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Single-bundle or double-bundle for anterior cruciate ligament reconstruction: A meta-analysis

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ABSTRACT

Purpose: To compare the clinical outcomes of anterior cruciate ligament (ACL) reconstruction with double-bundle and single-bundle techniques.
Study design: Meta-analysis
Methods: We searched electronic databases including PubMed, Embase, Cochrane Central Register of Controlled Trials, and Google Scholar from 1966 to Jan 2012 to identify randomized controlled trials (RCTs) comparing clinical outcomes of anterior cruciate ligament (ACL) reconstruction with double-bundle and single-bundle techniques. Two reviewers independently extracted data and assessed trial quality. Meta-analysis was performed to pool results.
Results: Nineteen RCTs were included with a total of 1686 patients. The pooled analysis across all studies showed that the double-bundle ACL reconstruction technique could have significantly better outcomes in rotational laxity, as assessed by the pivot-shift test, KT grading and IKDC grading than the single-bundle techniques. We found no evidence of a difference in function measured by IKDC scores, KT arthrometer, Lysholm knee, or Tegner activity scores and complications after operations between single and double-bundle ACL reconstruction groups.
Conclusion: Our meta-analysis demonstrated the superiority of double-bundle over single-bundle anterior cruciate ligament reconstruction. The double-bundle ACL reconstruction technique has better outcomes in rotational laxity (pivot-shift test, KT grading and IKDC grading). However, for functional recovery, there was no significant difference between single-bundle and double-bundle reconstruction techniques.

1. Introduction

The anterior cruciate ligament (ACL), in addition to its primary role restraining anterior tibial translation, has been shown to contribute to rotational stability of the knee [1]. Anatomical and biomechanical studies have characterized that normal ACL can be divided into two bundles, anteromedial (AM) and posterolateral (PL) [2]. And each appears to function at different angles of flexion of the knee, together providing responsibility for the stability of the joint [3]. Anterior cruciate ligament disruption is a common cause of anterior knee instability, particularly as a result of sports activities. The arthroscopic single-bundle (SB) technique has been the gold standard for ACL reconstruction and showed good results over the past decade. However, a failure rate of 11–30% is reported in the literature with persistent instability of the knee, especially in rotational stability as revealed by a positive pivot shift test result [4,5]. In order to overcome these limitations of the single-bundle ACL reconstruction technique, the double-bundle (DB) reconstruction technique was proposed as a method to anatomically replicate both the anteromedial and the posterolateral bundles [6]. Anatomic double-bundle reconstructions are able to more closely restore normal kinematics to the knee when compared with a single-bundle technique in a cadaver model [7]. But these reports were based mainly on experimental studies that did not consider the biological healing process. Consequently, clinical results of the double- and single-bundle techniques are still controversial. Some studies show benefits of the double-bundle technique in AP and rotational laxity [8–10], whereas other studies report different conclusion [11,12]. Furthermore, there were two meta-analyses published in 2008 and 2012 respectively, “and no accordant conclusion was reported” in the two studies [13,14]. Moreover, more RCTs have been published recently. The purpose of this meta-analysis is to compare the outcome of single-bundle versus double-bundle reconstruction of the ACL.

2. Materials and methods

2.1. Criteria for considering studies for this review

2.1.1. Studies included

We included randomized controlled trials with a follow up of at least two years.

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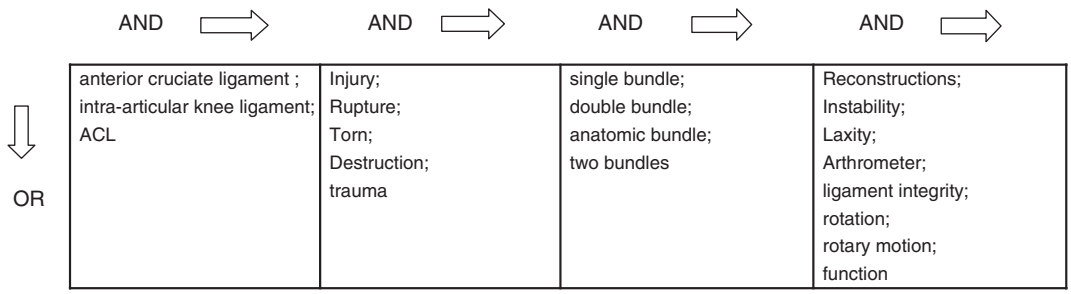

Fig. 1. Keywords and boolean (logical) operators used in the database searches.

2.1.2. Types of participants

The study population included adults who underwent ACL reconstruction.

2.1.3. Types of interventions

All patients underwent single or double-bundle ACL reconstruction. And only the appropriate comparisons between single-bundle vs double-bundle reconstructions were selected.

2.1.4. Types of outcome measures

Outcome measures included pivot-shift test, anterior laxity by KT1000/2000 arthrometer, and functional outcome by Lysholm, International Knee Documentation Committee (IKDC). Other outcomes such as Lachman test, Tegner scores, and complications also were considered.

2.2. Search strategy for identification of studies

All relevant RCTs meeting the inclusion criteria were identified by the following:We searched the PubMed, Embase, Cochrane Central Register of Controlled Trials, and Google Scholar databases. Two authors independently searched for relevant studies in any language from 1966 to Jan 2012. The search strategy was created with the assistance of a librarian using a combination of terms including anterior cruciate ligament, intra-articular knee ligament; injury, rupture, torn, destruction, trauma; single bundle, double bundle, anatomic bundle, two bundles; reconstructions, instability, translation, laxity, arthrometer, ligament integrity; rotation, rotary motion, pivot-shift; and function, Lysholm, IKDC, KOOS, Tegner. We limited searches to randomised controlled trials, systematic reviews, and meta-analyses and imposed no language or other limitations. The electronic search was complemented by the following hand searching the reference lists. Fig. 1 gives details of the search strategy.

2.2.1. Selection of studies

Two reviewers (Li and Ning) independently screened the titles and abstracts of studies identified by the search strategy and discarded clearly irrelevant studies. The same two reviewers also independently applied the selection criteria to the studies retrieved by the literature search. They discussed to resolve any disagreement; if any uncertainty remained, they consulted further reviewer and expert (Feng) to decide.

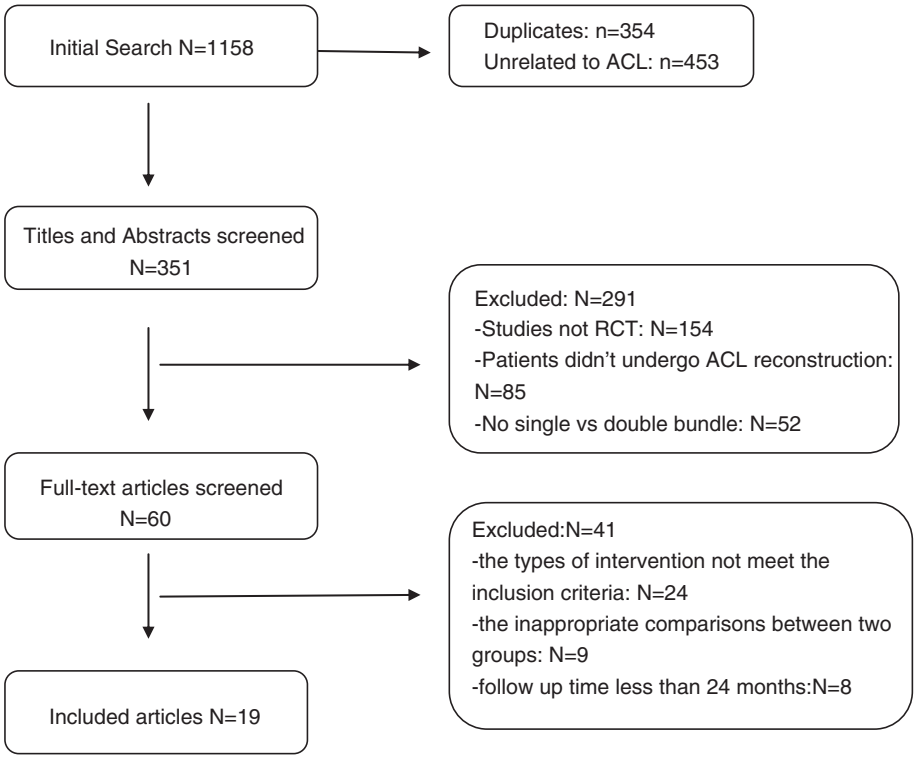

Fig. 2. Flowchart of trials selection process.

Table 1
Description of included trials.

Author	Study design	Mean age (year)	Male/ Female	Mean follow-up (months)	Number of patients		Implant	Screw type	Meniscus%	Outcome	Level of Evidence
					Single bundle	Double bundle					
Adachi N/2004 [15]	RCT	29.4	65/43	32	55	53	HT	EB + Staple	47	KT-1000	II
Kazunori Y/2006[16]	RCT	25.5	27/21	24	24	24	HT	EB + Staple	–	KT-2000; IKDC grading	II
Muneta T/2007[10]	RCT	23.7	34/34	25.4	34	34	ST/GT	EB + Staple	85	KT-1000; PS; Lysholm score	II
Nikolaus A/2008[17]	RCT	29.6	25/24	24	25	24	ST	EB + Staple	–	KT-1000; IKDC grading; Lysholm score	II
Jarvela T/2008[18]	RCT	33	51/26	24	27	25	ST/GT	BS	65	KT-1000; PS; Lysholm score; IKDC grading	II
Kondo E/2008[19]	RCT	25	186/142	24	157	171	ST/GT	EB + Staple	–	KT-2000; Lysholm score	II
Tsuda E/2009[20]	RCT	23.5	57/68	38	62	82	PT/ST	EB + Staple	–	KT-1000; PS; IKDC grading	II
Streich NA/2008[21]	RCT	29.6	50/0	24	25	25	ST/GT	EB + Staple	53	KT-1000, pivot shift, IKDC score, Lysholm knee score, Tegner activity score, complication	II
Ibrahim SA/2009[22]	RCT	28	200/0	29	150	50	ST/GT	EB + Staple	–	KT-1000; IKDC score	II
Zaffagnini S/2011[23]	RCT	26.8	42/37	103	39	40	PT/ST	Staple	63	KT-1000, KT grading, PS, IKDC grading, Tegner activity score, complication	II
Aglietti P/2010[24]	RCT	28	53/17	24	35	35	ST/GT	EB + Staple	–	KT-1000; IKDC score; VAS; KOOS	I
Kyoung HY/2011[12]	RCT	27.8	45/8	32	25	28	HT	BS	–	Tegner activity score, Lysholm score, IKDC grading	II
Sergi S/2010[25]	RCT	30	26/14	24	20	20	ST/GT	EB + Staple	–	IKDC score	II
Siebold R/2011[26]	RCT	32	38/16	40	28	26	ST/GT	EB + BS	–	KT-1000; IKDC score; VAS; KOOS; CKS	II
SuomalainenP/2011[27]	RCT	32	110/43	27	78	75	HT	SB	–	KT-1000; IKDC score; Lysholm knee score; MRI	II
Gobbi A/2011[28]	RCT	29.5	33/27	46.2	30	30	ST	EB + Staple	–	ROM, PS, IKDC, Noyes, Lysholm, Marx, and Tegner activity scales.	II
Fujita N/2011[29]	RCT	26.4	13/23	33.7	18	18	ST/GT	EB + Staple	–	Lysholm knee score, Tegner activity score, KT-1000, PS	II
Stefani G/2011[30]	RCT	–	–	44	27	25	ST/GT	EB + Staple	–	IKDC scale, Lysholm score, KT-1000	II
Sahnghoon LEE/2012[31]	RCT	30	37/5	24	21	21	ST/GT	EB + Staple	–	Rotation; Lysholm knee score, Tegner activity score, IKDC scale, PS, KT-1000	II

CCS: Case-control study; CS: Cohort study; HT: Hamstring tendons; St: Semitendinosus; GT: Gracilis tendons; PT: patellar tendon; EB: Endobutton; BS: bioabsorbable screw; PS: pivot shift test; IKDC: International Knee Documentation Committee; IE: Intraoperative evaluation; KOOS: knee injury and osteoarthritis outcome scores; ALRI: anterolateral rotatory instability; CKS: Cincinnati Knee Score.

2.2.2. Data extraction and management

Two reviewers independently extracted the data using a standardized form regarding inclusion criteria (study design, participants, interventions, and outcomes). A consensus method was used to resolve disagreements, and a third reviewer was consulted if disagreements persisted.

2.2.3. Methodological quality of included studies

Two reviewers assessed the quality of the studies independently; the revised Jadad Scale was used to perform the quality assessment. This scale includes the random sequence production (2 points), allocation concealment (2 points), appropriateness of blinding (2 points), and description of dropouts and withdrawals (1 point). The total score is 7 points, 0–3 points means poor quality and 4–7 points means high quality. And Consolidated Standards on Reporting Trials (CONSORT) checklist and scoring system was used to evaluate the quality of included trials: scores of 18 to 22 are considered excellent study quality; 13 to 17, good; 8 to 12, fair; and less than 7 poor.

Table 2
Quality assessment of included randomized controlled trials with revised Jadad scale and CONSORT Statement.

Author	Random sequence production	Allocation concealment	Blind method	Withdrawal	Revised Jadad's Scale score	CONSORT statement
Adachi N/2004	1	1	1	1	4	11
Kazunori Y/2006	1	1	1	1	4	12
Muneta T/2007	1	1	1	1	4	16
Nikolaus A/2008	1	1	1	1	4	15
Jarvela T/2008	2	2	1	1	6	19
Kondo E/2008	2	1	1	1	5	14
Tsuda E/2009	1	1	0	1	3	10
Streich NA/2008	1	1	1	1	4	18
Ibrahim SA/2009	2	1	1	1	5	16
Zaffagnini S/2011	2	1	1	1	5	19
Aglietti P/2010	2	1	1	1	5	19
Kyoung HY/2011	2	1	1	1	5	18
Sergi S/2010	2	1	1	1	5	14
Siebold R/2011	0	0	0	1	1	8
Suomalainen P/2011	2	1	1	1	5	18
Gobbi A/2011	1	1	1	1	4	14
Fujita N/2011	1	1	1	1	4	11
Stefani G/2011	1	1	1	1	4	13
Sahnghoon LEE/2012	1	1	1	1	4	15

2.3. Statistical analysis

For dichotomous variables, we derived the relative risks and 95% confidence intervals for each outcome. For continuous variables, we calculated the mean differences and 95% confidence intervals for each outcome. We performed the meta-analysis using a fixed-effect model if no significant heterogeneity was present. To assess heterogeneity between studies, we performed a chi-square test and estimated the I^2 statistic. A random effects model was selected to account for heterogeneity in the design and patient selection among included studies. And the subgroup analyses were conducted for different outcomes.

3. Results

3.1. Description of studies

3.1.1. Search results

A search of the PubMed, Embase, Cochrane Central Register of Controlled Trials, and Google Scholar databases retrieved 1158 articles. We excluded 354 duplicate articles after we reviewed the titles and abstracts. Then reading the whole paper, we included 19 papers. These studies included a total population of 1686 participants with 880 in the SB group and 806 in DB group. Fig. 2 summarizes the study selection process.

Table 3
Data extraction of dichotomous outcomes.

Author	Pivot shift grading			
	Single bundle		Double bundle	
	Grade 0	Grade>0	Grade 0	Grade>0
Kazunori Y/2006	12	12	21	3
Muneta T/2007	20	14	29	5
Nikolaus A/2008	19	6	23	1
Jarvela T/2008	16	11	18	7
Kondo E/2008	80	77	139	32
Ibrahim SA/2009	65	85	48	2
Tsuda E/2009	46	16	58	24
Aglietti P/2010	23	12	29	6
Streich NA/2008	19	6	23	1
ZaffagniniS/2011	26	13	36	4
Author	KT grading			
	Single bundle		Double bundle	
	Grade1	Grade>1	Grade1	Grade>1
Muneta T/2007	19	14	25	9
Aglietti P/2010	23	12	29	6
Author	IKDC grading			
	Single bundle		Double bundle	
	Grade A	Grade(BCD)	Grade A	Grade(BCD)
Kazunori Y/2006	10	14	16	8
Jarvela T/2007	11	14	17	13
Muneta T/2007	22	12	20	14
Jarvela T/2008	11	16	13	12
Ibrahim SA/2009	78	72	32	18
Kyoung HY/2011	6	19	15	13
Author	Complication			
	Single bundle		Double bundle	
	Yes	No	Yes	No
Muneta T/2007	5	29	3	31
Nikolaus A/2008	3	22	2	22
Jarvela T/2008	0	41	1	22
Aglietti P/2010	2	33	2	33
Streich NA/2008	3	22	3	22
Zaffagnini S/2011	0	39	0	40
Sergi S/2010	2	18	0	20

3.1.2. Included studies

All the studies were published in English [10,12,15–31]. All studies reported mean follow-up more than 24 months after randomization. All studies presented appropriate comparisons between single-bundle verse double-bundle reconstructions.

Characteristics of the 19 studies were described in Table 1. All the studies were randomized controlled trials. Of the 19 trials, 10 studies reported the pivot shift grading; 2 studies reported KT grading; 6 studies reported IKDC grading; 7 studies reported complications. For continuous variables, 6 studies reported IKDC scores; 5 studies reported Lysholm knee scores; 2 studies reported Tegner activity scores; and 9 studies reported KT arthrometer.

3.2. Methodological quality

Of all the 19 trials, 1 study was level I evidence; 18 studies were level II evidence (Table 1). For the revised Jadad Scale, 2 studies were 1–3 points with a poor quality; 17 studies were 4–7 points with a high quality. 19 RCTs were evaluated by the Consolidated Standards on Reporting Trials (CONSORT) checklist and scoring system, 5 studies were 8–12 scores; 8 studies were 13–17 scores; and 6 studies were 18–22 scores, all the RCTs had satisfied quality. The details were described in Table 2.

3.3. Outcomes

3.3.1. Pivot shift grading

All 10 included trials reported Pivot shift grading (Table 3), and the pooled analysis across all studies showed evidence of a significant difference in Pivot shift grading between single and double-bundle ACL reconstruction groups (OR, 0.27, 95% CI 0.20, 0.36; $p=0.000$, $I^2=67.3\%$). Evidence showed moderate heterogeneity (Fig. 3). However, contour funnel plots suggested some asymmetry of the funnel in Fig. 4.

3.3.2. KT grading

Two of the trials reported validated measures of KT grading (Table 3). Overall, there were significant differences in KT grading between single and double-bundle ACL reconstruction groups (OR, 0.44, 95% CI 0.21, 0.95; $p=0.035$, $I^2=0.00\%$). Evidence showed no heterogeneity, the pooled result was stable (Fig. 5).

3.3.3. IKDC grading

Six of the trials reported IKDC grading (Table 3). A pooled analysis of the studies found a significant difference in IKDC grading between single and double-bundle ACL reconstruction groups (OR, 0.59, 95% CI 0.40, 0.87; $p=0.008$, $I^2=0.00\%$). Evidence showed no heterogeneity (Fig. 6).

3.3.4. Complications

Seven of the trials reported complications (Table 3). A pooled analysis of the studies found no evidence of a significant difference in complications between single and double-bundle ACL reconstruction groups (OR, 1.30, 95% CI 0.60, 2.83; $p=0.510$, $I^2=0.0\%$) (Fig. 7). Evidence showed no heterogeneity, the pooled result was stable.

3.3.5. IKDC scores

Six of the trials reported on patients' IKDC scores (Table 4). No evidence indicated a difference in the IKDC scores between two groups. The mean difference was similar across studies ($I^2=0.0\%$) with an standardized mean difference of −0.19 (95% CI: −0.40, 0.03; $p=0.087$) (Fig. 8). Evidence showed no heterogeneity.

3.3.6. Lysholm knee scores

Lysholm knee scores were reported in five trials (Table 4). The pooled standardized mean difference was −0.13 (95% CI: −0.30, 0.05; $p=0.148$) with no heterogeneity ($I^2=0.7\%$). And the results found no evidence of a significant difference between single and double-bundle ACL reconstruction groups (Fig. 9).

3.3.7. Tegner activity score

Two of the trials reported Tegner activity scores (Table 4). A pooled analysis of the studies found no evidence of a significant difference between single and double-bundle ACL reconstruction groups, the standardized mean difference was −0.05 (95% CI −0.45, 0.32; $p=0.748$) with no heterogeneity ($I^2=0.0\%$) (Fig. 10).

3.3.8. KT arthrometer

Nine of the trials reported KT arthrometer (Table 4). A pooled analysis of the studies found no significant difference in KT arthrometer between single and double-bundle ACL reconstruction groups, the standardized mean difference was 0.21 (95% CI −0.10, 0.52; $p=0.179$) with notable heterogeneity ($I^2=73.9\%$). (Fig. 11). However, none of the co-variables (year $p=0.439$, study_type $p=0.764$) could explain heterogeneity by meta-regression, and the heterogeneity may due to the different follow up.

4. Discussion

In this meta-analysis we assessed the evidence from randomized controlled trials that compared outcomes with single and double-bundle ACL reconstruction. Our review suggests that the double-

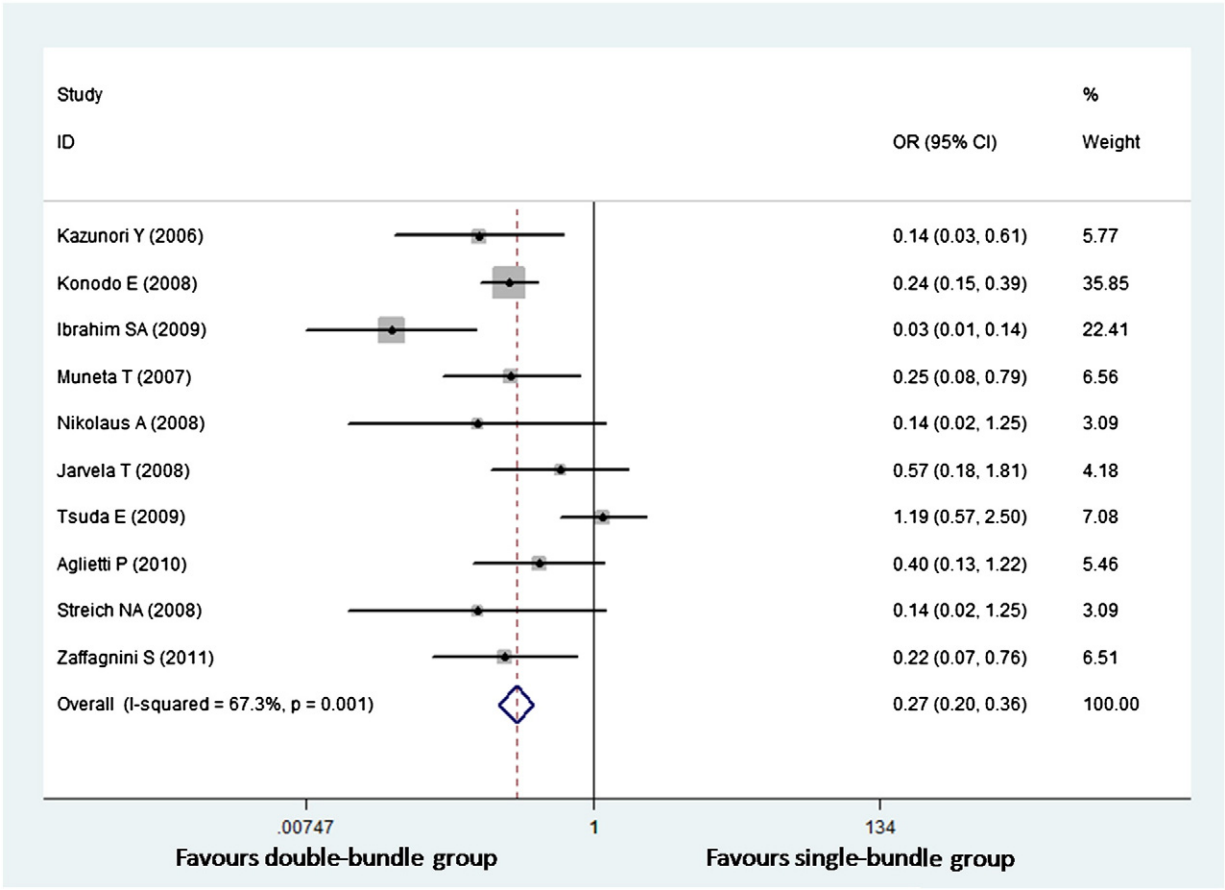

Fig. 3. Forest plots of pooling pivot shift grading.

bundle ACL reconstruction technique could have significant better outcomes in rotational laxity, as assessed by the pivot-shift test, KT grading and IKDC grading than the single-bundle techniques. We found no evidence of a difference in function measured by IKDC scores, KT arthrometer, Lysholm knee, or Tegner activity scores and complications after operations in patients who received single and double-bundle ACL reconstruction. Although the result showed a significant difference in the objective IKDC grading, we could not detect the significant difference in the subjective IKDC score. This was due to the fact that both IKDCs measured differently; and the subjective score usually can't reflect the restoration of anatomical structure and the stability of knee.

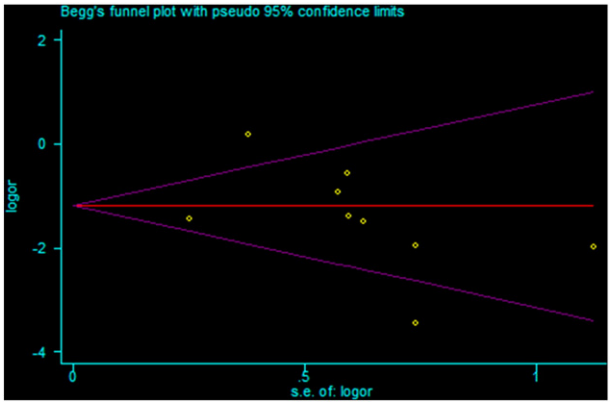

Fig. 4. Analysis of publication bias for pivot shift grading.

Our findings are basically consistent with a recent systematic review by Kongtharvonskul et al. [14] which included 13 trials. However, more studies with higher amount cases were included in the analysis. This study was a complete Meta-analysis about clinical results in ACL reconstruction using either single or double-bundle technique; more comprehensive evaluating indicators were discussed in this study which included pivot-shift test, KT grading, IKDC grading, IKDC scores, KT arthrometer, Lysholm knee, Tegner activity scores and complications. What's more, some evaluating indicators were just described systematically instead of quantitative analysis in the Kongtharvonskul's study. All evaluating indicators were made quantitative analysis in our study, and getting a reverse result in KT grading compared to Kongtharvonskul's. This is a powerful evidence for supporting the advantage of double-bundle ACL reconstruction technique. Richard B et al. [32] reported the reverse results that double-bundle reconstruction does not result in clinically significant differences in KT-1000 arthrometer or pivot shift testing. In our study, significant differences in KT arthrometer, IKDC grading and pivot shift testing between single and double-bundle ACL reconstruction groups were detected. Firstly, the previous meta-analysis [32] included only three studies with a total subject of 210; our review included 19 studies with 1686, so we can get more stable and creditable results. What's more, the previous study included the level III trials with a low methodological quality, which resulted in the high heterogeneity.

Our review has several strengths; we used an exhaustive search strategy, including a great amount of high quality RCTs. All included studies were assessed rigorously by revised Jadad Scale and

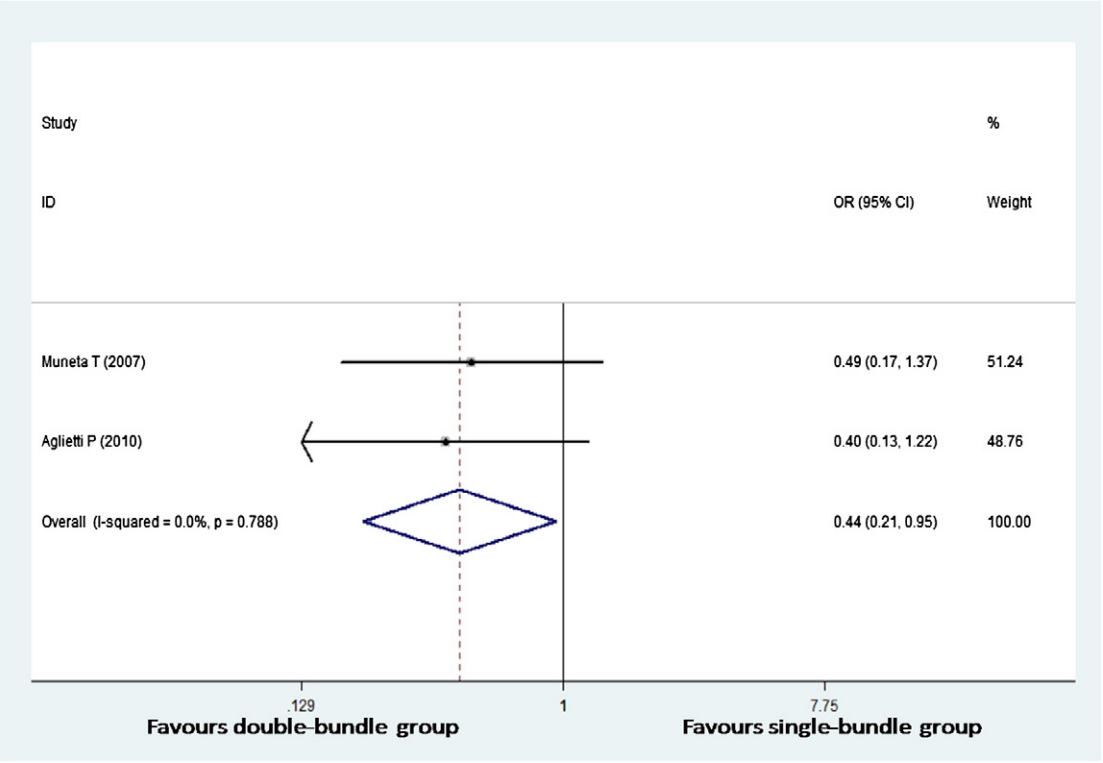

Fig. 5. Forest plots of pooling KT grading.

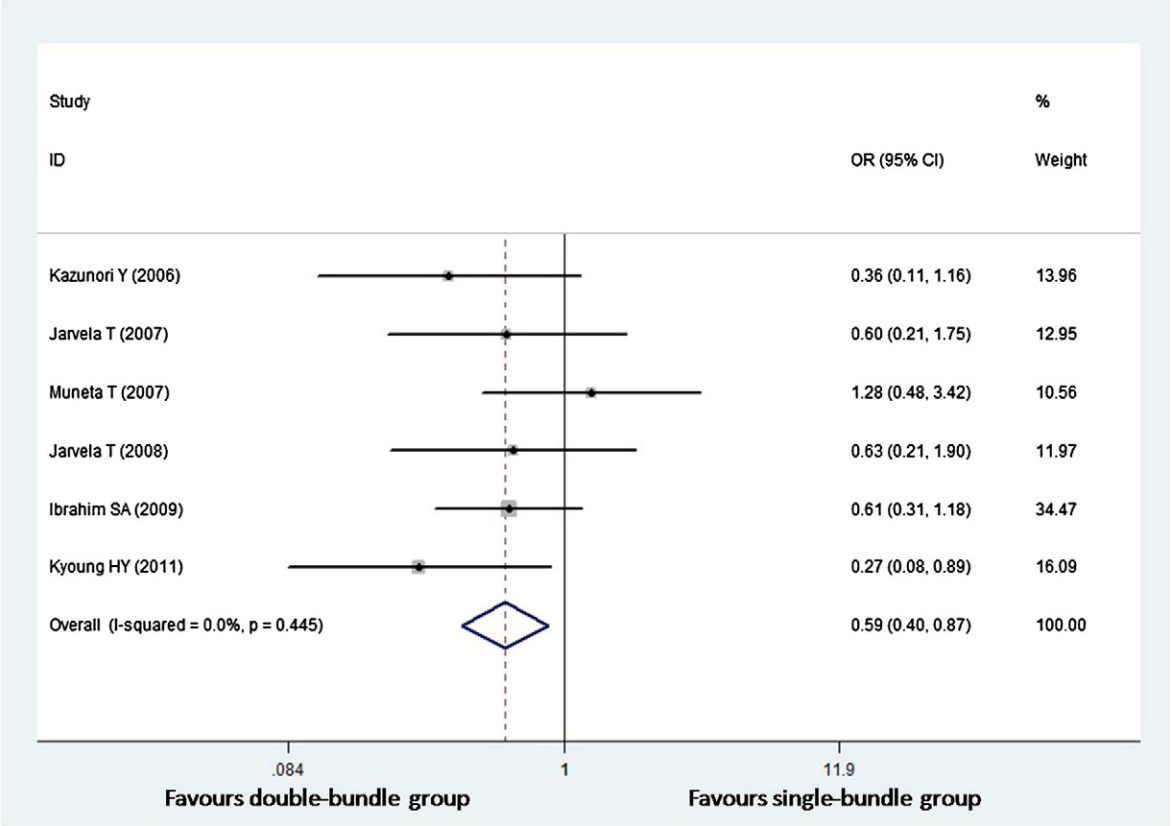

Fig. 6. Forest plots of pooling IKDC grading.

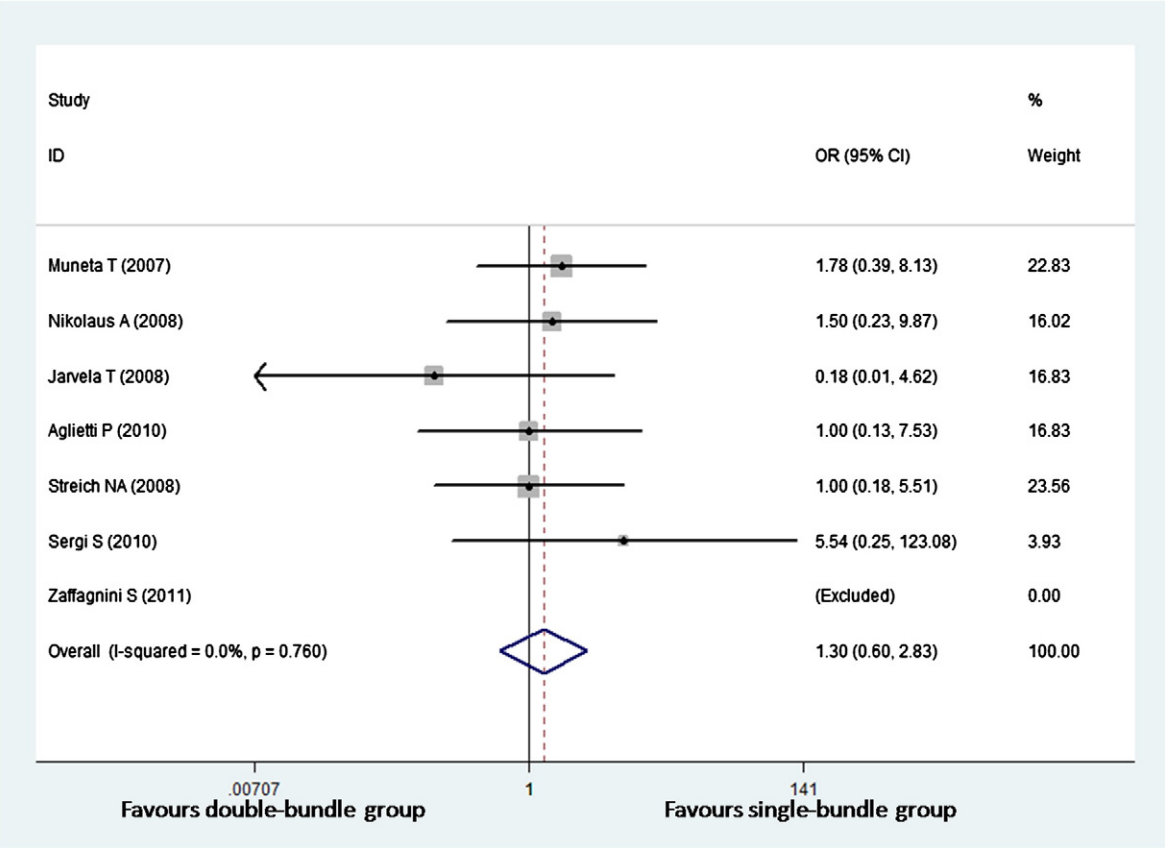

Fig. 7. Forest plots of pooling complications.

Table 4
Data extraction of continuous outcomes.

Author	IKDC scores					
	Single bundle			Double bundle		
	N	Mean	SD	N	Mean	SD
Nikolaus A/2008	25	88.6	6.5	24	89.5	6.4
Jarvela T/2008	27	9	1	25	9	1
Aglietti P/2010	35	78	13	35	83	15
Streich NA/2008	25	88.6	6.5	24	89.5	6.4
Zaffagnini S/2011	39	82	20	40	88	9
Sergi S/2010	20	81	6	20	80	8
Author	Lysholm knee scores					
Nikolaus A/2008	25	91.5	6.3	24	91.8	7.3
Jarvela T/2008	27	94	7	25	92	6
Streich NA/2008	25	91.5	6.3	24	91.8	7.3
Kondo E/2008	157	96.5	5.8	171	97.3	3.3
Kyoung HY/2011	25	89	4.5	28	91	4.5
Author	Tegner activity scores					
Nikolaus A/2008	25	7.1	1.6	24	7.3	1.4
Kyoung HY/2011	25	2.0	1.0	28	2.0	1.0
Author	KT arthrometer					
Adachi N/2004	55	1.2	2.5	53	1.3	2.5
Kazunori Y/2006	24	2.8	1.9	24	1.1	1.5
Muneta T/2007	34	2.4	1.4	34	1.4	1.4
Nikolaus A/2008	25	0.94	1.76	24	1.10	1.57
Jarvela T/2008	27	2.1	2.0	25	1.3	2.1
Tsuda E/2009	62	1.25	1.2	82	1.3	1.5
Aglietti P/2010	35	2.3	1.4	35	1.3	1.3
Streich NA/2008	25	0.94	1.76	24	1.10	1.57
Zaffagnini S/2011	39	0.4	0.6	40	1.1	1.9

Consolidated Standards on Reporting Trials (CONSORT) checklist and scoring system. When it came to heterogeneity, meta regression analysis and sensitivity analysis were performed to control the veracity and stability of pooled results.

Although we believe this to be the most comprehensive meta-analysis of RCT-based evidence for the comparisons between single-bundle vs double-bundle reconstructions, we acknowledge that this study has a number of limitations. The general lack of random sequence production and allocation concealment methods in the included RCTs made it difficult to assess their methodological quality, thereby the risk of bias and potential to overestimate the effect may be existent. Our evidence showed considerable statistical heterogeneity for several outcomes across the trials, the different follow-ups between trials were considered to cause statistical heterogeneity. Nevertheless, it is reassuring that our findings were generally consistent across various sensitivity analyses undertaken to explore this heterogeneity, except for the result of the KT arthrometer.

In conclusion, our meta-analysis demonstrated the superiority of double-bundle over single-bundle anterior cruciate ligament reconstruction. Double-bundle ACL reconstruction technique has better outcomes in objective measures, because the double-bundle technique reconstructs both anteromedial and posterolateral bundles, and keeping the knee more stable. However, for functional recovery, there was no significant difference between single-bundle and double-bundle reconstructions technique.

5. Conflict of interest

The authors declare no conflict of interest.

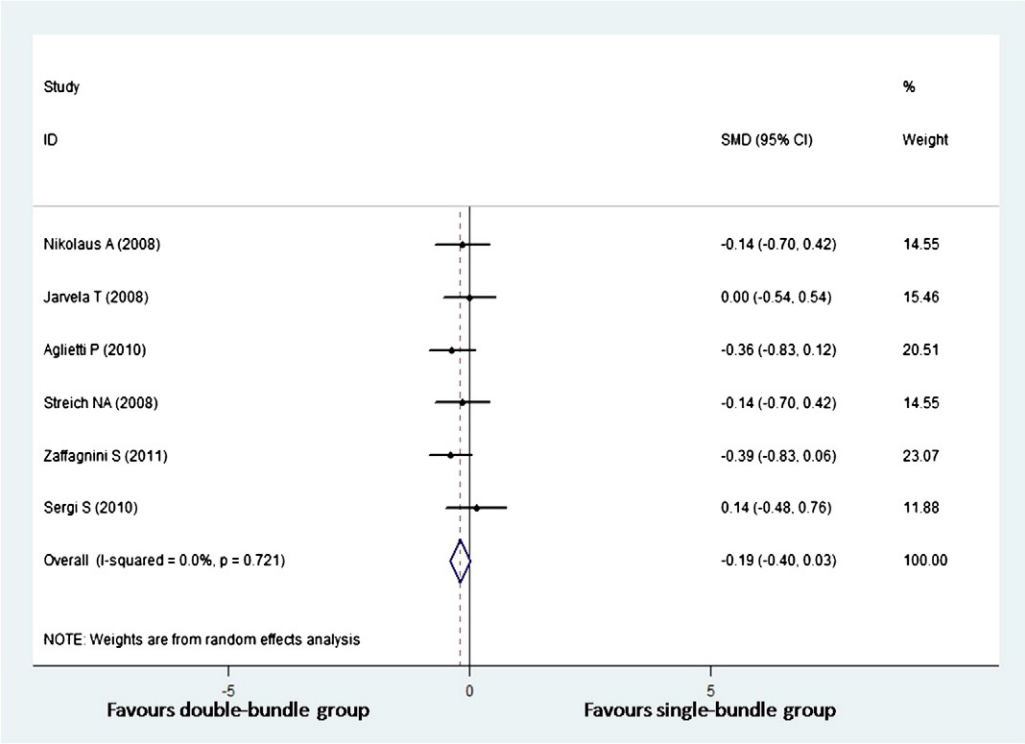

Fig. 8. Forest plots of pooling IKDC scores.

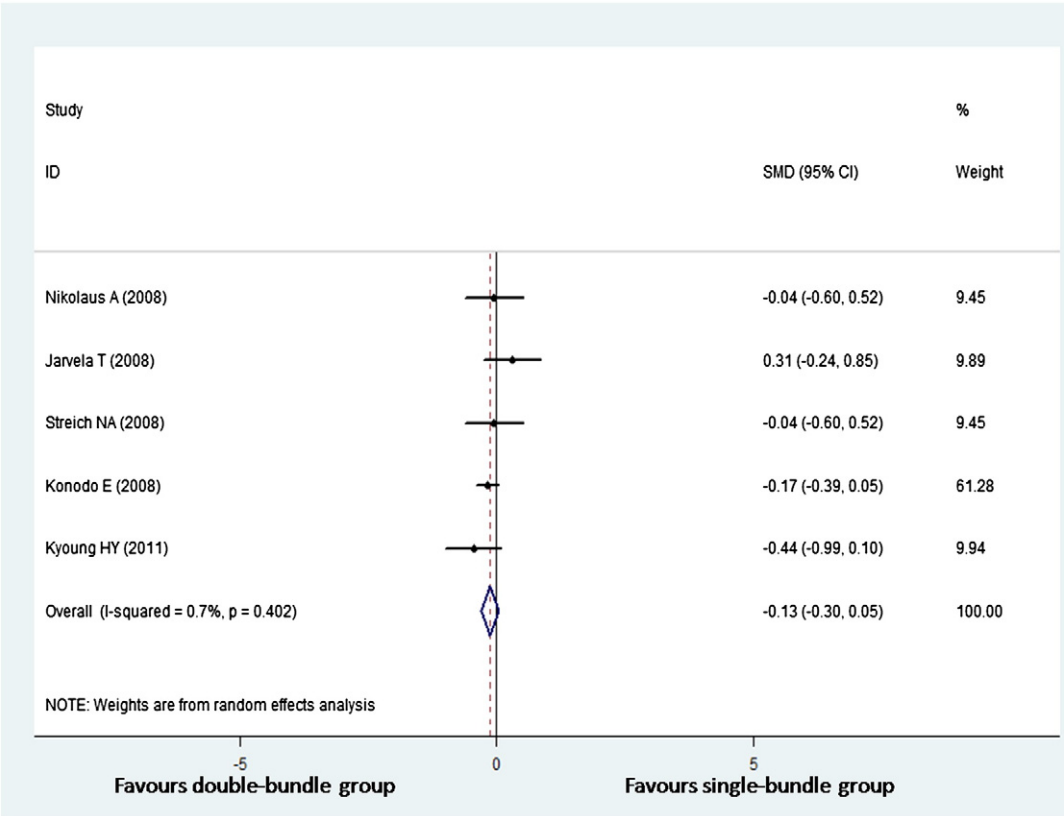

Fig. 9. Forest plots of pooling Lysholm knee scores.

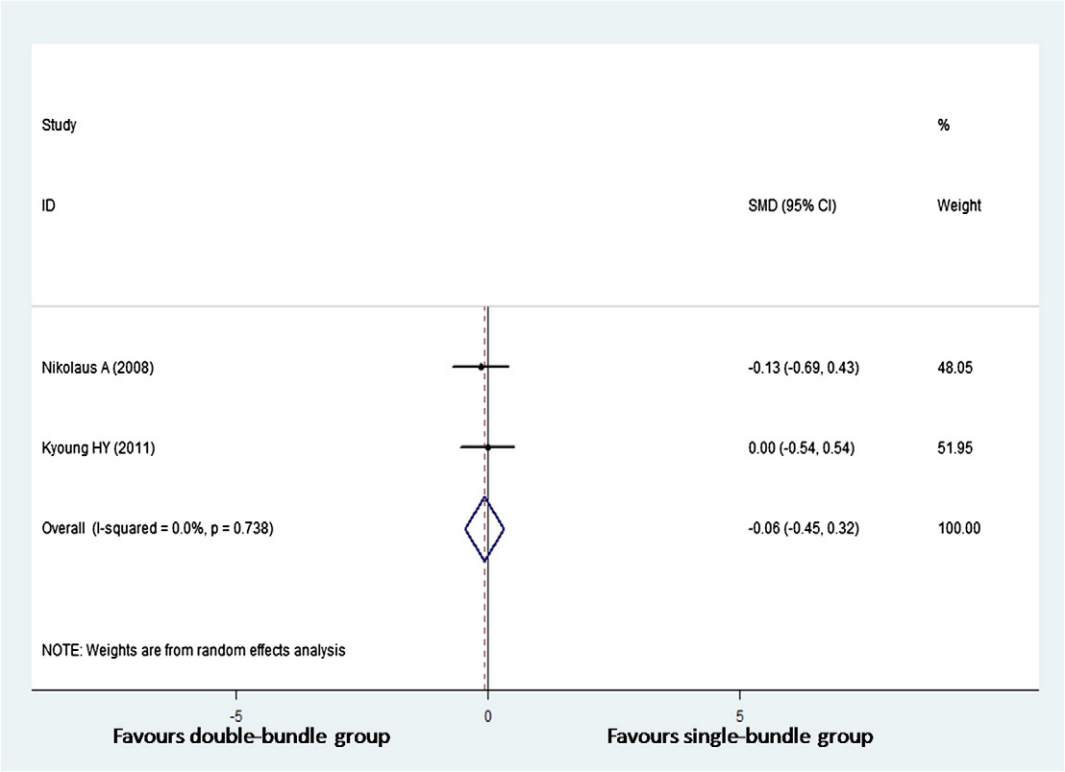

Fig. 10. Forest plots of pooling Tegner activity scores.

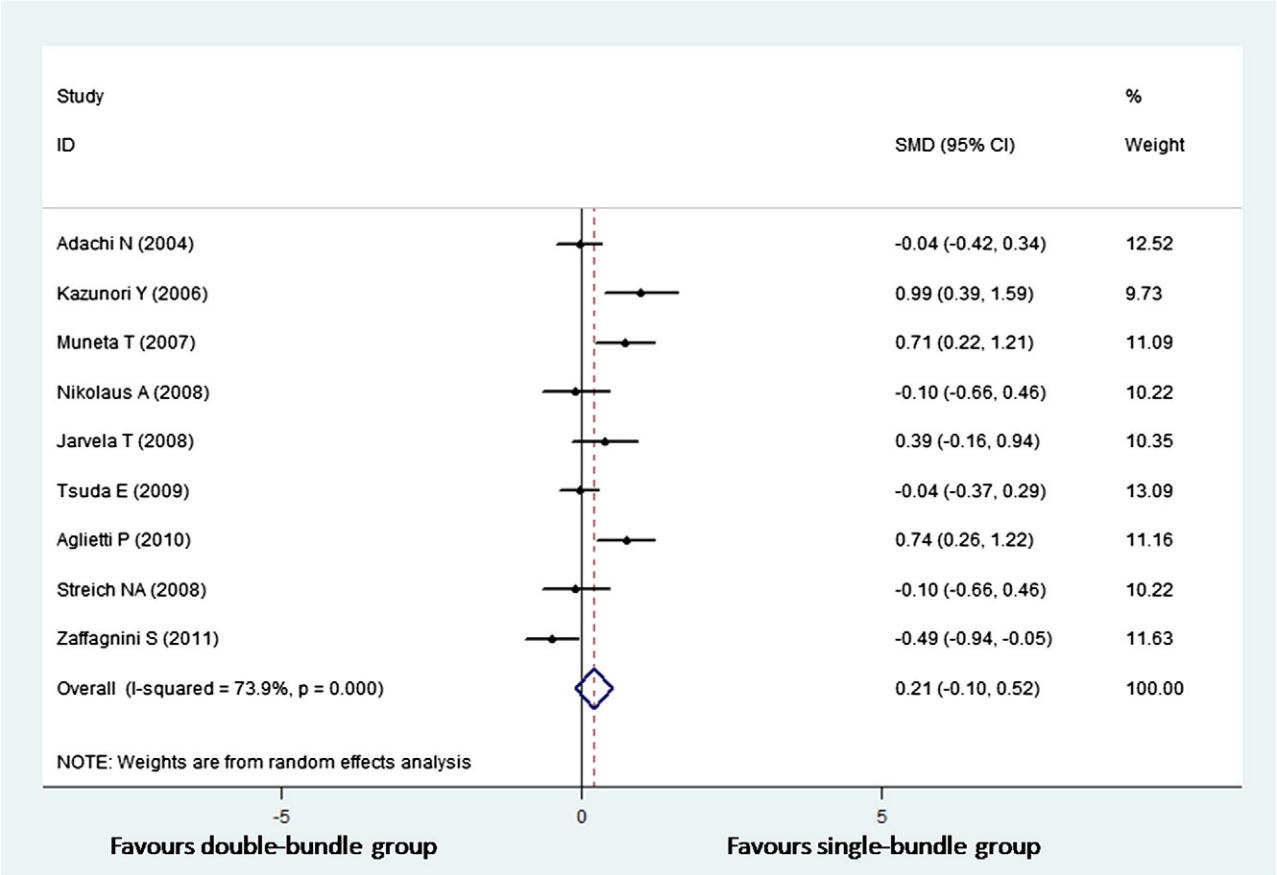

Fig. 11. Forest plots of pooling KT arthrometer.

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