Systematic Review

Clinical and Functional Outcomes After Anterior Cruciate Ligament Reconstruction Using Cortical Button Fixation Versus Transfemoral Suspensory Fixation: A Systematic Review of Randomized Controlled Trials

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Purpose: To compare clinical and functional outcomes after anterior cruciate ligament (ACL) reconstruction using cortical button versus transfemoral suspensory fixation. **Methods:** This systematic review was conducted following the Cochrane handbook guidelines and PROSPERO registration. Only Level I and II randomized controlled trials comparing cortical button and transfemoral suspensory fixation in hamstring ACL reconstruction were included. A literature search was performed using electronic databases. The methodologic quality of included studies was assessed using The Cochrane Collaboration's risk-of-bias tool. All outcomes reported by each study were evaluated. Primary outcome measures were postoperative International Knee Documentation Committee (IKDC) and Lysholm knee scores. Statistical analysis was performed using RevMan software (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen). Dichotomous data were reported as risk ratio and 95% confidence intervals. Heterogeneity was assessed using I^2. **Results:** Five studies involving 317 patients were included. The mean follow-up period was 21.7 ± 7.0 months (range, 12 to 38 months). The mean age of participants was 26.7 ± 1.89 years (range, 16 to 48 years). The Lysholm score, Tegner activity score, and IKDC score were compiled. Clinical assessment was performed by Lachman testing, assessment of side-to-side differences on KT-1000 (MEDmetric, San Diego, CA) testing, and measurements of thigh atrophy, as well as imaging (radiography and computed tomography) to assess for femoral tunnel widening. Pooled statistical analysis was possible only for postoperative IKDC and Lysholm scores. No significant differences were found between the cortical button and transfemoral fixation groups. Included studies did not report differences in clinical outcomes between the 2 groups. Radiographic results suggest increased femoral tunnel widening in the cortical button group. However, tunnel widening was not found to affect clinical results. **Conclusions:** The present evidence suggests that there are no short- to medium-term differences in knee-specific outcome measures between patients treated with cortical button femoral graft fixation and those treated with suspensory transfemoral fixation when undergoing ACL reconstruction. In addition, radiologic evidence of tunnel widening does not seem to affect short- to medium-term clinical outcomes. **Level of Evidence:** Level II, systematic review of Level I and II studies.

There are currently many options available for femoral-sided graft fixation in anterior cruciate ligament (ACL) reconstruction. They can be divided into 2 main categories: intratunnel fixation (interference screw) and extratunnel fixation (cortical fixation devices or femoral loops).

Fixation of soft-tissue grafts is generally considered the weak point early in the postoperative course after ACL reconstruction.[1] Therefore many different devices have been developed for soft-tissue femoral fixation. Despite numerous options, a gold standard for femoral fixation has not yet been identified. Soft-tissue femoral

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fixation methods can be categorized as follows: compression, expansion, and suspension. Suspensory devices can be further subdivided as follows: cortical (metal plates with or without suture loops), cancellous, and corticocancellous.[2]

Several biomechanical studies of animal models comparing intratunnel and extratunnel femoral fixation devices have shown superior mechanical properties with extratunnel fixation.[2-5] More recent studies comparing different extratunnel fixation devices have shown that cortical button fixation devices provide adequate femoral fixation strength and high failure loads.[6,7] That being said, 2 recent studies comparing cortical and corticocancellous suspensory devices (cortical button and cross pin) showed no significant differences on load-to-failure or cyclical testing.[8,9]

Suspensory femoral fixation implants are popular and reliable and provide predictable femoral-sided fixation in ACL reconstruction. The purpose of this systematic review was to compare clinical results and functional outcomes after ACL reconstruction using cortical button fixation versus transfemoral suspensory fixation. The null hypothesis was that there would be no difference in outcomes between fixation options.

Methods

This systematic review was conducted according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines using a PRISMA checklist[10] (Fig 1). Systematic review registration was performed using the PROSPERO international prospective register of systematic reviews (registration CRD42013005359). Two reviewers independently conducted the search using the following databases: PubMed, Embase, and the Cochrane Central Register of Controlled Trials. The electronic search citation algorithm used was as follows: ((anterior cruciate ligament [Title/Abstract]) AND randomized [Title/Abstract]) AND (Endobutton [Title/Abstract]) OR transfemoral [Title/Abstract]) NOT AND (English [lang]). Limits applied to the search were randomized clinical trials, human species, and English language. There was no restriction on the date of publication. Only Level I and II prospective randomized controlled clinical trials comparing cortical button and transfemoral suspensory fixation in hamstring ACL reconstruction were included. Retrospective studies and biomechanical studies were excluded. Only published data in peer-reviewed journals were considered.

Studies enrolling patients with acute or chronic ACL rupture undergoing arthroscopic reconstruction with cortical button or transfemoral suspensory fixation were considered. Within the included studies, the inclusion criteria were as follows: patients aged 16 years or older with a diagnosis of unilateral ACL rupture on clinical examination and imaging who underwent ACL reconstruction with hamstring autograft. The exclusion criteria were previous knee surgery or serious knee injuries in the operative knee, advanced articular cartilage lesions, knee malalignment, and other concomitant ligamentous injuries requiring surgical treatment.

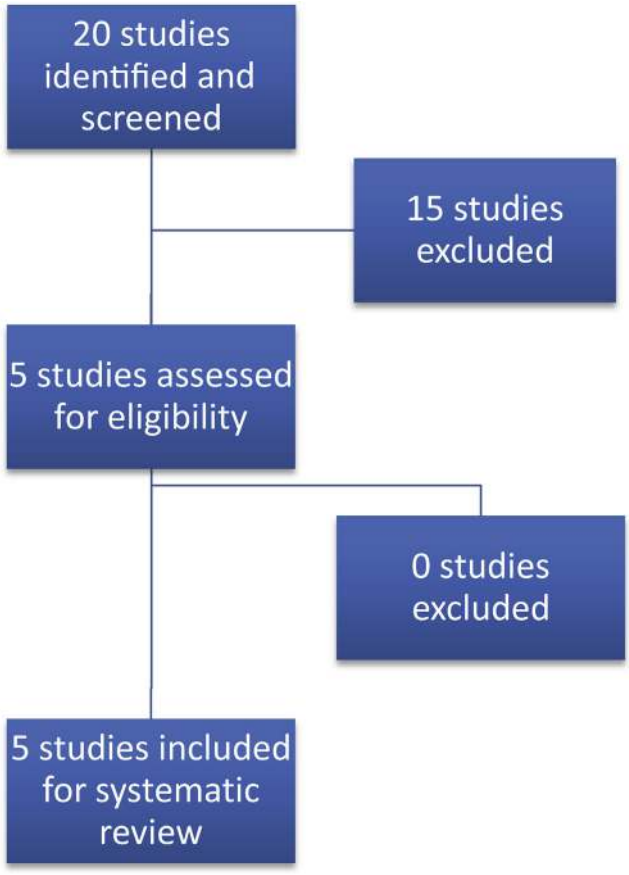

Fig 1. PRISMA flowchart.

All clinical and radiologic outcomes reported by each study were evaluated. Outcome measures included validated objective and subjective assessment scores such as the Lysholm score, Tegner activity score, and International Knee Documentation Committee (IKDC) score; clinical assessments such as Lachman testing, side-to-side difference using a knee laxity testing device (KT-1000; MEDmetric, San Diego, CA), and thigh atrophy; and imaging including radiography and computed tomography (CT) for femoral tunnel widening. Our primary outcome measures were postoperative IKDC and Lysholm knee scores.

Eligible trials for inclusion were independently selected by 2 authors and screened using the aforementioned predefined criteria. In cases of disagreement, a consensus was achieved through discussion. Titles of journals, names of authors, and supporting institutions were not masked at any stage. All references within included studies were cross-referenced for

inclusion if missed by the initial search. Data were then extracted from each included study. By use of RevMan software (version 5.2, The Cochrane Collaboration, Copenhagen, Denmark) data were combined to perform a meta-analysis when amenable. Incomplete data were excluded from meta-analysis.

The methodologic quality of included studies was assessed without masking by 2 review authors using The Cochrane Collaboration's risk-of-bias tool.[11] This tool incorporates assessment of randomization (sequence generation and allocation concealment), blinding (participants, personnel, and outcome assessors), completeness of outcomes data, selection of outcomes reported, and other sources of bias. According to this assessment, the risk of bias was categorized as low, unclear, or high for each of the included studies. Disagreements were resolved by consensus.

Statistical analysis of the data was performed using RevMan software.[10] Dichotomous data were reported as risk ratio (RR) and 95% confidence intervals (CIs). When possible, the outcomes were dichotomized into good and poor results. Heterogeneity was assessed using I^2 for each meta-analysis. An I^2 of less than 60% was the cutoff for homogeneity of the data, thus justifying pooling.

Results

The literature search resulted in 20 studies undergoing the initial screening process. Fifteen studies were excluded, leaving 5 studies for inclusion (Fig 1). After the full text was analyzed, all the selected studies were included in the review: 4 studies were Level I[12-15] and 1 study was Level II.[16] The 5 studies selected for inclusion comprised 317 patients. Baseline characteristics are reported in Table 1. The mean patient follow-up period ranged from 12 to 38 months, with participant age ranging from 16 to 48 years.

Surgical Technique

In all 5 studies, the ACL was reconstructed by an arthroscopically assisted technique.[12-16] Sabat et al.[16] used the anteromedial portal technique to create the femoral tunnel in the cortical button group whereas the transtibial technique was used in the transfemoral suspensory group. One study did not report the technique used to drill the femoral tunnel,[12] and the remaining 3 studies used the transtibial technique for all cases.[13-15]

IKDC Scores

A meta-analysis of postoperative IKDC scores was performed. All studies reported IKDC scores, but 1 study could not be included because only the mean difference between the preoperative and postoperative evaluation was reported.[16] From the remaining 4 studies, 256 patients were evaluated: 129 underwent surgical treatment with cortical button femoral graft fixation compared with 136 in whom a transfemoral device was used. The IKDC scores were dichotomized into good results (grade A plus grade B) and poor results (grade C plus grade D). There were no significant differences in good results (grade A plus grade B) between cortical button and transfemoral fixation (RR, 0.99; 95% CI, 0.93 to 1.04; $P = .63$). There was no heterogeneity ($I^2 = 0\%$, $\chi^2 = 2.98$, $df = 3$, $P = .39$) (Fig 2).

Table 1. Characteristics of Included Studies

Study	Level of Evidence	Cortical Button	Transfemoral	Sample Size	Mean Age (yr)	Length of Outcome (mo)	Outcome Measure
Fauno and Kaalund[12] (2005)	I	50	50	100	25 (cortical button) 26 (transfemoral)	12	IKDC KT-1000 Radiography
Kuskucu[13] (2008)	I	24	32	56	23.9 (21-44)	26.7 (16-36) (cortical button) 23.2 (12-36) (transfemoral)	IKDC Lysholm Tegner Thigh atrophy Telos stress device Radiography
Ibrahim et al.[14] (2009)	I	48	50	98	29 (25-38)	29 (25-38)	IKDC Lysholm Tegner Anterior drawer Lachman Pivot shift KT-1000
Price et al.[15] (2010)	I	13	16	29	26.5 (16-47) (cortical button) 26.3 (16-48) (transfemoral)	24	IKDC Lachman KT-1000
Sabat et al.[16] (2011)	II	17	17	34	Not reported	22 (19-32)	IKDC (subjective) Lysholm CT

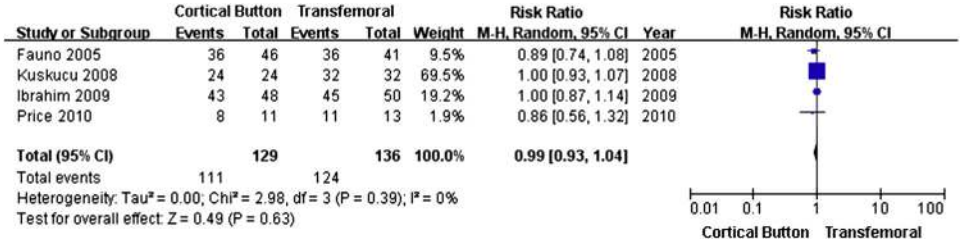

Fig 2. Forest plot of IKDC outcomes in included randomized controlled trials. There were no significant differences in good results (grade A plus grade B) between cortical button and transfemoral fixation. (M-H, Mantel-Haenszel.)

Lysholm Scores

Although postoperative Lysholm scores were reported in 3 studies,[13,14,16] only 2 studies could be included in the meta-analysis.[13,14] The study by Sabat et al.[16] could not be included in the meta-analysis because they reported only mean and range. One hundred fifty-four patients were evaluated: 72 underwent surgical treatment by cortical button fixation, and 82 were treated with the transfemoral device. The Lysholm score results were dichotomized into good results (excellent plus good) and poor results (fair plus poor). No statistically significant differences were seen in good results (excellent plus good) between cortical button and transfemoral fixation (RR, 0.98; 95% CI, 0.88 to 1.08; $P = .63$). Heterogeneity was moderate ($I^2 = 43\%$, $\chi^2 = 1.75$, $df = 1$, $P = .19$) (Fig 3).

Tegner Scores

No other meta-analyses could be performed because of the variability of outcomes reported in the studies. Kuskucu[13] and Ibrahim et al.[14] reported Tegner activity scores. Both studies showed improvement between preoperative and postoperative scores in both groups but did not find any significant difference between the cortical button and transfemoral fixation methods. A meta-analysis for Tegner activity score could not be performed because postoperative data were not clearly reported by Ibrahim et al.

Clinical Examination

Clinical laxity evaluations were reported in 3 studies.[12,14,15] Price et al.[15] assessed their patients by Lachman and KT-1000 testing. They specified side-to-side differences in anteroposterior (AP) laxity as measured in millimeters using 67 N, 89 N, 133 N, and manual maximum force at both 1 and 2 years postoperatively. They did not find any significant differences between groups. Fauno and Kaalund[12] only reported KT-1000 data, and they performed measurements at 30 lb of force. They dichotomized their results into 4 mm of translation or greater and 3 mm of translation or less and did not find any differences between groups. Ibrahim et al.[14] reported anterior drawer, Lachman, pivot-shift, and KT-1000 results measured at 20 lb. This study also did not find any differences between groups. Because the amount of force applied for KT-1000 assessment during laxity testing was not uniform in each study, a meta-analysis could not be performed for KT-1000 data. Another study used the Telos stress device (Telos, Marburg, Germany) to evaluate side-to-side differences but did not find any difference between the 2 groups.[13]

Tunnel Expansion

Three studies used imaging to assess tunnel widening. Two studies used standard radiographs,[12,13] and 1 study used CT scan.[16] Fauno and Kaalund[12] reported significant differences in the cortical button group between radiographs taken at 2 weeks postoperatively and those taken at the 1-year mark in the cortical button group for both the femoral ($P = .044$) and tibial ($P = .005$) tunnels. They only compared preoperative and postoperative results within each fixation group and did not compare results between the cortical button and transfemoral groups. Kuskucu[13] reported tunnel enlargement of 43.71% on the femoral side and 51.11% on the tibial side in the cortical button group compared with 32.71% on the femoral side and 25.62% on the tibial side in the transfemoral group at 1-year follow-up. Significant differences between groups were only observed in tibial tunnel enlargement ($P < .05$). Sabat et al.[16] assessed tunnel widening using

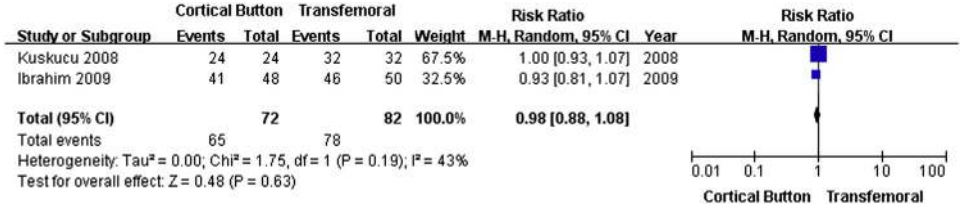

Fig 3. Forest plot of Lysholm scores in included randomized controlled trials. There were no significant differences in good results (excellent plus good) between cortical button and transfemoral fixation. (M-H, Mantel-Haenszel.)

CT scan and reported mean increases in diameter expressed as percentages at both 3 and 6 months postoperatively. At 6 months, femoral tunnel widening at both the aperture and midportion of the tunnel was significantly greater in the cortical button group.

Complications

Three studies reported complications.[13,15,16] The patients in the study by Kuskucu[13] did not have any intraoperative or postoperative complications. Price et al.[15] reported 1 intraoperative and 2 postoperative complications in the cortical button group and 4 intraoperative and 4 postoperative complications in the transfemoral group. All intraoperative complications were related to guidewire use. The postoperative complications were related to graft failures in 2 patients, both of whom were in the transfemoral group. Three patients had trouble with tibial graft fixation and 1 patient had lateral knee pain, which resolved with removal of the transfemoral implant. Ibrahim et al.[14] reported failure of meniscal repair in 2 patients but no complications related to ACL graft fixation were found. Sabat et al.[16] reported graft failure in 1 patient at 6 months.

Methodologic Quality Assessment

The results of the methodologic quality assessment of included studies using the Cochrane risk-of-bias tool are presented in Figure 4. Sequence generation and allocation were adequately reported by all studies except 1. Kuskucu[13] did not clearly explain how randomization or allocation was performed. Two studies did not specify whether patients and therapists were informed of fixation type.[12,13] Hence they were also judged to have an unclear risk of bias. Only 1 study was judged to be at low risk for detection bias because of blinding of the outcome assessor.[14] The remaining studies did not comment on blinding of the assessors. No studies reported significant loss of follow-up. The study by Fauno and Kaalund[12] only reported preoperative Lysholm scores and was consequently judged to be at high risk for incomplete outcome data and selective outcome reporting. The study by Kuskucu was judged to be at high risk for selection bias because it only included male patients who were all military personnel. In addition, this study had complete follow-up with favorable results and no complications. Two studies included power analysis data,[15,16] but Price et al.[15] did not achieve their calculated power because of a small sample size.

Discussion

The purpose of this systematic review was to identify, summarize, and pool evidence from randomized controlled trials comparing femoral fixation devices in ACL reconstruction. This review showed no significant differences in knee-specific outcome measures in patients treated with cortical button versus transfemoral suspensory fixation when undergoing ACL reconstruction. To our knowledge, this is the first meta-analysis that compares cortical button and transfemoral suspensory fixation for ACL reconstruction. There are 2 previous meta-analyses that compared intratunnel and extratunnel fixation.[1,17] Colvin et al.[17] only assessed 1 of the studies included in our review, whereas Han et al.[1] excluded cross-pin fixation because it represented a combination of both intratunnel and extratunnel soft-tissue graft fixation. Both studies reported comparable postoperative functional outcomes between intratunnel and extratunnel fixation at a minimum of 2 years' follow-up.

Biomechanical studies have shown superior mechanical properties using extratunnel fixation over intratunnel devices. Several studies have also compared different extratunnel fixation devices without showing

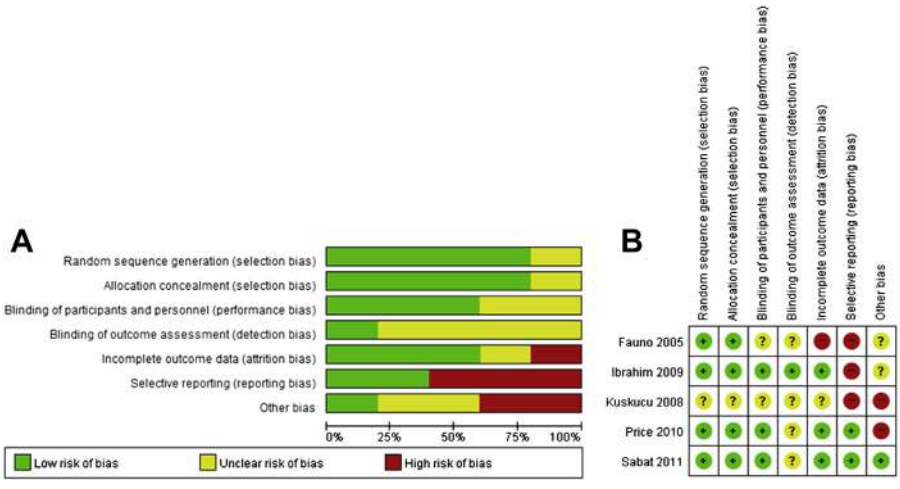

Fig 4. Risk-of-bias summary. (A) Risk of bias as percentage across all included studies (green, low risk; yellow, unclear; red, high risk). (B) Cross-sectional representation of risk of bias across all studies.

clinically relevant differences between them in terms of structural properties under load-to-failure or cyclic loading conditions.[6-9,18]

Clinical studies seem to suggest increased femoral tunnel widening in the cortical button group.[13,19,20] The exact cause of tunnel widening remains unclear, although most authors claim multifactorial biological and biomechanical causes. Biological factors may include immune response from allografts, toxic effects of ethylene oxide sterilization, cytokines (interleukins 1β, 6, and 8; bone morphogenetic protein; tumor necrosis factor α; and nitric oxide) in the synovial fluid affecting bone resorption, and bone necrosis from tunnel drilling.[21,22] Biomechanical causes include the bungee-cord effect[23] and windshield-wiper effect.[24,25] The bungee-cord effect refers to elastic longitudinal deformation of the graft created by increasing the distance between the location of fixation and the native ACL insertion. On the other hand, the windshield-wiper effect is described as sagittal intratunnel graft motion. Other potential causes of tunnel widening include aggressive rehabilitation and improper graft placement.[26] In the study by Asik et al.,[27] ACL reconstruction was performed using the transfemoral device on the femur in 271 patients. Ninety-five percent of patients showed less than 2 mm of side-to-side laxity on postoperative KT-1000 arthrometer testing. At 12 months' follow-up, Asik et al. found that tunnel widening measured 18% on the femoral side, and there was no progressive increase in this widening at final follow-up when compared with the 12-month follow-up measurements. More recently, Choi et al.[28] reported on outcomes after hamstring reconstruction using the bioabsorbable cross-pin device at a minimum of 2 years' follow-up in 50 patients. Follow-up magnetic resonance imaging scans showed that the bioabsorbable cross pin was broken in 11 patients and intact in 39. In the intact group, on the AP and lateral radiographs, there was an increase in femoral tunnel widening of 13.1% and 17.1%, respectively. Comparatively, in the broken group, the femoral tunnel widening was significantly greater ($P < .001$). However, the clinical outcomes measured by Lysholm and Tegner scores were not affected in either group.

Most published studies report that cortical button fixation results in greater tunnel widening when compared with other hamstring fixation devices. Buelow et al.[29] compared tunnel widening for intratunnel fixation using bioabsorbable interference screws versus cortical button fixation. They found that femoral tunnel widening was 76% and tibial tunnel widening was 45% at a minimum of 2 years' follow-up. Baumfeld et al.[19] compared tunnel widening between the cortical button and transfemoral suspensory devices using radiographs. In the cortical button group, a 15-mm loop was used in all patients. At 2 years' follow-up, patients in the cortical button group exhibited a significantly greater absolute change and greater percent change in femoral tunnel diameter compared with patients with double cross-pin fixation ($P \leq .05$). This difference was noted on both AP and lateral radiographs. Although these previous studies suggest long fixation distance as a cause of postoperative tunnel widening in the cortical button group, Choi et al.[22] recently showed that the cause of tunnel widening in the cortical button group may not be simply explained by a "long fixation distance" theory. They reported the outcomes of 171 consecutive patients after hamstring ACL reconstruction with cortical button femoral fixation. A 15-mm loop was used in 20 patients, a 20-mm loop in 53, a 25-mm loop in 58, and loop greater than 30 mm in 40. Two years after surgery, no significant differences in tunnel widening were present according to the length of the cortical button loop among the 4 groups.

The findings of our systematic review are in agreement with the current literature that suggests that cortical button femoral fixation is associated with radiographic femoral tunnel enlargement within 3 months after surgery. That being said, it appears that tunnel widening does not affect clinical results. At short-term follow-up, there were no significant differences in functional outcomes in patients treated with either cortical button or transfemoral ACL graft fixation. Future randomized controlled trials with long-term follow-up are required, and outcome measures should be reported uniformly. Such studies should include measures that assess disease-specific quality of life (Lysholm score), generic knee function (IKDC score), anterior laxity (KT-1000), tunnel widening (CT scans or plain radiographs), rate of failure, and complications.

The strengths of this systematic review lie in our inclusion of only Level I and II randomized controlled trials, thus minimizing bias that may be present in prospective cohort and retrospective studies. Furthermore, the groups were homogeneous regarding baseline patient characteristics such as age, unilateral ACL injury, normal contralateral knee, and absence of degenerative changes or severe concomitant ligament injuries on the affected side.

Limitations

There are some limitations of this study. The variability in reporting of results across studies limited the number of outcome measures that were amenable to meta-analysis. For example, assessments of side-to-side differences in knee laxity were performed using the KT-1000 arthrometer in 3 of 5 studies.[12,14,15] However, the studies were not uniform in the amount of anterior force applied when measuring tibial translation, and the information was not reported in a standard fashion among studies. Tunnel widening could not be compared

for similar reasons. Among the studies, radiography and CT reporting varied and specific information regarding measurement technique was not provided. The length of follow-up (ranging from 12 to 38 months) was relatively short, with follow-up averaging 2 years or less in 3 of the 5 studies.[12,15,16] Long-term follow-up is required to validate the reported findings. In 4 of the 5 studies,[12,13,15,16] it was unclear whether individuals assessing patient outcomes were blinded. Furthermore, tibial fixation varied across studies. One study used a bicortical screw and washer,[12] and 3 studies used bioabsorbable interference screws.[14-16] One study did not specify the type of interference screw that was used and supplemented the fixation with a staple.[13] In addition, differences in parameters such as postoperative rehabilitation protocol, duration of postoperative bracing, weight-bearing status, range of motion, and return to activity among the 5 studies could affect the study outcomes.

Conclusions

The current evidence suggests that there are no statistically significant differences in knee-specific outcome measures in patients treated with cortical button versus single cross-pin transfemoral suspensory femoral tunnel fixation when undergoing ACL reconstruction.

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