The American Journal of Sports Medicine

http://ajs.sagepub.com/

Tibial Fixation of Anterior Cruciate Ligament Allograft Tendons

Daniel K. Park, Harold A. Fogel, Sanjeev Bhatia, Bernard R. Bach, Jr, Aman Gupta, Elizabeth F. Shewman, Vincent Wang, Nikhil Verma and Matthew T. Provencher *Am J Sports Med* 2009 37: 1531 originally published online May 21, 2009 DOI: 10.1177/0363546509332504

> The online version of this article can be found at: http://ajs.sagepub.com/content/37/8/1531

> > Published by: SAGE http://www.sagepublications.com

> > > On behalf of:



American Orthopaedic Society for Sports Medicine

Additional services and information for The American Journal of Sports Medicine can be found at:

Email Alerts: http://ajs.sagepub.com/cgi/alerts

Subscriptions: http://ajs.sagepub.com/subscriptions

Reprints: http://www.sagepub.com/journalsReprints.nav

Permissions: http://www.sagepub.com/journalsPermissions.nav

				1		
Report Documentation Page			Form Approved OMB No. 0704-0188			
maintaining the data needed, and c including suggestions for reducing	ompleting and reviewing the collect this burden, to Washington Headqu uld be aware that notwithstanding ar	o average 1 hour per response, inclu- ion of information. Send comments arters Services, Directorate for Infor ay other provision of law, no person	regarding this burden estimate mation Operations and Reports	or any other aspect of th s, 1215 Jefferson Davis I	is collection of information, Highway, Suite 1204, Arlington	
1. REPORT DATE 2009		2. REPORT TYPE		3. DATES COVE 00-00-2009	RED • to 00-00-2009	
4. TITLE AND SUBTITLE	5a. CONTRACT NUMBER					
Tibial Fixation of Anterior Cruciate Ligament Allograft Tendons					5b. GRANT NUMBER	
				5c. PROGRAM E	LEMENT NUMBER	
6. AUTHOR(S)				5d. PROJECT NU	MBER	
	5e. TASK NUMBER					
	5f. WORK UNIT NUMBER					
	ZATION NAME(S) AND AE hopedic Surgery,Ru	DDRESS(ES) Ish University Medi	cal	8. PERFORMINO REPORT NUMB	ORGANIZATION ER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)			10. SPONSOR/MONITOR'S ACRONYM(S)			
			11. SPONSOR/MONITOR'S REPORT NUMBER(S)			
12. DISTRIBUTION/AVAII Approved for publ	LABILITY STATEMENT ic release; distributi	ion unlimited				
13. SUPPLEMENTARY NC	DTES					
14. ABSTRACT						
15. SUBJECT TERMS						
16. SECURITY CLASSIFIC			19a. NAME OF			
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified	Same as Report (SAR)	0F PAGES 9	RESPONSIBLE PERSON	

Standard Form 298 (Rev. 8-98) Prescribed by ANSI Std Z39-18

Tibial Fixation of Anterior Cruciate Ligament Allograft Tendons

Comparison of 1-, 2-, and 4-Stranded Constructs

Daniel K. Park,* MD, Harold A. Fogel,* BA, Sanjeev Bhatia,* MD, Bernard R. Bach Jr,* MD, Aman Gupta,* Elizabeth F. Shewman,* PhD, Vincent Wang,* PhD, Nikhil Verma,* MD, and LDCR Matthew T. Provencher,^{†‡} MD MC USN

From the *Department of Orthopedic Surgery, Rush University Medical Center, Chicago, Illinois, and the [†]Department of Orthopaedic Surgery, Division of Sports Surgery, Naval Medical Center San Diego, San Diego, California

Background: In sum, 1-, 2-, and 4-stranded allografts are used for soft tissue anterior cruciate ligament reconstruction; however, the fixation properties of fixation devices are not well assessed.

Hypothesis: There are no differences in the biomechanical characteristics of 1 (Achilles)-, 2 (posterior tibialis)-, and 4 (semitendinosus)-stranded allograft tibial fixation.

Study Design: Controlled laboratory study.

Methods: Sixty-three fresh-frozen porcine tibiae were used to evaluate the fixation of 1-, 2-, and 4-stranded human tendon allografts (Achilles, posterior tibialis, and semitendinosus) with 3 fixation devices (Delta, Intrafix, and Calaxo screws). With use of a materials testing system, each graft was subjected to 500 cycles of loading (50-250 N, 0.75 mm/sec) to determine displacement and cyclic stiffness, followed by a monotonic failure test (20 mm/min) to determine maximum load and pullout stiffness.

Results: For each graft type, there were no significant biomechanical differences between fixation devices. However, the 1-stranded graft (Achilles) construct demonstrated significantly higher mean displacement (3.17 ± 1.62 mm), lower cyclical stiffness (156 ± 25 N/mm), lower load to failure (479 ± 87 N), and lower pullout stiffness (140 ± 28 N/mm). In comparison with the 2-stranded graft (posterior tibialis), the 4-stranded graft (semitendinosus) exhibited lower displacement (0.86 ± 0.44 to 1.12 ± 0.51 mm) and higher ultimate failure load (832 ± 255 to 656 ± 168 N). Numerous differences in fixation properties were noted when comparing a device to each of the 3 grafts.

Conclusion: The 1-stranded allograft demonstrated inferior biomechanical tibial fixation properties when compared with 2 (posterior tibialis)- and 4 (semitendinosus)-stranded allograft constructs for all fixation devices tested.

Clinical Relevance: This study demonstrated that not all tibial fixation devices are designed to adequately accommodate different types of anterior cruciate ligament allografts. Biomechanical evidence suggests that caution is warranted when using an Achilles allograft fixated solely with an interference device.

Keywords: anterior cruciate ligament; tibia; fixation; interference screw; biomechanics

No potential conflict of interest declared.

The American Journal of Sports Medicine, Vol. 37, No. 8 DOI: 10.1177/0363546509332504 © 2009 The Author(s) Anterior cruciate ligament (ACL) reconstruction remains one of the most common orthopaedic procedures performed today, with more than 100000 ACL reconstructions performed annually in the US.^{3,5} Allograft reconstruction is becoming a common choice for ACL reconstruction. Advantages of allograft use include decreased perioperative morbidity, more rapid recovery of function and return to activities of daily living, and improved cosmesis.²⁴ Potential limitations include disease transmission, infection and graft rejection, and failure of biological incorporation.^{14,29,31} The most commonly used allograft tissue includes bone-patellar tendon-bone constructs, Achilles tendon with calcaneal bone

[‡]Address correspondence to LCDR Matthew T. Provencher, MD MC USN, Naval Medical Center San Diego, Department of Orthopaedic Surgery, 34800 Bob Wilson Drive, Suite 112, San Diego, CA 92134-1112 (e-mail: matthew.provencher@med.navy.mil).

Presented at the 34th annual meeting of the AOSSM, Orlando, Florida, July 2008.

Disclaimer: The views expressed in this article are those of the authors and do not reflect the official policy or position of the Department of the Navy, the Department of Defense, or the US government.

block, and soft tissue grafts, such as anterior or posterior tibialis (PT) and semitendinosus (ST) tendons.¹⁷ Soft tissue grafts, however, have become popular because there is no difficulty with graft tunnel mismatch, which can occur with patellar tendon constructs and complicate graft fixation.^{28,37}

Fixation options for soft tissue grafts most commonly involve interference fixation within the bone tunnel. Many commonly used fixation devices have been designed and tested using multiple-strand soft tissue grafts, such as quadrupled ST grafts or quadrupled bovine extensor tendons.[§] Furthermore, tibial fixation studies have focused on the inherent capabilities of the fixation device and not necessarily the graft type.^{II} Few studies have compared the biomechanical properties of 1 fixation device using various numbers of soft tissue graft strands.²³ Therefore, there is a paucity of information regarding the biomechanical performance of various tibial soft tissue fixation devices commonly used for allograft fixation. Furthermore, the differences in biomechanical properties between single-, double-, and quadruple-stranded soft tissue grafts are unknown.

The purpose of this study was to evaluate the initial biomechanical properties of commonly used tibial ACL fixation devices for 3 types of soft tissue allografts (1-, 2-, and 4-stranded constructs). The null hypothesis was that the initial failure load and slippage of 3 allografts would not be significantly different when fixated with 3 different ACL interference devices.

MATERIALS AND METHODS

A total of 63 skeletally mature fresh porcine tibiae were obtained from a local abattoir (Peoria Packing Company, Chicago, Illinois); animals were of the same age at the time of slaughter (11-12 months). Each tibia was dissected of all soft tissue and then stored in airtight bags in a freezer at -20°C until the day of testing. Previous studies have reported on the influence of bone mineral density (BMD) on ACL graft fixation strength.²³ Among the complete set of porcine tibiae used for experimentation in the present study, 21 were randomly selected for BMD determination, using a dual energy x-ray absorptiometry scanner (General Electric Lunar Prodigy, Madison, Wisconsin). During the scan, each tibia was positioned such that BMD was assessed in the proximity of the fixation site. To minimize bias, the 21 bones were divided into 3 groups of approximately equal BMD: Delta group, 1.02 ± 0.16 g/cm²; Intrafix group, 1.00 ± 0.15 g/cm²; Calaxo group, 1.02 ± 0.21 g/cm². The remaining tibiae not scanned were tested under the assumption that their BMD values were similar to those that were scanned. Before biomechanical testing, tibiae were thawed at room temperature for 12 hours.

The 3 groups corresponded to 3 tibial fixation devices: the Delta screw (Arthrex, Naples, Florida), the Intrafix device (Mitek, Raynham, Massachusetts), and the Calaxo screw (Smith & Nephew, Andover, Massachusetts).

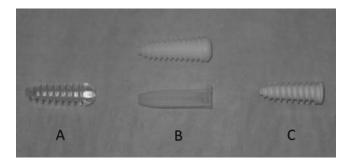


Figure 1. Types of interference screws: A, Arthrex Delta screw; B, Mitek Intrafix; C, Smith and Nephew Calaxo.

Fresh-frozen human ST, PT, and Achilles tendon allografts (n = 21 each) were obtained from LifeNet Health Inc (Virginia Beach, Virginia), wrapped in saline-soaked gauze, and stored in airtight bags in a freezer at -20° C. The grafts were divided into 3 experimental groups, each corresponding to a screw type (n = 21 per group) (Figure 1) such that each group contained 7 grafts of each tendon type of the same approximate age (Delta group, 42.7 ± 15.8 years; Intrafix group, 44.8 ± 15.8 years; Calaxo group, 42.4 ± 15.2 years). On the day of testing, grafts were reconstituted with normal saline at room temperature 1 hour before testing. Testing order was randomized.

Graft Preparation and Fixation

Grafts were prepared for implantation on a tensioning board (Smith and Nephew Graftmaster II, Andover, Massachusetts). All 3 types of grafts were measured to provide 30 mm of tibial tunnel length and 30 mm of tendon length outside the bone tunnel. For the ST graft, the original allograft was divided into 2 equal segments, each doubled over to create a 4-stranded graft and then sized using sizing tubes to a 7- or 8-mm diameter. The PT was doubled over to achieve a 2-stranded graft and then sized to a 7- or 8-mm diameter using the same sizing tubes. If the allograft was smaller, a 7-mm preparation was used. The Achilles allografts were prepared by first potting the calcaneal bone block in wedge molds using acrylic polymer cement (Isocryl, Lang Dental, Chicago, Illinois), based on a previously described technique.^{10,37} This cement block simulated femoral fixation, and it was secured in a wedge-shaped clamp during biomechanical testing. The tendon was sized to a 10-mm graft. This size was chosen because it corresponds to the clinical situation in which a 10-mm bone plug is fashioned from the calcaneal bone block. If the bone block is placed in the femoral tunnel and an endoscopic approach is employed, a 10-mm tibial tunnel must be created to allow for placement of a 10-mm femoral tunnel. For all grafts, a No. 5 Ethibond suture (Ethicon, Somerville, New Jersey) was used to whipstitch the free ends of the graft.

To determine the potential influence of graft size on biomechanical results, geometric measurements of all allografts were taken before testing. Thickness measurements were recorded at 5 locations along the tendon length, using a laser displacement sensor (model LK-G82; spot diameter,

[§]References 6, 9, 12, 16, 30, 33, 34, 36, 40, 41.

References 1, 6, 8, 9, 16, 25, 27, 34, 41.

~70 μ m; repeatability, 0.2 μ m; Keyence Corp, Woodcliff Lake, New Jersey). Five width measurements, equally spaced along the graft length, were made using precision calipers (resolution 0.01 mm). The cross-sectional area of the tendon was calculated by multiplying average thickness by average width. Last, after standard tissue protocol for presurgical implantation was performed, the allografts were preconditioned at 67 N for 10 minutes on the Graftmaster before testing.

Tibial tunnels were prepared using a tibial tunnel guide set to 55° and an entry site placed midway between the tibial tubercle and the posteromedial cortex. The tunnel intra-articular exit site was centered at the "footprint" of the native porcine ACL. For 2- and 4-stranded grafts, a 7- or 8-mm reamer was used in an antegrade fashion for a 7- or 8-mm sized graft, respectively, whereas a 10-mm reamer was used for the 1-stranded Achilles graft. During screw fixation, a Mitek tensioner was used to tension each strand of the graft to 15 N.

For Delta and Calaxo testing, all allografts were fixed using screws 1 mm larger than the tunnel diameter. In comparison, Intrafix fixation for Achilles allograft used an 8- to 10-mm screw and standard sheath, whereas the other grafts used a 6- to 8-mm screw (7-mm tunnel) or 8- to 10-mm screw (8-mm tunnel) and standard sheath, depending on the size of the allograft. With use of a guide wire, each screw was inserted colinear to the tibial tunnels. Each screw was inserted until the distal end of the screw abutted the cortical border of the tibia. The testing sequence (graft and screw type) was randomized to minimize potential surgical bias. All surgical fixations were performed by the same orthopaedic surgeon.

Biomechanical Testing

Mechanical testing was performed with a servohydraulic materials testing system (Instron 8874, Canton, Massachusetts). Each tibia was secured in a customdesigned vise fixture that allowed unconstrained positioning of tibial specimens before testing. Two metal plates $(13 \times 10 \text{ cm})$ on the vise grip faces were used to clamp the tibia via machine screws inserted anterior and posterior to the tibia through screw holes on the plates. The base of the vise was mounted to the Instron testing platform, and the tibia was positioned so that the tunnel was parallel to the test actuator axis during testing. This allowed for testing in a worst-case scenario with direct, in-line force on the graft. For ST and PT testing, the proximal end of the graft was looped around the cross-pin of a "trapeze" fixture, whereas for Achilles tendons, a wedge-shaped clamp was used to grip the calcaneal bone block as described above. In either case, the upper grip was connected directly to a 5000-N load cell. The tests were conducted at room temperature, and the allografts were regularly moistened with saline during testing. An initial preload of 5 N was applied to each graft before testing, and the length of tendon outside the tibial tunnel (approximately 30 mm) was maintained. Each specimen was then preconditioned at a displacement rate of 0.75 mm/s between 10 and 50 N for 10 cycles. Cyclic tensile testing (havertriangle waveform) followed at the same displacement rate, using 500 cycles between 50 and 250 N. Finally, a load-to-failure test was performed at 20 mm/min. For each specimen, 4 parameters were computed for analysis: from the cyclic protocol, (1) cyclic displacement (net change in peak cyclic displacement over the 500 cycles) and (2) cyclic stiffness (the slope of the secant line joining minimum and maximum points of the loading phase of the load deformation curve reported from the 500th cycle); from the load-to-failure test, (3) maximum failure load and (4) pullout stiffness (steepest slope of the load deformation curve spanning 20% of the data points up to maximum load).

A total of 3 specimens (1 Intrafix Achilles, 1 Calaxo Achilles, and 1 Calaxo ST) did not complete the full 500cycle protocol and failed via complete tendon pull-out from the tibial tunnel. These 3 specimens were deleted from statistical analysis.

Statistical Analysis

Nonparametric statistical methods were used to analyze the data. A Kruskal-Wallis test (SPSS 14.0, SPSS Inc, Chicago, Illinois) was used for each fixation device when comparing the 3 allografts, as well as for each allograft when comparing the 3 fixation devices. When the Kruskal-Wallis test revealed statistically significant (P < .05) differences for a given factor (ie, graft type or fixation device), Mann-Whitney tests were carried out to determine differences between levels within each factor.

RESULTS

The statistical analysis yielded a power of 80%. Low correlations (ie, R < .50) were found between cross-sectional area and biomechanical parameters.

In comparison of graft type, independent of fixation, the 4-stranded graft (ST) constructs demonstrated significantly lower cyclic displacement $(0.86 \pm 0.44 \text{ mm})$ than the PT $(1.12 \pm 0.51 \text{ mm}, P = .022)$, and both the ST and the PT exhibited a lower cyclic displacement than the Achilles tendon $(3.17 \pm 1.62 \text{ mm}, P < .001)$. The single-stranded graft (Achilles) constructs showed a significantly lower cyclic stiffness (156 \pm 25 N/mm) than the PT (229 \pm 48 N/mm, P < .001) and the ST (251 ± 36 N/mm, P < .001). With regard to ultimate failure load, the ST demonstrated significantly higher mean ultimate load to failure (832 \pm 255 N) than the PT (656 \pm 168 N, P = .021) and the Achilles $(479 \pm 87 \text{ N}, P < .001)$, whereas the 2-stranded PT exhibited a higher ultimate failure load than the Achilles (P <.001). The mean pullout stiffness of the Achilles (140 \pm 28 N/mm) was lower than that of the ST (219 ± 39 N/mm, P < .001) and the PT (199 ± 37 N/mm, P < .001) (Figure 2). Independent of graft type, there were no significant biomechanical differences in comparison of fixation devices ($P \ge$.98) (Tables 1 and 2).

Further analysis was achieved by evaluating the biomechanical performance of each construct with consideration

Fixation Technique	Cyclic Displacement mm	Cyclical Stiffness N/mm	Maximum Load at Failure Failure, N	Pullout Stiffness N/mm
Semitendinosus				
Delta	0.72 ± 0.24	265 ± 39	847 ± 266	241 ± 46
Intrafix	0.88 ± 0.56	258 ± 35	926 ± 215	219 ± 34
Calaxo	1.00 ± 0.49	225 ± 23	705 ± 274	193 ± 19
Total	0.86 ± 0.44	251 ± 36	832 ± 255	219 ± 39
Posterior tibialis				
Delta	0.94 ± 0.37	235 ± 40	755 ± 197	209 ± 39
Intrafix	1.10 ± 0.34	224 ± 51	653 ± 159	182 ± 22
Calaxo	1.31 ± 0.74	227 ± 58	559 ± 84	202 ± 45
Total	1.12 ± 0.51^a	229 ± 48	656 ± 168^b	199 ± 37
Achilles				
Delta	3.17 ± 2.07	161 ± 26	501 ± 83	153 ± 27
Intrafix	3.21 ± 1.08	159 ± 28	476 ± 106	137 ± 24
Calaxo	3.13 ± 1.79	146 ± 20	455 ± 80	128 ± 31
Total	3.17 ± 1.62^c	156 ± 25^d	479 ± 87^d	140 ± 28^d

TABLE 1 Cyclic Displacement, Cyclical Stiffness, Maximum Load to Failure, and Pullout Stiffness for Each Graft Using the 3 Fixation Devices

^{*a*}Posterior tibialis > semitendinosus (P < .05).

^{*b*}Posterior tibialis < semitendinosus (P < .05).

^cAchilles > semitendinosus, posterior tibialis (P < .05).

^{*d*}Achilles < semitendinosus, posterior tibialis (P < .05).

TABLE 2					
Biomechanical Properties That Demonstrated Statistically Significant Differences $(P < .05)$					

	Delta	Intrafix	Calaxo
Semitendinosus > Achilles	Creep	Creep	Creep
	Maximum failure	Maximum failure	Cyclic stiffness
	Cyclic stiffness	Cyclic stiffness	Pullout stiffness
Posterior tibialis > Achilles	Pullout stiffness Creep	Pullout stiffness Creep	Creep
	Maximum failure	Cyclic stiffness	Cyclic stiffness
	Cyclic stiffness Pullout stiffness	Pullout stiffness	Pullout stiffness
Semitendinosus > posterior tibialis		Maximum failure	
*		Pullout stiffness	

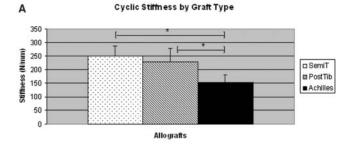
of both variables: graft type and screw type. The ST grafts exhibited a significantly lower cyclic displacement than the Achilles with use of all 3 screw types. The PT also showed a lower cyclic displacement than the Achilles with implantation of all 3 screw types. There were no significant differences between ST and PT cyclic displacements with any fixation device (Figure 3C).

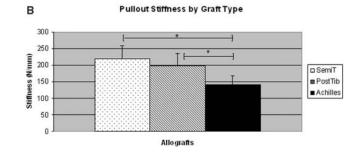
Similar statistical results were found for cyclic stiffness. In Delta, Intrafix, and Calaxo fixation, the 4-stranded ST displayed a higher stiffness than the 1-stranded Achilles. The 2-stranded PT, in comparison to Achilles, also exhibited a greater cyclic stiffness for all 3 screw types. No significant differences between ST and PT for cyclic stiffness were found (Figure 3A).

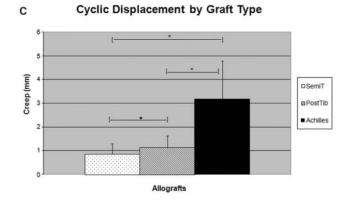
All constructs failed by graft pullout from the tunnel. Pullout stiffness during the load-to-failure test showed superior stiffness in the ST group as compared with the Achilles tendon for all 3 screws. Similarly, the PT also demonstrated significantly higher pullout stiffness than the Achilles tendon with 3 screw types. When ST was compared with PT, only the Intrafix screw group exhibited a significant difference (Figure 3B).

The maximum load to failure of the grafts demonstrated the ST group to have a higher failure load than that of the Achilles for the Delta implant and the Intrafix implant. The PT, in comparison with the Achilles, exhibited a greater failure load for the Delta screw and showed a trend of a significantly greater failure load for the Calaxo screw. When ST was compared with PT, only the Intrafix screw group displayed a higher failure load (Figure 3D).

As stated previously, of the 63 specimens tested, 1 Mitek Achilles, 1 Calaxo Achilles, and 1 Calaxo ST failed during cyclical testing by pulling out of the tunnel.







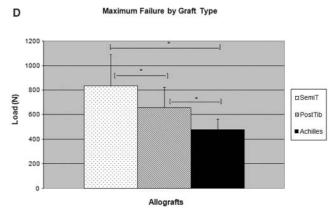
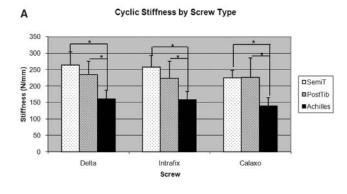
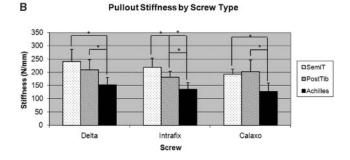


Figure 2. Comparison of each allograft for (A) cyclic stiffness, (B) pullout stiffness, (C) cyclic displacement, and (D) maxi-

mum failure.

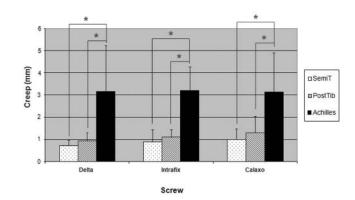






D

Cyclic Displacement by Screw Type



Maximum Failure by Screw Type

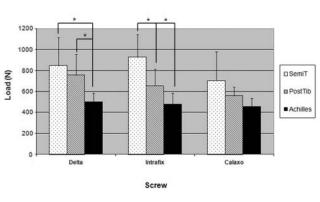


Figure 3. Comparison of screw fixation with each allograft for (A) cyclic stiffness, (B) pullout stiffness, (C) cyclic displacement, and (D) maximum failure.

DISCUSSION

The principal findings of our study demonstrated that the 1-stranded Achilles allograft construct exhibited inferior biomechanical properties, as compared with the PT and ST constructs. We found statistically significant differences in cyclic stiffness, maximum load at failure, pullout stiffness, and graft slippage for the Achilles during cyclic loading, when compared with the other 2 graft choices for all fixation devices. The results of this study suggest that secondary graft fixation, such as screw and post or staple fixation, should be used in addition to interference fixation when using the single-stranded Achilles allograft for ACL reconstruction.

The poor performance of the Achilles graft is likely multifactorial. First, the use of this graft requires drilling a tunnel larger than that for the other graft types. This larger tunnel is required when using a transtibial endoscopic technique because the calcaneal bone block is placed in the femoral tunnel. Because of the limitations of endoscopic reconstruction and the curved nature of the calcaneus, a minimum 10-mm bone plug is required. This anatomic limitation likely results in an increased disparity between soft tissue size and tunnel size, which compromises fixation strength. The soft tissue is not as thick in diameter as the bone plug; however, the portion of the graft that is prepared is more cylindrical than the proximal aspect of the Achilles tendon, thereby minimizing the geometrical mismatch between the tunnel and the graft. Second, the use of a single strand limits surface area contact between bone, soft tissue, and fixation device. With a multistrand construct, increased surface area contact for fixation is available. Furthermore, the Achilles tendon is not as cylindrical as the other grafts, thereby limiting the snug fit of the graft in the tunnel.

A second finding of our study is that the Intrafix device demonstrated a statistically significant difference in ultimate load to failure and pullout stiffness between quadrupled hamstring tendon grafts and both PT and Achilles grafts. However, the Intrafix device may theoretically favor the stability of multistrand graft construct. The shape of the sheath is designed to compress each of the 4 strands of a soft tissue graft in its own canal, thus providing interference fixation against the wall of the bone tunnel.¹⁶ Sectioning the Achilles or PT grafts into 4 strands at the fixation site would possibly have improved the performance of this device. A third finding is that in all specimens, failure occurred with the graft slipping past the fixation device (ie, as opposed to graft failure). Zantop et al⁴² reported that the use of titanium interference screws can damage soft tissue allografts; therefore, our 2 interference screws for testing were not composed of titanium.

To achieve knee stability, adequate initial fixation of the graft must be achieved. Mechanical fixation must be sufficient to provide stability to the graft during the initial postoperative period, before biological integration of the graft occurs. During this period, a graft fixation device must provide a minimum ultimate load to failure to allow for an accelerated rehabilitation program with immediate weightbearing and range of motion. However, with the use of interference fixation, graft healing to bone may be inhibited at

the screw insertion site. Furthermore, Noyes et al^{20,21} have calculated this minimum requirement to be approximately 450 N. In addition, the fixation device must provide appropriate stiffness with limited graft laxity. Although this number has not been clearly defined, side-to-side differences of 3 mm or more of anterior translation using arthrometric measurements have been defined as ACL deficiency.^{2,11} Thus, graft laxity must be minimized to prevent postoperative knee laxity and functional instability. Of note, all fixation devices in this study, irrespective of graft choice, demonstrated adequate fixation strength greater than 450 N, albeit with the Achilles being very close to the threshold. Although cyclic displacement does not directly correspond to anterior translation, cyclic displacement greater than 3 mm does cause concern that anterior translation may be similar in magnitude. Cyclic displacement was less than 3 mm for all testing in this study, except for Achilles fixation.

When allograft tissue is used, options include bone patellar tendon constructs, Achilles tendon, or all soft tissue allografts, such as anterior or PT tendon. Because of cost, availability, and potential graft tunnel mismatch, some orthopaedic surgeons have favored the use of soft tissue allografts in ACL reconstruction. Allografts are not without flaws, however. To our knowledge, only 1 study has reported a high clinical failure rate for allografts (return to sport was 4 months).³² To date, most biomechanical studies compared 1 type of soft tissue graft using various devices. Many of these studies using soft tissue grafts focused on 4-stranded grafts.[¶] Few studies analyzed 1-stranded⁸ and 2-stranded^{6,8,12,13} soft tissue grafts. Furthermore, to our knowledge, no biomechanical study has been performed using a single-stranded Achilles graft. Farmer et al¹³ used an Achilles tendon allograft in their biomechanical study: however, they doubled the graft to make a 2-stranded graft. As such, no current study has evaluated the use of ACL fixation devices with several types of soft tissue grafts. Although the use of soft tissue allografts is increasing, the biomechanical performance of commonly used fixation devices when used in this setting remains unknown.

Although no study has simulated all testing conditions performed here, our study compares favorably with previous reports where applicable. For the Delta screw fixation using 2-stranded grafts, Chang et al⁸ reported a cyclic displacement of 0.9 mm (versus 0.97 mm in the present study), a maximum load to failure of 1042 N (versus 755 N), and a pullout stiffness of 257 N/mm (versus 209 N/mm). For 4-stranded grafts using Intrafix device, results were comparable.¹⁶ Furthermore, in comparison of 4-stranded grafts using Intrafix or Delta screw fixation, no significant difference was found in a prior study,⁹ as in this study. The current study's results do differ from those of Caborn et al.⁶ who reported that Intrafix fixation exhibited higher displacement than a bioabsorbable Arthrex interference screw using 4-stranded human hamstring grafts. These differences may be attributable to the loading protocols of the respective studies; that is, Caborn et al used 1000 cycles between 50 and 200 N, whereas our protocol consisted of 500 cycles of 50 to 250 N. Caborn et al also used

¹References 6, 7, 9, 16, 23, 26, 30, 33, 34, 36, 39, 40, 42.

human tibiae, which may have affected their outcomes as well.

The main limitation of our study is the use of porcine tibiae in lieu of human bone; thus, direct extrapolation to human tibial fixation cannot be made. Nurmi et al²³ have called into question the acceptability of using porcine tibiae in evaluating tibial interference fixation, although in another study Nurmi et al²² defended the use of porcine tibiae in tibial fixation studies. However, because of the limited availability of young human cadaveric tibiae and extreme variability in age, sex, and physical condition of human specimens and the fact that other studies 8,15,16 have used porcine tibiae, we believe that the porcine tibial model was an acceptable substitute. Furthermore, because ultimate strength of a construct is directly related to BMD⁴ and because our BMDs are close to those of young cadaveric models, we believe that our study closely models young human tibia. Nagarkatti et al¹⁹ published findings suggesting that the average density of porcine bone is similar to that of young human bone (1.30 g/cm^2) and significantly higher than that of elderly human cadaveric bone (0.3 g/ cm²). Vuori et al³⁸ also measured the BMD of young active women and reported a mean of 1.09 g/cm^2 . The average BMDs obtained in this study ranged from 1.00 to 1.02 g/cm^2 , closer to the range of younger human bone density than that of elderly human tibia. The tibial side was selected for testing because the bone density of the tibial metaphysis is inferior to the femoral side and because the tibia is commonly considered to be the weak link in the initial graft construct. Furthermore, in this study, a bone scan was performed for 21 tibiae, and these were sorted into 3 equivalent groups; the remaining 42 tibiae were randomly assigned. To minimize variation, each animal (and, thus, each tibia) was the same age at time of slaughter. Nevertheless, this randomization may have created a bias to favor one experimental group, but because the allocation was random and the animals were the same age at slaughter, it is unlikely to have substantially influenced the results.

Another consideration that needs to be addressed is the difference in graft fixation technique into the testing equipment. Specifically, the Achilles graft was grasped through the bone block, whereas the other 2 grafts were not grasped through the collagenous portion but rather looped around the metal bar. Although the methods are slightly different, we believe it not to be a significant difference. By nature of the surgical configuration, these experiments are structural assessments of the allograft fixation properties. The experimental techniques used for testing the tendon-bone grafts (Achilles) and soft tissue grafts (PT and ST) represent standard, validated methods for quantifying biomechanical responses of tendon grafts. In our laboratory, each setup was validated to ensure minimal mechanical compliance of the test fixtures. The fact that the PT and ST constructs did not fail at the bar (over which the tendons were looped) suggests that this boundary condition did not considerably weaken the tissues at this location. During testing, no slippage was observed at the bar-tendon or bone cement-tendon insertion interfaces. Although the boundary conditions for these 2 configurations differ, it is not possible to reliably test all 3 graft types (with clinical relevancy) using an identical grasping technique, owing to their anatomical and geometric differences.

When compared with other studies comparing tibial fixation of soft tissue constructs in human cadaveric bone, our results in general are similar in load to failure but different in displacement and stiffness. These differences may be attributed to different tibial models or different biomechanical testing setups. In the first study, Caborn et al⁷ used human tibiae (BMD, 0.847 g/cm^2). Maximum load at failure was similar between our results and those of Caborn and colleagues, based on the larger bioabsorbable interference screw (35 mm), but we found lower displacement and higher stiffness than they did. In another study (BMD, 0.74 g/cm²), Caborn et al⁶ demonstrated a higher displacement and lower stiffness for Intrafix and interference screw fixation but a similar load to failure for quadrupled tendon grafts, relative to the current study. Magen et al¹⁸ also used young cadaveric tibia bone tunnels and reported a significantly lower load at failure; however, BMD was not reported. A last human tibia study³⁵ investigating fixation strength demonstrated in elderly cadaveric tibiae (BMD, 0.604 g/cm²) a load to failure that was significantly lower than ours. Nevertheless, because our testing resulted in improved biomechanical stability relative to the aforementioned studies, our results may provide the best-case scenario.

A last shortcoming of this study is that the Calaxo screw has been officially taken off the market. Despite this fact, this study demonstrated the use of a well-performing interference screw using 3 different allografts. This interference fixation performed well biomechanically. Interestingly, there were minimal differences noted between the Calaxo and Arthrex interference screws.

In conclusion, initial biomechanical fixation properties of the Achilles allograft are inferior to PT and quadrupled hamstring grafts for 3 commonly used tibial fixation devices. When using the Achilles allograft for ACL reconstruction, secondary forms of tibial graft fixation should be considered to decrease risk of fixation failure or graft slippage.

ACKNOWLEDGMENT

We thank Susan Shott for her tremendous assistance with the statistical analysis, as well as Arthrex, Mitek, and Smith & Nephew for donating the fixation devices.

REFERENCES

- 1. Abate JA, Fadale PD, Hulstyn MJ, Walsh WR. Initial fixation strength of polylactic acid interference screws in anterior cruciate ligament reconstruction. *Arthroscopy.* 1998;14:278-284.
- 2. Anderson AF, Synder RB, Federspiel CF, Lipscomb AB. Instrumented evaluation of knee laxity: a comparison of five arthrometers. *Am J Sports Med.* 1992;20:135-140.
- 3. Bach BR Jr. Revision anterior cruciate ligament surgery. *Arthroscopy.* 2003;19(10):14-29.
- 4. Brand JC Jr, Pienkowski D, Steenlage E, Hamilton D, Johnson DL, Caborn DN. Interference screw fixation strength of a quadrupled hamstring tendon graft is directly related to bone mineral density and insertion torque. *Am J Sports Med.* 2000;28:705-710.

- 5. Brown CH Jr, Carson EW. Revision anterior cruciate ligament surgery. *Clin Sports Med.* 1999;18:109-171.
- Caborn DN, Brand JC Jr, Nyland J, Kocabey Y. A biomechanical comparison of initial soft tissue tibial fixation devices: the Intrafix versus a tapered 35-mm bioabsorbable interference screw. *Am J Sports Med.* 2004;32:956-961.
- Caborn DN, Nyland J, Selby J, Tetik O. Biomechanical testing of hamstring graft tibial tunnel fixation with bioabsorbable interference screws. *Arthroscopy.* 2003;19:991-996.
- Chang HC, Nyland J, Nawab A, Burden R, Caborn DN. Biomechanical comparison of the bioabsorbable RetroScrew system, BioScrew XtraLok with stress equalization tensioner, and 35-mm Delta screws for tibialis anterior graft-tibial tunnel fixation in porcine tibiae. *Am J Sports Med.* 2005;33:1057-1064.
- Coleridge SD, Amis AA. A comparison of five tibial-fixation systems in hamstring-graft anterior cruciate ligament reconstruction. *Knee Surg Sports Traumatol Arthrosc.* 2004;12:391-397.
- Cooper DE, Deng XH, Burstein AL, Warren RF. The strength of the central third patellar tendon graft: a biomechanical study. *Am J Sports Med.* 1993;21:818-824.
- 11. Daniel DM, Malcom LL, Losse G, Stone ML, Sachs R, Burks R. Instrumented measurement of anterior laxity of the knee. *J Bone Joint Surg Am.* 1985;67:720-726.
- Fabbriciani C, Mulas PD, Ziranu F, Deriu L, Zarelli D, Milano G. Mechanical analysis of fixation methods for anterior cruciate ligament reconstruction with hamstring tendon graft: an experimental study in sheep knees. *Knee.* 2005;12(2):135-138.
- Farmer JM, Lee CA, Curl WW, Martin DF, Kortesis B, Poehling GG. Initial biomechanical properties of staple-anchor Achilles tendon allograft and interference screw bone-patellar tendon-bone autograft fixation for anterior cruciate ligament reconstruction in a cadaveric model. *Arthroscopy.* 2006;22:1040-1045.
- Harner CD, Olson E, Irrgang JJ, Silverstein S, Fu FH, Silbey M. Allograft versus autograft anterior cruciate ligament reconstruction: 3- to 5-year outcome. *Clin Orthop Relat Res.* 1996;324:134-144.
- Kousa P, Jarvinen TL, Kannus P, Jarvinen M. Initial fixation strength of bioabsorbable and titanium interference screws in anterior cruciate ligament reconstruction: biomechanical evaluation by single cycle and cyclic loading. *Am J Sports Med.* 2001;29:420-425.
- Kousa P, Jarvinen TL, Vihavainen M, Kannus P, Jarvinen M. The fixation strength of six hamstring tendon graft fixation devices in anterior cruciate ligament reconstruction, part II: tibial site. *Am J Sports Med.* 2003;31:182-188.
- Kuhn MA, Ross G. Allografts in the treatment of anterior cruciate ligament injuries. Sports Med Arthrosc. 2007;15(3):133-138.
- Magen HE, Howell SM, Hull ML. Structural properties of six tibial fixation methods for anterior cruciate ligament soft tissue grafts. *Am J Sports Med.* 1999;27:35-43.
- Nagarkatti DG, McKeon BP, Donahue BS, Fulkerson JP. Mechanical evaluation of a soft tissue interference screw in free tendon anterior cruciate ligament graft fixation. *Am J Sports Med.* 2001;29:67-71.
- Noyes FR, Butler DL, Grood ES, Zernicke RF, Hefzy MS. Biomechanical analysis of human ligament grafts used in knee-ligament repairs and reconstructions. *J Bone Joint Surg Am.* 1984;66:344-352.
- Noyes FR, Butler DL, Paulos LE, Grood ES. Intra-articular cruciate reconstruction, I: perspectives on graft strength, vascularization, and immediate motion after replacement. *Clin Orthop Relat Res.* 1983;172:71-77.
- Nurmi JT, Jarvinen TL, Kannus P, Sievanen H, Toukosalo J, Jarvinen M. Compaction versus extraction drilling for fixation of the hamstring tendon graft in anterior cruciate ligament reconstruction. *Am J Sports Med.* 2002;30:167-173.
- 23. Nurmi JT, Sievanen H, Kannus P, Jarvinen M, Jarvinen TL. Porcine tibia is a poor substitute for human cadaver tibia for evaluating interference screw fixation. *Am J Sports Med.* 2004;32:765-771.
- 24. Olsen EJ. Use of soft tissue allografts in sports medicine. *Adv Oper Orthop.* 1993;1:111-128.

- 25. Pena F, Grontvedt T, Brown GA, Aune AK, Engebretsen L. Comparison of failure strength between metallic and absorbable interference screws: influence of insertion torque, tunnel-bone block gap, bone mineral density, and interference. *Am J Sports Med.* 1996;24:329-334.
- Rittmeister ME, Noble PC, Bocell JR Jr, Alexander JW, Conditt MA, Kohl HW III. Components of laxity in interference fit fixation of quadrupled hamstring grafts. *Acta Orthop Scand.* 2002;73:65-71.
- Rupp S, Seil R, Schneider A, Kohn DM. Ligament graft initial fixation strength using biodegradable interference screws. *J Biomed Mater Res.* 1999;48:70-74.
- Shaffer B, Gow W, Tibone JE. Graft-tunnel mismatch in endoscopic anterior cruciate ligament reconstruction: a new technique of intraarticular measurement and modified graft harvesting. *Arthroscopy.* 1993;9:633-646.
- Shelton WR, Treacy SH, Dukes AD, Bomboy AL. Use of allografts in knee reconstruction, I: basic science aspects and current status. J Am Acad Orthop Surg. 1998;6:165-168.
- Shino K, Pflaster DS. Comparison of eccentric and concentric screw placement for hamstring graft fixation in the tibial tunnel. *Knee Surg Sports Traumatol Arthrosc.* 2000;8(2):73-75.
- Simonds RJ, Holmberg SD, Hurwitz RL, et al. Transmission of human immunodeficiency virus type 1 from a seronegative organ and tissue donor. N Engl J Med. 1992;326:726-732.
- Singhal MC, Gardiner JR, Johnson DL. Failure of primary anterior cruciate ligament surgery using anterior tibialis allograft. *Arthroscopy*. 2007;23:469-475.
- 33. Stadelmaier DM, Lowe WR, Ilahi OA, Noble PC, Kohl HW III. Cyclic pull-out strength of hamstring tendon graft fixation with soft tissue interference screws: influence of screw length. *Am J Sports Med.* 1999;27:778-783.
- 34. Starch DW, Alexander JW, Noble PC, Reddy S, Lintner DM. Multistranded hamstring tendon graft fixation with a central fourquadrant or a standard tibial interference screw for anterior cruciate ligament reconstruction. Am J Sports Med. 2003;31:338-344.
- 35. Steenlage E, Brand JC Jr, Johnson DL, Caborn DN. Correlation of bone tunnel diameter with quadrupled hamstring graft fixation strength using a biodegradable interference screw. *Arthroscopy.* 2002;18:901-907.
- 36. Tetsumura S, Fujita A, Nakajima M, Abe M. Biomechanical comparison of different fixation methods on the tibial side in anterior cruciate ligament reconstruction: a biomechanical study in porcine tibial bone. *J Orthop Sci.* 2006;11:278-282.
- 37. Verma N, Noerdlinger MA, Hallab N, Bush-Joseph CA, Bach BR Jr. Effects of graft rotation on initial biomechanical failure characteristics of bone-patellar tendon-bone constructs. *Am J Sports Med.* 2003;31:708-713.
- 38. Vuori I, Heinonen A, Sievanen H, Kannus P, Pasanen M, Oja P. Effects of unilateral strength training and detraining on bone mineral density and content in young women: a study of mechanical loading and deloading on human bones. *Calcif Tissue Int.* 1994;55:59-67.
- Weimann A, Rodieck M, Zantop T, Hassenpflug J, Petersen W. Primary stability of hamstring graft fixation with biodegradable suspension versus interference screws. *Arthroscopy.* 2005;21:266-274.
- Yoo JC, Ahn JH, Kim JH, et al. Biomechanical testing of hybrid hamstring graft tibial fixation in anterior cruciate ligament reconstruction. *Knee.* 2006;13:455-459.
- 41. Zantop T, Weimann A, Rummler M, Hassenpflug J, Petersen W. Initial fixation strength of two bioabsorbable pins for the fixation of hamstring grafts compared to interference screw fixation: single cycle and cyclic loading. *Am J Sports Med.* 2004;32:641-649.
- 42. Zantop T, Weimann A, Schmidtko R, Herbort M, Raschke MJ, Petersen W. Graft laceration and pullout strength of soft-tissue anterior cruciate ligament reconstruction: in vitro study comparing titanium, poly-d,l-lactide, and poly-d,l-lactide-tricalcium phosphate screws. *Arthroscopy.* 2006;22:1204-1210.

For reprints and permission queries, please visit SAGE's Web site at http://www.sagepub.com/journalsPermissions.nav