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Review Article

Clinical efficacy of anterior cruciate ligament reconstruction: is an anatomical double - bundle or anatomical single - bundle better? A meta-analysis

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Abstract: Purpose: In recent years, anterior cruciate ligament reconstruction (ACLR) technology has developed rapidly and patients report better satisfaction relating to the clinical efficacy. However surgeons remain unsure whether the use of anatomical double-bundle reconstruction is superior to the single bundle. This review aims to compare the clinical outcomes between anatomical double bundle ACL reconstruction (ADB-ACLR) and anatomical single bundle ACL reconstruction (ASB-ACLR) in primary anterior cruciate ligament reconstruction. Methods: A search was performed in the Medline, Embase, and Cochrane databases. Only randomized clinical trials (RCTs) were included in the meta-analysis and all of them were Level I evidence. The comparative outcomes were instrument-measured anterior laxity, Lachman test, pivot shift, clinical outcomes including objective/subjective International Knee Documentation Committee (IKDC) score, Lysholm score, Tegner activity scale and complication rates of graft failure, including early osteoarthritis and extension/flexion deficits. Results: A total of 13 RCT articles and 1887 patients are included. ADB-ACLR led to more rotational stability measured by pivot shift with odds ratio (OR) of 1.70 (95% confidence interval [CI] = 1.18 to 2.45) with heterogeneity ($P = 0.01$ $I^2 = 50\%$) and revealed statistical significance in a subjective IKDC score with a standard mean difference (SMD) of 0.17 (95% CI = 0.02 to 0.31, $P = 0.15$ $I^2 = 31\%$) compared with ASB-ACLR. Conclusion: Patients who underwent ADB-ACLR showed better rotational stability, a higher subjective IKDC sore and less flexion deficits compared with ASB-ACLR with no human differences. By using ADB-ACLR, Asian patients had higher Tegner activity scale while American and European patients showed no difference. Other comparative outcomes were not significantly different between ADB-ACLR, ASB-ACLR and human race.

Keywords: Anterior cruciate ligament reconstruction, anatomic, single-bundle, double-bundle, meta-analysis

Introduction

ACL injuries are increasingly common in athletes and those involved in traffic accidents with 250 000 cases occurring annually in the United States [1, 2]. ACL injuries can lead to long-term knee functional deficits, often significantly limiting the patients' involvement in sporting activities. ACL reconstruction (ACLR) aims at restoring both the kinematics and stability of the injured knee to prevent future degenerative changes. ACLR has become a commonly performed procedure and beneficial clinical outcomes have been reported. However, the success rates of ACL reconstruction vary between 69% and 95%, which is still far from excellent [3-6].

The natural ACL consists of two bundles, the anteromedial (AM) and the posterolateral (PL). AM bundle controls anteroposterior (AP) laxity whereas the PL bundle ensures rotational stability independently [7, 8]. For a long time, transtibial single-bundle (SB) ACLR has been the standard treatment in orthopedic sports medicine to treat ACL-injured knees [9, 10]. But this approach does not restore the normal two-bundle anatomy and may therefore not restore normal knee kinematics [11], which could lead to early osteoarthritic changes over time [12, 13]. Laboratory and clinical studies have also demonstrated that double-bundle (DB) ACLR can better restore the stability of the knee compared to SB-ACLR [14-17]. It must be stressed that DB-ACLR is different form anatomic ACLR

[18]. DB-ACLR is merely a step closer to replicating the native ACL anatomy without regard to the precision of graft tunnel positions so it can still be performed non-anatomically. Anatomic ACLR refers to the restoration of the functions of the ACL and its native insertion sites, which is believed to be the key to the success of this operation. Thus, the anatomy of ACL and anatomic ACLR have been the focus issues discussed in recent years [19, 20].

In 2008 Meredick et al. [21] published a meta-analysis that reported no difference in the outcome of single- and double-bundle reconstruction in the middle-term following-up, as measured by the KT-1000 arthrometer and the pivot-shift test. Possibly their meta-analysis was the first, however they included a mix of a small sample of randomized and observational studies without anatomic reconstruction. Up to recently, several meta-analyses have compared outcomes of single and double-bundle reconstructions and drawn some conclusions, which is still defective independently. In conducting this meta-analysis we explored a wide range of literature and only included anatomic DB-ACLR and SB-ACLR and performed subgroup analysis for race via American and European versus Asian. Most importantly, we only included randomized clinical trials (RCTs) with level I evidence. The purpose of this meta-analysis is to provide an up-to-data assessment of whether anatomic DB-ACLR leads to better clinical outcomes than anatomic SB-ACLR. We hypothesized that anatomic DB-ACLR would achieve better clinical outcomes compared with anatomic SB-ACLR.

Methods

Search strategy

This meta-analysis was conducted according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guideline (www.prisma-statement.org/) and followed the guidelines provided by the Cochrane Handbook [22]. Two authors separately performed Internet MEDLINE (www.ncbi.nlm.nih.gov/pubmed), EMBASE (www.elsevier.com/online-tools/embase), and Cochrane (www.cochrane.org) database searches for all English-language studies published before April 19, 2017. The key terms were "anterior cruciate ligament" OR "ACL" AND "surgery" OR "reconstruction" AND "anatomical".

Eligibility criteria

The eligibility criteria for inclusion were as follows: (1) studies were conducted in the recent ten years; (2) RCTs with level I evidence was included; (3) both the SB and DB reconstruction techniques were regarded as anatomic regardless of graft type, and the fixation method should be stated in literature that grafts were placed in the native ACL footprints on both the tibial and femoral sides; (4) ACL rupture of human adults where without additional knee injuries; (5) studies comparing anatomic SB and DB primary arthroscopic ACLR; (6) full reports of both postoperative kinematic and clinical function outcomes.

RCTs (Level II evidence) comparative clinical studies, case series, expert opinions, reviews, and editorial comments were excluded, in addition studies reporting nonclinical outcomes or in vitro and animal studies were excluded.

Study selection and data collection

Two authors selected relevant studies according to the titles and abstracts for full review. Then two authors analyzed the full articles using the eligibility criteria for inclusion of studies. If the abstract was not comprehensive enough to make a decision, the full text was analyzed. The two authors worked independently in previous steps, and any disagreement was resolved by consensus or by consultation with the senior author when the consensus was not reached.

Data extracted from included studies were as follows: general information (author, published year, journal, title, study type, level of evidence and country); surgical intervention data on the basis of Anatomic ACL Reconstruction Checklist [23]; number of patients; follow-up time, and evaluation indices which included kinematic data (pivot-shift test, Lachman test, KT-1000/2000 measurements, objective International Knee Documentation Committee [IKDC]), functional scores (subjective IKDC score, Lysholm score, Tegner activity scale), and complication events (graft failure, osteoarthritis rates, flexion/extension deficits [FD/ED]).

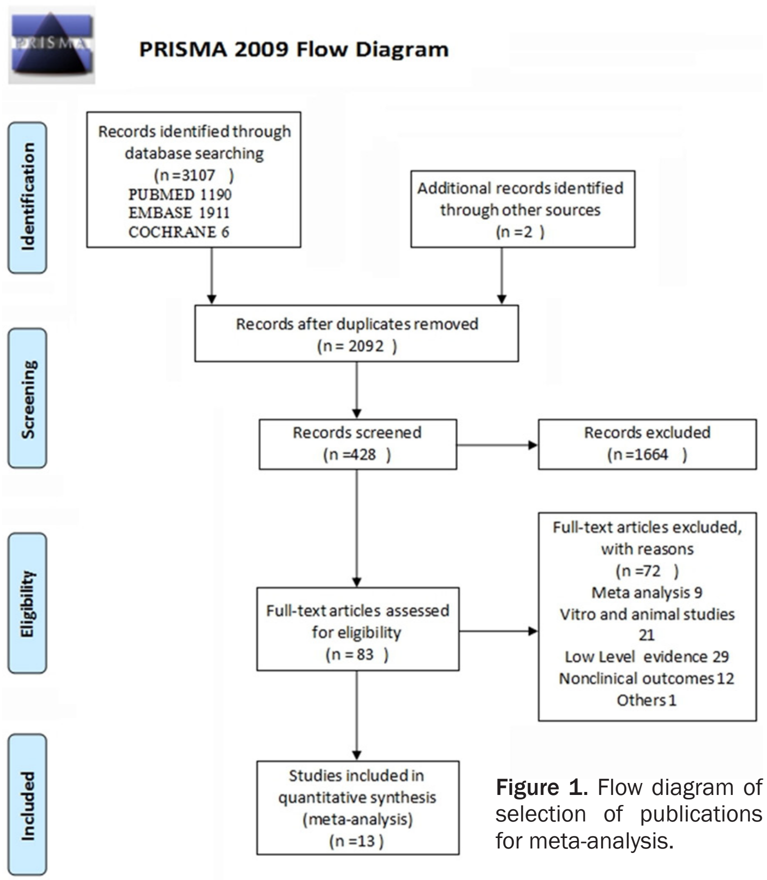

Figure 1. Flow diagram of selection of publications for meta-analysis.

Statistical analysis

The data analysis and meta-analysis were performed via the RevMan software (RevMan 5.3.5; The Nordic Cochrane Centre/The Cochrane Collaboration, Copenhagen, Denmark). Dichotomous data (pivot-shift test, Lachman test, objective IKDC, graft failure, osteoarthritis rates) were reported by odds ratios (ORs) with 95% confidence intervals (CIs) by the Mantel-Haenszel statistical method and Random Effects analysis model. While continuous data (KT-1000/2000 measurements, subjective IKDC score, Lysholm score, Tegner activity score, FD/ED) were expressed as standardized mean differences (SMDs) with 95% Cis by Inverse Variance statistical method and Random Effects analysis model. Heterogeneity was assessed by Q test and I-square, according to the Cochrane Handbook a p less than 0.01 or an I-square more than 50% was regarded as having high heterogeneity. Contacting the Authors and data processing.

We contacted the authors of all included articles for relevant unpublished outcomes. There were 3 studies [24-26] that used median and range to report relevant results, but authors did not respond to our request for their original data. These 3 articles included sample sizes of 50 and 48, 32 and 34, and 34 and 32, respectively, in DB-ACLR and SB-ACLR. Hence, a reliable formula was used to transform the median and range into mean and standard deviation (SD) to obtain a comprehensive database. The formulas were as follows: when the sample size is between 25 and 70, the median and range/4 could best estimate the mean and SD, respectively [27].

Subgroup analysis

Subgroup analysis revealed that Asian ACL was different in Americans and Europeans. For this reason, the included studies were divided into 2 subgroup of race to provide evidence for better ACLR options. Subgroup analysis was conducted in all the previously mentioned evaluation indices with the exception of the Lachman test, because of the lack of Asian data.

Risk of bias

Two authors independently assessed risk of bias for each included RCT according to The Cochrane Collaboration's tool [28]. Any disagreements were resolved by consultation with the senior author.

Results

Study selection and study characteristics

Our search through key terms resulted in 3107 hits: 1190 from Medline; 1911 from Embase; and 6 from the Cochrane database. After removal of duplicates, 2092 studies remained. After review of titles and abstracts, 83 full text of studies were retrieved according to the eligibility criteria. After cross reference searching, 2 more studies were added-13 RCTs [24-26,

Table 1. Characteristics of included studies

Race	Surgery	Sample of patients, n	Follow-up, month	Number of Strands, AM; PL	Tension Pattern (flexion angle at tensioning)	Diameter of Strands, mm, AM; PL	Drilling, AM; PL	Femoral Fixation	Tibial Fixation
Asian	DB	10	13.5	2 ST; 2 GT	AM60/PL15	U	TT; TP	EndoButton	Cancellous screws
	SB	10	12	4 ST+GT	15		TP		
European	DB	131	51	U	AM60/PL0	U	TP; TP	EndoButton	Bioabsorbable screws
	SB	78	50.5	U	0		TP		
European	DB	50	24	2 ST; 2/3 GT	AM40-60/PL5-10	6-6.5; 5-5.5	TP; TP	Metal interference screws	Bioresorbable screws
	SB	48	24	4/5 ST+GT	(10-20)	7.5-5.5	TP		
Asian	DB	34	16.3		AM60/PL0	6.9±0.5; 5.6±0.5	TP; TP	Endobutton	Bioabsorbable screws+staple
	SB	32	16.3			7.3±0.5	TP		
Americian	DB	108	24	2 ST; 2 GT	AM45/PL10-20	U	TP; TP	Endobutton	Bioabsorbable screws
	SB (PT)	106	24	U	(10-20)	9-10	TT		
	SB (HT)	108	24	4 ST+GT	(10-20)	U	TT OR TP		
European	DB	34	26	2 GT; 2 ST	AM50/PL10	U	TP; TP	Biodegradable cross pins	Bioabsorbable screws
	SB	28	26	4 ST+GT	30	7.5-10	TP		
European	DB	35	24	2 ST; 2 GT	AM40/PL20	U	OI; OI	Titanium RCI screws	Metal bridge
	SB	35	24	4 ST+GT			OI		Bony bridge
European	DB	20	60	2 ST; 2 GT	U	7; 6	TP; TP	Bioabsorbable screws	Bioabsorbable screws
	SB (BS)	21	60	4 ST+GT		8	TP		
	SB (MS)	24	60	4 ST+GT		8	TP		
European	DB	35	19	2 ST; 2 GT	AM60/PL20	U	TT; TP	EndoButton	Biodegradable screws
	SB	35	19	4 ST+GT			U		
Asian	DB (AU)	154	36	2ST; 2GT	AM30/PL0	7-8; 6-7	TP; TP	EndoButton	Biodegradable screws
	DB (AL)	128	36	2 TA; 2 TA ALLOGRAFT	AM30/PL0	>8	TP; TP		
	SB (AL)	142	36	4 TA	U	>8	TP		
European	DB	46	60	2 ST; 2/3 GT	AM40-60/PL5-10	6.5-7; 6	TP; TP	Metal interference screws	Bioresorbable screws
	SB	41	60	4/5 ST+GT	(10-20)	7.5-8.5	TP		
Asian	DB	32	80	3/4 ST; 3/4 GT	AM80:PL20	7-8; 6-7	TP; TP	EndoButton	Bioabsorbable screws+staple
	SB	34	80	3/4 ST+3/4 GT	30	7-10	TP		
Asian	DB (HT)	67	24	ST OR GT	U	4.5-7.0	TP/OI; TP	EndoButton	Biodegradable screws
	SB (PT)	69	24	BPTB		10	TP		

Table 2. Reporting of Outcomes of Included Studies

Study	Pivot-Shift Test	Lachman Test	KT-1000/2000 Measurements	Objective IKDC	Subjective IKDC	Lysholm Score	Tegner Activity scale	ROM	Revision	OA Radiograph
Agliett (2009)	Y	Y	Y1000	Y	Y				Y	
Ahlden (2013)	Y	Y	Y1000			Y	Y	Y		
Araki (2011)	Y (EMS)	Y (EMS)	Y1000			Y		Y (HHD)		
Hussein (2012)	Y		Y1000	Y	Y	Y		Y	Y	
Karikis (2016)	Y	Y	Y1000			Y	Y	Y		Y
Liu (2016)	Y	Y	Y2000		Y	Y	Y	Y		
Mayr (2016)			Y1000	Y	Y				Y (NO)	Y
Mohtadi (2015)	Y		Y1000	Y	Y		Y		Y	
Sasak (2016)	Y		Y1000				Y	Y	Y	
Siebold (2008)	Y		Y1000	Y	Y	Y		Y		Y
Sun (2015)	Y			Y	Y	Y				Y
Suomalainen (2012)	Y		Y1000	Y		Y			Y	Y
Xu (2014)	Y		Y1000		Y	Y	Y			

Table 3. Grading of anatomic ACL reconstruction checklist in randomized controlled studies

Checklist Items	Araki (2011)	Hussein (2012)	Ahlden (2013)	Xu (2014)	Mohtadi (2015)	Mayr (2016)	Agliett (2009)	Suomalainen (2012)	Siebold (2008)	Sun (2015)	Karikis (2016)	Liu (2016)	Sasak (2016)
Individualization of surgery for each patient	N	N	N	N	N	N	N	N	N	N	N	N	N
Use of 30 scope	?	?	?	?	?	?	?	?	?	?	?	?	?
Use of an accessory medial portal	Y	Y	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y
Direct visualization of the femoral insertion site	Y	Y	Y	N	N	Y	Y	N	Y	Y	Y	N	Y
Measuring the femoral insertion site	N	N	N	N	N	Y	N	N	N	N	Y	N	Y
Visualization of the lateral intercondylar ridge	Y	Y	Y	N	N	Y	N	N	N	N	N	N	N
Visualization of the lateral bifurcate ridge	N	Y	Y	N	N	Y	N	N	N	N	N	N	N
Femoral tunnel in insertion site	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Transportal drilling of femoral ACL insertion sites	Y	Y	Y	Y	N	Y	Y	Y	N	Y	Y	Y	Y
Direct visualization of the tibial insertion site	Y	Y	N	N	N	N	Y	N	Y	Y	Y	N	N
Measuring the tibial insertion site	N	N	N	N	N	N	N	N	N	N	Y	N	Y
Tibial tunnel in the insertion site	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Femoral fixation documentation	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Tibial fixation documentation	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Knee flexion angle during femoral tunnel drilling	Y	Y	N	Y	Y	Y	Y	N	Y	Y	Y	Y	Y
Graft type documentation	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Knee flexion angle during tensioning	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	N
Suitable documentation of radiography	N	N	Y	N	N	Y	Y	Y	Y	N	Y	Y	Y
Total score	12	13	13	9	8	15	12	8	12	11	15	11	13

Y: clear documentation+1, N: no documentation+0, ?: unclear documentation+0.

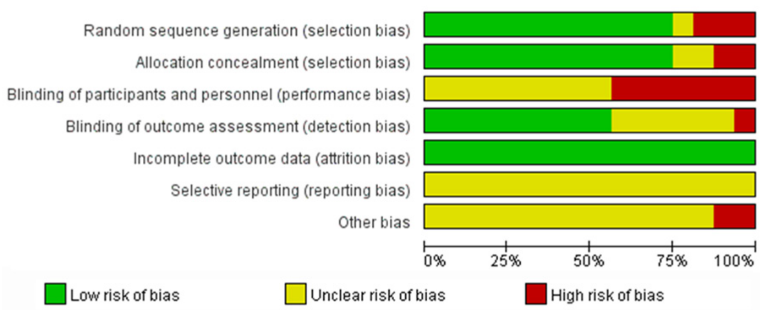

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

29-38] with 1887 patients were initially included in this meta-analysis (**Figure 1**). Studies with level I evidence were published in the most recent ten years. The 13 studies' general information is reported in **Table 1**, outcome evaluation indices are shown in **Table 2**. Mohtadi et al. [34] used the patellar tendon or the hamstring tendon as grafts for DB-ACLR. Sun et al. [37] studied 2 DB-ACLR techniques using either hamstring tendon autografts or tibialis anterior tendon allografts. Suomalainen et al. [38] investigated 2 SB-ACLRs using either metallic screws or bioabsorbable screws to fix the graft. The three studies, therefore, were respectively divided into 2 separate analyses to formulate a comprehensive database. Surgical intervention data according to the Anatomic ACL Reconstruction Checklist are listed in **Table 3**.

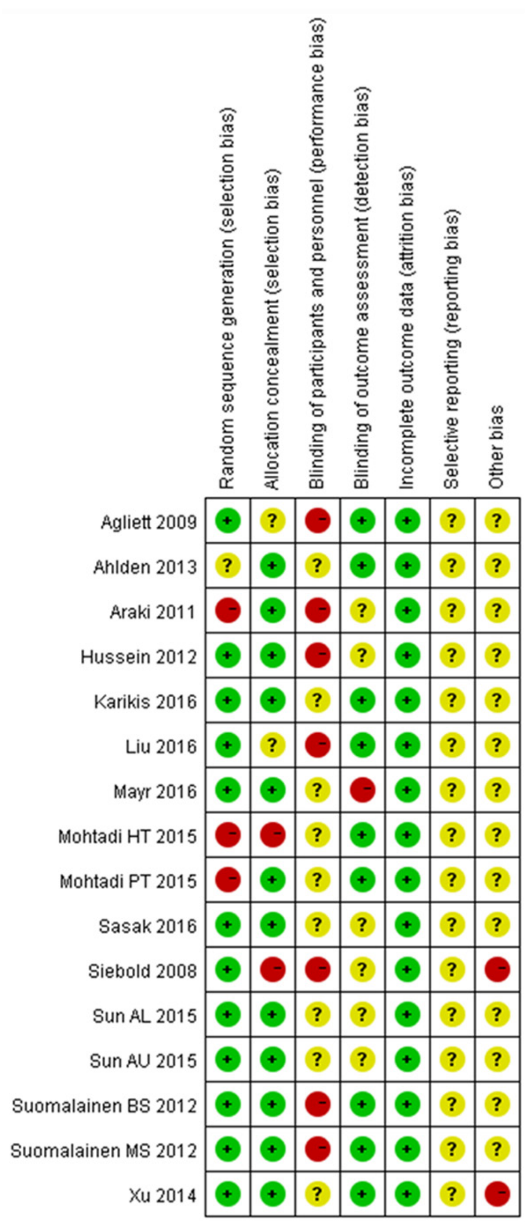

Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Assessment risk of bias

All of the selected RCTs had one or more limitations in the study design. Risk of bias graph and Risk of bias summary are reported in **Figures 2** and **3**, which showed a high risk of selection bias. As for reporting bias and other bias, with the exception of two studies [26, 36] that reported possible biases by themselves, it was difficult to judge if the level of bias was high or low risk.

Meta-analysis of outcomes evaluation indices

Anatomic DB versus SB ACLR: results of kinematic data

The pivot-shift test is widely used in rotational stability examinations. The outcome is often reported as 0 (negative), 1 (+), 2 (++), and 3 (+++), where 0 (negative) is normal. In total, 15 studies [24-26, 29-32, 34-38] reported the test. The OR was 1.70 (95% CI = 1.18 to 2.45) and the test of heterogeneity did not detect significant heterogeneity ($P = 0.01$; $I^2 = 50\%$) suggesting that anatomic DB-ACLR had a better postoperative rotational stability (**Figure 4**).

The Lachman test is an examination for anterior stability and its outcome also is graded as 0

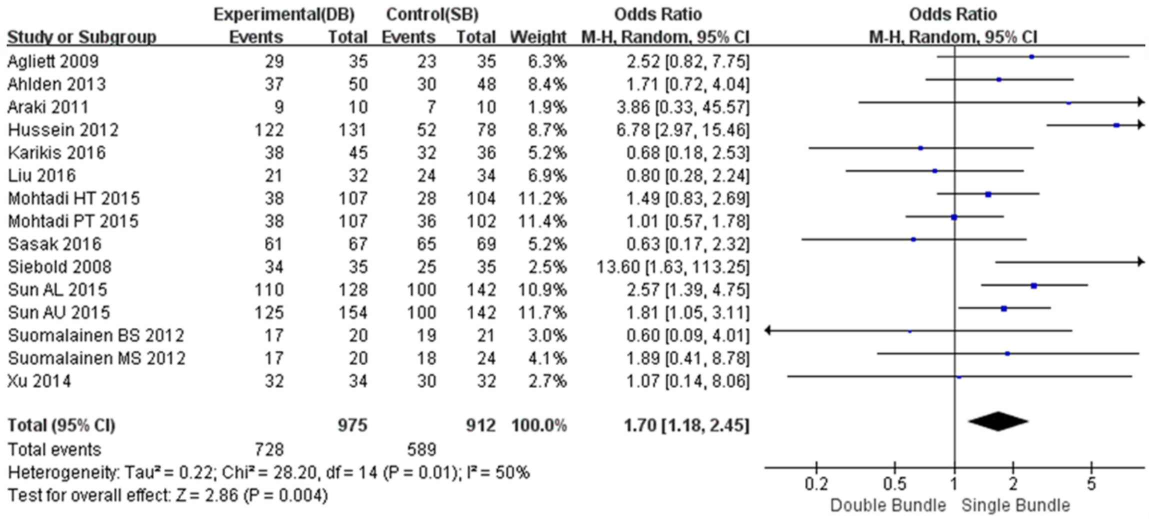

Figure 4. Forest plot shows odds ratio (OR) of pivot-shift test between anatomic double- and single-bundle anterior cruciate ligament reconstructions.

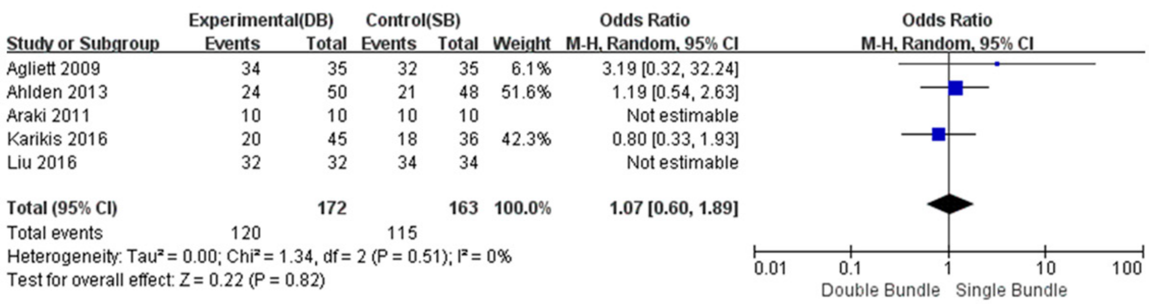

Figure 5. Forest plot shows odds ratio (OR) of Lachman test between anatomic double- and single-bundle anterior cruciate ligament reconstructions.

(negative), 1 (+), 2 (++), and 3 (+++), where 0 (negative) is considered as normal. The test of heterogeneity of the 5 studies [24, 25, 29, 30, 32] showed very low heterogeneity (P = 0.51, I^2 = 0%) but there was no statistical significant difference between anatomic DB-ACLR and SB-ACLR of anterior stability (OR = 1.07, 95% CI = 0.60 to 1.89) (**Figure 5**).

The side-to-side difference (SSD, mean ± SD) between the injured and intact knee, measured with KT arthrometer devices, is a quantitative evaluation of anterior laxity, in which a larger difference between the knees represents worse stability. A total of 13 studies [24, 26, 29-36, 38] reported values measured by a KT-1000 arthrometer and 1 [25] by a KT-2000 arthrometer. Both DB-ACLR and SB-ACLR patients showed no significant differences (SMD = 0.07, 95% CI = -0.26 to 0.13) between the injured and healthy legs, but significant heterogeneity was found in the test of heterogeneity (P = 0.0002, I^2 = 66%) (**Figure 6**).

Objective IKDC is a standard examination for anteroposterior and rotational stability. The domains include normal (A), nearly normal (B), abnormal (C), and severely abnormal (D). The A and B grade are regarded as normal. The OR in 10 studies [29, 31, 33, 34, 36-38] is 1.06 (95% CI = 0.75 to 1.50) were without significant heterogeneity (P = 0.67, I^2 = 0%) (**Figure 7**).

Functional scores

The subjective IKDC scores including symptoms, sports activities and function of daily activities are used to assess subjective feeling by patients. The scoring scale, which is the sum of 3 sector ranges from 0 to 100, and the higher score equates a better keen status. The test of heterogeneity did not show significant het-

Study or Subgroup	Experimental (DB) Mean	SD	Total	Control(SB) Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Agliett 2009	1.3	1.3	35	2.3	1.4	35	6.8%	-0.73 [-1.22, -0.25]
Ahlden 2013	2.6	3.4	50	1.9	2.8	48	7.8%	0.22 [-0.17, 0.62]
Araki 2011	0.7	1.8	10	1.8	1.7	10	3.3%	-0.60 [-1.50, 0.30]
Hussein 2012	1.2	0.9	131	1.6	0.8	78	9.3%	-0.46 [-0.75, -0.18]
Karikis 2016	2.6	3	45	2.8	3.1	36	7.3%	-0.07 [-0.50, 0.37]
Liu 2016	1.8	1.25	32	1.7	1.5	34	6.8%	0.07 [-0.41, 0.55]
Mayr 2016	1.3	1.6	34	0.7	1.4	28	6.5%	0.39 [-0.11, 0.90]
Mohtadi HT 2015	2.7	2.4	107	3	2.1	104	9.5%	-0.13 [-0.40, 0.14]
Mohtadi PT 2015	2.7	2.4	107	1.9	2.5	102	9.5%	0.33 [0.05, 0.60]
Sasak 2016	0.5	1	67	0.3	1	69	8.6%	0.20 [-0.14, 0.54]
Siebold 2008	1	1	35	1.6	1.3	35	6.8%	-0.51 [-0.99, -0.04]
Suomalainen BS 2012	1.6	3	20	2.2	2.8	21	5.4%	-0.20 [-0.82, 0.41]
Suomalainen MS 2012	1.6	3	20	2.3	3.8	24	5.6%	-0.20 [-0.79, 0.40]
Xu 2014	1	0.9	34	0.7	0.8	32	6.7%	0.35 [-0.14, 0.83]
Total (95% CI)			**727**			**656**	**100.0%**	**-0.07 [-0.26, 0.13]**

Heterogeneity: Tau² = 0.08; Chi² = 38.45, df = 13 (P = 0.0002); I² = 66%
Test for overall effect: Z = 0.68 (P = 0.49)

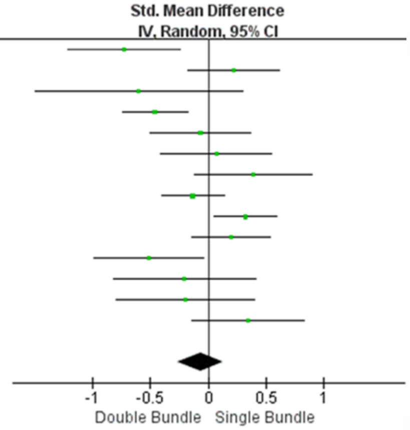

Figure 6. Forest plot shows standardized mean difference (SMD) of KT arthrometer measurement between anatomic double- and single-bundle anterior cruciate ligament reconstructions.

Study or Subgroup	Experimental(DB) Events	Total	Control(SB) Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Suomalainen MS 2012	16	20	15	24	6.3%	2.40 [0.61, 9.47]
Suomalainen BS 2012	16	20	16	21	5.4%	1.25 [0.28, 5.53]
Sun AU 2015	149	154	135	142	8.6%	1.55 [0.48, 4.98]
Sun AL 2015	122	128	135	142	9.5%	1.05 [0.34, 3.22]
Siebold 2008	34	35	33	35	2.0%	2.06 [0.18, 23.83]
Mohtadi PT 2015	75	107	77	101	31.1%	0.73 [0.39, 1.35]
Mohtadi HT 2015	75	107	74	104	33.7%	0.95 [0.53, 1.72]
Mayr 2016	34	34	26	28	1.2%	6.51 [0.30, 141.39]
Hussein 2012	131	131	78	78		Not estimable
Agliett 2009	34	35	32	35	2.2%	3.19 [0.32, 32.24]
Total (95% CI)		**771**		**710**	**100.0%**	**1.06 [0.75, 1.50]**
Total events	686		621			

Heterogeneity: Tau² = 0.00; Chi² = 5.83, df = 8 (P = 0.67); I² = 0%
Test for overall effect: Z = 0.33 (P = 0.74)

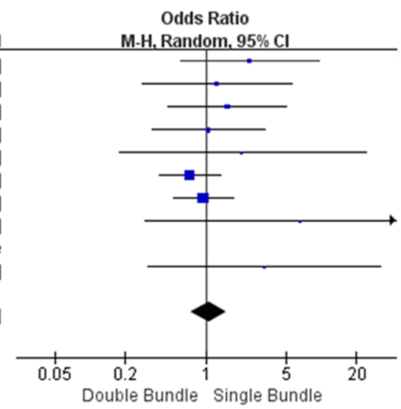

Figure 7. Forest plot shows odds ratio (OR) of Objective IKDC scores between anatomic double- and single-bundle anterior cruciate ligament reconstructions.

Study or Subgroup	Experimental (DB) Mean	SD	Total	Control(SB) Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Agliett 2009	83	15	35	78	13	35	5.4%	0.35 [-0.12, 0.82]
Hussein 2012	92.1	5.5	131	90.6	6.4	78	12.9%	0.26 [-0.03, 0.54]
Liu 2016	92.2	7.1	32	93.4	10.1	34	5.2%	-0.14 [-0.62, 0.35]
Mayr 2016	91.5	7.2	34	86.6	16.2	28	4.7%	0.40 [-0.11, 0.91]
Mohtadi HT 2015	84.2	11.8	107	85.3	11.6	107	13.8%	-0.09 [-0.36, 0.17]
Mohtadi PT 2015	84.2	11.8	107	84.6	13.8	105	13.7%	-0.03 [-0.30, 0.24]
Siebold 2008	88	10	35	90	10	35	5.4%	-0.20 [-0.67, 0.27]
Sun AL 2015	93.7	4	128	92.7	4.3	142	16.3%	0.24 [-0.00, 0.48]
Sun AU 2015	92.9	4.3	154	92.7	4.3	142	17.4%	0.05 [-0.18, 0.27]
Xu 2014	81.1	9.4	34	82.5	15.4	32	5.2%	-0.11 [-0.59, 0.37]
Total (95% CI)			**797**			**738**	**100.0%**	**0.08 [-0.04, 0.19]**

Heterogeneity: Tau² = 0.01; Chi² = 11.05, df = 9 (P = 0.27); I² = 19%
Test for overall effect: Z = 1.31 (P = 0.19)

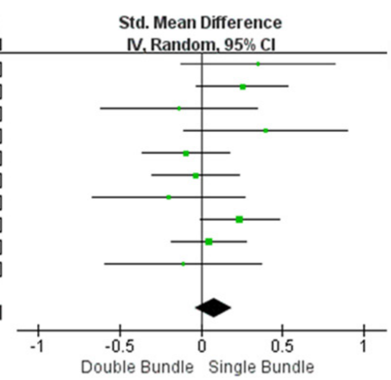

Figure 8. Forest plot shows standardized mean difference (SMD) of subjective IKDC scores between anatomic double- and single-bundle anterior cruciate ligament reconstructions.

erogeneity (P = 0.27 I^2 = 19%); the SMD was 0.08 (95% CI = -0.04 to 0.19) (**Figure 8**) suggesting no preference between DB-ACLR and SB-ACLR [25, 26, 29, 31, 33, 34, 36, 37].

The Lysholm knee function score commonly reflects the patients' ability to manage their daily lives. The scale ranges from 0 to 100, and a higher score reflects a better performance.

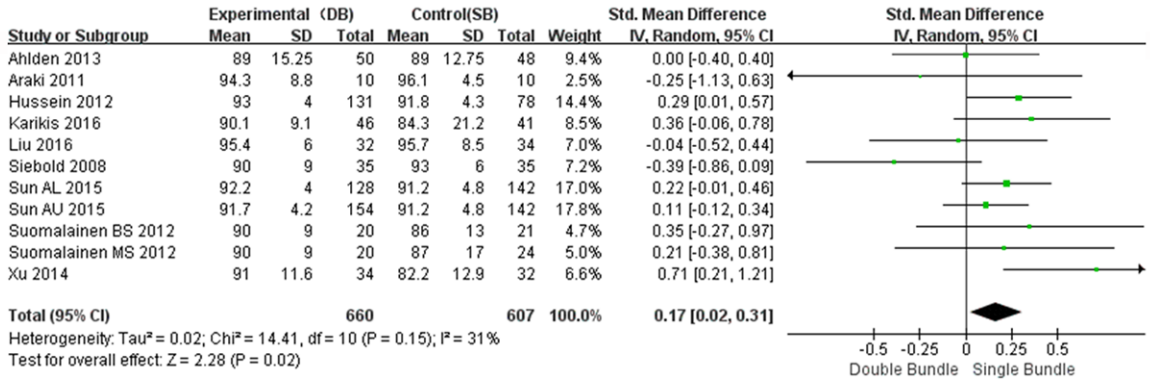

Figure 9. Forest plot shows standardized mean difference (SMD) of Lysholm scores between anatomic double- and single-bundle anterior cruciate ligament reconstructions.

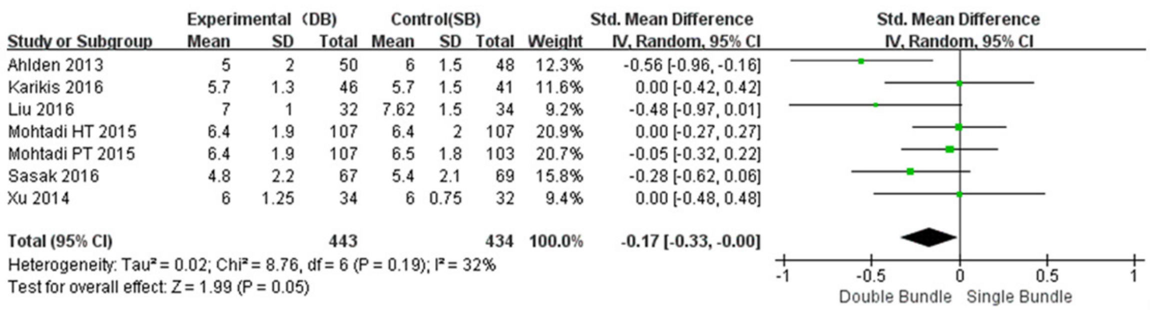

Figure 10. Forest plot shows standardized mean difference (SMD) of Tegner activity scale between anatomic double- and single-bundle anterior cruciate ligament reconstructions.

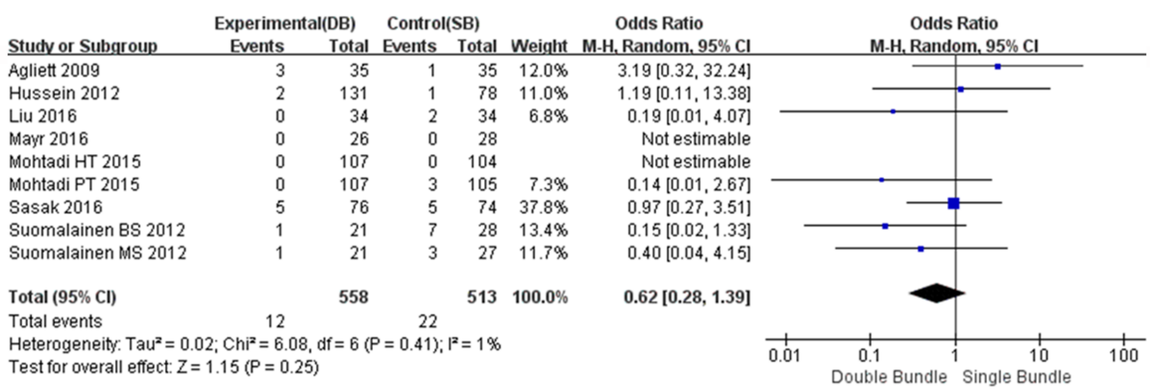

Figure 11. Forest plot shows odds ratio (OR) of graft failure scores between anatomic double- and single-bundle anterior cruciate ligament reconstructions.

The SMD was 0.17 (95% CI = 0.02 to 0.31), which found no significant difference between DB-ACLR and SB-ACLR) (**Figure 9**). The test of heterogeneity also did not detect significant heterogeneity ($P = 0.15$ $I^2 = 31\%$) [25, 26, 29-32, 36-38].

The Tegner activity scale is used to compare the highest level of activity preoperatively and postoperatively. The level ranges from 0 to 10, also a higher level equates to a more competitive activity. The test of heterogeneity did not detect significant heterogeneity ($P = 0.19$ $I^2 = 32\%$). The SMD was-0.17 (95% CI = -0.33 to 0.00), but from the results of the forest plot it was difficult to judge (**Figure 10**) whether the sensitivity analysis was conducted [25, 26, 29, 30, 34, 35].

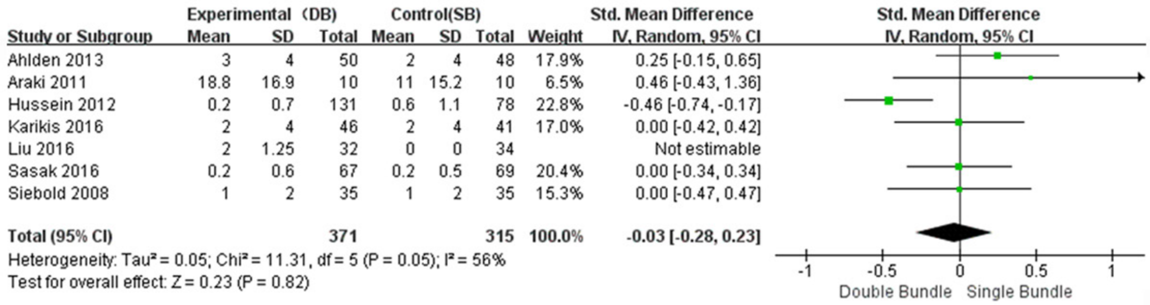

Figure 12. Forest plot shows standardized mean difference (SMD) of extension deficits(ED) between anatomic double- and single-bundle anterior cruciate ligament reconstructions.

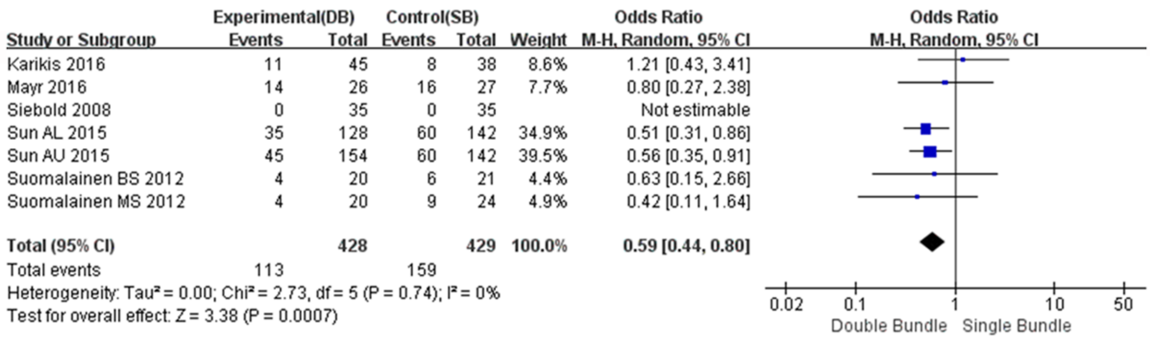

Figure 13. Forest plot shows odds ratio (OR) of osteoarthritis rates between anatomic double- and single-bundle anterior cruciate ligament reconstructions.

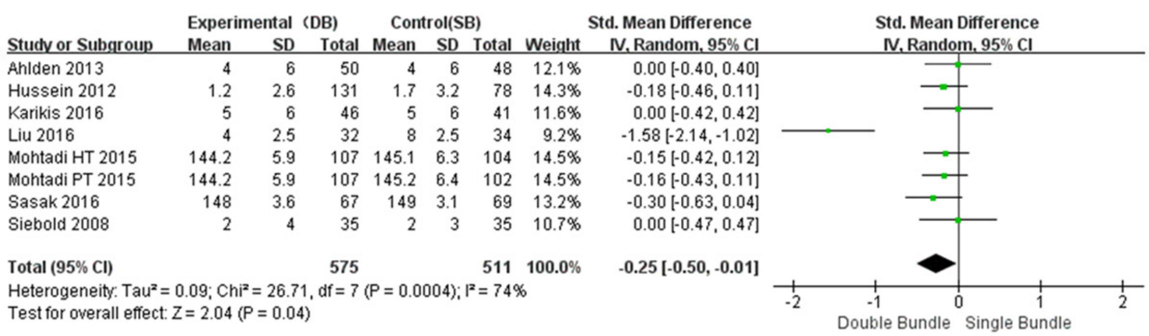

Figure 14. Forest plot shows standardized mean difference (SMD) of flexion deficits (FD) between anatomic double- and single-bundle anterior cruciate ligament reconstructions.

Complication events

Complication events mainly included graft failure, osteoarthritis rates and flexion/extension deficits. The graft failure [25, 29, 31, 33-35, 38] (OR = 0.62, 95% CI = 0.28 to 1.39, P = 0.41 I^2 = 1%) (**Figure 11**) and extension deficits [24, 25, 30-32, 35, 36] (SMD = -0.03, 95% CI = -0.28, -0.23, P = 0.05 I^2 = 56%) (**Figure 12**) had no significant differences between DB-ACLR and SB-ACLR. DB-ACLR patients showed better outcomes in osteoarthritis rates [32, 33, 36-38] (OR = 0.59, 95% CI = 0.44 to 0.80, P = 0.74 I^2 = 0%) (**Figure 13**) and flexion deficits [24, 25, 31, 32, 34-36] (SMD = -0.25, 95% CI = -0.50 to -0.01, P = 0.0004, I^2 = 74%) (**Figure 14**).

The results of sensitivity analysis

Various sensitivity analyses were performed relating to the bias of changing the inclusion criteria and results of assessment risk of bias to remove high-risk study. Liu et al. [25] derives the heterogeneity of FD results. The heterogeneity of ED results comes from Hussein et al. [31]. Although after removal of the two articles, heterogeneity significantly reduced, and it did not alter the meta-analysis results.

Subgroup analysis based on race

The outcome of comparison of pivot-shift test, KT-1000/2000 measurements, objective IKDC, subjective IKDC score, Lysholm score, graft failure and flexion/extension deficits detected no significant difference between Asian patients and American or European patients. Asian DB-ACLR patients showed a better Tegner activity scale compared with SB-ACLR. While American or European patients did not show a significant difference. Asian DB-ACLR patients performed less osteoarthritis rates. No difference between DB-ACLR and SB-ACLR was found amongst American or European patients. There does not exist any Asian study that reported the Lachman test.

Discussion

Conducting systematic reviews and meta-analyses can provide the most useful information for clinical decisions.

Summary of findings

The first important finding of this meta-analysis was that rotational stability, as examined, with the pivot-shift test showed results favoring anatomic DB-ACLR patients. The subgroup analysis between Asian patients and American or European patients was confirmed as positive for the results. Moreover, the same results were also reported by previous meta-analyses [39, 40]. It could be explained that the addition of a PL bundle to control the rotation of the knee increases rotational stability [41-43]. The pivot-shift test is an important comparison and is an available clinical examination to detect rotational instability between DB-ACLR and SB-ACLR. The results are divided into negative and positive. However, the test is performed by a clinician not an instrument measurement, which is highly subjective showing large variability among different observers. Therefore, it is imperative that the test be performed by a trained clinician who can perform and interpret the test to minimize bias in interpretation of the results in the future. For an individual RCT, the clinician who performs the test should be blinded to the reconstruction strategy or be an independent doctor who is not involved in the experiment. The subject should also be blinded to the reconstruction procedure. The inclusion studies almost all followed these principles, which increased the reliability of the results. The second finding was that anatomic DB-ALCR patients achieved higher Lysholm scores. In the subgroup analysis, no difference of the Lysholm scores was found in both Asian and American or European patients between the two reconstruction procedures. The test of heterogeneity detected decreasing heterogeneity combined with subgroups. The Lysholm score is a subjective assessment of patients, influenced by their psychology, which maybe not objectively reflect the effect of reconstruction. With the aims of restoring the kinematics and stability of the injured knee to prevent future degenerative changes, ACLR also aims to remodel the feeling of health. Asian patients with DB-ACLR achieved higher on the Tegner activity scale while American and European patients showed no difference between DB-ACLR and SB-ACLR. In recent years, more studies focused on early osteoarthritis [44-46]. Early osteoarthritis favored DB-ACLR patients were found in this meta-analysis. However, data relating to Asian patients were completely from one study [37], in which DB-ACLR techniques involved either autografts or allografts, whereas SB-ACLR only used allografts. Because of this it has been shown that the use of allografts can increase the risk of osteoarthritis [44]. This study was excluded in the osteoarthritis rates comparison and no difference was ultimately found. Flexion deficit results suggested that DB-ACLR patients had better outcomes but were associated with significant heterogeneity. In the sensitivity analysis, heterogeneity was significantly reduced with no change of result after Liu et al. [25].

Comparison with existing meta-analysis

In 2008 Meredick et al. [21] published a meta-analysis comparing single- and double-bundle reconstruction of the ACL. Their study included 9 literatures, which reported no difference in the outcome of single- and double-bundle reconstruction, as measured by the KT-1000 arthrometer and the pivot-shift test. However, they included a mix of a small sample of randomized and observational studies, and reckoned without anatomic reconstruction. In 2012, literature published in The Cochrane

Library by Tiamklang et al. [47] selected a total of 17 RCTs and quasi RCTs. They concluded that DB-ACLR may have some superior results in the ability of return to pre-injury level of activity, objective measurement of knee stability (objective IKDC, instrumented knee with KT-1000 arthrometer, manual stability test by the pivot-shift test), and protection against recurrent injury. In addition, they reckoned with anatomic reconstruction. In 2012 the meta-analysis conducted by Van et al. [39] showed that, compared with single-bundle reconstruction, double-bundle achieved less anterior laxity measured by the KT arthrometer and Lachman test, and a better rotational laxity measured by the pivot-shift test. The results of subgroup analysis between anatomic and non-anatomic reconstruction emphasized the importance of anatomic ACLR. This study selected comparative clinical studies, which may not have been rigorous in nature. In 2016 Zhang et al. [40] compared anatomic DB-ACLR and anatomic SB-ACLR according to the subgroup analysis of femoral tunnel drilling techniques in SB-ACLR. They found that anatomic DB-ACLR showed better anterior and rotational stability and a higher objective IKDC score via the TT drilling technique; however, via the independent drilling technique anatomic DB-ACLR only showed superiority in rotational stability. Although, their study should be praised for the consideration of anatomic reconstruction, nevertheless it still involved many comparative clinical studies.

This meta-analysis included 13 RCT literatures with Level I evidence, all using anatomic SB and DB reconstructions techniques. In comparison with existing meta-analyses including few comparative clinical studies [21, 39, 40], which may lower their overall level of evidence, this study selected reliable RCTs. The operative techniques of the studies included in the meta-analysis had accepted differences. TT or independent drilling techniques are commonly used in femoral tunnel drilling and it has been reported that patients experienced better outcomes via the independent drilling technique; 2 studies [34, 36] used the TT drilling technique, while the others used the independent drilling technique. Either autografting (commonly using the patellar tendon or the hamstring tendon) or allografting was used to replace the injured ACL. In this study almost all selected the hamstring tendon for grafts. Studies were included according to the eligibility criteria regardless of graft type or femoral tunnel drilling techniques, however more future literatures are needed to explain the wider options for the hamstring tendon and the independent drilling technique. As mentioned earlier, the subgroup analysis was performed based on human race rather than graft types or femoral tunnel drilling techniques for the incorrect number of articles. ACL holds differences in Asian patients and American or European patients, so personized approaches should be adopted to adapt to different people. Furthermore, a critical eligibility criteria were formualted to include studies with high quality, which however lead to a smaller sample size.

The limitations of this meta-analysis

This meta-analysis holds several limitations, as with any meta-analysis. First, data was translated from 3 databases into statistically useful data for a comprehensive analysis, as our request for relevant unpublished outcomes was ignored. Hence the results may be implicated by consequentially estimated outcomes. Second, a critical eligibility criteria was formulated to search for high quality RCTs where only English language literatures were included, which lead to a smaller samples size and possibly publication bias. Third, judgements of race, based on the correspondence address, produced a risk of bias, such as Chinese entering America for surgery. Fourth, although the Anatomic ACL Reconstruction Checklist was used to estimate whether it was anatomic reconstruction or not, differences of surgery methods still were present in each inclusion study.

All the selected RCTs had one or more limitations in the study design. Influences such as graft types or femoral tunnel drilling techniques cannot be ignored. We hope for a higher quality of RCTs with convincing data, and it is imperative to standardizing statements of both research outcomes and data across all research. Future research should create an accurate, reliable and easy-to-perform procedure to assess subjective/objective clinical outcomes of ACLR, as well as provide more evaluation indices, especially for graft failure, osteoarthritis rates, flexion/extension deficits, and other complication events. Finally, importance should be attached to the Anatomic ACL Reconstruction Checklist and it should continue to be modified and applied.

Conclusion

Anatomic DB-ACLR patients showed better rotational stability, a higher subjective IKDC sore, and reduced flexion deficits compared with anatomic SB-ACLR, with no human differences. Via ADB-ACLR, Asian patients achieved higher on the Tegner activity scale, while American and European patients showed no differences. Other comparative outcomes were not significantly different between anatomic DB-ACLR, anatomic SB-ACLR and human race.

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Disclosure of conflict of interest

None.

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