

[Orthopaedics]



Clinical Outcomes After Anterior Cruciate Ligament Reconstruction: A Meta-Analysis of Autograft Versus Allograft Tissue

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Background: Clinical outcomes of autograft and allograft anterior cruciate ligament (ACL) reconstructions are mixed, with some reports of excellent to good outcomes and other reports of early graft failure or significant donor site morbidity.

Objective: To determine if there is a difference in functional outcomes, failure rates, and stability between autograft and allograft ACL reconstructions.

Data Sources: Medline, Cochrane Central Register of Controlled Trials (Evidence Based Medicine Reviews Collection), Cochrane Database of Systematic Reviews, Web of Science, CINAHL, and SPORTDiscus were searched for articles on ACL reconstruction. Abstracts from annual meetings of the American Academy of Orthopaedic Surgeons, American Orthopaedic Society for Sports Medicine, and Arthroscopy Association of North America were searched for relevant studies.

Study Selection: Inclusion criteria for studies were as follows: primary unilateral ACL injuries, mean patient age less than 41 years, and follow-up for at least 24 months postreconstruction. Exclusion criteria for studies included the following: skeletally immature patients, multiligament injuries, and publication dates before 1990.

Data Extraction: Joint stability measures included Lachman test, pivot-shift test, KT-1000 arthrometer assessment, and frequency of graft failures. Functional outcome measures included Tegner activity scores, Cincinnati knee scores, Lysholm scores, and IKDC (International Knee Documentation Committee) total scores.

Results: More than 5000 studies were identified. After full text review of 576 studies, 56 were included, of which only 1 directly compared autograft and allograft reconstruction. Allograft ACL reconstructions were more lax when assessed by the KT-1000 arthrometer. For all other outcome measures, there was no statistically significant difference between autograft and allograft ACL reconstruction. For all outcome measures, there was strong evidence of statistical heterogeneity between studies. The sample size necessary for a randomized clinical trial to detect a difference between autograft and allograft reconstruction varied, depending on the outcome.

Conclusions: With the current literature, only KT-1000 arthrometer assessment demonstrated more laxity with allograft reconstruction. A randomized clinical trial directly comparing allograft to autograft ACL reconstruction is warranted, but a multicenter study would be required to obtain an adequate sample size.

Keywords: anterior cruciate ligament reconstruction; allograft; autograft; meta-analysis

Up to 300 000 anterior cruciate ligament (ACL) reconstructions are performed annually in the United States.¹⁴ An estimated 80% of these reconstructions are done with autografts, with the remainder being performed with allografts from various

sources.¹⁴ The best graft source remains a controversial topic. An ideal graft would replicate the anatomy and biomechanics of the native ACL, with rapid incorporation and low donor site morbidity.^{4,26} Both common types of autograft—bone-patellar tendon-bone and

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quadrupled hamstring tendon—have relatively rapid incorporation but are associated with donor site morbidity. In comparison, bone-patellar tendon-bone allograft and various types of soft tissue allograft have slower incorporation^{4,14,43} but no donor site morbidity.

Each of these 4 most commonly used graft types has other advantages and disadvantages. Although excellent results have been reported in the literature for all graft types, no one study has demonstrated a clear advantage of one graft type over another. In addition, over the past 20 years, graft fixation and allograft-processing techniques have been refined and improved, making some previous studies obsolete. A number of retrospective and prospective studies have compared the results following autograft and allograft ACL reconstruction.^{4,43} Overall, the results of clinical outcome studies have been mixed, with some studies finding similar rates of excellent and good outcomes in both populations^{4,43} and with other studies reporting an increased failure rate or gradual deterioration of stability over time.⁴³ No randomized controlled trial has been conducted directly comparing the 2 types of grafts. Two meta-analyses comparing autograft and allograft results have been reported, one with inconclusive results³⁶ and another that had significant methodological limitations.⁵¹

Given the limitations in the current literature, we performed a meta-analysis of all available studies on ACL reconstruction to compare the results of autograft and allograft reconstructions. To obtain the most clinically applicable result from our analysis, we included only studies using validated outcome measures and current techniques of graft fixation and sterilization and those comparing similar patient populations with a minimum 2-year follow-up. We hypothesized that there would be no difference in long-term functional outcomes, failure rates, and knee stability between autograft and allograft ACL reconstructions.

METHODS

Eligibility Criteria

Our inclusion criteria for studies were as follows: primary unilateral ACL injuries, mean patient age less than 41 years, and follow-up for at least 24 months postreconstruction. We excluded studies with skeletally immature patients, multiligament injuries (medial collateral ligament injuries were, however, included), and publication dates before 1990. Because our goal was to include young athletic individuals with acute ACL tears and without a significant amount of preexisting arthritis, we chose studies with patients whose average age was less than 41 years and with surgical techniques that did not include physal-sparing procedures. To exclude chronic ACL tears and decrease the likelihood of preexisting arthritic changes, we required the average time from injury to surgery to be less than 24 months. To ensure adequate follow-up data, every patient had to have at least 24 months of follow-up (rather than a study average of 24 months). To standardize the outcome for the ACL surgery, all procedures had to be primary unilateral ACL reconstructions

without concomitant microfracture, osteoarticular or cultured cartilage transfer, or other ligamentous reconstruction or injury. Grade 1-2 medial collateral ligament sprains treated nonoperatively were included, as were meniscal repairs and debridements. Studies were excluded that included patients with prior knee surgery (except diagnostic arthroscopy or meniscal procedures).

The specific procedure for the ACL reconstruction had to include bone tunnels for fixation of the graft; thus, no studies were included using extra-articular reconstructions or over-the-top femoral fixation, mini-arthrotomy, or press-fit fixation of graft. Furthermore, we excluded studies with fascia lata grafts, ethylene oxide allograft sterilization, less than 4 strands of hamstrings, and synthetic or hybrid grafts. We also excluded studies that included postoperative casting or return to sports before 4 months postoperatively.

Search Strategy

In December 2007, one reviewer searched Medline through PubMed using the search terms *anterior cruciate ligament* and *anterior cruciate ligament AND allograft*. The search was restricted to studies published after 1990. Limits included human studies, English language, and the subheading *surgery*. There were no restrictions on study design or level of evidence. More than 3000 studies were identified.

During the same month, the Cochrane Central Register of Controlled Trials (Evidence Based Medicine Reviews Collection) was searched for *anterior cruciate ligament reconstruction* limited for English language and year 1990 to present. Approximately 250 studies were identified. The Cochrane Database of Systematic Reviews was also searched, and the bibliographies of appropriate studies were searched by hand.

In January 2008, the Web of Science was searched by the same reviewer for the terms *anterior cruciate ligament AND allograft* as well as *anterior cruciate ligament AND autograft*, with the limits of English language and year of publication 1990 to present. A third search was performed, for *anterior cruciate ligament AND reconstruction* with the same limits but with exclusion of *cadaver, animal, sheep, dog, goat, rat, rabbit, ovine, bovine, and caprine*. This search was repeated in the CINAHL databases. More than 2000 studies were identified.

In February 2008, the SPORTDiscus database was searched for the term *anterior cruciate ligament* with *allograft* or *autograft*. Limits for English language and year of publication from 1990 to present were placed. A separate search was performed with *anterior cruciate ligament AND reconstruction*, with the additional exclusion of *cadaver, animal, sheep, dog, goat, rabbit, ovine, bovine, and caprine*.

In addition, abstracts for poster and podium presentations from the 2006, 2007, and 2008 American Academy of Orthopaedic Surgeons annual meetings were searched for appropriate studies. Abstracts were searched for poster and podium presentations from the 2006 and 2007 American Orthopaedic Society for Sports Medicine annual meetings and specialty days, as were available abstracts from the

Arthroscopy Association of North America 2007 annual meeting. Authors of seemingly appropriate studies were contacted to obtain results and information on the study to ensure that it met inclusion criteria.

In July 2008, all included databases were searched again with the search term *anterior cruciate ligament* and a date range of 2008 only.

Study Selection

One reviewer scanned all titles and abstracts of studies identified in the original search. After obtaining full-text articles of potentially relevant studies, the reviewer assessed the eligibility of each study. During this assessment, the reviewer was blinded to the studies' authors and institutions. Difficulties in determining the eligibility of a study were resolved through consensus with a second reviewer.

Study Characteristics

A standard protocol was used to record the following properties of each study: study design (case series, case control, prospective cohort, retrospective cohort, or randomized controlled trial); type of graft (autograft or allograft); type of allograft preservation (fresh, fresh frozen, irradiated, ethylene oxide, or other); source of graft (patellar, hamstrings, quadriceps, tibialis anterior, Achilles, or fascia lata); mean age and sex of participants; inclusion of skeletally immature participants; mean time from injury to surgery; concomitant injuries to the menisci, cartilage, or other ligaments; mean length of follow-up; range of follow-up; and outcome measures. Studies were subsequently excluded from further analysis when they were found in the course of data extraction to meet exclusion criteria (eg, those that included skeletally immature participants, had less than 2 years of minimum follow-up, or included ethylene oxide allograft preservation).

Outcome Measures

We collected information on multiple outcome measures taken 2 or more years after surgery. Joint stability measures included Lachman test, pivot-shift test, KT-1000 arthrometer assessment (hereafter, KT-1000 assessment), and frequency of graft failures. Functional outcome measures included Tegner activity scores, Cincinnati knee scores, Lysholm scores, and IKDC (International Knee Documentation Committee) total scores.

Ultimately, we found that only 3 allograft studies met our predefined inclusion and exclusion criteria. As such, our comparison of graft materials was limited to the outcome measures used in these studies—namely the Lachman test, the pivot-shift test, the KT-1000 assessment, the IKDC total score, and the frequency of graft failures.

All outcome measures were dichotomized for calculation of composite outcome measures by meta-analysis. Positive Lachman and pivot-shift tests were defined as a grade greater than or equal to 2. KT-1000 assessment was deemed positive for joint laxity

if displacement was greater than or equal to 3 mm. IKDC total scores were recorded according to the number of patients in each IKDC grade (A, B, C, or D) and then dichotomized into those graded as C or D and those graded as A or B.

Data Extraction

Two reviewers independently extracted data on study characteristics and outcome measures. The 2 reviewers initially addressed discrepancies through discussion, and they could not reach consensus, a third reviewer was consulted for resolution. If there appeared to be multiple reports using the same patient sample, the most recent version was extracted. When specific aspects of the data required clarification, the authors of the original articles were contacted.

Quantitative Data Synthesis and Sensitivity Analysis

Stata/IC 10.0 (StataCorp LP, College Station, Texas) was used to calculate the mean proportions and binomial exact 95% confidence intervals (CIs) for each outcome measure of interest (ie, positive Lachman test, positive pivot-shift test, KT-1000 assessment greater than or equal to 3 mm, IKDC grade C or D, and graft failure). The 95% CIs were 2-sided unless the lower bound of the interval was less than zero, in which case the lower bound was designated as zero and the upper bound as the 1-sided 97.5% CI. Composite proportions and their 95% CIs were separately calculated for autograft and allograft studies. Data for each graft type were pooled across studies via the Mantel-Haenszel fixed effects model. Statistical heterogeneity was assessed using the I^2 statistic. Values of the I^2 statistic that exceed 50% are considered to have substantial statistical heterogeneity.

A sensitivity analysis was performed to explore the influence of the statistical model on our estimates of proportions (fixed and random effects models). We also used the Laplace rule of succession to assess the influence of studies with small sample sizes and no observed occurrence of an outcome event (eg, small studies where graft failure was not observed). When an outcome such as graft failure is not observed in a given study sample, the implied probability of that outcome event is zero. Assigning zero probability to these studies is problematic for the probability-based models used to generate the composite estimates, particularly because we know that the probability of these events is rare but not zero in the population. The Laplace rule of succession is one way to deal with this zero-frequency problem.³³ The rule of succession is a formula that estimates the likelihood of a rare outcome event, even though the outcome event has not been observed within the sample. The Laplace rule was applied to these studies by changing the proportion of observed outcomes from zero to $(n + 1) / (N + 2)$ where N is the sample size and n is the number of observed outcomes.

We compared autograft and allograft composite outcome measures for all 5 outcome measures by assessing the degree of overlap of the 95% CIs. We declared a statistically significant difference if the 95% CIs did not overlap. We used the Higgins I^2

statistic to assess for heterogeneity among the included studies. The Higgins I^2 is a test that determines whether variation in the results of studies appears to be a result of true differences between the studies (heterogeneity) or variation attributed to chance alone (homogeneity).²⁹ The Higgins I^2 statistic is expressed as a percentage representing the share of total variation across studies that is due to heterogeneity. I^2 values of 25%, 50%, and 75% are generally considered to represent low, moderate, and high study heterogeneity, respectively.

Sample Size Calculation

Given the composite outcome measures derived in the meta-analysis, we determined the number of patients that would be required for a randomized controlled trial to detect statistically significant differences between autograft and allograft ACL reconstruction for various outcome measures. For these calculations, we set power at 0.80 and alpha at 0.05. We calculated the sample sizes such that patients receiving autograft would outnumber those receiving allograft by 2 to 1. This was done to reflect most surgeons' preference for autograft. The approach minimizes the number of allograft patients while yielding the same power and type I error rate.

RESULTS

More than 8000 titles were identified through the search engines and through hand-searching methods. Many of these were duplicate citations, leaving approximately 5000 studies identified by the initial literature searches (Figure 1). After title and abstract review, 576 studies were identified as being potentially relevant. These 576 studies were printed for review. The 2 most common reasons for exclusion were as follows: less than 2 years of follow-up (135 studies) or reasons related to surgical technique and graft type (140 studies) (Figure 1).

Table 1 gives descriptive summaries of included autograft and allograft studies. Only 1 study that met our inclusion and exclusion criteria directly compared autograft and allograft ACL reconstruction. One study meeting our inclusion criteria directly compared autograft and allograft patients, albeit as a retrospective cohort.⁶⁶ Autograft and allograft patients were otherwise taken from separate studies, including case series, cohort studies, and randomized controlled trials that were not comparing the outcomes of autograft and allograft against each other (eg, a trial comparing hamstring and patellar tendon autografts). As such, in the context of our study, a randomized controlled trial is not truly level 1 evidence but closer to a prospective cohort study. Specifically, both types of studies follow patients prospectively but do not directly compare autograft versus allograft reconstructions.

Among the 54 included autograft studies, slightly less than half (46%) were randomized controlled trials, 17% were prospective cohort studies, and 37% were retrospective cohort studies or case series (Table 1). Study sample sizes at 2-year

follow-up ranged from 13 to 200, and the aggregate number of autograft patients across all studies was 3887. The most common source of autograft was the patellar tendon (44% of studies), followed by the hamstring tendon (24%). A number of studies used both patellar and hamstring grafts (26%). Only 2 studies used the quadriceps tendon. Across the studies, the mean age of patients ranged from 21 to 34 years, with a median of 28. The patients in most studies were predominantly male (median value across studies was 66%). Mean time from injury to surgery varied widely across studies, from 1 to 26 months, and many studies did not report the statistic.

Only 3 allograft studies met all inclusion and exclusion criteria, including a case series, a prospective cohort study, and a retrospective cohort study (Table 1). Sample sizes ranged from 30 to 50; the total number of allograft patients was 113. Grafts were derived from fresh-frozen Achilles and patellar tendons. The mean age of patients ranged from 27 to 36 years. The patients in most allograft studies were almost evenly split by sex. Mean time from injury was only reported in 1 study (2 months).

Composite Outcome Measures for Autograft

In general, only small proportions of autograft patients had physical examination findings suggestive of joint laxity (Tables 2 and 3) or graft failure (Table 4) at 2 or more years after surgery. Composite estimates of the proportion of autograft patients with positive Lachman and pivot-shift tests were 1% (95% CI, 0.5%-1.6%) (Table 2) and 0.5% (95% CI, 0.1%-1.0%) (Table 3), respectively, whereas the proportion with graft failure was similarly low (1.3% with 95% CI 0.8%-1.8%) (Table 4). The composite proportion of autograft patients with IKDC grade C or D, the sole functional outcome measure, was 5.5% (95% CI, 4.4%-6.5%) (Table 5). A greater share of autograft patients had evidence of joint laxity by KT-1000 assessment; nearly 15% (95% CI, 13.4%-16.3%) had translation ≥ 3 mm at 2-year follow-up (Table 6).

There was strong evidence of statistical heterogeneity among the included studies for all 5 outcome measures. The Higgins I^2 statistic ranged from a minimum of 48.9% (for graft failure) to a maximum of 90.2% (for IKDC).

Composite Outcome Measures for Allograft

In general, the composite estimates of allograft outcome measures had wide 95% CIs; in most cases, the lower bound of this interval included zero. Composite estimates of the proportion of allograft patients with positive Lachman and pivot-shift tests were 4.6% (95% CI, 0.1%-9.1%) (Table 2) and 2.2% (95% CI, 0.0%-5.9%) (Table 3), respectively. Estimates of the proportion of patients with joint laxity by KT-1000 assessment exceeded 30% (95% CI, 20.4%-41.7%) (Table 6). Graft failure was not observed in any of the 3 studies. The composite proportion of allograft patients with IKDC grade C or D was 9.1% (95% CI, 2.3%-16.0%) (Table 5).

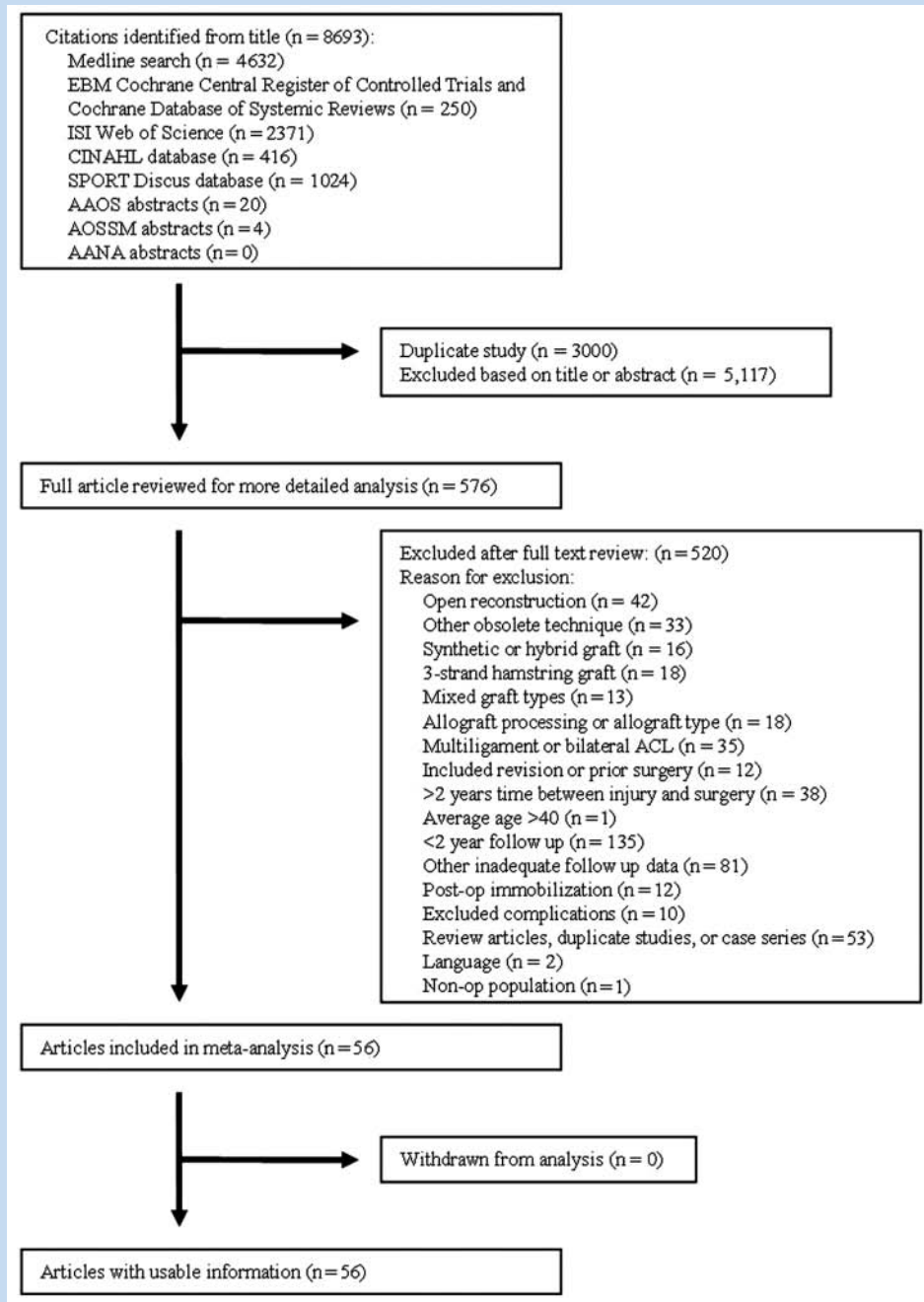


Figure 1. Flow diagram of literature search and study selection process.

As with autograft, there was strong evidence of statistical heterogeneity among the included studies. The Higgins I^2 statistic exceeded 50% for 3 of the 5 outcome measures.

Comparison of Autograft and Allograft Composite Measures

We found no statistically significant difference between autograft and allograft ACL reconstruction for 4 of the 5

outcome measures summarized by this meta-analysis. These included composite estimates of the proportions of positive Lachman test, positive pivot-shift test, IKDC grade C or D, and graft failure. Although the composite proportions were in each case larger for allograft than for autograft, the 95% CIs of the estimates broadly overlapped when compared across the 2 graft materials (Tables 2-5). One outcome measure did, however, show a statistically significant difference across graft

Table 1. Included autograft and allograft studies.^a

| Study | Autograft Source | Study Type | n at Latest Follow-up | Lost to Follow-up, % | Mean Age, Years | Male, % | Mean Time From Injury, Months |
|--------------------------------|-------------------------|------------|-----------------------|----------------------|-----------------|---------|-------------------------------|
| Aglietti et al ¹ | Patellar and hamstring | RCT | 120 | 0 | 25 | 77 | 26 |
| Aglietti et al ² | Hamstring | PCS | 25 | 0 | 28 | 64 | 23 |
| Anderson et al ³ | Patellar | RCT | 35 | 0 | 24 | 66 | — |
| Barber et al ⁵ | Patellar | CS | 40 | 2 | — | 76 | — |
| Beynon et al ⁶ | Patellar | RCT | 22 | 21 | 29 | 64 | 3 |
| Beynon et al ⁷ | Patellar | CS | 19 | 24 | 22 | 58 | 4 |
| Beynon et al ⁸ | Patellar | CS | 13 | 24 | 27 | 94 | — |
| Birmingham et al ⁹ | Hamstring | RCT | 127 | 15 | 27 | 49 | 10 |
| Brandsson et al ¹⁰ | Patellar | RCT | 50 | 17 | 28 | 67 | — |
| Brandsson et al ¹¹ | Patellar | RCT | 43 | 14 | 27 | 74 | 11 |
| Buchner et al ¹² | Hamstring | CS | 70 | 18 | 34 | 63 | 2 |
| Buelow et al ¹³ | Hamstring | PCS | 58 | 3 | 32 | 60 | — |
| Cooley et al ¹⁵ | Hamstring | CS | 20 | 39 | 31 | — | — |
| Corry et al ¹⁶ | Patellar and hamstring | PCS | 161 | 7 | 25 | 55 | — |
| Deehan et al ¹⁷ | Patellar | CS | 80 | 11 | 25 | 53 | — |
| Drogset et al ¹⁸ | Patellar | RCT | 37 | 10 | 26 | 46 | 22 |
| Ejerhed et al ¹⁹ | Patellar | RCT | 32 | 6 | 26 | 66 | 11 |
| Eriksson et al ²⁰ | Patellar and hamstring | RCT | 160 | 2 | 26 | 59 | 16 |
| Fabriziani et al ²¹ | Hamstring | CS | 18 | 0 | 27 | 100 | 13 |
| Feller et al ²² | Patellar and hamstring | RCT | 57 | 12 | 25 | 72 | 17 |
| Ferrari et al ²³ | Patellar | RCS | 200 | 27 | 29 | 69 | 1 |
| Giron et al ²⁴ | Hamstring | CS | 43 | 17 | 29 | 79 | 19 |
| Gobbi et al ²⁵ | Patellar and hamstring | PCS | 80 | 0 | 29 | 60 | 3 |
| Han et al ²⁷ | Patellar and quadriceps | RCS | 144 | 0 | 28 | 94 | 22 |
| Harilainen et al ²⁸ | Hamstring | RCT | 26 | 13 | 27 | 63 | 6 |
| Ibrahim et al ³⁰ | Patellar and hamstring | RCT | 85 | 23 | 22 | 100 | 10 |
| Isberg et al ³² | Patellar | RCT | 22 | 0 | 21 | 64 | 4 |
| Jennings et al ³⁴ | Patellar | PCS | 50 | 37 | 30 | 64 | 24 |
| Lajtai et al ³⁷ | Patellar | CS | 28 | 13 | 29 | 78 | 1 |
| Laxdal et al ³⁸ | Hamstring | RCT | 35 | 3 | 26 | 75 | 11 |
| Lee et al ³⁹ | Quadriceps | CS | 137 | 0 | 27 | 90 | 15 |
| Maletis et al ⁴¹ | Patellar and hamstring | RCT | 96 | 3 | 28 | 77 | — |

(continued)

Table 1. (continued)

| Study | Autograft Source | Study Type | n at Latest Follow-up | Lost to Follow-up, % | Mean Age, Years | Male, % | Mean Time From Injury, Months |
|---------------------------------|------------------------|------------|-----------------------|----------------------|-----------------|---------|-------------------------------|
| Mariani et al ⁴² | Patellar | RCT | 55 | 50 | 25 | 36 | 15 |
| Matsumoto et al ⁴⁴ | Patellar and hamstring | RCT | 72 | 10 | — | 50 | — |
| McDevitt et al ⁴⁵ | Patellar | RCT | 95 | 5 | — | — | — |
| Moller et al ⁴⁶ | Patellar | RCT | 56 | 10 | 30 | 73 | 8 |
| Muneta et al ⁴⁷ | Hamstring | CS | 135 | 26 | 26 | 42 | — |
| Myers et al ⁴⁸ | Hamstring | RCT | 100 | 12 | 30 | 58 | 6 |
| Pinczewski et al ⁴⁹ | Patellar and hamstring | PCS | 149 | 17 | 25 | 53 | — |
| Plaweski et al ⁵⁰ | Hamstring | RCT | 60 | 0 | 29 | 67 | — |
| Rupp et al ⁵² | Patellar | CS | 51 | 12 | 28 | 67 | — |
| Sajovic et al ⁵³ | Patellar and hamstring | RCT | 54 | 16 | 26 | 50 | 24 |
| Salmon et al ⁵⁴ | Hamstring | RCS | 143 | 29 | — | 51 | — |
| Salmon et al ⁵⁵ | Patellar | CS | 67 | 0 | 27 | 70 | — |
| Scranton et al ⁵⁶ | Hamstring | PCS | 120 | 32 | 33 | 57 | — |
| Shaieb et al ⁵⁷ | Patellar and hamstring | RCT | 66 | 20 | 31 | — | 5 |
| Siebold et al ⁵⁹ | Patellar and hamstring | RCS | 64 | 32 | 29 | 0 | 10 |
| Tecklenburg et al ⁶⁰ | Patellar | PCS | 55 | 8 | 32 | 70 | — |
| Tow et al ⁶¹ | Patellar and hamstring | PCS | 32 | 53 | 27 | 94 | 15 |
| Tsuda et al ⁶² | Patellar | CS | 75 | 19 | 22 | 52 | 1 |
| van Dijk et al ⁶³ | Patellar | CS | 196 | 5 | 34 | 80 | 17 |
| Webster et al ⁶⁴ | Patellar and hamstring | RCT | 61 | 6 | 27 | 66 | — |
| Zaffagnini et al ⁶⁵ | Patellar | RCT | 25 | 0 | 31 | 64 | 8 |
| Zijl et al ⁶⁶ | Patellar | RCS | 23 | 11 | 33 | 69 | — |
| | Allograft Source | | | | | | |
| Indelli et al ³¹ | Achilles—fresh frozen | CS | 50 | 0 | 36 | 58 | — |
| Shelton et al ⁵⁸ | Patellar—fresh frozen | PCS | 30 | 0 | 27 | 60 | 2 |
| Zijl et al ⁶⁶ | Patellar—fresh frozen | RCS | 33 | 24 | 32 | 43 | — |

^aThere were no randomized controlled trials that met our inclusion and exclusion criteria and compared autograft to allograft reconstruction of the anterior cruciate ligament. *Study type* thus refers to the type of study from which the subset of autograft patients were taken. As such, a study listed as a randomized controlled trial did not compare autograft to allograft but instead compared other aspects of the reconstruction. Dashes (—) indicate *unknown*. RCT, randomized controlled trial; PCS, prospective cohort study; RCS, retrospective cohort study; CS, case series.

Table 2. Proportion of patients with positive Lachman test 2+ years postreconstruction.

| Autograft Study | n / N | % | 95% Confidence Interval (%) |
|--|----------|------|-----------------------------|
| Aglietti et al ¹ | 0 / 120 | 0.0 | 0.0-3.0 |
| Barber et al ⁵ | 0 / 40 | 0.0 | 0.0-8.8 |
| Beynnon et al ⁶ | 2 / 22 | 9.1 | 1.1-29.2 |
| Beynnon et al ⁸ | 2 / 213 | 15.4 | 1.9-45.4 |
| Birmingham et al ⁹ | 5 / 127 | 3.9 | 1.3-8.9 |
| Buchner et al ¹² | 5 / 70 | 7.1 | 2.4-15.9 |
| Cooley et al ¹⁵ | 0 / 20 | 0.0 | 0.0-16.8 |
| Corry et al ¹⁶ | 2 / 161 | 1.2 | 0.2-4.4 |
| Drogset et al ¹⁸ | 1 / 37 | 2.7 | 0.1-14.2 |
| Ejerhed et al ¹⁹ | 2 / 32 | 6.3 | 0.8-20.8 |
| Eriksson et al ²⁰ | 3 / 160 | 1.9 | 0.4-5.4 |
| Ferrari et al ²³ | 4 / 200 | 2.0 | 0.5-5.0 |
| Harilainen et al ²⁸ | 1 / 26 | 3.8 | 0.1-19.6 |
| Ibrahim et al ³⁰ | 0 / 85 | 0.0 | 0.0-4.2 |
| Jennings et al ³⁴ | 3 / 50 | 6.0 | 1.3-16.5 |
| Lajtai et al ³⁷ | 11 / 28 | 39.3 | 21.5-59.4 |
| Lee et al ³⁹ | 24 / 137 | 17.5 | 11.6-24.9 |
| Mariani et al ⁴² | 1 / 55 | 1.8 | 0.0-9.7 |
| McDevitt et al ⁴⁵ | 2 / 95 | 2.1 | 0.3-7.4 |
| Muneta et al ⁴⁷ | 6 / 135 | 4.4 | 1.6-9.4 |
| Myers et al ⁴⁸ | 0 / 100 | 0.0 | 0.0-3.6 |
| Pinczewski et al ⁴⁹ | 1 / 149 | 0.7 | 0.0-3.7 |
| Plaweski et al ⁵⁰ | 1 / 60 | 1.7 | 0.0-8.9 |
| Sajovic et al ⁵³ | 2 / 54 | 3.7 | 0.5-12.7 |
| Salmon et al ⁵⁴ | 0 / 143 | 0.0 | 0.0-2.5 |
| Salmon et al ⁵⁵ | 3 / 67 | 4.5 | 0.9-12.5 |
| Scranton et al ⁵⁶ | 0 / 120 | 0.0 | 0.0-3.0 |
| Siebold et al ⁵⁹ | 0 / 64 | 0.0 | 0.0-5.6 |
| van Dijck et al ⁶³ | 8 / 196 | 4.1 | 1.8-7.9 |
| Zaffagnini et al ⁶⁵ | 2 / 25 | 8.0 | 1.0-26.0 |
| Zijl et al ⁶⁶ | 3 / 23 | 13.0 | 2.8-33.6 |
| Composite estimates | | | |
| All studies | | 1.0 | 0.5-1.6 |
| All studies: Laplace rule of succession ^a | | 2.4 | 1.7-3.1 |
| Allograft Study | | | |
| Indelli et al ³¹ | 1 / 50 | 2.0 | 0.1-10.6 |
| Shelton et al ⁵⁸ | 2 / 30 | 6.7 | 0.8-22.1 |
| Zijl et al ⁶⁶ | 7 / 33 | 21.2 | 9.0-38.9 |
| Composite estimates: All studies | | 4.6 | 0.1-9.1 |

^aThe Laplace rule of succession can be used to estimate the probability of an event that has not been observed within a given sample. As such, we applied this rule to studies in our meta-analysis that did not observe a single patient with a positive Lachman at follow-up. For these studies, the proportion of patients with a positive Lachman was calculated as follows: $(n + 1) / (N + 2)$.

Table 3. Proportion of patients with positive pivot-shift test 2+ years postreconstruction.

| Autograft Study | n / N | % | 95% Confidence Interval (%) |
|--|----------|------|-----------------------------|
| Aglietti et al ¹ | 0 / 120 | 0.0 | 0.0-3.0 |
| Aglietti et al ² | 2 / 25 | 8.0 | 1.0-26.0 |
| Anderson et al ³ | 7 / 35 | 20.0 | 8.4-36.9 |
| Barber et al ⁵ | 0 / 40 | 0.0 | 0.0-8.8 |
| Beynon et al ⁶ | 0 / 22 | 0.0 | 0.0-15.4 |
| Beynon et al ⁷ | 0 / 19 | 0.0 | 0.0-17.6 |
| Birmingham et al ⁹ | 5 / 127 | 3.9 | 1.3-8.9 |
| Cooley et al ¹⁵ | 0 / 20 | 0.0 | 0.0-16.8 |
| Corry et al ¹⁶ | 0 / 161 | 0.0 | 0.0-2.3 |
| Drogset et al ¹⁸ | 2 / 37 | 5.4 | 0.7-18.2 |
| Eriksson et al ²⁰ | 3 / 160 | 1.9 | 0.4-5.4 |
| Ferrari et al ²³ | 0 / 200 | 0.0 | 0.0-1.8 |
| Giron et al ²⁴ | 3 / 43 | 7.0 | 1.5-19.1 |
| Harilainen et al ²⁸ | 1 / 26 | 3.8 | 0.1-19.6 |
| Ibrahim et al ³⁰ | 0 / 85 | 0.0 | 0.0-4.2 |
| Jennings et al ³⁴ | 2 / 50 | 4.0 | 0.5-13.7 |
| Lajtai et al ³⁷ | 1 / 28 | 3.6 | 0.1-18.3 |
| Lee et al ³⁹ | 37 / 137 | 27.0 | 19.8-35.3 |
| Maletis et al ⁴¹ | 1 / 96 | 1.0 | 0.0-5.7 |
| Mariani et al ⁴² | 1 / 55 | 1.8 | 0.0-9.7 |
| McDevitt et al ⁴⁵ | 3 / 95 | 3.2 | 0.7-9.0 |
| Muneta et al ⁴⁷ | 3 / 135 | 2.2 | 0.5-6.4 |
| Myers et al ⁴⁸ | 2 / 100 | 2.0 | 0.2-7.0 |
| Pinczewski et al ⁴⁹ | 0 / 149 | 0.0 | 0.0-2.4 |
| Plaweski et al ⁵⁰ | 1 / 60 | 1.7 | 0.0-8.9 |
| Sajovic et al ⁵³ | 2 / 54 | 3.7 | 0.5-12.7 |
| Salmon et al ⁵⁴ | 0 / 143 | 0.0 | 0.0-2.5 |
| Salmon et al ⁵⁵ | 0 / 67 | 0.0 | 0.0-5.4 |
| Scranton et al ⁵⁶ | 0 / 120 | 0.0 | 0.0-3.0 |
| Shaieb et al ⁵⁷ | 0 / 66 | 0.0 | 0.0-5.4 |
| Siebold et al ⁵⁹ | 1 / 64 | 1.6 | 0.0-8.4 |
| van Dijck et al ⁶³ | 6 / 196 | 3.1 | 1.1-6.5 |
| Zaffagnini et al ⁶⁵ | 4 / 25 | 16.0 | 4.5-36.1 |
| Zijl et al ⁶⁶ | 1 / 23 | 4.4 | 0.1-22.0 |
| Composite estimates | | | |
| All studies | | 0.5 | 0.1-1.0 |
| All studies: Laplace rule of succession ^a | | 1.5 | 0.9-2.0 |
| Allograft Study | | | |
| Indelli et al ³¹ | 1 / 50 | 2.0 | 0.1-10.6 |
| Shelton et al ⁵⁸ | 0 / 30 | 0.0 | 0.0-11.6 |
| Zijl et al ⁶⁶ | 5 / 33 | 15.2 | 5.1-31.9 |

(continued)

Table 3. (continued)

| Autograft Study | n / N | % | 95% Confidence Interval (%) |
|--|-------|-----|-----------------------------|
| Composite estimates | | | |
| All studies | | 2.2 | 0.0-5.9 |
| All studies: Laplace rule of succession ^a | | 3.6 | 0.0-7.8 |

^aThe Laplace rule of succession can be used to estimate the probability of an event that has not been observed within a given sample. As such, we applied this rule to studies in our meta-analysis that did not observe a single patient with a positive pivot-shift test at follow-up. For these studies, the proportion of patients with a positive pivot-shift test was calculated as follows: $(n + 1) / (N + 2)$.

Table 4. Proportion of patients with graft failure 2+ years postreconstruction.

| Autograft Study | n / N | % | 95% Confidence Interval (%) |
|---------------------------------|---------|------|-----------------------------|
| Aglietti et al ¹ | 0 / 120 | 0.0 | 0.0-3.0 |
| Aglietti et al ² | 1 / 25 | 4.0 | 0.1-20.4 |
| Anderson et al ³ | 1 / 35 | 2.9 | 0.1-14.9 |
| Barber et al ⁵ | 0 / 40 | 0.0 | 0.0-8.8 |
| Beynon et al ⁷ | 0 / 19 | 0.0 | 0.0-17.6 |
| Beynon et al ⁸ | 0 / 13 | 0.0 | 0.0-24.7 |
| Birmingham et al ⁹ | 6 / 127 | 4.7 | 1.8-10.0 |
| Brandsson et al ¹⁰ | 1 / 50 | 2.0 | 0.1-10.6 |
| Brandsson et al ¹¹ | 0 / 43 | 0.0 | 0.0-8.2 |
| Buchner et al ¹² | 5 / 70 | 7.1 | 2.4-15.9 |
| Cooley et al ¹⁵ | 1 / 20 | 5.0 | 0.1-24.9 |
| Corry et al ¹⁶ | 9 / 161 | 5.6 | 2.6-10.3 |
| Deehan et al ¹⁷ | 3 / 80 | 3.8 | 0.8-10.6 |
| Drogset et al ¹⁸ | 0 / 37 | 0.0 | 0.0-9.5 |
| Ejerhed et al ¹⁹ | 1 / 32 | 3.1 | 0.1-16.2 |
| Eriksson et al ²⁰ | 5 / 160 | 3.1 | 1.0-7.1 |
| Fabbriciani et al ²¹ | 0 / 18 | 0.0 | 0.0-18.5 |
| Feller et al ²² | 1 / 57 | 1.8 | 0.0-9.4 |
| Ferrari et al ²³ | 0 / 200 | 0.0 | 0.0-1.8 |
| Giron et al ²⁴ | 5 / 43 | 11.6 | 3.9-25.1 |
| Gobbi et al ²⁵ | 1 / 80 | 1.3 | 0.0-6.8 |
| Han et al ²⁷ | 3 / 144 | 2.1 | 0.4-6.0 |
| Harilainen et al ²⁸ | 1 / 26 | 3.8 | 0.1-19.6 |
| Isberg et al ³² | 0 / 22 | 0.0 | 0.0-15.4 |
| Jennings et al ³⁴ | 2 / 50 | 4.0 | 0.5-13.7 |
| Lajtai et al ³⁷ | 0 / 28 | 0.0 | 0.0-12.3 |
| Laxdal et al ³⁸ | 2 / 35 | 5.7 | 0.7-19.2 |
| Maletis et al ⁴¹ | 1 / 96 | 1.0 | 0.0-5.7 |
| Matsumoto et al ⁴⁴ | 0 / 72 | 0.0 | 0.0-5.0 |
| McDevitt et al ⁴⁵ | 2 / 95 | 2.1 | 0.3-7.4 |
| Moller et al ⁴⁶ | 1 / 56 | 1.8 | 0.0-9.6 |

(continued)

Table 4. (continued)

| Autograft Study | n / N | % | 95% Confidence Interval (%) |
|--|----------|------|-----------------------------|
| Myers et al ⁴⁸ | 1 / 100 | 1.0 | 0.0-5.4 |
| Pinczewski et al ⁴⁹ | 19 / 149 | 12.8 | 7.9-19.2 |
| Plaweski et al ⁵⁰ | 0 / 60 | 0.0 | 0.0-6.0 |
| Rupp et al ⁵² | 3 / 51 | 5.9 | 1.2-16.2 |
| Sajovic et al ⁵³ | 4 / 54 | 7.4 | 2.1-17.9 |
| Salmon et al ⁵⁴ | 21 / 143 | 14.7 | 9.3-21.6 |
| Salmon et al ⁵⁵ | 9 / 67 | 13.4 | 6.3-24.0 |
| Scranton et al ⁵⁶ | 5 / 120 | 4.2 | 1.4-9.5 |
| Shaieb et al ⁵⁷ | 4 / 66 | 6.1 | 1.7-14.8 |
| Siebold et al ⁵⁹ | 1 / 64 | 1.6 | 0.0-8.4 |
| Tecklenburg et al ⁶⁰ | 0 / 55 | 0.0 | 0.0-6.5 |
| van Dijk et al ⁶³ | 5 / 196 | 2.6 | 0.8-5.9 |
| Webster et al ⁶⁴ | 1 / 61 | 1.6 | 0.0-8.8 |
| Composite estimates | | | |
| All studies | | 1.3 | 0.8-1.8 |
| All studies: Laplace rule of succession ^a | | 2.3 | 1.7-3.0 |
| Allograft Study | | | |
| Indelli et al ³¹ | 0 / 50 | 0.0 | — |
| Shelton et al ⁵⁸ | 0 / 30 | 0.0 | — |
| Composite estimates | | | |
| All studies | | 0.0 | — |
| All studies: Laplace rule of succession ^a | | 2.3 | 0.0-6.0 |

^aThe Laplace rule of succession can be used to estimate the probability of an event that has not been observed within a given sample. As such, we applied this rule to studies in our meta-analysis that did not observe a single patient with graft failure at follow-up. For these studies, the proportion of patients with graft failure was calculated as follows: $(n + 1) / (N + 2)$.

material. The composite proportion of patients with KT-1000 assessment greater than or equal to 3 mm was 31% across allograft studies and 15% across autograft studies, with no overlap of 95% CIs (Table 6).

Sensitivity Analysis

The estimates obtained from the random effects model were similar to those obtained from the fixed effects model (ie, Mantel-Haenszel). KT-1000 assessment continued to show a statistically significant difference across graft material, and the remaining 4 outcome measures remained nonsignificant. In all cases, applying the Laplace rule of succession increased the composite estimates of the outcome measures for both autograft and allograft (Tables 2-6). KT-1000 assessment continued to show a statistically significant difference across graft material after applying the rule, and the remaining 4 outcome measures remained nonsignificant.

Power Analysis

Given the composite outcome measures derived in the meta-analysis, we calculated the sample size necessary for a randomized controlled trial to detect statistically significant differences between autograft and allograft ACL reconstruction for various outcome measures (Table 7). We found that for 4 of the 5 outcome measures we examined, the sample sizes necessary to detect these differences exceeded not only the sample size of any 1 study that met our inclusion and exclusion criteria but also the aggregate number of patients used in our meta-analysis. For example, if graft failure rates were truly 2.3% and 3.2% for autograft and allograft, respectively, then more than 6500 autograft patients and more than 3200 allograft patients would be required to detect this difference with power of 0.80 and type I error rate of 0.05. These sample sizes exceed the

Table 5. IKDC scores 2+ years postreconstruction.^a

| Autograft Study | N | Patients by IKDC Grades A-D (%) | | | | Patients by IKDC Grade C or D (%) | |
|--|-----|---------------------------------|----|----|----|-----------------------------------|-------------------------|
| | | A | B | C | D | C or D | 95% Confidence Interval |
| Aglietti et al ¹ | 120 | 60 | 40 | 0 | 0 | 0.0 | 0.0-3.0 |
| Aglietti et al ² | 25 | 56 | 36 | 8 | 0 | 8.0 | 1.0-26.0 |
| Anderson et al ³ | 35 | 31 | 66 | 3 | 0 | 2.9 | 0.1-14.9 |
| Beynon et al ⁷ | 19 | 16 | 58 | 26 | 0 | 26.3 | 9.1-51.2 |
| Beynon et al ⁸ | 13 | 46 | 23 | 23 | 8 | 30.8 | 9.1-61.4 |
| Brandsson et al ¹⁰ | 50 | 44 | 48 | 6 | 2 | 8.0 | 2.2-19.2 |
| Brandsson et al ¹¹ | 43 | 30 | 47 | 23 | 0 | 23.3 | 11.8-38.6 |
| Buchner et al ¹² | 70 | 40 | 46 | 13 | 1 | 14.3 | 7.1-24.7 |
| Cooley et al ¹⁵ | 20 | 25 | 60 | 10 | 5 | 15.0 | 3.2-37.9 |
| Corry et al ¹⁶ | 161 | 42 | 43 | 7 | 7 | 14.3 | 9.3-20.7 |
| Eriksson et al ²⁰ | 160 | 4 | 51 | 23 | 18 | 40.6 | 32.9-48.7 |
| Fabriziani et al ²¹ | 18 | 56 | 33 | 11 | 0 | 11.1 | 1.4-34.7 |
| Feller et al ²² | 57 | 37 | 47 | 14 | 2 | 15.8 | 7.5-27.9 |
| Giron et al ²⁴ | 43 | 33 | 53 | 12 | 0 | 11.6 | 3.9-25.1 |
| Gobbi et al ²⁵ | 80 | 58 | 41 | 10 | 1 | 11.3 | 5.3-20.3 |
| Harilainen et al ²⁸ | 26 | 27 | 58 | 8 | 8 | 15.4 | 4.4-34.9 |
| Ibrahim et al ³⁰ | 85 | 62 | 24 | 14 | 0 | 14.1 | 7.5-23.4 |
| Isberg et al ³² | 22 | 36 | 55 | 9 | 0 | 9.1 | 1.1-29.2 |
| Laxdal et al ³⁸ | 35 | 37 | 40 | 17 | 6 | 22.9 | 10.4-40.1 |
| Mariani et al ⁴² | 55 | 16 | 58 | 18 | 7 | 25.5 | 14.7-39.0 |
| Matsumoto et al ⁴⁴ | 72 | 28 | 51 | 17 | 4 | 20.8 | 12.2-32.0 |
| Pinczewski et al ⁴⁹ | 149 | 40 | 40 | 18 | 3 | 20.8 | 14.6-28.2 |
| Rupp et al ⁵² | 51 | 29 | 45 | 24 | 2 | 25.5 | 14.3-39.6 |
| Sajovic et al ⁵³ | 54 | 44 | 52 | 4 | 0 | 3.7 | 0.5-12.7 |
| Siebold et al ⁵⁹ | 64 | 39 | 59 | 2 | 0 | 1.6 | 0.0-8.4 |
| Tecklenburg et al ⁶⁰ | 55 | 80 | 20 | 0 | 0 | 0.0 | 0.0-6.5 |
| van Dijk et al ⁶³ | 196 | 40 | 42 | 15 | 3 | 17.9 | 12.8-23.9 |
| Webster et al ⁶⁴ | 61 | 23 | 31 | 28 | 7 | 34.4 | 22.7-47.7 |
| Zaffagnini et al ⁶⁵ | 25 | 24 | 48 | 20 | 8 | 28.0 | 12.1-49.4 |
| Zijl et al ⁶⁶ | 23 | 26 | 43 | 30 | 0 | 30.4 | 13.2-53.0 |
| Composite estimates | | | | | | | |
| All studies | | | | | | 5.5 | 4.4-6.5 |
| All studies: Laplace rule of succession ^b | | | | | | 10.4 | 9.0-11.8 |
| Allograft Study | | | | | | | |
| Indelli et al ³¹ | 50 | 44 | 5 | 6 | 0 | 6.0 | 1.3-0.2 |

(continued)

Table 5. (continued)

| Autograft Study | N | Patients by IKDC Grades A-D (%) | | | | Patients by IKDC Grade C or D (%) | |
|-------------------------------------|----|---------------------------------|----|----|---|-----------------------------------|-------------------------|
| | | A | B | C | D | C or D | 95% Confidence Interval |
| Zijl et al ⁶⁶ | 33 | 42 | 36 | 15 | 6 | 21.2 | 9.0-0.4 |
| Composite estimates: All studies | | | | | | 9.1 | 2.3-16.0 |

[¶]IKDC, International Knee Documentation Committee.

[‡]The Laplace rule of succession can be used to estimate the probability of an event that has not been observed within a given sample. As such, we applied this rule to studies in our meta-analysis that did not observe a single patient with IKDC of C or D at follow-up. For these studies, the proportion of patients with IKDC of C or D was calculated as follows: $(n + 1) / (N + 2)$.

Table 6. Proportion of patients with KT-1000 arthrometer assessments > 3 mm at 2+ years postreconstruction.

| Autograft Study | n / N | % | 95% Confidence Interval (%) |
|---------------------------------|----------|------|-----------------------------|
| Aglietti et al ¹ | 47 / 120 | 39.2 | 30.4-48.5 |
| Aglietti et al ² | 10 / 25 | 40.0 | 21.1-61.3 |
| Anderson et al ³ | 10 / 35 | 28.6 | 14.6-46.3 |
| Barber et al ⁵ | 0 / 40 | 0.0 | 0.0-8.8 |
| Beynon et al ⁶ | 5 / 22 | 22.7 | 7.8-45.4 |
| Brandsson et al ¹⁰ | 2 / 50 | 4.0 | 0.5-13.7 |
| Buchner et al ¹² | 18 / 70 | 25.7 | 16.0-37.6 |
| Cooley et al ¹⁵ | 0 / 20 | 0.0 | 0.0-16.8 |
| Corry et al ¹⁶ | 23 / 161 | 14.3 | 9.3-20.7 |
| Deehan et al ¹⁷ | 15 / 80 | 18.8 | 10.9-29.0 |
| Drogset et al ¹⁸ | 3 / 37 | 8.1 | 1.7-21.9 |
| Fabbriciani et al ²¹ | 5 / 18 | 27.8 | 9.7-53.5 |
| Feller et al ²² | 5 / 57 | 8.8 | 2.9-19.3 |
| Ferrari et al ²³ | 35 / 200 | 17.5 | 12.5-23.5 |
| Giron et al ²⁴ | 12 / 43 | 27.9 | 15.3-43.7 |
| Gobbi et al ²⁵ | 8 / 80 | 10.0 | 4.4-18.8 |
| Han et al ²⁷ | 44 / 144 | 30.6 | 23.2-38.8 |
| Harilainen et al ²⁸ | 7 / 26 | 26.9 | 11.6-47.8 |
| Ibrahim et al ³⁰ | 12 / 85 | 14.1 | 7.5-23.4 |
| Jennings et al ³⁴ | 21 / 50 | 42.0 | 28.2-56.8 |
| Lajtai et al ³⁷ | 2 / 28 | 7.1 | 0.9-23.5 |
| Maletis et al ⁴¹ | 43 / 96 | 44.8 | 34.6-55.3 |
| Matsumoto et al ⁴⁴ | 9 / 72 | 12.5 | 5.9-22.4 |
| McDevitt et al ⁴⁵ | 6 / 95 | 6.3 | 2.4-13.2 |

(continued)

Table 6. (continued)

| Autograft Study | n / N | % | 95% Confidence Interval (%) |
|--|----------|------|-----------------------------|
| Muneta et al ⁴⁷ | 17 / 135 | 12.6 | 7.5-19.4 |
| Myers et al ⁴⁸ | 20 / 100 | 20.0 | 12.7-29.2 |
| Pinczewski et al ⁴⁹ | 30 / 149 | 20.1 | 14.0-27.5 |
| Rupp et al ⁵² | 7 / 51 | 13.7 | 5.7-26.3 |
| Sajovic et al ⁵³ | 12 / 54 | 22.2 | 12.0-35.6 |
| Salmon et al ⁵⁵ | 14 / 67 | 20.9 | 11.9-32.6 |
| Scranton et al ⁵⁶ | 14 / 120 | 11.7 | 6.5-18.8 |
| Shaieb et al ⁵⁷ | 17 / 66 | 25.8 | 15.8-38.0 |
| Tow et al ⁶¹ | 8 / 32 | 25.0 | 11.5-43.4 |
| Tsuda et al ⁶² | 9 / 75 | 12.0 | 5.6-21.6 |
| van Dijck et al ⁶³ | 47 / 196 | 24.0 | 18.2-30.6 |
| Webster et al ⁶⁴ | 5 / 61 | 8.2 | 2.7-18.1 |
| Zaffagnini et al ⁶⁵ | 14 / 25 | 56.0 | 34.9-75.6 |
| Composite estimates | | | |
| All studies | | 14.9 | 13.5-16.3 |
| All studies: Laplace rule of succession ^a | | 16.0 | 14.6-17.4 |
| Allograft Study | | | |
| Indelli et al ³² | 17 / 50 | 34.0 | 21.2-48.8 |
| Shelton et al ⁵⁸ | 8 / 30 | 26.7 | 12.3-45.9 |
| Composite estimates: All studies | | 31.1 | 20.4-41.7 |

^aThe Laplace rule of succession can be used to estimate the probability of an event that has not been observed within a given sample. As such, we applied this rule to studies in our meta-analysis that did not observe a single patient with KT-1000 arthrometer assessments > 3 mm at follow-up. For these studies, the proportion of patients with KT-1000 arthrometer assessments > 3 mm was calculated as follows: $(n + 1) / (N + 2)$.

Table 7. Sample sizes for a randomized controlled trial: autograft versus allograft.

| Outcome Measure | Assumed Rates of Occurrence, % ^a | | Sample Size, n ^b | |
|--------------------------------|---|-----------|-----------------------------|-----------|
| | Autograft | Allograft | Autograft | Allograft |
| Positive Lachman test | 1.0 | 4.6 | 527 | 264 |
| Positive pivot-shift test | 0.5 | 2.2 | 1154 | 577 |
| KT-1000 > 3 mm ^c | 14.9 | 31.1 | 170 | 80 |
| IKDC grade C or D ^d | 5.4 | 9.1 | 1197 | 599 |
| Graft failure | 2.3 | 3.3 | 6551 | 3276 |

^aUnless otherwise stated, the assumed rates of occurrence are based on the composite estimates of our meta-analysis. Note that selecting different values for the assumed rates changes the sample sizes necessary to detect a difference between graft materials.

^bWe deliberately chose to calculate sample sizes where autograft patients would outnumber allograft patients by 2 to 1, reflecting most surgeons' preference for autograft. As such, fewer allograft patients would be necessary to achieve the desired power.

^cKT-1000 arthrometer assessment.

^dIKDC, International Knee Documentation Committee.

number of patients available for meta-analysis of graft failure, 2-fold for autograft and 40-fold for allograft.

Smaller sample sizes would likely be sufficient for the other outcome measures given that the outcomes appear to occur more frequently and the differences between their rates of occurrence appear larger in magnitude across graft material (Table 7). For example, a trial might require as few as 170 autograft and 80 allograft patients to detect a difference in KT-1000 assessment, provided that the measurement truly exceeds 3 mm in roughly 15% and 30% of autograft and allograft patients, respectively.

DISCUSSION

Our meta-analysis comparing autograft and allograft ACL reconstruction found only 1 statistically significant difference in outcome measures, with more allograft patients having increased joint laxity as measured by KT-1000 arthrometer. For all other negative outcome measures—including positive Lachman test, positive pivot-shift test, IKDC grade C or D, and graft failure—proportions were larger for allograft than for autograft, but after statistical analysis, the differences were not significant.

There was a large amount of heterogeneity between studies despite our relatively strict inclusion and exclusion criteria. This indicates that there is great diversity in patient populations, surgical techniques, and assessment methods among available studies. As a result, our 95% CIs were broad, and we were unable to detect a statistically significant difference between allograft and autograft reconstructions, other than the increased laxity observed by KT-1000 measurements.

Prodromos and colleagues conducted a meta-analysis comparing all types of autograft and allograft used in ACL reconstruction (bone-patellar tendon-bone and soft tissue).⁵¹ They subdivided their analysis by graft type and whether or not the allograft had been irradiated. They found allograft reconstruction to be less stable than autograft reconstruction, even after excluding irradiated grafts. The authors recommended using autografts for routine primary ACL reconstruction and reserving allograft for multiligamentous reconstruction, where more graft tissue is necessary. Their study had several limitations. The literature search was restricted to English-language articles in the PubMed database, which indicates that it may have been subject to publication bias. There was no analysis of study heterogeneity or inclusion of validated outcome scores. Finally, their statistical methods are questionable at best; the use of weighted means by the methods they describe gives inappropriate statistical weight to smaller studies. Instead, they should have used either a fixed or random effects model for their analysis.

A meta-analysis comparing bone-patellar tendon-bone autograft and bone-patellar tendon-bone allograft was published in 2008.³⁶ This meta-analysis used subjective and objective outcome scores to evaluate multiple outcomes, including graft failure, Lachman test, pivot-shift test, return

to sport, and IKDC score. Only 5 studies met the researchers' inclusion criteria, 1 of which was found to be significantly dissimilar to the other included studies on statistical heterogeneity analysis, likely owing to the effects of acetone and irradiation on allograft preparation. When this study was excluded from the analysis, there were no statistically significant differences in outcome measures between the groups. Their study was well conducted, but like ours, it was limited by the available data.

The strength of our meta-analysis was the comprehensive nature of our literature search for published and unpublished data, thereby limiting the effect of publication bias. Our study was likely still subject to some bias because we limited our search to studies published in English. In particular, studies published in English may be more likely to find a positive treatment effect than studies published in another language.⁶⁷ In addition, we used relatively strict inclusion and exclusion criteria with respect to age, time to reconstruction, surgical technique, allograft preparation, and postoperative follow-up. This narrowed our patient population to young, presumably healthy adults without preexisting osteoarthritis. By also excluding studies using techniques of ACL reconstruction that are no longer in practice, the results of our meta-analysis are more applicable to current clinical practice and decision making.

The major limitation of our study was the lack of level 1 evidence. As mentioned earlier, there are no randomized controlled trials directly comparing autograft and allograft ACL reconstruction. Based on strict inclusion and exclusion criteria, only 10% of potentially relevant ACL literature could be included in our study (56 studies out of the initial 576 selected for review). Specifically, only 3 allograft studies using current sterilization and fixation methods and standard outcome measures could be included. This limited our ability to observe a statistically significant difference between graft types. Using the observed difference in reported graft failures between autograft and allograft ACL reconstruction, we calculated the number of patients necessary to conduct a randomized controlled trial and detect a statistically significant difference in graft failure. The reported incidence of graft failure for autograft and allograft reconstructions at a minimum of 24 months postoperatively is low: 2.3% and 3.2%, respectively. Consequently, more than 6500 autograft patients and more than 3200 allograft patients would be required to detect this difference. These are daunting numbers for any one center, but they could be achieved in a multicenter study. Furthermore, it will be important to obtain 5- and 10-year follow-up for patients to determine if graft failure rates increase in the long-term.

Our meta-analysis was also limited by the quality of the available data. Although nearly half the autograft studies were randomized controlled trials, the remainder was made up of prospective or retrospective cohort studies, with several outcome measures reported. Ideally, investigators reporting results of ACL reconstruction would prospectively enroll

patients and use a standardized, validated outcome measure (eg, Lysholm, IKDC, or Tegner score^{29,35}) so that the results can be combined in aggregate and different interventions can be compared across studies. In addition, more long-term follow-up of autograft and allograft ACL reconstruction is necessary. Some authors have suggested that allograft failure rates increase over time,⁵¹ although most reported studies found no difference in graft failure rates between the 2 graft types.^{4,43} Furthermore, data suggest that the incidence of osteoarthritis is similar for patients who have sustained an ACL rupture 15 years following injury, regardless of whether or not they undergo reconstruction.⁴⁰ It would be important to ascertain if graft type has an influence on the incidence or progression of osteoarthritis following ACL reconstruction.

Finally, although autografts are still far more commonly used for ACL reconstruction, results of allograft reconstruction are comparatively limited. After conducting our power analysis for the effect sizes that we observed for graft failure, we believe that a multicenter randomized controlled trial will be necessary to obtain a large-enough sample size to detect a statistically significant difference between graft types (Table 7).

With the data available, patients undergoing allograft reconstruction may have increased joint laxity as measured by the KT-1000 arthrometer. For all other outcome measures, including Lachman testing, pivot-shift test, IKDC grade, and graft failure rates, we could not statistically determine a difference between the 2 graft types. Our analysis was limited by the limited number of studies that have been published for patients with allograft reconstruction. To detect a significant difference in graft failure rates and ultimately determine the best option between the 2 graft types, a large multicenter randomized clinical trial comparing autograft and allograft ACL reconstruction is warranted.

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