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[Intervention Review]

Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

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ABSTRACT

Background

Arthroscopic reconstruction for anterior cruciate ligament rupture is a common orthopaedic procedure. One area of controversy is whether the method of double-bundle reconstruction, which represents the 'more anatomical' approach, gives improved outcomes compared with the more traditional single-bundle reconstruction.

Objectives

To assess the effects of double-bundle versus single-bundle for anterior cruciate ligament reconstruction in adults with anterior cruciate ligament deficiency.

Search methods

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (to February 2012), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2012, Issue 2), MEDLINE (1966 to February week 3 2012) and EMBASE (1980 to 2012 Week 8). We also searched trial registers, conference proceedings, and contacted authors where necessary.

Selection criteria

Randomised and quasi-randomised controlled clinical trials comparing double-bundle versus single-bundle reconstruction for anterior cruciate ligament (ACL) rupture in adults.

Data collection and analysis

Two review authors independently selected articles, assessed risk of bias and extracted data. We contacted investigators to obtain missing information. Where appropriate, results of comparable studies were pooled.

Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults (Review)

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Main results

Seventeen trials were included. These involved 1433 people, mostly young physically active adults. All included trials had methodological weaknesses and were at risk of bias, notably selection bias from inadequate or lack of allocation concealment. Data for pooling individual outcomes were available for a maximum of nine trials and 54% of participants.

There were no statistically or clinically significant differences between double-bundle and single-bundle reconstruction in the subjective functional knee scores (subjective IKDC score, Tegner activity score, Lysholm score) in the intermediate (six months up to two years since surgery) or long term (two to five years from surgery). For example, the long term results for the Lysholm score (0 to 100: best score) were: mean difference (MD) 0.12, 95% confidence interval (CI) -1.50 to 1.75; 5 trials, 263 participants). The only trial reporting on long term knee pain found no statistically significant differences between the two groups. There were no significant differences between the two groups in adverse effects and complications (e.g. infection reported by nine trials (7/285 versus 7/393; risk ratio (RR) 1.14, 95% CI 0.46 to 2.81); graft failure reported by six trials (1/169 versus 4/185; RR 0.45; 95% CI 0.07 to 2.90).

Limited data from five trials found a better return to pre-injury level of activity after double-bundle reconstruction (147/162 versus 208/255; RR 1.15, 95% CI 1.07 to 1.25). At long term follow-up, there were statistically significant differences in favour of double-bundle reconstruction for IKDC knee examination (normal or nearly normal categories: 325/344 versus 386/429; RR 1.05, 95% CI 1.01 to 1.08; 9 trials), knee stability measured with KT-1000 arthrometer (MD -0.74 mm, 95% CI -1.10 to -0.37; 5 trials, 363 participants) and rotational knee stability tested by the pivot-shift test (normal or nearly normal categories: 293/298 versus 382/415; RR 1.06, 95% CI 1.02 to 1.09; 9 trials). There were also statistically significant differences in favour of double-bundle reconstruction for newly occurring meniscal injury (9/240 versus 24/358; RR 0.46, 95% CI 0.23 to 0.92; 6 trials) and traumatic ACL rupture (1/120 versus 8/149; RR 0.17, 95% CI 0.03 to 0.96; 3 trials). There were no statistically significant differences found between the two groups in range of motion (flexion and extension) deficits.

Authors' conclusions

There is insufficient evidence to determine the relative effectiveness of double-bundle and single-bundle reconstruction for anterior cruciate ligament rupture in adults, although there is limited evidence that double-bundle ACL reconstruction has some superior results in objective measurements of knee stability and protection against repeat ACL rupture or a new meniscal injury. High quality, large and appropriately reported randomised controlled trials of double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults appear justified.

PLAIN LANGUAGE SUMMARY

Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

Anterior cruciate ligament injury is a common soft-tissue knee injury. Patients with anterior cruciate ligament deficiency, especially young physically active males, usually do not return to pre-injury level of activities due to knee instability. Surgical treatment of ACL rupture involves reconstruction of the anterior cruciate ligament by use of a graft (a piece of tendon usually obtained from the patient) that is passed through tunnels drilled into the tibia and femur at the insertion points of the ligament and then fixed. Repair may use a single-bundle or double-bundle technique. The ACL mainly consists of two distinct portions or 'bundles'. In single-bundle reconstruction, one of these bundles is restored whereas in double-bundle reconstruction, both are restored. Double-bundle reconstruction may give greater knee stability but is more technically demanding and invasive than single-bundle reconstruction. This review aimed to find out if double-bundle reconstruction gives a better result than single-bundle reconstruction.

Seventeen trials were included. These involved 1433 patients, who were mostly young physically active adults. All included trials had methodological weaknesses that are likely to undermine the reliability of their results. Data for pooling individual outcomes were available for a maximum of nine trials.

There was not enough evidence of differences between two groups in terms of functional knee scores, adverse effects and complications (infection, hardware problem such as pain from fixation device, graft failure), range of motion (flexion and extension deficit). At long term follow-up, some clinician-assessed measures of knee stability and repeated rupture rate or occurrence of new meniscal injuries were better after double-bundle reconstruction.

We concluded that there was not enough evidence to say whether double-bundle reconstruction gives better results than single-bundle reconstruction for anterior cruciate ligament rupture in adults. However, there is limited evidence that double-bundle ACL

reconstruction has some superior results for knee stability and protection against repeat ACL rupture or newly occurring meniscal injury.

BACKGROUND

The anterior cruciate ligament (ACL), which is located within the knee joint, performs a key role in stabilising the knee. It acts to prevent forward movement (anterior translation) of the tibia (shin bone) relative to the femur (thigh bone) as well as to control rotational movements within the knee joint. It is made up of dense connective tissue covered with a synovial membrane (Arnoczky 1983; Dienst 2002). The ACL mainly consists of two distinct portions or 'bundles': an anteromedial (AM) bundle and a posterolateral (PL) bundle, named according to their insertion sites to the tibia (Girgis 1975). Both bundles are critical to knee stability but act differently. The anteromedial band is tight in flexion (knee is bent) whereas the posterolateral band is tight in extension (knee is straightened out). A biomechanical study found that the anteromedial bundle is the primary restraint against anterior tibia translation, while the posterolateral bundle secures the knee when near full extension, particularly against rotational loads (Petersen 2007).

Description of the condition

The exact incidence of anterior cruciate ligament injuries is unknown; however, approximately 200,000 people per year sustain an ACL injury (usually a rupture) in the USA (AAOS 2007). These injuries are most often a result of deceleration, non-contact injuries, jumping, or sideways cutting movements (Griffin 2000). The person often hears or feels a pop as the ligament tears and the knee loses stability. Resumption of activity is usually not possible, and walking with full weight bearing is often difficult. Within two hours, the knee often swells and there is bleeding within the joint. The Lachman test, the most sensitive test for anterior cruciate ligament tears, is usually positive (Benjaminse 2006). Other injuries often occur at the time of the anterior cruciate ligament injury. Approximately 50% to 70% of patients with anterior cruciate ligament injuries also have meniscal injuries. In acute anterior cruciate ligament injuries, the lateral meniscus is more commonly torn (Bellabarba 1997); while in chronic anterior cruciate ligament instability, the medial meniscus is more commonly torn (Naranje 2008). Osteochondral injuries also occur with anterior cruciate ligament tears and are associated with a worse prognosis. People who have a torn ACL usually have knee pain and instability and cannot readily return to their former sport participation. In general, people with anterior cruciate ligament-deficient knees

who continue sport activities with repeat incidents of instability risk further meniscus tears and osteochondral (articular cartilage and the bone underneath it) injuries that ultimately lead to osteoarthritis of the knee (Lohmander 2007).

Description of the intervention

Surgical treatment for ACL rupture usually involves reconstruction of the anterior cruciate ligament by use of a graft (a piece of tendon) that is passed through tunnels drilled into the tibia and femur at the insertion points of the ligament and then fixed. ACL reconstruction is an increasingly common orthopaedic procedure (Lyman 2009). Lyman 2009 estimated there had been over 105,000 reconstructions in the USA in 2006. Reconstruction of the ACL produces better knee stability during daily activities and strenuous activities than non-surgical treatment especially in active individuals (Linko 2005). Over the years, an increased understanding of technical issues of graft selection, placement, tension, and fixation as well as of postoperative rehabilitation has led to improved outcomes from ACL reconstruction. The standard technique for anterior cruciate ligament reconstruction is currently arthroscopic single-bundle (SB) reconstruction with autografts (graft is taken from the patient) such as bone-patellar tendon-bone (BPTB), medial hamstring tendons (semitendinosus and gracilis), or the quadriceps tendon. The single-bundle reconstruction technique has mainly focused on the restoration of the anteromedial bundle while giving limited attention to the posterolateral bundle. Thus single-bundle ACL reconstructions are successful at restoring anterior stability to the knee, but not rotational stability (Woo 2002). Recent advances in arthroscopic knee surgery have allowed separate reconstruction of the two bundles to restore more closely the natural anatomy of the anterior cruciate ligament. The double-bundle anterior cruciate ligament reconstruction technique was first described by Mott 1983. In double-bundle reconstruction, four bone tunnels (two in tibia, two in femur) are made at the anatomic insertion of the anteromedial bundle and posterolateral bundle. Numerous technical modifications to both single-bundle and double-bundle procedures have been introduced to improve the rotational stability of the reconstructed knee. However, double-bundle reconstruction will always be more technically demanding and invasive (four bone tunnels are required instead of two) than single-bundle reconstruction.

How the intervention might work

Theoretically, double-bundle reconstruction is more likely to restore normal knee kinematics compared with a single-bundle technique. Anatomical and biomechanical studies have shown that double-bundle ACL reconstruction restores anterior knee stability and rotational stability in an ACL-deficient knee better than single-bundle ACL reconstruction because of better 'footprint' recreation (restoration of ACL attachments) and restoration of biomechanical functions (Buoncrisiani 2006). With the additional restoration of the posterolateral bundle as in double-bundle reconstruction, rotational stability in particular is increased significantly (Yagi 2002). Therefore, it may prevent repeat incidents of instability, reduce the risk of further meniscus tears and osteochondral injuries that ultimately lead to osteoarthritis of the knee. There is also a theoretical advantage to improved graft-bone healing of the double-bundle ACL reconstruction resulting from greater graft-bone contact area than that in single-bundle reconstruction (Cho 2004).

Why it is important to do this review

Single-bundle techniques remain the standard approach and are generally, but not always, successful. However, the potential for improved knee stability and the proven technical feasibility of double-bundle ACL reconstruction have led to an increased interest and application of this relatively 'young' and technically more demanding arthroscopic procedure. But there is concern that double-bundle ACL reconstruction may result in a worse outcome for patients, including in those cases where revision surgery is required. A systematic review of the evidence from randomised clinical trials comparing double-bundle versus single-bundle reconstruction should help to inform decisions in this controversial area of current practice.

OBJECTIVES

To assess the effects of anatomic double-bundle versus standard single-bundle for anterior cruciate ligament reconstruction in adults with ACL deficiency.

METHODS

Criteria for considering studies for this review

Types of studies

Any randomised or quasi-randomised (method of allocating participants to a treatment which is not strictly random: e.g. by date of birth, hospital record number, alternation) controlled clinical trials comparing double-bundle versus single bundle reconstruction for anterior cruciate ligament (ACL) rupture in adults were considered.

Types of participants

Skeletally mature patients (≥ 14 years old) with documented ACL rupture, either isolated or combined with other soft-tissue knee injuries, requiring primary ACL reconstruction.

Types of interventions

Comparisons of double-bundle versus single-bundle reconstruction for treating ACL rupture in adults. Tendon grafts can be either autograft (from the patient) or allograft (from another person) and include semitendinosus tendon alone, gracilis and semitendinosus tendon, quadriceps tendon and bone-patellar tendon-bone. Methods of surgical fixation include screw fixation and Endobutton fixation. We excluded trials that only compared different methods of double-bundle reconstruction or different methods of single-bundle reconstruction.

Types of outcome measures

Primary outcomes

1. Patient or clinician-rated functional knee scores (e.g. IKDC score, Tegner activity score, Lysholm score (Lysholm 1982)) and patient-derived health related quality of life measures (e.g. physical domain of the SF-36)
2. Long-term knee pain (visual analogue scale)
3. Adverse effects and complications (e.g. graft failure; infection; hardware problem such as pain from fixation device; Cyclops lesion; arthrofibrosis)

Secondary outcomes

1. Return to pre-injury level of activity/sport participation
2. Objective measures of knee stability (e.g. KT-1000 arthrometer, KT-2000 arthrometer results; rotational stability (pivot shift test); anterior stability (e.g. Lachman test, anterior drawer test))
3. Range of motion (flexion-extension deficit)
4. Recurrent or newly occurring (new) soft-tissue knee injury with or without surgery (e.g. traumatic ACL rupture, new meniscal injury)

Timing of outcome assessment

We considered grouping outcomes as follows:

1. Short term (within six months of ACL reconstruction)
2. Intermediate term (six months up to two years of ACL reconstruction)
3. Long term
 - i) Long term (two years up to five years of ACL reconstruction)
 - ii) Extended term (greater than five years of ACL reconstruction)

Search methods for identification of studies

Electronic searches

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (to February 2012), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, 2012 issue 2), MEDLINE (1966 to February week 3 2012) and EMBASE (1980 to 2012 Week 8). We also searched [Current Controlled Trials](#) and the [WHO International Clinical Trials Registry Platform](#) (to March 2012) for ongoing and recently completed trials. No language restrictions were applied.

In MEDLINE (OVID WEB), the subject specific strategy was combined with the sensitivity-maximizing version of the Cochrane Highly Sensitive Search Strategy for identifying randomised trials ([Lefebvre 2009](#)). In EMBASE (OVID WEB), the subject specific strategy was combined with the RCT search filter developed by the [Scottish Intercollegiate Network](#). Details of search strategies, including *The Cochrane Library* (Wiley Online Library), are shown in [Appendix 1](#).

Searching other resources

Conference proceedings published in supplements of the Journal of Bone and Joint Surgery - British Volume (2002 to 2012) were searched via the journal website ([JBJS-Br](#)) up to March 2012 using the term 'double-bundle'.

Data collection and analysis

The intended methodology for data collection and analysis was described in our published protocol ([Tiamklang 2010](#)), which was based on the Cochrane Handbook of Systematic Reviews of Interventions ([Higgins 2009](#)).

Selection of studies

Two review authors (TT and SS) independently selected references identified by the searches for retrieval of full articles. Where there

was disagreement or doubt, the full article was retrieved. The same two review authors independently assessed the full study report to see if it met the review inclusion criteria. A third review author (TF) was consulted in cases of unresolved disagreement.

Data extraction and management

Two review authors (TT and SS) independently extracted trial details and data for the included trials using a data collection form. A third author (TF) was consulted in cases of unresolved disagreement. Trial authors were contacted directly to complete data forms or clarify methodology. Data were entered into Review Manager software ([RevMan 2011](#)) and checked for accuracy.

Assessment of risk of bias in included studies

Two review authors (TT and SS) independently assessed the risk of bias for each study using The Cochrane Collaboration's tool, adjusted for the review ([see Table 1](#)). Each study was graded for risk of bias (low, high, unclear) in each of the following domains: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and two other sources of bias (selection bias from major differences in baseline characteristics; and performance bias from important differences in the provision of care other than the trial interventions). We assessed separately the risk of bias associated with patient-rated outcomes and clinician-rated outcomes for blinding and incomplete outcome data. Any unresolved disagreement was resolved by discussion with a third review author (TF). Titles of journals, names of authors or supporting institutions were not masked at any stage.

Measures of treatment effect

Where appropriate, quantitative data reported in individual trials for outcomes listed in the inclusion criteria were presented in the results. Risk ratios with 95% confidence intervals (CIs) were calculated for dichotomous outcomes, and mean differences (MDs) with 95% CIs for continuous outcomes.

Unit of analysis issues

The unit of randomisation in trials for comparing double-bundle versus single-bundle reconstruction for treating ACL rupture was usually the individual patient. However, in the case of trials including people with bilateral ACL ruptures, data were presented for ACL ruptures rather than individual participants. If such unit of analysis issues had arisen and appropriate corrections had not been made, we would have considered presenting the data for such trials only where the effect of disparity between the units of analysis and randomisation was small. Should such data have been pooled, we planned a sensitivity analysis to examine the effects of pooling incorrectly analysed trials with the other correctly analysed trials.

Dealing with missing data

Where appropriate, we performed intention-to-treat analyses to include all people randomised to the intervention groups. We planned to investigate the effect of drop outs and exclusions by conducting worst and best scenario analyses as part of sensitivity analysis. We were alert to the potential mislabelling or non-identification of standard errors and standard deviations. Unless missing standard deviations could be derived from confidence interval data, we did not assume values in order to present these in the analyses.

Assessment of heterogeneity

Heterogeneity was assessed by visual inspection of the forest plot (analysis) along with consideration of the test for heterogeneity and the I^2 statistic (Higgins 2003).

Assessment of reporting biases

Where sufficient data are available in future updates of this review, we will assess publication bias by preparing a funnel plot.

Data synthesis

For each study, mean differences and 95% confidence intervals (CIs) were calculated for continuous outcomes, and relative risks (RRs) and 95% CIs for dichotomous outcomes. If considered appropriate, results of comparable groups of trials were pooled. Initially we used the fixed-effect model and 95% CIs. We also considered using the random-effects model, especially where there was unexplained heterogeneity.

Subgroup analysis and investigation of heterogeneity

Currently there are insufficient data to perform our planned subgroup analyses, which were intended to explore heterogeneity. Should this be possible in future, our pre-specified primary subgroup analyses are by gender, acute versus chronic injuries, isolated ACL rupture versus ACL rupture combined with other soft-tissue knee injuries, and autograft versus allograft. We would also consider other subgroup analyses of various types of grafts, forms of fixation methods, numbers of strands of tendon graft, operative techniques and rehabilitation protocols. We will use the test for subgroup differences provided in RevMan to examine whether the subgroups are statistically significantly different from one another.

Sensitivity analysis

Where possible, we planned sensitivity analyses examining various aspects of trial and review methodology, including the effects of trials at high risk of bias (such as from lack of allocation concealment) and worst and best scenario analyses for missing data.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

Results of the search

[Appendix 1](#) shows the search results for three databases (*The Cochrane Library*, MEDLINE and EMBASE), firstly up to May 2010 and then from 2010 up to February 2012. In all, these electronic searches produced 129 references. A further 15 references were identified via searches of conference proceedings, nine from searches of trial registers, and 17 from the Cochrane Bone, Joint and Muscle Trauma Group's Specialised Register. After screening, including obtaining full text articles of potentially eligible trials, 41 were put forward for study selection. Of these, 21 articles were included, 18 were excluded, nine are listed as ongoing (see the [Characteristics of ongoing studies](#)) and three incompletely reported trials are awaiting assessment (see the [Characteristics of studies awaiting classification](#)). However, four of the 21 trial reports are interim reports of the same trial (listed under [Suomalainen 2011](#)). Correspondence with the lead author ([Jarvela 2012](#)) of three of these reports ([Jarvela 2007](#); [Jarvela 2008a](#); [Jarvela 2008b](#)) revealed that there was one trial for which ethical committee permission was obtained "already 10 years ago" for a "10-year time to perform the trial" and for a sample size of 200 patients. A long-term follow-up of one trial ([Yagi 2007](#)) was reported in [Fujita 2011](#).

Included studies

Of 17 included trials, 12 were randomised controlled trials ([Adachi 2004](#); [Aglietti 2010](#); [Araki 2011](#); [Ibrahim 2009](#); [Sastre 2010](#); [Siebold 2008](#); [Streich 2008](#); [Suomalainen 2011](#) (also reported in [Jarvela 2007](#); [Jarvela 2008a](#); [Jarvela 2008b](#)); [Volpi 2010](#); [Wang 2009](#); [Zaffagnini 2008](#); [Zaffagnini 2011](#)) and five were confirmed quasi-randomised controlled trials ([Misonoo 2012](#); [Muneta 2007](#); [Park 2010](#); [Song 2009](#); [Yagi 2007](#)). All the included trials were reported in medical journals. The publication dates of the trials span nine years, with [Adachi 2004](#) being the earliest. The trials were conducted in eight countries: China (1), Finland (1), Germany (2), Italy (4), Japan (5), Kuwait (1), Spain (1), and South Korea (2) (see [Table 2](#)).

The 17 included trials involved 1433 people, mostly young active adults. Where provided, median or mean ages of trial participants ranged between 22 and 35 years. The youngest recorded was 14 years ([Adachi 2004](#); [Muneta 2007](#)) and the oldest was 58 years ([Song 2009](#)). Three trials specified the lower limit age of patients with closed epiphysis ([Aglietti 2010](#); [Suomalainen 2011](#); [Wang 2009](#)). Three trials ([Araki 2011](#); [Misonoo 2012](#); [Muneta 2007](#))

had equal numbers of males and females. Otherwise the participants in the trials were predominately male (53.2% up to 100%), except in [Yagi 2007](#) (30%).

Injuries were generally reported to be chronic, unilateral anterior cruciate ligament deficiency; one trial ([Aglietti 2010](#)) provided a more tightly defined duration of injury before surgery by stipulating that this needed to be more than six weeks. Meniscal injuries were found as associated injury in every included trial, and one trial included patients with grade III MCL injury ([Muneta 2007](#)). Most of the included trials were comparisons between one group treated with double-bundle ACL reconstruction and one group treated with single-bundle ACL reconstruction. Three trials ([Ibrahim 2009](#); [Suomalainen 2011](#) (as reported in [Jarvela 2008a](#)); [Yagi 2007](#)) had two or more groups in the single-bundle category. Tendon graft from hamstring tendon (semitendinosus and/or gracilis tendon) were mostly used in double-bundle and single-bundle ACL reconstruction, except one trial ([Song 2009](#)) that used tibialis anterior allograft tendon for both double-bundle and single-bundle ACL reconstruction and two trials ([Volpi 2010](#); [Zaffagnini 2011](#)) that used bone-patellar tendon-bone for single-bundle ACL reconstruction (see [Table 2](#)).

As far as we could ascertain, rehabilitation programmes following surgery were similar in all groups of each included trial. In six trials ([Adachi 2004](#); [Misonoo 2012](#); [Muneta 2007](#); [Siebold 2008](#); [Wang 2009](#); [Yagi 2007](#)), rehabilitation involved the use of a knee brace while participants of seven trials ([Aglietti 2010](#); [Ibrahim 2009](#); [Streich 2008](#); [Suomalainen 2011](#); [Volpi 2010](#); [Zaffagnini 2008](#); [Zaffagnini 2011](#)) were given functional treatment without a knee brace. The remaining four studies ([Araki 2011](#); [Park 2010](#); [Sastre 2010](#); [Song 2009](#)) did not describe whether a knee brace was used or not.

Further details of the individual trials are presented in the [Characteristics of included studies](#).

Excluded studies

Eighteen trials were excluded for reasons given in the [Characteristics of excluded studies](#). Fourteen studies were excluded because they were not randomised or quasi-randomised trials. Although a quasi-randomised study, [Gobbi 2012](#) was excluded of high selection bias from a large proportion of post-randomisation exclusions. One trial ([Kanaya 2009](#)) reported intra-operative findings only. The other two studies were excluded because they were conducted in a laboratory setting only ([Hemmerich 2011](#)) or on cadavers ([Hemmerich 2011a](#)).

Ongoing studies

Nine trials were listed as ongoing studies (see the [Characteristics of ongoing studies](#)). Of these, six are stated to be recruiting, one is yet to start and two have completed patient recruitment.

Risk of bias in included studies

All five quasi-randomised trials ([Misonoo 2012](#); [Muneta 2007](#); [Park 2010](#); [Song 2009](#); [Yagi 2007](#)) were judged at high risk of selection bias, reflecting their inadequate method of randomisation. Four of these ([Misonoo 2012](#); [Park 2010](#); [Song 2009](#); [Yagi 2007](#)) were judged at high risk for other domains, relating to lack of blinding or incomplete outcome data, or both in [Park 2010](#). All included trials had methodological weaknesses which put them at high or unclear risk of various biases (see [Figure 1](#)). An overall summary is provided in [Figure 2](#).

Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Adachi 2004	?	?	+	-	?	?
Aglietti 2010	?	?	+	+	?	?
Araki 2011	-	?	-	+	?	?
Ibrahim 2009	?	?	?	+	?	?
Misonoo 2012	-	-	-	+	?	?
Muneta 2007	-	-	+	-	?	?
Park 2010	-	-	-	-	?	?
Sastre 2010	+	?	-	+	?	?
Siebold 2008	+	?	+	+	?	?
Song 2009	-	-	-	+	?	?
Streich 2008	?	?	+	+	?	?
Suomalainen 2011	?	?	+	-	-	?
Volpi 2010	?	?	+	+	?	?
Wang 2009	?	?	-	+	?	-
Yagi 2007	-	-	-	+	?	?
Zaffagnini 2008	+	?	+	-	?	-
Zaffagnini 2011	+	?	+	-	?	?

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Allocation

In terms of sequence generation, four trials ([Sastre 2010](#); [Siebold 2008](#); [Zaffagnini 2008](#); [Zaffagnini 2011](#)) were at low risk of selection bias, six trials ([Araki 2011](#); [Misonoo 2012](#); [Muneta 2007](#); [Park 2010](#); [Song 2009](#); [Yagi 2007](#)) were at high risk of selection bias, and six trials were unclear risk due to inadequate information.

For allocation concealment, five trials ([Misonoo 2012](#); [Muneta 2007](#); [Park 2010](#); [Song 2009](#); [Yagi 2007](#)) were high risk of selection bias and 12 trials were unclear risk due to a lack of information about their method of allocation concealment.

Blinding

For blinding of outcome assessors, nine trials ([Adachi 2004](#); [Aglietti 2010](#); [Muneta 2007](#); [Siebold 2008](#); [Streich 2008](#); [Suomalainen 2011](#); [Volpi 2010](#); [Zaffagnini 2008](#); [Zaffagnini 2011](#)) were at low risk of bias, seven trials ([Araki 2011](#); [Misonoo 2012](#); [Park 2010](#); [Sastre 2010](#); [Song 2009](#); [Yagi 2007](#); [Wang 2009](#)) were at high risk of bias due to no blinding, and one trial ([Ibrahim 2009](#)) was at unclear risk due to inadequate descriptions of the method of blinding outcome assessment.

Incomplete outcome data

A total of seven trials ([Aglietti 2010](#); [Araki 2011](#); [Misonoo 2012](#); [Sastre 2010](#); [Siebold 2008](#); [Volpi 2010](#); [Wang 2009](#)) were at low

risk of attrition bias because no patients were lost to follow-up and there were no exclusions from the analyses. Six trials ([Adachi 2004](#); [Muneta 2007](#); [Park 2010](#); [Suomalainen 2011](#); [Zaffagnini 2008](#); [Zaffagnini 2011](#)) were at high risk of attrition bias because the percentages of the population missing from analyses (lost to follow-up and exclusion data) was high. Four trials ([Ibrahim 2009](#); [Song 2009](#); [Streich 2008](#); [Yagi 2007](#) ([Fujita 2011](#) report)) were also at low risk due to some patients being lost to follow-up and no exclusion from the analyses.

Selective reporting

[Suomalainen 2011](#), which was reported in four different trial reports ([Jarvela 2007](#); [Jarvela 2008a](#); [Jarvela 2008b](#); [Suomalainen 2011](#)) in different ways, was considered at high risk of selective reporting bias.

Other potential sources of bias

Baseline imbalance was evident in two trials ([Wang 2009](#); [Zaffagnini 2008](#)). [Wang 2009](#) found more lateral meniscus injury in the double-bundle group and [Zaffagnini 2008](#) had a significant difference between the two groups in the pre-operative Psychovitality Questionnaire scores. For performance bias, most of the included trials were at low risk of performance bias because all ACL reconstructions were performed by the same experienced or senior surgeons except in two trials ([Adachi 2004](#); [Volpi 2010](#)).

Effects of interventions

The primary comparison in this review was of double-bundle versus single-bundle anterior cruciate ligament reconstruction. In the following, the results for most outcomes are presented according to short (within six months of ACL reconstruction), intermediate term (six months up to two years of ACL reconstruction), long term (two years up to five years of ACL reconstruction), and extended term (greater than five years of ACL reconstruction) follow-up periods. For two trials (Ibrahim 2009; Yagi 2007) with two or more groups in the same category, which was always the single-bundle category, outcomes were combined and analysed for that category. An exception was made for Suomalainen 2011, where interim-analysis data presented for an additional single-bundle group with metal screw fixation in one of the four reports available for this trial (Jarvela 2008a) were not considered in this review. Several included trials (Muneta 2007; Sastre 2010; Suomalainen 2011 (and earlier reports Jarvela 2007, Jarvela 2008a, Jarvela 2008b); Volpi 2010; Zaffagnini 2011) inadequately reported outcome data for inclusion in the analyses. The investigators of these all trials were successfully contacted to obtain missing information.

Insufficient data precluded pre-planned subgroup analyses by gender, acute versus chronic injuries, isolated ACL rupture versus ACL rupture combined with other soft-tissue knee injuries, various types of tendon graft, forms of fixation methods, numbers of strands of tendon graft, operative techniques and rehabilitation protocols. Some sensitivity analyses were performed to explore the effects of excluding the results of quasi-randomised clinical trials (Misonoo 2012; Muneta 2007; Park 2010; Song 2009; Yagi 2007) at high risk of selection bias from lack of allocation concealment. There were insufficient data available to perform the planned sensitivity analyses for missing data.

Unless specified otherwise, fixed-effect analyses were presented in the following.

Primary outcomes

Patient or clinician-rated functional knee scores

Functional knee scores were measured using various scales in the included trials as displayed in Analysis 1.1 and Analysis 1.2.

Subjective IKDC score

Six studies (Aglietti 2010; Park 2010; Sastre 2010; Siebold 2008; Streich 2008; Wang 2009) presented subjective IKDC score (evaluated by summing the scores for symptoms, sports activities and function of the knee) scales from 0 to 100 (best outcome). Pooled mean differences of subjective IKDC scores between the two groups were not statistically significant at intermediate term follow-up (mean difference (MD) -0.43, 95% CI -3.49 to 2.62; 3

trials) or at long term follow-up (MD 1.66, 95% CI -0.73 to 4.06; 4 trials) (see Analysis 1.1.1 and Analysis 1.1.2). Excluding the results from Park 2010, the results remained non-significant at long term follow-up (MD 0.87, 95% CI -1.69 to 3.44; 3 trials) (see Analysis 1.1.3).

One study (Suomalainen 2011 (reported in Jarvela 2007)) found no difference in the IKDC functional scores (evaluated by daily activities that the patient can perform: scales from 0 to 10: best outcome) between two groups at intermediate term follow-up: MD 0.00, 95% CI -0.53 to 0.53 (see Analysis 1.1.4).

Tegner activity score

Eight studies (Misonoo 2012; Muneta 2007; Park 2010; Song 2009; Streich 2008; Wang 2009; Zaffagnini 2008; Zaffagnini 2011) presented Tegner activity level score data (evaluated by the highest activity in which the patient can participate: scales from 0 to 10: best outcome). The pooled mean differences of Tegner activity score between the two groups were not statistically significant at intermediate term follow-up: MD 0.31, 95% CI -0.19 to 0.82; 3 trials and at long term (2 to 5 years) follow-up: MD 0.15, 95% CI -0.19 to 0.50; 5 trials (see Analysis 1.1.5 and Analysis 1.1.6). Excluding the results from three quasi-randomised trials did not materially change these results at long term follow-up: MD 0.40, 95% CI -0.18 to 0.99; 2 trials (see Analysis 1.1.7). At extended term (> 5 years) follow-up, Zaffagnini 2011 found a statistically significant better Tegner activity score in the double-bundle group: MD 2.00, 95% CI 1.12 to 2.88 (see Analysis 1.1.8). One study (Ibrahim 2009) found no statistically significant difference of patients having a Tegner activity score of greater than 7 between the two groups at long term follow-up: risk ratio (RR) 1.17, 95% CI 0.95 to 1.43 (see Analysis 1.2.2).

Lysholm score

Nine studies (Araki 2011; Misonoo 2012; Muneta 2007; Siebold 2008; Song 2009; Streich 2008; Suomalainen 2011 (reported in Jarvela 2007; Jarvela 2008b); Yagi 2007 (reported in Fujita 2011); Wang 2009) presented Lysholm scores (evaluated by summing the score for functional score, activity grading and static stability assessment and functional test: scale from 0 to 100: best outcome). Pooled mean differences of Lysholm score between the two groups were not statistically significant at intermediate term follow-up (MD -0.28, 95% CI -1.62 to 1.07; 6 trials) and at long term follow-up (MD 0.12, 95% CI -1.50 to 1.75; 5 trials) (see Analysis 1.1.9 and Analysis 1.1.10). Upon excluding the results from the three quasi-randomised trials, the results remained non-significant at long term follow-up: MD -1.37, 95% CI -4.06 to 1.32; 2 trials (see Analysis 1.1.11). One study (Ibrahim 2009) also found no statistically significant difference between the two groups in the number of patients having a Lysholm score of more than 95 at

long term follow-up: RR 1.16, 95% CI 0.85 to 1.60 (see Analysis 1.2.1).

Cincinnati knee score

One study (Siebold 2008) found no statistically significant difference of Cincinnati knee score (evaluated by physical examination, instrumented knee stability, testing, and radiographic findings) between the two groups at intermediate term follow-up: MD -1.00, 95% CI -5.24 to 3.24 (see Analysis 1.1.12).

Long term knee pain

One study (Zaffagnini 2011) found no statistically significant difference effect of patients having anterior knee pain between double-bundle and single-bundle group at long term follow-up: 8/40 versus 14/39, RR 0.56, 95% CI 0.26 to 1.18 (see Analysis 1.3).

Adverse effects and complications

Infection

Pooled results on infection from nine studies (Ibrahim 2009; Muneta 2007; Park 2010; Sastre 2010; Siebold 2008; Song 2009; Streich 2008; Volpi 2010; Yagi 2007) showed no statistically significant difference between the two groups: 7/285 versus 7/393, RR 1.14, 95% CI 0.46 to 2.81 (see Analysis 1.4.1). This overall finding was unchanged upon exclusion of the four quasi-randomised trials: 3/149 versus 1/250, RR 3.78, 95% CI 0.73 to 19.61 (see Analysis 1.4.2).

Hardware problem

The difference between the two groups in the pooled results for patients having hardware problems (pain from fixation device that needed its removal) from four studies (Aglietti 2010; Ibrahim 2009; Siebold 2008; Zaffagnini 2008) did not attain statistical significance: 5/157 versus 1/255, RR 4.13, 95% CI 0.95 to 17.87 (see Analysis 1.4.5).

Cyclops lesion

Two studies (Siebold 2008; Yagi 2007) presented data on Cyclops lesion, a localized form of arthrofibrosis (scar tissue in the front part of the anterior cruciate ligament). The difference between the two groups in the number of patients with Cyclops lesion was not statistically significant at intermediate term follow-up: 2/55 versus 4/75, RR 0.78, 95% CI 0.14 to 4.28 (see Analysis 1.4.8).

Graft failure

Six studies (Aglietti 2010; Sastre 2010; Song 2009; Yagi 2007 (reported in Fujita 2011); Zaffagnini 2008; Zaffagnini 2011) presented data on graft failure. There was no statistically significant difference between the double-bundle and single-bundle group in the numbers of participants with graft failure: 1/169 versus 4/185, RR 0.45, 95% CI 0.07 to 2.90 (see Analysis 1.4.9). The results remained non-significant upon excluding the results from two quasi-randomised trials (see Analysis 1.4.10).

Secondary outcomes

Return to pre-injury level of activity / sport participation

Five studies (Araki 2011; Aglietti 2010; Ibrahim 2009; Suomalainen 2011 (reported in Jarvela 2007); Zaffagnini 2008) presented the number of people who returned to their pre-injury level of activity. The pooled return to pre-injury level of activity data showed a significantly better result after double-bundle reconstruction at the last follow-up: 147/162 versus 208/255, RR 1.15, 95% CI 1.07 to 1.25; 5 trials and at long term follow-up: 110/122 versus 181/220, RR 1.14, 95% CI 1.05 to 1.24; 3 trials (see Analysis 1.5). However, the difference between the two groups in this outcome was not statistically significant at intermediate term follow-up: 37/40 versus 27/35, RR 1.21, 95% CI 0.98 to 1.48; 2 trials (see Analysis 1.5.1).

Objective measures of knee stability

IKDC knee examination

Twelve studies (Aglietti 2010; Ibrahim 2009; Muneta 2007; Park 2010; Sastre 2010; Streich 2008; Siebold 2008; Suomalainen 2011; Volpi 2010; Yagi 2007; Zaffagnini 2008; Zaffagnini 2011) presented results from the IKDC knee examination (based on the objective assessment of several aspects such as effusion, passive motion deficit and ligament examination) categorised into four groups: A (normal), B (nearly normal), C (abnormal), and D (severely abnormal). The pooled difference effect of patients having normal or nearly normal IKDC knee examination findings was statistically significantly better in the double-bundle reconstruction at long term follow-up: 325/344 versus 386/429, RR 1.05, 95% CI 1.01 to 1.08; 9 trials (see Analysis 1.6.2). After excluding the two quasi-randomised trials (Muneta 2007; Park 2010), the results remained significant at long term follow-up: 232/247 versus 309/345, RR 1.06, 95% CI 1.01 to 1.10; 7 trials (see Analysis 1.6.3). The pooled difference effect between the two groups at intermediate term follow-up was not statistically significant: 83/85 versus 92/100, RR 1.02, 95% CI 0.97 to 1.08;

3 trials (see [Analysis 1.6.1](#)). At extended term (> 5 years) follow-up, one study ([Zaffagnini 2011](#)) found no statistically significant difference between the two groups in those with normal or nearly normal IKDC findings (39/40 versus 38/39, RR 1.00, 95% CI 0.93 to 1.07) (see [Analysis 1.6.4](#)).

Knee stability measured by arthrometer

Eight studies ([Aglietti 2010](#); [Araki 2011](#); [Misonoo 2012](#); [Muneta 2007](#); [Siebold 2008](#); [Streich 2008](#); [Suomalainen 2011](#); [Yagi 2007](#)) presented side-to-side difference (mm) measured by KT-1000 arthrometer. Mean side-to-side differences, as measured by the KT-1000 arthrometer, were statistically significantly smaller in the double-bundle group at intermediate term follow-up (MD -0.31 mm, 95% CI -0.52 to -0.10; 6 trials) and at long term follow-up (MD -0.74 mm, 95% CI -1.10 to -0.37; 5 trials) (see [Analysis 1.7.1](#) and [Analysis 1.7.3](#)). After removing the quasi-randomised trials, the results remained significantly better in the double-bundle group at both intermediate follow-up (MD -0.69 mm, 95% CI -1.07 to -0.31; 4 trials) and long term follow-up: MD -0.49 mm, 95% CI -0.95 to -0.03; 3 trials (see [Analysis 1.7.2](#), 1.7.4). Statistically significantly more participants in the double bundle group had less than 3 mm side-to-side difference, measured by a KT-1000 arthrometer, at long term follow-up: RR 1.17, 95% CI 1.05 to 1.30; 4 trials (see [Analysis 1.8.1](#)). However, these data were heterogeneous ($I^2 = 58\%$) and the results using the random-effects model were not statistically significant (RR 1.14; 95% CI 0.95 to 1.36; analysis not shown).

Five studies ([Adachi 2004](#); [Park 2010](#); [Wang 2009](#); [Zaffagnini 2008](#); [Zaffagnini 2011](#)) presented side-to-side difference measured by KT-2000 arthrometer. Pooled mean differences of knee stability (mm) measured by KT-2000 arthrometer were not statistically significant at long term follow-up: MD -0.11 mm, 95% CI -0.54 to 0.32; 3 trials (see [Analysis 1.7.6](#)). After excluding the results from a quasi-randomised trial, the results remained non-significant at long term follow-up: MD 0.03 mm, 95% CI -0.72 to 0.78; 2 trials (see [Analysis 1.7.7](#)). At intermediate term follow-up, one study ([Wang 2009](#)) also reported that there were no statistically significant differences between the two groups for knee stability (mm) measured by KT-2000 arthrometer: MD 0.21 mm, 95% CI -0.36 to 0.78 (see [Analysis 1.7.5](#)). At extended term (> 5 years) follow-up, [Zaffagnini 2011](#) reported there was no significant difference between the two groups. However, the available data showed statistically significantly better knee stability measured by KT-2000 arthrometer in the single-bundle group: MD 0.70 mm, 95% CI 0.08 to 1.32 (see [Analysis 1.7.8](#)). [Zaffagnini 2008](#) found no statistically significant difference between the two groups in the number of patients having < 3 mm side-to-side difference measured by KT-2000 arthrometer at long term follow-up: RR 0.98, 95% CI 0.73 to 1.32 (see [Analysis 1.8.2](#)).

Two studies ([Park 2010](#); [Song 2009](#)) presented side-to-side difference (mm) measured by a Telos device. Pooled mean differences of

knee stability measured by Telos device were not statistically significant at long term follow-up: MD -0.11 mm, 95% CI -0.64 to 0.43 (see [Analysis 1.7.10](#)). At intermediate term follow-up, [Song 2009](#) also reported there were no statistically significant differences between two groups for knee stability measured by Telos device: MD -0.30 mm, 95% CI -1.66 to 1.06 (see [Analysis 1.7.9](#)).

Intraoperative knee stability

[Song 2009](#) found a statistically significant better intraoperative anteroposterior translation (MD -1.00 mm, 95% CI -1.84 to -0.16) and intraoperative rotational stabilities (degree) in double-bundle reconstruction group: MD -6.20 degrees, 95% CI -8.62 to -3.78 (see [Analysis 1.9](#)).

Anterior knee stability

Two studies ([Ibrahim 2009](#); [Muneta 2007](#)) presented the results of the anterior drawer test (manual stability test for anterior instability) categorised into four grades: negative (normal), positive + (nearly normal), positive ++ (abnormal), and positive +++ (severely abnormal). The pooled data of patients having a normal or nearly normal anterior drawer test showed no statistically significant difference between the two groups at long term follow-up: 83/84 versus 180/184, RR 1.01, 95% CI 0.97 to 1.05; 2 trials (see [Analysis 1.10.1](#)).

Six studies ([Aglietti 2010](#); [Araki 2011](#); [Ibrahim 2009](#); [Muneta 2007](#); [Song 2009](#); [Yagi 2007](#)) presented the results of the Lachman test (manual stability test for anterior cruciate ligament injury) categorised into four grades: negative (normal), positive + (nearly normal), positive ++ (abnormal), and positive +++ (severely abnormal). Pooled data of patients having a normal or nearly normal Lachman test showed no statistically significant difference between the two groups at long term follow-up when using the random-effects model because of substantial heterogeneity: 136/138 versus 215/238, random RR 1.06, 95% CI 0.98 to 1.15; 4 trials ($I^2 = 65\%$) (see [Analysis 1.11](#)). Upon excluding the results from two quasi-randomised trials, the results remained not significant at long term follow-up: 84/85 versus 164/185, RR 1.11, 95% CI 1.04 to 1.17; 2 trials (see [Analysis 1.10.4](#)). At intermediate term follow-up, there was also no statistically significant difference between the two groups: 49/50 versus 63/70, RR 1.08, 95% CI 0.98 to 1.18; 3 trials (see [Analysis 1.10.2](#)).

Rotational knee stability

Thirteen studies ([Aglietti 2010](#); [Araki 2011](#); [Ibrahim 2009](#); [Misonoo 2012](#); [Muneta 2007](#); [Sastre 2010](#); [Siebold 2008](#); [Song 2009](#); [Streich 2008](#); [Suomalainen 2011](#); [Yagi 2007](#); [Zaffagnini 2008](#); [Zaffagnini 2011](#)) presented the results of the pivot-shift test

(manual stability test for rotational instability) categorised into four grades: negative (normal), positive + (nearly normal), positive ++ (abnormal), and positive +++ (severely abnormal). Pooled data showed statistically significantly more patients having a normal or nearly normal pivot-shift test in the double-bundle group at long term follow-up: 293/298 versus 382/415, RR 1.06, 95% CI 1.02 to 1.09; 9 trials (*see Analysis 1.12.3*). The results remained significantly better in the double-bundle group at long term follow-up after excluding the results from three quasi-randomised trials: 223/227 versus 302/325, RR 1.05, 95% CI 1.01 to 1.08; 6 trials (*see Analysis 1.12.4*). At intermediate term follow-up, however, there was no statistically significant difference between the two groups for all trials reporting this outcome (136/137 versus 145/152, RR 1.03, 95% CI 0.98 to 1.08; 6 trials) (*see Analysis 1.12.1*) or after excluding the results from three quasi-randomised trials: 74/75 versus 70/70, RR 0.99, 95% CI 0.94 to 1.04; 3 trials (*see Analysis 1.12.2*). At extended term (> 5 years) follow-up, Zaffagnini 2011 also found no statistically significant difference between the two groups (39/40 versus 38/39, RR 1.00, 95% CI 0.93 to 1.07) (*see Analysis 1.12.5*).

Range of motion (flexion-extension deficit)

Eight studies (Aglietti 2010; Ibrahim 2009; Muneta 2007; Song 2009; Streich 2008; Suomalainen 2011; Volpi 2010; Wang 2009) presented flexion-extension deficit data. There was no statistically significant difference between the two groups in the incidence of patients with flexion deficit: 5/244 versus 8/340, RR 0.88, 95% CI 0.29 to 2.67; 8 trials (*see Analysis 1.13.1*). Excluding the results from quasi-randomised trials gave the same result (*see Analysis 1.13.2*). There was no statistically significant difference between the two groups in the incidence of patients with extension deficit: 12/225 versus 14/321, RR 0.93, 95% CI 0.49 to 1.78; 7 trials (*see Analysis 1.13.5*). Presenting the results for randomised trials only gave the same result (*see Analysis 1.13.6*).

Recurrent injury with and without re-operation

Meniscal injuries

Six studies (Aglietti 2010; Ibrahim 2009; Muneta 2007; Suomalainen 2011; Yagi 2007; Zaffagnini 2011) presented data for new meniscal injuries. The pooled results for new meniscal injuries showed statistically significantly fewer patients having new meniscal injuries in the double-bundle than the single-bundle group: 9/240 versus 24/358; RR 0.46, 95% CI 0.23 to 0.92; 6 trials (*see Analysis 1.14.1*). After excluding the results from two quasi-randomised trials, the results remained significantly better in the double-bundle group: RR 0.44, 95% CI 0.20 to 0.97 (*see Analysis 1.14.2*). But the pooled data for patients having new meniscal injuries showed no statistically significant difference between the

double-bundle and single-bundle group at intermediate term follow-up: 1/50 versus 2/65, RR 0.75, 95% CI 0.10 to 5.85; 2 trials; or at long term follow-up: 5/180 versus 10/279, RR 0.67, 95% CI 0.25 to 1.84; 4 trials (*see Analysis 1.14.3* and *Analysis 1.14.4*). At extended term (> 5 years) follow-up, Zaffagnini 2011 found statistically significantly fewer patients incurring new meniscal injuries in the double-bundle group: 4/40 versus 13/39, RR 0.30, 95% CI 0.11 to 0.84 (*see Analysis 1.14.5*).

Traumatic ACL rupture

Three studies (Aglietti 2010; Streich 2008; Suomalainen 2011) presented traumatic ACL rupture data. The pooled data for traumatic ACL rupture showed statistically significantly fewer patients having traumatic ACL rupture in the double-bundle group than in the single-bundle group: 1/120 versus 8/149; RR 0.17, 95% CI 0.03 to 0.96; 3 trials (*see Analysis 1.14.6*). These data applied to the long term follow-up (*see Analysis 1.14.8*). At intermediate term follow-up, Suomalainen 2011 (reported in Jarvela 2007) found no statistically significant difference between the double-bundle and single-bundle groups: 0/30 versus 4/29, RR 0.11, 95% CI 0.01 to 1.91 (*see Analysis 1.14.7*).

DISCUSSION

Summary of main results

This systematic review included 12 randomised controlled trials and five quasi-randomised controlled trials comparing double-bundle with single-bundle reconstruction for anterior cruciate ligament rupture in 1433 adults.

The primary outcomes were patient functional knee scores, long-term knee pain, and adverse effects and complications. The majority of the results of the primary outcomes were based on data from not more than five trials with a maximum of 340 participants for any functional knee score (Tegner activity score). There were no statistically or clinically significant differences between double-bundle and single-bundle reconstruction in the subjective functional knee scores (subjective IKDC score, Tegner activity score, Lysholm score) in the intermediate (six months up to two years since surgery) or long term (two to five years from surgery). The only trial reporting on long term knee pain found no statistically significant differences between the two groups. There were no significant differences between the two groups in adverse effects and complications (e.g. infection reported by nine trials; or graft failure reported by six trials).

The secondary outcomes were return to pre-injury level of activity, objective measurement of knee stability, range motion, and recurrent injury. None of the pooled secondary outcomes were

reported by more than nine trials. Limited data from five trials found a better return to pre-injury level of activity after double-bundle reconstruction. At long term follow-up, there were statistically significant differences in favour of double-bundle reconstruction for IKDC knee examination (9 trials), knee stability measured with KT-1000 arthrometer (5 trials) and rotational knee stability tested by the pivot-shift test (9 trials). There were also statistically significant differences in favour of double-bundle reconstruction for new meniscal injury (6 trials) and traumatic ACL rupture (3 trials). There were no statistically significant differences found between the two groups in range of motion (flexion and extension) deficits. Thus there is some evidence that indicating that double-bundle ACL reconstruction may enhance knee stability and protect against further injury.

Overall completeness and applicability of evidence

This review, including 17 trials of which five were quasi-randomised, was conducted to compare the effect of anatomical double-bundle versus single-bundle reconstruction for adults with chronic ACL deficiency. A further nine trials are listed as ongoing studies, with a potential for future evidence from over 600 patients, and there are three trials awaiting classification. Additional unpublished data were obtained by contact of trial investigators for six included trials (Muneta 2007; Sastre 2010; Suomalainen 2011 (as in Jarvela 2007); Volpi 2010; Yagi 2007 (as in Fujita 2011); Zaffagnini 2011). Various measures for assessing knee function (subjective IKDC score, Tegner activity score, Lysholm score) were reported in most of the included trials. All trials investigated a variety of objective measures of knee stability (arthrometer (KT-1000, KT-2000 arthrometer); rotational stability (pivot shift test); anterior stability (Lachman test, anterior drawer test)). While pooled data are presented for most outcomes, these were available for a maximum of 340 participants (24% of total randomised) for any functional knee score, and for a maximum of 773 (54%) participants for any objective measure of knee stability. These deficiencies in the available data hamper interpretation of the results and assessment of their applicability, especially when the differences in effects between the two groups are small and not statistically significant.

The applicability of the evidence is further limited by the heterogeneity in the included trials; in particular, differences in the trial populations (e.g. gender mix) and interventions (e.g. variation in the techniques for double-bundle ACL reconstruction). However, it is noteworthy that tendon grafts from hamstring tendon (semitendinosus and/or gracilis tendon) were mostly used in both double-bundle and single-bundle ACL reconstruction (see Table 2). In terms of setting, 14 of the 17 included studies were from a wide range of high-income countries. There were wide differences in the context of each study site but the operations were performed on the whole by experienced single surgeons. Overall, caution is

recommended when the evidence is applied in other settings than the ones tested in the trials. There were insufficient data to perform our planned subgroup analyses intended to explore heterogeneity.

Quality of the evidence

For functional outcomes and recurrent injury, the quality of the available evidence was graded as 'low quality'; thus, "Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate". For objective measures of knee stability, the quality of the available evidence was graded as 'moderate quality'; thus, "Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate". When grading the quality of the evidence, we placed strong emphasis on the risk of bias findings for the included trials. Crucially, most failed to control for selection bias or to demonstrate that they had done so and only half had adequate outcome assessment blinding to protect against detection bias. Incompleteness of the evidence, especially for the primary outcomes, was also very important in our assessment. Pooling of data for individual outcomes was hindered by the variety of outcomes, inconsistent availability of data and the variation of the outcome measures. At maximum, data were pooled from just over half of the trials and just over half of the randomised participants.

Potential biases in the review process

As recommended by The Cochrane Collaboration, two review authors independently searched, selected studies, assessed risk of bias and extracted data from individual studies. While our search is up to date and included a search of conference proceedings and trials registers, it is possible that we have missed some trials in this topical area of relatively high research activity. This is unavoidable. One key strength of this review is our successful contact with several trial investigators for clarification of trial methods and unpublished data. A key discovery was that four articles (Jarvela 2007; Jarvela 2008a; Jarvela 2008b; Suomalainen 2011a) were all interim reports of one trial (Suomalainen 2011).

We were transparent in our approach to presenting the data from the included trials. We dichotomised the ordinal outcome data of IKDC knee examination, anterior drawer test, Lachman test, and Pivot-shift test and used risk ratios as the data for meta-analysis in RevMan. For dichotomisation of ordinal outcome data, the categorical data in the 'normal' and 'nearly normal' grades were combined into one group, while the categorical data in the 'abnormal' and 'severely abnormal' grades were combined into the other group. Thus data observed in our review may differ from the original trials. We combined data of some outcomes from two trials (Ibrahim 2009; Yagi 2007) having two or more groups in the same category of comparison (see Table 2).

Sensitivity analyses where the results of the five quasi-randomised trials were excluded indicated that our decision to include such trials did not materially alter the findings.

Agreements and disagreements with other studies or reviews

Despite the inclusion of several more trials, the findings of our review in terms of insufficient evidence broadly agree with an earlier published meta-analysis on this topic (Meredick 2008). There are two features of the latter which merit some comment. Firstly, Meredick 2008 presented data from the first two reports (Jarvela 2007; Jarvela 2008a) of Suomalainen 2011 as if these were separate trials. This is understandable because neither report acknowledges that they had participants in common nor that these are interim reports of the same trial. Secondly, while it does not substantially affect their conclusions, Meredick 2008 appears to have incorrectly pooled the data from two trials (Jarvela 2008a; Yagi 2007) that had two groups in the same category; this resulted in the double counting of patients from the double-bundle group in the analyses. This is avoided in our review. In contrast to our findings, Meredick 2008 reported that double-bundle reconstruction did not result in clinically significant differences in KT-1000 arthrometer or pivot-shift testing. Additionally, we also found some, albeit limited, evidence for a lower incidence of meniscal tear and ACL re-injury post double-bundle ACL reconstruction.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence to determine the relative effects (patient functional knee scores; adverse effects, complications, and range of motion deficit) of double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults.

Double-bundle ACL reconstruction may have some superior results in the ability to return to pre-injury level of activity, objective measurement of knee stability (IKDC knee examination, instrumented knee arthrometer with KT-1000, manual stability test by the pivot-shift test), and protection against recurrent injury.

Implications for research

There is a need for high quality and large, preferably multi-centre, randomised controlled trials to assess the effectiveness of double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults. These trials should feature proper random sequence generation, adequate allocation concealment and, where possible, blinding of outcome assessors, and should meet the CONSORT criteria for the design and reporting of non-pharmacological studies (Bouton 2008). The use of well-defined and validated functional outcome measures, including patient-derived health related quality of life measures, is essential. Given that some outcomes need more time to assess (graft failure, revision rate, further injuries, osteoarthritis), there is need for trials with long term follow-up. There also a need to acknowledge the future contribution of ongoing trials and to keep this systematic review updated in this research active area.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Adachi 2004

Methods	RCT Randomisation method: not stated Assessor blinding: one of the authors who was blinded as to the group and details of each patient, performed all the tests of anterior stability Loss to follow-up: 10 patients	
Participants	133 patients with chronic, unilateral ACL deficiency (+ meniscal injury) After allocation, 15 patients were excluded with contralateral knee injury, severe osteoarthritis or ligamentous instability of the knee Country: Japan Gender (female, male): D (20,33), S (23,32) Mean age (years): D (29.2, 14-47), S (29.5,14-49) Mean time since injury (months): D (21), S (26)	
Interventions	Period of study: between July 1998 and May 2000 1. Double-bundle group: Used doubled (semitendinosus/gracilis) tendon+doubled (semitendinosus/gracilis) tendon and fixed with two Endobuttons CL (11, 9.30 or 1, 2.30 o'clock) and two Endobutton tape + two staples 2. Single-bundle group: Used quadrupled (semitendinosus/gracilis) tendon and fixed with Endobutton CL (10 or 2 o'clock) and Endobuton tape + two staples The same post-operative regimen was followed in all cases (brace 2 days) Assigned: 133 (65/68) Analysed: 108 (53/55)	
Outcomes	Mean length of follow-up: 32 months (24 to 36) 1. Knee joint stability (side-to-side differences): KT 2000 knee arthrometer with the knee at 20 and 70 degree flexion 2. Joint position sense: a Cybex II dynamometer at low angle and the greater angles 3. Incidence of notchplasty 4. Complications: infection, deep thrombosis, nerve or arterial injury	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No available information.
Allocation concealment (selection bias)	Unclear risk	No available information.

Adachi 2004 (Continued)

Blinding (performance bias and detection bias) All outcomes	Low risk	Outcome assessment was blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	10 patients were lost to follow-up but the paper did not mention how many patients were lost from each group After allocation, 15 patients were excluded with contralateral knee injury, severe osteoarthritis or ligamentous instability of the knee
Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	Unclear risk	No other obvious bias.

Aglietti 2010

Methods	RCT Randomisation method: not stated Assessor blinding: an independent and blinded observer Participants blinding: blinded to the type of procedure 1 year after surgery Loss to follow-up: none
Participants	70 patients with complete, unilateral, and chronic ACL lesion (> 6 weeks) (+ meniscal injury) Inclusion criteria: closed physes and younger than 40 years old, healthy contralateral knee, no previous surgeries in the index knee, chondral lesion < Outerbridge grade III, no patellofemoral symptoms, absence of systemic illnesses, compliance to 2 years follow-up study Country: Italy Gender (female, male): D (7,28), S (10,25) Mean age (years): 28 (16-24) Mean time since injury (months): D (28), S (24)
Interventions	Period of study: ? 1. Double-bundle group: Used singled (semitendinosus/gracilis) tendon+singled (semitendinosus/gracilis) tendon and fixed with two titanium RCI screws (outside-in)+staple and looped around bony bridge of tibia 2. Single-bundle group: Used doubled (semitendinosus/gracilis) tendon and fixed with titanium RCI screws (outside-in) + staple and PAG metallic suspension device All the procedures were performed by the senior author. The same brace-free post-operative protocol for rehabilitation was used for both groups Assigned: 70 (35/35) Analysed: 70 (35/35)

Aglietti 2010 (Continued)

Outcomes	Mean length of follow up: 2 years 1. Manual laxity tests: Lachman test, Pivot-shift test 2. Anterior knee laxity measurement(side-to-side differences): KT 1000 arthrometer at 30 degree knee flexion 3. ROM deficit: flexion, extension 4. Knee scores: objective IKDC, subjective IKDC, KOOS 5. VAS score 6. Return to pre-injury level 7. Complications: nontraumatic failures, traumatic rupture	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No available information.
Allocation concealment (selection bias)	Unclear risk	No available information.
Blinding (performance bias and detection bias) All outcomes	Low risk	Blinded participants and outcome assessor.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up and the exclusions from the analyses.
Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	Unclear risk	No other obvious bias. All the procedures were performed by the senior author.

Araki 2011

Methods	RCT Randomisation method: randomised with closed envelopes into two groups according to their sex and age Assessor blinding: A single surgeon performed preoperative assessment and follow-up examinations one year after surgery Loss to follow-up: none
Participants	20 consecutive patients with chronic ACL deficiency in one knee and had an indication for ACL reconstruction Exclusion criteria: medial, lateral, or posterior instability as evaluated by physical examinations or had any history of surgery on either knee Country: Japan

	Gender (female,male): 10, 10 Mean age (years): D (25.2+12.1), S (24.7+11.8) Mean time since injury (months): ?	
Interventions	Period of study: ? 1. Double-bundle group: Used doubled (semitendinosus) tendon+doubled (gracilis) tendon and fixed with two Endobuttons CL and cancellous post screw with washer 2. Single-bundle group: Used quadrupled (semitendinosus/gracilis) tendon and fixed with Endobuttons CL and cancellous post screw with washer An experienced surgeon performed or directly supervised all surgery All patients followed the same postoperative program. Assigned: 20 (10/10) Analysed: 20 (10/10)	
Outcomes	Mean length of follow up: 12 months 1. Manual laxity tests: Lachman test, Pivot-shift test 2. Anterior knee laxity measurement(side-to-side differences): KT 1000 arthrometer 3. Range of motion deficit: Heel-height difference 4. Quantitative assessment during the Lachman test and the pivot shift test: using an electromagnetic device 5. Return to previous sport activity level. 6. Complications	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "... were randomised with closed envelopes into two groups according to their sex and age."
Allocation concealment (selection bias)	Unclear risk	Quote: "... were randomised with closed envelopes into two groups according to their sex and age." Comment: No information of assignment envelope to judge whether was used with or without appropriate safeguards
Blinding (performance bias and detection bias) All outcomes	High risk	A single surgeon performed preoperative assessment and follow-up examinations one year after surgery
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up and the exclusions from the analyses.

Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	Unclear risk	No other obvious bias. An experienced surgeon performed or directly supervised all surgery

Ibrahim 2009

Methods	<p>RCT</p> <p>Randomisation method: closed envelope method</p> <p>Assessor blinding: A blinded, well-trained orthopedic surgeon performed the pivot-shift test</p> <p>Loss to follow-up: 18 patients</p>
Participants	<p>218 men with ACL deficiency (+ meniscal injury, chondral lesion)</p> <p>Exclusion criteria: patients had medial, lateral or posterior laxity on physical examination</p> <p>Country: Kuwait</p> <p>Gender (male): 218</p> <p>Mean age (years): 28 (21-33)</p> <p>Mean time since injury (months): 2-4</p>
Interventions	<p>Period of study: ?</p> <p>1. Double-bundle group: used doubled (semitendinosus) tendon+ doubled (gracilis) tendon and fixed with two Endobuttons and two Intrafix bioabsorbable screws</p> <p>2. Single-bundle group: Used quadrupled (semitendinosus/gracilis) tendon and fixed with Endobutton (2 or 10 o'clock) and Intrafix bioabsorbable screw</p> <p>3. Single-bundle group: Used quadrupled (semitendinosus/gracilis) tendon and fixed with two RigidFix cross-pins and Intrafix bioabsorbable screw</p> <p>4. Single-bundle group: Used quadrupled (semitendinosus/gracilis) tendon and fixed with TransFixII screw and Intrafix bioabsorbable screw</p> <p>All the reconstructions were operate by one experienced orthopedic surgeon</p> <p>Rehabilitation was the same for all patients (no brace).</p> <p>Assigned: 218</p> <p>Analysed: 200(50/48/52/50)</p>
Outcomes	<p>Mean length of follow up: 29 months (25 to 38)</p> <p>1. Rotational stability: Pivot-shift test</p> <p>2. Manual knee laxity testing: Lachman's test, Anterior drawer test</p> <p>3. Anterior knee laxity measurement (side-to-side differences): KT 1000 arthrometer</p> <p>4. ROM: extension lag, lacked full flexion</p> <p>5. Knee scores: Lysholm knee scores, Tegner activity scores, the IKDC scores</p> <p>6. Return to pre-injury level</p> <p>7. Patients-satisfaction questionnaire</p> <p>8. Complications: migration of Endobutton, superficial wound infection, re-injured</p>

	knee	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No available information.
Allocation concealment (selection bias)	Unclear risk	Quote: "The randomisation was by a closed envelope method." Comment: No information of assignment envelope to judge whether was used with or without appropriate safeguards
Blinding (performance bias and detection bias) All outcomes	Unclear risk	A blinded, well-trained orthopedic surgeon performed the pivot-shift test but information for other outcomes were unavailable
Incomplete outcome data (attrition bias) All outcomes	Low risk	18 patients were loss follow-up but did not mention how many patients from each group No exclusions from the analyses.
Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	Unclear risk	No other obvious bias. All the reconstructions were operate by one experienced orthopedic surgeon

Misonoo 2012

Methods	Quasi-RCT Randomisation method: odd-even month of birth Assessor blinding: not mentioned Loss to follow-up: none
Participants	44 patients with ACL deficiency Exclusion criteria: concomitant knee injuries (such as a meniscal tear or a combined ligament injury); a previous injury to either the reconstructed or the contralateral knee Country: Japan Gender (female, male): D (11,11), S (11,11) Mean age (years): D (22+2), S (22+6) Mean time since injury (months): ?

Interventions	Period of study: July 2007 and July 2009 1. Double-bundle group: Used doubled (semitendinosus/gracilis) tendon + doubled (semitendinosus/gracilis) tendon and fixed with two Endobuttons CL and 6.5 mm cancellous screw with washer 2. Single-bundle group: Used quadrupled (semitendinosus/gracilis) tendon and fixed with Endobutton CL (2 o'clock) and 6.5 mm cancellous screw with washer All patients underwent the same rehabilitation protocol (brace) A single surgeon performed an arthroscopically assisted ACL reconstruction in all patients Assigned: 44 Analysed: 44 (22,22)	
Outcomes	Mean length of follow up: 12.4 months 1. Manual laxity tests: Pivot-shift test 2. Anterior knee laxity measurement (side-to-side differences): KT 1000 arthrometer 3. Knee scores: Tegner score, Lysholm score 4. Tibial rotation	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "DB group was selected in patients whose month of birth was odd-number, and SB group was selected in those whose month of birth was even-number."
Allocation concealment (selection bias)	High risk	Comment: Possibly foreseen assignment.
Blinding (performance bias and detection bias) All outcomes	High risk	Not mentioned for assessor blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up and the exclusions from the analyses.
Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	Unclear risk	No other obvious bias. A single surgeon performed an arthroscopically assisted ACL reconstruction in all patients

Muneta 2007

Methods	Quasi-RCT Randomisation method: odd-even date of birth Assessor blinding: 2 examiners blindly and independently assessed the outcomes Loss to follow up: 8 patients	
Participants	84 patients (85 knees) with ACL deficiency (+ meniscal injury, MCL grade III) After allocation, patients were excluded with bilateral ACL injuries (6 patients (7 knees)), with re-injury before 18 months' follow-up (1 patient in double-bundle group, 1 patient in single-bundle group) Country: Japan Gender (female, male): D (14,20), S (20,14) Mean age (years): D (24.0,(14-49)), S (23.4,(14-48)) Mean time since injury (months): D (15.1,(1-82)), S (14.2,(1-110))	
Interventions	Period of study: July 2002 and March 2004 1. Double-bundle group: Used doubled (semitendinosus) tendon + doubled (semitendinosus) tendon and fixed with two Endobuttons CL(1.30,3.30 o'clock) and two anchor staple with sutures 2. Single-bundle group: Used quadrupled (semitendinosus) tendon and fixed with Endobutton CL (2 o'clock) and anchor staple with sutures The same preoperative and postoperative program was used for both groups (brace) All reconstructive surgeries were performed by the senior surgeon (T Muneta) or fellow doctors with the assistance of the senior surgeon Assigned: 84 Analysed: 68 (34,34)	
Outcomes	Mean length of follow-up: 25.4 months (18-41) 1. Operation time 2. ROM: extension/flexion deficit and thigh girth 3. Manual laxity tests: Lachman test, ADT, Pivot-shift test 4. Anterior knee laxity measurement(side-to-side differences): KT 1000 arthrometer 5. The maximum extension and flexion strength using Cybex testing 5. Knee scores: Tegner score, Lysholm score, IKDC form score 6. Return to pre-injury level: recovery score, time 7. Complications: loss of knee motion, prolonged inflammatory reaction, meniscus tear, secondary tear	
Notes	Included torn MCL Grade III (1 in single-bundle group, 1 in double-bundle group) Acute ACL rupture < 6 weeks (2 single-bundle, 1 double-bundle)	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "Single-bundle reconstruction was selected in patients whose birthdays were on odd-numbered days, and double-bundle reconstruction was selected in those

Muneta 2007 (Continued)

		whose birthdays were on even-numbered days."
Allocation concealment (selection bias)	High risk	Comment: Possibly foreseen assignment.
Blinding (performance bias and detection bias) All outcomes	Low risk	Outcome assessment was blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	Eight patients were lost to follow-up but no mention was made about how many patients from each group After allocation, patients were excluded with bilateral ACL injuries (6 patients (7 knees)), with re-injury before 18 months' follow-up (1 patient in double-bundle group, 1 patient in single-bundle group)
Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	Unclear risk	No other obvious bias. All reconstructive surgeries were performed by the senior surgeon (T Muneta) or fellow doctors with the assistance of the senior surgeon

Park 2010

Methods	Quasi-RCT Randomisation method: order of admittance to hospital Assessor blinding: the postoperative physical examination was performed by a specially trained physician assistant in orthopaedic department Loss to follow-up: 7 cases
Participants	147 patients with unilateral primary ACL reconstruction (+ meniscal injury) Inclusion criteria: primary ACL reconstruction with no combined PCL injury, lateral collateral ligament injury, PL rotatory instability, or fracture around knee; no previous knee ligament surgery; no arthritic changes; no subtotal or total meniscectomy; no malalignment; and a normal contralateral knee After allocation, 26 patients were excluded when the examination under anaesthesia or intraoperative findings did not meet the previously mentioned inclusion criteria, and 1 case was omitted because revision ACL surgery was performed after postoperative infection developed Country: South Korea Gender (female, male): D (15,48), S (16,34) Mean age (years): D (29.6(17-57)), S (28.3(16-54)) Mean time since injury (months): ?

Interventions	<p>Period of study: April 2004 to February 2007</p> <p>1. Double-bundle group: Used tripled (semitendinosus) tendon and tripled (gracilis) tendon, and fixed with the RigidFix for the AM bundle and an EndoButton for the PL bundle and two bioabsorbable screws for tibial fixation</p> <p>2. Single-bundle group: Used quadrupled (semitendinosus and gracilis) tendon and fixed with the Rigid-Fix system for femoral fixation (at 10 or 2 o'clock) and bioabsorbable interference screws with an Intrafix technique for tibial fixation</p> <p>All ACL reconstruction surgeries were performed by the senior surgeon</p> <p>Postoperative rehabilitation protocol was identical for both groups</p> <p>Assigned: 147</p> <p>Analysed: 113 (63/50)</p>
Outcomes	<p>Mean length of follow-up: 2 years</p> <p>1. Manual laxity tests: Pivot-shift test</p> <p>2. Anterior knee laxity measurement: Telos device, KT-2000 arthrometer</p> <p>3. ROM deficit: flexion, extension</p> <p>4. Knee scores: Tegner activity score, IKDC score</p> <p>5. Complications: infection</p>
Notes	The hamstring tendons were harvested from the patient's normal-functioning limb on the opposite side of injury

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "Patients were sequentially selected to undergo either single-bundle or double-bundle reconstruction based on order of admittance to our hospital."
Allocation concealment (selection bias)	High risk	Possibly foreseen assignment.
Blinding (performance bias and detection bias) All outcomes	High risk	Quote: "the postoperative physical examination was performed by a specially trained physician assistant in orthopaedic department." Not mentioned for assessor blinding.
Incomplete outcome data (attrition bias) All outcomes	High risk	7 patients were lost to follow-up but the report did not mention how many patients from each group After allocation, 26 patients were excluded when the examination under anaesthesia or intraoperative findings did not meet the previously mentioned inclusion crite-

Park 2010 (Continued)

		ria, and 1 case was omitted because revision ACL surgery was performed after postoperative infection developed
Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	Unclear risk	No other obvious bias. All ACL reconstruction surgeries were performed by the senior surgeon

Sastre 2010

Methods	RCT Randomisation method: a computer-generated list of random numbers Assessor blinding: not mentioned Loss to follow up: none	
Participants	40 patients with ACL deficiency Inclusion criteria: age 18 - 50 years, < 2 years from the initial injury to surgery, no previous knee surgery, follow-up of no less than 1 year Country: Spain Gender (female,male): ? Mean age (years): ? Mean time since injury (months): ?	
Interventions	Period of study: ? 1. Double-bundle group: Used doubled (semitendinosus) tendon + doubled (gracilis) tendon and fixed with two Endobuttons CL (9,11 and 3,1 o'clock) and two bioabsorbable screws 2. Single-bundle group: Used quadrupled (semitendinosus/gracilis) tendon and fixed with Endobutton CL (10 or 2 o'clock) and bioabsorbable screw All the procedures were performed by the first author. The same preoperative and postoperative program was used for both groups Assigned: 40 (20/20) Analysed: 40 (20/20)	
Outcomes	Mean length of follow up: 2 years 1. Knee scores: subjective IKDC, objective IKDC score 2. Manual laxity tests: pivot-shift test 3. Complications: infection, graft failure	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Low risk	Quote: "... were randomised into two groups by means of a computer-generated list of random numbers."
Allocation concealment (selection bias)	Unclear risk	No available information.
Blinding (performance bias and detection bias) All outcomes	High risk	Not mentioned for assessor blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up and the exclusions from the analyses.
Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	Unclear risk	No other obvious bias. All the procedures were performed by the first author.

Siebold 2008

Methods	RCT Randomisation method: at day of surgery using computer (1-35 for single-bundle reconstruction, 36-70 for double-bundle reconstruction) Assessor blinding: a single blind orthopedic surgeon who was not the operative surgeon Loss to follow-up: none
Participants	70 patients with ACL deficiency (+ meniscal injury, chondral lesion) Inclusion criteria: ACL rupture without additional knee ligament injuries, no previous knee ligament surgery, no arthritic changes, no subtotal or total meniscectomy, no malalignment and a normal contralateral knee Country: Germany Gender (female, male): D (3,32), S (4,31) Mean age (years): 29 Mean time since injury (months): D (3+3), S (4+5)
Interventions	Period of study: between May 2004 and March 2005 1. Double-bundle group: Used doubled (semitendinosus) tendon + doubled (gracilis) tendon and fixed with two Endobuttons CL and two bioabsorbable screws 2. Single-bundle group: Used quadrupled (semitendinosus/gracilis) tendon and fixed with Endobutton (10.30 o'clock) and bioabsorbable screw ACL reconstructions were performed by the senior surgeon. The same preoperative and postoperative program was used for both groups (brace) Assigned: 70 (35/35) Analysed: 70 (35/35)

Siebold 2008 (Continued)

Outcomes	Mean length of follow up: 19 months (13-24) 1. Manual laxity tests: pivot-shift test 2. Anterior knee laxity measurement: KT 1000 arthrometer 3. ROM deficit: flexion, extension 4. Knee scores: objective IKDC, subjective IKDC, Cincinnati knee score, Lysholm score 6. Return to pre-injury level: recovery score, time 7. Complications: infection, Cyclops lesion	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "... were randomised at day of surgery using a computer to either SB (numbers 1 to 35) or DB (numbers 36 to 70)."
Allocation concealment (selection bias)	Unclear risk	Comment: Using computer but have no available information about concealment
Blinding (performance bias and detection bias) All outcomes	Low risk	A single blind orthopedic surgeon who was not the operative surgeon
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up and the exclusions from the analyses.
Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	Unclear risk	No other obvious bias. ACL reconstructions were performed by the senior surgeon

Song 2009

Methods	Quasi-RCT Randomisation method: alternative fashion by the order of treatment Assessor blinding: not mentioned Loss to follow-up at two years: 1 in double-bundle group, 1 in single-bundle group
Participants	40 patients with unilateral primary ACL reconstruction (+meniscal injury) Exclusion criteria: multiple ligament injuries, previous surgeries, and OA >grade 3 Country: South Korea Gender (female, male): D(4,16), S(5,15) Mean age (years): D(35.5(19-58)), S(30.3(17-50)) Mean time since injury (months): D (8.3(1-26)), S (7.6(2-20))

Interventions	Period of study: 1. Double-bundle group: Used doubled (tibialis anterior allograft) tendon and fixed with Endobuttons CL (1 or 11 o'clock) and bioabsorbable screws + staple 2. Single-bundle group: Used two doubled (tibialis anterior allograft) tendon and fixed with Endobutton CL (1.30 or 10.30 o'clock) and bioabsorbable screw + staple All the ACL reconstructions were performed by the same surgeon Assigned: 40 (20/20) Analysed: 40 (20/20) at 1year/ 38(19/19) at 2 years	
Outcomes	Mean length of follow-up: 2 years (24-31 months) 1. Manual laxity tests: Lachman test, Pivot-shift test 2. Anterior knee laxity measurement: Telos device 3. ROM deficit: flexion, extension 4. Knee scores: Tegner activity score, Lysholm score 5. Complications infection, graft failure	
Notes	Another account of the trial (Seon 2009) reports knee stability outcomes only.	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Alternative fashion by the order of treatment.
Allocation concealment (selection bias)	High risk	Possibly foreseen assignment.
Blinding (performance bias and detection bias) All outcomes	High risk	Not mentioned for assessor blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up at one year. Loss to follow-up at two years: 1 in double-bundle group, 1 in single-bundle group No exclusions from the analyses.
Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	Unclear risk	No other obvious bias. All the ACL reconstructions were operated by the same surgeon

Streich 2008

Methods	RCT Randomisation method: not mentioned Assessor blinding: independent and blinded observer Loss to follow up: none
Participants	50 male with chronic ACL deficiency (+ meniscal injury) Exclusion criteria: previous operation in the same knee After allocation, one patient in double bundle group was excluded with lung embolism Country: Germany Gender (male): 50 Mean age (years): 29.4 (16-37) Mean time since injury (months): D (5.9+2.3), S (4.2+2.1)
Interventions	Period of study: between 10/2004 and 04/2005 1. Double-bundle group: Used doubled (semitendinosus) tendon + doubled (semitendinosus) tendon and fixed with Endobutton CL (11,9.30 or 1,2.30 o'clock) and Suture Disc 2. Single-bundle group: Used quadrupled (semitendinosus) tendon and fixed with Endobutton CL (10 or 2 o'clock) and Suture Disc All patients were operated by the well-experienced senior author The same brace-free post-operative protocol for rehabilitation was used for both groups Assigned: 50 (25/25) Analysed: 49 (24/25)
Outcomes	Mean length of follow up: 24 months (23-25) 1. Clinical examination: KT-1000(20 and 60 degrees flexion), pivot-shift test 2. Overall evaluation: Tegner activity score, Lysholm score, IKDC score 3. Complications: wound complications, lung embolism, graft failure
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "... was preoperatively randomised consecutively into one of the two sub-groups (SB vs. DB)."
Allocation concealment (selection bias)	Unclear risk	No available information.
Blinding (performance bias and detection bias) All outcomes	Low risk	Outcome assessment was blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	One lung embolism patient in double-bundle group was excluded from the study

Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	Unclear risk	No other obvious bias. All patients were operated by the well-experienced senior author

Suomalainen 2011

Methods	<p>RCT</p> <p>Randomisation method: closed envelopes technique</p> <p>Assessor blinding: 2 blinded and independent examiners</p> <p>Loss to follow-up: 15 patients (8 in the double-bundle group, and 7 in the single-bundle group)</p> <p>Jarvela 2007: Assessor blinding: all clinical examinations were performed by one examiner</p> <p>Loss to follow-up: 6 patients</p> <p>Jarvela 2008a: Assessor blinding: an independent and blinded examiner</p> <p>Loss to follow-up: 4 patients (1 in double-bundle group, 1 in single-bundle bioabsorbable group, 2 in single-bundle metallic group)</p> <p>Jarvela 2008b: Assessor blinding: an independent and blinded examiner</p> <p>Loss to follow-up: 1 patient (DB) was contacted by phone.</p>
Participants	<p>153 patients with ACL deficiency (+ meniscal injury)</p> <p>Inclusion criteria: (1) primary ACL reconstruction, (2) closed growth plates, and (3) absence of ligament injury to the opposite knee</p> <p>After allocation, 8 patients (1 in the double-bundle group and 7 in the single-bundle group) were excluded with a graft failure because a new knee trauma, and 9 patients (4 in the SB group and 5 in the DB group) were excluded with ACL reconstruction of the contralateral knee during the follow-up</p> <p>Country: Finland</p> <p>Gender (female, male): 43, 110</p> <p>Mean age (years): 33+10</p> <p>Mean time since injury (months): ?</p> <p>Jarvela 2007: 65 patients with ACL deficiency (+ meniscal injury)</p> <p>After allocation, 4 patients (single-bundle group) were excluded with a graft failure because a new knee trauma</p> <p>Mean age (years): 33+9</p> <p>Jarvela 2008a: 77 patients with ACL deficiency (+ meniscal injury)</p> <p>After allocation, 7 patients were excluded with an injury-induced graft failure (1 in double-bundle group, 5 in single-bundle bioabsorbable group, 1 in single-bundle metallic group), and 3 patients (single-bundle metallic group) were excluded with torn ACL of contralateral knee</p> <p>Gender (female, male): 26, 51</p> <p>Mean age (years): 33+9</p> <p>Jarvela 2008b: 60 patients with ACL deficiency (+ meniscal injury)</p> <p>After allocation, 4 patients were excluded with an injury-induced graft failure (1 in double-bundle group, 3 in single-bundle group), and 2 patients were excluded with ACL of contralateral knee (1 in double-bundle group, 1 in single-bundle group)</p> <p>Gender (female, male): 17, 43</p>

	Mean age (years): D (35+10), S (30+7)
Interventions	<p>Period of study: between March 2003 and February 2008</p> <p>1. Double-bundle group: used doubled (semitendinosus) tendon+ doubled (gracilis) tendon;and fixed with two bioabsorbable screws (10 or 2 o'clock) and two bioabsorbable screws</p> <p>2. Single-bundle group: used quadrupled (semitendinosus/gracilis) tendon and fixed with bioabsorbable screw (10 or 2 o'clock) and bioabsorbable screw</p> <p>All of the operations were performed by 1 experienced orthopaedic surgeon Rehabilitation was the same in both groups. (no brace)</p> <p>Assigned: 153 (75/78) Analysed: 121 (61/60)</p> <p>Jarvela 2007: Period of study: ? Assigned: 65 (35/30) Analysed: 55 (30/25)</p> <p>Jarvela 2008a: Period of study: between March 2003 and May 2005</p> <p>1. Double-bundle group (as above)</p> <p>2. Single-bundle bioabsorbable group (as above)</p> <p>3. Single-bundle metallic group: used quadrupled (semitendinosus/gracilis) tendon and fixed with metallic screws(10 or 2 o'clock)and metallic screw</p> <p>All the double-bundle ACL reconstructions were performed by one experienced orthopedic surgeon and all the single-bundle ACL reconstructions by two experienced orthopedic surgeon</p> <p>Assigned: 77 (25/27/25) Analysed: 63 (22/21/20)</p> <p>Jarvela 2008b: Period of study: ? Assigned: 60 (35/25) Analysed: 53 (32/21)</p>
Outcomes	<p>Mean length of follow up: 24 months (24-37)</p> <p>1. Operative time</p> <p>2. Rotational stability: Pivot-shift test</p> <p>3. Anterior knee laxity measurement : KT 1000 arthrometer</p> <p>4. ROM: full extension</p> <p>5. Knee scores: IKDC final score, Lysholm score</p> <p>6. MRI evaluation</p> <p>7. Complications: graft failure</p> <p>Jarvela 2007: Mean length of follow up: 14 months (12-20)</p> <p>1. Operative time</p> <p>2. Rotational stability: Pivot-shift test</p> <p>3. Anterior knee laxity measurement : KT 1000 arthrometer</p> <p>4. ROM: full extension</p> <p>5. Knee scores: Lysholm score, IKDC final score, the IKDC functional score</p> <p>6. Return to pre-injury level of sporting activity</p> <p>7. Complications</p> <p>Jarvela 2008a: Mean length of follow up: 2 years (24-35)</p> <p>1. Operation time</p>

	2. Rotational stability: pivot-shift test 3. Anterior knee laxity measurement: KT 1000 arthrometer 4. ROM: full extension 5. Knee scores: Lysholm score, IKDC final score, the IKDC functional score 6. Return to pre-injury level 7. Complications: second-look, revision ACL reconstruction Jarvela 2008b : Mean length of follow-up: 27 months (24 to 36) 1. Tunnel widening: femoral, tibial side 2. Rotational stability: Pivot-shift test 3. Anterior knee laxity measurement: KT 1000 arthrometer 4. ROM: full extension 5. Knee scores: Lysholm score, IKDC final score, the IKDC functional score 6. Complications: graft failure	
Notes	Analysis were performed after excluding new traumatic ACL rupture patients The preliminary results of the first 65 patients (SB, n = 30; DB, n = 35) were previously published in Jarvela 2007 . Correspondence with the author revealed that the participants of Jarvela 2008a and Jarvela 2008b “were partly the same”. Subsequent correspondence revealed that Jarvela 2008b “has almost similar population” to Jarvela 2007 .	
<i>Risk of bias</i>		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No available information.
Allocation concealment (selection bias)	Unclear risk	Quote: “randomisation was done by a closed envelopes technique into 2 different groups ...” Comment: No information of assignment envelope to judge whether was used with or without appropriate safeguards
Blinding (performance bias and detection bias) All outcomes	Low risk	All clinical examinations were performed by 2 blinded and independent examiners
Incomplete outcome data (attrition bias) All outcomes	High risk	15 patients (8 in the double-bundle group, and 7 in the single-bundle group) were not compliant to follow-up study 8 patients (1 in the double-bundle group and 7 in the single-bundle group) were excluded with a graft failure because a new knee trauma, and 9 patients (4 in the SB group and 5 in the DB group) were excluded with ACL reconstruction of the contralateral knee during the follow-up

Selective reporting (reporting bias)	High risk	The reporting in several publications of different outcomes for different sized populations at different follow-up times puts this trial at high risk of selective reporting bias
Other bias	Unclear risk	No other obvious bias. All of the operations were performed by one experienced orthopaedic surgeon. (In Jarvela 2008a , the single-bundle ACL reconstructions were performed by two experienced orthopedic surgeons.)

Volpi 2010

Methods	RCT Randomisation method: not stated Assessor blinding: an orthopaedic surgeon different from the one who performed the surgery Loss to follow-up: none
Participants	40 patients with ACL deficiency (+ meniscal injury) Inclusion criteria: specific sports activities age 18-45, no additional ligamentous lesions, absence of rheumatic pathologies, of type IV Outerbridge chondral lesions, of axial deviation of the knee, of any previous surgery to the examined knee Country: Italy Gender (female, male): 8,32 Mean age (years): D (30+4.9), S (27+5.7) Mean time since injury (months): D (31), S (28)
Interventions	Period of study: between 2002 and 2006 at the Sports Traumatology and Arthroscopic Surgery Unit of the Galeazzi Orthopaedic Institute of Milan 1. Double-bundle group: Used doubled (semitendinosus) tendon+ doubled (gracilis) tendon and fixed with pins, whilst at the tibial side both bundles were fixed with a metal staple or bioscrew 2. Single-bundle group: Used bone-patellar tendon-bone and fixed with two re-absorbable cross pins for the femoral fixation and both tibial rigid fix and re-absorbable pins for the tibial fixation Rehabilitation was the same in both groups (no brace). Assigned: 40 (20/20) Analysed: 40 (20/20)
Outcomes	Mean length of follow-up: 30 months 1. Anterior knee laxity measurement: KT 1000 arthrometer 2. ROM: full extension 3. Knee scores: Lysholm score, Tegner activity scale 4. Complications: infections, aseptic necrosis, condyle fractures, Cyclop's syndrome, restriction of the ROM or deep venous thrombosis

Notes	Outcomes: Lysholm score and Tegner activity score were presented median and range	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No available information.
Allocation concealment (selection bias)	Unclear risk	No available information.
Blinding (performance bias and detection bias) All outcomes	Low risk	An orthopaedic surgeon other than the one who performed the surgery
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up and the exclusions from the analyses.
Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	Unclear risk	No other obvious bias.

Wang 2009

Methods	RCT Randomisation method: not mentioned Assessor blinding: not mentioned Loss to follow-up: none
Participants	64 patients with ACL deficiency (+ meniscal injury, chondral lesion) Inclusion criteria: primary reconstruction, no combined PCL, MCL, LCL, no open plate, and no abnormal contralateral extremity morbidity Country: China Gender (female, male): D (3,29), S (12,20) Mean age (years): D (23.6+5.2), S (27.3+10.0) Mean time since injury (months): D (14.7+26.5), S (23.3+42.2)
Interventions	Period of study: May 2005 to May 2006 1. Double-bundle group: Used doubled (semitendinosus) tendon + doubled (gracilis) tendon and fixed with two Endobutton (11,11.30 or 1.00,1.30 o'clock) and two bioabsorbable screws or staples 2. Single-bundle group: Used quadrupled (semitendinosus/gracilis) tendon and fixed with Endobutton (11 or 1 o'clock) and bioabsorbable screw or staples All the ACL reconstructions were operated by one senior surgeon The same rehabilitation protocol was applied to both groups (brace) Assigned: 64 (32/32)

	Analysed: 64 (32/32)	
Outcomes	Mean length of follow up: 14.4 months 1. Operative time 2. ROM deficit: flexion, extension 3. Thigh diameter 4. KT-2000 at 30 and 90 degree 5. Knee flexion-extension strength using Biodex 6. Knee scores: Lysholm score, Tegner score, IKDC score	
Notes	Double-bundle group had a significant higher lateral meniscus tear incidence and higher bilateral meniscus tear incidence	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "... were randomly assigned into two groups ... "
Allocation concealment (selection bias)	Unclear risk	No available information.
Blinding (performance bias and detection bias) All outcomes	High risk	Not mentioned for assessor blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up and the exclusions from the analyses.
Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	High risk	Double-bundle group had a significant higher lateral meniscus tear incidence and higher bilateral meniscus tear incidence All the ACL reconstructions were operated by one senior surgeon

Yagi 2007

Methods	Quasi-RCT Randomisation method: the patient's month of birth Assessor blinding: two independent surgeons who were not blinded Loss to follow-up at 1 year: none Loss to follow-up at 33 months: 5 patients (2 patients in the DB group, 2 patients in the AM group, and 1 patient in the PL group) (Fujita 2011)
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Participants	<p>60 patients with unilateral ACL deficiency (+ meniscal injury)</p> <p>Inclusion criteria: ACL insufficiency (clinical & MRI), no previous ligament reconstruction or concomitant ligament injury of the affected knee</p> <p>Country: Japan</p> <p>Gender (female, male): D (13,7), S-AM (14,6), S-PL (15,5)</p> <p>Mean age (years): D (22.3), S-AM (22.9), S-PL (22)</p> <p>Mean time since injury (months): D (10.8+12.8), S-AM (11.3+13.9), S-PL (10.6+14.1)</p>
Interventions	<p>Period of study: ?</p> <p>1. Double-bundle group: Used quadrupled (semitendinosus/gracilis) tendon + doubled (semitendinosus) tendon and fixed with two Endobuttons and post screws</p> <p>2. Single-bundle anteromedial group: Used quadrupled (semitendinosus) tendon + doubled (gracilis) tendon and fixed with Endobutton CL (1.30, 10.30 o'clock) and post screw</p> <p>3. Single-bundle posterolateral group: Used quadrupled (semitendinosus) tendon + doubled (gracilis) tendon and fixed with Endobutton CL and post screw</p> <p>All procedures were performed, or directly supervised, by the single surgeon</p> <p>The same postoperative regimen was followed in all groups (brace)</p> <p>Assigned: 60 (20/20/20)</p> <p>Analysed: 60 (20/20/20) (1 year)</p> <p>Analysed: 55 (18/18/19) (33 months)</p>
Outcomes	<p>Mean length of follow up: 1 year / 33 months (Fujita 2011)</p> <p>1. Manual laxity tests: Lachman test, Pivot-shift test</p> <p>2. Anterior knee laxity measurement: KT 1000 arthrometer, acceleration of the tibial motion</p> <p>3. ROM deficit: Heel height difference</p> <p>4. Knee scores: Lysholm knee scores, Tegner activity scores, IKDC score</p> <p>5. Maximum extension and flexion strength using Cybex testing</p> <p>6. Complication: rerupture</p>
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "was quasi-randomised ... according to the patient's month of birth."
Allocation concealment (selection bias)	High risk	Comment: Possibly foreseen assignment.
Blinding (performance bias and detection bias) All outcomes	High risk	Two independent surgeons who were not blinded.

Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up and the exclusions from the analyses at 1 year follow-up. Two patients in the DB group, 2 patients in the AM group, and 1 patient in the PL group were loss to follow-up at 33 months follow-up (Fujita 2011).
Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	Unclear risk	No other obvious bias. All procedures were performed, or directly supervised, by the single surgeon

Zaffagnini 2008

Methods	RCT Randomisation method: computer-generated randomisation tables Assessor blinding: an independent, blinded surgeons Loss to follow-up: 10 patients
Participants	100 patients with unilateral ACL insufficiency (+ meniscal injury, MCL grade II, chondral lesion) Inclusion criteria: positive Lachman and Pivot shift test respect to contralateral healthy knee After allocation, 4 patients with grade III MCL, 12 patients with PCL, and 2 patients with Outerbridge grade 3-4 chondral injuries were excluded from the study Country: Italy Gender (female, male): 32, 40 Mean age (years): D (27,(21-46)), S (26,(19-45)) Mean time since injury (months): D (6.9+10.4), S (8.2+10.4)
Interventions	Period of study: between 2000 and 2002 1. Double-bundle group: Used doubled (semitendinosus/gracilis) tendon looped around lateral condyle and fixed with staple 2. Single-bundle plus lateral plasty group: Used doubled (semitendinosus/gracilis) tendon + lateral plasty and fixed with staple ACL insufficiency who were operated by the same surgical staff All patients of both groups underwent the same post-operative rehabilitation protocol. (no brace) Assigned: 100 (50, 50) Analysed: 72 (37,35)
Outcomes	Mean length of follow up: 3.9 years (3-5) 1. Manual laxity tests: Pivot-shift test 2. Anterior knee laxity measurement: KT 2000 arthrometer, acceleration of the tibial motion 3. ROM deficit: Heel height difference

	4. Knee scores: IKDC score, Tegner score, activity rating scale score 5. Harvest site pain, subjective evaluation 6. Return to sport activity, time to recover sport	
Notes	Cointervention with lateral plasty in single-bundle group. Significant difference regarding pre-operative Psychovitality Questionnaire score between the two groups (double bundle: 15; single bundle: 13; P = 0.009)	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "... were assigned to ... systematically following a completely randomised protocol based on the use of computer-generated randomisation tables."
Allocation concealment (selection bias)	Unclear risk	No available information.
Blinding (performance bias and detection bias) All outcomes	Low risk	Outcome assessment was blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	10 patients were lost follow-up but did not mention how many patients from each group After allocation, 4 patients with grade III MCL, 12 patients with PCL, and 2 patients with Outerbridge grade 3-4 chondral injuries were excluded from the study
Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	High risk	Significant difference regarding pre-operative Psychovitality Questionnaire score between the two groups (double bundle: 15; single bundle: 13; P 5 0.009) ACL insufficiency who were operated by the same surgical staff

Zaffagnini 2011

Methods	RCT Randomisation method: computer-generated randomisation tables Assessor blinding: four independent observers Loss to follow-up: 8 patients	
Participants	100 patients with unilateral ACL insufficiency (+ meniscal injury, MCL grade II, chondral lesion) Inclusion criteria: positive Lachman and Pivot shift test respect to contralateral healthy knee After allocation, 3 patients with grade III MCL, 10 patients with PCL injury or with Outerbridge grade 3-4 chondral injuries were excluded from the study Country: Italy Gender (female,male): 37, 42 Mean age (years): D (27+9), S (26+9.5) Mean time since injury (months): D (8.9+10.4), S (8.6+10.4)	
Interventions	Period of study: between 1992 and 2000 1. Double-bundle group: used doubled (semitendinosus/gracilis) tendon looped around lateral condyle and fixed with cortical staple at femoral side and with staple at tibial side 2. Single-bundle group: used bone-patellar tendon-bone and fixed with interference screw (10, or 2 o'clock) at femoral side and with interference screw at tibial side All patients were operated by the two senior authors or under their supervision All patients of both groups underwent the same post-operative rehabilitation protocol. (no brace) Assigned: 100 (50, 50) Analysed: 79 (40,39)	
Outcomes	Mean length of follow up: 8.6 years (8 to 10) 1. Manual laxity tests: Pivot-shift test 2. Anterior knee laxity measurement: KT 2000 arthrometer 3. ROM deficit 4. Knee scores: IKDC score, Tegner score 5. Anterior knee pain 6. Time to sport resumption 7. Complication: graft failure, meniscal injury	
Notes	The outcome of IKDC score were presented as frequency in graph figure	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "... using of computer-generated randomisation tables."
Allocation concealment (selection bias)	Unclear risk	No available information.

Blinding (performance bias and detection bias) All outcomes	Low risk	Outcome assessment was blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	8 patients were lost follow-up but the report did not mention how many patients from each group After allocation, 3 patients with grade III MCL, 10 patients with PCL injury or with Outerbridge grade 3-4 chondral injuries were excluded from the study
Selective reporting (reporting bias)	Unclear risk	No available information.
Other bias	Unclear risk	No available information. All patients were operated on by the two senior authors or under their supervision

ACL: anterior cruciate ligament

D: double-bundle

MCL: medial cruciate ligament

PCL: posterior cruciate ligament

S: single-bundle

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Aglietti 2007	Not a randomised trial: a prospective comparative cohort study was performed to compare among single or double incision double-bundle and single bundle ACL reconstruction
Asagumo 2007	Not a randomised trial: a retrospective comparative study to compare the clinical outcomes of anatomic double-bundle anterior cruciate ligament reconstruction via hamstring tendons with single-bundle reconstruction
Branch 2011	Not a randomised trial: a matched pair analysis to compare instrumented tests of knee stability between patients treated with double-bundle and single-bundle ACL reconstruction
Gobbi 2012	While this seemed to be a quasi-randomised study where patients were allocated to the one treatment or the other depending on their order of arrival, it had a very high risk of selection bias from post-randomisation exclusions amounting to over 56% of the study sample
Gudas 2008	Not a randomised trial: a non-randomised clinical study was performed to compare the clinical and radiological outcome between double-bundle and single-bundle anterior cruciate ligament (ACL) reconstructions with semitendinosus tendon in athletes

(Continued)

Hemmerich 2011	Randomised comparison of single- versus double-bundle reconstruction for rotational knee kinematics during a dynamic task. Not in scope of the review
Hemmerich 2011a	Not a clinical trial: randomised controlled cadaver study to determine differences in rotational laxity outcome in single-bundle and double-bundle reconstructions
Hofbauer 2010	Not a randomised trial: a retrospective comparative study to compare rotational and translational stability after computer-navigated standard single-bundle, and anatomic double-bundle ACL reconstruction
Izawa 2011	Not a randomised trial: a prospective comparative cohort study was performed to compare rotatory stability between double-bundle and single bundle ACL reconstruction
Kanaya 2009	Quasi-randomised trial comparing the lower femoral tunnel placed single-bundle ACL reconstruction with double-bundle ACL reconstruction intraoperatively. Knee stability was measured by non-standard measuring device and there are insufficient details for analysis
Kim 2009	Not a randomised trial: a retrospective comparative study was performed to compare between single-bundle and double-bundle ACL reconstruction with use of quadriceps tendon-bone autografts
Kondo 2008	Not a randomised trial: a prospective, comparative cohort study of >300 patients to compare anatomic double-bundle and single-bundle ACL reconstruction procedures
Monaco 2007	Not a randomised trial and different research question from our objective review: the goal of this comparative study is to evaluate the effect of a lateral reconstruction in addition to a standard single bundle ACL reconstruction as compared with an anatomic double bundle ACL reconstruction
Plaweski 2011	Not a randomised trial: this clinical study was performed to compare anteroposterior and rotational stabilities using in vivo computer navigation between double-bundle and single-bundle ACL reconstruction
Sadoghi 2011	Not a randomised trial: a prospective comparative cohort analysis of bone-patellar tendon-bone single-bundle versus double-bundle ACL reconstruction procedure
Tsuda 2009	Not a randomised trial: a prospective comparison study to compare between lateralized single-bundle and double-bundle ACL reconstruction. Patient assignment was not randomised and the choice was made by the patients
Xu 2008	Not a randomised trial: a retrospective comparative study to compare the clinical results of double and single bundle anterior cruciate ligament ACL reconstruction
Yasuda 2006	Not a randomised trial: a prospective comparative cohort study to compare the clinical outcome of anatomic double-bundle anterior cruciate ligament (ACL) reconstruction with that of nonanatomic single- and double-bundle reconstructions

Characteristics of studies awaiting assessment *[ordered by study ID]*

Cermak 2011

Methods	RCT
Participants	18 participants, all sportsmen
Interventions	Period of study: not stated 1. Double-bundle reconstruction: four stranded semitendinosus/gracilis tendon 2. Single-bundle reconstruction: four stranded semitendinosus/gracilis tendon
Outcomes	Follow-up: 2 years 1. IKDC 2. Objective knee tests 3. Gait analysis 4. Lysholm knee score 5. Pain
Notes	Brief preliminary report (description without data of 3 months data) of trial in French

Nikolopoulos 2011

Methods	RCT
Participants	36 patients from 17 to 36 years old (mean age 23)
Interventions	Period of study: January 2006 to May 2008 1. Double-bundle reconstruction: four stranded hamstring tendons 2. Single-bundle reconstruction: four stranded hamstring tendons
Outcomes	Mean length of follow-up (months): 16 (8 to 22) Primary outcomes are: 1. Pivot-shift test 2. anterior laxity test with KT-1000 arthrometer 3. Lysholm knee score
Notes	Available in printed conference abstract only.

Stefani 2011

Methods	RCT
Participants	60 patients with chronic anterior knee instability
Interventions	Period of study: Between July and October 2005 1. Double-bundle reconstruction: double bundle ACL reconstruction with hamstrings, tibial fixation with 1 bioscrew in each tunnel + a single staple for both grafts, in-out femoral tunnels with 2 Endobuttons 2. Single-bundle reconstruction: single bundle ACL reconstruction with hamstrings, tibial fixation with a staple and a bioscrew, femoral tunnel at 10.30 - 13.30 and Endobutton fixation

	Rehabilitation protocol was the same for both groups.
Outcomes	Mean length of follow-up (months): 44 (42-45) Primary outcomes are: 1. IKDC score 2. anterior laxity test with KT-1000 arthrometer 3. Lysholm knee score
Notes	Available in printed conference abstract only.

Characteristics of ongoing studies [ordered by study ID]

DRKS00000333

Trial name or title	Kinematics of the knee after single bundle and double bundle anterior cruciate ligament (ACL) reconstruction. A prospective randomised study
Methods	Randomised clinical trial.
Participants	Estimated enrolment: ? patients with isolated ACL tear, aged >18 years
Interventions	1. Double-bundle ACL reconstruction 2. Single-bundle ACL reconstruction
Outcomes	Follow-up: 24 months Primary outcomes are: Determination of the knee joint kinematics by means of gait analysis, computer tomographies and fluoroscopy
Starting date	March 2010
Contact information	Julius Wolff Institut, Charité- Universitätsmedizin Berlin Centrum für Sportwissenschaft und Sportmedizin Berlin. Email: bill.taylor@charite.de
Notes	Recruiting. End date: ?

NCT00418964

Trial name or title	Functional, clinical & radiological outcome of anterior cruciate ligament reconstruction: A prospective randomised control clinical trial studies comparing bone patella bone, single bundle and double bundle method
Methods	Randomized clinical trial.
Participants	Estimated enrolment: 62 patients with ACL rupture; aged 18 to 40 years

NCT00418964 (Continued)

Interventions	1. Double-bundle ACL reconstruction: used hamstring tendons 2. Single-bundle ACL reconstruction: used hamstring tendons 3. Single-bundle ACL reconstruction: used bone-patellar tendon-bone
Outcomes	Follow-up: 24 months Primary outcomes are: 1. IKDC Subjective Knee Form Score 2. Percentage Distal Femoral Bone Mineral Density (BMD) Decrease
Starting date	December 2006
Contact information	Pauline Lui, Assistant Professor, Chinese University of Hong Kong
Notes	Completed. End date: June 2011

NCT00529958

Trial name or title	A randomised clinical trial comparing three methods for anterior cruciate ligament reconstruction: patellar tendon, quadruple semitendinosus/gracilis and double-bundle semitendinosus/gracilis grafts
Methods	Randomised clinical trial, double-blind.
Participants	Estimated enrolment: 60 patients with isolated ACL lesion; aged 14 to 50 years
Interventions	1. Double-bundle ACL reconstruction: used semitendinosus/gracilis (Hamstring) Tendon autograft 2. Single-bundle ACL reconstruction: used semitendinosus/gracilis (Hamstring) Tendon autograft 3. Single-bundle ACL reconstruction: used patellar tendon autograft
Outcomes	Follow-up: 1, 2, 5 and 10 years Primary outcomes are: 1. Quality of life outcome 2. Incidence of traumatic ACL re-ruptures and atraumatic graft failures 3. Knee laxity as measured by the KT arthrometer 4. Radiographic (x-ray) changes using the International Knee Documentation Committee (IKDC) grading 5. Pivot Shift 6. Complications 7. Surgical times 8. Return to pre-injury activity level as measured by the Tegner Activity Scale 9. IKDC subjective score and overall group grade 10. Work-related outcomes using the Cincinnati Occupational Rating Scale
Starting date	September 2007
Contact information	Denise Chan, Orthopaedic Research Coordinator, University of Calgary

NCT00529958 (Continued)

Notes	Ongoing. End date: December 2020
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NCT01025895

Trial name or title	Anterior cruciate ligament (ACL) reconstruction: Single bundle versus double bundle
Methods	Randomised clinical trial.
Participants	Estimated enrolment: 60 patients with ACL injury; aged 16 to 40 years
Interventions	1. Double-bundle ACL reconstruction 2. Single-bundle ACL reconstruction
Outcomes	Follow-up: 24 months Primary outcomes are: 1. WOMAC 2. VAS 3. SF-36 4. Lysholm score 5. Knee society score 6. isokinetic muscle strength testing
Starting date	January 2010
Contact information	Assaf-Harofeh Medical Center
Notes	Not yet open for participant recruitment. End date: January 2013

NCT01033188

Trial name or title	Single bundle or double bundle anterior cruciate ligament reconstruction. a randomised, controlled trial
Methods	Randomised clinical trial, single-blind.
Participants	Estimated enrolment: 150 patients with ACL rupture; aged 18 to 40 years
Interventions	1. Double-bundle ACL reconstruction 2. Single-bundle ACL reconstruction Use of semitendinosus/gracilis tendon, autograft.
Outcomes	Follow-up: 1,2,5 years Primary outcomes are: 1. KOOS score(QOL) 2. Lachman test 3. pivot shift test

NCT01033188 (Continued)

	4. return to sport activity 5. Osteoarthritic change
Starting date	November 2009
Contact information	Prof. Lars Engebretsen, Ullevål Universitetssykehus. Email: bjzl@uus.no
Notes	Recruiting. End date: June 2012

NCT01319409

Trial name or title	Single- vs. double-bundle ACL reconstruction: A prospective randomised trial
Methods	Randomized clinical trial, double-blind.
Participants	Estimated enrolment: 160 patients scheduled for ACL reconstruction within 6 months of injury; aged 16 to 50 years
Interventions	1. Double-bundle ACL reconstruction 2. Single-bundle ACL reconstruction Use of autograft quadriceps tendon with a bone block.
Outcomes	Follow-up: 24 months Primary outcomes are: 1. knee adduction 2. knee external rotation 3. anterior tibial translation 4. graft elongation 5. pivot shift test 6. KT-1000 knee ligament arthrometer 7. IKDC Subjective Knee Form Score
Starting date	March 2011
Contact information	James J Irrgang, UPMC Centerfor Sports Medicine, Pittsburgh, Pennsylvania, United States, 15203. Email: jirrgang@pitt.edu
Notes	Recruiting. End date: February 2016

NCT01358656

Trial name or title	Comparison of the anterior cruciate ligament reconstruction using single bundle and double bundle techniques: prospective clinical study
Methods	Randomised clinical trial, single-blind.
Participants	Estimated enrolment: 40 patients with isolated ACL injury; aged 20 to 45 years
Interventions	1. Double-bundle ACL reconstruction 2. Single-bundle ACL reconstruction Use of semitendinosus/gracilis tendon.
Outcomes	Follow-up: 2 years Primary outcomes are: 1. Isokinetic testing 2. Subjective and Objective IKDC Scores 3. Kinematic evaluation
Starting date	January 2010
Contact information	Isabela U Luques, MSc, São Paulo, Brazil. Email: isabela@vita.org.br
Notes	Recruiting. End date: January 2012

NCT01377129

Trial name or title	Reconstruction of the anterior cruciate ligament: a comparative MRI study evaluating residual rotational laxity for single versus double bundle surgical techniques
Methods	Randomised clinical trial.
Participants	Estimated enrolment: 54 patients with ACL injury; aged >18 years
Interventions	1. Double-bundle ACL reconstruction 2. Single-bundle ACL reconstruction
Outcomes	Follow-up: 24 months Primary outcomes are: 1. Residual rotational laxity during MRI 2. Lysholm score 3. IKDC score
Starting date	October 2011
Contact information	Philippe Marchand, MDCentre Hospitalier Universitaire de Nîmes Email: philippe.marchand@chu-nimes.fr

NCT01377129 (Continued)

Notes	Recruiting. End date: October 2015
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NCT01391650

Trial name or title	Rotational and anteroposterior stability of the knee joint after single- and double- bundle ACL reconstruction
Methods	Randomized clinical trial, single-blind.
Participants	Estimated enrolment: 60 patients with isolated ACL lesion and primary ACL replacement; aged 18 to 53 years
Interventions	1. Double-bundle ACL reconstruction: AM bundle being reconstructed first 2. Double-bundle ACL reconstruction: PL bundle being reconstructed first 3. Single-bundle ACL reconstruction Use of autograft quadriceps tendon with a bone block.
Outcomes	Follow-up: ? Primary outcomes are: 1. rotational movement tibia to femur 2. anterior-posterior movement tibia to femur 3. KT-1000 knee ligament arthrometer
Starting date	March 2010
Contact information	Komzak Martin, M.D., Hospital Znojmo
Notes	Completed. End date: May 2011

DATA AND ANALYSES

Comparison 1. Double-bundle versus single-bundle ACL reconstruction

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Subjective functional knee scores (I)	14		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Subjective IKDC score (Intermediate term)	3	204	Mean Difference (IV, Fixed, 95% CI)	-0.43 [-3.49, 2.62]
1.2 Subjective IKDC score (Long term)	4	272	Mean Difference (IV, Fixed, 95% CI)	1.66 [-0.73, 4.06]
1.3 Subjective IKDC score (Long term): RCTs only	3	159	Mean Difference (IV, Fixed, 95% CI)	0.87 [-1.69, 3.44]
1.4 IKDC functional score (Intermediate term)	1	55	Mean Difference (IV, Fixed, 95% CI)	0.0 [-0.53, 0.53]
1.5 Tegner activity score (Intermediate term)	3	148	Mean Difference (IV, Fixed, 95% CI)	0.31 [-0.19, 0.82]
1.6 Tegner activity score (Long term)	5	340	Mean Difference (IV, Fixed, 95% CI)	0.15 [-0.19, 0.50]
1.7 Tegner activity score (Long term): RCTs only	2	121	Mean Difference (IV, Fixed, 95% CI)	0.40 [-0.18, 0.99]
1.8 Tegner activity score (Extended term: > 5 years)	1	79	Mean Difference (IV, Fixed, 95% CI)	2.0 [1.12, 2.88]
1.9 Lysholm score (Intermediate term)	6	293	Mean Difference (IV, Fixed, 95% CI)	-0.28 [-1.62, 1.07]
1.10 Lysholm score (Long term)	5	263	Mean Difference (IV, Fixed, 95% CI)	0.12 [-1.50, 1.75]
1.11 Lysholm score (Long term): RCTs only	2	102	Mean Difference (IV, Fixed, 95% CI)	-1.37 [-4.06, 1.32]
1.12 Cincinnati knee score (Intermediate term)	1	70	Mean Difference (IV, Fixed, 95% CI)	-1.0 [-5.24, 3.24]
2 Subjective functional knee scores (II)	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.1 Lysholm score > 95 (Long term)	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.2 Tegner activity score > 7 (Long term)	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Long term knee pain	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
4 Adverse effects and complications	12		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.1 Infection	9	678	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.46, 2.81]
4.2 Infection: RCTs only	5	399	Risk Ratio (M-H, Fixed, 95% CI)	3.78 [0.73, 19.61]
4.3 Infection (Intermediate term)	2	130	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.07, 15.36]
4.4 Infection (Long term)	7	548	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [0.45, 3.01]
4.5 Hardware problem	4	412	Risk Ratio (M-H, Fixed, 95% CI)	4.13 [0.95, 17.87]
4.6 Hardware problem (Intermediate term)	1	70	Risk Ratio (M-H, Fixed, 95% CI)	2.0 [0.19, 21.06]

4.7 Hardware problem (Long term)	3	342	Risk Ratio (M-H, Fixed, 95% CI)	6.96 [0.92, 52.62]
4.8 Cyclop lesion (Intermediate term)	2	130	Risk Ratio (M-H, Fixed, 95% CI)	0.78 [0.14, 4.28]
4.9 Graft failure	6	354	Risk Ratio (M-H, Fixed, 95% CI)	0.45 [0.07, 2.90]
4.10 Graft failure: RCTs only	4	261	Risk Ratio (M-H, Fixed, 95% CI)	0.5 [0.05, 5.27]
4.11 Graft failure (Long term)	5	275	Risk Ratio (M-H, Fixed, 95% CI)	0.45 [0.07, 2.90]
4.12 Graft failure (Extended term > 5 years)	1	79	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Return to pre-injury level of activity / sport participation	5	417	Risk Ratio (M-H, Fixed, 95% CI)	1.15 [1.07, 1.25]
5.1 Intermediate term	2	75	Risk Ratio (M-H, Fixed, 95% CI)	1.21 [0.98, 1.48]
5.2 Long term	3	342	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [1.05, 1.24]
6 Objective measures of knee stability (1): IKDC examination	12		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
6.1 IKDC knee examination (Intermediate term): normal or nearly normal	3	185	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.97, 1.08]
6.2 IKDC knee examination (Long term): normal or nearly normal	9	773	Risk Ratio (M-H, Random, 95% CI)	1.05 [1.01, 1.08]
6.3 IKDC knee examination (Long term): normal or nearly normal (RCTs only)	7	592	Risk Ratio (M-H, Random, 95% CI)	1.06 [1.01, 1.10]
6.4 IKDC knee examination (Extended term > 5 years): normal or nearly normal	1	79	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.93, 1.07]
7 Objective measures of knee stability (2): side-to-side difference	14		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
7.1 Side-to-side difference (mm) measured by KT-1000 arthrometer (Intermediate term)	6	319	Mean Difference (IV, Fixed, 95% CI)	-0.31 [-0.52, -0.10]
7.2 Side-to-side difference (mm) measured by KT-1000 arthrometer (Intermediate term): RCTs only	4	215	Mean Difference (IV, Fixed, 95% CI)	-0.69 [-1.07, -0.31]
7.3 Side-to-side difference (mm) measured by KT-1000 arthrometer (Long term)	5	363	Mean Difference (IV, Fixed, 95% CI)	-0.74 [-1.10, -0.37]
7.4 Side-to-side difference (mm) measured by KT-1000 arthrometer (Long term): RCTs only	3	240	Mean Difference (IV, Fixed, 95% CI)	-0.49 [-0.95, -0.03]
7.5 Side-to-side difference (mm) measured by KT-2000 arthrometer (Intermediate term)	1	64	Mean Difference (IV, Fixed, 95% CI)	0.21 [-0.36, 0.78]

7.6 Side-to-side difference (mm.) measured by KT-2000 arthrometer (Long term)	3	293	Mean Difference (IV, Fixed, 95% CI)	-0.11 [-0.54, 0.32]
7.7 Side-to-side difference (mm.) measured by KT-2000 arthrometer (Long term): RCTs only	2	180	Mean Difference (IV, Fixed, 95% CI)	0.03 [-0.72, 0.78]
7.8 Side-to-side difference (mm) measured by KT-2000 arthrometer (Extended term > 5 years)	1	79	Mean Difference (IV, Fixed, 95% CI)	0.70 [0.08, 1.32]
7.9 Side-to-side difference (mm) measured by Telos device (Intermediate term)	1	40	Mean Difference (IV, Fixed, 95% CI)	-0.30 [-1.66, 1.06]
7.10 Side-to-side difference (mm) measured by Telos device (Long term)	2	151	Mean Difference (IV, Fixed, 95% CI)	-0.11 [-0.64, 0.43]
8 Objective measures of knee stability (3): side-to-side difference < 3 mm	4		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
8.1 Side-to-side difference < 3 mm measured by KT-1000 arthrometer (long term)	4	391	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [1.05, 1.30]
8.2 Side-to-side difference < 3 mm measured by KT-2000 arthrometer (long term)	1	72	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.73, 1.32]
9 Intraoperative stabilities	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
9.1 Intraoperative anteroposterior translations (mm) at 30° of flexion	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
9.2 Intraoperative rotational stabilities (degree) at 30° of flexion	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Anterior stability	6		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
10.1 Anterior Drawer test (Long term): normal or nearly normal	2	268	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.97, 1.05]
10.2 Lachman test (Intermediate term): normal or nearly normal	3	120	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.98, 1.18]
10.3 Lachman test (Long term): normal or nearly normal	4	376	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [1.03, 1.13]
10.4 Lachman test (Long term): normal or nearly normal (RCTs only)	2	270	Risk Ratio (M-H, Fixed, 95% CI)	1.11 [1.04, 1.17]
11 Anterior stability (random-effects meta-analysis)	4		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
11.1 Lachman test (Long term): normal or nearly normal	4	376	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.98, 1.15]
12 Rotational stability (Pivot-shift test)	13		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

12.1 Pivot-shift test (Intermediate term): normal or nearly normal	6	289	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.98, 1.08]
12.2 Pivot-shift test (Intermediate term): normal or nearly normal (RCTs only)	3	145	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.94, 1.04]
12.3 Pivot-shift test (Long term): normal or nearly normal	9	713	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [1.02, 1.09]
12.4 Pivot-shift test (Long term): normal or nearly normal (RCTs only)	6	552	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [1.01, 1.08]
12.5 Pivot-shift test (Extended term > 5 years)	1	79	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.93, 1.07]
13 Range of motion deficit	8		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
13.1 Flexion deficit	8	584	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.29, 2.67]
13.2 Flexion deficit: RCTs only	6	478	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.29, 2.67]
13.3 Flexion deficit (Intermediate term)	3	159	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.26, 3.41]
13.4 Flexion deficit (Long term)	7	518	Risk Ratio (M-H, Fixed, 95% CI)	1.35 [0.26, 7.02]
13.5 Extension deficit	7	546	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.49, 1.78]
13.6 Extension deficit: RCTs only	6	478	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.49, 1.78]
13.7 Extension deficit (Intermediate term)	2	119	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.45, 1.83]
13.8 Extension deficit (Long term)	6	480	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.20, 5.26]
14 Recurrent injury with and without re-operation	7		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
14.1 Overall Meniscal injury	6	598	Risk Ratio (M-H, Fixed, 95% CI)	0.46 [0.23, 0.92]
14.2 Overall Meniscal injury: RCTs only	4	470	Risk Ratio (M-H, Fixed, 95% CI)	0.44 [0.20, 0.97]
14.3 Meniscal injury (Intermediate term)	2	115	Risk Ratio (M-H, Fixed, 95% CI)	0.75 [0.10, 5.85]
14.4 Meniscal injury (Long term)	4	459	Risk Ratio (M-H, Fixed, 95% CI)	0.67 [0.25, 1.84]
14.5 Meniscal injury (Extended term > 5 years)	1	79	Risk Ratio (M-H, Fixed, 95% CI)	0.3 [0.11, 0.84]
14.6 Overall Traumatic ACL rupture	3	240	Risk Ratio (M-H, Fixed, 95% CI)	0.17 [0.03, 0.96]
14.7 Traumatic ACL rupture (Intermediate term)	1	59	Risk Ratio (M-H, Fixed, 95% CI)	0.11 [0.01, 1.91]
14.8 Traumatic ACL rupture (Long term)	3	240	Risk Ratio (M-H, Fixed, 95% CI)	0.17 [0.03, 0.96]

Analysis 1.1. Comparison 1 Double-bundle versus single-bundle ACL reconstruction, Outcome 1 Subjective functional knee scores (I).

Review: Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

Comparison: 1 Double-bundle versus single-bundle ACL reconstruction

Outcome: 1 Subjective functional knee scores (I)

(Continued ...)

(... Continued)

(Continued ...)

(... Continued)

(1) Interim data from Jarvela 2007

(2) Interim data from Jarvela 2007

(3) Interim data from Jarvela 2008b. Results for Suolalainen 2011: mean scores 88 versus 88

(4) Data from Fujita 2011

(5) Interim data from Jarvela 2008b. Results for Suolalainen 2011: mean scores 88 versus 88

Analysis 1.2. Comparison 1 Double-bundle versus single-bundle ACL reconstruction, Outcome 2 Subjective functional knee scores (II).

Review: Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

Comparison: 1 Double-bundle versus single-bundle ACL reconstruction

Outcome: 2 Subjective functional knee scores (II)

Analysis 1.3. Comparison 1 Double-bundle versus single-bundle ACL reconstruction, Outcome 3 Long term knee pain.

Review: Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

Comparison: 1 Double-bundle versus single-bundle ACL reconstruction

Outcome: 3 Long term knee pain

Analysis 1.4. Comparison 1 Double-bundle versus single-bundle ACL reconstruction, Outcome 4 Adverse effects and complications.

Review: Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

Comparison: 1 Double-bundle versus single-bundle ACL reconstruction

Outcome: 4 Adverse effects and complications

(Continued ...)

(1) Data from Fujita 2011

(2) Data from Fujita 2011

Analysis 1.5. Comparison 1 Double-bundle versus single-bundle ACL reconstruction, Outcome 5 Return to pre-injury level of activity / sport participation.

Review: Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

Comparison: 1 Double-bundle versus single-bundle ACL reconstruction

Outcome: 5 Return to pre-injury level of activity / sport participation

(Continued ...)

(1) Subgroup data from Jarvela 2007a

Analysis 1.6. Comparison 1 Double-bundle versus single-bundle ACL reconstruction, Outcome 6 Objective measures of knee stability (I): IKDC examination.

Review: Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

Comparison: 1 Double-bundle versus single-bundle ACL reconstruction

Outcome: 6 Objective measures of knee stability (I): IKDC examination

(Continued ...)

(1) Subgroup data from Jarvela 2007

Analysis 1.7. Comparison 1 Double-bundle versus single-bundle ACL reconstruction, Outcome 7 Objective measures of knee stability (2): side-to-side difference.

Review: Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

Comparison: 1 Double-bundle versus single-bundle ACL reconstruction

Outcome: 7 Objective measures of knee stability (2): side-to-side difference

(Continued ...)

(... Continued)

(Continued ...)

(... Continued)

(1) Interim data from Jarvela 2007

(2) Interim data from Jarvela 2007

(3) Data from Fujita 2011

Analysis 1.8. Comparison 1 Double-bundle versus single-bundle ACL reconstruction, Outcome 8 Objective measures of knee stability (3): side-to-side difference < 3 mm.

Review: Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

Comparison: 1 Double-bundle versus single-bundle ACL reconstruction

Outcome: 8 Objective measures of knee stability (3): side-to-side difference < 3 mm

Analysis 1.9. Comparison 1 Double-bundle versus single-bundle ACL reconstruction, Outcome 9 Intraoperative stabilities.

Review: Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

Comparison: 1 Double-bundle versus single-bundle ACL reconstruction

Outcome: 9 Intraoperative stabilities

Analysis 1.10. Comparison 1 Double-bundle versus single-bundle ACL reconstruction, Outcome 10 Anterior stability.

Review: Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

Comparison: 1 Double-bundle versus single-bundle ACL reconstruction

Outcome: 10 Anterior stability

Analysis 1.11. Comparison 1 Double-bundle versus single-bundle ACL reconstruction, Outcome 11 Anterior stability (random-effects meta-analysis).

Review: Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

Comparison: 1 Double-bundle versus single-bundle ACL reconstruction

Outcome: 11 Anterior stability (random-effects meta-analysis)

Analysis 1.12. Comparison 1 Double-bundle versus single-bundle ACL reconstruction, Outcome 12 Rotational stability (Pivot-shift test).

Review: Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

Comparison: 1 Double-bundle versus single-bundle ACL reconstruction

Outcome: 12 Rotational stability (Pivot-shift test)

(Continued ...)

(1) Interim data from Jarvela 2007

(2) Interim data from Jarvela 2007

(3) Data from Fujita 2011

Analysis 1.13. Comparison 1 Double-bundle versus single-bundle ACL reconstruction, Outcome 13 Range of motion deficit.

Review: Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

Comparison: 1 Double-bundle versus single-bundle ACL reconstruction

Outcome: 13 Range of motion deficit

(Continued ...)

(1) Interim data from Jarvela 2007

(2) Interim data from Jarvela 2007

(3) Interim data from Jarvela 2007

(4) Interim data from Jarvela 2008b

(5) Interim data from Jarvela 2007

(6) Interim data from Jarvela 2007

(7) Interim data from Jarvela 2007

(8) Interim data from Jarvela 2008b

Analysis 1.14. Comparison 1 Double-bundle versus single-bundle ACL reconstruction, Outcome 14 Recurrent injury with and without re-operation.

Review: Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults

Comparison: 1 Double-bundle versus single-bundle ACL reconstruction

Outcome: 14 Recurrent injury with and without re-operation

(Continued ...)

(1) Interim data from Jarvela 2007

(2) Interim data from Jarvela 2007

ADDITIONAL TABLES

Table 1. Risk of bias tool

Domain	Review authors' judgement
Sequence generation (<i>selection bias</i>)	Was the allocation sequence adequately generated? HIGH RISK / LOW RISK / UNCLEAR RISK
Allocation concealment (<i>selection bias</i>)	Was allocation adequately concealed? HIGH RISK / LOW RISK / UNCLEAR RISK
Blinding of participants, personnel and outcome assessors (<i>performance and detection bias</i>) <i>Outcome:</i> Patient-rated outcomes (e.g. functional knee scores, joint position sense, pain, recurrent injury)	Was knowledge of the allocated intervention adequately prevented during the study? HIGH RISK / LOW RISK / UNCLEAR RISK
Blinding of participants, personnel and outcome assessors (<i>performance and detection bias</i>) <i>Outcome:</i> Clinician-rated outcomes (e.g. knee stability tests, range of motion, complications)	Was knowledge of the allocated intervention adequately prevented during the study? HIGH RISK / LOW RISK / UNCLEAR RISK
Incomplete outcome data (<i>attrition bias</i>) <i>Outcome:</i> Patient-rated outcomes (e.g. functional knee scores, joint position sense, pain, recurrent injury)	Were incomplete outcome data adequately addressed? HIGH RISK / LOW RISK / UNCLEAR RISK
Incomplete outcome data (<i>attrition bias</i>) <i>Outcome:</i> Clinician-rated outcomes (e.g. knee stability test, range of motion, complications)	Were incomplete outcome data adequately addressed? HIGH RISK / LOW RISK / UNCLEAR RISK
Selective outcome reporting (<i>reporting bias</i>)	Are reports of the study free of suggestion of selective outcome reporting? HIGH RISK / LOW RISK / UNCLEAR RISK
Other sources of bias Selection bias: imbalance in confounders at entry. Major differences in baseline characteristics: age, sex, acute versus chronic injuries, isolated ACL rupture versus ACL rupture combined with other soft-tissue knee injuries	Was the study apparently free of other problems that could put it at a high risk of bias? HIGH RISK / LOW RISK / UNCLEAR RISK
Other sources of bias Performance bias: for instance, provision of other interventions that should be comparable in both groups (e.g. various forms of fixation methods, number of strands of tendon graft, operative techniques, rehabilitation protocols, timing of intervention; or major differences in experience or personal characteristics of treatment providers, especially experience)	Was the study apparently free of other problems that could put it at a high risk of bias? HIGH RISK / LOW RISK / UNCLEAR RISK

Table 2. Further characteristics of included studies

Journal	Country	Double bundle	Single bundle			Brace	Partici-pants	%male	%loss to F/U	% miss-ing from analyses data
			group I	group II	group III					
Adachi 2004	Japan	4(ST/G)	4(ST/G)	-	-	Y	133	60	7.5	18.8
Aglietti 2010	Italy	2(ST/G)	2(ST/G)	-	-	N	70	75.7	0	0
Araki 2011	Japan	4(ST/G)	4(ST/G)	-	-	?	20	50	0	0
Ibrahim 2009	Kuwait	4(ST/G)	4(ST/G)	4(ST/G)	4(ST/G)	N	218	100	8.3	8.3
Misonoo 2012	Japan	4(ST/G)	4(ST/G)	-	-	Y	44	50	0	0
Muneta 2007	Japan	4(ST)	4(ST)	-	-	Y	84	50	9.5	19
Park 2010	South Korea	6(ST/G)	4(ST/G)	-	-	?	147	72.6	4.8	23.1
Sastre 2010	Spain	4(ST/G)	4(ST/G)	-	-	?	40	?	0	0
Siebold 2008	Germany	4(ST/G)	4(ST/G)	-	-	Y	70	90	0	0
Song 2009	South Korea	4(TA)	4(TA)	-	-	?	40	77.5	5	5
Streich 2008	Germany	4(ST)	4(ST)	-	-	N	50	100	2	2
Suoma-lainen 2011	Finland	4(ST/G)	4(ST/G)	-	-	N	153	71.9	9.8	20.9
		-----	-----	-----	-----	-----	-----	-----	-----	-----
		4(ST/G)	4(ST/G)	-	-	N	65	?	9.2	7.7
Other re-ports		4(ST/G)	4(ST/G)	4(ST/G)	-	N	77	66.2	5.2	18.2
Jarvela 2007		4(ST/G)	4(ST/G)	-	-	N	60	71.7	1.7	11.7
Jarvela 2008a										
Jarvela 2008b										

Table 2. Further characteristics of included studies (Continued)

Volpi 2010	Italy	4(ST/G)	BPTB	-	-	N	40	80	0	0
Wang 2009	China	4(ST/G)	4(ST/G)	-	-	Y	64	76.6	0	0
Yagi 2007 Other re- port Fujita 2011	Japan	6(ST/G)	6(ST/G)	6(ST/G)	-	Y	60	30	0 8.3	0 8.3
Zaffagnini 2008	Italy	2(ST/G)	2(ST/G)	-	-	N	100	55.6	10	28
Zaffagnini 2011	Italy	4(ST/G)	BPTB	-	-	N	100	53.2	8	21

number: number of strands

BPTB: bone-patellar tendon-bone

TA: tibialis anterior tendon

ST: semitendinosus tendon

ST/G: semitendinosus/gracilis tendon

APPENDICES

Appendix I. Search strategies

The Cochrane Library (Wiley Online Library)

Up to May 2010

#1 MeSH descriptor Anterior Cruciate Ligament, this term only (528)

#2 (anterior NEAR/2 cruciate* NEAR/2 ligament*):ti,ab,kw (778)

#3 (#1 OR #2) (778)

#4 MeSH descriptor Joint Instability, this term only (383)

#5 MeSH descriptor Orthopedic Procedures, this term only (592)

#6 MeSH descriptor Tendon Transfer, this term only (44)

#7 MeSH descriptor Arthroscopy, this term only (854)

#8 MeSH descriptor Reconstructive Surgical Procedures, this term only (384)

#9 MeSH descriptor Transplants, this term only (31)

#10 MeSH descriptor Transplantation, Autologous, this term only (986)

- #11 MeSH descriptor Transplantation, Homologous explode all trees (1035)
- #12 MeSH descriptor Tendons, this term only with qualifier: TR (126)
- #13 (graft* or reconstruct* or autograft* or autoplasty or allograft* or homograft*):ti,ab,kw (13534)
- #14 (#4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13) (15802)
- #15 (double-bundle* or double bundle* or anatomic* or double fascicle*):ti,ab,kw (2072)
- #16 (single-bundle* or single bundle* or standard* or single fascicle*):ti,ab,kw (53544)
- #17 (#15 AND #16) (374)
- #18 (#3 AND #14 AND #17) (18)

Search extension 2010 to 27 February 2012

- #1 MeSH descriptor Anterior Cruciate Ligament, this term only (604)
- #2 (anterior NEAR/2 cruciate* NEAR/2 ligament*):ti,ab,kw (867)
- #3 (#1 OR #2) (867)
- #4 MeSH descriptor Joint Instability, this term only (451)
- #5 MeSH descriptor Orthopedic Procedures, this term only (678)
- #6 MeSH descriptor Tendon Transfer, this term only (53)
- #7 MeSH descriptor Arthroscopy, this term only (945)
- #8 MeSH descriptor Reconstructive Surgical Procedures, this term only (471)
- #9 MeSH descriptor Transplants, this term only (31)
- #10 MeSH descriptor Transplantation, Autologous, this term only (1129)
- #11 MeSH descriptor Transplantation, Homologous explode all trees (1085)
- #12 MeSH descriptor Tendons, this term only with qualifier: TR (142)
- #13 (graft* or reconstruct* or autograft* or autoplasty or allograft* or homograft*):ti,ab,kw (14793)
- #14 (#4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13) (17321)
- #15 (double-bundle* or double bundle* or anatomic* or double fascicle*):ti,ab,kw (2389)
- #16 (single-bundle* or single bundle* or standard* or single fascicle*):ti,ab,kw (59064)
- #17 (#15 AND #16) (435)
- #18 (#3 AND #14 AND #17) (26)
- #19 (#3 AND #14 AND #17), from 2010 to 2012 (9)

MEDLINE (OVID WEB)

Run May 2010 (Ovid MEDLINE)

1. Anterior Cruciate Ligament/ (7947)
2. (anterior adj2 cruciate\$ adj2 ligament\$ or ACL).tw. (10836)
3. or/1-2 (12150)
4. Joint Instability/ (12140)
5. Orthopedic Procedures/ (9951)
6. Tendon Transfer/ (3134)
7. Arthroscopy/ (13490)
8. Reconstructive Surgical Procedures/ (23525)
9. Transplants/ (1590)
10. Transplantation, Autologous/ (40111)
11. Tendons/tr or Tendons, Para-Articular/tr (17655)
12. (graft\$ or reconstruct\$ or autograft\$ or autoplasty or allograft\$ or homograft\$).tw. (346433)
13. or/4-12 (419010)
14. (double-bundle\$ or double bundle\$ or anatomic\$).tw. (132200)
15. (single-bundle\$ or single bundle\$ or standard\$).tw. (582641)
16. and/14-15 (8822)
17. and/3,13,16 (202)

18. Randomised controlled trial.pt. (307044)
19. Controlled clinical trial.pt. (82583)
20. randomized.ab. (213548)
21. placebo.ab. (124800)
22. Drug therapy.fs. (1454000)
23. randomly.ab. (154964)
24. trial.ab. (220571)
25. groups.ab. (1032095)
26. or/18-25 (2688707)
27. Humans/ (11751423)
28. 26 and 27 (2194646)
29. and/17,28 (36)

Search extension 2010 to 27 February 2012 (Ovid MEDLINE, Ovid MEDLINE In-Process & Other Non-Indexed Citations, and Ovid MEDLINE Daily Update)

1. Anterior Cruciate Ligament/ (8404)
2. ((anterior adj2 cruciate\$ adj2 ligament\$) or ACL).tw. (12121)
3. or/1-2 (13408)
4. Joint Instability/ (12938)
5. Orthopedic Procedures/ (10988)
6. Tendon Transfer/ (3234)
7. Arthroscopy/ (14428)
8. Reconstructive Surgical Procedures/ (23097)
9. Transplants/ (1678)
10. Transplantation, Autologous/ (40486)
11. Tendons/tr or Tendons, Para-Articular/tr (3274)
12. (graft\$ or reconstruct\$ or autograft\$ or autoplasty or allograft\$ or homograft\$).tw. (380723)
13. or/4-12 (443211)
14. (double-bundle\$ or double bundle\$ or anatomic\$).tw. (146274)
15. (single-bundle\$ or single bundle\$ or standard\$).tw. (660484)
16. and/14-15 (9830)
17. and/3,13,16 (271)
18. Randomised controlled trial.pt. (320830)
19. Controlled clinical trial.pt. (83585)
20. randomized.ab. (236643)
21. placebo.ab. (133322)
22. Drug therapy.fs. (1504762)
23. randomly.ab. (174086)
24. trial.ab. (244320)
25. groups.ab. (1140885)
26. or/18-25 (2876941)
27. exp Animals/ not Humans/ (3668183)
28. 26 not 27 (2455157)
29. 17 and 28 (73)
30. (2010\$ or 2011\$ or 2012\$).ed. (2100062)
31. 29 and 30 (26)

EMBASE (OVID WEB)

Run May 2010

- 1 Anterior Cruciate Ligament Rupture/ or Anterior Cruciate Ligament Reconstruction/ or Anterior Cruciate Ligament Injury/ (4405)
- 2 Anterior Cruciate Ligament/ (3893)
- 3 ((anterior adj2 cruciate\$ adj2 ligament\$) or ACL).tw. (9330)
- 4 or/1-3 (10581)
- 5 Tendon Graft/ or Tissue Graft/ or Muscle Graft/ or exp Bone Graft/ (20410)
- 6 exp Transplantation/ (367670)
- 7 (graft\$ or reconstruct\$ or autograft\$ or autoplasty or allograft\$ or homograft\$).tw. (271844)
- 8 or/5-7 (492196)
- 9 (double-bundle\$ or double bundle\$ or anatomic\$ or double fascicle\$).tw. (103709)
- 10 (single-bundle\$ or single bundle\$ or standard\$ or single fascicle\$).tw. (479393)
- 11 and/9-10 (7338)
- 12 and/4,8,11 (141)
- 13 Clinical Trial/ (591488)
- 14 Randomized Controlled Trial/ (186217)
- 15 Randomization/ (28005)
- 16 Single Blind Procedure/ (9322)
- 17 Double Blind Procedure/ (77383)
- 18 Crossover procedure/ (22820)
- 19 Placebo/ (141046)
- 20 randomi?ed controlled trial\$.tw. (39310)
- 21 rct.tw. (3429)
- 22 random allocation.tw. (680)
- 23 randomly allocated.tw. (11045)
- 24 allocated randomly.tw. (1405)
- 25 (allocated adj2 random).tw. (573)
- 26 single blind\$.tw. (8075)
- 27 double blind\$.tw. (89889)
- 28 ((treble or triple) adj blind\$).tw. (152)
- 29 placebo\$.tw. (118161)
- 30 Prospective study/ (93844)
- 31 or/13-30 (776747)
- 32 Case Study/ (7026)
- 33 case report.tw. (130350)
- 34 Abstract report/ or Letter/ (534311)
- 35 or/32-34 (669024)
- 36 31 not 35 (749902)
- 37 limit 36 to Human (714422)
- 38 and/12,37 (22)

Search extension 2010 to 27 February 2012

1. Anterior Cruciate Ligament Rupture/ or Anterior Cruciate Ligament Reconstruction/ or Anterior Cruciate Ligament Injury/ (5382)
2. Anterior Cruciate Ligament/ (6989)
3. ((anterior adj2 cruciate\$ adj2 ligament\$) or ACL).tw. (14099)
4. or/1-3 (16236)
5. Tendon Graft/ or Tissue Graft/ or Muscle Graft/ or exp Bone Graft/ (23925)
6. exp Transplantation/ (598335)
7. (graft\$ or reconstruct\$ or autograft\$ or autoplasty or allograft\$ or homograft\$).tw. (427679)
8. or/5-7 (801494)
9. (double-bundle\$ or double bundle\$ or anatomic\$ or double fascicle\$).tw. (166923)
10. (single-bundle\$ or single bundle\$ or standard\$ or single fascicle\$).tw. (794845)
11. and/9-10 (12241)
12. and/4,8,11 (300)

13. Clinical trial/ (824578)
14. Randomized Controlled Trial/ (297832)
15. Randomization/ (55780)
16. Single Blind Procedure/ (14842)
17. Double Blind Procedure/ (103205)
18. Crossover Procedure/ (31939)
19. Placebo/ (192988)
20. randomized controlled trial\$.tw. (68991)
21. rct.tw. (8544)
22. random allocation.tw. (1093)
23. randomly allocated.tw. (16267)
24. allocated randomly.tw. (1736)
25. (allocated adj2 random).tw. (692)
26. single blind\$.tw. (11543)
27. double blind\$.tw. (121530)
28. ((treble or triple) adj blind\$).tw. (256)
29. placebo\$.tw. (165407)
30. Prospective Study/ (183136)
31. or/13-30 (1176973)
32. Case Study/ (14853)
33. case report.tw. (214550)
34. Abstract Report/ or Letter/ (809058)
35. or/32-34 (1034217)
36. 31 not 35 (1143050)
37. limit 36 to Human (1042082)
38. and/12,37 (50)
- 39 (2010\$ or 2011\$ or 2012\$).em. (2678891)
- 40 38 and 39 (18)

CONTRIBUTIONS OF AUTHORS

Thavatchai Tiamklang is the guarantor of the review.

Thavatchai Tiamklang drafted the protocol and full review. Sermsak Sumanont, Thanit Foocharoen and Malinee Laopaiboon revised and approved the protocol and full review.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Khon Kaen Hospital, Ministry of Public Health, Thailand.
- Khon Kaen University, Faculty of Medicine, Khon Kaen, Thailand.
- Khon Kaen University, Faculty of Public Health, Thailand.

External sources

- Thai Cochrane Network, Thailand.
- Thailand Research Fund (Senior Research Scholar), Thailand.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Searches

As it was archived in 2007, we did not search the National Research Register (NRR) Archive as stated in our protocol.

We did not handsearch bibliographies of trial reports or contact the corresponding authors of studies identified by the search strategies to obtain other relevant studies.

Due to a lack of access, we have not searched specific proceedings of knee surgery, arthroscopic surgery and sports medicine meetings and conferences from the following organizations: [European Society of Sports Traumatology Knee Surgery and Arthroscopy \(ESSKA\)](#), [American Orthopaedic Society for Sports Medicine \(AOSSM\)](#), [International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine \(ISAKOS\)](#), [American Academy of Orthopaedic Surgeons \(AAOS\)](#), World Congress on Orthopaedic Sports Trauma, and [Arthroscopy Association of North America \(AANA\)](#) as stated in our protocol.

Types of outcome assessment

Clarification added regarding secondary outcome: 'recurrent injury' so that this include new injuries (e.g. meniscal injuries).

Timing of outcome assessment

We have added another follow-up category 'extended term' (greater than five years of ACL reconstruction) to the 'Types of outcome measures'.

INDEX TERMS

Medical Subject Headings (MeSH)

*Anterior Cruciate Ligament Injuries; Anterior Cruciate Ligament [surgery]; Anterior Cruciate Ligament Reconstruction [*methods]; Knee Joint; Pain, Postoperative [etiology]; Randomized Controlled Trials as Topic; Rupture [surgery]

MeSH check words

Adult; Humans