Patellar Tendon Versus Hamstring Tendon Autografts for Anterior Cruciate Ligament Reconstruction

A Randomized Controlled Trial Using Similar Femoral and Tibial Fixation Methods

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Background: Controversy remains over the most appropriate graft for anterior cruciate ligament reconstruction.

Hypothesis: There is no significant difference in outcomes after 4-strand hamstring and patellar tendon autograft anterior cruciate ligament reconstructions using similar fixation techniques.

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: Between August 2000 and May 2003, 64 Keller Army Hospital patients with complete anterior cruciate ligament tears were randomized to hamstring (n = 32) or patellar tendon (n = 32) autograft anterior cruciate ligament reconstruction. Operative graft fixation and rehabilitative techniques were the same for both groups. Follow-up assessments included the Single Assessment Numeric Evaluation score, Lysholm score, International Knee Documentation Committee score, and Knee Injury and Osteoarthritis Outcome Score. Postoperative radiographs were analyzed for tunnel location and orientation.

Results: Eleven women and 53 men were randomized. Eighty-three percent of the patients (53 of 64) had follow-up of greater than 2 years, or to the point of graft rupture or removal (average follow-up, 36 months). Four hamstring grafts (12.5%) and three patellar tendon grafts (9.4%) ($P = .71$) ruptured. One deep infection in a hamstring graft patient necessitated graft removal. Forty-five of the 56 patients with intact grafts had greater than 2-year follow-up. Patients with patellar tendon grafts had greater Tegner activity scores ($P = .04$). Single Assessment Numeric Evaluation scores were 88.5 (95% confidence interval: 83.1, 93.8) and 90.1 (95% confidence interval: 85.2, 96.1) for the hamstring and patellar tendon groups, respectively ($P = .53$). Lysholm scores were 90.3 (95% confidence interval: 84.4, 96.1) and 90.4 (95% confidence interval: 84.5, 96.3) for the hamstring and patellar tendon groups, respectively ($P = .97$). There were no significant differences in knee laxity, kneeling pain, isokinetic peak torque, International Knee Documentation Committee score, or Knee Injury and Osteoarthritis Outcome Scores. Postoperative graft rupture correlated with more horizontal tibial tunnel orientation.

Conclusion: Hamstring and patellar tendon autografts provide similar objective, subjective, and functional outcomes when assessed at least 2 years after anterior cruciate ligament reconstruction.

Keywords: anterior cruciate ligament reconstruction; randomized controlled trial; ACL; hamstring autograft; patellar tendon autograft

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Reconstruction of the anterior cruciate ligament (ACL) has gained wide acceptance in the orthopaedic community to become one of the most common procedures performed.[1,2,9,11,14,23,27,43] There are several different types of grafts used for ACL reconstruction, although the bone–patellar tendon–bone (BTB) autograft, which uses the central third of the patellar tendon, is considered by some to be the standard to which other grafts should be compared.[13,15] The BTB autograft has the reported advantage of having bone plugs on each end of the graft that provide excellent fixation points for the graft-screw interface and rapid healing within bone tunnels.[9,11,14,23,27] This method of reconstruction can, however, be associated with donor-site morbidity,[25,39] anterior knee pain, disturbances in knee sensitivity, and kneeling discomfort.[2,9] Therefore, alternative graft choices have been explored with the hamstring (HS) autograft being the most popular alternative.[2,7,25] Reported advantages to HS autografts include decreased donor-site morbidity[12] and, potentially, decreased anterior knee pain.[5,9,10,27,38] Reported disadvantages associated with HS autografts include limitations in graft fixation due to the absence of bone blocks on each end of the graft leading to potentially less rigidity compared to a BTB autograft.[24,40]

Previous studies comparing the results of BTB to HS reconstructions often have been performed using different femoral and tibial fixation techniques for each graft type. The use of different fixation methods may introduce confounding factors when comparing the 2 techniques. Several methods for securing the HS autograft have been used, including ligament buttons, screw-washer fixation, suture-screw posts, and metal pins. Another means of fixation is the interference screw, which can be used for both bony and soft tissue fixation[7] at the aperture of tunnels. Both the patellar tendon and HS tendon grafts can be secured on the femur and tibia using interference screws.

The purpose of this study was to conduct a randomized controlled trial (RCT) comparing the outcomes of ACL reconstructions performed with BTB and HS tendon autografts. Our study emphasized a common method of fixation, dual tibial and dual femoral, for both groups. The study population was a young, active military population that was required to return to a vigorous lifestyle. With these surgical techniques in this study population, we sought to determine if there was a significant difference in outcomes between BTB and 4-strand semitendinosus/gracilis HS autograft ACL reconstructions.

MATERIALS AND METHODS

Patients

Between August 2000 and May 2003, we conducted an RCT comparing BTB and HS autograft ACL reconstructions. This study was reviewed and approved by the Keller Army Hospital Institutional Review Board and the US Army Clinical Investigation Research Office. Informed consent was obtained from each participant enrolled.

Patients were eligible for inclusion in this study if they were between the ages of 17 and 45 years and had (1) a history of a knee injury, (2) symptoms and a physical examination consistent with the diagnosis of ACL deficiency, and (3) MRI indicating ACL deficiency. The knee was evaluated arthroscopically to verify the ACL deficiency and to assess whether the patient had multiple knee ligament injuries, associated injuries, or both. Exclusion criteria included a prior ACL reconstruction on either knee, multiple knee ligament injuries that required concomitant surgery, or the presence of full-thickness chondral lesions. Patients with other associated injuries (eg, meniscal tear, partial-thickness articular cartilage injury) were included. Patients meeting all inclusion criteria were randomized to either BTB or HS reconstruction after diagnostic arthroscopy. Randomization was stratified by surgeon, and accomplished using randomly ordered sealed envelopes.

Surgical Technique

General. Four surgeons experienced in both techniques performed all reconstructions. Patients were positioned supine and the operative surgeon determined tourniquet use. Anesthetic technique (spinal or general anesthesia) was determined by the patient's preference. The surgeon performed an examination under anesthesia and a diagnostic arthroscopy of the knee in all patients to determine eligibility. Eligible patients were randomized after the diagnostic arthroscopy. Independent of the autograft used, both types were secured with dual fixation techniques on both the femoral and tibial sides.

After fixing the graft, the surgeon examined the knee to ensure that there was a full range of motion, a negative Lachman test, and no pivot shift. At the conclusion of each procedure, a sterile dressing was applied and the operative knee was placed in a knee immobilizer fixed in a hyperextension position appropriate for the maximum hyperextension achieved in the knee. The patient wore the knee immobilizer for 2 to 3 weeks, while asleep and during ambulation. Patients were encouraged to maintain the knee in maximum hyperextension while at rest for the first 3 to 4 weeks. The knee immobilizer was discontinued once the patient had regained good quadriceps control and was able to ambulate without a limp. No additional bracing was used after patients stopped wearing the knee immobilizer.

BTB Autograft Reconstruction. Bone–patellar tendon–bone grafts were harvested through a midline incision over

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the patellar tendon. In general, a 10-mm–wide tendon graft was harvested with 10-mm–wide bone plugs from the patella and tibial tubercle. No. 5 nonabsorbable tape was passed through the femoral-side bone plug and through an EndoButton (Smith & Nephew Endoscopy, Andover, Massachusetts). Three No. 5 braided nonabsorbable sutures were passed through the tibial-side bone plug.

A 10-mm tibial tunnel was drilled over a guidewire starting at the anterior edge of the medial collateral ligament in the medial metaphysis of the proximal tibia. This tunnel exited in the posterior half of the tibial ACL insertion. A 10-mm–diameter femoral tunnel was drilled endoscopically using a cannulated acorn reamer over a guidewire passed through the tibial tunnel and positioned 7 mm forward from the over-the-top position at the 10-o'clock location in the intercondylar notch for a right knee and the 2-o'clock position for a left knee. Over the guidewire, a 4.5-mm hole was drilled through the lateral femoral cortex for passage of the EndoButton.

The EndoButton-BTB construct was passed into the tunnels, and the EndoButton was deployed on the lateral cortex of the distal femur. An interference-fit Bioscrew (Arthrex, Naples, Florida) was used for additional femoral fixation, positioning the screw forward of the graft, with the tendinous portion of the graft in the rear position of the femoral tunnel. Subsequently, the knee was cycled through flexion and extension approximately 20 times with the graft pulled taut through the tibial tunnel. On the tibial side, the graft was fixed with an interference-fit Bioscrew inserted with the knee in approximately 15° of flexion. For secondary fixation, the sutures from the tibial-side bone plug were tied over a 6.5-mm cancellous screw and washer positioned just distal to the opening of the tibial tunnel.

The tibial periosteum was closed with absorbable No. 0 braided sutures over the tibial tunnel and hardware. Excessive bone from the bone plugs was placed in the patellar and tibial tubercle defects. The patellar tendon sheath was closed with absorbable No. 0 braided sutures.

Hamstring Autograft Reconstruction. The HS group operations were performed in the same manner as the BTB operations with the 5 exceptions noted hereafter. (1) A vertical skin incision located over the pes anserine tendon insertions at the proximal, medial tibia was used. (2) The semitendinosus and gracilis tendons were harvested through this incision with an appropriately sized tendon stripper, and a 4-strand HS graft with the semitendinosus and gracilis tendons was prepared. The 2 tendons were folded over the No. 5 nonabsorbable tape, which was connected to the EndoButton. In each tendon end, No. 2 nonabsorbable braided sutures were placed for traction so that each tendon strand had approximately equal tension during tibial fixation. (3) Femoral and tibial tunnel sizes were determined by the diameter of the graft constructs. The femoral tunnel was drilled so that there was approximately 1 mm of bone between the tunnel and the over-the-top position. The tibial tunnel was positioned as described for the BTB grafts. (4) Interference-fit screw sizes were determined by the operative surgeon. In general, femoral interference-fit screws were 1 mm smaller in diameter than the femoral tunnel and tibial interference-fit screws were the same size as the tibial tunnel. These screw sizes were determined by the recommendations of the manufacturer (Arthrex) at the time the study was initiated. (5) A 6.5-mm cancellous screw and spiked ligament washer (Innovasive Devices Inc, Marlborough, Massachusetts) was used for secondary fixation of the semitendinosus and gracilis tendons to the proximal tibial cortex. The screw and washer were placed just distal to the tibial tunnel opening.

Rehabilitation

All patients began rehabilitation on postoperative day 1. Patients initiated quadriceps-strengthening exercises and were allowed to bear weight as tolerated. Patients were instructed to maintain the operative knee in full hyperextension while at rest. Active and passive range of motion was advanced as tolerated. As range of motion progressed, closed kinetic chain strengthening exercises and functional activities, such as stationary bike riding, were added to the rehabilitation program. Patients were allowed to resume running between 3 and 4 months postoperatively if they had regained full motion, had good knee flexion and extension strength, and had no knee effusion. During the 3- to 6-month postoperative period, functional rehabilitation progressed with emphasis on sport-specific activities. Patients were allowed to return to full activity once they had no significant side-to-side functional deficits, and no knee effusion, but not before 6 months postoperatively.

Follow-up Assessments

Study participants were assessed preoperatively and at 2, 3, and 4 years postoperatively using both subjective and objective evaluation tools. For this study, we used only the longest follow-up point for each patient. Study participants who had revision ACL reconstructions subsequent to their index operation were not included in this analysis.

Radiographic Assessment of Tunnel Placement

Available (n = 51) postoperative AP and lateral radiographs were assessed for tunnel placement by one author (T.M.D.). An average of 3 values were obtained using the digital measuring tools and graphical interface software provided with our picture archiving and communication radiographic system.

Femoral tunnel position was assessed using the techniques described by Amis et al[3] and validated by Klos et al[26] (Figure 1). Briefly, on the lateral radiograph a circle was made using the distal curvature of the lateral femoral condyle. A line bisecting the circle was made along Blumensaat's line (length A). Along this line, the distance was measured from the circle distally to the distal opening of the femoral tunnel (length B). The femoral tunnel position was recorded as a percentage (length B/length A × 100%).

Tibial tunnel placement was assessed using the techniques described by Howell et al.[19] The presence or absence

Figure 1. Lateral radiograph demonstrating the assessment of femoral tunnel position as described by Amis et al[3] and validated by Klos et al.[26] In this example, the femoral tunnel position is 2.88/4.75 × 100% = 60.6%. Also, there is no intercondylar roof impingement in this case as demonstrated by the position of the anterior edge of the tibial tunnel posterior to Blumensaat's line.

Figure 2. Anteroposterior radiograph demonstrating the assessment of coronal tibial tunnel angle and containment of the tibial tunnel within the tibial eminences as described by Howell et al.[19] In this example, the coronal tibial tunnel angle is 64.2° and the tibial tunnel is contained between the tibial eminences.

of graft roof impingement was determined from the lateral radiograph with the knee positioned in hyperextension. Radiographic roof impingement was present if, on the lateral radiograph, the anterior edge of the tibial tunnel was anterior to Blumensaat's line. Containment of the tibial tunnel within the confines of the tibial eminences was also checked on the AP radiograph. The coronal tibial tunnel angle was obtained by measuring on the AP radiograph the acute angle between a line drawn along the axis of the tibial tunnel and a line drawn parallel to the tibial plateau (Figure 2).

Tunnel position measurements were compared between the BTB and HS groups, as well as between patients with ruptured and intact grafts.

Clinical and Functional Evaluations

The Lysholm score,[29] Tegner activity score,[41] Single Assessment Numeric Evaluation (SANE) score,[44,45] International Knee Documentation Committee (IKDC) evaluation system,[18] and Knee Injury and Osteoarthritis Outcome Score (KOOS)[35] were used to evaluate the patient's functional outcome. The Lysholm, Tegner, SANE, KOOS, and the subjective and symptoms portion of the IKDC evaluation system were self-administered.

The objective portion of the 2000 IKDC evaluation system[21] was completed by orthopaedic surgeons throughout the military who were blinded to treatment (during follow-up evaluations, the patients' knees were covered with stockinettes, preventing the evaluator from determining the graft type based on the incision location). At Keller Army Hospital, an orthopaedic surgeon who was not involved in any of the operations (B.J.N.) completed all evaluations.

Physical therapists who were not involved in the patient's rehabilitation conducted objective evaluations to assess differences between the involved and uninvolved limb. These evaluations included differences in heel height, range of motion, knee and thigh girth, functional performance on hop tests, and isokinetic strength. Anterior tibial displacement was measured using the KT-2000 arthrometer (MEDmetric, San Diego, California). These physical therapy assessments were not blinded.

Differences in heel height, used to detect subtle knee flexion contractures, were measured with the patient lying prone on a firm examination table with the legs off the end of the table. The difference in heel height was measured to the nearest half-centimeter.[36]

Range of motion was assessed using a universal goniometer. The hinge of the goniometer was centered over the lateral joint line of the knee at the midsagittal position, and range of motion was assessed to the nearest 5°. The deficits (in degrees) of the involved limb compared with the uninvolved limb were measured for both active and passive hyperextension (A_1 uninvolved, A_2 involved), extension deficit from full extension (B_1 uninvolved, B_2 involved), and flexion (C_1 uninvolved, C_2 involved). Using these values, flexion deficit (C_1–C_2), extension deficit ($[A_1–B_1] – [A_2–B_2]$), and arc deficit ($[A_1+C_1–B_1] – [A_2+C_2–B_2]$) were calculated.

Differences in knee and thigh girth were measured by assessing the difference in circumference between the limbs (uninvolved – involved girths) at the midpatella level, 10 cm superior to the patella, and at 15 cm superior to the patella.

Functional tests were performed using the single-legged hop for distance and 6-m single-legged hop for time.[33] Two trials were performed for each hop test on both the involved and uninvolved limbs, and the mean scores were reported as a percentage of the uninvolved limb for both tests. For the 6-m hop for time, a percentage greater than 100% indicates a slower time and thus a deficit in performance.

A Biodex Medical System 3 dynamometer (Biodex, Shirley, New York) was used to assess peak isokinetic concentric knee extension and flexion torque at a slow (60 deg/s, 10 repetitions) and fast (300 deg/s, 20 repetitions) speed. Strength deficits were recorded as a percentage deficit in the involved limb relative to the uninvolved limb.

Side-to-side differences in anterior tibial displacement (involved-uninvolved displacement) were measured using a KT-2000 (at Keller Army Hospital) or KT-1000 (at other evaluation sites) arthrometer (MEDmetric). Anterior translations at 134 N of pull are reported and categorized by the IKDC criteria.[18,21]

Statistical Methods

Median values and ranges are presented for continuous variables and frequency statistics are presented for categorical variables. Group differences were assessed using least-square means estimates for continuous variables, controlling for the stratifying variable of surgeon, and the mean score statistic (Cochran-Mantel-Haenszel) for ordinal variables. We used the Mann-Whitney statistics to assess for differences in the ordinal Tegner score. The difference in the proportion of failures based on graft type was assessed using the Fisher exact test and survival analysis. Survival analysis incorporates the follow-up time for those who did not fail in comparing the estimated hazard functions (probability of graft failure over time) by group, accounting for surgeon.

Before the study, we identified the SANE score as our primary outcome measurement. The SANE score was selected as the primary outcome because of good correlation with other outcome measures,[45] and because we had SANE data from our population to provide variability for sample size determination. We used a standard deviation of 13.5 based on previous unpublished SANE data from our institution. We considered a difference of 10 points in the SANE between the 2 treatment groups as a clinically significant difference based on our experience with the SANE score in other research. With a 5% probability of a type I error and a power of 80%, we determined that a sample size of 60 patients was necessary for this study. To accommodate for patient dropout, we enrolled 64 patients. Statistical analysis was performed using SAS software (SAS Institute, Cary, North Carolina) by the Center for Data Analysis and Statistics at the US Military Academy, West Point, New York.

RESULTS

Figure 3 provides a flow diagram for patients evaluated for this study. The surgeons in this study performed a total of 159 ACL operations during the 34-month period in which patients were enrolled into the study. Twenty-six patients declined to participate in the randomized controlled trial, selected their graft, and were subsequently followed in a prospective manner (results not included in this report). Sixty-four patients were excluded before enrollment or declined to participate. Most of these patients were excluded due to previous ACL reconstructions on either knee or because of multiligament knee injuries. Five patients who consented to participate were excluded at the time of surgery due to exclusion criteria such as full-thickness articular cartilage defects. Sixty-four patients (40%) consented to participate and were randomized to BTB or HS reconstruction. One surgeon performed 17 BTB and 17 HS reconstructions, 1 surgeon performed 4 of each type, the third performed 7 BTB and 5 HS reconstructions, and the fourth surgeon performed 4 BTB and 6 HS reconstructions. Both groups were similar in terms of age, gender distribution, and time from injury to surgery (Table 1).

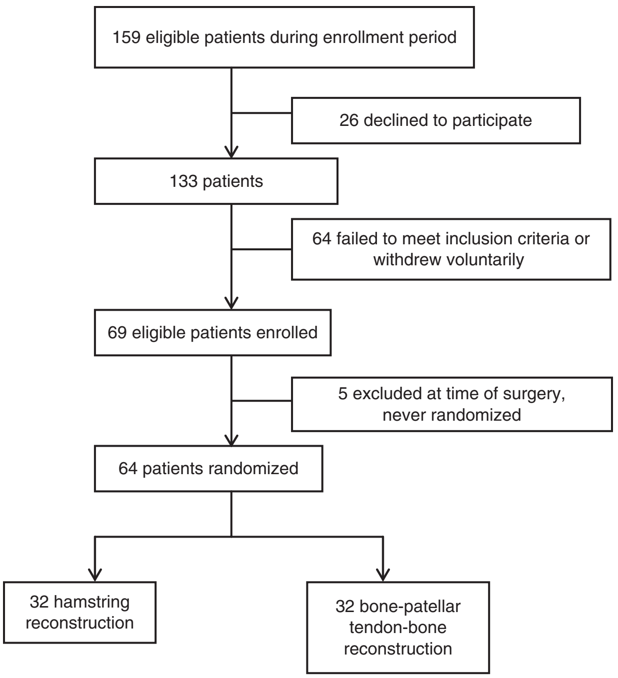

Figure 3. Study participant flow chart.

Most ACL tears were due to noncontact injuries (65.6%), although most injuries occurred while playing contact or collision sports (59.4%). The greatest number of injuries occurred playing football (27.0%), followed by basketball (9.5%), soccer (7.9%), and track and field (7.9%).

Other injuries present at the time of surgery in the HS group included 17 patients with meniscal injuries (53%) and 7 patients with partial-thickness articular cartilage lesions. Cartilage lesions were located on the lateral femoral condyle (3 patients), the central femoral trochlea (1 patient), lateral facet of the patella (1 patient), medial femoral condyle (1 patient), and the central ridge of the patella (1 patient). Three of the patients with cartilage lesions also had meniscal injuries. Therefore, there were 21 patients in the HS group (65.6%) with other injuries noted.

TABLE 1
Summary of Patient Characteristics by Surgical Graft Group[a]

	BTB (N = 32)	HS (N = 32)	P Value
Age (range)	21.7 (18-37)	22.1 (17-44)	.79
Gender			.32
Male	25 (78.1%)	28 (87.5%)	
Female	7 (21.9%)	4 (12.5%)	
Time between injury and surgery			.78
Acute[b]	23 (71.9%)	24 (75.0%)	
Chronic	9 (28.1%)	8 (25.0%)	
Time point of follow-up			N/A[c]
2 y	13 (44.8%)	10 (37.0%)	
3 y	3 (10.3%)	4 (14.8%)	
4 y	4 (13.8%)	8 (29.6%)	
≥ 5 y	1 (3.4%)	2 (7.4%)	
Unable to contact for follow-up	8 (27.6%)	3 (11.1%)	

[a]BTB, bone–patellar tendon–bone; HS, hamstring.
[b]<3 months.
[c]N/A, not applicable due to the inability to determine differences across so many categories with such small numbers in each cell.

In the BTB group, there were 16 patients (50%) with meniscal injuries and 4 patients with partial-thickness articular cartilage lesions. Isolated cartilage lesions were located on the patella (1 patient), the lateral tibial plateau (1 patient), and the medial femoral condyle (1 patient). One patient with a partial-thickness cartilage lesion of the lateral tibial plateau also had a cartilage lesion of the medial femoral condyle and softening of the articular cartilage of the lateral femoral condyle and medial tibial plateau. Only 1 patient with a cartilage lesion in the BTB group also had a meniscal injury. Therefore, there were 20 patients (62.5%) with other injuries noted in the BTB group. There was no statistically significant difference in the number of associated injuries between the 2 groups (P = .79).

Table 2 summarizes the complications and graft ruptures. There were 3 BTB (9.4%) and 4 HS (12.5%) graft ruptures (P = .71). Seventy-five percent of the HS ruptures occurred before or at 1 year, while 100% of the BTB ruptures occurred after 1 year. Six of the graft ruptures occurred due to a noncontact injury mechanism and 1 in a contact injury. These 7 patients had revision ACL reconstructions and their follow-up data were not included in the final analysis. Seven patients in the BTB group and 5 patients in the HS group had subsequent operations on the reconstructed knee (Table 3).

Two patients (both in the BTB group) sustained contralateral ACL tears during the follow-up period. In 1 patient, the contralateral ACL tear occurred 8 months after the index operation. Because the objective evaluations were dependent on a normal contralateral knee, only the subjective outcomes for this patient are included in the follow-up data. In the other patient, the contralateral ACL tear occurred 30 months after the index operation. This individual's 2-year subjective and objective data are included in the follow-up data.

One patient had a serious adverse event. At 1 month postoperatively, this patient developed a deep infection of the knee and was treated with irrigation and debridement to include removal of the ACL graft and all hardware. This patient was in the HS group. A later revision was performed without subsequent complication; however, due to the removal of the original graft, the follow-up data on this patient were not included in the final analysis.

Survival analysis showed no significant difference in estimated time to graft failure in the 2 groups with a hazard ratio of 0.75 (P = .69). Graft failure for this survivor analysis included the 7 patients with graft ruptures and the 1 patient with graft removal due to infection.

Including study participants with graft ruptures, graft removal for infection, and those with greater than 2-year follow-up, overall study follow-up was 83% (53 of 64 enrolled). Two-year or greater outcome assessments were aggregated using the most recent evaluation for the 56 patients who had not undergone revision ACL reconstruction. Subjective outcome assessments were available for 80.4% (45 of 56) of these patients at an average follow-up of 36 months (range, 24-60.3 months). One patient died after reaching the 4-year follow-up evaluation. We have included this patient in the analysis.

There was no significant difference in average follow-up time between the 2 groups (P = .16). The average follow-up time was 2.7 years (95% confidence interval [CI]: 2.2, 3.1) for the BTB group and 3.2 years (95% CI: 2.6, 3.7) in the HS group. This study included a large number of active duty personnel. At the time of enrollment, 51 of the participants were cadets and 13 were active duty or dependents. At the time follow-up was completed for this study, there were 48 participants who were on active duty or who were dependents of active duty personnel (including 1 who died), 5 who had left the military, and 11 who were lost to follow-up. Objective evaluations of overseas study participants were sometimes not obtainable. Therefore, the number of objective evaluations obtained in this cohort of patients is less than the number of subjective evaluations obtained. This is noted throughout the results.

Radiographic Evaluation of Tunnel Placement

Radiographic assessment of tunnel placements were analyzed to see if there was a difference in graft position between the BTB and HS groups as well as to see whether tunnel position was related to graft rupture. When viewed on the lateral radiograph, the grafts in all groups appeared to be adequately positioned to avoid roof impingement.

There was no significant difference (P = .99) for femoral tunnel placement (as assessed by the method of Klos et al[26] and Amis et al[3]) between the BTB and HS grafts (Table 4). The average femoral tunnel position was 5% more distal for the 7 patients whose grafts ruptured compared with the 44 patients whose grafts were intact at follow-up. This difference was not statistically significant (P = .13).

There was no significant difference (P = .51) in coronal tibial tunnel angle between the BTB and HS grafts (Table 4). There was, however, a significant difference (P = .03) for the coronal tibial tunnel angle between the 7 participants

TABLE 2
Summary of Characteristics of Participants Who Experienced Graft Rupture or Postoperative Surgical Complication[a]

	Additional Procedures With Initial Operation	Time to Rupture (mo)	Sport of Reinjury	Reinjury Type
BTB graft				
Graft rupture	Partial lateral meniscectomy	46	Basketball	Noncontact
Graft rupture	Medial meniscus repair	14	Soccer	Noncontact
Graft rupture	Abrasion of lateral meniscus	21	Handball	Noncontact
HS graft				
Graft rupture	None	3	Kick to knee	Contact
Graft rupture	Medial meniscus repair	11	Javelin	Noncontact
Graft rupture	Partial lateral meniscectomy	26	Running	Noncontact
Graft rupture	Partial lateral meniscectomy	12	Wrestling	Noncontact
Infection	Partial lateral meniscectomy	N/A	N/A	N/A

[a]BTB, bone–patellar tendon–bone; HS, hamstring; N/A, not applicable.

TABLE 3
Summary of Subsequent Operations by Graft Type and Side[a]

	BTB Graft		HS Graft	
	Involved	Contralateral	Involved	Contralateral
Revision or contralateral ACL reconstruction	2	2	4	0
Medial meniscus repair and ACL debridement	1[b]	0	0	0
Unspecified surgery	1	0	1	0
Medial meniscus transplant	1	0	0	0
Partial meniscectomy	1	0	0	0
Debridement of adhesions	1	0	0	0

[a]BTB, bone–patellar tendon–bone; HS, hamstring; ACL, anterior cruciate ligament.
[b]Patient subsequently ruptured the primary ACL reconstruction and underwent revision surgery.

whose graft ruptured and the 44 whose grafts were intact. All tibial tunnels were contained within the tibial eminences except for 1 patient whose HS graft did not fail despite its placement.

Subjective Assessments

There were no statistically significant differences between the 2 groups on the patient-reported Lysholm, SANE, or KOOS subscales (Table 5). The SANE scores were 88.5 (95% CI: 83.1, 93.8) and 90.1 (95% CI: 85.2, 96.1) for the HS and BTB groups, respectively (P = .53). Eighty-one percent of the BTB patients reported that they were able to return to their preinjury activity levels, compared with 52% of the HS patients (P = .15). The overall average Tegner score was 6.8 for the BTB group and 5.3 for the HS group (P = .04) (Table 6). A total of 75% of the patients in the BTB group and 50% in the HS group had a Tegner score of 6 or better.

Functional Testing

There were no statistically significant differences with respect to performance on the single-legged hop for distance or the 6-m single-leg hop for time (see Appendix, available in the online version of this article at http://ajs.sagepub.com/supplemental/). These scores were available for 21 of the subjects in this analysis.

Range of Motion

There were no statistically significant differences with respect to heel height difference or range of motion (see Appendix, available in the online version of this article at http://ajs.sagepub.com/supplemental/). Heel height difference was 1.2 cm in the BTB group and 0.9 cm in the HS group. There were no statistically significant differences in total range of motion arc, extension deficits, or flexion deficits (see online Appendix for this article at http://ajs.sagepub.com/supplemental/).

Thigh Atrophy and Isokinetic Strength

Although the girth at 10 and 15 cm superior to the patella was greater on the uninvolved limb for each of the 2 groups, the girth difference (uninvolved–involved) between the 2 groups was not statistically significant (see online Appendix for this article at http://ajs.sagepub.com/supplemental/). There were no significant differences noted between the HS and BTB groups in peak torque knee extension or flexion when measured at 60 deg/s or 300 deg/s (see Appendix, available in the online version of this article at http://ajs.sagepub.com/supplemental/).

Difficulty Kneeling

There was no significant difference between the 2 groups for patient-reported pain associated with kneeling

TABLE 4
Femoral and Tibial Tunnel Measurements (With 95% Confidence Interval) by Graft Assignment and Graft Success[a]

	Graft Choice		Graft Success	
	BTB	HS	Intact	Ruptures
Femoral tunnel position[3,25] (%)	58.6 (54.0, 62.7)	58.3 (54.2, 62.4)	60.8 (57.6, 63.9)	55.9 (49.9, 63.9)
Tibial tunnel[18] (deg)	66.44 (62.2, 70.6)	65.0 (61.0, 69.1)	69.3[b] (66.2, 72.4)	62.2[b] (56.3, 68.1)

[a]BTB, bone–patellar tendon–bone; HS, hamstring.
[b]$P < .05$.

TABLE 5
Means (With 95% CI) of Subjective Outcomes by Surgical Graft Group[a]

	BTB N	BTB Least Square Mean (95% CI)	HS N	HS Least Square Mean (95% CI)	P Value
SANE	21	90.7 (85.2, 96.1)	23	88.5 (83.1, 93.8)	.53
Lysholm	21	90.4 (84.5, 96.3)	23	90.3 (84.4, 96.1)	.97
KOOS					
Pain	20	94.0 (87.7, 100.3)	24	91.0 (85.1, 96.9)	.44
Symptoms	21	90.5 (83.4, 97.6)	24	88.4 (81.5, 95.3)	.64
Activities of daily living	20	97.8 (92.9, 102.7)	23	95.7 (90.7, 100.7)	.52
Sport and recreation	21	87.3 (77.8, 90.2)	22	85.3 (75.6, 95.0)	.74
Quality of life	21	79.8 (69.4, 90.2)	24	75.5 (65.3, 85.6)	.52

[a]CI, confidence interval; BTB, bone–patellar tendon–bone; HS, hamstring.

TABLE 6
Tegner Activity Scores[a]

Tegner Score	BTB Number (of 20)	BTB %	HS Number (of 24)	HS %
0	0	0	0	0
1	0	0	2	8.3
3	1	5.0	3	12.5
4	1	5.0	3	12.5
5	3	15.0	4	16.7
6	5	25.0	6	25.0
7	3	15.0	3	12.5
8	1	5.0	1	4.2
9	6	30.0	1	4.2
10	0	0	1	4.2

[a]BTB, bone–patellar tendon–bone; HS, hamstring.
$P = .04$, using Wilcoxon (Mann-Whitney) test of location.

(Table 7). Neither of the groups reported extreme pain when kneeling; the majority of patients in both groups reported no pain when kneeling.

International Knee Documentation Committee Scores and Knee Laxity

There were no differences between groups in the overall IKDC score, nor in the IKDC subjective and objective evaluations (Tables 7 and 8). There was no significant difference between groups in anterior tibial displacement measured at 134 N using the KT-2000 arthrometer (Table 8).

DISCUSSION

This study was designed to compare outcomes of ACL reconstruction using either BTB or 4-strand HS autografts while controlling for other potential confounding variables. These are the most widely used grafts and their biomechanical properties meet or exceed that of the native ACL.[8,16] Our results were similar to those of other trials that have compared BTB and 3- to 5-strand HS autografts in that we found no statistically significant differences between the 2 groups on objective, subjective, or patient-reported measures.

Three RCTs[4,6,34] have compared BTB and 2-strand HS autografts. Two of the 3 studies did find increased laxity on instrumented testing in the HS group. None of these studies found significant differences in patient-reported subjective outcome measures. Similarly, there were no significant differences in patient-reported subjective outcome measures in 3 commonly referenced nonrandomized studies (patients were assigned on an alternating basis)[1,2,31] that compared BTB and 4-strand HS autografts.

There have been 12 published RCTs[#] comparing BTB autografts with 3- to 5-strand hamstring autografts. Not

[#]References 5, 9-11, 20, 23, 27, 30, 32, 37, 38, 47.

TABLE 7
Frequency of Categorical Responses to Subjective Outcomes in the BTB and HS Autograft Groups[a]

	BTB Number (of 21)	BTB %	HS Number (of 24)	HS %	*P* Value[b]
Pain when kneeling					.77
None	13	61.9	13	54.2	
Mild	6	28.6	6	25.0	
Moderate	1	4.8	2	8.3	
Severe	1	4.8	3	12.5	
Extreme	0	0	0	0	
IKDC subjective assessment					.33
Normal	14	66.7	10	41.7	
Nearly normal	6	28.6	12	50.0	
Abnormal	0	0	1	4.2	
Severely abnormal	1	4.8	1	4.2	
IKDC symptoms assessment					.29
Normal	12	57.1	12	50.0	
Nearly normal	8	38.1	9	37.5	
Abnormal	0	0	3	12.5	
Severely abnormal	1	4.8	0	0	

[a]BTB, bone–patellar tendon–bone; HS, hamstring; IKDC, International Knee Documentation Committee.
[b]Cochran-Manzel-Haenszel statistic based on row mean table score.

TABLE 8
Frequency of Categorical Responses to Objective Outcomes in the BTB and HS Autograft Groups[a]

	BTB N	BTB Number (%)	HS N	HS Number (%)	*P* Value[b]
KT-2000 arthrometer (134 N)	8		11		.85
–1 to <3 mm		4 (50.0)		7 (63.6)	
3 to 5 mm or <–1 to –3		3 (37.5)		3 (27.3)	
6 to 10 mm or <–3 >10 mm		1 (12.5) 0		1 (9.1) 0	
IKDC range of motion	14		18		.51
Normal		12 (85.7)		17 (94.4)	
Nearly normal		1 (7.1)		1 (5.6)	
Abnormal		1 (7.1)		0	
Severely abnormal		0		0	
IKDC ligament examination	14		18		.69
Normal		8 (57.1)		9 (50.0)	
Nearly normal		6 (42.9)		9 (50.0)	
Abnormal		0		0	
Severely abnormal		0		0	
IKDC overall evaluation	14		18		.22
Normal		6 (42.9)		2 (11.1)	
Nearly normal		6 (42.9)		12 (66.7)	
Abnormal		1 (7.1)		3 (16.7)	
Severely abnormal		1 (7.1)		1 (5.6)	

[a]BTB, bone–patellar tendon–bone; HS, hamstring; IKDC, International Knee Documentation Committee.
[b]Cochran-Manzel-Haenszel statistic based on row mean table score.

included in these 12 RCTs are 2 commonly cited studies with longer follow-up of an original report (Harilainen et al[17] is the 5-year follow-up of Jansson and colleagues[23] and Liden et al[28] appears to be a longer-term follow-up of the patients initially reported in Ejerhed[9]). Four of these RCTs[9,11,27,30] used strict randomization processes. These 12 RCTs represent the best scientific clinical studies comparing BTB and HS autografts with techniques that are commonly used today. The most consistent finding in these studies has been the similarity in the results between the 2 groups. As in our study, none of the other 12 RCTs found differences in the patient-reported subjective outcome measures between the BTB and HS groups. Our normal or nearly normal overall IKDC scores of 86% in the BTB group and 78% in the HS group are consistent with the results of the 11 other RCTs that reported IKDC data. In the other RCTs, the normal or nearly normal IKDC scores averaged 73.5% (range, 50-97) for BTB groups and 80.8% (range, 55-97) for HS groups.

The most commonly identified differences between groups are related to donor-site morbidity when selecting the BTB graft. In the 12 published RCTs, the BTB grafts were associated with more pain or difficulty with kneeling,[5,10,11,27,30] more loss of knee motion,[11,20,38,47] and more anterior knee pain.[11,20,27,32,47] The most commonly reported limitation associated with HS grafts was decreased isokinetic knee flexion strength.[5,23,32,40] None of these differences were identified in our study.

Our study differed from the other 12 RCTs in patient age and the activity level to which they were required to return. We also saw more ACL reinjuries than in any other study, with graft rupture rates of 9.4% and 12.5% in the BTB and HS groups, respectively. The average age of the patients in all but 1[19] of the other 12 RCTs was 24 years or greater (range, 22-31). Our average age was 22 years, and the vast majority of the patients were cadets at the US Military Academy and US Army soldiers. The cadets and active duty soldiers are required to return to vigorous activity level, including graded obstacle course tests and 2-mile runs. The age of our patients and the level of activity may explain our higher reinjury rates compared with that in other RCTs. We have also seen higher than expected rates of recurrent shoulder instability in this population[42] after open shoulder reconstructions, lending support to the argument that the physical demands of the military environment leads to significant reinjury rates.

We are unable to explain why our BTB patients showed a higher rate of return to preinjury activity level and a higher average Tegner rating at follow-up. Although not statistically significant, the 81% return to preinjury activity level in the BTB group appears to be clinically significant compared with the 52% return in the HS group. Although the mean Tegner rating for the BTB group was 6.8 and for the HS group was 5.3, 50% of the BTB patients had a Tegner rating of 7 or greater, yet only 1 in 4 HS patients scored 7 or above. These findings are similar to the results of Maletis et al.[30] No other RCT demonstrated this difference, but a meta-analysis by Yunes et al[46] of nonrandomized studies found a greater return to preinjury activity levels in BTB patients. Further study in this area is warranted. Perhaps a biomechanical study designed to assess for more subtle differences in knee control during demanding activities such as landing and cutting could offer additional insights.

One strength of this study is a design that minimized potential biases. First, we randomized treatment allocation to help eliminate potentially confounding factors. Specifically, the randomization process at the time of the operation led to similar patient populations and similar associated injuries in the 2 groups. Second, we tried to limit transfer bias through extensive efforts at obtaining follow-up of our patients throughout the world. We had a follow-up rate of 80.4% on patient-reported outcome measures at an average of nearly 3 years postoperatively and an overall follow-up of 83% for greater than 2 years. We minimized detection bias through follow-up by independent examiners (both physical therapists and orthopaedic surgeons) who were not involved in the operations and by the use of stockinettes to cover both knees, which hid signs of the graft choice from the evaluating surgeons. We also minimized bias by ensuring all operations were performed in the same manner, in the same operating room by 4 surgeons (often working together) who had extensive experience in both methods of reconstruction. In addition, the postoperative rehabilitation and bracing were the same for both groups. Finally, apart from a different washer type used to back up the tibial interference screw, fixation was the same for both groups.

We elected to perform dual fixation on both sides of the graft for 2 reasons. First, when this study was initiated in 1999, we were concerned about reports of increased strain in the grafts with fixation outside the tunnels and an emphasis on "aperture" fixation.[22] Second, bioabsorbable screws were relatively new when this study was initiated and we preferred to back up the screws with more permanent fixation in the event that the graft–bioabsorbable screw–tunnel fixation became compromised over time. The fixation techniques did not appear to influence the results as all reruptures occurred within the substance of the grafts. Six of the other RCTs[9,27,30,32,37,38] also used similar fixation techniques for both groups. When comparing these studies with the other 6 RCTs that had different fixation techniques between groups, there do not appear to be any differences in the results, also suggesting that fixation techniques do not significantly influence the results.

Using multiple outcome measures strengthens our results. The SANE score quantifies the patient's subjective impression of the outcome of their operation into a single number that correlates well with other outcome measures for both the shoulder[44] and the knee.[45] By examining the SANE score with the other validated outcome measures used in this study (IKDC, KOOS, and Lysholm scores), we were able to assess overall outcomes and specific outcome measures. In this study, we did not see any difference in the overall outcomes or the specific outcomes as evaluated with the instruments used. If the overall outcome was different between the 2 groups using the SANE score, the other measures could provide answers as to why that difference existed.

Interestingly, we did find that the 7 patients whose grafts ruptured had a smaller (more horizontal) mean coronal tibial tunnel angle (62.2°) than the 44 (69.3°) whose grafts were intact at follow-up (Table 4). Howell et al[19] asserted that tibial tunnel orientation is important when the femoral tunnel is drilled through the tibial tunnel, and that vertical tibial tunnels should be avoided. They recommended a coronal tibial tunnel angle between 65° and 70°. We applied their guidance of avoiding vertical tibial tunnels; however, our data suggest that some of our failures may have been related to tibial tunnels that were oriented too horizontally in the coronal plane.

Although Howell et al[19] found that angles greater than 75° were associated with increased anterior tibial translation and loss of knee flexion, leading to their recommendation of 65° to 70° tibial tunnel orientation, they did not have adequate numbers to assess the results of tibial tunnels at less than 65°. Our study suggests that angles less than 65° may be associated with increased likelihood of graft rupture. When the femoral tunnel is drilled through the tibial tunnel, the position of the femoral tunnel will be determined by the angle of the tibial tunnel.[19] If the orientation of the tibial tunnel in the coronal plane is too vertical, the femoral tunnel cannot be put in an anatomic position.[19] Similarly, the femoral tunnel may be malpositioned if the angle of the tibial tunnel is too horizontal in the coronal plane, which appears to be the case in our patients whose grafts failed. Our study also showed that graft ruptures were associated with a more distal placement of the femoral tunnel, although this difference was not statistically significant. This finding is likely related to femoral tunnel positioning being influenced by the tibial tunnel as previously discussed. Our findings support the suggestion by Howell et al[19] that femoral tunnels drilled through the tibial tunnel should be between 65° and 70° when measured in the coronal plane. Alternatively, techniques involving femoral tunnel drilling independent of the tibial tunnel position may allow for more anatomic femoral tunnel placement.

Another interesting finding in this study was that 75% of HS grafts that ruptured did so in the first year, while no BTB graft ruptured in the first year. These findings suggest that the relationship between knee extension strength and knee flexion strength may influence patients' risk of graft rupture during early return after ACL reconstruction. If the flexion strength is decreased due to harvesting of a HS graft, then there may be a significant increase in the quadriceps/HS strength ratio. This increased ratio may place the graft at risk due to the anterior tibial translation forces applied to the tibia by an intact extensor mechanism in the face of lower antagonistic HS strength. The implications of these findings warrant further study.

We recognize that the main weakness of this study is the incomplete follow-up of objective measures. Subsequent changes in the assignments of United States military personnel since the conception of this study in 1999, its initiation in 2000, and especially after September 11, 2001, led to greater than anticipated overseas deployments by our patients, frequently to remote, hostile environments. These changes in location for our study population offered unique challenges to capture the planned objective follow-up. We have reported the follow-up data obtained and, although incomplete, we suspect that these data are an accurate reflection of the overall population. Transfer bias due to incomplete follow-up is less likely than in most studies for 2 reasons. First, we were able to achieve subjective follow-up on over 80% of the patients, and the objective measures reported are in line with the subjective data. Second, the reason for incomplete follow-up is unlikely related to poor results. In the closed military health system, patients with poor results limiting their performance would be more likely to be identified and included in follow-up than those with good results. Nevertheless, even if transfer bias risk is minimal, we acknowledge that the limited follow-up does reduce the power in our objective data and weakens the study, especially with results showing no significant differences between the 2 groups.

Our ability to draw significant conclusions is also limited because of the lack of follow-up radiographic data, and because the study with an average follow-up of 3 years can at best be considered a midterm duration study of ACL reconstruction. Studying these patients with a variety of measures, including radiographically, will, in the long-term, provide important information about ACL reconstructions in general and about any differences that may exist between the BTB and HS autograft reconstructions.

CONCLUSION

At midterm follow-up averaging 3 years, we found that the BTB group had higher Tegner activity scores than the HS group. Further study is warranted on this finding. More horizontal tibial tunnel angles were associated with graft ruptures, independent of graft choice. Aside from these results, we found no other significant differences in patient-reported outcome measures, objective evaluations, and functional testing after ACL reconstruction when using either a BTB or HS autograft. Both grafts provided acceptable results in this very active military population, allowing our patients to return to strenuous activities in demanding environments.

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