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Review article

The effect of knee bracing on the knee function and stability following anterior cruciate ligament reconstruction: A systematic review and meta-analysis of randomized controlled trials

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ABSTRACT

Background: Knee brace has been commonly used as a device to protect the graft after reconstruction of anterior cruciate ligament (ACL). Studies have focused on the effects of braces after ACL reconstruction, and controversial results were reported. The current meta-analysis was conducted to identify whether knee braces could provide superior clinical outcomes on knee functional scores and stability evaluations.
Hypothesis: Knee braces could not provide superior clinical outcomes on knee functional scores and stability evaluations.
Materials and Methods: Two reviewers independently retrieved the literature on PubMed, Embase and the Cochrane Central Register of Controlled Trials (CENTRAL). Data related to the knee functional scores and stability evaluations, including International Knee Documentation Committee (IKDC) evaluation, Lachman test, manual anterior drawer test, single leg hop test, pivot shift test, side-to-side difference, Lysholm score and Tegner score, were extracted and pooled using meta-analysis with fixed or random-effect models when applicable.
Results: A total of 7 studies with 440 participants were finally included. The IKDC objective score was pooled using the odds ratio (OR) as effect size, which was demonstrated to be non-significantly different between the brace and no brace groups. All of the other clinical outcomes, including Lysholm score, Tegner score, side-to-side difference, single-leg hop test and VAS pain score, were pooled using the standard mean difference (SMD) as effect size. At final follow up, the aforementioned clinical outcomes were demonstrated to be similar between the brace and non-brace groups.
Discussion: Knee bracing does not appear to improve the clinical outcomes on the function and stability for ACL-reconstructed knees. Thus, bracing for patients treated with ACL reconstruction should not be recommended routinely.
Level of Evidence: I, Meta-analysis.

1. Introduction

Anterior cruciate ligament (ACL) rupture is a very common injury, especially after many vigorous sports programs, such as ball games and contact sports. As reported in the study of Zbrojkiewicz et al. [1], the number of patients with reconstructed ACL has improved from 54.0 in 2000 to 77.4 in 2015 per 10,000 person per year, and the prevalence of ACL reconstruction in people aged 20–24 years was as high as 283 cases per 10,000 person per year. ACL reconstruction is the primary approach to restore the knee function and stability, which is often associated with a high incidence of re-rupture of graft and contralateral ACL [2]. It has been reported that 86% of the anterior restraining forces in the knee and functions as the primary restraint against rotational instability is provided by the ACL [3]. Thus, the knee brace has been commonly used as a device to postoperatively protect the graft, which could limit the range of motion of the knee, protect against excessive varus-valgus forces, and prevent anterior-posterior translation and rotation of the tibia [3,4]. According to the American Orthopaedic Society for Sports Medicine (AOSSM), the brace is used in about 85% of the cases following ACL reconstruction procedure [5]. There are generally three types of knee braces, including prophylactic braces (designed to prevent injury or reduce the severity of knee injury

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during sports activities), rehabilitative braces (designed to allow early controlled motion of the injured joint treated with surgical or non-surgical approaches) and functional braces (it is also referred to as the derotational brace, which was designed to provide stability for patients with unstable knee) [6,7].

A lot of studies have focused on the effects of braces on the knee functional performance and stability, proprioception and electromyographic and biomechanic properties after ACL reconstruction, which have been controversial on the results [8–11]. Mayr et al. [8] have compared the clinical results of patients treated with brace and without brace after ACL reconstruction, and found that there were no significant differences between the two groups on the IKDC subjective and objective scores, instrumental measurement of anteroposterior laxity with KT-1000, radiographic osteoarthritic findings and tunnel widening, in a 4 years follow-up. DeVita et al. [10] found that the patients with recent ACL reconstructions used greater extensor and plantar flexor moments at the hip and ankle and lower extensor moment at the knee, while produced more work at these joints when walking with a brace compared with walking without a brace. Therefore, in addition to promoting the moment and power adaptations, a functional knee brace may also reduce loads on recently repaired ACL during walking, thereby providing an indirect protective mechanism. In some other researches, knee brace was demonstrated to be only protective in low-intensity anteroposterior displacement and subphysiological rotational movements, while minimal protection could be provided by bracing during an unexpected movement [12,13].

In this meta-analysis, we aimed to identify whether knee braces could provide patients with ACL reconstructions superior clinical outcomes on the knee functional scores and knee stability evaluations. The working hypothesis of this review was that no superior knee functional and stability outcomes could be provided by using knee braces after ACL reconstruction.

2. Materials and Methods

2.1. Data sources and study searches

This review was conducted according to the guidelines outlined in Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement (Appendix 1). Two individual researchers conducted the searching on the platforms of PubMed, Embase and the Cochrane Central Register of Controlled Trials (CENTRAL) from the inception dates to July 2018, for potential eligible researches. Literature retrieving was carried out through a combined searching using the subject terms ("MeSH" on PubMed and CENTRAL and "Emtree" on Embase) and free terms. The key words used included: "Anterior cruciate ligament", "ACL", "Reconstruction", "Brace" and "Randomized controlled trials". The searching strategies performed were presented in electronic Appendix 2. Additionally, the references of relative articles and reviews were screened and potentially related studies were hand-searched for possible inclusion.

2.2. Inclusion and exclusion criteria

According to the "PICOS" principle, studies were selected based on the following inclusion criteria for eligibility: (1) Patients (P): patients treated with ACL reconstruction; (2) Interventions (I): patients wore a knee brace for protection or functional assistance after operation; (3) Comparison (C): patients did not wear a knee brace after operation; (4) Outcomes (O): studies reported clinical outcomes on the knee function and stability evaluations; (5) Studies (S): randomized controlled trials (RCTs) with a follow-up of more than 2 years. Exclusion criteria were: (1) duplicated studies; (2) studies designed as observational study, non-randomized clinical study, literature review, systematic review and/or meta analysis, case series or case report and letter to editors; (3) studies used repeated participants with each other. When several cohorts used the same population with each other, only the most recent one was included for data extraction. The publication language was restricted in English but there were no limitations on the participants' nationalities.

2.3. Study selection

All the possible eligible studies retrieved from platforms were imported into the software EndNote X7 version 17.0 (Clarivate Analytics, Philadelphia, USA) and checked for duplicates. After merging of the duplicated studies, two researchers independently reviewed the studies' titles/abstracts and full texts, successively. The whole process of study selection was strictly in accordance with the inclusion and exclusion criteria, and all the disagreements were discussed by the two review authors to reach a consensus.

2.4. Data extraction and quality assessment of included studies

Two authors independently extracted the following information from included studies: (1) study characteristics: lead author, publication year, lead author's country and follow-up; (2) patients information: subjects number, number of patients dropped, male percentage and age at operation; (3) treatment information: graft type used for ACL reconstruction, fixation method and treatment period with brace post-operation; (4) status of knee function and stability at final follow-up: International Knee Documentation Committee (IKDC) evaluation (in the evaluations by IKDC, data referring to the objective IKDC score, Lachman test, manual anterior drawer test, single leg hop test and pivot shift test were extracted), side-to-side difference by KT-1000/KT-2000, Lysholm score and Tegner score. Data extracted was entered into a pre-built Microsoft Excel spreadsheet. We figured out difference on the obtained information and resolved disagreement after discussion with a third senior reviewer. The process of data extraction was conducted according to the checklists of data collection which was proposed by the Cochrane Collaboration [14].

The quality of the included RCTs was assessed independently by the two reviewers based on the Cochrane Collaboration tool for assessing risk of bias. The tool included the following items: randomization sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias. All disagreements were resolved by the third reviewer.

2.5. Statistical analysis

When data was reported with the mean value and standard deviation (SD), an exploratory meta-analysis would be conducted using standard mean difference (SMD) as the effect size. While outcomes were reported as ordered categorical data, such as IKDC objective score (grade A–D), they were transferred to dichotomous variables as normal (grade A–B including normal and near normal grades) and abnormal groups (grade C–D including abnormal and obviously abnormal grades) and pooled using the odds ratio (OR) as effect size. In the studies reported median and range values, the calculation spreadsheet was used to assist us in estimating the mean values and SD according to the study of Hozo SP et al. [15]. The heterogeneity was tested with I^2. In case with significant heterogeneity ($I^2 > 50\%$) random-effect model and sensitivity analysis was employed, while fixed-effect model was selected when presenting with excellent homogeneity [16]. Z test was used to test

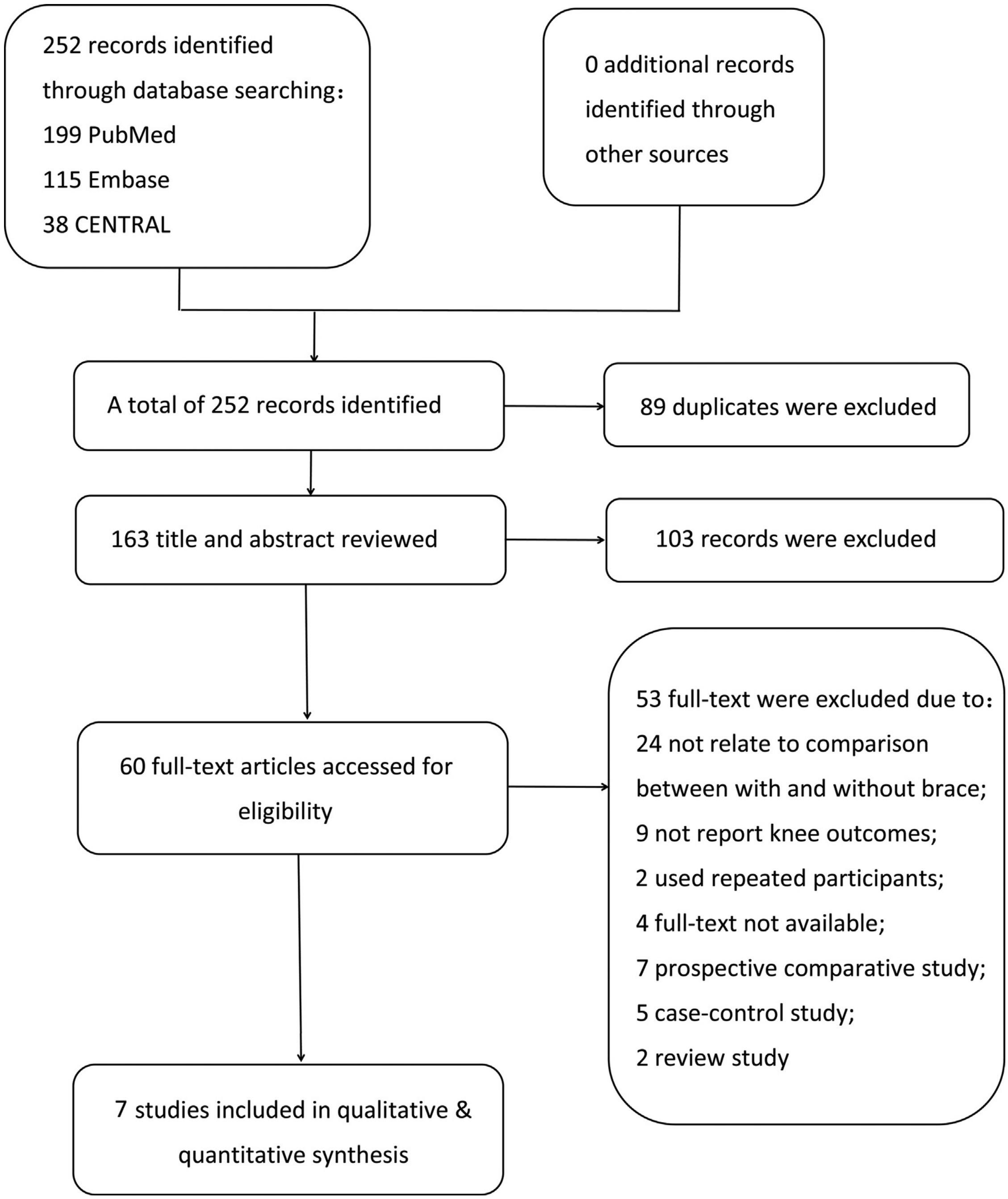

Fig. 1. Flowchart describing the literature search and study selection.

the statistical significance on the pooled effect sizes. Funnel plot was used to detect the existing publication bias [17]. The statistical significance was defined at a two-sided p value of less than 0.05. Additionally, a meta regression analysis was performed based on the treatment period of knee bracing. The statistical procedures were conducted through software of Review Manager version 5.3 (Cochrane Collaboration).

3. Results

3.1. Study retrieving and selection

The flowchart of the study searching and selecting is shown in Fig. 1. In total, 252 articles were identified through database searching and manual retrieving. The titles and abstracts of 163 articles were reviewed after duplicates removed. A total of 103 studies not related to this topic were excluded after reviewing the titles and abstracts. Then, the full texts of 60 studies were remained for the final selection. A total of 7 studies [8,11,18–22] were finally included. Two studies of Harilainen et al. [22,23] were related to repeated participants with different follow-up periods, and only the recent one [22] was included.

3.2. Summaries of the included studies

The summaries of the studies and patients are presented in Table 1. The follow-up periods were 2, 4 and 5 years in 4, 2 and 1 studies, respectively. The number of patients included in the studies was 440 (219 in brace group and 221 in no brace group) and numbers of patients dropped were both 24 in the two groups at

Table 1
Summary of included studies.

Study ID	Country	Group	Patients (N)	Dropped (N)	Age (years)	Male %	Graft used for ACL reconstruction	Fixation method	Type of brace	Treatment period with brace post-op	Follow-up
Mayr, 2014 [8]	Germany	Brace	27	5	Mean: 40 ± 11	81.5	BPTB-auto	F&T: titanium interference screw	Functional brace	6 weeks	4 years
		No brace	25	7	Mean: 35 ± 8	88.0					
Risberg, 1999 [11]	Norway	Brace	28	2	Mean: 28 (15–47)	53.0	BPTB-auto	N/A	Rehabilitative brace	12 weeks	2 years
		No brace	28	2							
Möller, 2001 [18]	Sweden	Brace	27	3	Median: 28 (21–53)	50.0	PT-auto	F&T: titanium interference screw	Rehabilitative brace	6 weeks	2 years
		No brace	29	3	Median: 31 (19–48)	46.9					
McDevitt, 2004 [19]	USA	Brace	47	3	N/A	N/A	BPTB-auto	F&T: interference metallic screw	Functional brace	6 weeks	2 years
		No brace	48	2							
Brandsson, 2000 [20]	Sweden	Brace	22	3	Median: 28.5 (15–42)	76.0	PT-auto	F&T: interference screws	Rehabilitative brace	3 weeks	2 years
		No brace	20	5	Median: 25 (16–40)	72.0					
Feller, 1997 [21]	Australia	Brace	19	1	Mean: 30 ± 9	60.0	PT-auto	F&T: interference screws	Rehabilitative brace	6 weeks	4 years
		No brace	20	0	Mean: 28 ± 9	60.0					
Harilainen, 2006 [22]	Finland	Brace	23	7	Median: 26 (16–42)	53.3	PT-auto	F&T: metal interference screw	Rehabilitative brace	12 weeks	5 years
		No brace	25	5	Median: 25 (15–50)	60.0					

BPTB-auto: bone-patella tendon-bone autograft; PT-auto: patella tendon autograft; F&T: femoral & tibial.

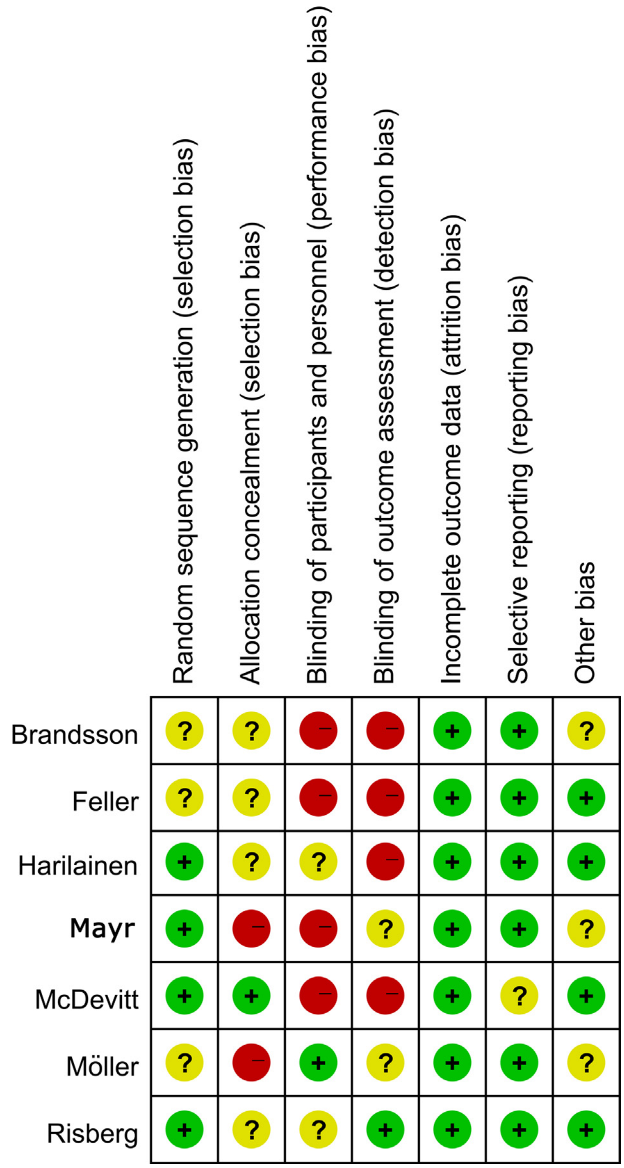

Fig. 2. Results of quality assessment on the studies based on the Cochrane Collaboration tool for assessing risk of bias.

the final follow-up. The male percentage was ranged from 46.9% to 88.0% in the included studies. Three studies conducted the ACL reconstruction with bone-patella tendon-bone autograft and the other four selected patella tendon autograft without bone block for reconstruction. The mean treatment period with knee brace postoperatively was 7.3 ± 3.4 weeks in the brace group.

All included studies were assessed by the Cochrane Collaboration tool for assessing risk of bias (Fig. 2). In general, the studies were of a low risk of bias on the random sequence generation, incomplete outcome data, selective reporting and other bias. But only one study was presented to be with a low risk of bias for the allocation concealment, blinding of participants and personnel and blinding of outcome assessment.

3.3. *Results of quantitative syntheses*

The results of the quantitative syntheses are shown in the Fig. 3. The IKDC objective score (graded as A–D) was pooled using the OR as effect size. A I^2 of 0% was presented and the fixed-effect model was selected. As a result, the IKDC objective score was demonstrated to be non-significantly different between the brace and no brace groups (OR = 1.02, CI95% 0.40–2.64, Z = 0.05, p = 0.96). All of the other clinical outcomes were pooled using the SMD as the effect size. Of these, the Lysholm score, side-to-side difference and single-leg hop test were pooled with fixed effect model while Tegner score and VAS with random effect model. Additionally, one study was excluded by sensitivity analysis for causing of obvious heterogeneity in the pooling of VAS [20]. As a result, the Lysholm score (SMD = – 0.01, CI95% – 0.29–0.27, Z = 0.09, p = 0.93), side-to-side difference (SMD = – 0.03, CI95% – 0.26–0.20, Z = 0.29, p = 0.77), single-leg hop test (SMD = 0.19, CI95% – 0.06–0.44, Z = 1.48, p = 0.14), Tegner score (SMD = 0.11, CI95% – 0.45–0.68, Z = 0.39, p = 0.70) and VAS (SMD = 0.15, CI95% – 0.38–0.68, Z = 0.56, p = 0.58) were all demonstrated to be non-significantly different between the brace and non-brace groups at the final follow-up.

Favorable symmetries were presented in all of the funnel plots which indicates non-existing of obvious publication bias (Supplementary data, Fig. S1). Meta regression analysis found that post-operative treatment period of knee bracing is not a significant factor to cause between-study heterogeneity (Supplementary data, Fig. S2 and Table S1).

4. Discussion

The main finding of this meta-analysis is that no superior treatment results is related to the application of knee brace after ACL reconstruction, on the knee function and stability evaluations as well as the VAS pain score. Our hypothesis is confirmed.

Bracing after ACL reconstruction has become a very common practice, as clinicians believed that it improves the post-operative knee outcome by decreasing the mechanical load, improving extension, decreasing asymmetry of the limb force, and limiting the excessive tibial rotation during pivoting [24–29]. However, controversy has been proposed in plenty of recent studies on the role of post-operative knee bracing after ACL reconstruction [19,22,30–34]. Dai et al. [30] recently found that functional knee brace has little effect on limb kinematic and kinetic asymmetries and little potency on reducing the risk of re-injury following ACL reconstruction. Wu et al. [31] compared the functional performances (including speed of running and turning, speed of running and jumping, and accuracy of landing after the jump) of brace and non-brace groups with unilateral ACL reconstruction, and found that knee bracing could not improve functional performances of subjects 5 months after operation. Reversely, the use of such a brace could actually slow down running and turning, irrespective of the mechanical constraints of the brace. Kruse et al. [32] performed an evidence-based systematic review of level-I and II clinical trials, pointing out that bracing following ACL reconstruction remains neither necessary nor beneficial and adds to the cost of the procedure. Bordes et al. [33] retrospectively compared the clinical outcomes of knee bracing in the early phase of rehabilitation after ACL reconstruction in a large cohort of athletes (N = 969), giving no significant difference in the clinical outcomes between bracing and no bracing groups. Rodriguez-Merchán et al. [34] also reviewed available literature observing the treatment results of knee bracing for ACL-reconstructed patients, raising same conclusion as our meta-analysis that there is no sufficient evidence to inform current practice of routine use of a knee brace following successful ACL reconstruction in the postoperative course. It could be speculated that knee bracing merely helps the patients to compensate for their deficits on the ACL after surgery, and the effect only exists at the time when wearing a brace. Thus, the protective effect of the brace may not exist anymore in a mid- to long-term follow-up. The temporary effects of braces on the operated knee joints are not

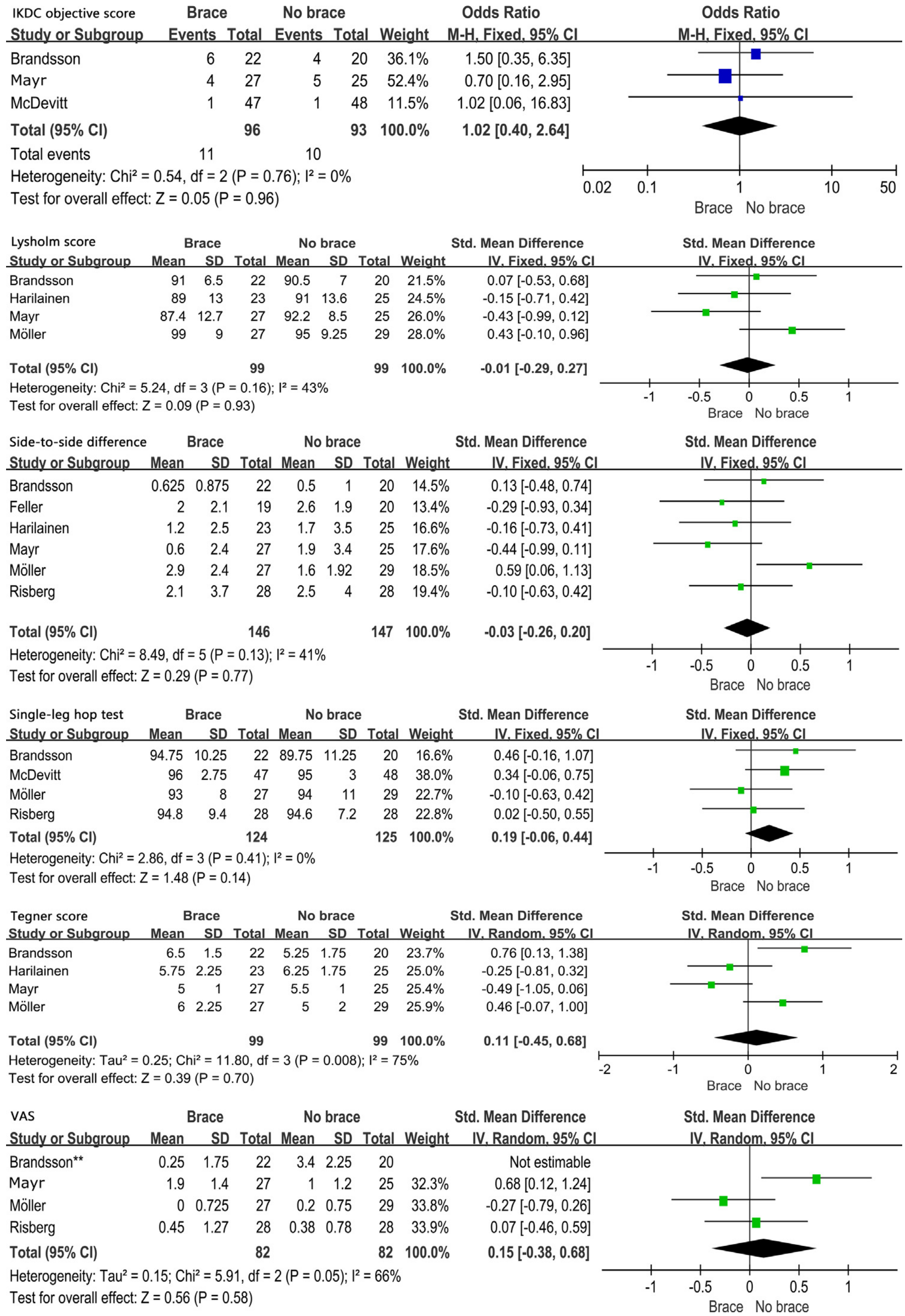

Fig. 3. Forest plots comparing the clinical outcomes between patients treated with and without knee brace after ACL reconstruction including IKDC objective score, Lysholm score, side-to-side difference, single-leg hop test, Tegner score and VAS. As a result, all of the clinical outcomes were demonstrated to be similar in the two groups of patients.

correspondingly related to improved treatment results, meaning the rationale behind asking patients to wear a brace is unpersuasive.

By contrast, knee bracing after ACL reconstruction has been reported to be associated with some additional adverse effects to the operated knees [18,33,35–37]. Di Miceli et al. [35] showed that bracing and delayed weight bearing after ACL reconstruction have a negative influence on long-term functional outcomes according to the subjective IKDC score. This finding is consistent with results of some previous systematic reviews which showed that accelerated rehabilitation, early weight bearing, and early gaining on range of motion are generally safe and beneficial to patients' outcomes. Möller et al. [18] found that patients treated with braces were more likely to be associated with higher knee circumference and prevalence of postoperative swelling, as increased compress on the soft tissues of leg may be caused by knee bracing. Some other disadvantages have also been claimed, including potential thigh atrophy, loss of flexion range of motion and increased fatigability during sports [33,36,37].

With the emergence of the vast majority of evidences to oppose the routinely application of knee braces following ACL reconstruction, it is time to reconsider the rationale and cost performance of this common practice. Though most clinicians selected to apply functional braces for patients undergoing ACL reconstruction, according to Decoster et al. [38], 36% of them have recently made changes in their brace prescription practices, including using bracing less often. Indubitably, the mounting pressure to reduce the cost of operation and rehabilitation is now posing a great challenge on the use of knee brace in ACL-reconstructed patients for increased cost [32,39]. Thus, knee braces should not be routinely applied for ACL-reconstructed patients based on the currently available evidences.

This study, nevertheless, has some limitations. First, most of the studies included were showed to be with high risk of bias in the blinding of participants and personnel and blinding of outcome assessment. It may be due to that the blinding process was unrealizable for the primary researchers. Then, the follow-up of each study was inconsistent which was ranged 2–5 years. However, only studies which were followed for at least 2 years were included in this article. Finally, with limited RCT evidences included in this meta-analysis, data for some else vital outcomes (such as Lachman and pivot-shift tests for evaluating the rotational stability of knee joints) were not available to be quantitatively synthesized.

5. Conclusions

In general, knee bracing does not appear to improve the clinical outcomes on the function and stability for ACL-reconstructed knees. On the contrary, some negative influence on the knee outcome and additional cost may be caused in the rehabilitation process with braces. Thus, bracing for patients treated with ACL reconstruction should not be recommended routinely.

Disclosure of interest

The authors declare that they have no competing interest.

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Contribution

Yang XG: methodology, validation, formal analysis, investigation, data curation, writing-original draft, writing-reviewing and editing, project administration. Feng JT: investigation, writing-reviewing and editing. He X: methodology, validation, investigation, writing-reviewing and editing. Wang F: conceptualization, methodology and validation. Hu YC: conceptualization, methodology, validation, investigation, writing-reviewing and editing.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.otsr.2019.04.015.

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