Does Double-Bundle Anterior Cruciate Ligament Reconstruction Improve Postoperative Knee Stability Compared With Single-Bundle Techniques? A Systematic Review of Overlapping Meta-analyses


Purpose: Multiple meta-analyses of randomized controlled trials, the highest available level of evidence, have been conducted to determine whether double-bundle (DB) or single-bundle (SB) anterior cruciate ligament reconstruction (ACL-R) provides superior clinical outcomes and knee stability; however, results are discordant. The purpose of this study was to conduct a systematic review of meta-analyses comparing SB and DB ACL-R to discern the cause of the discordance and to determine which of these meta-analyses provides the current best available evidence. Methods: We evaluated available scientific support for SB as compared with DB ACL-R by systematically reviewing the literature for published meta-analyses. Data on patient clinical outcomes and knee stability (as measured by KT arthrometry and pivot-shift testing) were extracted. Meta-analysis quality was judged using the Oxman-Guyatt and Quality of Reporting of Meta-analyses systems. The Jadad algorithm was then applied to determine which meta-analyses provided the highest level of evidence. Results: Nine meta-analyses were included, of which 3 included Level I Evidence and 6 included both Level I and Level II Evidence. Most studies found significant differences favoring DB reconstruction on pivot-shift testing, KT arthrometry measurement of anterior tibial translation, and International Knee Documentation Committee objective grading. Most studies detected no significant differences between the 2 techniques in subjective outcome scores (Tegner, Lysholm, and International Knee Documentation Committee subjective), graft failure, or complications. Oxman-Guyatt and Quality of Reporting of Meta-analyses scores varied, with 2 studies exhibiting major flaws (Oxman-Guyatt score <3). After application of the Jadad decision algorithm, 3 concordant high-quality meta-analyses were selected, with each concluding that DB ACL-R provided significantly better knee stability (by KT arthrometry and pivot-shift testing) than SB ACL-R but no advantages in clinical outcomes or risk of graft failure. Conclusions: The current best available evidence suggests that DB ACL-R provides better postoperative knee stability than SB ACL-R, whereas clinical outcomes and risk of graft failure are similar between techniques. Level of Evidence: Level II, systematic review of Level I and II studies.


See commentary on page 1197
Improvements in femoral tunnel positioning for SB ACL-R to a more lateral position may negate the biomechanical stability benefits of DB ACL-R. DB ACL-R has gained popularity because of an improved ability to replicate the normal anatomy of the AM and PL bundles of the ACL and the potential benefit of restoring more normal knee kinematics and stability than with SB ACL-R. Numerous clinical studies, including many prospective, randomized controlled trials, have been published to compare SB ACL-R and DB ACL-R. On the basis of the proliferation of clinical studies comparing SB and DB ACL-R, multiple authors have conducted systematic reviews and meta-analyses comparing SB ACL-R and DB ACL-R. Meredith et al. conducted the first such meta-analysis in 2008, finding a small (0.52 mm) but statistically significant improvement in knee stability as determined by KT arthrometry (MEDmetric, San Diego, CA) in favor of DB ACL-R with no other differences between techniques. Although numerous overlapping meta-analyses have been performed to compare SB and DB ACL-R, the results of the meta-analyses have been discordant in their findings regarding the clinical outcomes and knee stability provided by these 2 techniques.

The purposes of this study were (1) to conduct a systematic review of meta-analyses comparing SB and DB ACL-R, (2) to propose a guide through the currently discordant best available evidence to provide treatment recommendations, and (3) to highlight gaps in the literature that require future research. The null hypothesis was that SB and DB ACL-R would exhibit similar clinical outcomes.

Methods

A systematic review of the literature was performed using the PubMed database, Cochrane Database of Systematic Reviews, Scopus database, and Embase database. The following search terms were used, with study type limits set to meta-analysis or systematic review: single-bundle, double-bundle, and anterior cruciate ligament. The search was performed on March 22, 2014, and repeated on May 27, 2014, while being limited to articles written in English. Broad search query terms were used to identify all possibly applicable studies. All reviewed articles were then manually cross-referenced to ensure that all eligible studies were included.

The abstracts that resulted from these searches were reviewed by 2 of the authors (R.M., G.L.C.). The inclusion criteria were (1) meta-analyses that compared SB and DB ACL-R techniques and (2) English language. The exclusion criteria were (1) narrative reviews or those without an organized and reported search algorithm, (2) studies without clinical outcomes data, (3) systematic reviews that did not pool data or perform a meta-analysis, and (4) cadaveric or other laboratory studies. We then obtained full manuscripts for those studies that met the inclusion and exclusion criteria. The references for each of these citations were then manually screened to ensure that no studies were missed. The tables of contents for the past 2 years of the Journal of Bone and Joint Surgery, American Journal of Sports Medicine, Clinical Orthopaedics and Related Research, and Arthroscopy were manually searched as well for any additional studies. A PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram shows our study selection algorithm (Fig 1).

For those studies that met the eligibility criteria, the following data were extracted from each article: study criteria, study methods, surgical details, and patient satisfaction. The following standardized outcome scores were collected: International Knee Documentation Committee (IKDC) score and grade, Lysholm score, and Tegner score. Outcomes were extracted for knee stability, including pivot-shift testing, KT arthrometry, Lachman testing, and anterior drawer testing. The incidence of complications was also recorded. From each meta-analysis, the following methodologic characteristics were recorded: the rationale for repeating the meta-analysis; the number of “possible” previous meta-analyses cited as compared with the number “actually” cited; the databases that were searched; and the conclusions of the meta-analysis as to whether SB versus DB ACL-R provided superior knee stability, clinical outcomes, and graft failure rates.

Meta-analysis quality was scored using the Quality of Reporting of Meta-analyses (QUOROM) system. This system provides a method for evaluating meta-analyses based on the quality of their reporting and methodology in 18 categories. Each meta-analysis was awarded 1 point in each category if it met over half of the criteria given in that category, for a total of 18 points possible. Meta-analysis quality was also graded using the Oxman-Guyatt quality appraisal tool. The Modified Coleman Methodology Score was extracted from individual studies when available. In addition, where known biases within the literature reviewed were reported by individual trials, these were recorded.

The Jadad decision algorithm was used to guide interpretation of discordant meta-analyses. Sources of discordance among meta-analyses as described by Jadad et al. include differences in the clinical question, inclusion and exclusion criteria, data extraction, quality assessment, data pooling, and statistical analysis. Scoring was performed based on assessment of randomization, randomization methodology, double blinding, withdrawals/dropouts, and allocation concealment. It was independently applied by 3 study authors (R.M., G.L.C., E.T.S.), and their results were compared to most robustly determine which of the included meta-analyses provided the best possible evidence for treatment recommendations. All statistical analyses were performed using Excel X (Microsoft, Redmond, WA).
Results

The initial search revealed 198 abstracts, and after application of our study selection algorithm, the 16 remaining studies were narrowed down to 9 studies that fulfilled our inclusion and exclusion criteria and were selected for further analysis (Fig 1).12-20 These studies were published between 2008 and 2014, with all 9 performing a meta-analysis.4,6-9,14-17 Only 2 studies reported a potential conflict of interest.14,16 Three of the studies included Level I Evidence only,16,18,19 and 6 included Level I and Level II Evidence.12-15,17,20 The studies included from 754 patients16 to 1,686 patients,17 with mean follow-up of studies included in the meta-analyses ranging from 5 months15 to 103 months.26

Authors’ Assessment of Prior Systematic Review Literature

Authors of the included meta-analyses cited all of the available previous meta-analyses or systematic reviews (Table 1). The rationale for repeating the meta-analysis was provided in 8 of the 9 studies, with the remaining study being the first meta-analysis on the topic (Table 2). Commonly cited reasons for repeating the meta-analysis included updating the meta-analysis based on randomized controlled trials published since the previous meta-analysis, discordant conclusions from prior meta-analyses, and statistical and methodologic concerns with the prior studies (Table 2).

Outcome Measures

The included studies showed some differences in the standardized and non-standardized patient outcome measures that they reported (Table 3). Although each meta-analysis theoretically reported on a similar population of patients, variance was seen in standard mean differences in IKDC scores from −0.4315 to 1.41,18 in Lysholm scores from −1.5512 to 0.05,18 and in Tegner scores from −0.4112 to 0.38.12 In addition, the included studies showed some heterogeneity with respect to their analysis of postoperative knee stability, range of motion, strength, and complications, evidenced by their non-uniform use of the risk ratio, odds ratio, or logarithm of the odds ratio to assess graft failure and other dichotomous outcomes.

Search Methodology

Although all of the included studies searched Medline and Embase, some studies did not include searches of Scopus, the Cochrane Database of Systematic Reviews, the Cumulative Index to Nursing and Allied Health
Table 2. Authors’ Rationale for Repeating Systematic Review

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<th>Authors</th>
<th>Cited Meta-analyses</th>
<th>Rationale for Repeating Meta-analysis as Abstracted From Article</th>
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<tr>
<td>Li et al. 17 (2014)</td>
<td>Meredick et al., Kongtharvonskul et al. 19</td>
<td>“Furthermore, there were two meta-analyses published in 2008 and 2012 respectively, and no accordant conclusion was reported in the two studies. Moreover, more RCTs have been published recently.”</td>
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<td>Desai et al. 20</td>
<td>Meredick et al., 16 van Eck et al. 14</td>
<td>“A shortcoming common to all these are that there are no strict distinctions between anatomic and non-anatomic techniques.”</td>
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<td>Zhu et al. 12</td>
<td>Meredick et al. 16</td>
<td>“In our opinion, the conclusion of the prior meta-analysis is not convincing. First, the clinical outcomes of nonanatomic DB ACL reconstruction were excluded. Second, the statistics in the prior meta-analysis used to pool the results of the pivot shift test was odds ratio (OR). However, when events are common (such as when the rate of events is more than 20%), the risk ratio (RR) should be used… the misuse of OR in the prior meta-analysis will tend to overestimate the pooled effects. Finally, the prior meta-analysis did not take the length of follow-up into consideration…”</td>
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<td>Kongtharvonskul et al. 19</td>
<td>Meredick et al. 16</td>
<td>“…this meta-analysis did not consider other clinically relevant outcomes (e.g., function outcomes and complications) and sources of heterogeneity (e.g., grade of injury, age, sex, and use of instrument assessments) were not assessed. Moreover, other RCTs have since been published recently.”</td>
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<td>Li et al. 18 (2013)</td>
<td>Meredick et al., 16 Kongtharvonskul et al. 19</td>
<td>“A previously published meta-analysis which included only four randomised controlled trials (RCTs) showed that there were no clinically significant differences in KT1000 arthrometer and pivot-shift results between single-bundle and double-bundle techniques in 2008. Therefore, it remains unclear which technique has much more advantages.”</td>
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<td>Xu et al. 13</td>
<td>Meredick et al., 16 Chen et al. 27</td>
<td>“However, the meta-analysis [of Meredick et al.] included a limited number of randomized controlled trials (RCTs). Chen et al. included RCTs reconstructing the ACL using only anatomical technique and reported results similar to those of Meredick et al. Yet, their follow-up was short and the evaluation time points in this work are unknown.”</td>
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<td>Tiamklang et al. 15</td>
<td>Meredick et al. 16</td>
<td>“Firstly, Meredick 2008 presented data from the first two reports… as if these were separate trials… Secondly, while it does not substantially affect their conclusions, Meredick 2008 appears to have incorrectly pooled the data from two trials… this resulted in the double counting of patients from the double-bundle group in the analyses.”</td>
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<td>van Eck et al. 14</td>
<td>Meredick et al. 16</td>
<td>“Their meta-analysis included a mix of a small sample of randomized and observational studies… we expanded the search to include more studies; we explored a wider variety of outcomes, including patient-reported outcomes; and most importantly, we aimed to avoid inappropriate pooling of data by performing subgroup analysis for studies with more than 2 years’ follow-up, anatomic single- versus anatomic double-bundle reconstructions, and nonanatomic single- versus nonanatomic double-bundle reconstructions.”</td>
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<td>Meredick et al. 16</td>
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ACL, anterior cruciate ligament; DB, double bundle; NA, not applicable; RCT, randomized controlled trial.
Literature, and other databases. Of the studies, 4 searched 4 databases,\textsuperscript{13-15,17} 4 searched 3 databases,\textsuperscript{12,18-20} and 1 searched 2 databases\textsuperscript{16} (Table 4).

The total number of unique primary studies cited by the included meta-analyses was 47 (Table 5). The number of primary studies varied widely from 9\textsuperscript{16} to 21,\textsuperscript{15} with a median of 17 studies cited (Tables 4 and 5).

**Study Results**

One study reported lower rates of graft failure for DB compared with SB ACL-R,\textsuperscript{18} whereas 2 studies found no difference.\textsuperscript{15,20} Higher IKDC subjective scores were found in 1 study favoring DB compared with SB ACL-R,\textsuperscript{18} whereas 4 studies found no difference.\textsuperscript{13,15,17,19} No studies found significant differences in Tegner or Lysholm scores between DB and SB ACL-R.\textsuperscript{12-15,17-19} A lower complication rate was seen in 1 study in the setting of DB ACL-R when compared with SB ACL-R,\textsuperscript{12} whereas 4 studies found no difference.\textsuperscript{14,15,17,19}

Two studies found no significant difference in pivot-shift testing between DB and SB ACL-R,\textsuperscript{16,20} whereas 7 studies found DB ACL-R to have superior pivot-shift results.\textsuperscript{12-15,17-19} Similarly, 8 studies found superior KT arthrometry data for DB as compared with SB ACL-R,\textsuperscript{12-16,18-20} whereas 1 study found no significant difference (but did report a significant difference in KT grade).\textsuperscript{17} IKDC objective grade was found to be superior for DB ACL-R by 6 studies,\textsuperscript{12-15,17,19} with no difference found in 1 study.\textsuperscript{18} Results of the Lachman test were superior for DB ACL-R in 3 studies,\textsuperscript{12-14} with no significant difference found in 2 studies.\textsuperscript{15,20}

**Study Quality and Validity**

QUOROM scores were assessed for each study and varied from 14\textsuperscript{16} to 18,\textsuperscript{14} with a median of 15 and a maximum possible score of 18 (Table 4). Oxman-Guyatt scores varied from 2\textsuperscript{16,18} to 4\textsuperscript{14,15,17} on a scale of 1 to 7, with a median score of 3 (Table 4). Two studies had Oxman-Guyatt scores of 2,\textsuperscript{16,18} with scores of 1 and 2 generally considered to indicate that the study had “major flaws.”\textsuperscript{22,71}

**Heterogeneity Assessment**

Several methods were used to assess study heterogeneity. Of the 9 studies, 8 performed a statistical heterogeneity analysis.\textsuperscript{12-15,17-20} Studies varied in performing sensitivity analyses for parameters such as primary study quality, gender, age, graft type, and outcome measures (Table 6). Some studies addressed sources of study heterogeneity through discussion without analysis (Table 6).

**Application of Jadad Decision Algorithm**

The Jadad decision algorithm was applied to determine which of the 9 studies included meta-analyses that
provides improved postoperative knee stability compared with SB ACL-R as measured by KT arthrometry and pivot-shift testing, although the effect on clinical outcomes and risk of graft failure was not found to be significant. Our null hypothesis was thus rejected, and surgeons caring for patients with ACL injuries must consider whether the stability benefits of DB ACL-R without definite evidence of improved functional outcomes or reduced graft failure rates justify the increased complexity of the DB ACL-R technique.

Of the 9 studies included in this review, 3 had Oxman-Guyatt scores of 4, indicating no major flaws with their methodology, whereas 2 had scores of 2, indicative of major methodologic flaws. In addition, application of the Jadad algorithm for evaluation of systematic review quality identified the same 3 studies that scored 4 on the Oxman-Guyatt scale as having the highest level of evidence. These studies were therefore determined to be the highest level of evidence available on the subject of SB versus DB ACL-R. Li et al. found that DB ACL-R patients had improved rotational stability (pivot-shift test, KT grading, and IKDC grading) but showed no differences in functional outcomes when compared with SB ACL-R (IKDC score, KT arthrometer testing, Lysholm score, Tegner score, and complication rate). Van Eck et al. reported data in favor of DB ACL-R for anterior and rotational laxity (KT arthrometer testing, Lachman testing, IKDC grading, and pivot-shift testing) but reported no differences in range of motion, Lysholm scores, or complications when compared with SB ACL-R. Finally, Tiamklang et al. found data in favor of DB ACL-R for return to preinjury activity level and knee stability (IKDC grading, KT-1000 testing, pivot-shift testing) but no differences in range of motion or functional outcomes (IKDC score, Tegner score, Lysholm score, and complications). They also found limited evidence that DB ACL-R results in lower rates of subsequent meniscal injury and traumatic ACL rupture.

The pivot-shift and Lachman tests, along with anterior drawer testing, are the key physical examination...
Table 5. Primary Studies Included in Meta-analyses

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Maneuvers in the diagnosis of an ACL tear. The Lachman and anterior drawer tests assess anterior translation of the tibia on the femur, whereas the pivot-shift test assesses rotational stability. Although the best evidence from the highest-quality meta-analyses suggests that DB ACL-R yields superior postoperative knee stability (based on KT arthrometry and pivot-shift testing) when compared with SB ACL-R, these tests show some user subjectivity in grading, interexaminer variability, and dependence on patient cooperation. One could not ascertain from these studies the placement of the femoral tunnel location; a more vertically oriented graft could explain these pivot-shift differences. Of interest would be the comparison of an SB graft placed centrally within the femoral footprint and a DB graft that fills more of the femoral footprint. KT arthrometry allows objective assessment of anteroposterior laxity and may provide good reliability for experienced users. The statistically significant KT arthrometry difference between SB and DB ACL-R may have questionable clinically significance because the observed difference between SB and DB ACL-R ranged from 0.56 to 0.74 mm. The statistically significant, it is unlikely that this difference of less than 1 mm is a clinically meaningful result. Moreover, the observed differences in stability on physical examination could be clinically insignificant because the meta-analyses overall identified no difference in functional outcome scores and graft failure rates. The clinical significance of small improvements in anterior and rotational translation of the knee thus
requires further investigation. Morimoto et al.\textsuperscript{76} found that DB ACL-R led to higher tibiofemoral contact areas and lower contact pressures than SB procedures. Similarly, Tajima et al.\textsuperscript{77} found that DB ACL-R restored patellofemoral contact area and pressure more closely to the normal state than did SB ACL-R. Several authors have since concluded that DB ACL-R may lead to a lower incidence of osteoarthritis in the injured knee after DB reconstruction as opposed to SB surgery based on clinical randomized controlled trials.\textsuperscript{78,79} The relation between tibiofemoral and patellofemoral joint pressures and the small improvement in knee stability (as measured by KT arthrometry and pivot-shift testing) afforded by DB reconstruction needs to be further examined in both laboratory and long-term clinical cohort studies. In addition, these benefits must be weighed against the increased complexity, increased operative time, increased difficulty in revision of failed DB procedures, and associated higher inherent costs of DB reconstruction. Several cost analyses have shown SB ACL-R to be more cost-effective than DB techniques,\textsuperscript{80,81} and this needs to be taken into consideration with any potential benefits of the DB procedure. The strength of our review lies in the use of several validated quality assessment tools by 3 independent authors with consensus agreement to define the meta-analyses of highest quality on which to provide the best available evidence for treatment recommendations.\textsuperscript{21,22,24}

\textbf{Limitations}

Our study also has several limitations. Our analysis is limited based on the data from the included studies, which could be underpowered and susceptible to β error if DB versus SB ACL-R has a small effect on clinical

\begin{table}[h]
\centering
\caption{Heterogeneity or Subgroup Analyses of Primary Studies}
\label{tab:heterogeneity}
\begin{tabular}{lccccccccc}
\hline
 & Li et al.\textsuperscript{17} & Desai et al.\textsuperscript{20} & Li et al.\textsuperscript{18} & Zhu et al.\textsuperscript{12} & Kongtharvonskul et al.\textsuperscript{19} & Xu et al.\textsuperscript{13} & Tiamklang et al.\textsuperscript{15} & van Eck et al.\textsuperscript{14} & Meredith et al.\textsuperscript{16} \\
\hline
Statistical heterogeneity analysis & + & + & + & + & + & + & + & + & - \\
Subgroup or sensitivity analysis & + & + & + & + & + & + & + & + & - \\
Primary study quality & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 \\
Age & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 \\
Gender & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 \\
Follow-up interval & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 \\
Meniscal injury & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 \\
Anatomic v nonanatomic & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 \\
Graft type & + & + & + & + & + & + & + & + & + \\
Implant type & + & + & + & + & + & + & + & + & + \\
\hline
\end{tabular}
\textbf{NOTE.} A plus sign indicates formal sensitivity or subgroup analysis was performed, a minus sign indicates formal sensitivity or subgroup analysis was not performed, and a zero indicates descriptive data were provided or discussed, but no analysis was performed.

IKDC, International Knee Documentation Committee.
outcome metrics and graft failure rates. Much of the available literature comparing SB and DB ACL-R consists of relatively short-term follow-up, such that a significant difference that only manifests itself in long-term follow-up would be missed in this analysis. An additional limitation lies in the heterogeneity among included studies in terms of combined analysis of anatomic and nonanatomic ACL-R techniques, the former being defined by tibial and femoral tunnel drilling in the native ligament or bundle insertion site or sites, which may yield different stabilities particularly regarding rotational laxity. Van Eck et al. conducted a subgroup analysis of anatomic and nonanatomic ACL-R techniques, showing no significant difference in outcomes for the nonanatomic ACL-R technique. It is therefore possible that tunnel location could be more critical in ACL-R outcome than the choice between SB and DB reconstruction. It is conceivable that differences in postoperative knee laxity (as measured by KT-1000 and pivot-shift testing) seen between SB and DB reconstruction techniques could be due to SB grafts being used to re-create the AM or PL bundle alone rather than a hybrid of the 2 bundles.

Conclusions
In this systematic review of overlapping meta-analyses comparing SB and DB ACL-R, the current highest level of evidence suggests that DB ACL-R provides better postoperative knee stability by KT arthrometry and pivot-shift testing when compared with SB ACL-R, although the effect on clinical outcomes and risk of graft failure was not found to be significant.

References


SINGLE- V DOUBLE-BUNDLE ACL RECONSTRUCTION


