Components of laxity in interference fit fixation of quadrupled hamstring grafts

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ABSTRACT – We tested in vitro 15 Poly-L-lactic acid and 14 titanium interference screws in male human cadaver tibia-hamstring constructs. Elongation of the graft, displacement of the screw in the tibial tunnel, and slippage at the graft/screw interface were measured as outcomes with an infrared optical system.

All constructs failed by slippage of the graft past the interference screw. On average, graft slippage accounted for 92% of total construct laxity at 5mm total construct elongation, whereas permanent stretching of the mid-substance of the graft accounted for only 8%. Movement of the interference screw in the tibial canal was minimal, averaging 0.01 (0–0.5) mm at construct failure.

Inadequacy of isolated tibial interference screw fixation of soft tissue grafts may be overcome if early failure at the graft/screw interface is prevented.

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Experience with reconstruction of the ACL-deficient knee has confirmed that quadrupled autografts harvested from the semitendinosus and gracilis tendons provide the required strength and stiffness with minimal morbidity of the donor site (Otero and Hutcheson 1993, Aglietti et al. 1994, Maeda et al. 1996, Frank and Jackson 1997, Corry et al. 1999, Hamner et al. 1999, Wilson et al. 1999). Many methods of attachment of the graft to the tibia have been proposed, but interference screw fixation (Caborn et al. 1998, Stadelmaier et al. 1999, Fu et al. 2000) has become widely adopted because the surgeon can minimize the free length of the graft, thereby increasing its stiffness and reducing its motion in the tibial tunnel (Steiner et al. 1994, Ishibashi et al. 1997, Weiler et al. 1998). However, tibial interference fixation of soft tissue grafts may be the weak link in the ACL reconstructed knee before the occurrence of graft osteointegration around 3 months postoperatively (Rodeo et al. 1993, Pinczewski et al. 1997, Scranton et al. 1998), as failure loads in human tibiae average 200–350N (Caborn et al. 1998, Weiler et al. 1998, Magen et al. 1999, Stadelmaier et al. 1999).

Reports on failure loads of fixation are generally derived from mechanical testing system data on total construct displacement (Steiner et al. 1994, Caborn et al. 1998, Weiler et al. 1998, Magen et al. 1999, Stadelmaier et al. 1999). However, to address the problem of fixation failure and residual laxity of the construct better, it seems necessary to break down total construct displacement into its three possible components contributing to laxity, i.e., elongation of the graft, migration of the screw in the tibial tunnel, and slippage of the graft past the screw/bone interface. This study was done to isolate and quantify the components of laxity in interference fixation of soft tissue grafts.

Material and methods

23 fresh-frozen male human lower extremities (without known bone pathology) from 14 individuals (mean age 52 (27–82) years) were used to test 15 Poly-L-lactic acid and 14 titanium interference screws in tibia-hamstring constructs. The 29 experimental units were each treated as an independent observation for the data analyses.

Quantitative computed tomograms (QCT) of each tibia were taken using a spiral CT (Picker PQ

5000, Helical System; Cleveland, OH) operating in bone algorithm mode (KV 120, MA 150, 1.25 pitch with a high resolution full field). 30 continuous axial slices (3 mm thickness) were obtained through the proximal tibia.

Each scan was done with a bone density phantom composed of known mixtures of hydroxyapatite and plastic (CIRS, Norfolk, VA) placed on top of the knee. In every axial slice, the average QCT attenuation of each hydroxyapatite phantom was determined. Slice specific linear regressions were used to convert the CT attenuation data to units of bone density, using the known densities of the hydroxyapatite phantom (Eriksson et al. 1988). An isosurface reconstruction of the tibia was created from the converted QCT data. In each computer model, the tibial tunnel was modeled as a virtual cylinder of 12 mm diameter and 30 mm length. This cylinder was superimposed on the reconstruction of the tibia. The starting point at the tibial plateau and the orientation (flexion/extension and axial rotation) of the virtual cylinder were set to match the orientation of the two tunnel sites in each tibia. The bone mineral content of the tissue in the virtual cylinder was then calculated by summing the densities of all volume elements in the tunnel site and then multiplying by the volume of the tunnel site.

Hamstring autografts, harvested using the gracilis and semitendinosus tendons, were prepared with standard surgical technique to form four-stranded cylindrical grafts. Each graft was pretensioned with 25 lbs (111 N) for 20 minutes before implantation (Fu et al. 2000).

Using a tibial targeting guide, two parallel tunnels (separation: 20 mm) were drilled over guide wires from the anteromedial aspect of the proximal tibia to the tibial plateau. The first tunnel was prepared by inserting a guide pin at a preset angle of 55° from a point about 4 cm distal to the anatomic insertion site of the ACL. A second guide pin was inserted at a preset angle of 55° from a point about 6 cm distal to the joint line (about 1 cm below pes anserinus and 2 cm medial to the midline of the tibial tubercle) to a point on the non-weightbearing area of the tibial plateau 2 cm posterior to the anatomic insertion site of the ACL.

The hamstring grafts were fixed with fully threaded interference screws of two designs: (a) RCI screws (Smith&Nephew Endoscopy Inc., Andover, MA), fabricated from titanium alloy, with a thread diameter of 7 mm or 9 mm and a thread length of 25 mm; the head size of the 7 mm RCI screw was 8 mm and (b) Poly-L-lactic acid (PLA) Bio-Interference screws (Arthrex, Naples, FL) with a thread diameter of 8 mm or 9 mm and a thread length of 28 mm.

Each tibia-graft specimen was assigned to one of the following four groups according to the diameter of the graft and the screw design:

Group A (n 7): 7 mm RCI screw; graft diameter 7.5 mm or smaller; anterior tunnel.

Group B (n 7): 9 mm RCI screw; graft diameter larger than 7.5 mm; anterior tunnel.

Group C (n 8): 8 mm PLA screw; graft diameter 7.5 mm or smaller; posterior tunnel.

Group D (n 7): 9 mm PLA screw; graft diameter larger than 7.5 mm; posterior tunnel.

30 mm of the unsutured, looped portion of the graft protruded from the proximal opening of the bone tunnel. The graft was secured with an interference screw anterior to the graft and advanced to the joint line. The torque exerted during placement and final tightening of each interference screw was recorded with a torque wrench (SO Tools Corp., Kenosha, WI). At the entrance of the tibial tunnel, the distal end of the graft was sutured to a spring-loaded sliding rod mounted on the tibia. This apparatus applied a preload of 5 N to the graft before testing to ensure that the sutures remained taut during loading. Movement of the graft distal to the tibial plateau was indicated by two reflectors attached to the sliding rod.

Immediately after preparation, mechanical tests were done on each specimen to measure (1) the resistance of each construct to the initiation of graft slippage under repetitive subfailure loading, and (2) the maximum load-carrying capacity of each construct. These tests were performed at room temperature with the tibia mounted in a customized jig in a servohydraulic mechanical testing machine (MTS Corp., Eden Prairie, MN). The looped portion of the graft was placed over a metal rod attached to the actuator of the testing machine with the loading axis aligned with the tibial tunnel. Each graft was loaded in tension at 25 N/sec to a peak value that was increased by 25 N per cycle from a starting load of 0 N. The construct was then unloaded

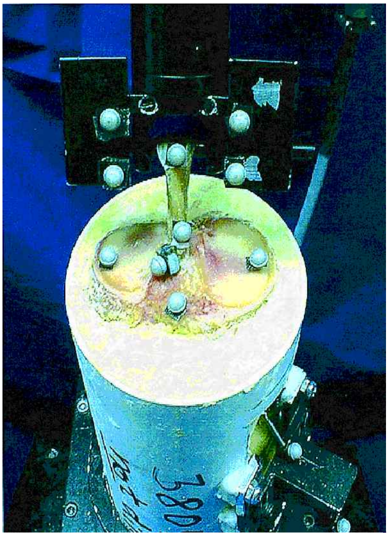

Figure 1. A quadrupled 9 mm diameter hamstring graft was secured with a 9 mm PLA screw in the posterior tibial tunnel. Reflective markers mounted on the surface of the specimen were attached to the jig suspending the tendon loop, to the graft itself, to the tip of the interference screw, to the tibial plateau, and to a spring-loaded sliding rod at the entrance of the tibial tunnel.

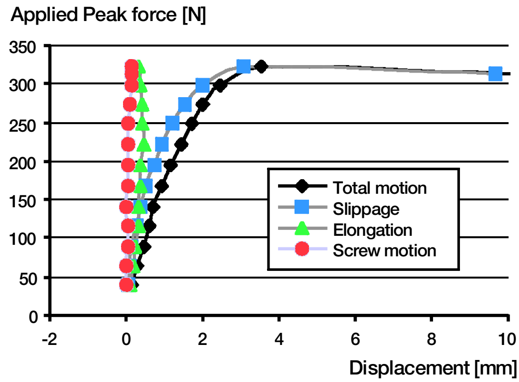

Figure 2. Contribution of various displacement mechanisms to total construct displacement for a typical loading sequence.

in 1 second and left under zero load for 60 seconds before reloading, to allow time-dependent recovery of the graft. Loading was done until the displacement of the construct exceeded 15 mm.

Elongation of the graft, migration of the screw, and slippage of the graft at the screw/bone interface were monitored during loading with a non-contacting, optical measurement system (PCReflex, Qualisys Inc., Glastonbury, CN) previously used for biomechanical measurement (Gelberman et al. 1999). This system consisted of two infrared strobed cameras that tracked the three-dimensional position of an array of 12 spherical reflective markers mounted on the surface of the specimen (Figure 1).

As regards the accuracy of PC reflex, the system resolution is 1 part in 30,000 of the field of view. In our experiments, the field of view was 100 mm, corresponding to a resolution of about 3 microns and an absolute accuracy of 10 microns. Data from previous experiments address the question of reproducibility of our displacement data. In our earlier studies, data were collected while we cyclically loaded ACL grafts. The data from repeated cycles were highly reproducible, with variations in the range of 0.02–0.05mm between load-displacement curves (data not published). Over a gauge length of about 20 mm, this represents one part in 400–1000, mainly due to viscoelastic effects in the graft. In view of the demonstrated accuracy and reproducibility of this novel method of displacement measurement, we are confident that graft displacements can be reported to better than 0.02 mm in individual runs, and 0.01 mm in averaging the data from several experiments.

The marker data were analyzed to determine the time- and load-dependent variations in the relative position of the graft, the interference screw, and the tibial tunnel. This allowed isolation of the following components of laxity: (1) stretching of the graft, (2) slippage of the graft past the screw, and (3) migration of the screw in the tibial tunnel.

A curve relating each of these components to the amplitude of each load cycle was generated (Figure 2). Such a technique permits quantification of the performance of each graft-bone construct in terms of the load to initiate graft slippage (permanent elongation 0.5 mm), the load causing 2 mm permanent elongation, and the load causing clinical failure (permanent elongation 5 mm) of each graft construct.

The effects of interference screw design and diameter on the tensile properties of the quadrupled hamstring grafts were tested using least squares analysis of variance techniques. For analysis of effects of screw type (material type), the two sizes of screws were combined (7 mm and 9 mm RCI versus 8 mm and 9 mm Bio) for analysis. Statistical analyses were done using the STATA statistical software package.

Table 1. Mechanical performance of graft-screw-bone constructs at various displacement loads

	Group A 7 mm RCI	Group B 9 mm RCI	Group C 8 mm Bio	Group D 9 mm Bio	Overall mean (SD)	P-value
No. of observations	7	7	8	7		
Age (years), mean (SD)	55 (15)	51 (16)	50 (11)	54 (13)	52 (13)	
Screw diameter (mm)	7.0	9.0	8.0	9.0		
Graft diameter (mm), mean (SD)	7.0 (0.0)	8.6 (0.53)	7.0 (0.0)	9.0 (0.58)	7.9 (0.99)	
BMC (gm)	0.67	0.60	0.52	0.64	0.61 (0.16)	
Screw torque (Nm)	1.13	1.9	0.71	0.89	1.16 (0.72)	
Loads (N) at						
0.5 mm permanent displacement	150	162	144	131	147 (68)	0.9
1 mm permanent displacement	217	220	181	178	198 (88)	0.7
2 mm permanent displacement	283	298	231	255	266 (102)	0.6
5 mm permanent displacement	323	372	301	356	336 (105)	0.7

Table 2 . Contribution of various displacement mechanisms to 5mm permanent total construct displacement. Mean and 95% confidence interval

	Group A 7 mm RCI	Group B 9 mm RCI	Group C 8 mm Bio	Group D 9 mm Bio	Overall	P–value
Interference screw movement (mm)	0.00	0.12	0.05	0.00	–0.01	0.03
Lower 95% confidence limit	–0.08	–0.29	–0.08	–0.90	–0.05	
Upper 95% confidence limit	0.08	0.04	0.10	0.90	0.03	
Graft stretching (mm)	0.40	0.77	0.03	0.59	0.42	0.4
Lower 95% confidence limit	0.12	–0.66	–0.63	–0.40	0.12	
Upper 95% confidence limit	0.68	2.20	0.69	1.22	0.73	
Graft slippage past screw (mm)	4.63	4.28	4.87	4.39	4.56	0.5
Lower 95% confidence limit	4.34	2.98	4.23	3.80	4.28	
Upper 95% confidence limit	4.93	5.57	5.51	4.97	4.84	

Results (Tables 1 and 2)

Screw torque positively correlated with the load to initiate graft slippage (r = 0.73; p = 0.00) and with failure load (r = 0.73; p = 0.00), however, screw torque did not correlate with BMC (r = 0.03; p = 0.9).

All constructs failed by slippage of the graft past the interference screw. On average, graft slippage accounted for 70% of total construct laxity at 0.5 mm displacement (mean = 0.35 mm; 95% CI = 0.26–0.43), 85% at 2 mm (mean = 1.69 mm; 95% CI = 1.53–1.85), and 92% at 5 mm permanent total construct displacement (mean = 4.6 mm; 95% CI = 4.28–4.84). Graft slippage did not vary significantly with test group (p = 0.45), screw diameter (p = 0.1), or screw design (p = 0.6) (Figure 3).

Permanent stretching of the mid-substance of the graft accounted for 32% of total construct laxity at 0.5 mm of permanent displacement (mean = 0.16 mm; 95% CI = 0.09–0.22), 15% at 2 mm (mean = 0.30 mm; 95% CI = 0.16–0.44), and only 8% at 5 mm displacement (mean = 0.42 mm; 95% CI = 0.12–0.73). At 5 mm permanent displacement, graft stretching was 60% less in constructs fixed with 7 mm or 8 mm screws (mean = 0.20 mm; 95% CI = -0.14–0.54) than with grafts fixed with 9mm screws (mean = 0.67 mm; 95% CI = 0.11–1.22) and 46% less in specimens fixed with Bio screws (mean = 0.31 mm; 95% CI = 0.11–0.73) compared with RCI screws (mean = 0.57 mm; 95% CI = 0.05–1.09).

Movement of the interference screw in the tibial canal was minimal, averaging only –0.01 ± 0.10 mm at construct failure (range: 0.00–0.45 mm; 95%CI = –0.05–0.03). At failure of the construct, movement of the 9 mm diameter screws (mean = –0.05 mm; 95% CI = –0.13–0.03) was 65%

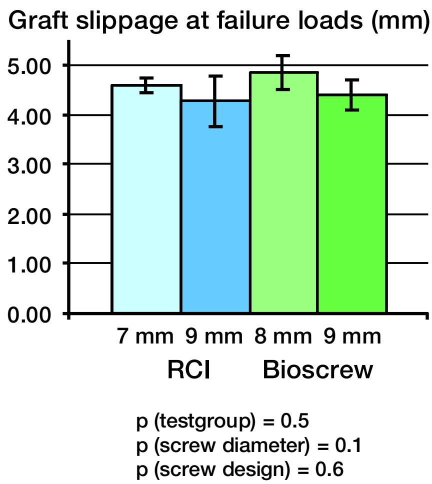

Figure 3. Effect of interference screw design and diameter on slippage of the graft past the screw at failure loads (= 5 mm permanent construct displacement) (mean±SD).

greater than 7 mm (mean = 0.00 mm; 95%CI = –0.08–0.08) and 8 mm screws (mean = 0.04 mm; 95%CI = –0.08–0.10) ($p = 0.07$). Moreover, the bioabsorbable screws moved only one-third (mean = 0.02 mm; 95% CI = –0.02–0.07) the distance of the RCI screws (mean = 0.06 mm; 95% CI = –0.14–0.02).

Adjustment for potential confounding influences of bone mineral content and screw torque did not change the findings for graft slippage or graft elongation or interference screw movement.

The p-values in Tables 1 and 2 correspond to an overall probability of the means in the four groups being judged as significantly different from each other. These results were obtained from an analysis of variance comparing the mean force (Table 1), the mean interference screw movement, graft stretching, graft slippage past screw (Table 2) at each of the indicated loads.

Discussion

Despite the clinical success of intra-articular reconstruction of the ACL-deficient knee, controversy exists as to the best type of graft to use, how to place the tunnels, how to pretension the graft, and how to fix the graft to the femur and tibia (Howell 1998). Over the past few years, autografts made from tripled or quadrupled hamstring tendons have become increasingly popular (Wolf 1998), primarily because of the reduction in graft-site morbidity as compared to patellar tendon grafts (Aglietti et al. 1994, Corry et al. 1999, Fu et al. 2000). Quadrupled hamstring grafts also have mechanical properties superior to the native ACL and conventional 10 mm wide bone-patella tendon-bone grafts in terms of strength and stiffness (Hamner et al. 1999).

Despite these inherent advantages, the potential benefits of alternate graft materials for knee reconstruction remain limited by the reliability of current methods of fixing grafts to the tibia. A primary requirement is that the method of fixation must prevent any significant motion between the graft and the tibia, leading to lengthening of the working length of the graft in the knee and increased joint laxity. Graft motion in the tunnel may create shear forces at the tunnel wall promoting adverse phenomena, such as tunnel enlargement, delayed osseous graft incorporation, loss of isometricity and increased graft stretch (Frank and Jackson 1997, Howell 1998, Wolf 1998). Prevention of motion between graft and tibia is difficult to achieve with repetitive loading, as ligamentous loads of up to 500 N are generated during contemporary therapy protocols (Holden et al. 1994, Beynnon et al. 1995, Howell and Hull 1998). These load levels often exceed the pull-out strength of hamstring grafts fixed with interference screws, which have been reported to average only 201 N (Weiler et al. 1998), 242 N (Steiner et al. 1994), 336 N (Stadelmaier et al. 1999), and 350 N (Magen et al. 1999) in human tibiae.

Our data suggest that slippage of the hamstring graft in the tibial tunnel accounts for most of the permanent laxity. Permanent graft slippage past the interference screw occurred at various load levels, and it was initiated by loads well below failure load. Neither rocking of the screw with loading and unloading, nor permanent screw displacement contributed to the laxity. Permanent graft stretching accounted for about a tenth of permanent construct displacement at failure loads. To our surprise the intraarticular portion of the graft contributed minimally to construct laxity in our experiment. However, our in vitro model reflects the status of the graft on the day of implantation before the onset of graft degradation and remodeling. Permanent graft deformation may well be of importance for knee laxity in later stages after ACL reconstruction.

Conclusions drawn from our experiment may be restricted by the advanced donor age of the specimen used. Ideally, biomechanical experiments involving ACL reconstructions should be done using cadavers of similar age to the target patient population. In view of this potential limitation of our study—the average age of our donors was 52 years—we excluded specimens with any evidence of bone pathology, restricted our study to male donors, and made a very accurate assessment of bone quality in the immediate vicinity of the reamed tunnels. The bone mineral content (BMC) of the tibial tunnel site was calculated instead of the bone mineral density to avoid errors that would have been created by including unmineralized tissue at the starting point of the 3D-cylinder at the tibial plateau. Since bone mineral content is known to be linearly related to the bone mineral density (Eriksson et al. 1988), any association between such density and graft pull-out strength would also exist between bone mineral content and pull-out strength.

Inadequacy of isolated tibial interference screw fixation of soft tissue grafts may be overcome if failure at the graft/screw interface at load levels as low as 150–200 N is prevented. Our results suggest that changes in the graft/screw interface are more likely to increase the reliability of isolated interference fit fixation of quadrupled hamstring tendons in ACL reconstruction than those dealing with the bone/screw interface.

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