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SYMPOSIUM: CONTROVERSIES IN ORTHOPAEDICS

What Is the Best Femoral Fixation of Hamstring Autografts in Anterior Cruciate Ligament Reconstruction?

A Meta-analysis

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Abstract

Background Several methods are available for fixing the femoral side of a hamstring autograft in ACL reconstruction and the best method is unclear. Biomechanical studies have shown varying results with regard to fixation failure.

Questions/purposes We asked whether there were any differences with regard to graft failures and functional outcome measures with differing methods of femoral fixation of hamstring autografts in ACL reconstruction.

Methods We systematically reviewed the literature using PubMed, MEDLINE, Scopus, and Cochrane Controlled Trial Register databases with regard to interference screw fixation (aperture fixation) versus noninterference screw fixation (fixation away from the joint line). A meta-analysis was performed of those studies reporting on surgical failures and postoperative International Knee Documentation Committee score. Eight studies met our inclusion criteria of Level I or II evidence.

Results Use of interference screws for femoral fixation resulted in a trend toward decreased risk of surgical failure (relative risk = 0.57; confidence interval, 0.1678–1.0918). When only Level I trials were evaluated, the same trend was noted toward a decreased risk of surgical failures using femoral interference screws (relative risk = 0.52; confidence interval, 0.1794–1.3122). There was no difference in postoperative International Knee Documentation Committee score with Level I and II studies (relative risk = 0.9940; confidence interval, 0.6230–1.5860) or only Level I studies (relative risk = 1.0380; confidence interval, 0.6381–1.6886).

Conclusions The literature suggests a trend toward decreased surgical failures with femoral fixation at the joint line with an interference screw. However, there is no difference when postoperative functional outcomes are compared. Future studies are needed with standardized fixation methods and outcomes assessment to determine the importance of femoral fixation.

Each author certifies that he or she has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.
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Introduction

There is currently no gold standard for the fixation of soft tissue grafts for ACL reconstruction. A major cause for concern with the use of hamstring autografts is the soft tissue can take up to 12 weeks to heal to the osseous tunnel [17, 30]. The rate of failure of hamstring autografts has been reported to range from 4% [23] to 27.3% [3]. However, this percentage may be underreported as the exact number of failed ACL reconstructions is difficult to calculate [18]. Thus, a secure fixation technique is needed to withstand the forces on the graft resulting from current rehabilitation protocols that allow for unrestricted ROM, weightbearing, and early return to athletic activity after ACL reconstruction

[4, 17]. Current techniques include suspensory fixation [17], joint line fixation with interference screws [24], and transfemoral fixation with crosspins [8].

Several mechanical studies compare these three methods of soft tissue fixation with varying results. Milano et al. [26] found corticocancellous fixation was superior to two 2.7-mm crosspins and interference screws in terms of fixation strength and stiffness and amount of graft elongation. The authors attributed the poorer performance of the interference screws to the lack of cortical purchase [26]. Ahmad et al. [1] also found greater graft slippage with two 2.7-mm crosspins and interference screws when compared with suspensory fixation or one 5-mm crosspin. The interference screw had a lower load to failure than suspensory fixation and both the one 5-mm crosspin and the two 2.7-mm crosspins [1]. Failures were attributed to weakness of the graft-screw interface [1]. However, suspensory fixation also has its potential downsides. A "bungee effect" may result whereby the graft moves longitudinally within the tunnel [12]. Hoher et al. [17] observed up to 3 mm of hamstring graft motion in the tunnel with loading in a cadaver model. They hypothesized early stress on the graft with rehabilitation activities could cause large graft-tunnel motion. Sagittal graft motion, known as the windshield wiper effect, can also occur [12]. Furthermore, under cyclic loading, suspensory fixation, two 2.7-mm crosspins, and interference screws allow for similar amounts of displacement of the graft [19]. Thus, there is no clear biomechanical advantage to one method of fixation versus another. It is also unknown whether these biomechanical differences result in fewer surgical failures and/or improved functional outcome scores. Strong fixation of the graft is necessary for using current rehabilitation protocols, which allow for early weightbearing, full ROM, and return of neuromuscular function [4].

The purpose of our study was twofold: (1) to determine whether there is a difference in the number of surgical failures with joint line fixation using interference screws versus noninterference screw fixation of hamstring autografts in ACL reconstruction and (2) to investigate whether there is any difference in functional outcomes with these fixation methods as measured by the International Knee Documentation Committee (IKDC) score.

Search Strategy and Criteria

A meta-analysis was performed in accordance with the Cochrane and QUORUM guidelines. A literature search was performed to identify studies comparing femoral interference screw fixation of soft tissue grafts with alternate forms of femoral fixation using PubMed, MEDLINE, Scopus, and Cochrane Controlled Trial Register databases. Search terms were "endobutton" AND "hamstring OR semitendinosus OR gracilis," "suspensory femoral fixation" AND "hamstring OR semitendinosus OR gracilis," "transfixation" AND "hamstring OR semitendinosus OR gracilis," "cross pin" OR "cross pins" AND "hamstring OR semitendinosus OR gracilis," "interference screw" AND "hamstring OR semitendinosus OR gracilis." Inclusion criteria were prospective, randomized controlled or prospective studies (Levels I and II) written in English reporting comparisons of joint line fixation using interference screws with noninterference screw fixation of hamstring autografts and reporting outcomes of surgical failure or IKDC score. Exclusion criteria included biomechanical studies, retrospective reviews, and case series. Retrospective reviews were excluded because they are Level III evidence and biomechanical studies were excluded because they are performed on cadavers.

There were 1058 initial studies identified (Fig. 1). A total of 1033 of these studies were excluded, leaving 12 potentially relevant studies. The eliminated studies were removed after abstract review by two of the authors (AC, CS). Four of these studies were eliminated due to use of fixation methods not relevant to our comparison groups. Eight studies met our selection criteria. Six of these studies were prospective, randomized controlled trials [6, 11, 15, 16, 19, 29] and two studies were prospective nonrandomized trials [5, 22]. The fixation methods addressed in these studies included the suspensory fixation (EndoButton®; Smith and Nephew Inc, Andover, MA), corticocancellous fixation (TransFix® or Bio-TransFix®; Arthrex Inc, Naples, FL), RigidFix® (DePuy Mitek Inc, Raynham, MA), and metal or biointerference screw. Outcome measures uniformly reported in the studies were number of surgical failures and postoperative IKDC score.

Study quality was judged independently by three authors (AC, CS, MP): appropriateness of patient selection for ACL reconstruction, length of followup, and number of surgical failures.

Eight studies met our criteria (Appendix 1), six of which were prospective, randomized studies. Cochran's Q statistic was calculated to evaluate the heterogeneity of effect across studies. The lack of heterogeneity of the studies in terms of the estimate was reflected in a $Q = 0.6$, $p = 0.96$.

There was great variability in the clinical parameters assessed among the different studies. The majority of studies included used number of surgical failures and/or postoperative IKDC rating and were thus used for this study. The postoperative IKDC scores were either a numeric value or a categorical value (A, B, C, D).

Studies were not included in the analysis if they did not report on either number of surgical failures or postoperative IKDC score. The IKDC score was grouped into A and B versus C and D.

The relative risks of surgical failure and poor IKDC score were pooled across studies using both a fixed-effects analysis and a random-effects analysis using the method of DerSimonian and Laird [9] to account for heterogeneity of effects across studies. Heterogeneity across studies was measured by Cochran's Q statistic. Statistical analysis was performed using the R package (www.r-project.org).

Results

Seven of the eight studies included surgical failure as an outcome. Five of the seven studies were randomized. Cochran's Q statistic ($Q = 0.6$, $p = 0.96$) indicated a lack of heterogeneity in the reported relative risks across studies. An analysis of all seven studies indicated a trend toward decreased risk of surgical failure using an interference screw for femoral fixation (relative risk [RR] = 0.57; confidence interval [CI], 0.1678–1.0918; $p = 0.0757$) (Fig. 2). The wide CI is largely the result of the small number of patients and the small number of reported failures across all of the studies, which also reduces power to detect a difference. When only randomized trials were evaluated, the same trend was noted toward a decreased risk of surgical failures with use of a femoral interference screw (RR = 0.52; CI, 0.1794–1.3122; $p = 0.1542$) (Fig. 3).

As for the surgical failure outcome, no study heterogeneity was evident ($Q = 4.47$, $p = 0.48$). When all prospective studies were analyzed, there was no difference in postoperative outcome IKDC score (RR = 0.9940; CI, 0.6230–1.5860; $p = 0.9799$) (Fig. 4). When only randomized studies were analyzed, there was also no difference in postoperative outcome IKDC score (RR = 1.0380; CI, 0.6381–1.6886; $p = 0.8806$) (Fig. 5).

Discussion

Femoral fixation of hamstring grafts in ACL reconstruction is controversial. We sought to answer two questions. First, is there a difference in the number of surgical failures with aperture fixation versus fixation methods that are away from the joint line? Second, is there a difference in functional outcome, as measured by the IKDC score, between the different fixation methods?

There were a number of limitations of this meta-analysis and the literature. First is the small number of studies. Second is the small number of patients in the studies (ranging from 15 [6, 22] per group to 46 [11] per group). Third is the length of followup (ranging from 12 [11] to 35 [22] months) for studies comparing interference screw fixation with other methods of femoral soft tissue fixation. Fourth, inconsistencies across the studies in terms of reported results also limited what information could actually be analyzed. Specifically, we could not compare pre- and postoperative laxity on physical examination and instrumented testing or preoperative IKDC scores because this information was not reported in a standard way. The ability to compare results among different studies is also

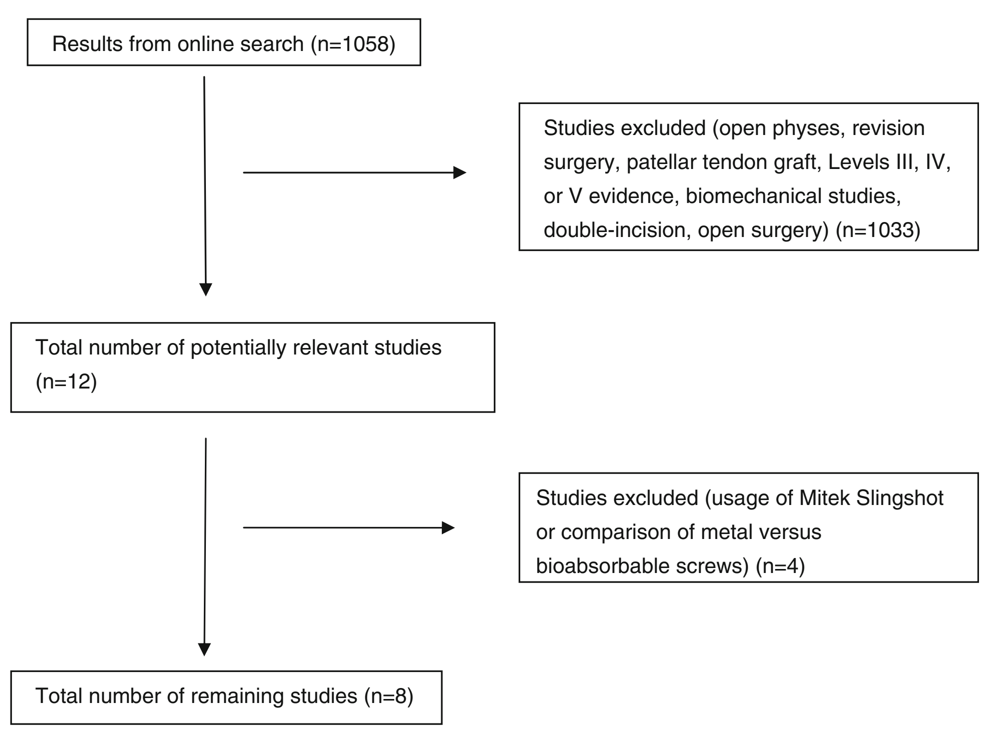

Fig. 1 A flowchart illustrates the selection process. Eight studies met the inclusion criteria from the 1058 studies initially identified.

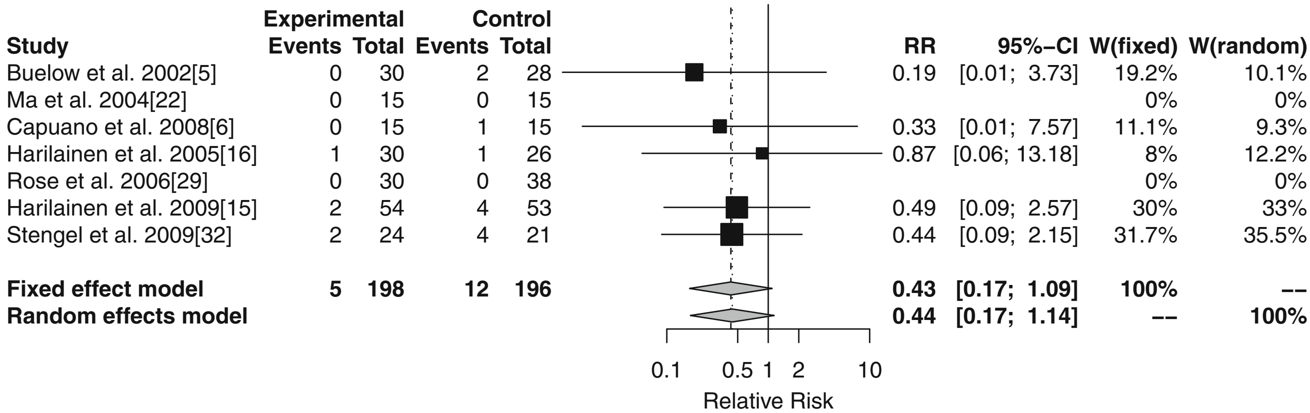

Fig. 2 There is a trend toward decreased risk of surgical failure with use of an interference screw for femoral fixation when analyzing prospective studies.

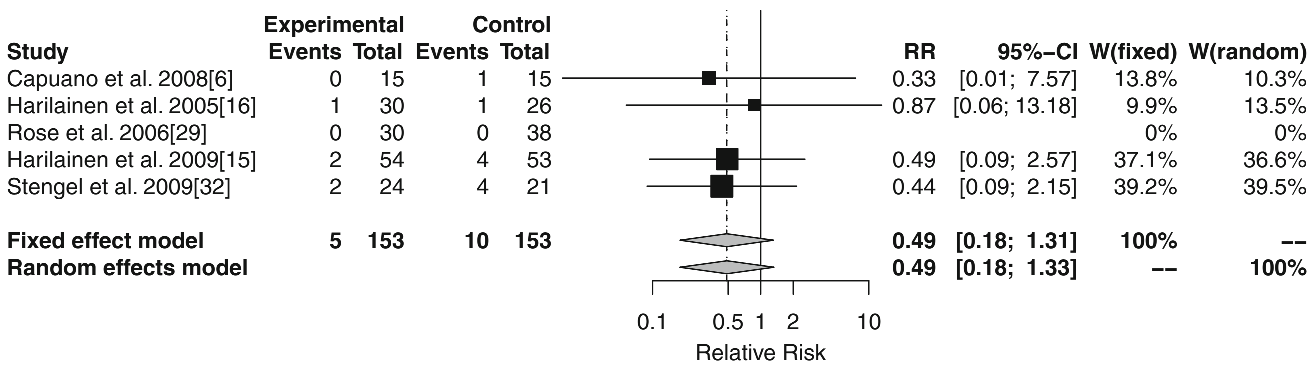

Fig. 3 There is a trend toward decreased risk of surgical failure with use of an interference screw for femoral fixation when analyzing only randomized, prospective studies.

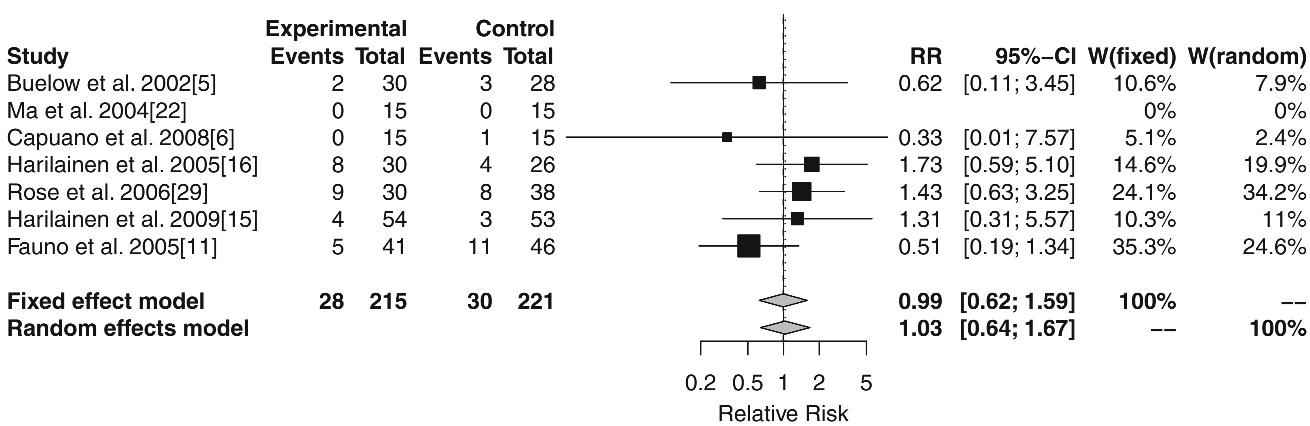

Fig. 4 Analysis of prospective studies demonstrated no difference in postoperative IKDC scores.

limited by inconsistent reporting of outcome measures used. Finally, there was variability among the studies with regard to type of tibial fixation. Tibial-sided biointerference screw fixation is reportedly associated with an ultimate failure strength greater than what the native ACL is subjected to during most activities of daily living [25]. However, graft failure can occur via graft slippage with use of the screw [25]. The use of a screw and washer for tibial fixation can lead to increased graft-tunnel motion, which can be prevented by ensuring a snug fit between the graft

Study	Experimental Events	Experimental Total	Control Events	Control Total	RR	95%–CI	W(fixed)	W(random)
Capuano et al. 2008[6]	0	15	1	15	0.33	[0.01; 7.57]	5.7%	2.7%
Harilainen et al. 2005[16]	8	30	4	26	1.73	[0.59; 5.10]	16.3%	21.7%
Rose et al. 2006[29]	9	30	8	38	1.43	[0.63; 3.25]	26.9%	36.7%
Harilainen et al. 2009[15]	4	54	3	53	1.31	[0.31; 5.57]	11.5%	12.2%
Fauno et al. 2005[11]	5	41	11	46	0.51	[0.19; 1.34]	39.5%	26.8%
Fixed effect model	**26**	**170**	**27**	**178**	**1.04**	**[0.64; 1.69]**	**100%**	**--**
Random effects model					**1.08**	**[0.65; 1.79]**	**--**	**100%**

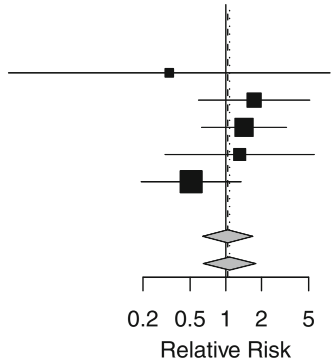

Fig. 5 Analysis of randomized, prospective studies demonstrated no difference in postoperative IKDC scores.

and the tibial tunnel [13]. The use of a washer to compress the graft will also increase stiffness of the construct [14]. Monaco et al. [27] have highlighted failure of the graft after ACL reconstruction may be dependent on the combination of femoral and tibial fixation used rather than on either fixation alone. For instance, if the tibial fixation is stronger than the femoral fixation, the femoral fixation may actually become the weak point in the construct [27]. Thus, there are still many issues to be resolved regarding the best method of soft tissue graft fixation.

One potential reason for fewer failures with interference screw fixation may be the result of its position closer to the joint line than the other fixation methods. In a rabbit model, increased motion at the aperture results in a delay in graft-tunnel healing [28]. Femoral fixation away from the joint line results in femoral tunnel expansion with the use of hamstring grafts [21]. Although the natural history of tunnel expansion is currently unknown, extensive expansion complicates future revision surgery [4]. Interestingly, Chhabra et al. [7] compared their results with the medial portal versus the transtibial technique for drilling the femoral tunnel and found a lower amount of femoral tunnel expansion with the medial portal technique. Post fixation was used in all cases. The lower femoral tunnel expansion may reflect the ability to get a more anatomic placement of the femoral insertion site with the medial portal technique. Thus, placement of the graft may be more important than what is used for fixation when trying to prevent tunnel widening. Anatomic placement of tunnels, in addition to aperture fixation, for both the femoral and tibial sites may help to decrease the number of surgical failures. A more anatomic reconstruction may also result in improved knee kinematics and healing [10].

We did not find femoral fixation influenced postoperative IKDC score. Other variables that have demonstrated no correlation to the IKDC score include the technique used to drill the femoral tunnel (transtibial versus anteromedial) with bone-patellar tendon-bone autograft [2] and the use of a single- or double-bundle ACL reconstruction [31]. IKDC score after ACL reconstruction is negatively influenced by obesity, smoking, and severe chondrosis at the time of surgery [20].

Our results suggest there is a trend toward fewer reported surgical failures with the use of an interference screw for femoral fixation of hamstring autografts. However, functional outcome, as measured by postoperative IKDC score, does not differ with method of femoral fixation.

Appendix 1

Description of the Eight Studies Meeting Our Inclusion Criteria

Buelow et al. [5] performed a prospective nonrandomized trial comparing femoral fixation with a bioabsorbable interference screw (Arthrex, Karlsfeld, Germany) with an EndoButton® (Smith and Nephew Inc, Andover, MA). In the interference screw group, tibial fixation was accomplished with two bioabsorbable interferences screws, one placed anteriorly to the graft at the joint line and one placed posterior to the graft at the cortical opening. In the EndoButton® group, the graft was secured with a suture washer on the tibial side. There were 30 patients in each arm. Outcome measures used at 2 years' followup were radiographs, International Knee Documentation Committee (IKDC) score, Cincinnati Knee Score, and KT-1000™ (MEDmetric Corp, San Diego, CA) measurements. The results demonstrated ACL reconstruction with a doubled semitendinosus and gracilis tendon graft is associated with femoral and tibial tunnel enlargement. The authors found considerably more tunnel widening in the grafts fixed with extracortical fixation. However, there was no correlation between tunnel enlargement and clinical scores or laxity measurements.

Capuano et al. [6] performed a pilot randomized controlled trial in 30 patients comparing the clinical differences between femoral fixation of a hamstring autograft using either a biointerference screw (Arthrex Inc, Naples, FL) or the Bio-TransFix® (Arthrex). Tibial fixation was achieved with an interference screw in both arms. Minimum followup was 8 months (average, 13 months; range, 8–16 months). Outcomes were measured by change in side-to-side laxity and change in IKDC score. This preliminary study demonstrated comparable mechanical stability and clinical outcomes between the two arms at 13 months' followup.

Fauno and Kaalund [11] performed a prospective randomized study comparing femoral fixation of a hamstring autograft using the TransFix® (Arthrex) or the EndoButton®. Tibial fixation was achieved with an interference screw in the TransFix® arm and with a bicortical screw and spiked washer in the EndoButton® arm. Tunnel widening, measured on standardized radiographs, and clinical outcomes, including KT-1000™ data, IKDC ratings, and Lysholm score, were assessed. One hundred patients were randomized and 87 patients were assessed at 1-year followup. Considerably more tunnel widening was found in the group in which fixation was away from the joint line in both the femur and the tibia (EndoButton® and screw and washer). However, there was no correlation between tunnel widening and clinical outcome.

Harilainen et al. [16] performed a randomized control trial investigating femoral fixation with the TransFix® as compared with a metal interference screw (Linvatec, Largo, FL). Tibial fixation in the TransFix® group was performed with an AO screw with a spiked washer post (AO, Bern, Switzerland) and metal interference screw in the femoral interference screw group. Sixty-two patients were followed for 2 years. Patients were evaluated on CA 4000 laxity (OSI, Hayward, CA), isokinetic muscle torque (Lido MultiJoint II; Loredon Biomedical Inc, West Sacramento, CA), Tegner activity level, and IKDC, Lysholm knee, and Kujala patellofemoral scores. There were no major clinical differences observed between the two treatment arms at 1- and 2-year followup.

Harilainen and Sandelin [15] also conducted a randomized control trial comparing four different combinations of femoral and tibial fixation. There were 120 patients randomized into four groups of 30: femoral RigidFix® (DePuy Mitek Inc, Raynham, MA) and tibial IntraFix® (DePuy Mitek), femoral RigidFix® and tibial BioScrew® (Linvatec), femoral BioScrew® and tibial IntraFix®, or femoral and tibial BioScrew®. Clinical parameters analyzed included Lachman, pivot shift, and KT-2000™ (MEDmetric) testing, isokinetic peak muscle torques, and Tegner activity, Lysholm, and IKDC scores. There were no statistically or clinically relevant differences among the four groups at the 2-year followup.

Ma et al. [22] performed a prospective nonrandomized study comparing aperture fixation with bioabsorbable interference screws (Linvatec) in both femoral and tibial tunnels versus distant fixation using the EndoButton® for femoral fixation and a screw-post for tibial fixation. There were 15 patients in each arm with a minimum 2-year followup (mean, 35 months). Followup evaluation included arthrometer measurements, radiographs and MRI, and IKDC score. There was more femoral tunnel widening in the sagittal plane in the EndoButton® group; otherwise, there were no differences between the two groups. Furthermore, there were no major differences in clinical outcomes at 24 to 40 months.

Rose et al. [29] performed a prospective randomized study comparing femoral fixation using the TransFix® versus a bioabsorbable interference screw (Arthrex). There were a total of 76 patients with final followup at 12 months. Outcomes measured included ROM, Lachman and pivot shift testing, laxity as assessed with a Rolimeter™ (Aircast, Summit, NJ), and IKDC, Lysholm, and Tegner activity scores. There were no differences in the outcome measures between the two groups.

Stengel et al. [32] performed a randomized control trial comparing RigidFix® pins (DePuy Mitek, Norderstedt, Germany) versus Biocryl® (DePuy Mitek) interference screws for femoral fixation. There were a total of 54 patients followed for 2 years. Patients were assessed using the KT-1000™, the SF-36, and the IKDC scores. No major differences were observed between the two groups. One serious procedure-specific adverse event involving a pin dislocation occurred.

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