel in the proximal metaphysis of an animal tibia. One advantage of this extraarticular model is that it avoids variables associated with intraarticular ACL graft positioning and tensioning.[16, 17] Another advantage is that this model allows the testing of one site of fixation, thus avoiding the difficulties in determining the strength and stiffness of one site of fixation when two sites of fixation are tested simultaneously, as in an ACL reconstruction.[13, 18] The sole disadvantage of the extraarticular model is that the healing environment in the extraarticular model may be different than in the intraarticular model.[16, 17]

One methods issue that must be addressed at the outset of this type of study is when to determine the strength and stiffness of the complex after implantation. Practically, the strength and stiffness of the complex can be determined until the mode of failure changes from pullout of the tendon from the bone tunnel to rupture of the tendon outside the tunnel. Studies using the extraarticular model in canines have determined that the mode of failure changes at about 4 weeks of implantation.[16, 17] On the basis of these studies, we anticipated that 4 weeks of implantation was the latest time interval that the strength and stiffness of the complex could be determined in an extraarticular animal model.

The purpose of our study was to determine the effect of 4 weeks of implantation on the strength and stiffness of a tendon graft in a bone tunnel when two low-profile fixation devices were used in an extraarticular ovine model. The first objective of our study was to measure the change in strength and stiffness of the complex after 4 weeks of implantation for each fixation device. The second and third objectives were to determine the strength and stiffness contributed by the tendon graft-bone tunnel interface and the strength and stiffness contributed by the fixation device after 4 weeks of implantation.

MATERIALS AND METHODS

Experimental Design

We transplanted the long digital extensor tendon into a 30-mm bone tunnel drilled in the tibial metaphysis in 32 skeletally mature Poly Pay ewe sheep. Fixation was performed with either a bioabsorbable interference screw (Bio-Interference Screw, Arthrex, Inc., Naples, Florida) (16 sheep) or a WasherLoc (Arthrotek, Inc., Warsaw, Indiana), which is a spiked washer that is compressed into the tendon graft and bone by a cortical screw (16 sheep). After 4 weeks of implantation, the animals were sacrificed and both limbs were harvested. For each fixation device, the strength and stiffness of the complex (eight sheep) and the tendon graft-bone tunnel interface (eight sheep) (that

is, testing after device removal) were determined by incrementally loading the specimens to failure. As a control, the strength and stiffness of the complex at the time of implantation (8 sheep) were determined by testing a tendon transplantation performed in the contralateral leg at the time of harvest.

Animals were cared for in compliance with the directives established by the Department of Defense (DOD) and United States Air Force in *The Use of Animals in DOD Programs* and the Institute of Laboratory Animal Resource's *Guide for Care and Use of Laboratory Animals*.[9]

Surgical Procedure

General endotracheal anesthesia was performed with inhalation agents. A 10-cm longitudinal incision was made lateral to the patellar tendon. The common digital extensor tendon was detached from the lateral femoral condyle. The cross section of the tendon was trimmed until the tendon passed snugly through a 7-mm diameter cylinder (Sizing Sleeve, Arthrotek, Inc.).

A 30-mm long tunnel was placed obliquely across the dense metaphyseal bone of the proximal tibia by using the following technique. A needle was inserted to mark the level of the medial joint line. The distance between the tip of a drill sleeve and the tip of a C-shaped drill guide was set at 30 mm. The tip of the drill sleeve was positioned 25 mm distal to the tibial articular surface in the groove of the common digital extensor 10 mm posterior and 10 mm lateral to the anterior crest of the tibia. The tip of the C-shaped drill guide was positioned 15 mm distal to the medial joint line proximally, medially, and posteriorly to the tip of the drill sleeve. A 2.4-mm diameter guide wire was drilled.

The fixation device was selected using a randomization protocol. Fixation with the bioresorbable interference screw was performed by following the instructions of the manufacturer of the implant (Arthrex, Inc.). The entire length of tendon was sewn with a whipstitch using a nonabsorbable, braided suture (No. 2 Ethibond, Ethicon, Somerville, New Jersey). A 6-mm cannulated reamer was used to drill the bone tunnel. The tunnel diameter was dilated to 7.0 mm in 0.5-mm increments by using 6.5- and 7.0-mm tunnel dilators (Size Specific Cannulated Dilator, Arthrex, Inc.). The tendon was pulled through the bone tunnel until muscle was within 1 cm from the tunnel entrance. A guide wire (1.1-mm diameter Nitinol Guide Pin, Arthrex, Inc.) was passed through the tibial tunnel anterior to the tendon. A 7.0-mm diameter, 28-mm long bioresorbable interference screw was screwed from proximal to distal until the tip reached the distal end of the tibial tunnel at the entrance of the tendon (Fig. 1).

Fixation with the WasherLoc was performed by following the instructions of the manufacturer of the device (Arthrotek, Inc.). The proximal 3 cm of the tendon was sewn with a whipstitch. A 7.0-mm diameter bone tunnel was drilled with a cannulated reamer. A 20 × 20 mm rectangle of soft tissue was removed from the proximal end of the bone tunnel. A 17-mm diameter counterbore
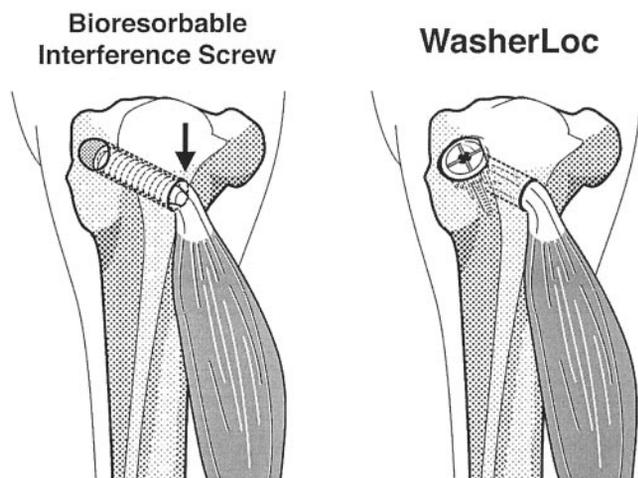
Figure 1. Depiction of two left tibias showing the orientation of the tunnel in the proximal metaphysis of the tibia and the placement of the bioresorbable interference screw and the WasherLoc that fixed the tendon graft to the tibia. The bioresorbable interference screw, 28 mm in length and 7.0 mm in diameter, was inserted in a 30-mm long bone tunnel that was dilated to 7 mm in diameter. The interference screw was cannulated and was inserted between the anterior tibial cortex and the tendon graft over a guide wire until the tip of the screw reached the distal end of the bone tunnel (arrow). The WasherLoc, 16 mm in diameter with 4 peripheral spikes 11 mm in length and 13 central spikes 6 mm in length, which penetrated the graft, were recessed in an 18-mm diameter counterbore placed in the proximal end of a 30-mm long, 7-mm diameter bone tunnel.

was drilled parallel to the posterior wall of the bone tunnel (Counterbore Guide, Awl, and Reamer, Arthrotek, Inc.) to create a recess for the WasherLoc within the proximal end of the bone tunnel. The WasherLoc, with 4 peripheral spikes 11 mm in length and 13 central spikes 6 mm in length, was impacted with a mallet into the tendon and posterior wall of the bone tunnel (WasherLoc Driver, Arthrotek, Inc.). A 3.2-mm diameter hole was drilled by using a guide through the center of the spiked washer, tendon, and opposite cortex. The length of the drill hole was measured. A self-tapping 4.5-mm diameter cortical screw that engaged the posterior cortex of the tibia was inserted to compress the WasherLoc against the tendon graft and compress the tendon graft against the posterior wall of the bone tunnel (Fig. 1).

The incision was closed in layers with absorbable sutures and the skin was closed with staples. A modified Robert-Jones pressure bandage was applied and removed 24 to 48 hours later. The sheep ambulated ad libitum in a pen 3.7 meters in length and 1.2 meters wide. Four weeks later, they were sacrificed by intravenous injection (B-Euthanasia solution, Schering-Plough Animal Healthcare Corp., Kenilworth, New Jersey). The hindlimb was amputated above the knee and tagged for identification. The limbs were refrigerated overnight at 0°C and thawed the next day for tensile testing.

Specimen Allocation, Preparation, and Tensile Testing

For each fixation device, eight animals were assigned at random for testing with the fixation device in place (that is, the complex) and eight with the fixation device removed (that is, the tendon graft-bone tunnel interface). The animals assigned for testing with the fixation device in place had the same surgical procedure with the same fixation device performed in the contralateral limb after harvest. This limb functioned as the control and was used to determine the strength and stiffness of the complex at implantation.

The limbs were prepared for testing by disarticulating the tibia from the femur and removing all soft tissue from the tibia except for the common digital extensor tendon and muscle. Adhesions were sharply freed between the muscle-tendon unit and tibia to the tunnel entrance. The fixation device was removed in the legs assigned for testing the tendon graft-bone tunnel interface. The tibia was potted in a 6-cm diameter by 20-cm long aluminum tube with polymethyl methacrylate.

A materials testing machine (Instron 5566, Instron Corp., Canton, Massachusetts) applied the tensile test. The potted tibia was mounted in a custom-designed alignment fixture attached to the base of the materials testing machine (Fig. 2). The muscle-tendon unit was gripped in a custom-designed freeze clamp attached to the crosshead of the materials testing machine. The alignment fixture enabled the tensile load to be applied to the graft in line with the bone tunnel. Elongation was measured by an extensometer incorporating a linear variable differential transformer (1000-DCD, Schaevitz Eng., Pennsauken, New Jersey). The extensometer was attached to the tibia by bolting it to a 4.7-mm diameter by 15-cm long threaded steel bar that was drilled transversely across the proximal tibia just distal to the joint line and proximal to the tunnel exit. The other end of the extensometer was clamped to the freeze clamp. The freeze line on the muscle-tendon unit was held 5 mm from the entrance of the tendon in the bone tunnel.

The testing protocol was adopted from a study previously published.[13] Tensile load was measured with a 5-kN load cell. Adding the length of unfrozen tendon (5 mm) to the length of tendon within the tunnel (30 mm) gave a total graft length of 35 mm, which was used to calculate the 5% strain rate (1.75 mm per second) of the crosshead. A tare load of 10 N was applied to the preparation and the gauge length was measured by the extensometer. A load to 50 N was applied and the load was reduced to 10 N. The length of the preparation was remeasured after the length of the preparation reached a steady state at the 10-N tare load. This loading and measurement cycle was performed under increasing loads, in 50-N increments, until failure.[13] Load and elongation were recorded at 100 Hz by use of a personal computer (Instron Series IX Software, Instron Corp.). The mechanism of failure was recorded as either pullout of the tendon from the tunnel if a portion or the entire tendon dislodged from within the bone tunnel, or rupture of the tendon outside the tunnel if none of the tendon dislodged from the bone tunnel.
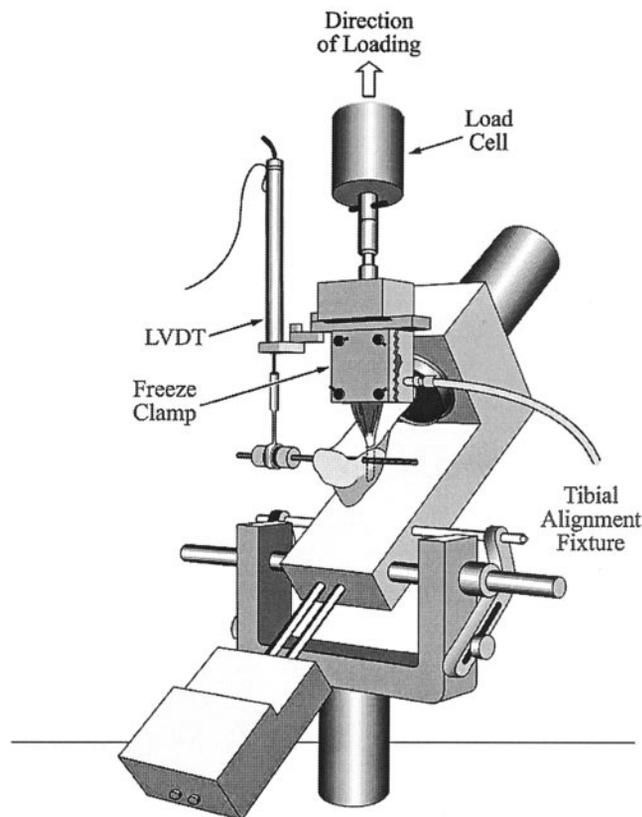
Figure 2. Fixture used to mount, align, and test the tendon-tibia-fixation method complex. The tibia was cemented in an aluminum tube and clamped in an adjustable fixture bolted to the base of the materials testing machine. The tendon and muscle were held in a freeze clamp bolted to a 5-kN load cell attached to the actuator. The long axis of the tibial tunnel and tendon was aligned in the direction of loading by adjusting the fixture. Displacement was measured with a linear variable differential transformer (LVDT).

Data Analyses

Strength and stiffness of the specimens were determined from the load-displacement curve by using a previously described method.[13] Stiffness was determined from the 150-N load cycle because this was the lowest load cycle with a linear region in the load-displacement curve.

A paired *t*-test was used to determine whether the strength and stiffness of the complex changed between implantation and after 4 weeks of implantation for each fixation device. The paired *t*-test was the appropriate statistical test because both knees from each animal were compared. An unpaired *t*-test was used to compare the strength and stiffness of the tendon graft-bone tunnel interface after 4 weeks of implantation with that of the complex at implantation for each fixation device. The unpaired *t*-test was the appropriate statistical test because knees from different animals (that is, not the contralateral knee) were compared. The contribution of the fixation device to the strength and stiffness of the complex after 4 weeks of implantation was calculated by subtracting the

strength and stiffness of the tendon graft-bone tunnel interface from the strength and stiffness of the complex after 4 weeks of implantation.

RESULTS

Mechanism of Failure

At implantation, all complexes fixed with the bioresorbable interference screw and the WasherLoc failed by pullout of the tendon from the tunnel. After 4 weeks of implantation, all complexes fixed with the bioresorbable interference screw failed by pullout of the tendon from the tunnel, and six of eight specimens (75%) fixed with the WasherLoc failed by pullout of the tendon from the tunnel, and two of eight specimens (25%) failed by rupture of the tendon outside the tunnel. After 4 weeks of implantation, the tendon graft-bone tunnel interface fixed with the bioresorbable interference screw failed by pullout of the tendon from the tunnel in all specimens, and five of seven (71%) specimens fixed with WasherLoc failed by pullout of the tendon from the tunnel and two of seven specimens (29%) failed by rupture of the tendon outside the tunnel. The data for one WasherLoc specimen was lost because of a power interruption to the computer.

Removal of Bioresorbable Interference Screw after 4 Weeks of Implantation

After 4 weeks of implantation, all the bioresorbable interference screws were easily removed. Resorption or breakage of the threads or the core of the bioresorbable interference screws was not observed.

Change in Strength and Stiffness of the Complex Between Implantation and after 4 Weeks of Implantation

With bioresorbable interference screw fixation, 4 weeks of implantation significantly decreased the strength (Fig. 3) and stiffness (Fig. 4) of the complex. The strength of the complex of 158 ± 158 N after 4 weeks of implantation was significantly less than the strength of the complex of 423 ± 93 N at implantation, indicating that the strength deteriorated 63% ($P = 0.004$). The stiffness of the complex of 232 ± 165 N/mm after 4 weeks of implantation was significantly less than the stiffness of the complex of 387 ± 101 N/mm at implantation, indicating that the stiffness deteriorated 40% ($P = 0.003$).

With WasherLoc fixation, 4 weeks of implantation did not significantly change the strength of the complex, and significantly increased the stiffness of the complex (Figs. 3 and 4). The strength of the complex of 488 ± 277 N after 4 weeks of implantation was not significantly different from the strength of the complex of 559 ± 94 N at implantation, indicating that the strength was maintained (not significant, $P = 0.540$). The stiffness of the complex of 701 ± 338 N/mm after 4 weeks of implantation was significantly greater than the stiffness of the complex of 297 ± 77 N/mm at implantation, indicating that the stiffness increased 136% ($P = 0.040$).
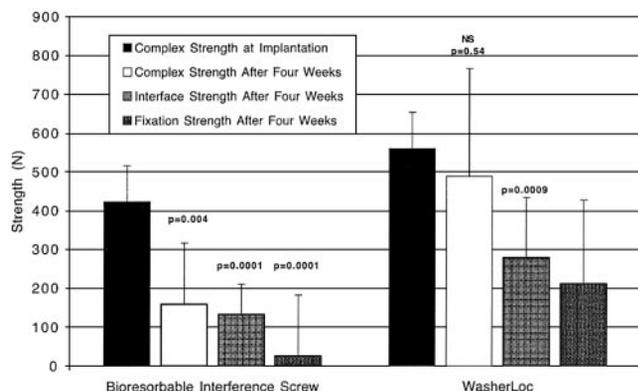
Figure 3. Graph comparing the strength of the complex at implantation, and the strength of the complex, the strength of the tendon graft-bone tunnel interface, and the strength contributed by the fixation device after 4 weeks of implantation for both the bioresorbable interference screw and WasherLoc.
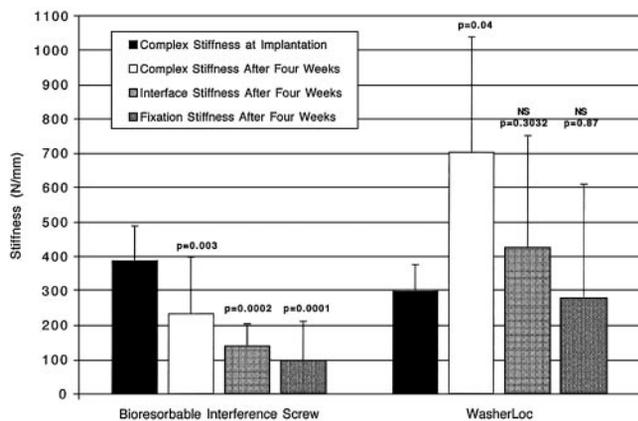

Figure 4. Graph comparing the stiffness of the complex at implantation, and the stiffness of the complex, the stiffness of the tendon graft-bone tunnel interface, and the stiffness contributed by the fixation device after 4 weeks of implantation for both the bioresorbable interference screw and WasherLoc.

Development of the Tendon Graft-Bone Tunnel Interface after 4 Weeks of Implantation

With bioresorbable interference screw fixation, the strength and stiffness of the tendon graft-bone tunnel interface developed relatively slowly after 4 weeks of implantation (Figs. 3 and 4). The strength of the interface of 132 ± 78 N after 4 weeks of implantation was 31% of the strength of the complex of 423 ± 93 N at implantation, indicating slow development of the strength of the tendon graft-bone tunnel interface ($P = 0.0009$). Similarly, the stiffness of the interface of 138 ± 66 N/mm after 4 weeks of implantation was 36% of the stiffness of the complex of 387 ± 101 N/mm at implantation, indicating slow development of the stiffness of the tendon graft-bone tunnel interface ($P = 0.0002$).

With WasherLoc fixation, the strength and stiffness of the tendon graft-bone tunnel interface developed relatively rapidly after 4 weeks of implantation. The strength of the interface of 277 ± 156 N after 4 weeks of implantation was 50% of the strength of the complex of 559 ± 94 N at implantation, indicating relatively rapid development of the strength of the tendon graft-bone tunnel interface ($P < 0.0001$). The stiffness of the interface of 424 ± 327 N/mm after 4 weeks of implantation was similar to the stiffness of the complex of 297 ± 77 N/mm at implantation, indicating very rapid development of the stiffness of the tendon graft-bone tunnel interface ($P = 0.3032$).

Contribution of the Fixation Device after 4 Weeks of Implantation

The bioresorbable interference screw contributed less strength and stiffness after 4 weeks of implantation than at implantation. The strength contributed by the bioresorbable interference screw of 26 ± 118 N after 4 weeks of implantation was only 6% of the strength of the complex of 423 ± 93 N at implantation ($P = 0.0001$), indicating that the interference screw lost almost all of the grip on the tendon graft. The stiffness contributed by the bioresorbable interference screw of 94 ± 116 N/mm after 4 weeks of implantation was only 24% of the stiffness of the complex of 387 ± 101 N/mm at implantation ($P = 0.0001$), indicating that the interference screw contributed significantly less stiffness.

The WasherLoc contributed less strength but comparable stiffness after 4 weeks of implantation than at implantation. The strength contributed by the WasherLoc after 4 weeks of implantation of 211 ± 216 N was 38% of the strength of the complex of 559 ± 94 N at implantation ($P = 0.002$), indicating that the spiked washer lost some of the grip on the tendon. The stiffness contributed by the WasherLoc of 277 ± 332 N/mm after 4 weeks of implantation was 93% of the stiffness of the complex of 297 ± 77 N/mm at implantation ($P = 0.87$), indicating that the WasherLoc continued to contribute comparable stiffness.

DISCUSSION

Although the strength and stiffness of the complex at implantation have been measured for a variety of fixation methods,[6,12,13,18,21,22] little information is available about how the first few weeks of implantation affect the strength and stiffness of the complex. Our study showed that the strength and stiffness of the complex deteriorated after 4 weeks of implantation for one fixation device, but was either maintained or improved for the other fixation device. Furthermore, the development of the tendon graft-bone tunnel interface during the first 4 weeks of implantation was slow for one fixation device and more rapid for the other. Finally, both fixation devices contributed less strength, and the bioresorbable interference screw contributed less stiffness, after 4 weeks of implantation than at implantation. Before interpreting these results, several methods issues should be discussed.

Methods Issues

One methods issue was the choice of the two fixation devices, the bioresorbable interference screw and Washer-Loc, instead of other fixation devices. One reason these two fixation devices were selected is that the first few weeks of implantation were expected to have different effects on the strength and stiffness of the complex for each of these devices. Different effects were expected because the two devices compress different lengths of the tendon graft, grip the graft differently, and purchase bone of different quality.[13] For example, the bioresorbable interference screw compresses the tendon graft along the entire length of the bone tunnel, uses friction to grip the tendon graft, and purchases the weak cancellous bone compared with cortical bone, which is 30 times stronger.[2] Compression of the tendon graft along the length of the tunnel either may enhance the attachment of the tendon to the bone tunnel[15] or may interfere with the attachment because the screw prevents circumferential contact of the tendon graft to the wall of the bone tunnel. In contrast, the WasherLoc compresses the tendon graft only at the distal end of the bone tunnel, uses 13 penetrating spikes to grip the tendon graft, and purchases strong cortical bone.[13] Fixation of the tendon graft at the distal end may enhance the attachment by allowing circumferential contact of the tendon graft to the wall of the bone tunnel.

Another reason that these fixation devices were selected is because they are both commonly used to fix hamstring ACL grafts in humans. Their common use is due in part to the fact that both devices rarely either cause irritation or require removal because they are recessed inside the tunnel.[4, 11]

A second methods issue was the decision to use a 7-mm diameter tibial tunnel in the ovine tibia, which is relatively large compared with the tibial tunnel made in a human tibia. It is unlikely that the relatively larger diameter tibial tunnel adversely affected the fixation of the interference screw more than the WasherLoc for the following two reasons. First, the tibial tunnel was dilated in 0.5-mm increments from 6 to 7 mm, a technique that is recommended to improve the fixation of the interference screw.[10, 22] Tunnel dilation was not performed with the WasherLoc. Second, the strength (423 N) and stiffness (387 N/mm) of the complex in ovine tibia with bioresorbable interference screw fixation at implantation was greater than the strength (350 N) and greater than the stiffness (229 N/mm) of the complex in human tibia at implantation.[13] In contrast, the strength (559 N) and stiffness (297 N/mm) of the complex with WasherLoc fixation in ovine tibia at implantation was less than the strength (905 N) and similar to the stiffness (273 N/mm) of the complex in human tibia at implantation.[13] We do not believe that the 7-mm diameter tibial tunnel adversely affected the performance of the bioresorbable interference screw; in contrast, it was more likely that the larger diameter tibial tunnel adversely affected the performance of the WasherLoc.

A third methods issue was the decision to use a slightly undersized bioresorbable interference screw with a diameter that matched the diameter of the tunnel rather than 1 mm larger, as is recommended for human tibia.[3] In our study, the undersized interference screw was necessary because a larger diameter screw was difficult to insert in ovine bone because of the relatively higher density of ovine tibia compared with human tibia.[1] Even though we were forced to use an undersized screw, the strength (423 N) and stiffness (387 N/mm) of the complex in ovine tibia at implantation was substantially greater than the strength (350 N) and stiffness (229 N/mm) of the complex in human tibia at implantation.[13] The slightly undersized bioresorbable interference screw provided strong, stiff fixation in the ovine tibia at implantation and did not affect the conclusions of our study.

A fourth issue was the decision to determine the strength and stiffness of the complex at only one time interval after implantation, specifically after 4 weeks of implantation. The decision to test at this time interval was based on a canine model that showed that the failure mode changes from pullout of the tendon from the bone tunnel to rupture of the tendon outside the tunnel at about 4 weeks of implantation.[16, 17] In our study, pullout of the tendon from the bone tunnel was the predominant failure mode (87%, 27 of 31 specimens); however, even after 4 weeks of implantation 4 complexes (13%) failed by tendon rupture outside the tunnel. Because the incidence of tendon rupture increases with time,[16, 17] and testing 6 or 8 weeks after implantation would not have allowed the strength and stiffness of the complex to be evaluated, the decision not to test specimens more than after 4 weeks of implantation prevented injudicious and wasteful use of animals.

A fifth issue was that removal of the fixation device to test the tendon graft-bone tunnel interface may have disrupted some of the attachment of the tendon graft to the bone tunnel and, hence, led to the strength and stiffness of the interface being underestimated. Underestimating the strength and stiffness of the tendon graft-bone tunnel interface would cause a concomitant overestimation in the contribution of the fixation device to the strength and stiffness of the complex after 4 weeks of implantation. The underestimation/overestimation error may have been greater for fixation with the bioresorbable interference screw than with the WasherLoc because the interference screw gripped the tendon graft along the entire length of the bone tunnel. Our data suggest that this error was small for the bioresorbable interference screw because the strength of the complex after 4 weeks of implantation (158 N) was similar to the strength of the tendon graft-bone tunnel interface (132 N), indicating that removal of the screw did not substantially disrupt the interface.

The final methods issue was the decision to omit histologic evaluation of the healing of the tendon graft-bone tunnel-fixation device interface. Histologic evaluation can detect qualitative differences in the healing of a tendon graft in a tunnel[16, 17] and may have provided insight as to why the strength and stiffness deteriorated after 4 weeks of implantation with the bioresorbable interference screw and why the stiffness improved after 4 weeks of implantation with the WasherLoc. However, since the purpose of

our study was to quantify the strength and stiffness of the complex and tendon graft-bone tunnel interface, the omission of qualitative information from histologic evaluation does not compromise the conclusions of our study.

Interpretation of Results

The most important finding from our study is that the strength and stiffness of the complex measured after implantation are not the same as those measured at implantation, and may either deteriorate or improve, depending on the type of fixation device. For the bioresorbable interference screw, both the strength and stiffness of the complex deteriorated after implantation. For the WasherLoc, the strength of the complex was maintained and the stiffness improved after implantation. Because the change in strength and stiffness during implantation was so different for the two fixation devices, it is unjustified to use in vitro tests of ACL fixation methods to predict their effectiveness in humans after implantation. Instead, in vitro cadaveric tests should have a more limited role, and be used to evaluate whether a fixation device has the potential to be effective. Our results indicate that clinical studies and not in vitro studies should be used to determine the effectiveness of a fixation device.

Another important finding of our study is that the tendon graft-bone tunnel interface is not fully developed after 4 weeks of implantation. The interface developed slowly with the bioresorbable interference screw because the strength and stiffness of the interface were only 31% and 36%, respectively, of the strength and stiffness of the complex at implantation. On the other hand, the interface developed relatively rapidly with the spiked screw and washer and screw because the strength and stiffness of the interface were 50% and 143%, respectively, of the strength and stiffness of the complex at implantation. Therefore, the rate of development of the tendon graft-bone tunnel interface after 4 weeks of implantation is different for the two fixation devices that were evaluated in this animal model.

One explanation for the slow development of the tendon graft-bone tunnel interface with the bioresorbable interference screw is that the screw may have interfered with the formation of the biologic bond. The strength of the interface between a tendon graft and bone tunnel increases as the surface area of the tunnel increases.[8, 16] There was about a 50% decrease in the surface area of the tunnel with bioresorbable interference screw fixation because the screw blocks contact between one side of the tendon graft and bone tunnel along the length of the tunnel. The decrease in surface area was less with WasherLoc fixation because the washer fixes the distal end of the tendon graft and not the entire length of the tendon graft in the tunnel.

These results suggest that the development of the tendon graft-bone tunnel interface after implantation might be promoted by using fixation devices that grip the tendon graft either at the end or outside of the bone tunnel, and not by using fixation devices that grip the tendon graft along the length of the bone tunnel. Maximizing tendon

length within a bone tunnel does maximize the strength of a tendon-bone tunnel complex at 6 weeks.[8] The conjecture that direct contact between the graft and bone by interference screw fixation is important for the early formation of the tendon graft-bone tunnel interface[15] is not supported by our study; in fact, the opposite is true.

A second explanation for the slow development of the tendon graft-bone tunnel interface with the interference screw is that there was a different mechanism of tendon graft-tunnel attachment for the two fixation devices. Weiler et al.[20] have shown, using a tendon ACL reconstruction in sheep fixed with a biodegradable interference screw, that the tendon graft heals directly to bone without a fibrous interzone and requires 3 to 6 months to develop. In contrast, a tendon graft fixed outside the tunnel to periosteum with suture heals more rapidly, with scar formation in 4 weeks, and matures into an indirect insertion with Sharpey-like fibers by 3 to 6 months.[5, 7, 16, 19]

In our study, we did not determine whether the tendon graft-tunnel interface formed by a direct or indirect mechanism. However, if the tendon graft-tunnel interface formed directly with the bioresorbable interference screw and indirectly with the WasherLoc, then one may conclude, at least after 4 weeks of implantation, that direct tendon graft-tunnel healing has inferior structural properties than indirect healing. This is in contrast to the assertion by Weiler et al.[20] that interference-fit fixation is beneficial for tendon-to-bone incorporation by leading to the development of a direct type of ligament insertion.

A third explanation for the slow development of the tendon graft-bone tunnel interface with the interference screw is that the blood supply to the tendon graft may have been different for the two fixation devices. The bioresorbable interference screw compressed the tendon graft along the length of the tunnel, which may have prevented the ingrowth of blood vessels along the entire length of the tendon graft. The WasherLoc compressed the tendon graft at the distal end of the tunnel, which may have allowed circumferential ingrowth of blood vessels in the 2 cm of the tendon graft not compressed by the implant.

Avoiding deterioration in the strength and stiffness of the complex after implantation is important in ACL reconstruction because large forces in the graft during both the early postoperative period and aggressive rehabilitation may jeopardize the fixation of the graft[14] and cause a loss of knee stability. It remains to be determined whether aggressive, brace-free rehabilitation can be used with bioresorbable interference screw fixation of hamstring grafts without compromising the stability of the knee.[21] Our results suggest that an aggressive rehabilitation program should be used cautiously with bioresorbable interference screw fixation because of the slow development of the tendon graft-bone tunnel interface and a minimal contribution of strength and stiffness by the interference screw after 4 weeks of implantation. This opinion is supported by a clinical study that used a nonaggressive, braced rehabilitation program and still showed a high incidence of instability with bioresorbable interference screw fixation at 2 years. Although the author reported

favorable results in terms of patient satisfaction with improved functional outcomes, maximum manual KT arthrometer measurements revealed that 65% of the patients had greater than 3 mm side-to-side difference, with 24% having greater than 5 mm side-to-side difference at 2 years.[4]

SUMMARY

As far as we know, our study is the first one to quantify how the first 4 weeks of implantation affect the healing of a tendon graft in a bone tunnel. Our study showed that the strength and stiffness after 4 weeks of implantation are not the same as those at implantation, and that the changes in strength and stiffness during implantation are very different for two commonly used fixation devices. These findings suggest that clinical studies should be used to determine the effectiveness of a fixation device rather than in vitro studies in animal or human cadaveric bone. On the basis of our observations, we recommend that clinicians consider the effect that the first few weeks of implantation have on the early healing of a tendon graft in a bone tunnel for a particular fixation device when deciding whether to use aggressive rehabilitation after reconstruction of a knee with a torn ACL.

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