Systematic Review

Bioabsorbable Versus Metallic Interference Screws in Anterior Cruciate Ligament Reconstruction: A Systematic Review of Overlapping Meta-analyses

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Purpose: Multiple meta-analyses of randomized controlled trials have been conducted to compare clinical and functional outcomes after anterior cruciate ligament (ACL) reconstruction using metallic interference screw (MIS) versus bioabsorbable interference screw (BIS) fixation, but discrepancies in their findings have prevented a consensus conclusion. The purposes of this study were (1) to conduct a systematic review of meta-analyses comparing MISs and BISs in ACL reconstruction, (2) to provide surgical treatment recommendations for ACL graft fixation based on the highest available evidence, and (3) to propose future research avenues in areas of practice lacking high-level evidence. **Methods:** The literature was systematically reviewed to identify meta-analyses comparing MISs and BISs in ACL reconstruction. Data were extracted for clinical and functional outcomes, and methodologic quality was assessed using the validated Quality of Reporting of Meta-analyses and Oxman-Guyatt systems. To determine which meta-analyses provided the current best available evidence, the Jadad decision algorithm was used. **Results:** One Level I and 2 Level II meta-analyses were included. None showed differences between BISs and MISs in validated outcome scores, pivot-shift testing, KT arthrometry (MEDmetric, San Diego, CA), or loss of knee motion. Subgroup analyses found no differences in clinical outcomes or knee stability across biomaterials. All meta-analyses were of high quality according to the Quality of Reporting of Meta-analyses and Oxman-Guyatt systems. Two meta-analyses were determined by the Jadad algorithm to represent the current best available evidence. Both studies showed prolonged knee effusion with BIS use, with 1 also showing an increased incidence of femoral tunnel widening and screw breakage with BIS use. **Conclusions:** Whereas clinical and functional outcomes are similar with MISs and BISs, prolonged knee effusion, femoral tunnel widening, and screw breakage are more common with BIS use. Future cost-effectiveness analyses may help weigh the known advantages of BISs against their costs and adverse-event profile. **Level of Evidence:** Level II, systematic review of Level I and II studies.

Anterior cruciate ligament (ACL) injury is common in the active population, with the annual incidence of reconstructive procedures nearing 300,000 in the United States.[1] The goals of ACL reconstruction are to improve functional outcomes, restore knee joint stability, and prevent subsequent damage to the remaining intra-articular structures.[2] Interference screws are used in bone–patellar tendon–bone ACL graft fixation to allow rigid fixation, facilitate osseous healing, and allow early range of motion. Traditionally, metallic interference screws (MISs) have afforded reliably positive clinical outcomes, prevention of excessive laxity, and low complication rates.[3] MISs promote early integration into bone with high initial fixation strength and have a higher failure load than bioabsorbable interference screws (BISs) in biomechanical studies.[4]

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Notwithstanding their established efficacy, a major drawback of MISs is their complicated hardware removal during revision surgery.[5,6] In recent years a trend away from MIS use has ensued, with a 2013 international survey of orthopaedic surgeons reporting a nearly 3-fold preference for BISs over MISs.[2] BISs dissolve after 2 to 3 years[7] and thus simplify revision.[8] In addition, BISs enable magnetic resonance imaging follow-up because of the absence of artifact.[9] However, complications have been reported with BIS use, including foreign-body tissue reaction against screw remnants,[10,11] intra-articular screw migration,[12-16] cyst or abscess formation,[17] breakage during surgery,[18] and bone tunnel widening due to incomplete integration of the bioabsorbable material into bone.[19]

Clinical outcomes and complications have generally appeared similar with BIS use and MIS use in comparative trials and case series.[5,7,20-23] Meta-analyses of available literature recently have been completed with the intent to determine superiority between screw types with respect to clinical outcome scores, knee joint stability or function, tunnel widening, knee effusion, or complication rates.[24-26] The results of these reviews are mixed, with a spectrum of conclusions ranging from a general lack of most outcome differences associated with either screw type in ACL reconstruction[25,26] to a significant difference in adverse events with BISs.[24] The authors provide their analyses but allude to the value of use of high—methodologic quality randomized controlled trials in further meta-analyses,[25] as well as a consideration of the proposed benefits with each construct with respect to cost-effectiveness,[24] when providing conclusive recommendations for screw choice.

The purposes of this study were (1) to conduct a systematic review of meta-analyses comparing MISs and BISs in ACL reconstruction, (2) to provide surgical treatment recommendations for ACL graft fixation based on the current best available evidence in the literature, and (3) to propose future research avenues based on areas of practice in which high-level evidence is lacking.

Methods

The English-language literature was searched on March 12, 2014, using the following databases: PubMed, Embase, and the Cochrane Database of Systematic Reviews. The following key words were used: "bioabsorbable," "metallic OR metal," and "anterior cruciate ligament." General search terms were used to ensure thorough study inclusion. The resultant study titles and abstracts were reviewed and manually cross-referenced to identify all potentially eligible studies. The inclusion criteria were (1) meta-analyses comparing MIS and BIS fixation in ACL reconstruction and (2) English-language literature. The exclusion criteria were (1) systematic reviews that did not pool data or perform a meta-analysis; (2) narrative reviews or reviews without an organized and reported search algorithm; and (3) cadaveric, animal, and other laboratory studies. Full articles were procured for meta-analyses meeting the eligibility criteria. The references of 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 eligible studies.

The following study-related data were extracted: the number of previously published meta-analyses or systematic reviews that could have been cited and the number that were in fact cited, the authors' rationale for repeating the meta-analysis, the search methodology and databases used in the review, and the results of the analyses. In addition, the date and journal of publication, conflicts of interest reported, level of evidence, number and publication dates of primary studies included, inclusion and exclusion criteria, performance of heterogeneity analytics, sample size, follow-up period, and follow-up rate were extracted. Data on surgical technique included the specific type of BIS or MIS, donor graft choice, location and bundling, and rehabilitation protocol. Standardized clinical outcome scores obtained included the Lysholm, International Knee Documentation Committee (IKDC), and Tegner scores. Knee stability data were extracted for pivot-shift testing, KT arthrometry (MEDmetric, San Diego, CA), and range of motion. Radiologic outcomes for postoperative tunnel widening were also procured. The incidence of intraoperative and postoperative complications was noted.

The Quality of Reporting of Meta-analyses (QUOROM) system[27] was implemented to score the meta-analysis quality. Each meta-analysis was awarded a category point if at least half of the criteria were met, with a maximum possible total of 18 points. Meta-analysis quality was also evaluated using the Oxman-Guyatt quality assessment system.[28] The 3 lead authors (R.M., B.S., E.S.) determined which of the meta-analyses provided the current best available evidence for treatment recommendations using the Jadad decision algorithm.[29] Excel X software (Microsoft, Redmond, WA) was used for data extraction and analysis.

Results

The initial search of terms resulted in 52 total articles (Fig 1), of which 3 studies published between 2010 and 2014 met the eligibility criteria.[24-26] They consisted of 1 Level I study[25] and 2 Level II studies.[24,26] No conflict of interest was present in any study. All studies performed heterogeneity analytics. The total sample size ranged from 711 patients[24] to 790 patients.[26] The follow-up

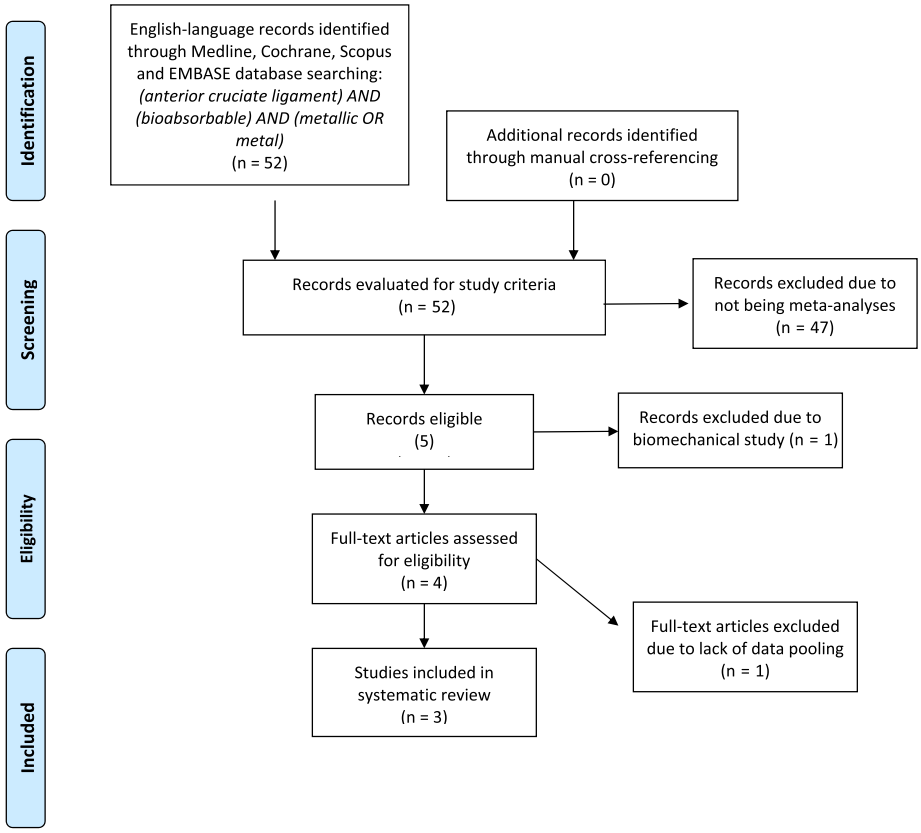

Fig 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses diagram chronicling the process by which studies were excluded to ultimately determine which studies would be included for analysis.

periods included in these studies ranged from 12 months[25,26] to 96 months.[24] The follow-up rate was 77.3% in the 1 study in which this was recorded[25]; a second study noted that 3 of 8 primary studies had a greater than 20% loss to follow-up.[26]

Authors' Inclusion of Prior Systematic Reviews

Only 1 meta-analysis had the ability to cite previous systematic reviews or meta-analyses at the time the study was performed, and it cited both published studies.[24] This study's rationale for repeating the meta-analysis was provided, namely to focus primarily on complications of interference screw use (Table 1).

Search Methodology

All 3 studies searched PubMed/Medline; 1 study searched 2 databases,[25] and 2 studies searched 3 databases in total (Table 2).[24,26] The number of primary studies included in the meta-analyses ranged from 8 studies[26] to 11 studies[24] (Table 3).

Study Results

All 3 meta-analyses generally concluded that the clinical and functional results of ACL reconstruction with BIS and MIS fixation were similar but found differences in adverse events. Shen et al.[25] reported no significant differences in measurements of functional outcomes (IKDC and Lysholm scores), knee stability (KT arthrometry and pivot-shift testing), or infection rate but did find that knee joint effusion was more common with BIS fixation. Emond et al.[26] reported no significant differences in IKDC, Lysholm, or Tegner scores; KT arthrometry; or complication rates. Laupattarakasem et al.[24] found greater femoral tunnel widening and higher rates of screw breakage and knee effusion with BIS use. However, using short- and long-term follow-up data, the authors reported no differences in KT arthrometry, Lysholm scores, or IKDC scores between the groups. The subgroup analyses, which compared MISs with poly-l-lactide acid (PLLA) and polyglycolic acid/trimethylene carbonate screws, found no differences in clinical outcome measures or knee stability across biomaterials. However, Laupattarakasem et al. noted a significantly higher risk of prolonged joint effusion and femoral tunnel widening with PLLA screws compared with MISs.

Study Quality and Validity

Disparate indices were used by the meta-analyses to assess primary study quality. The meta-analyses exhibited a mean QUOROM score of 15.3 (range, 13 to 17; maximum, 18). The Oxman-Guyatt score ranged from 3 to 7, with all surpassing the threshold of 3 to consider the studies devoid of "major flaws" (Table 4).

Table 1. Number of Prior Systematic Reviews or Meta-analyses Actually Cited as Compared With Maximum Number That Could Possibly Have Been Cited, in Addition to Authors' Rationale for Repeating Systematic Review

Authors	Date of Publication	Date of Last Literature Search	No. of Systematic Reviews or Meta-analyses Possible to Cite	No. of Systematic Reviews or Meta-analyses Cited	Rationale for Repeating Meta-analysis as Abstracted From Article
Shen et al.[25]	May 2010	December 1, 2008	0	0	NA
Emond et al.[26]	March 16, 2011	August 31, 2009	0	0	NA
Laupattarakasem et al.[24]	January 2014	June 2012	2	2	"The main reason that meta-analysis on similar groups of participants is still performed further is to investigate on the particular properties claimed as advantages of the BS over disadvantages being blamed for the MS, specifically related with expected benefits in revision surgery…This review is therefore set primarily on complications, and secondarily on functional and clinical results. . ."

BS, bioabsorbable screw; MS, metal screw; NA, not applicable.

Heterogeneity Assessment

All meta-analyses performed statistical heterogeneity analysis. Sensitivity analyses were performed for primary study quality, Lysholm score, IKDC score, pivot-shift testing, KT arthrometry, deep infection, prolonged joint effusion, tunnel widening, graft material, and fixation site. Descriptive data were provided for several other parameters (Tables 5 and 6).

Application of Jadad Decision Algorithm

To determine which of the 3 meta-analyses provides the best available evidence, the Jadad decision algorithm was used by the 3 lead authors independently. This led to the determination that 2 of the 3 included studies provided the highest level of currently available evidence.[24-26] Both meta-analyses showed a prolonged presence of knee effusion with BIS use, with 1 also showing increased femoral tunnel widening and screw breakage with BIS use.

Discussion

The major findings of this study were prolonged knee effusion, increased femoral tunnel widening, and increased screw breakage associated with BIS use. This study did not assess cost aspects associated with BIS use versus MIS use.

With an increasing number of ACL reconstructions performed annually, it is critical that the procedure be performed in a manner that provides the patient with the best chance for successful clinical and functional outcomes with the lowest rate of adverse events. Many of the variables of the procedure have been extensively debated in the literature in recent years, including graft choice,[42] graft bundling,[43] and surgical technique.[44,45] In recent years discussion regarding graft fixation techniques has gained new interest, particularly regarding the transition from traditional MISs to BISs. Evidence has often shown equivocal results in clinical and functional comparisons of these 2 graft fixation constructs.[5,7,20-23] Whereas MISs have been shown to have a high initial fixation strength and failure load,[4] the difficulty of their removal in revision surgery[6] has been 1 of several factors leading to the development of bioabsorbable screws. The use of BISs may alleviate some of the difficulties seen in revision procedures because of their absorption, limiting the necessity for hardware removal.[8] BISs, though, are not devoid of construct-specific complications, which may include foreign-body tissue reaction[10] and screw migration into the joint or loss of fixation.[12-16]

Our literature search provided 1 Level I[25] and 2 Level II[24,26] meta-analyses for critical examination. High

Table 2. Search Methodology Used by Each Included Study

Authors	PubMed/Medline	Embase	Cochrane Library	CINAHL	Scopus	Other	No. of Primary Studies	Primary Studies Included Only RCTs
Shen et al.[25]	+	−	+	−	−	−	10	+
Emond et al.[26]	+	+	−	−	+	−	8	+
Laupattarakasem et al.[24]	+	−	+	−	+	−	11	+

CINAHL, Cumulative Index to Nursing and Allied Health Literature; Embase, Excerpta Medica Database; RCTs, randomized controlled trials.

Table 3. Primary Studies Included in Meta-analysis

Primary Study	Shen et al.[25]	Emond et al.[26]	Laupattarakasem et al.[24]
Drogset et al., 2011[30]	−	−	+
Stener et al., 2010[31]	−	−	+
Jarvela et al., 2008[32]	+	−	−
Moisala et al., 2008[33]	+	+	+
Myers et al., 2008[34]	+	+	+
Laxdal et al., 2006[35]	+	+	+
Drogset et al., 2006[36]	+	+	+
Kaeding et al., 2005[37]	+	+	+
Benedetto et al., 2000[38]	+	+	+
Fink et al., 2000[39]	+	+	+
McGuire et al., 1999[40]	+	+	+
Barber et al., 1995[41]	+	−	+

QUOROM and Oxman-Guyatt quality assessments in each of the 3 included meta-analyses support the validity of drawing firm conclusions and practice management recommendations from them. The different results between MISs and BISs were seen most prominently with complications from BIS use, including a higher occurrence of intraoperative complications,[24] as well as prolonged joint effusion and femoral site tunnel widening with PLLA BISs relative to MISs. Specifically, the 2 articles deemed to provide the highest level of current evidence by the Jadad decision algorithm reported the following significant differences in complication rates: a relative risk of 12.81[24] for screw breakage and a relative risk of between 2.57[25] and 2.81[24] for prolonged postoperative joint effusion for BISs when compared with MIS use. On subgroup analysis by 1 of the 2 articles, there was a significant relative risk of 2.35 for prolonged joint effusion when comparing PLLA BISs with MISs, which increased further to 2.54 when comparing bone–patellar tendon–bone graft BISs with MISs.[24] The authors also reported a relative risk of 3.78 for tunnel widening at the femoral site with PLLA BISs versus MISs.[24] These risk values are appreciably high on these clinically relevant measures; however, although this would seem to give credence to surgeons opposed to the use of BISs, similar clinical and functional outcomes persisted despite this higher incidence of complications. This leads to the question of whether there is value to the use of BISs in patients who may be deemed at high risk for the need for revision surgery or who will require frequent monitoring or follow-up by magnetic resonance imaging. None of these studies, however, performed a cost-benefit analysis of the use of BISs versus MISs, the former of which has a substantially higher associated cost.

Table 5. Heterogeneity or Subgroup Analyses of Primary Studies

	Shen et al.[25]	Emond et al.[26]	Laupattarakasem et al.[24]
Statistical heterogeneity analysis	+	+	+
Subgroup or sensitivity analysis			
Primary study quality	+	+	+
Age	−	−	−
Gender	−	−	−
Time to surgery	−	−	−
Follow-up interval	0	−	0
Follow-up rate	0	−	0
Type of MIS	0	0	−
Type of BIS	0	0	0
Graft material	0	0	0
Treatment of concomitant pathology	−	0	−
Rehabilitation protocol	0	−	−
Lysholm score (type of BIS)	+	−	−
IKDC score (type of BIS)	+	−	−
Pivot-shift testing (type of BIS)	+	−	−
KT arthrometry (type of BIS)	+	−	−
Deep infection (type of BIS)	+	−	−
Prolonged joint effusion (type of BIS)	+	−	+
Tunnel widening (type of BIS)	−	−	+
Tunnel widening (graft material)	−	−	+
Tunnel widening (site of fixation)	−	−	+

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.

BIS, bioabsorbable interference screw; IKDC, International Knee Documentation Committee; MIS, metal interference screw.

Limitations

There are limitations present with this study, reflected by those limitations identified in the 3 meta-analyses that have been included in our analysis. Selection, reporting/outcome, and performance biases

Table 4. Comparisons Performed by Each Meta-analysis and Quality Scores for Each Meta-analysis

		IKDC Score			KT Arthrometry					
Authors	Lysholm (SMD)	RR	Logarithm of OR	Tegner Score (SMD)	Pivot-Shift Testing (RR)	SMD	RR	Loss of ROM (RR)	QUOROM Score	Oxman-Guyatt Score
Shen et al.[25]	+	+	−	−	+	+	−	−	17	4
Emond et al.[26]	+	−	+	+	−	+	−	−	13	3
Laupattarakasem et al.[24]	+	+	−	−	+	+	+	+	16	7

NOTE. All three studies performed data pooling. IKDC, International Knee Documentation Committee; OR, odds ratio; QUOROM, Quality of Reporting of Meta-analyses; ROM, range of motion; RR, relative risk; SMD, standardized mean difference.

Table 6. Outcome Measures Assessed in Each Included Study

	Shen et al.[25]	Emond et al.[26]	Laupattarakasem et al.[24]
Clinical indices			
Lysholm score	+	+	+
IKDC score	+	+	+
Tegner score	−	+	+
Knee stability			
Pivot-shift testing	+	−	+
KT arthrometry	+	+	+
Loss of knee motion	−	−	+
Complications			
Overall complications	−	+	−
Intraoperative complications	−	+	−
Postoperative complications	−	+	−
Screw breakage	−	+	+
Graft damage	−	+	−
Graft failure	−	+	−
Deep infection	+	+	+
Prolonged joint effusion	+	+	+

IKDC, International Knee Documentation Committee.

were identified in some of the primary comparison studies referenced by the meta-analyses.[24,26] Some primary studies also had potential venues for bias in that they were funded by industry sources or used donated implants.[26] Some primary studies did not provide details of follow-up data or specific outcome measurement results.[25] Most primary studies did not blind follow-up testing,[25] which may also contribute to bias. Variability in techniques, implants, graft choices, and follow-up periods[25,26] among primary studies in the included meta-analyses limited the ability to pool data in some cases. In addition, the included meta-analyses often could not ultimately analyze the provided radiologic outcome data because of the limitations imposed by the varied methods in radiologic assessment[25,26] that were used in the various primary studies.[24] Moreover, Shen et al.[25] addressed the notion that the IKDC final score and Lysholm score are not sensitive to changes over time and thus do not accurately detail the long-term subjective clinical outcomes in these patients. Finally, 1 meta-analysis had attempted to contact corresponding authors for additional data gathering or clarification of existing data with limited response.[24]

Conclusions

Ultimately, the meta-analyses with the best available evidence showed prolonged knee effusion, increased femoral tunnel widening, and increased screw breakage with BIS use. In a health care generation particularly conscious of cost-effectiveness, further detailed analyses of the cost-benefit ratio of BISs compared with MISs would be valuable in making further definitive recommendations for or against the continued use of BISs in specific situations or in particular patient populations in which their advantages over MISs could be used.

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