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Review

No difference in outcomes between femoral fixation methods with hamstring autograft in anterior cruciate ligament reconstruction – A network meta-analysis☆

Eoghan T. Hurley, MB, BCh [a,b,*], Arianna L. Gianakos, DO [a,c], Utkarsh Anil, BSc [a], Eric J. Strauss, MD [a], Guillem Gonzalez-Lomas, MD [a,c]

[a] Department of Orthopaedic Surgery, New York University Langone Health, NY, New York, United States of America
[b] Department of Trauma & Orthopaedic Surgery, Royal College of Surgeons in Ireland, Dublin, Ireland
[c] Department of Orthopaedic Surgery, RWJ Barnabas Health - Jersey City Medical Center, Jersey City, New Jersey

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ABSTRACT

Background: There is mixed opinion regarding the optimal femoral fixation method for hamstring tendon autograft in anterior cruciate ligament (ACL) reconstruction. Currently, no study exists showing a superior method of femoral fixation, and thus the topic has remained controversial. The purpose of this study is to network meta-analyze the randomized control trials comparing cortical-button (CB), cross-pin (CP) and interference screws (IS) for femoral fixation with hamstring tendon autograft in ACL reconstruction.
Methods: The literature review was conducted in accordance with the PRISMA guidelines. Randomized control trials comparing CB, CP and IS were included. Clinical outcomes were compared using a frequentist approach to network meta-analysis, with all statistical analysis performed using R, with a p-value <0.05 being considered statistically significant.
Results: There were 11 studies included comparing; 194 patients with CB to 201 patients with CP (6 studies), 48 patients with CB to 50 patients with IS (1 study), and 172 patients with CP to 162 patients with IS (5 studies). One study compared all three groups, including 48 patients with CB, 50 patients with IS, and 52 with CP. There was a mean follow-up time of 26.4 months. No statistically significant difference was found between the fixation methods when evaluating knee stability, functional outcomes, graft failures, or revision procedures.
Conclusion: Using a network meta-analysis, our study found that, there was no difference in failure rate, knee stability, functional outcomes or incidence of revision procedures between CB, CP or IS femoral fixation techniques of hamstring tendon autografts in ACL reconstruction.
Level of evidence: Level I, network meta-analysis of Level I studies.

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* Corresponding author at: Royal College of Surgeons in Ireland, Department of Trauma & Orthopaedic Surgery, 123 St. Stephens Green, Dublin 2, Ireland.
E-mail address: eoghanhurley@rcsi.ie. (E.T. Hurley).

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Contents

1. Introduction

Hamstring tendon autograft (HT) is one of the most commonly utilized graft choices for anterior cruciate ligament (ACL) reconstruction in the United States [1]. HT has the primary advantage of reduced donor site morbidity when compared to bone-patellar tendon autograft (BPTB), with several studies demonstrating a reduced risk of the development of future osteoarthritis [2]. A cause of concern with utilizing HT is that the soft tissue can take up to 12 weeks to heal within the osseous tunnel [3]. Therefore, secure fixation is necessary to withstand the forces on the graft resulting from post-operative rehabilitation, early weight-bearing, increased range of motion, and return of neuromuscular function in order to maintain knee stability and improve overall functional outcomes [4]. The optimal HT reconstruction fixation method remains controversial within the sports medicine literature. Fixation techniques include three main devices: suspensory fixation with cortical-buttons (CB), transfemoral fixation with cross-pins (CP), and tunnel aperture fixation with interference screws (IS) [5].

Although the choice of femoral fixation is typically based on surgeon preference, studies have shown that tunnel aperture fixation is the most commonly utilized method of femoral fixation [6]. Biomechanical studies have found mixed results with the various fixation methods [4,7–11]. While several meta-analyses and systematic reviews exist comparing femoral fixation methods of HT in ACL reconstruction, consensus on which method is superior has yet to be established [12–14]. To date, there has been no network meta-analysis comparing the clinical outcomes of CB to CP to IS femoral fixation with HT in ACL reconstruction. A network meta-analysis differs from a standard meta-analysis in that it allows for comparisons of more than two groups using direct and indirect comparisons, and then provides subsequent ranking of the groups. When more than two treatment options exist, network meta-analysis generates a more comprehensive evaluation of the variables being studied and, as a result, has been of recent interest to surgeons [15,16].

The purpose of the current study is to network meta-analyze the randomized control trials comparing various femoral fixation methods with HT in ACL reconstruction to determine whether there is a difference in surgical failures or functional outcomes. Our hypothesis is that there will be no difference in re-rupture rate, knee stability or functional outcomes between the fixation methods.

2. Methods

2.1. Study Selection

Two independent reviewers performed the literature search based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and reviewed the search results, with a third author arbitrating in the event of a disagreement [17]. The title and abstract were reviewed for all search results and potentially eligible studies received a full text review. In addition, the reference lists of all included studies and all literature reviews found in the search results were manually screened for additional articles that met the inclusion criteria.

2.2. Search Strategy

The following search terms were used in MEDLINE, EMBASE and The Cochrane Library databases on November 13th 2017 from their inception, with the search algorithm: (cross pin OR crosspin OR cross pins OR crosspins OR cross-pins OR cross-pin OR rigidfix OR rigid fix OR rigid-fix OR transfix OR trans fix OR trans-fix OR pinn-acl OR bilok ST OR bilok OR slingshot OR sling shot OR interference screw OR interference-screw OR bioscrew OR bio screw OR metallic screw OR metallic-screw OR screw OR endobutton or extracortical fixation or suspensory fixation or ent or loop button) AND (acl OR anterior cruciate ligament) AND (hamstring tendon OR hamstring autograft OR hamstring tendon autograft). No time limit was given to publication date.

2.3. Eligibility Criteria

The inclusion criteria were: 1) randomized control trials comparing a) CB & CP, b) CB & IS, or c) CP & IS, 2) hamstring autograft, 3) clinical outcomes reported, 4) published in a peer reviewed journal, 5) published in English, and 6) full text of studies available. The exclusion criteria were: 1) non-randomized cohort studies, 2) case series, 3) review studies, 4) cadaver studies, 5) biomechanical studies, 6) radiological studies, or 7) abstract only.

2.4. Data Extraction

All relevant information regarding the study were collected by two independent reviewers using a predetermined data sheet. When required information was not available in the text, the authors were contacted. The risk of bias of the included randomized studies was assessed using the Cochrane Collaboration risk of bias tool [18]. Studies were considered as low risk of bias when on every single item of bias 'low risk' was scored. Studies were considered as moderate risk of bias when 'high risk' or 'unsure risk' on one or two items of bias was scored. Studies were considered as high risk of bias when more than two 'high risk' or 'unsure risk' were scored.

2.5. Data Analysis & Statistics

Outcomes analyzed were graft failure, anterior laxity >3 mm using a KT Arthrometer, anterior laxity >5 mm using a KT Arthrometer, positive Lachmann test, positive pivot shift test, International Knee Documentation Committee (IKDC) score Grade A or B, Lysholm score, and additional procedures.

All statistical analyses were performed using R (R Foundation for Statistical Computing, Vienna, Austria). As standard meta-analysis can only use information about treatments that are directly compared, a frequentist approach to network meta-analysis with a random effects model was performed using the *netmeta* package version 0.9–6 in R [19]. For continuous outcomes such as Lysholm score, the relative effect sizes were reported as standardized mean differences (MD). For binary outcomes as graft failure, the relative effect sizes were reported as odds ratios (OR). Both sets of effect sizes were reported with 95% confidence intervals (95% CI). To rank the treatments, we used the frequentist analogue to the surface under the cumulative ranking (SUCRA) probabilities called the P-score [20,21].

3. Results

3.1. Literature Search

The initial literature search resulted in 838 total studies, which were screened for inclusion/exclusion criteria and full texts were assessed for eligibility. Eleven randomized control trials with 779 patients were included in this review (Figure 1).

3.2. Study Characteristics

There were 11 studies included comparing: 194 patients with CB to 201 patients with CP (6 studies), 48 patients with CB to 50 patients with IS (1 study), and 172 patients with CP to 162 patients with IS (5 studies). One study compared all three groups, including 48 patients with CB, 50 patients with IS, and 52 with CP. There was a mean follow-up time of 26.4 months [22–32]. The overall risk of bias was 3 high risk of bias, 3 low risk of bias, and 5 moderate risk of bias. The study characteristics are reported in Table 1.

3.3. Surgical Technical Factors

All but one of the included studies used a single-bundle semitendinosus/gracilis autograft either doubled or quadrupled, and Ibrahim et al. used a double-bundle semintendinosus/ gracilis atuograft [28]. The drilling technique was reported in 7 studies, most commonly via a transtibial approach. There was a variety of tibial fixation methods, although the majority of studies reported using an IS in the tibial tunnel. There was no difference in any study between the reported rehabilitation techniques of the different groups. The surgical technical factors are reported in Table 2.

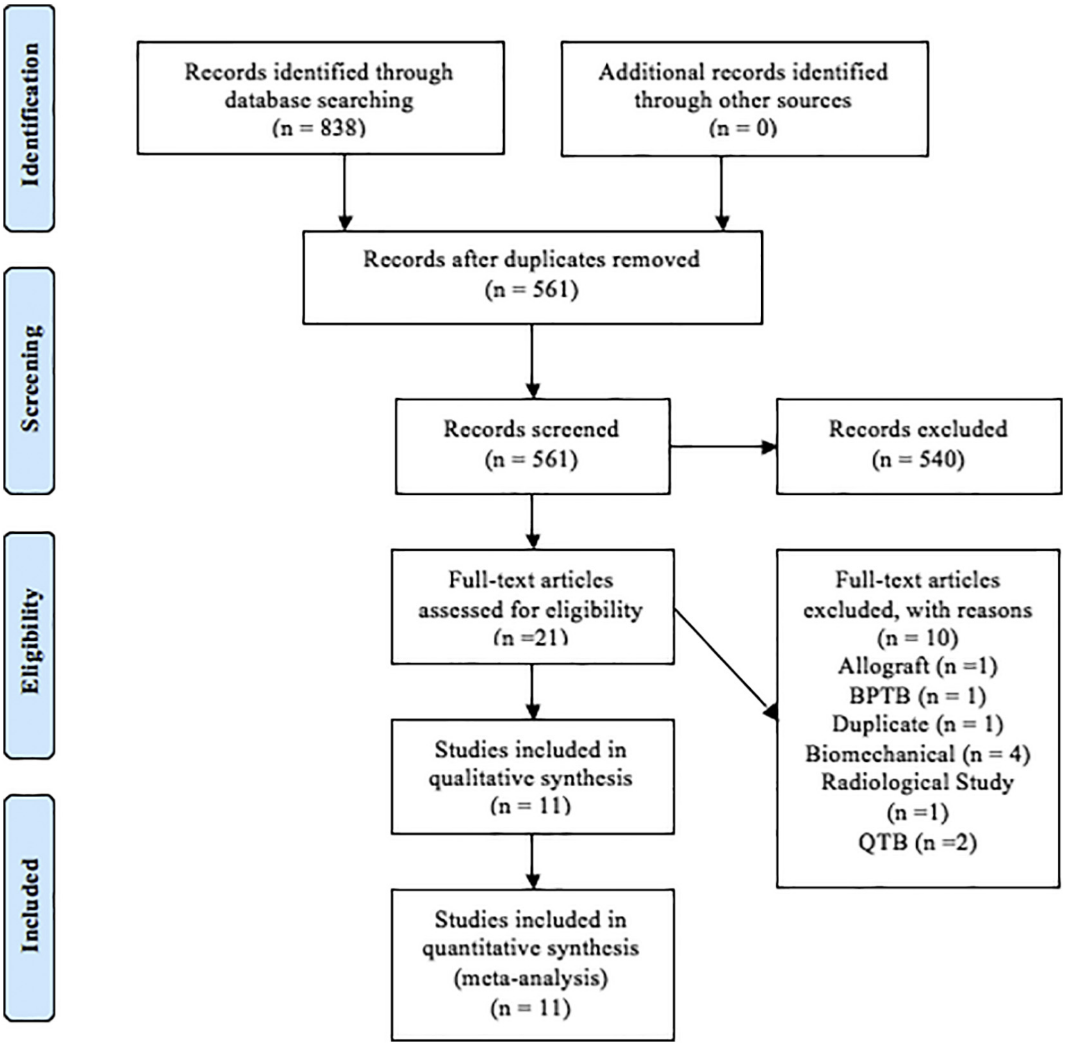

Figure 1. PRISMA Study Selection Flow Diagram.

Table 1
Study Characteristics.

Author	LOE	Design	Risk of Bias	N		Follow-up (mo.)	Country
Cortical Button versus Crosspin							
				CB	CP		
Eajazi et al. 2013 [24]	II	RCT	High	33	29	24	Iran
Fauno and Kaalund 2005 [25]	I	RCT	Moderate	46	41	12	Denmark
Ibrahim et al. 2009 [27]	I	RCT	Moderate	48	52	29	Kuwait
Ibrahim et al. 2015 [28]	II	RCT	Moderate	32	34	30	Kuwait
Kuskucu et al. 2008 [29]	II	RCT	High	24	32	27	Turkey
Price et al. 2010 [30]	I	RCT	Low	11	13	24	Australia
Cortical Button versus Interference Screw							
				CB	IS		
Ibrahim et al. 2009 [27]	I	RCT	Moderate	48	50	29	Kuwait
Crosspin versus Interference Screw							
				CP	IS		
Bjorkman et al. 2014 [22]	I	RCT	Moderate	31	31	60	Finland
Capuano et al. 2008 [23]	I	RCT	Low	15	15	13	France
Harilainen et al. 2009 [26]	I	RCT	Low	60	60	24	Finland
Rose et al. 2006 [31]	I	RCT	High	38	30	12	Germany
Stengel et al. 2009 [32]	I	RCT	Moderate	28	26	24	Germany

CB; cortical button, CP; cross-pin, IS; interference screw, LOE; level of evidence, Mo; months, N; number, RCT; randomized control trial.

Table 2
Surgical Techinal Factors.

Author	Group	Graft Type	Drilling Technique	Tibial Fixation	Femoral Tunnel Position (R/L)
Cortical Button versus Crosspin					
Eajazi et al. 2013	CB CP	STG	N/R	IS	N/R
Fauno and Kaalund 2005	CB CP	STG	N/R	PLLA IS Bicortical Screw/Spiked Wahser	N/R
Ibhrahim et al. 2009	CB CP	STG	TT	IntraFix	2:00/10:00
Ibhrahim et al. 2015	CB CP	DB STG	AM	BioIntraFix	2:00/10:00
Kuskucu et al. 2008	CB CP	STG	N/R	IS	10:00–11:00/1:00–2:00
Price et al. 2010	CB CP	STG	TT	Bio IS	N/R
Cortical Button versus Interference Screw					
Ibrahim et al. 2009	CB IS	STG	TT	IntraFix	2:00/10:00
Crosspin versus Interference Screw					
Bjorkman et al. 2014	CP IS	STG ST/STG	TT OI	AO Screw/Spiked Washer	N/R
Frosch et al. 2012	CP IS	ST/STG	AM	Milagro IS	N/R
Harilainen et al. 2009	CP IS	STG	TT OI	BioScrew/IntraFix	10:30/1:30
Rose et al. 2006	CP IS	STG	TT AM	Bone Plug Delta Screw	11:00/1:00
Stengel et al. 2009	CP IS	ST/STG	N/R	RigidFix BioCryl	10:30/1:30

AM; anteromedial, CB; cortical button, CP; cross-pin, DB; double-bundle, HT; hamstring tendon autograft, IS; interference screw, N/R; not reported, OI; outside in, ST; semitendinosus, STG; semintendinosus & gracilis, TT; transtibial.

3.4. Graft Failure

Graft failures were reported in 5 studies. In the network meta-analysis with random effects model, compared to CB there was no statistically significant difference in the rate of graft failure with CP (OR 0.88, CI 0.25–3.12, p = 0.8422) and IS (OR 1.55, CI 0.22–10.88, p = 0.6597). There was no statistically significant difference between the various fixation methods ($I^2 = 0$, heterogeneity statistic Q = 0.89, p = 0.8290). The odds ratio of CB vs the other treatment methods graft failure is shown in Figure 2.

3.5. Anterior Laxity > 3 mm

Anterior laxity >3 mm was reported in 6 studies. In the network meta-analysis with random effects model, compared to CB there was no statistically significant difference in the rate of anterior laxity >3 mm with CP (OR 0.58, CI 0.31–1.08, p = 0.0835) and IS (OR 0.78, CI 0.37–1.64, p = 0.5167). There was no statistically significant difference between the various fixation methods ($I^2 = 0$, heterogeneity statistic Q = 2.08, p = 0.7209). The odds ratio of CB vs the other treatment methods for anterior laxity >3 mm is shown in Figure 3.

3.6. Anterior Laxity > 5 mm

Anterior laxity >5 mm were reported in 4 studies. In the network meta-analysis with random effects model, compared to CB there was no statistically significant difference in the rate of anterior laxity >5 mm with CP (OR 2.88, CI 0.41–20.36, p = 0.3466)

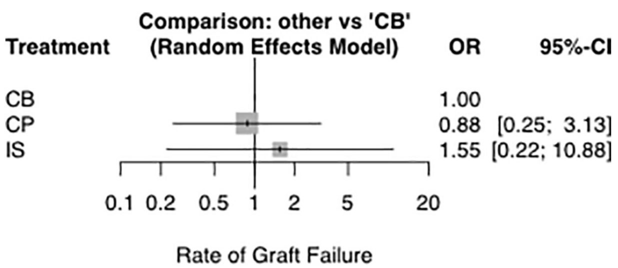

Figure 2. Graft Failure.

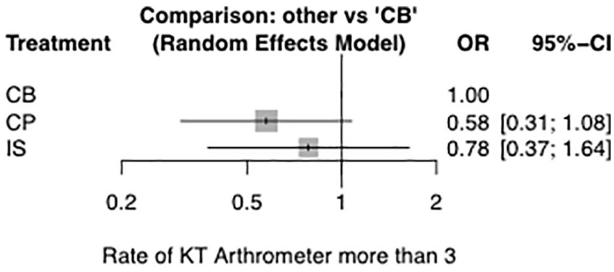

Figure 3. Anterior Laxity >3 mm.

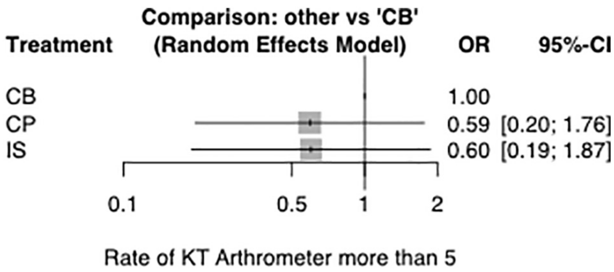

Figure 4. Anterior Laxity >5 mm.

and IS (OR 1.79, CI 0.34–9.48, p = 0.3772). There was no statistically significant difference between the various fixation methods ($I^2 = 0$, heterogeneity statistic Q = 1.83, p = 0.3997). The odds ratio of CB vs the other treatment methods for anterior laxity >5 mm is shown in Figure 4.

3.7. Lachman Test

The Lachman test was reported in 5 studies. In the network meta-analysis with random effects model, compared to CB there was no statistically significant difference in the rate of positive Lachman test with CP (OR 2.88, CI 0.41–20.36, p = 0.8079) and IS (OR 1.79, CI 0.34–9.48, p = 0.5849). There was no statistically significant difference between the various fixation methods ($I^2 = 0$, heterogeneity statistic Q = 2.50, p = 0.4748). The odds ratio of CB vs the other treatment methods for positive Lachman testing is shown in Figure 5.

3.8. Pivot Shift Test

The Pivot shift test was reported in 4 studies. In the network meta-analysis with random effects model, compared to CB there was no statistically significant difference in the rate of positive Pivot shift test with CP (OR 2.88, CI 0.41–20.36, p 0.7416) and IS (OR 1.79, CI 0.34–9.48, p = 0.3458). There was no statistically significant difference between the various fixation methods ($I^2 = 0$, heterogeneity statistic Q = 0.81, p = 0.6653). The odds ratio of CB vs the other treatment methods for positive Pivot shift is shown in Figure 6.

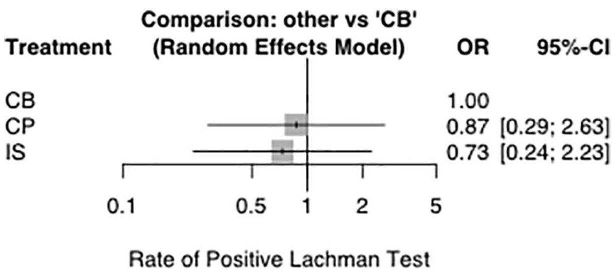

Figure 5. Lachmann Test.

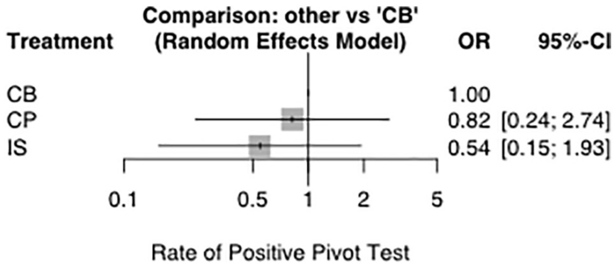

Figure 6. Pivot Shift Test.

3.9. IKDC Score Grade A or B

IKDC Score were reported in 9 studies. In the network meta-analysis with random effects model, compared to CB there was no statistically significant difference in the rate of of IKDC score A or B with CP (OR 2.88, CI 0.41–20.36, $p = 0.1614$) and IS (OR 1.79, CI 0.34–9.48, $p = 0.2653$). There was no statistically significant difference between the various fixation methods ($I^2 = 0$, heterogeneity statistic $Q = 6.08$, $p = 0.5306$). The odds ratio of CB vs the other treatment methods for IKDC score A or B is shown in Figure 7.

3.10. Lysholm Score

The Lysholm score was reported in 3 studies. In the network meta-analysis with random effects model, compared to CB there was no statistically significant difference in the rate of additional procedures with CP (MD 0.00, CI -4.74-4.74, $p = 1.000$) and IS (MD -0.66, CI -6.10-4.78, $p = 0.8119$). There was no statistically significant difference between the various fixation methods ($I^2 = 0$, heterogeneity statistic $Q = 0.20$, $p = 0.6519$). The odds ratio of CB vs the other treatment methods for additional procedures is shown in Figure 8.

3.11. Additional Procedures

Additional procedures were reported in 4 studies. In the network meta-analysis with random effects model, compared to CB there was no statistically significant difference in the rate of additional procedures with CP (OR 1.79, CI 0.34–9.48, p — 0.4919) and IS (OR 2.88, CI 0.41–20.36, $p = 0.2900$). There was no statistically significant difference between the various fixation methods ($I^2 = 0$, heterogeneity statistic $Q = 1.42$, $p = 0.7012$). The odds ratio of CB vs the other treatment methods for additional procedures is shown in Figure 9. The P Scores of each outcome are shown in Table 3.

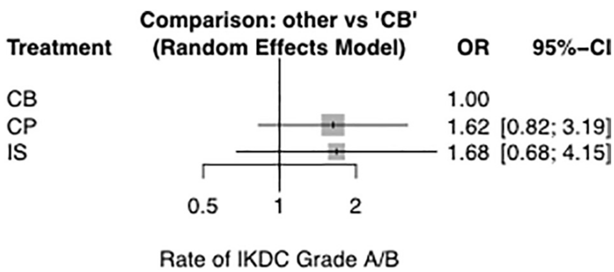

Figure 7. IKDC Score Grade A or B.

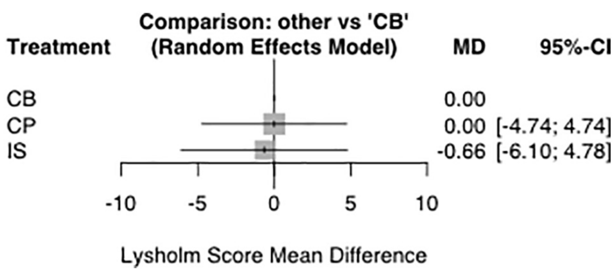

Figure 8. Lysholm Score.

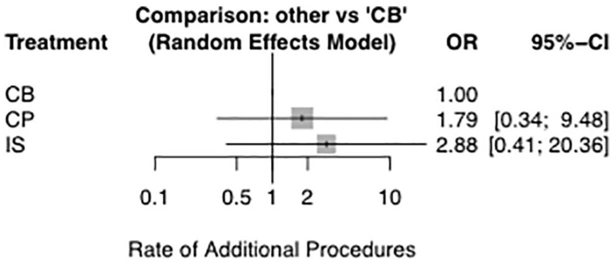

Figure 9. Additional Procedures.

4. Discussion

The most important finding from our study was that there was no statistically significant difference in failure rate, knee stability, functional outcomes, or incidence of revision procedures between CB, CP or IS femoral fixation of hamstring autografts in ACL reconstruction. These findings suggest that graft fixation method should be decided based on surgeon preference and experience.

Several previous meta-analyses have been conducted on femoral fixation methods for HT in ACL reconstruction. These have evaluated variable comparison groups including CP vs IS, CB vs CP and intratunnel vs extratunnel, but have failed to find a superior fixation method [12–14]. Based on these meta-analyses and our own findings it appears the choice of fixation method may not affect the graft stability. The advantage of a network meta-analysis is that it allows for comparison of all three fixation methods with the ability to rank them based on outcomes. As network meta-analyses are relatively new in orthopedic literature, it is important to address the method of interpretation of the results. The most definitive results of a network meta-analysis, similar to pairwise meta-analysis, are odds ratios for the various comparisons. For example, when comparing the rate of graft failure in IS to CB, the OR of 1.55 represents the odds that a graft failure would occur if the patient underwent femoral fixation with interference screw compared to cortical button. However, given the 95% confidence interval for the OR is 0.22 to 10.88 and crosses OR of 1, this relationship is not statistically significant. The P-score represents the probability that the fixation method is the ideal method for an optimal outcome and provides an intuitive method of ranking the treatment options. However, the optimal method of comparing treatments should be to look at the Odds Ratio and their confidence interval. It is important to understand that the P-score does not represent the magnitude of difference between the fixation methods, just the probability that one treatment is more likely to result in a better outcome than the other [21].

The primary outcome measure of interest in our study was the post-operative knee stability at final follow-up, as biomechanical studies have reported mixed outcomes on whether CB or CP or IS leads to enhanced stability [4,7–11]. Our study found no significant difference in knee stability when evaluating total laxity, positive Lachman test, or positive pivot shift test. Additionally, the subsequent rupture rate of the graft following surgery was not significantly different between the three methods. A recent study from the Norwegian Knee Ligament Registry found an increased rate of failure with CB fixation [34]. Our study, in contrast, found no difference in the Lysholm score, our primary functional outcome measure. of note, we were unable to report on any other outcome measure due to inconsistent outcomes reporting in the studies. Registry data may be more reflective of real life outcomes, due to the large numbers, heterogeneity of the surgeons performing the procedure. In contrast, randomized trials are likely to be performed in teaching centres by specialized surgeons.

Although the revision and complication rates were similar across the included studies, the type of complication associated with each fixation method was variable. Price et al. found that CB and CP experienced a low rate of intra-operative complications which were due to the guidewire breaking during insertion [30]. Additionally, while there were 2 patients in each group that were revised due to failures, there was an additional patient in the Transfix group who needed removal of the implant due to lateral sided knee pain. Ibrahim et al. compared all three fixation methods and reported only 2 problems with the cortical buttons in 48 patients, specifically button migration that resulted in pain on flexion [27]. Stengel et al. found the only fixation specific complication was a cross-pin dislocation in one patient of the 26 receiving a CP, and did not report any problems with IS [32].

Biomechanical studies included in this review demonstrate conflicting results when comparing various fixation methods. Milano et al. found higher load to failure, increased stiffness, and decreased graft elongation compared to interference screw fixation [9]. There are also differences between the various types of cross-pin fixation, including expansion devices and cortical

Table 3
P Scores.

Graft Failure	Anterior Laxity >3 mm	Anterior Laxity >5 mm	Lachmann Test	Pivot Shift Test	IKDC Score Grade A/B	Lysholm Score	Additional Procedures
CP: 0.6764	CP: 0.8901	CP: 0.6682	IS: 0.6666	IS: 0.7912	IS: 0.7021	CP: 0.5930	CB: 0.8045
CB: 0.5456	IS: 0.4598	IS: 0.6509	CP: 0.4852	CP: 0.4369	CP: 0.6912	CB: 0.5470	CP: 0.5150
IS: 0.2279	CB: 0.1500	CB: 0.1809	CB: 0.3482	CB: 0.2719	CB: 0.1067	IS: 0.3600	IS: 0.I804

CB; cortical button, CP; cross-pin, IS; interference screw.

cancellous devices, which have been shown to have different biomechanical properties through their different mechanisms of action [9,11]. Rigidfix produces a bulging of the graft through the CP passing through the graft and femoral tunnel. In contrast, Transfix is a transverse bar that produces resistance along the contact surface between the hardware and bone. Studies have found differences between metallic and bioabsorbable interference screws, with higher screw complication rates associated with bioabsorbable screws. Cortical-button fixation has been implicated in increasing tunnel widening compared to cross-pin, but the clinical significance of this has been disputed [35–37]. Overall, the literature demonstrates that the reported biomechanical differences do not appear to translate into any clinically significant difference.

4.1. Limitations

There are limitations in the validity of network meta-analysis as the findings are entirely dependent on the quality of the studies included and the actual number of studies included. In our study, this was mitigated by the inclusion of only randomized control trials. In addition, the reported outcomes were primarily continuous measures, and as a result of inconsistent reporting, we were only able to report on the Lysholm score. The components of the fixation were variable as some studies used metallic components and others used bioabsorbable components. This may impact the outcomes as bioabsorbable components have a higher complication rate and are more likely to fracture [38]. There were differences in tibial fixation and drilling techniques between the groups in the included studies, which may affect the outcome, although analysis showed the studies with differing tibial fixation and drilling techniques did not have any difference in the functional outcomes.

5. Conclusion

Our study found that there was no difference in failure rate, knee stability, functional outcomes or the incidence of revision procedures between CB, CP or IS femoral fixation of hamstring autografts in ACL reconstruction using a network meta-analysis as a tool to evaluate these three fixation types. Our findings suggest that graft fixation method should be decided based on surgeon preference and experience. In addition, NMA can successfully be employed to analyze outcomes involving more than two treatment arms.

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