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TightRope Versus Biocomposite Interference Screw for Fixation in Allograft ACL Reconstruction

Prospective Evaluation of Osseous Integration and Patient Outcomes

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Background: Anterior cruciate ligament (ACL) reconstruction is a commonly performed procedure with many options regarding graft choice and graft fixation. The purpose of this study was to compare suspensory and aperture fixation in terms of femoral osseous integration of the bone block after ACL reconstruction with an Achilles tendon allograft.

Methods: After institutional review board approval and patient consent were obtained, 37 patients underwent ACL reconstruction with an Achilles tendon allograft. The patients were randomized according to the graft femoral fixation technique, which was with either a suspensory device (Arthrex TightRope) or aperture fixation by a biocomposite interference screw (Arthrex BioComposite Interference Screw or DePuy Mitek MILAGRO Interference Screw). Tibial fixation, performed with a biocomposite screw and knotless anchor, was identical in all patients. All patients underwent a computed tomography (CT) scan at 6 months to evaluate bone block incorporation of the femoral graft within the femoral tunnel, which was the study's primary outcome. Secondary outcome measures included a postoperative visual analogue scale (VAS) pain score, range-of-motion measures, and International Knee Documentation Committee scores. Demographic data were collected.

Results: Thirty-three patients (89%) completed the study's 6-month follow-up, at which time the femoral ossification score was significantly greater in the aperture fixation group ($p = 0.025$). There was no substantial difference between the 2 groups with regard to any other outcome measure.

Conclusions: Performing Achilles tendon allograft ACL reconstruction with femoral aperture fixation results in greater femoral bone block incorporation at 6 months postoperatively compared with what is seen after suspensory fixation.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Anterior cruciate ligament (ACL) tears are a common injury, with >100,000 ACL reconstructions performed yearly, in the United States[1-3]. There are many options, and as a result controversies, regarding graft choice and graft fixation. Successful ACL reconstruction requires solid graft fixation within the tunnels[4,5]. Aperture and suspensory fixation remain the predominant strategies for femoral fixation of bone block grafts[6]. While aperture fixation theoretically results in less micromotion at the bone-graft interface, proponents of suspensory fixation suspect that the bone block grafts incorporate reliably with that method and without any implant remaining in the tunnel, which would be beneficial if revision reconstruction is needed[7].

Numerous studies have compared methods of fixation of all-soft-tissue grafts, with a particular focus on the 6-month postoperative mark as this is a common point at which patients are cleared for pivoting activities and sports[8]. However, we are not aware of any studies comparing femoral aperture and suspensory bone block fixation in patients treated with Achilles tendon allograft ACL reconstruction and the identical tibial-sided fixation. The purpose of our study was to compare suspensory (cortical button) and aperture (biocomposite interference screw) fixation in such patients, with bone block incorporation within the femoral tunnel determined with computed tomography (CT) as the primary outcome. Our null hypothesis was that there is no difference in osseous incorporation between the 2 types of femoral fixation in primary ACL

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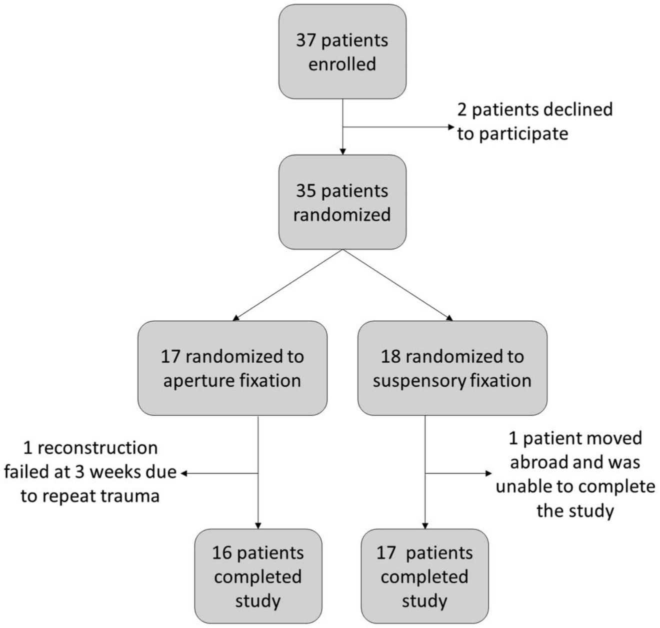

Fig. 1
Flow diagram of the study.

reconstruction with an Achilles tendon allograft. Our secondary outcomes were pain and clinical outcome scores.

Materials and Methods

After obtaining institutional review board approval, we conducted this prospective randomized controlled trial with a goal of a 1:1 allocation ratio between the 2 study groups. All subjects were recruited at the preoperative appointments, over a period of 24 months. The senior investigator, who performs approximately 100 ACL reconstructions per year, discussed ACL reconstruction with the patients. The patients received appropriate preoperative counseling regarding graft options, including risks of using allograft instead of autograft. The senior investigator utilizes Achilles tendon allograft when allograft reconstruction is indicated (on the basis of age, activity level, and the patient's willingness to accept the risks associated with allografts). The bone block placed into the femoral tunnel provides bone-to-bone healing. The tendinous portion is thicker and less elastic than other soft-tissue allografts.

Patients who met the inclusion criteria for this study received information about the study. Informed consent, including consent for a CT scan at 6 months postoperatively, was obtained from those who chose to enroll. Biswas et al. found the effective dose of radiation for a knee CT scan (0.16 mSv) to be substantially lower than that for hip, chest, abdomen, and pelvic scans (3.09, 5.27, 4.95, and 4.85 mSv, respectively). Overall, they concluded that the effective radiation dose declines substantially for anatomic structures that are further away from the torso[9]. At the institution where the present study took place, there is a foundation that helps coordinate patient visits and CT scans to ensure that they are ordered and completed at the correct time.

The patients were randomized to 1 of 2 fixation techniques—a biocomposite interference screw (aperture fixation) or a cortical button (suspensory fixation)—on the day of surgery from a list using medical record numbers. All of the grafts were non-irradiated. Figure 1 shows the flow diagram of this study.

This study was registered and approved by ClinicalTrials.gov (ClinicalTrials.gov ID: NCT03841500; Unique Protocol ID: SAIRB-14-0044).

Inclusion and Exclusion Criteria

To be included, patients had to be between the ages of 18 and 50 years, be able to provide informed consent, have an ACL tear meeting the indications for reconstruction, and choose to undergo reconstruction with an Achilles tendon allograft. Patients were excluded if they had a history of ACL reconstruction, were pregnant, had inflammatory disease or a primary bone disorder, were taking bone resorption inhibitor medications, or had an injury to the collateral ligaments or posterior cruciate ligament.

Surgical Technique

All surgical procedures were performed by a single surgeon using the same technique at a single institution. The initial diagnosis of ACL deficiency was made on physical examination and magnetic resonance imaging and confirmed with arthroscopy at the beginning of the procedure. The full Achilles tendon-calcaneal bone allograft (not preshaped) was thawed. The tendinous portion was tubularized and whip-stitched with a locking FiberLoop suture (Arthrex) 30 mm from the bone-tendon junction and sutured with at least 5 throws to the free edge of the tendon. The graft size was assessed to ensure that it fit "snugly" through a 10-mm-diameter tunnel. The graft was then pretensioned. Femoral tunnels were made using the anteromedial portal at 120° of knee flexion with the center point over the lateral bifurcate ridge or close to the 2 or 10 o'clock position on the right and left knee, respectively. The femoral tunnels were typically 10 mm in diameter. The tibial tunnel was created using an outside-in technique over a pin centered at the ACL footprint at approximately 20° to 25° of lateral angulation off the anatomic tibial axis.

In the aperture fixation group, the bone graft end was pulled through into the femoral tunnel and secured with a biocomposite interference screw (BioComposite Interference Screw [Arthrex] or MILAGRO Interference Screw [DePuy Mitek]). The interference screw was typically 7 × 23 mm. In the suspensory fixation group, a cortical button (TightRope [Arthrex]) was pulled through the femoral cortex and used to shuttle the Achilles bone plug into the femoral tunnel until it was just recessed within the medial intercondylar surface.

Tibial fixation was performed with the BioComposite or MILAGRO Interference Screw and a backup 4.5-mm Biomet PEEK (polyetheretherketone) knotless anchor and was identical in the 2 groups. The graft was fixed at near full extension after the knee was cycled through a range of motion with the graft tensioned.

Fig. 2-A

Fig. 2-B

Fig. 2-C

Fig. 2-D

Figs. 2-A through 2-D Femoral ossification scores of 1 (**Fig. 2-A**), 2 (**Fig. 2-B**), 3 (**Fig. 2-C**), and 4 (**Fig. 2-D**) on CT scans 6 months after screw (aperture) femoral fixation of an ACL allograft.

Fig. 3-A

Fig. 3-B

Fig. 3-B

Figs. 3-A, 3-B, and 3-C Femoral ossification scores of 1 (**Fig. 3-A**), 2 (**Fig. 3-B**), and 3 (**Fig. 3-C**) on CT scans 6 months after TightRope (suspensory) femoral fixation of an ACL allograft.

TABLE I Definitions of Femoral Ossification Score

Score	Degree of Ossification
0	No ossification/incorporation
1	≤1/3 ossification
2	>1/3 but <2/3 ossification
3	≥2/3 ossification
4	Complete ossification/incorporation into the femoral tunnel

Postoperative Course

All patients underwent an ACL postoperative rehabilitation protocol depending on concomitant pathological conditions. Cycling was permitted at the 6-week mark. In-line jogging typically was allowed at 4 months, with initiation of pivoting motions at 7 to 8 months. A full return to sports was allowed after 9 months. Younger patients enrolled in a sports metrics program, which was followed by a functional ACL examination prior to returning to sports. A CT scan of the treated knee was obtained at 6 months postoperatively.

Outcome Measures

Demographic data including age, sex, and body mass index were collected. The primary outcome measure was osseous incorporation of the bone block within the femoral tunnel as assessed on CT by 3 board-certified musculoskeletal fellowship-trained radiologists using a femoral ossification score. Figures 2-A through 2-D show examples of osseous integration seen on CT after aperture fixation, and Figures 3-A, 3-B, and 3-C show examples after suspensory fixation.

The femoral ossification score was devised as a practical means of semiquantitatively assessing the degree of bone incorporation around the femoral bone plug or screw fixation device in each patient. A purely quantitative model of measurement would have been cumbersome and potentially less accurate because numerous, small, variably sized spicules of bone were seen to have formed at various points along the femoral fixation device. With use of oblique coronal and sagittal images relative to the femoral fixation device, the radiologists determined the femoral ossification score through visual assessment of the amount of bone in contact with the surface area of the fixation device (0 = no ossification; 1 = bone in contact with one-third of the device or less, 2 = greater than one-third but less than two-thirds, 3 = two-thirds or more, and 4 = complete ossification/incorporation into the femoral tunnel) (Table I).

The CT protocol for ACL reconstruction included (1) 1.25-mm soft-tissue and bone algorithm axial images, (2) 3-mm straight coronal and sagittal images, (3) 1-mm oblique sagittal images perpendicular to the bone plug in the distal part of the femur relative to the femoral fixation device seen on the axial images, and (4) 1-mm oblique coronal images parallel to the bone plug in the distal part of the femur relative to the femoral fixation device seen on the axial images.

Each CT score assessment was performed by 1 of the 3 radiologists. Whenever an ossification score was deemed to be borderline between 2 categories, a consensus score was determined by 2 of the radiologists. The femoral ossification score was reported in the conclusion of the CT report, and the femoral ossification score table was included as a footnote after the conclusion to explain the meaning of the reported score.

At a minimum of 3 weeks after the first viewing session, the CT scans were placed in a different order and again presented independently to each of the 3 evaluators.

Secondary outcome measures included a pain score on a visual analogue scale (VAS) obtained preoperatively, at the first postoperative visit, and at the 6-month follow-up. The range of motion was measured preoperatively and at 6 months postoperatively. The International Knee Documentation Committee (IKDC) subjective knee evaluation score was calculated both preoperatively and at 6 months postoperatively.

Final follow-up for this study was at 6 months postoperatively.

TABLE II Demographic and Preoperative Data

	Interference Screw (Aperture) Fixation	TightRope (Suspensory) Fixation	Statistical Test	P Value
No. of patients	16	17		
Sex *(no.)*			Chi-square	0.598
Female	7	9		
Male	9	8		
Age* *(yr)*	36.9 ± 6.7	37.7 ± 5.3	Mann-Whitney U	0.533
Preoperative measures*				
VAS score	1.4 ± 1.3	1.1 ± 1.2	Mann-Whitney U	0.683
Range-of-motion arc	132 ± 9	130 ± 8	Mann-Whitney U	0.581
IKDC score	63.5 ± 4.7	63.8 ± 8.6	Mann-Whitney U	0.231

*The values are given as the mean and standard deviation.

TABLE III Postoperative Outcomes

	Interference Screw (Aperture) Fixation	TightRope (Suspensory) Fixation	Statistical Test	P Value
No. of patients	16	17		
Femoral ossification score*	2.81 ± 0.66	2.06 ± 0.90	Mann-Whitney U	0.025
Postoperative measures*†				
VAS score	2.3 ± 1.3	1.5 ± 0.7	Mann-Whitney U	0.025
Range-of-motion arc	132 ± 11	136 ± 7	Mann-Whitney U	0.606
IKDC score	90.3 ± 2.8	89.8 ± 4.1	Mann-Whitney U	0.873

*The values are given as the mean and standard deviation. †All values were recorded at 6 months postoperatively (final follow-up) except for the VAS score, which was measured at 2 weeks postoperatively

TABLE IV Femoral Ossification Scores for All Patients

Case	Date of Operation	Fixation Method	Femoral Ossification Score
1	2/5/2015	Suspensory	1
2	2/19/2015	Aperture	3
3	4/2/2015	Aperture	3
4	4/16/2015	Aperture	2
5	4/29/2015	Suspensory	1
6	5/27/2015	Suspensory	2
7	5/28/2015	Suspensory	1
8	5/28/2015	Suspensory	3
9	6/3/2015	Aperture	3
10	6/4/2015	Suspensory	4
11	6/25/2015	Aperture	3
12	6/25/2015	Aperture	1
13	8/5/2015	Suspensory	3
14	8/26/2015	Aperture	2
15	9/3/2015	Aperture	3
16	9/3/2015	Aperture	4
17	9/10/2015	Aperture	2
18	9/17/2015	Aperture	3
19	10/15/2015	Suspensory	2
20	10/15/2015	Suspensory	2
21	10/21/2015	Suspensory	2
22	11/25/2015	Suspensory	3
23	12/3/2015	Aperture	2
24	12/3/2015	Aperture	4
25	12/3/2015	Suspensory	2
26	12/10/2015	Aperture	3
27	12/16/2015	Suspensory	2
28	4/19/2016	Suspensory	3
29	1/7/2016	Aperture	3
30	6/21/2016	Suspensory	1
31	7/7/2016	Suspensory	1
32	2/24/2016	Aperture	4
33	8/25/2016	Suspensory	2

Statistical Analysis

Data were collected into a computerized database and manually verified. Means and standard deviations are reported unless otherwise stated. The chi-square test was used to assess for significant differences between groups with respect to categorical data, whereas the Mann-Whitney U test was used for continuous and ordinal data. All statistical procedures were done using SPSS software (version 24; IBM). Significance was set at $p < 0.05$.

See the Appendix for methods of calculating interobserver reliability and intraobserver reproducibility.

Results

Thirty-seven patients were enrolled in the study (Fig. 1). Two patients chose not to complete the study, and another moved abroad and was unable to return for final evaluation. One reconstruction failed at 3 weeks due to repeat trauma and needed a revision reconstruction. The remaining 33 patients (89%) had completed the study at the time that it was curtailed.

Ultimately, the study included 16 patients in the aperture fixation group and 17 in the suspensory fixation group. The aperture fixation group included 7 women and 9 men with a mean age of 36.9 ± 6.7 years. The suspensory fixation group included 9 women and 8 men with a mean age of 37.7 ± 5.3 years. There were no significant differences between the 2 groups with regard to sex ($p = 0.598$) or age ($p = 0.533$). Additionally, there were no differences between the 2 groups with regard to any of the preoperative measures, including the VAS score ($p = 0.683$), preoperative range of motion ($p = 0.581$), or IKDC score ($p = 0.231$). Table II shows the preoperative and demographic data.

At the first postoperative visit (typically 2 weeks after surgery), the VAS scores were higher in the aperture fixation group than in the suspensory fixation group ($p = 0.025$). The postoperative range of motion and IKDC scores showed no difference between the 2 groups at 6 months (Table III).

The primary outcome, the femoral ossification score as assessed on a 6-month postoperative CT scan, was significantly higher in the aperture fixation group than in the suspensory fixation group ($p = 0.025$) (Table IV).

See the Appendix for the results of the assessments of interobserver reliability and intraobserver reproducibility.

Discussion

The primary finding of this study is the increase in femoral bone block ossification within the femoral tunnel when ACL reconstructions with Achilles tendon allograft were done using aperture fixation rather than suspensory fixation. To our knowledge, this is the first clinical study comparing osseous integration of femoral bone blocks between these 2 methods of fixation. This finding is pertinent to surgeons who perform bone block fixation as part of their allograft ACL reconstructions.

The time point at which the graft is incorporated has implications for returning to pivoting and sports activities. While we did not investigate osseous incorporation in bone-patellar tendon-bone (BPTB) autografts, Lomasney et al. demonstrated no difference in tibial bone plug incorporation between autografts and allografts as assessed with CT[10].

Both advantages and complications have been described with aperture and suspensory fixation methods. Interference screws are subject to failure, fracture, and intra-articular migration[11-14], whereas suspensory buttons have been associated with iliotibial band and extensor tendon irritation, detachment, migration, and tunnel widening[15-18].

Numerous clinical and biomechanical studies have compared aperture and suspensory fixation in all-soft-tissue grafts, with mixed results[19-29]. Far fewer have compared bone block fixation between the 2 methods, particularly on the femoral side. In a study of BPTB autografts fixed with an interference screw, Suzuki et al. demonstrated femoral bone plug incorporation (albeit in a rectangular bone tunnel) on CT imaging at 8 weeks[30]. Taketomi et al. used CT, although at a later point, to evaluate osseous integration of femoral BPTB plugs fixed using suspensory buttons. In their study, all 34 patients demonstrated bone plug integration at 1 year with minimal bone plug migration[7]. While they demonstrated final incorporation at 1 year, our study demonstrated greater incorporation with femoral aperture fixation at an intermediate time point of 6 months.

The difference in bone plug incorporation between aperture and suspensory fixation in our study likely resulted from differences in the bone remodeling processes between these 2 methods. Bone can incorporate directly, or primarily, when fragments are compressed together without the generation of any callus[31,32]. Alternatively, bone heals indirectly, or secondarily, with intermediate callus formation as a result of the local strain environment[31,33]. It is thought that aperture fixation results in less graft micromotion within a tunnel. Evidence of early bone plug integration with aperture fixation has been demonstrated[30] and may account for the better findings compared with suspensory fixation in our study. A cadaveric biomechanical study of patellar tendon grafts demonstrated increased stiffness and less graft bone displacement after femoral fixation with interference screws than after suspensory fixation[34].

It should be noted that we terminated the study at 6 months, on ethical grounds, because we found that the osseous incorporation was less optimal with suspensory fixation than with aperture fixation. We believed that the radiographic differences were compelling enough to abandon suspensory fixation for primary ACL reconstruction using Achilles tendon bone block allograft.

At 2 weeks, VAS scores were equal between groups. Additionally, despite differences in osseous integration, we did not see any differences in clinical scores at 6 months. Although evidence points to eventual osseous integration of bone plugs using either aperture or suspensory fixation, we aimed to address which integrates earlier as this has implications for graft maturity.

Limitations

A main limitation of this study is that only Achilles tendon allograft bone block fixation was evaluated; BPTB autografts were not included. In addition, CT evaluation was performed at only a single time point (6 months postoperatively). It is important to note that, because our study was terminated after evaluation of the midpoint (6-month) data, some of the outcome measures have little value. There may have been important differences if clinical outcomes had been measured at a later time point.

Another point to be considered is whether the CT measurements were affected by the fixation technique at baseline because of artifact. To assess this possibility, we would have needed to perform CT scans immediately postoperatively to compare screw fixation and suspensory fixation. This would have exposed the patients to additional radiation, which we did not think was justified.

Conclusions

Performing Achilles tendon allograft ACL reconstruction with femoral aperture fixation results in greater femoral bone block incorporation at 6 months postoperatively compared with what is seen after suspensory fixation.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJSOA/A150). ■

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