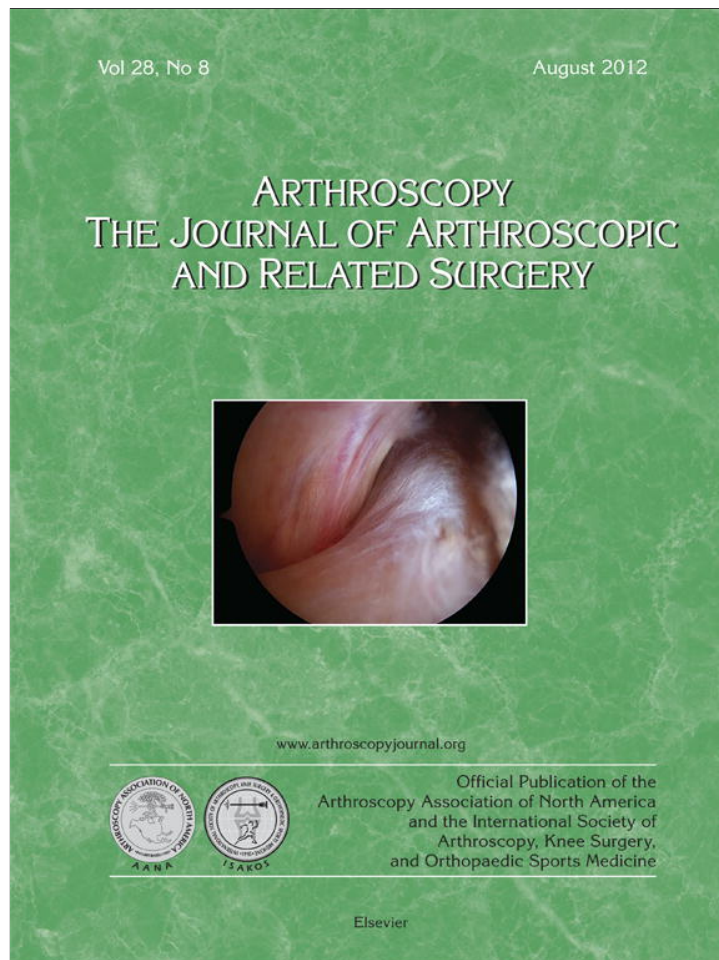


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# The Effect of Graft Tissue on Anterior Cruciate Ligament Outcomes: A Multicenter, Prospective, Randomized Controlled Trial Comparing Autograft Hamstrings With Fresh-Frozen Anterior Tibialis Allograft

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**Purpose:** To compare the results and outcome of anterior cruciate ligament (ACL) reconstruction using autogenous hamstring tendon versus fresh-frozen allograft anterior tibialis tendon. **Methods:** A prospective randomized study was conducted from September 2002 to October 2006. We randomized 147 patients to undergo ACL reconstruction with either autogenous hamstring or fresh-frozen allograft anterior tibialis tendon. Of these patients, 102 (69%) completed a minimum of 2 years' follow-up. There were 54 patients in the hamstring group (73% of those originally enrolled in the group) and 48 patients in the allograft group (66%). All patients underwent standardized subjective and objective evaluation with functional outcome assessments (International Knee Documentation Committee [IKDC]), and standardized radiographs were also obtained. **Results:** The mean age was 32.0 years for the autograft group and 33.3 years for the allograft group. There was no difference in stability between the 2 groups ( $P > .05$ ). The mean IKDC subjective score was 91.0 for the autograft group and 90.9 for the allograft group ( $P > .05$ ). The functional IKDC scores for the autograft group were normal in 46 patients (85%), nearly normal in 7 patients (13%), and severely abnormal in 1 patient. For the allograft group, the functional IKDC scores were normal in 43 patients (90%) and nearly normal in 5 (10%) ( $P > .05$ ). There were 4 reoperations in the allograft group and 3 reoperations in the autograft group. No patient underwent revision ACL surgery or planned to undergo revision surgery because of instability in either group during the study period despite the 1 patient in the autograft group with a pivot shift and a maximum manual KT measurement (MEDmetric, San Diego, CA) of 5 mm. **Conclusions:** The use of fresh-frozen anterior tibialis allograft (non-treated) for ACL reconstruction produced similar subjective and functional outcomes at 24 months' minimal follow-up compared with patients undergoing ACL reconstruction with autograft hamstring tendon. **Level of Evidence:** Level II, prospective comparative study.

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The authors report that they have no conflicts of interest in the authorship and publication of this article.

Received September 25, 2011; accepted May 8, 2012.

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0749-8063/11610/\$36.00

<http://dx.doi.org/10.1016/j.arthro.2012.05.010>

With the advent of improved fixation devices and more exacting tunnel techniques, hamstring tendon and tibialis allografts for anterior cruciate ligament (ACL) reconstruction continue to grow in popularity.<sup>1,2</sup> Many clinical studies comparing the outcomes of hamstring and bone–patellar tendon–bone (BPTB) grafts for ACL reconstruction show similar outcomes.<sup>2–6</sup> Despite the high success rates with autograft tissues, some surgeons continue to favor allograft use to avoid all harvest-site morbidity.

The effectiveness of allografts, however, remains controversial based on the current body of literature. Retrospective case-control studies and systematic reviews predominate the current body of literature, with these studies showing few to no control groups regarding graft preparation, types of allografts, tunnel

placement, and fixation among patients. A common finding in a number of these retrospective case series is that the pretreatment of the allograft tissue with either cryopreservation or 2.0- to 2.5-Mrad irradiation suggests a less-than-acceptable clinical outcome and stability compared with autogenous tissues, particularly in younger active patients.<sup>7-10</sup> Rejection and slow incorporation remain concerns with allograft tissue.<sup>11</sup> Some surgeons do not recommend the use of aggressive rehabilitation and they advocate a slower return to sport when using cryopreserved tibialis allografts.<sup>8,11</sup> Others have observed more tunnel widening in BPTB allografts than autografts, suggesting an immune reaction.<sup>12</sup> The purpose of this prospective randomized trial was to compare ACL reconstruction with autogenous hamstring tendon and fresh-frozen allograft anterior tibialis tendon and determine differences in clinical outcome and knee stability. We hypothesized that measures of stability, subjective and objective knee function, and hop test at 24 months would be similar for subjects treated with either graft using a standardized technique for ACL reconstruction with regard to tunnel placement, fixation, and rehabilitation.

## METHODS

Approval for the study was obtained from each respective hospital's institutional review board. Five surgeons in five different facilities participated in the study. Not all surgeons enrolled the same number of patients in the study. All patients agreed to the randomization of autograft hamstring or allograft anterior tibialis for ACL reconstruction before surgery. A computer-generated randomization program was used to determine graft type, that is, autogenous double-looped semitendinosus and gracilis or fresh-frozen, nonirradiated, non-chemically treated anterior tibialis allograft, for each patient. Patients identified with ACL disruption, either acute or chronic, were included in the study. Surgeons were made aware of the graft source before surgery. Patients were informed of the graft source after surgical reconstruction.

### Inclusion and Exclusion Criteria

The following inclusion criteria were implemented:

1. Unilateral isolated ACL tear with a contralateral normal knee
2. Extension and flexion within 5° of the opposite knee before surgery
3. Grades 0, 1, and 2 medial collateral ligament injury
4. Initial injury must be within 12 months of surgery

5. Patients may have had a previous arthroscopy, partial meniscectomy, or repair
6. Patients may have a concomitant meniscal tear
7. Patient agreed to be randomized to an autograft or allograft soft-tissue graft

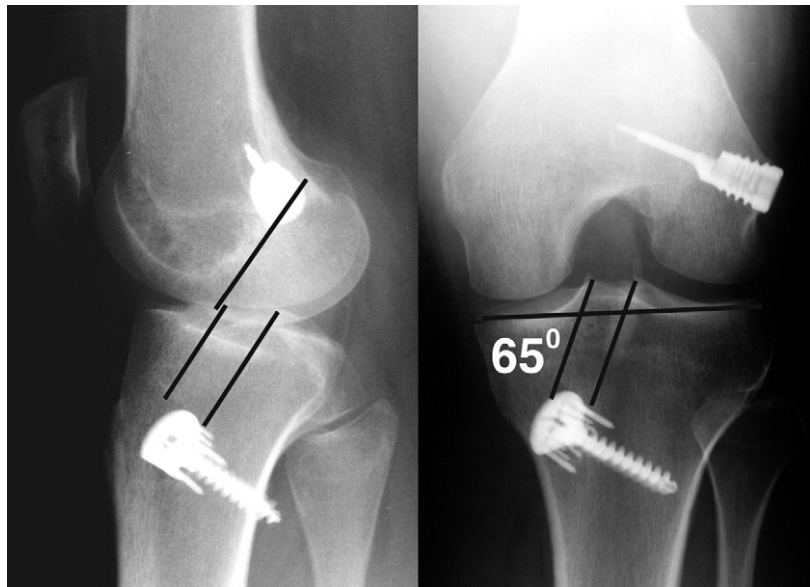
The following exclusion criteria were implemented:

1. Incompetent or unwilling to consent
2. Inability to comply with required follow-up assessments at 4 months, 1 year, and 2 years
3. Prior arthrotomy
4. Previous reconstructive procedure of either knee
5. Posterior cruciate ligament, lateral collateral ligament, and grade 3 medial collateral ligament injury in injured knee
6. Chondral injury requiring removal of defect, osteochondral allograft transfer, or autologous cartilage transfer
7. Degenerative joint disease
8. Known metabolic bone disease
9. Known collagen disease
10. Known neoplastic disease
11. Femoral, tibial, or patellar fracture

### Surgical Technique

All patients underwent arthroscopic ACL reconstruction with a previously described surgical technique.<sup>13</sup> In the hamstring autograft group, the semitendinosus and gracilis tendons were harvested through a 2- to 3-cm anteromedial incision. Grafts were prepared by placing a whipstitch in each end of the tendon for graft passage and tensioning. In the allograft group, nonirradiated fresh-frozen anterior tibialis grafts were prepared by placing a whipstitch in each end of the graft. All allografts were obtained from certified tissue banks using serologic and microbiologic testing set forth by the American Association of Tissue Banks and the Food and Drug Administration. Graft size varied between 8 and 9 mm for all patients regardless of graft source. Tunnel placement was performed with an established transtibial tunnel technique. The tibial tunnel was positioned using the technique described for the 1-step tibial guide with a coronal alignment rod.<sup>14,15</sup> Tibial tunnels were placed posterior and parallel to the Blumensaat line in the sagittal plane and angled at 65° with respect to the medial joint line in the coronal plane. Proper use of this guide system and tibial tunnel placement technique minimizes the risk of roof and posterior cruciate ligament impingement.<sup>16-18</sup> The femoral tunnel was positioned using a size-specific femoral aimer through

FIGURE 1. Anteroposterior and lateral radiographs of completed reconstruction.



the tibial tunnel. The femoral tunnel was positioned at the 10-o'clock position for a right knee or the 2-o'clock position for a left knee. Fixation was achieved on the femoral side using a cross-pin device and on the tibial side using a washer with multiple spikes and a compression screw. All graft bundles were equally tensioned and fixed with the knee in full extension for all patients. Unmeasured graft tensioning was performed.

### Rehabilitation

All patients were put through a standardized aggressive postoperative rehabilitation protocol. Postoperatively, patients were allowed full weight bearing without the use of a brace. Crutches were provided for comfort, and patients were encouraged to discontinue using the crutches when confident ambulating without them. All patients were encouraged to perform active and passive range-of-motion exercises focusing on early terminal extension. Patients were permitted to perform both open- and closed-chain exercises. Patients were cleared for full activity at 4 to 6 months postoperatively provided that their single-leg hop for distance was at least 85% of that of the contralateral normal limb.

### Clinical Assessment

The surgeons evaluated the patients at a minimum of 2 years postoperatively to determine functional outcome between the tibialis allograft and autogenous hamstring treatment groups. All patients underwent

evaluation by history, physical examination, anteroposterior and lateral radiographs (Fig 1), and functional assessment at a minimum of 24 months' follow-up. The presence of joint space narrowing and osteophyte formation defined degenerative joint disease. One surgeon (S.M.H.) evaluated all radiographs postoperatively for degenerative changes and evidence of graft impingement. The subjective and functional International Knee Documentation Committee (IKDC) scoring system was used, and the following dependent variables were measured: KT testing (MEDmetric, San Diego, CA), pivot shift, subjective questioning, range of motion, presence of effusion, thigh circumference, harvest-site symptoms, functional outcome determined by hop test, and degenerative changes on radiographs.

### Statistical Analysis

**Knee Stability:** A  $\chi^2$  test was used to determine whether the difference in KT-1000 (MEDmetric) manual maximum translation between the treated and contralateral knee was significant between treatment groups. The detection of a 1.0-mm difference in anterior laxity in 1 treatment group compared with the other is considered clinically significant because it equates to one-third of the 3-mm increase that is considered to indicate graft failure. A pre-study power analysis was conducted to estimate the minimum sample size needed to observe a clinically meaningful difference in the primary outcome variable of anterior knee laxity between the autograft and allograft treatment groups. This study, comprising 102 subjects (54

autografts and 48 allografts), was adequately powered to be able to detect a 1-mm difference in anterior knee laxity ( $\alpha < .05$ ) with 80% power assuming an SD of 1.5 mm, as was used in a previous trial.<sup>19</sup> That degree of power would be achieved with study groups comprising at least 35 knees. A  $\chi^2$  test was also used to determine whether the incidence of the pivot shift was different between treatment groups.

**Subjective Knee Dependent Variables:** A Satterthwaite *t* test was used to determine whether the subjective knee evaluation was different between treatment groups. A difference in score of 12 points or a greater change in score is considered clinically important, because it equates to the subject's assessment that the knee has improved or worsened.

**Objective Knee Examination:** A Pearson  $\chi^2$  test was used to determine whether the proportion of patients with an overall score of A or B was different between treatment groups. A 5% difference in the proportion of patients with an overall score of A or B is considered clinically important, because it equates to 5% of the subjects faring better or worse with 1 type of graft.

**One-Leg Forward Hop Test:** A Satterthwaite *t* test was used to determine whether the hop test was different between treatment groups.

## RESULTS

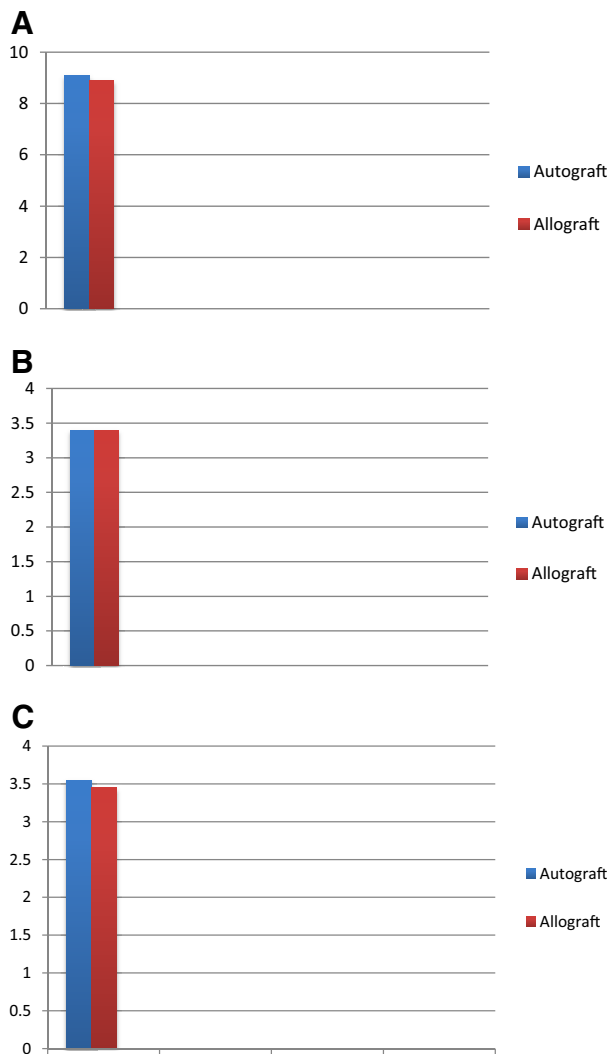
We enrolled 147 patients from 5 surgeons in the study from September 2002 to October 2006. There were 74 patients enrolled in the autograft group and 73 patients enrolled in the allograft group. One hundred two patients completed a minimum of 2 years' follow-up. Patients dropped out of the study if they failed to complete the minimum 2-year follow-up evaluation. There were 54 patients in the autograft group (72% of those originally enrolled in the group) and 48 patients in the allograft group (67%) who were available for follow-up. Patients' ages ranged from 16.4 to 53.4 years (mean, 33.5 years) in the study group. The mean age was 32.0 years for patients in the autograft group and 33.3 years in the allograft group. There were 32 men and 22 women in the autograft group available for follow-up. There were 34 right knees and 20 left knees in the autograft group. There were 38 men and 10 women in the allograft group. There were 23 right knees and 25 left knees in the allograft group (Table 1). No specific collection of data was performed regarding potential confounding factors such as meniscal tears, chondral injuries, or specific time to surgery other than the criteria that surgery be performed

TABLE 1. Demographics

	Hamstring Autograft	Allograft Anterior Tibialis
Enrolled	74 patients	73 patients
Completed 2-yr follow-up	54 patients (73%)	48 patients (66%)
Age	32.0 yr	33.3 yr
Male	32 patients	38 patients
Female	22 patients	10 patients
Right knee	34	23
Left knee	20	25

within 12 months of injury in an effort to simplify the amount of data collection required in this prospective, randomized, multicenter trial. The random allocation of subjects that was used ensured that the 2 groups were similar in all respects (distribution of potential confounding factors such as meniscal procedures, the timing for surgery, and other possible associated pathologies) with the exception of the therapeutic measure being tested, which was the type of ACL graft (autograft *v* allograft).

No statistical differences ( $P > .05$ ) were noted between the 2 groups for any of the measured dependent variables at the latest follow-up. Maximum manual KT measurements showed 46 patients (85%) with normal stability (1- to 2-mm side-to-side difference) and 7 patients (13%) with nearly normal stability (3- to 5-mm side-to-side difference) in the autograft group compared with 43 patients (90%) with normal stability and 5 patients (10%) with nearly normal stability in the allograft group ( $P > .05$ ). The mean IKDC subjective score was 91.0 for the autograft group and 90.9 for the allograft group ( $P > .05$ ) (Fig 2). The functional IKDC scores for the autograft group were normal in 46 patients (85%), nearly normal in 7 (13%), and severely abnormal in 1 (2%). The 1 patient with a severely abnormal functional IKDC score had a 3+ pivot shift on follow-up examination. For the allograft group, the functional IKDC scores were normal in 43 patients (90%) and nearly normal in 5 (10%). The 2 groups were not statistically different. Pivot-shift testing for the autograft group showed normal findings in 48 patients (89%), nearly normal findings in 5 patients (9%), and severely abnormal findings in 1 patient (2%) compared with normal findings in 44 patients (92%) and nearly normal findings in 4 patients (8%) in the allograft group ( $P > .05$ ). Only 1 of 54 autograft patients had a mild effusion and none of the 48 allograft patients had evidence of an effusion at a minimum of 2 years' follow-up ( $P > .05$ ). In the autograft



**FIGURE 2.** (A) Patients' responses to the question "How does your knee affect usual activities?" A score of 10 indicates none. (B) Patients' responses regarding the highest level of activity at which they participate on a regular basis. A score of 4 indicates very strenuous. (C) Patients' responses regarding the highest level of activity without knee pain. A score of 4 indicates very strenuous.

group, 51 patients (94%) had normal extension when compared with the normal contralateral side, 1 (2%) had nearly normal knee extension, and 2 (4%) had abnormal extension, as compared with 46 allograft patients (96%) with normal extension and 2 (4%) with nearly normal extension ( $P > .05$ ). Extension for a given patient was determined by comparison to the extension of the normal contralateral knee. Thigh circumference was not statistically different between the 2 groups ( $P > .05$ ). Results of testing of the single-leg hop for distance at 2 years were not different between the 2 groups ( $P > .05$ ).

Radiographic analysis (anteroposterior and lateral radiographs in full extension) at the latest follow-up showed no evidence of medial compartment arthrosis in 50 patients (93%) and mild medial compartment arthrosis in 2 patients (4%) in the autograft group compared with no evidence of medial compartment arthrosis in 42 patients (88%) and mild medial compartment arthrosis in 5 patients (10%) in the allograft group ( $P > .05$ ). Radiographic analysis at the latest follow-up showed no evidence of lateral compartment arthrosis in 52 patients (96%) in the autograft group and 42 patients (88%) in the allograft group, whereas 5 patients (10%) showed mild lateral compartment narrowing in the allograft group ( $P < .05$ ). There was no evidence of roof or posterior cruciate ligament impingement in either group.

There were 3 reoperations in the autograft group and 4 reoperations in the allograft group. Patients in the autograft group underwent 1 partial meniscectomy, 1 reoperation for hardware removal, and 1 reoperation for arthrofibrosis. Patients in the allograft group underwent additional surgery as follows: 1 partial meniscectomy, 2 for painful hardware removal, and 1 for arthrofibrosis. No patient underwent revision ACL surgery or planned to undergo revision surgery because of instability in either group during the study period despite the 1 patient in the autograft group with a pivot shift and a maximum manual KT measurement of 5 mm.

## DISCUSSION

Review of the current body of literature with regard to ACL reconstruction outcomes using allograft tissue remains controversial.<sup>7,8,20-22</sup> Most studies are retrospective and poorly controlled.<sup>23</sup> Some studies have indicated comparable results with allograft and autograft tissue,<sup>24-26</sup> whereas other studies have favored autograft tissue.<sup>8,9,27</sup> Recent studies using soft-tissue allografts have suggested an increased failure rate in younger more active patients compared with older more sedentary patients aged greater than 40 years.<sup>8,9,28</sup> Singhal et al.<sup>8</sup> published a retrospective telephone follow-up study in patients undergoing allograft ACL reconstruction with a cryopreserved tibialis graft. They determined failure based on the need for subsequent surgery consisting primarily of meniscectomy and revision ACL surgery. There were 125 patients enrolled, with only 69 patients contacted for telephone interview. In patients aged 25 years or younger, 55% required additional surgery, whereas 24% of patients aged over 25 years required additional surgery. The authors concluded

that the use of allografts in young patients participating in high-level sports activity is not warranted given the high rate of revision surgery.

A recent case-control study evaluated the failure of ACL reconstruction in a cohort of 322 patients from a single surgeon using a single reconstruction technique of cross-pin femoral fixation and interference screw tibial fixation over a 2-year period.<sup>9</sup> The authors reported 21 failures during this time frame, with 16 allograft failures and 5 autograft hamstring failures. All allograft tissue used in the study was irradiated tibialis anterior graft. The authors did not mention the irradiation dose used to sterilize the allografts in this study. Statistical analysis of the Marx score and tissue type using a logistical regression model and odds ratio determined increased failure rates for patients with a higher level of activity and allograft tissue compared with autograft reconstruction patients. The study suggests that irradiated soft-tissue allografts in patients with a high activity level should be avoided. Other studies have also shown increased failure rates and instability in patients undergoing ACL reconstruction using irradiated allograft tissue compared with nonirradiated allograft tissue and autograft.<sup>10,27,29</sup>

Most recently, Barrett et al.<sup>28</sup> performed a retrospective review of patients aged under 40 years undergoing fresh-frozen BPTB allograft or BPTB autograft ACL reconstruction. They used both 1- and 2-incision tunnel placement techniques along with intraoperative imaging to ensure that no graft impingement occurred. The fixation method was not reported. The authors determined inferior outcomes in active patients undergoing BPTB allograft reconstruction compared with the autograft patients because 17 of the 19 failures in the allograft group had a high Tegner preinjury activity level. They speculated that the increased failure of the allograft in higher-activity level patients was because of a failure of graft incorporation. It is unclear whether this failure of incorporation involved the bone plug, the graft tissue itself, or both.

In contrast, Nakata et al.<sup>30</sup> performed a retrospective study of 61 athletically active patients undergoing ACL reconstruction using a fresh-frozen single-strand anterior tibialis with an 8- or 9-mm graft. Intraoperative radiography was used to control tunnel placement, and a 2-incision technique using polyethylene buttons for fixation was used in all patients. The mean age was 20.9 years and follow-up ranged from 10 to 14 years in 52 of the 61 patients available for follow-up. KT testing showed a mean of  $1.6 \pm 1.3$  mm, negative pivot shift in 87%, and normal and nearly

normal IKDC scores in 100% of this cohort of young active patients.

In a recent systematic review of the literature comparing autograft with allograft for ACL reconstruction, the authors found no difference in short-term clinical outcomes comparing autograft with allograft.<sup>23</sup> The studies included in this review were considered the highest level of evidence available in the current literature. Eight of the nine studies included in the meta-analysis compared BPTB grafts, and only one study compared quadrupled hamstring autograft and quadrupled hamstring allograft.<sup>25</sup> This single soft-tissue graft study used a combination of fresh-frozen and cryopreserved hamstring allograft sources and showed no difference in outcomes based on KT-1000 measurement, IKDC score, Lysholm score, and Tegner score when compared with autograft.<sup>25</sup> However, the outcomes in the nonrandomized studies included in the meta-analysis were not stratified based on age or activity level.

The strength of our study lies in the prospective randomized design, using a standardized surgical technique and rehabilitation protocol. The success of ACL surgery is multifactorial, and without control of potential confounding variables, it would be difficult to know the exact reasons for clinical failures. In this study the use of fresh-frozen allograft tibialis tissue eliminates the effect of cryopreservation or irradiation on the biological incorporation of the allograft. Prospectively randomizing groups of patients undergoing an identical surgical technique using autograft hamstring tendon and allograft tibialis tendon better enables us to isolate the effect of graft tissue on clinical outcomes between patients in the 2 groups.<sup>16,17</sup> Under the reported conditions for this study, no difference in stability or subjective and functional outcomes was detected for either group. Stability, as well as subjective and functional outcomes scores, was high in both groups. Our results are quite similar to a recently published prospective, randomized controlled study comparing hamstring autograft with fresh-frozen hamstring allograft ACL reconstruction performed by a single surgeon using a standardized surgical technique and rehabilitation protocol.<sup>31</sup> In this published study, 93.4% of the autograft patients and 90.5% of the allograft patients returned to normal or nearly normal levels of function by use of the IKDC scoring system. Subjective IKDC scores were 90 and 89 for autograft and allograft patients, respectively. Therefore surgeons must question what effect irradiation has on allograft tissue, as well as the effect of operative technique and rehabilitation on the clinical results of

reported retrospective case series and case-control studies where a difference was noted.

Lastly, despite a meticulous attempt to control for and isolate the effect of graft tissue on clinical outcomes, the study does have several methodologic limitations. First, there was a considerable nonparticipation rate, raising concern for a selection or dropout bias. The 31% dropout rate in this prospective study was because of lack of 2-year follow-up. Patients were required to undergo clinical assessment and evaluation at a minimum of 2 years after surgery to be included in the final study results. Second, some of the data were incomplete, because all patients did not complete a postoperative radiographic series at latest follow-up. The lack of radiographs, however, would not affect stability and functional outcome assessment, which were the most important dependent variables measured in the study. Third, the 2 groups were not perfectly matched in that there were fewer female patients in the allograft group compared with the autograft group. Despite this sex difference between groups, there was no difference between the 2 groups based on stability, functional outcomes, and reoperations. Lastly, no attempt to determine outcomes based on age, sex, and activity level was performed. Matching the groups with regard to age, sex, and activity level would prove very difficult because of the prospective randomized design, with difficulty having younger patients and especially the parents of minors agreeing to the randomization process. Furthermore, the mean age was 33.5 years in the study group, which would suggest an older patient population and may have an influence on the results of this study. The older mean age of the patients in the study may be the result of the prospective randomized study design including only patients agreeable to undergo autograft or allograft tissue reconstruction based on the randomization process alone.

## CONCLUSIONS

On the basis of the results of this prospective randomized clinical trial, the use of fresh-frozen soft-tissue tibialis allograft for ACL reconstruction had similar stability and functional outcomes to autograft hamstring tendon with a minimum of 2 years' follow-up.

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