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Multistranded Hamstring Tendon Graft Fixation with a Central Four-Quadrant or a Standard Tibial Interference Screw for Anterior Cruciate Ligament Reconstruction

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Background: Tibial fixation of hamstring tendon grafts has been the weak link in anterior cruciate ligament reconstruction.
Hypothesis: Use of a central four-quadrant sleeve and screw provides superior fixation when compared with standard interference screw fixation.
Study Design: Controlled laboratory study.
Methods: In eight pairs of cadaveric knees each anterior cruciate ligament was reconstructed using either an interference screw or a central sleeve and screw on the tibial side. The specimens were then subjected to cyclic loading followed by a load-to-failure test.
Results: The load required to cause 1 and 2 mm of graft laxity, defined as the separation of the femur and the tibia at the points of graft fixation, was significantly greater with the sleeve and screw than with the interference screw (at 2 mm: sleeve and screw, 216.1 ± 30.1 N; interference screw, 167.0 ± 33.2 N). The force at initial slippage for each of the graft strands was significantly higher with use of the central sleeve and screw.
Conclusions: The four-quadrant sleeve and screw device may provide greater surface area for healing of hamstring tendon grafts and allow equal tensioning of graft strands before fixation. These factors are associated with increased strength of fixation and reduced laxity of the graft after cyclic loading.
Clinical Relevance: Use of the central four-quadrant sleeve and screw system offers increased strength of fixation in anterior cruciate ligament reconstruction with hamstring tendon graft.

Anterior cruciate ligament reconstruction techniques continue to evolve in regard to graft selection and harvest, graft fixation, and aggressiveness of rehabilitation. Many surgeons prefer to use quadrupled hamstring tendon grafts to avoid the incidence of anterior knee pain, extensor mechanism weakness and atrophy, and patellofemoral problems that have been reported with use of bone-patellar tendon-bone autografts.[1,2,6,11,15,18,21,25,27–31,37,39]

Femoral fixation of hamstring tendon grafts by using a crosspin device has been reported to be stronger than any other femoral fixation, regardless of graft choice.[10,17] Conversely, fixation of the graft within the tibial tunnel is generally accepted as the "weak link" of these reconstructive procedures. No single method is universally accepted as optimal in terms of reliability or convenience.[5,10,14,16,35,37,38] One factor known to influence the success of ACL reconstruction is tensioning of the graft before fixation and during physiologic activities.[3,4,6,7,13,15,21–23,36,37,42,43] Hamner et al.[15] demonstrated that equal tensioning of quadrupled hamstring tendon grafts is needed to maximize graft strength. Graft tensioning boards can be used in an attempt to equalize tension during preparation and strand bundling, as needed for interference screw fixation; however, retaining true equal tension to the point of graft fixation is difficult. One purported benefit of the central sleeve and screw technique (Intrafix, Mitek Products, Norwood, Massachusetts) is the use of a handheld tensioning device as a clinically applicable way to measure and equal-

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ize tension in each strand at the time of graft fixation. We compared Intrafix fixation with standard interference screw fixation in a cadaver model that simulated actual clinical conditions in hamstring tendon ACL reconstruction.

MATERIALS AND METHODS

We obtained eight matched pairs of fresh-frozen male cadaveric lower extremities from donors with a mean age of 65 years (range, 50 to 85). After each specimen was allowed to thaw at room temperature, the hamstring tendons (semitendinosus and gracilis) from each knee were harvested, quadrupled, and sized to the nearest 0.5 mm. All grafts were between 7.5 and 8.5 mm in diameter. The tendon grafts were individually identified, wrapped in a moist towelette, and frozen at –10°C.

Each lower extremity was sectioned 15 cm above and below the level of the joint line to provide a joint specimen for further testing. Each specimen was stripped of overlying skin and muscle, leaving only the posterior joint capsule, the collateral and posterior cruciate ligaments, and the menisci intact. After a limited notchplasty was performed, a tunnel matching the graft diameter was drilled within the proximal tibia, located in the posterior footprint of the resected ACL, at a 55° angle to the tibial plateau. In every specimen the tunnel was a minimum 40 mm in length. Whenever the graft diameter was 7.5 or 8.5 mm, the matching tibial tunnel was prepared with an 8- or 9-mm reamer.

In each specimen, a femoral tunnel of the same diameter as the tibial tunnel was drilled to a depth of 30 mm by using a transtibial posterior offset guide and leaving a 1.5-mm back wall. The 1-o'clock position was used for left knees and the 11-o'clock for right knees. The Sling Shot femoral guide (Mitek Products) was inserted into the femoral tunnel to a depth of 25 mm and was used to pass the guide pin. Central positioning of the guide pin in the femoral tunnel was verified before the Sling Shot cable graft passer was pulled through the femur. After the cable was secured, the tibia and femur were individually potted in rigid polyvinyl chloride cylinders. Each specimen was frozen at –10°C.

Over the 24 hours before testing, specimens and hamstring tendon grafts were thawed to room temperature. In all specimens, the graft was pulled into the femoral tunnel to the depth of 25 mm with a passing cable. A 6.5 × 50 mm crosspin (Mitek) was then passed over the cable and under the graft and screwed into the lateral femoral cortex. In the specimens to be fixed with a standard interference screw, the tibial portion of the graft was bundled by using a No. 2 Ethibond suture (Ethicon, Inc., Somerville, New Jersey) before fixation on the femoral side.

In all specimens, the suture tails from each tendon that exited the tibial tunnel were tied together and placed around the two arms of a tensioning device (Tie Tensioner, Mitek), and the knee was put through 10 cycles of full knee motion with the graft tension maintained at 20 pounds. Tendon orientation in the tibial tunnel was duplicated in each specimen, with the gracilis tendon being antero- and posterolateral and the semitendinosus tendon being antero- and posteromedial.

In half of the knees, the hamstring tendon graft was loaded with 20 pounds and secured to the tibia by using the Intrafix technique (Fig. 1). With the knee maintained in 30° of flexion, the four-quadrant plastic sheath was centrally placed within the graft and inserted into the tibial tunnel. The graft was then fixed in place with the internal screw threaded into the plastic sheath. The 7- to 9-mm Intrafix screw was placed in specimens with a tunnel diameter of 7 mm, and the 8- to 10-mm screw was used in 8- and 9-mm tunnels. In the corresponding specimen from each pair, a 9 × 25 mm RCI interference screw (Smith & Nephew Endoscopy, Inc., Andover, Massachusetts) was placed by positioning a guide wire anterior to the bundled graft and tightening until the tip of the screw engaged the tibial plateau subchondral bone. Tension of 20 pounds at 30° of knee flexion was maintained during tightening. In each pair, one side was randomly assigned to either the interference screw or the four-quadrant screw, with the matched specimen assigned to the other group (Fig. 2).

The tibia was positioned and mounted in a servohydraulic testing machine (Bionix Kinematic Knee Joint Simulator, MTS Systems Corp., Eden Prairie, Minnesota) with the anterior tibia facing up and the tibial shaft parallel to the floor. The femur was then flexed to 30° and oriented anatomically as allowed by the intact soft tissues. The femur was then fixed in place. Each of the four hamstring tendons exiting the tibial tunnel was attached to a linear displacement transducer (model LXPA-2, UniMeasure, Corvallis, Oregon) by using the previously placed Ethibond sutures (Fig. 3). During each experiment, the tibia was loaded at 25 N/sec in an anteroposterior direction with the knee flexed to 30°, simulating a Lachman test (Fig. 4). After application of a 10-N pretensioning load, each specimen was cyclically loaded in an anteroposterior direction. The amplitude of the loading cycles started at 25 N and increased by 25 N per cycle to a maximum of 400 N. After the peak load was reached in each cycle, the specimen was unloaded and allowed to rest for 30 seconds before reloading. The 30-second rest period allowed the machine to return to the pretensioning load value and enabled viscoelastic recovery of some of the graft elongation generated during loading. All knees that remained intact during the incremental loading test phase and reached the maximum load of 400 N were pulled to failure at the rate of 25 N/sec. The load generated by the testing machine, the crosshead displacement, and the output of the linear displacement transducer were sampled at 25 Hz for a total of 640 seconds during each load sequence.

The experimental data were analyzed to determine the load needed to cause 1, 2, 3, 4, and 5 mm of permanent graft laxity. Differences in the actuator position recorded at the end of each rest period between loading cycles were noted and then converted to the corresponding component of tibiofemoral separation in the direction of the graft. The conversion factor for calculating graft laxity from the actuator displacement was obtained by fixing a specimen on the servohydraulic testing machine with a single No. 2 braided suture placed in the center of the tibial tunnel

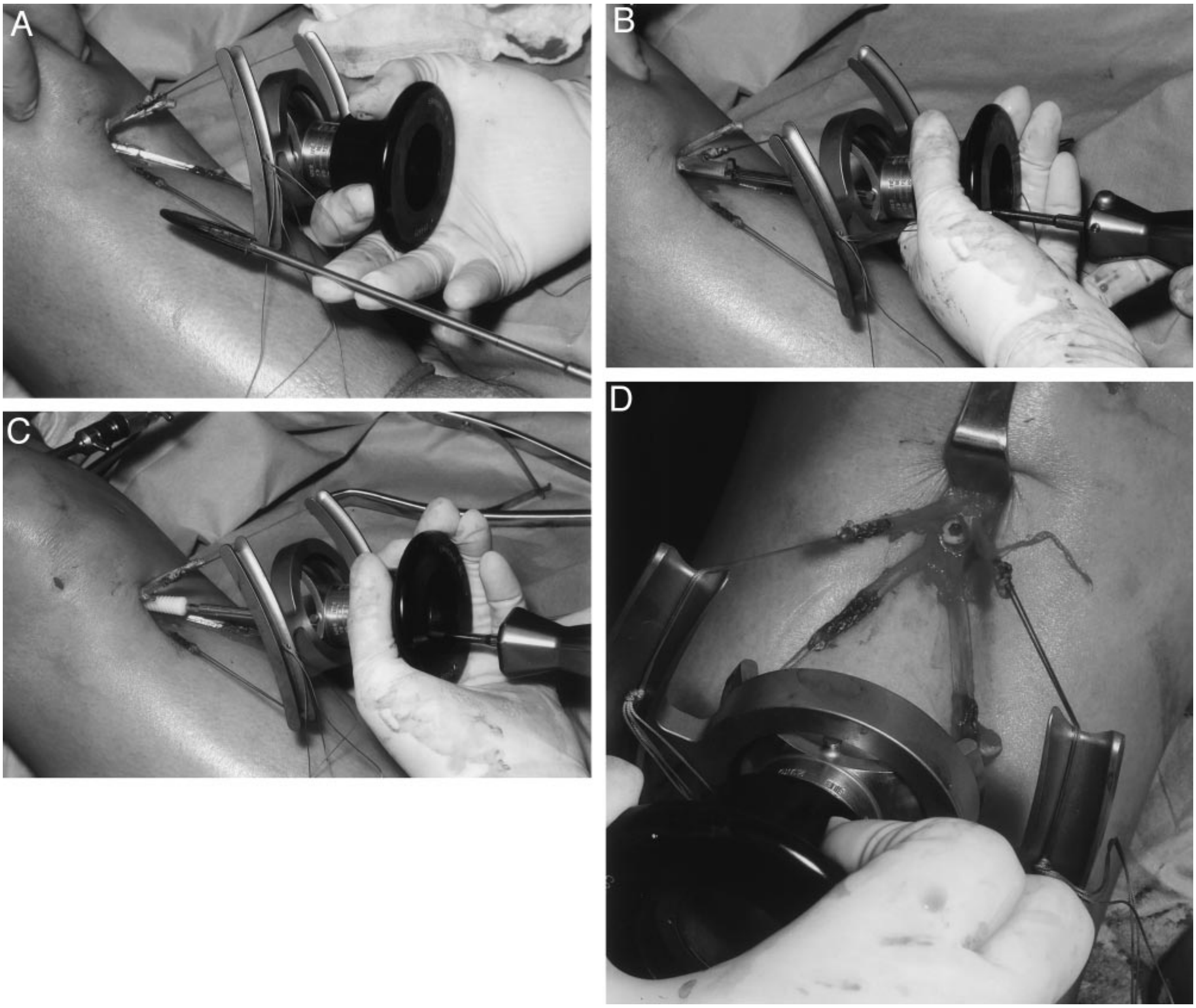

Figure 1. A, four hamstring tendons attached to the tensioning device are shown exiting the tibial tunnel of the right knee with tension applied. The tibial tunnel dilator rests on the surgeon's hand. B, insertion of the Intrafix central sleeve into the tibial tunnel after tunnel dilation; C, insertion of the Intrafix screw into the central sleeve. D, anterior view of hamstring tendon fixation with the Intrafix central sleeve and screw in the tibial tunnel of the right knee.

through the center of a cannulated interference screw. The suture was fixed at the aperture of the femoral tunnel and attached to a linear displacement transducer as it exited the tibial tunnel. Measurements were then recorded as the tibia was displaced in the anterior direction. The relationship of actuator displacement to movement as measured by the linear transducer was the conversion factor used for each specimen. A curve was constructed relating the peak load applied during each loading cycle to the laxity of the graft observed at the end of each relaxation period. Through interpolation of the curve of best fit to these data, we determined the loads corresponding to 1, 2, 3, 4, and 5 mm of graft laxity. The stiffness of each specimen was calculated from the slope of the linear portion of the load-deformation curve.

On the basis of our analysis of the experimental data, we defined the following outcome variables: the load required to cause initial slippage of each of the four strands within the graft; the load required to cause 1, 2, 3, 4, and 5 mm of graft laxity; and the stiffness of each construct. A univariate analysis of the experimental data was performed by using the Wilks lambda test to determine which variables were normally distributed. For each outcome variable, the statistical significance of differences between specimens fixed with the Intrafix device and the RCI screw were calculated by using the Student's *t*-test or the Wilcoxon signed rank test. Differences between forces at initial strand slippage were analyzed to determine the effect of fixation device and graft source. In all tests, statistical significance was set at $P < 0.05$.

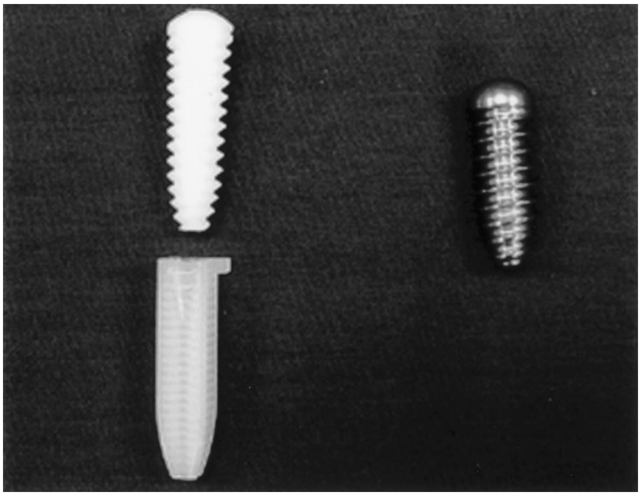

Figure 2. The Intrafix sleeve and the 7 to 9 × 30 mm Intrafix screw are shown on the left; the 9 × 25 mm RCI screw is shown on the right.

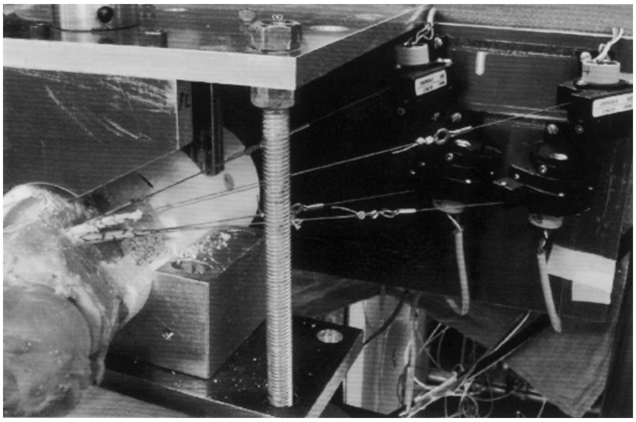

Figure 3. The testing apparatus is shown with the connection of the quadrupled hamstring tendon graft to the linear displacement transducers.

RESULTS

At 1 and 2 mm of graft laxity, the forces for the Intrafix group were significantly greater than for the RCI screw. Forces at laxities of 3, 4, and 5 mm continued to be greater in the Intrafix group, but these differences were not statistically significant (Table 1). Graft laxity data were not obtained from three specimens (two RCI runs and one Intrafix run) because intraarticular contact between the femur and tibia during unloading prevented relaxation of the graft between load cycles. These aberrations did not occur in any of the other runs and did not affect measurement of the loads required to initiate graft slippage.

The data from all eight pairs were analyzed to evaluate the initial slippage of the graft strands. The force values for the specimens were obtained at the point at which each individual graft strand began to move, as measured by the linear transducers. The data are shown in Table 2. The forces at which each graft strand began to slip were greater in the specimens secured with the Intrafix, with the average forces approximately two times those recorded for the RCI group. All of the differences noted in initial slippage were significant.

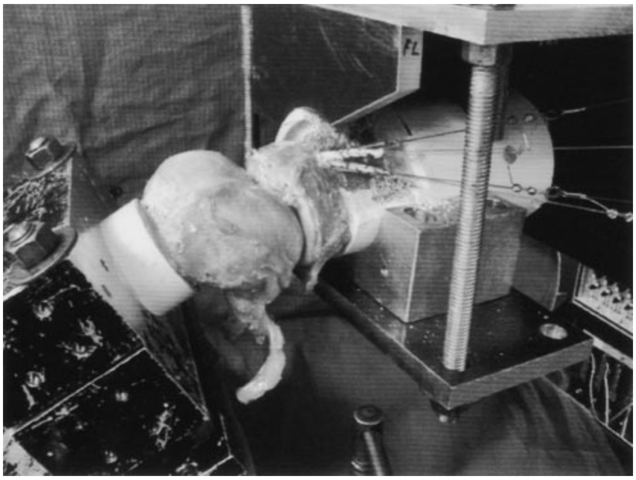

Figure 4. The testing apparatus is shown with the specimen at 30° of flexion; all soft tissues were removed with the exception of the ACL.

The data shown in Table 3 revealed no significant difference in stiffness between the two fixation techniques. One of the specimen pairs was not analyzed because of the problems with intraarticular contact between the femur and tibia during unloading.

DISCUSSION

Quadrupled hamstring tendon grafts have been noted to have inherent size, stiffness, and ultimate strength equivalent to or greater than bone-patellar tendon-bone grafts.[6,10,15,17,28,33,35,37] Moreover, clinical studies have shown no differences in the flexion strength or range of motion of the knee after recovery from hamstring tendon harvest.[9,20,21,29,31,41] The concerns with use of hamstring tendon grafts largely lie with the method of fixation.

Biomechanical evaluation in animal specimens of fixation on the femoral side has revealed that fixation with a crosspin has a strength greater than 700 N. This value is equal to or exceeds values achieved with comparable bone-patellar tendon-bone techniques.[10] De la Cruz et al. (unpublished data, 2001) evaluated femoral crosspin fixation strength in human cadavers (average age, 50 years) by using equal tensioning techniques and showed that the load necessary to generate 5 mm of elongation at the femoral fixation site averaged 844 N, with ultimate failure at 1107 N. However, numerous reports have indicated that the weakest link of the hamstring tendon ACL construct is the initial fixation of the tibial side.[5,10,14,16,35,37]

Attempts to increase the strength and elongation resistance of the weaker tibial fixation have included pretensioning of the strands within the quadruple graft, dilation of the tibial tunnel to enhance the quality of the bone stock

TABLE 1
Loads (in Newtons) at Different Graft Laxities during Incremental Loading

Specimen	Laxity measurements (mm)									
	1		2		3		4		5	
	RCI screw	Intrafix	RCI screw	Intrafix	RCI screw	Intrafix	RCI screw	Intrafix	RCI screw	Intrafix
1	145.8	297.1	172.8	297.1	192.6	297.1	208.0	297.1	212.7	297.1
2	185.3	264.4	214.1	304.6	234.1	336.4	248.9	358.2	265.7	379.3
3										
4	108.5	188.8	112.8	188.8	116.6	188.8	121.1	188.8	125.7	188.8
5	110.7	159.3	127.0	194.7	146.6	211.4	147.8	222.4	150.3	228.1
6	219.2	228.2	300.5	282.1	340.9	282.1	384.1	334.8	392.1	334.8
7	62.0	100.3	74.6	105.0	82.6	106.3	89.9	107.7	94.4	108.7
8		116.9		140.6		182.4		209.7		215.4
Mean	138.6	193.6	167.0	216.1	185.6	229.2	200.0	245.5	206.8	250.3
SEM	23.3	27.9	33.2	30.1	38.0	30.1	43.7	33.6	44.8	35.0
N	6	7	6	7	6	7	6	7	6	7
P value	0.028		0.046		0.075		0.075		0.075	

TABLE 2
Force (in Newtons) at which Initial Failure of Graft Strands Occurred

Specimen	Anterolateral gracilis tendon		Posterolateral gracilis tendon		Posteromedial semi-tendinosus tendon		Anteromedial semi-tendinosus tendon	
	RCI	Intrafix	RCI	Intrafix	RCI	Intrafix	RCI	Intrafix
1	77.4	172.15	94.3	187.27	86.07	75.62	102.98	216.63
2	60.27	216.63	82.07	184.82	86.52	262.44	96.75	290.02
3	56.93	212.62	88.07	200.17	67.39	218.41	134.11	197.28
4	45.37	98.97	64.72	165.03	57.38	168.81	60.27	84.29
5	60.5	66.95	68.28	96.75	74.06	145.9	71.17	85.62
6	84.29	239.76	104.76	260	126.33	137.23	130.56	238.2
7	23.8	19.57	23.35	32.03	38.25	44.48	29.8	42.25
8	35.14	195.72	37.59	166.81	52.27	92.52	40.7	89.19
Mean	55.46	152.8	70.39	161.61	73.53	143.18	83.29	155.44
SEM	7.17	28.49	9.93	24.42	9.55	25.86	13.85	32.07
N	8	8	8	8	8	8	8	8
P value	0.017		0.012		0.025		0.012	

TABLE 3
Stiffness (in Newtons per millimeter) for Each Specimen in the Interference Screw and Intrafix Groups

Specimen	RCI Screw	Intrafix
1	46.12	97.33
2	59.52	84.32
3	92.29	85.53
4	26.05	53.26
5	67.26	59.81
6	29.95	28.42
7	95.73	77.00
Mean	59.56	69.38
SEM	10.49	8.93
N	7	7
P value	0.339	

within the tibia, and improvements in the design of the graft fixation device itself. The role of strand tension when fixation devices are placed has also received recent attention. Hamner et al.[15] enhanced the biomechanical properties of multistranded tendon grafts by applying equal tension to each strand with weights before fixation. Although use of sterile weights in the operating room is not a realistic option for most surgeons, a feasible alternative is use of a handheld device that allows for equal strand tensioning at different levels of total tension, according to surgeon preference.

Improvement of the graft-bone interface for osseointegration has been evaluated as well. The results of numerous animal studies have shown that only areas of direct contact between graft and bone contribute to bone ingrowth.[12,26,34,40] Histologic examination of human specimens obtained at revision surgery has revealed that fibroblastic and myoblastic activity occurs at the periphery of hamstring tendon grafts, with development of continuity of collagen fibers from bone to graft at 12 weeks.[24] However, acellularity was noted in the central regions of the grafts.

Simonian et al.[32] described the use of a bioabsorbable interference screw placed centrally between the four bundles of a quadrupled hamstring tendon graft to maximize the surface area for graft-bone contact. No significant difference in fixation strength was shown when compared with an eccentrically placed interference screw, but difficulty with the strands wrapping around the central screw was noted. Damage to graft tissue has been a concern with use of interference screws, whether placed centrally or eccentrically.[8,14,32,39]

Intrafix is a central fixation system that incorporates a handheld tensioning device and uses a four-quadrant sleeve and screw to facilitate equal tensioning, to protect grafts from damage, and to increase the contact area between graft and bone for osseointegration. When we compared the Intrafix with a 9-mm interference screw placed eccentrically, the Intrafix had statistically greater fixation of force at initial slippage of each strand. Another observed difference was that the Intrafix maintained fixation at higher loads than the interference screw in regard to 1 and 2 mm of graft laxity; this favorable difference continued but lost statistical significance at 3, 4, and 5 mm of laxity.

The reliance of the central sleeve and screw on the quality of the tibial bone for fixation is a possible explanation for the similarity of results of the fixation methods at 3 to 5 mm of elongation. We noted that when failure began to occur in the Intrafix specimens, the entire graft-central screw construct began to move as one unit. After the initial movement began, the Intrafix construct behaved similarly to the interference screw, with roughly parallel load-deformation curves after the beginning difference (Fig. 5). At higher loads, the screw and sleeve were noted to eventually slip completely out of the tibial tunnel. We theorized that these movements occurred because the points of fixation for the central sleeve and screw depend on compressing the graft material against the tunnel wall. As the graft moves initially, these points of fixation are weakened. This method of failure might not have occurred as readily had the cadaveric specimens been younger and thus had greater bone density. In the clinical application of these devices, healing of the graft to the tunnel would introduce an additional compounding factor that would be expected to reduce slippage of the graft past the screw, especially after the immediate postoperative period. In the RCI screw specimens, posttest examination revealed no movement of the screw within the tibial tunnel, which allowed continued resistance to slippage as the graft was pulled past the screw threads. This observation has been recorded previously.[19]

In our study design, we attempted to simulate the clinical stress on an ACL hamstring tendon graft during the early postoperative period by using repetitive increasing cyclical loading, as suggested in previous studies, instead of loading to ultimate failure.[14,19,32,33,35] Linear displacement transducers were used to measure linear displacement along the axis of the transducer of each individual strand within the tibial tunnel in an attempt to evaluate fixation and behavior of the individual strands.

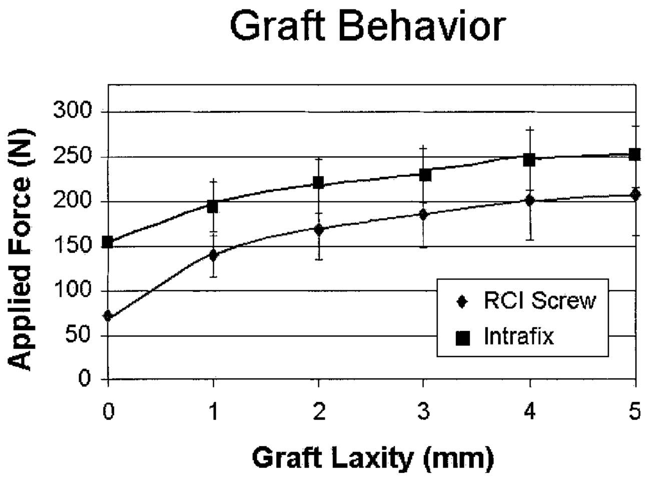

Figure 5. Load-displacement curves, in a schematic depiction of data from Table 1, demonstrate graft behavior of the two fixation methods.

A criticism of our study is that inclusion of the femur in our test construct allowed any movement of the femoral graft fixation system to contribute to the laxity of the reconstruction. In developing this experimental model, we considered passing the graft over an isolated post fixed to the actuator of the testing machine. However, our goal was to simulate the actual forces acting on the hamstring tendon graft in the reconstructed knee. Our model resulted in a line of pull on the ACL graft that was approximately in line with the tibial tunnel, giving physiologically relevant as well as worst-case scenario results. All of the specimens were visually inspected after completion of testing, and no movement of the femoral crosspins could be identified. We noted that the previously recorded loads that cause creep and failure of the crosspin femoral fixation far exceed those measured in our study. We believe that all of the failure in the construct was limited to the tibial side, and thus we did not directly measure the movement of the femoral crosspin.

Differences in the position of the screws used to fix the grafts on the tibial side could have influenced the measured values as well. The Intrafix screw was inserted until the head was even with the anterior tibial cortex, whereas the RCI screw was inserted further, until the tip engaged the subchondral bone. The results might have been different if the RCI screw had only been inserted as far as the Intrafix screw had been. However, placement of the RCI screw to engage the subchondral bone likely resulted in increased force values for initial slippage and elongation, giving a best-case scenario for that group.

A final improvement would have been to use cadaveric specimens closer in age to that of the patient population that undergoes ACL reconstruction. Although the absolute values cannot be directly extrapolated to younger patients, the use of paired specimens for testing should allow the findings to be related to the relevant population. We theorize that the use of younger specimens might have resulted in increased fixation in the central fixation device with less substantial increases in the standard interference screw method.

SUMMARY

We evaluated a new method of tibial fixation of looped semitendinosus and gracilis tendon grafts for ACL reconstruction. This technique is purported to allow equal tensioning of graft strands at initial fixation and to provide increased surface area for incorporation while protecting the strands from damage by the fixation device. Compared with the standard use of metal interference screws, this four-quadrant sleeve and central screw system offers these advantages with increased strength of fixation.

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