Hamstring Tendon Fixation Using Interference Screws: A Biomechanical Study in Calf Tibial Bone

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Summary: It has recently been shown that graft fixation close to the ACL insertion site is optimal in order to increase anterior knee stability. Hamstring tendon fixation using interference screws offers this possibility and a round threaded titanium interference screw has been previously developed. The use of a round threaded biodegradable interference screw may be equivalent. In addition, to increase initial fixation strength, graft harvest with a distally attached bone plug may be advantageous, but biomechanical data do not exist. This study compares the initial pullout force, stiffness of fixation, and failure modes of three strand semitendinosus grafts in 36 proximal calf tibiae using either biodegradable poly-(D,L-lactide) (Sysorb; Sulzer Orthopaedics Ltd, Münsingen, Switzerland) or round threaded titanium (RCI; Smith & Nephew DonJoy, Carlsbad, CA) interference screws, harvested either without (biodegradable: group I, titanium III) or with (biodegradable: group II, titanium: group IV) attached tibial bone plugs. Maximum pullout force in group I (507 $\pm$ 93 N) was significantly higher than in group III (419 $\pm$ 77 N). Pullout force of bone plug fixation was significantly higher than that of direct tendon fixation (717 $\pm$ 90 N in group II and 602 $\pm$ 117 N in group IV). Pullout force of biodegradable fixation was significantly higher in both settings. These results indicate that initial pullout force of hamstring-tendon graft interference screw fixation can be increased by using a biodegradable interference screw. In addition, initial pullout force of hamstring-tendon graft fixation with an interference screw can be greatly increased by harvesting the graft with its distally attached tibial bone plug. **Key Words:** Anterior cruciate ligament—Hamstring tendons—Biodegradable—Poly-(D,L-lactide)—Interference screw—Pullout force.

Reconstruction of the anterior cruciate ligament (ACL)–deficient knee using the central third of the patellar tendon is widely accepted. Interference screw fixation leads to strong initial fixation and early osseous integration of the bone–patellar tendon–bone (BPTB) graft,[1,2] thereby permitting an early and aggressive rehabilitation program and an accelerated postoperative recovery.[3-5] However, use of the BPTB graft is associated with an increase in postoperative dysfunction of the extensor mechanism.[6-8] In addition to a high incidence of patellofemoral problems that can ocurr in up to 50% of cases, complications such as patellar fracture or patellar tendon rupture have also been reported.[6-19]

To reduce donor site morbidity, several investigators have recommended the use of hamstring-tendon grafts.[19-24] However, the graft strength and initial fixation strength of these grafts are considered by some to be too low to allow for accelerated postoperative rehabilitation. The mechanical properties of the graft and its fixation have been improved using multiple looped hamstring tendons and several soft-tissue fixa-

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tion techniques to bone.[25-29] Currently, extra-articular graft fixation with soft-tissue washers is the hamstring-tendon graft fiaxtion technique that provides the highest fixation strength, even higher than that provided by BPTB graft fixation with interference screws.[28] However, the stiffness of this construct is far below that of the intact ACL or the BPTB graft.

It has been shown that failure load and stiffness of the multiple looped hamstring-tendon graft itself are favorable,[25,30,31] so that it is reasonable to assume that the extra-articular fixation techniques of hamstring-tendon grafts, such as the use of soft-tissue washers, staples, sutures over a post,and the Endobutton (Acufex Microsurgical, Andover, MA), may be responsible for the construct's inferior elastic properties because of the increase in construct length and the influence of suture material.[32,33] However, the inferior biomechanical properties of extra-articular or suture fixation may explain the higher incidence of anterior knee laxity in ACL reconstructed knees using hamstring tendons compared with the BPTB graft.[34-36] These observations led to a recommendation by some investigators to use the hamstring-tendon graft in acutely injured knees with only moderate instability.[33,35]

Recently, it has been shown that the fixation level of an ACL graft has a strong influence on anterior knee stability [37] and that anatomic graft fixation at the original ACL insertion site (aperture fixation) is the most preferable.[33,37-41] Given these arguments, it is reasonable to assume that the biomechanical properties of conventional hamstring-tendon graft fixation could be improved if anatomic fixation is used. In addition, anatomic fixation would eleminate tunnel enlargement associated with nonanatomic fixation sites and may also reduce wear-related graft damage.[42-44]

Special operative techniques using interference screw fixation have been investigated to facilitate and possibly improve hamstring graft aperture fixation. These include attaching bone plugs to the free hamstring-tendon graft and harvesting the tendons with their distally attached tibial bone plugs.[38,41,45-48] In particular, Morgan[47] made a significant contribution toward improving hamstring-tendon graft aperture fixation by introducing his ''all-inside'' technique for ACL reconstruction using a bone-hamstring-bone composite graft.[47] Another recent technique describes the use of metal interference screws for direct hamstring tendon fixation to bone without using bone plugs,[39] but conventional metal interference screws still bare the risk of graft laceration. To reduce that risk, a round threaded titanium interference screw has been developed (RCI [round cannulated interference] screw; Smith & Nephew DonJoy, Calsbad, CA).

The advantages of biodegradable interferene screws over their metal analogs that have led to the increased use of these implants in BPTB graft fixation include undistorted magnetic resonance imaging, easier revision surgery, and a decreased potential of graft laceration.[49-56] Recently, a round threaded biodegradable interference screw was developed and an ''all-inside'' hamstring graft fixation technique using direct biodegradable interference screw fixation was introduced [45]. Significantely, however, the biomechanical properties of this new setup have not yet been investigated.

The first objective of the present study was to compare the fixation properties of round threaded biodegradable and titanium interference screw used to fixate a three-strand semitendinosus tendon graft. The factors studied included the inital pullout force, stiffness of fixation, screw insertion torque, and failure modes of biodegradable and titanium screw fixation. The second objective of this study was to compare the fixation properties of a three-strand semitendinousus tendon graft with and without its distally attached tibial bone plug. We designed a standardized experiment to compare these groups in a simulation of femoral semitendinosus tendon graft fixation in calf tibial bone.

MATERIALS AND METHODS

Sample Size and Study Groups

Nine specimens were tested in each group. After specimen preparation and graft insertion, interference screws were chosen by lot to reduce observer-dependent variability. Four groups were assigned:

I Direct biodegradable screw fixation without bone plug
II Biodegradable screw fixation with attached tibial bone plug
III Direct titanium screw fixation without bone plug
IV Titanium screw fixation with attached tibial bone plug

Graft Harvest and Preparation

The semitendinosus tendon grafts were harvested from fresh human cadavers (mean age, 53.1 years; range, 33 to 85 years), while the knee was externally rotated and flexed to 60°. A 4-cm longitudinal incision was made beginning 2-cm distal and 1-cm medial to the tibial tuberosity. The semitendinosus tendon was identified under the sartorius fascia and the tendon harvested using an open tendon stripper. The graft was either dissected at its distal end or the distal end was freed up to its bony insertion. A 10-mm helical tube saw (HTS-Osteotome, Kaltec; Edwardstown, Australia) was used to harvest a 10- to 15-mm long bone plug (Fig 1).[45]

All tendons were folded to one third of their original length. In groups I and III a suture attached to the free end of the graft was pierced through the axilla of the tendon loop. The three strands were sewn to each other using a baseball stitch (Fig 2) while maintaining constant tension on all three strands. In groups II and IV, the tendon loop was folded over the top of the plug and the loop was secured to the bone plug using a 3-0 suture (Fig 2).

Interference Screws

The biodegradable interference screw (Sysorb; Sulzer Orthopaedics Ltd, Münsingen, Switzerland) is made from pure poly-(D,L-lactide) (Resomer R 208; Boehringer Ingelheim KG, Ingelheim, Germany). This material is amorphous, maintains its mechanical strength in vitro for over 20 weeks and degrades within 1 year.[57,58] The screw is 23 mm long (thread diameter, 8 mm; core diameter, 6.2 mm) and its thread pitch is 3 mm (Fig 3A). The screw and the driver are characterized by a specially designed turbine-like shape with six curved blades, which increases the material resistance against shear force thereby enlarging torque at failure.[59]

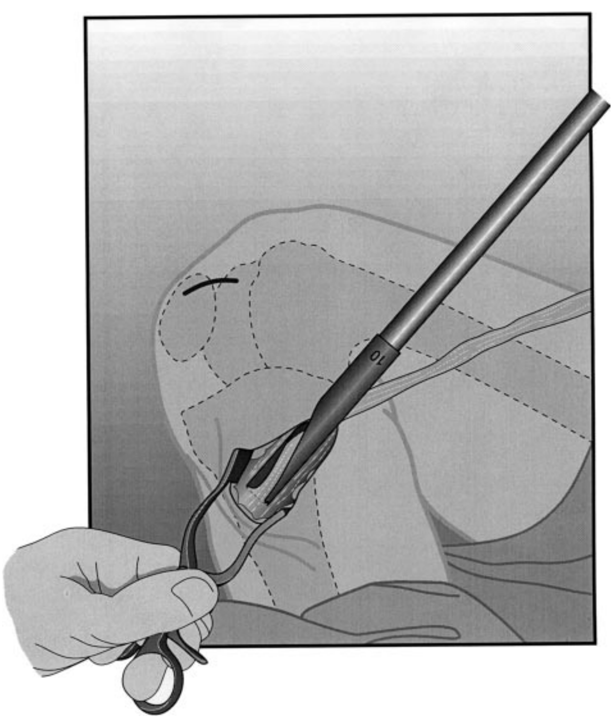

FIGURE 1. Tendon harvest with attached tibial bone plug using the 10-mm Helical Tube Saw (HTS-Osteotome). (Reprinted with permission.[45])

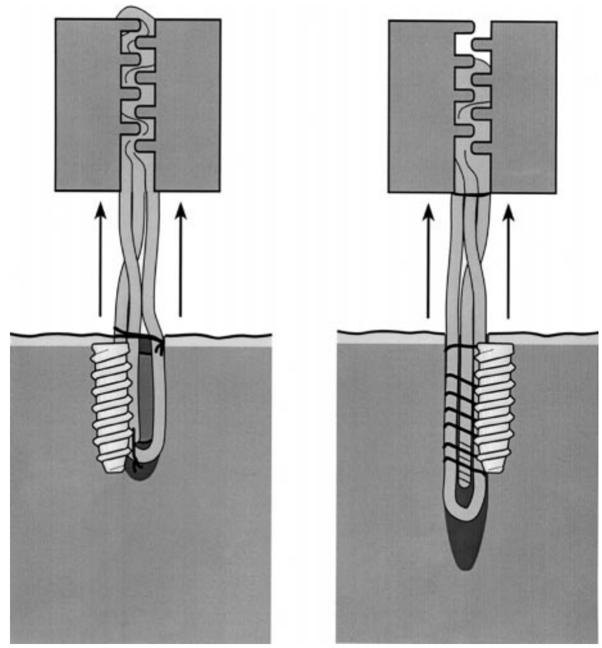

FIGURE 2. Right: Direct graft fixation using the biodegradable screw. The three strands were sewn to each other using a baseball stitch. Left: Bone plug interference screw fixation of the three-strand semitendinosus tendon graft using the biodegradable screw.

The RCI screw is 25 mm long (thread diameter, 7 mm; core diameter, 4 mm; head diameter, 8 mm) and its thread pitch is 2.25 mm. Its surface is polished (Fig 3B).

Biomechanical Model and Graft Fixation

In this study, fresh bovine proximal tibiae (age, 22 to 24 weeks) were used to simulate young human femoral bone density, partially due to findings described by Brown et al.[60] In addition, we found that trabecular bone density in the subchondral area of the graft insertion site of bovine knees is similar to that of human cortical bone. To refine the model, quantitative computed tomography of a proximal calf tibia was performed and a reproducible location was determined for the graft and screw insertion that had an approximate apparent trabecular bone density of 0.8 g/cm^3,[59,61] similar to that expected in young humans.[62]

Thirty-six proximal calf tibiae were procured from a local butcher. The specimen were stored at −20°C and were thawed for 12 hours before graft preparation and insertion. Proximal tibiae were cut 5.5 cm distally to the intercondylar spine and bone tunnels were prepared using the serial dilation technique described by

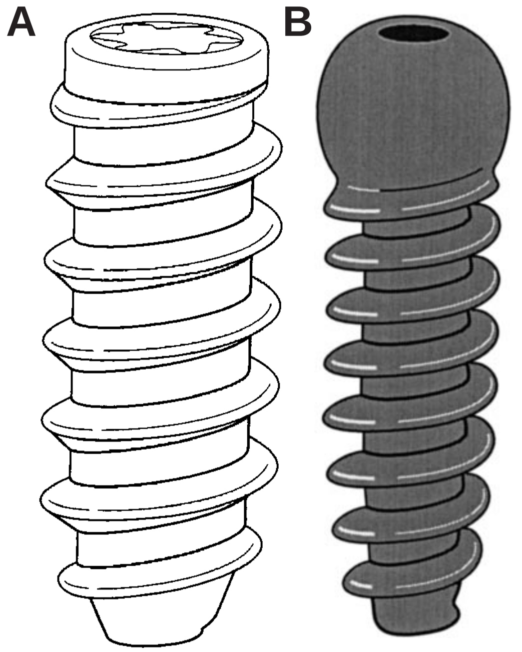

FIGURE 3. (A) Round threaded poly-(D,L-lactide) interference screw (Sysorb). (B) Round threaded titanium interference screw (RCI).

Johnson and van Dyk.[49] Dilators (Instrument Makar Inc, Okemos, MI, and Sulzer Orthopaedics Ltd) were inserted into the cancellous bone from the proximal direction. Bone tunnels for groups II and IV were dilated until a diameter of 10 mm and a length of 20 mm was reached. Tunnels in groups I and III were dilated to the smallest possible graft diameter (7 to 9 mm) previously measured in the sizing holes of a working station and a length of 25 mm. To minimize the influence of additional variables, the fluted reamer, which was initially recommended by the manufacturer to enlarge the tunnel entrance for RCI screw fixation in order to countersink the 8 mm screw, was not used.

Grafts in groups II and IV were inserted by pushing the bone plug with an 2-mm threaded K-wire, and grafts in groups I and III were pulled with a strong suture that had been previously passed through the tendon loop. To minimize possible graft laceration in groups I and III, a tunnel notcher was used (Linvatec Corp, Largo, FL) to create a small notch as a guide for screw insertion, thus preventing clockwise rotation of the screw around the tendon. Screws were inserted using a digitally controlled torque screw driver (Wera Werk; Hermann Werner GmbH & Co, Wuppertal, Germany) while recording peak insertion torque. The torque screw driver was scaled from 0.035 to 3.5 Nm in increments of 0.001 Nm. The screws were always inserted in the same position with respect to the bone tunnel (Fig 4).

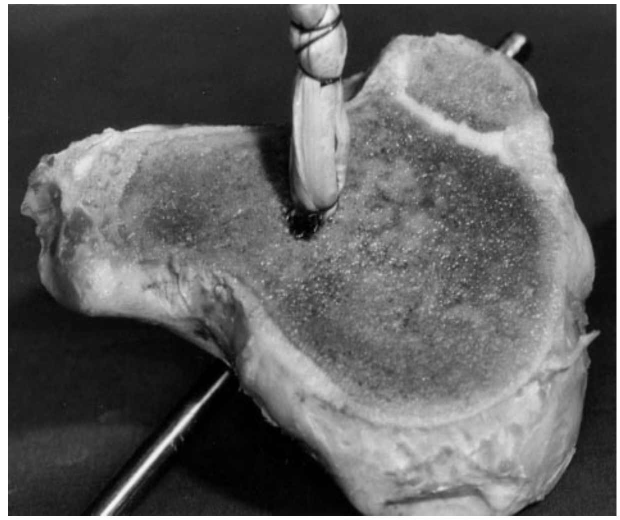

FIGURE 4. Direct graft fixation using the biodegradable screw. Screws were always inserted in the same position with respect to the bone tunnel.

Biomechanical Testing and Data Analysis

Specimens were kept moist with saline spray during all preparations and testing. Holes were drilled through the intercondylar eminentia perpendicular to the long axis of the bone tunnel, 8-mm steel bolts were passed through the drillholes, and the specimens were mounted into a material testing machine (Zwick 1455; Zwick GmbH, Ulm, Germany). Free graft ends were secured into a custom-made clamping device, leaving 25 mm of the graft length between the bone surface and the clamp (Fig 5). A preload of 10 N was applied and the construct was loaded until failure under displacement

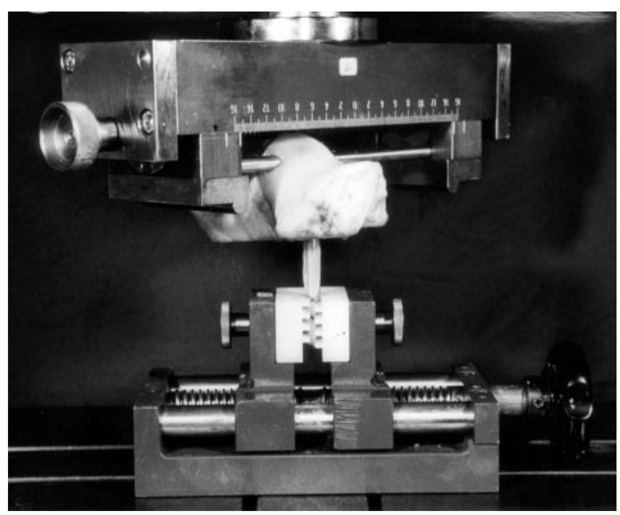

FIGURE 5. Construct mounted in material testing machine with the free graft end secured into a custom-made clamping device leaving a 25-mm graft length between the bone surface and the clamp.

control of 1 mm/s. The load was applied parallel to the long axis of the bone tunnel. Failure mode was recorded (graft pullout, graft rupture at the screw insertion site, midsubstance rupture) and maximum pullout force and stiffness of fixation were determined from the load-displacement curve. The four groups were compared using the Mann-Whitney U Wilcoxon rank sum test. Linear regression analysis was performed between maximum pullout force and screw insertion torque.

RESULTS

Mean initial pullout force was 507 ± 93 N in group I and 717 ± 90 N in group II ($P = .001$) and 419 ± 77 N in groups III and 602 ± 117 N group IV ($P = .002$). Regardless of whether or not the bone plug was harvested, mean initial pullout force of biodegradable screw fixation was significantly higher than that of titanium screw (groups I and III: $P = .038$, groups II and IV: $P = .031$).

Stiffness was 57.9 ± 13.8 N/mm in group I and significantly higher than the 39.7 ± 10.9 N/mm measured in group III ($P = .012$). There was no significant difference in stiffness of fixation between the groups II and IV. There was no significant difference in insertion torque between any of the groups (Table 1). Only in group I did linear regression analysis reveal a significant linear correlation between pullout force and screw insertion torque, with a coefficient of determination of 0.68 ($P = .006$) (Fig 6).

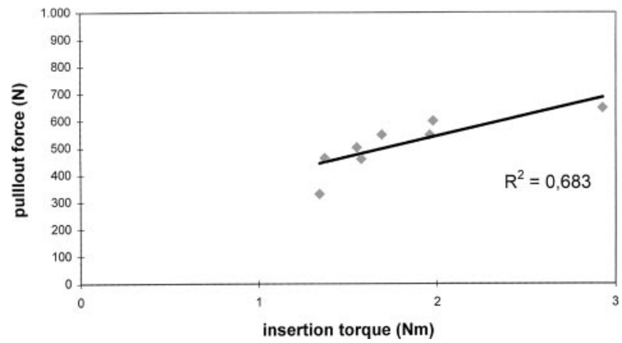

FIGURE 6. Correlation between pullout force and insertion torque for the biodegradable direct tendon fixation.

Midsubstance graft failure was not observed in any group. There was no graft rupture at the screw insertion site in the biodegradable groups, whereas there were 3 and 2 graft ruptures in groups II and IV, respectively, caused by tissue laceration at the screw tendon interface. Inspection of the grafts in groups II and IV after testing revealed that all bone plugs were still intact. No screw breakage or deformity during insertion or after testing was observed in groups I and III.

DISCUSSION

The first objective of these experiments was to compare initial fixation strength of round threaded biodegradable interference screws made from poly-(D,L-lactide) and round threaded titanium screws.

TABLE 1. *Results for Pullout*

	Biodegradable Direct	Biodegradable Bone Plug	Titanium Direct	Titanium Bone Plug
	Group I (n = 9)	Group II (n = 9)	Group III (n = 9)	Group IV (n = 9)
Maximum pullout force (N)	507*†	717‡†	419*§	602‡§
SD	±93	±90	±77	±117
Range (N)	332-647	600-821	316-558	467-770
Failure mode				
Rupture (pullout force range in N)	—	—	3 (411-491)	2 (605-770)
Pullout (pullout force range in N)	9 (332-647)	9 (600-821)	6 (316-558)	7 (467-701)
Stiffness (N/mm)	57.9‖	54.6	39.7‖	45.8
SD	±13.8	±14.9	±10.9	±8.4
Screw insertion torque (Nm)	1.75	1.63	2.05	1.79
SD	±0.50	±0.45	±0.43	±0.46
Mean tunnel diameter (range)	7.22 mm (7-9)	10 mm	7.78 mm (7-9)	10 mm
Width of proximal tibia (cm)	8.27	8.14	8.54	8.14
SD	±0.73	±0.66	±0.56	±0.82

*$P = .038$.
†$P = .001$.
‡$P = .031$.
§$P = .002$.
‖$P = .012$.

Results show that the initial pullout force of hamstring-tendon graft interference screw fixation is higher when a biodegradable interference screw rather than a round threaded titanium screw is used. In addition to higher pullout force, the biodegradable screw also showed a significantly higher stiffness of fixation compared with the titanium screw when the direct fixation method was used.

The higher pullout force and higher stiffness of fixation of the biodegradable screw may be a result of its surface texture, which might provide a better grip to the tendon tissue in contrast to the polished titanium surface. In addition, the stiffness gradient between the polymeric screw and the bone tendon construct may be lower than that of the titanium implant, resulting in a better transmission of the acting shear force. Furthermore, use of the titanium screw led to a high incidence of tendon ruptures caused by graft laceration at the screw insertion site, which strongly influences mean pullout force. However, previous studies in which RCI fixation of hamstring-tendon grafts has been investigated reported no such failure.[63,64] In these studies, elderly human cadaveric knees were used, the lower bone density of which may give more under compressive forces, thus protecting the tendon tissue against laceration. Therefore, the results of the present study suggest that RCI screw fixation still bares the risk of tendon laceration in younger patients.

The second objective of the present study was to compare initial fixation properties of direct and bone-plug fixation. Our data show that use of a construct of hamstring tendon with its distally attached tibial bone plug results in superior initial fixation strength. This may be important, particularly in improving the tibial graft fixation, which may be the weak link in direct interference screw fixation of a hamstring-tendon graft[63]

The initial graft fixation strength is one of the major limiting factors of the rehabilitation program in the immediate postoperative period before the graft is incorporated in its bony tunnels. Studies have indicated that the forces exerted on the graft fixation site during different activities range from 152 to 450 N.[65-70] Similarly, a recent study found that a BPTB graft could be loaded, depending on pretensioning, from 50 N to a maximum of 467 N in passive full extension.[71] These studies suggest that the pullout force of any graft fixation technique should exceed approximately 450 N to ensure a successful, early and aggressive rehabilitation program. However, complicating these requirements are the observations of Burkhart,[72] who calculated that the forces acting on a suture anchor are highly determined by the axis of the applied load. Therefore, one limitation of the present study is that pullout force was not tested by applying the load in a physiologically relevant direction. Steiner et al.[28] tested pullout force of various BPTB and hamstring-tendon graft fixation techniques under anterior tibial displacement with a knee flexion angle of 20°. Under these conditions, pullout forces are expected to be higher because additional shear forces may act on the graft fixation site and may increase graft fixation strength. However, our goal was to evaluate the fixation strength of different interference screws and, therefore, we adapted the experimental design to this question. Load application in the axis of the bone tunnel may transfer the highest forces directly to the screw fixation site and therefore represents a worst case scenario for a fixation technique.[73]

Taking the lower bone density and a different experimental design into account, our data in group III are consistent with the pullout force found in an investigation by the manufacturer of the RCI screw performed in elderly human cadaveric knees. They showed a maximum pullout force for the direct tendon fixation of 336 $\pm$ 59 N.[64] Using the RCI screw, Pinczewski et al.[74] developed a technique of quadrupled hamstring-tendon graft fixation and reported favorable midterm results in a series of 580 patients. Thus, we feel that all four tendon fixation techniques used in the present study provide sufficient initial fixation strength if the technique is performed properly. Using a biodegradable interference screw, we were even able to improve initial pullout force. In addition to this advantage, biodegradable interference screws do not impair magnetic resonance imaging and do not compromise revision surgery, a distinct advantage for the patient.

The results in groups II and IV of our study indicate mean pullout force for bone plug fixation substantially higher than those reported by Liu et al.,[46] who analyzed interference screw fixation of hamstring-tendon grafts using porcine knees. They found a mean pullout force of 354 $\pm$ 92 N for a bone-hamstring-bone composite graft using conventional metal interference screws. These differing results might be attributable to the fact that they inserted the composite graft with 8-mm bone plugs into 10-mm bone tunnels, wheras in the present study, 10-mm bone plugs were inserted into 10-mm bone tunnels. The bone plugs were oval shaped to allow the tendon to be folded over the plug, thus eliminating the necessity to increase the tunnel diameter. In addition, differences in the animal specimen and the experimental setting in the two studies may also have affected the results.

It is unlikely that the difference in screw diameter between the biodegradable and the titanium screws used in this study had a large effect on pullout force. Although some studies have shown such a dependance for BPTB graft fixation,[60,75-79] Shapiro et al.[79] showed that the biomechanical advantages of a 9-mm versus a 7-mm screw are minimal and Butler et al.[76] suggested that the influence of screw diameter affects pullout force only if the interference gap exceeds 3 mm. While these reports investigated fixation strength in BPTB graft fixation, no data exist about the influence of screw diameter on direct hamstring-tendon graft fixation. By evaluating a bone-hamstring-bone composite graft using 7- and 9-mm interference screws, Liu et al.[46] found no relationship between screw diameter and hamstring-tendon graft fixation. In the present study, we compared a 7-mm titanium with a 8-mm biodegradable screw. However, the head diameter of the titanium screw was 8 mm and the fluted reamer to increase the tunnel entrance diameter was not used, which may increase fixation strength. An additional aspect of screw design, thread height (thread diameter minus core diameter), has been recently shown to influence pullout force in BPTB graft fixation,[59] and might also affect the results in the present study. The thread height of the titanium screw was 3 mm and that of the biodegradable screw was 1.8 mm, which would be expected to be an advantage for the titanium screw.

In the present study, a positive linear correlation between screw insertion torque and pullout force was found in group I ($r^2 = .68$), suggesting that screw insertion torque may be useful as a positive predictor for pullout force when using the poly-(D,L-lactide) screw for direct tendon fixation. This correlation is higher then those previously reported for metal screws in BPTB graft fixation; Brown et al.[75] showed a moderate positive correlation ($r^2 = .45$) between screw insertion torque and pullout force for 5.5-mm, 7-mm, and 9-mm interference screws in elderly human cadaveric knees; whereas Brown et al.[60] found a moderate positive correlation ($r^2 = .44$) for 7-mm and 9-mm screws in young and elderly human cadaveric knees and in bovine knees. We did not find a positive linear correlation in groups II, III, and IV, possibly because of the different failure modes encountered and the additional variable of bone plug fixation.

Because the choice of test specimen is known to have a strong influence on biomechanical data when testing ACL fixation techniques, we selected a bovine model, partially because of the findings of Brown et al.[60] who found that bovine knees provide a more clinically relevant model of a young, human knee than do elderly human cadaveric knees. In addition, a bovine model is convenient in that a supply of relatively uniform specimens to ensure reproducible data is available. We further refined the bovine model by isolating a reproducible location for graft insertion, with an expected femoral bone density,[59,61] similar to that expected in young humans—0.8 g/cm^3.[62]

From a clinical perspective, the techniques presented in this report improve hamstring-tendon fixation by offering a reliable initial fixation strength at the anatomic site of the ACL. In a biomechanical model, Ishibashi et al.[37] reported stability results for a series of ACL reconstructed knees by measuring anterior tibial displacement at different flexion angles. In their study, BPTB grafts were fixed at the anatomic site, the mid-tibial tunnel and outside the tibial tunnel. They found that anatomic proximal graft fixation achieves the most stable results and should, therefore, be recommended.

Some questions still remain regarding the viability of direct tendon-to-bone fixation. It is still not known whether there is any relevant graft fixation slippage or decrease of fixation strength resulting from the viscoelastic properties of the construct, which might lead to fixation failure during postoperative rehabilitation.[46,80] Furthermore, it is still unclear how to customize weight bearing during rehabilitation programs, which are dependent on the time needed for tendon healing under interference screw compression.

CONCLUSION

Our data suggest that initial interference screw fixation of hamstring tendons in ACL reconstruction is better when round threaded biodegradable interference screws rather than round threaded titanium screws are used. Further research into tendon-to-bone healing with direct interference screw fixation is encouraged to confirm the potential advantages of this method.

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