



Sources, Quality, and Reported Outcomes of Superior Capsular Reconstruction: a Systematic Review

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Abstract

Purpose Superior capsular reconstruction (SCR) has gained attention as a potential treatment option for those with massive irreparable rotator cuff tears without significant arthritis. The aim of this systematic review is to review and evaluate the current sources and quality of SCR literature as well as reported outcomes.

Methods Three databases (PubMed, Ovid [MEDLINE], and EMBASE) were searched independently and in duplicate to systematically screen the literature. The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) checklist guided the reporting and data abstraction. The results are presented in a narrative summary fashion using descriptive statistics.

Results Overall, 58 studies were identified, including 304 different patients. There was a rapid increase in the number of publications observed over the past 3 years, with the most dramatic single-year increase noted from 2017 to 2018 (175% increase). There are no level 1 studies, and 95% of the included studies were level 4 and 5 evidence. Comparing pre-operative to post-operative pooled-weighted mean outcome scores, the American Shoulder and Elbow Surgeons score improved from 44.2 to 84.8, the Visual Analogue Scale from 5.0 to 1.5, and acromiohumeral distance from 6.5 to 8.4 mm, respectively. Range of motion in forward elevation also improved from 111° to 152°. Among studies reporting, the complication rate was 13.4% with a revision surgery rate of 4.3%.

Conclusion Over the past 3 years there has been considerable growth in the number of publications of publications related to SCR. Despite a lack of high-quality clinical evidence, preliminary available evidence does suggest promising results both functionally and radiographically. There is a need for future higher-quality research such as large randomized controlled trials to improve our current understanding of the benefits of SCR.

Keywords Superior capsular reconstruction · Shoulder capsule · Massive rotator cuff tear · Superior capsule repair

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Introduction

The management of massive rotator cuff tears poses significant challenges, particularly in the younger patient. It is estimated that up to 40% of all diagnosed rotator cuff tears fall into this category [1]. Chronic tears are sometimes deemed irreparable due to various factors including a combination of tear size, tendon retraction, inelasticity, muscle atrophy, fatty infiltration, and significant superior humeral head migration. Tears that are initially repairable have been found to have a re-tear rate of up to 75% [2]. Non-operative management has found some limited success, but not all patients respond to these treatments [3].

Historically, surgical options for the treatment of massive irreparable rotator cuff tears have included arthroscopic debridement, partial repair, tendon transfer, and arthroplasty. Arthroscopic debridement with biceps tenodesis or tenotomy

can provide pain relief [4], but has limited benefit with respect to improved range of motion and does not restore normal joint kinematics [1]. Partial rotator cuff repair may successfully restore the position of the humeral head, but often does not restore range of motion or completely address pathomechanics affecting loss of motion [5]. Latissimus dorsi transfer is an attractive option in young, high-demand patients; however, its primary indication is limited weakness and pain related to posterosuperior tears with an intact subscapularis [1]. As well, such tendon transfer procedures have a relatively high reported complication rate, estimated at nearly 10% in a recent systematic review [6]. Finally, reverse total shoulder arthroplasty (rTSA) has been used successfully in the treatment of massive rotator cuff tears with and without the presence of arthritis [7–9]. However, concerns regarding implant longevity discourage most surgeons from choosing this option for the more active and/or younger patient [10].

Superior capsular reconstruction (SCR) has recently gained attention as a potential treatment option for patients with massive irreparable rotator cuff tears in the absence of significant arthritis. Early biomechanical work by Mihata et al. demonstrated that reconstruction of the capsule with fascia lata grafts was found to significantly reduce superior translation of the humerus [11, 12]. He went on to demonstrate that the same phenomenon also occurred when the procedure was performed live patients with dramatic improvements in functional outcome scores. In one of the earliest clinical series published by the group, patients reported significant gains in patient-reported outcomes and range of motion. For example, mean American Shoulder and Elbow Surgeons (ASES) score improved from 23.5 pre-operatively to 92.9 post-operatively, while forward elevation improved from 84 to 148° [12].

These impressive results caught the attention of shoulder surgeons worldwide, particularly in North America, where the technique has largely evolved to utilize a dermal decellularized allograft eliminating the potential donor site morbidity associated with the fascia lata graft harvest techniques [13]. Over the past 3 years there has been a rapid growth in the number of publications on this topic [14], and the technique is being performed at an alarming rate, despite the fact that limited evidence exists that assesses efficacy of this new treatment. The aim of this systematic review is to review and evaluate the current sources and quality of SCR literature as well as the reported outcomes. It is hypothesized that as the clinical uptake of superior capsular reconstruction continues to increase, the sources and quality of the literature will improve as well.

Materials and Methods

The Cochrane Handbook was used to guide the methodology of this study and the Preferred Reporting Items for Systematic

Reviews and Meta-Analyses (PRISMA) statement was used to guide the reporting [15, 16].

Study Eligibility

Studies meeting the following inclusion criterion were included in this review: publication in a peer-reviewed journal, topic related to superior capsular reconstruction in any age or gender, all levels of evidence, and published in the English language.

Identification of Studies

Pubmed, MEDLINE, and Embase databases were independently search by two reviewers (MM, AA) for studies published since database inception to October 22, 2018. The search terms “superior capsular reconstruction,” “rotator cuff,” and “tissue scaffold,” along with appropriate permutations of each, were used. MeSH and Emtree terms were utilized in various combinations and supplemented with free text to increase search sensitivity (Appendix 1).

The articles were screened for eligibility using titles and abstracts. Following initial screening, a full text review was conducted on all studies deemed relevant. Any disagreements were resolved by consensus discussion between the reviewers. If a consensus could not be reached, a final decision on inclusion was made with the first author (S.E).

Data Extraction

A piloted data extraction form was used by a single reviewer (AA) to extract the data (Microsoft Excel, version 15.2, Microsoft Corporation, Redmond, WA, USA). All extracted data was verified for accuracy by a senior author (SE) prior to proceeding with statistical analysis. The data that was extracted included the following: year of publication, location of study, study design, type of study, level of evidence, patient demographics, type and title of journal, and funding.

Data Analysis

Inter-reviewer agreement for the title, abstract, and full-text articles were calculated using a kappa (κ) statistic. The values were categorized a priori as follows: κ of 0.81 to 0.99 was considered almost perfect agreement, κ of 0.61 to 0.80 substantial agreement; κ of 0.41 to 0.60, moderate agreement; κ of 0.21 to 0.40, fair agreement; and κ of 0.20 or less, slight agreement [17]. The data was summarized using descriptive statistics. All statistics were calculated using Microsoft Excel (version 15.2, Microsoft Corporation, Redmond, WA, USA) and Minitab® statistical software (version 17, Minitab Inc., State College, PA, USA).

Results

Identification of Studies

The electronic search identified 548 potentially relevant studies. Following exclusion of duplicate articles and application of inclusion criteria, 140 were eligible for full text review. Following full text review and hand search of included references, 58 articles were eligible for inclusion in this systematic review (Fig. 1). The kappa for overall agreement between reviewers for final eligibility decision was 0.72 (95% CI 0.68–0.77) indicating substantial agreement. Appendix 2 contains a reference list of all included studies.

Characteristics of Included Studies

The total number of patients included in this systematic review was 415 from 12 clinical studies. Due to overlapping cohorts among three studies [12, 18•, 19], there were 304 unique patients reported. The weighted mean age of patients undergoing superior capsular reconstruction was 62.9 years old (range 52.8–70 years). The median number of patients in each study was 19 (IQR 1–79.3). Of eight clinical studies reporting sex, 59 females (34.3%) and 113 males (65.7%) were included. Only one study was specifically identified as having received industry funding. Mean follow-up was 39.1 months

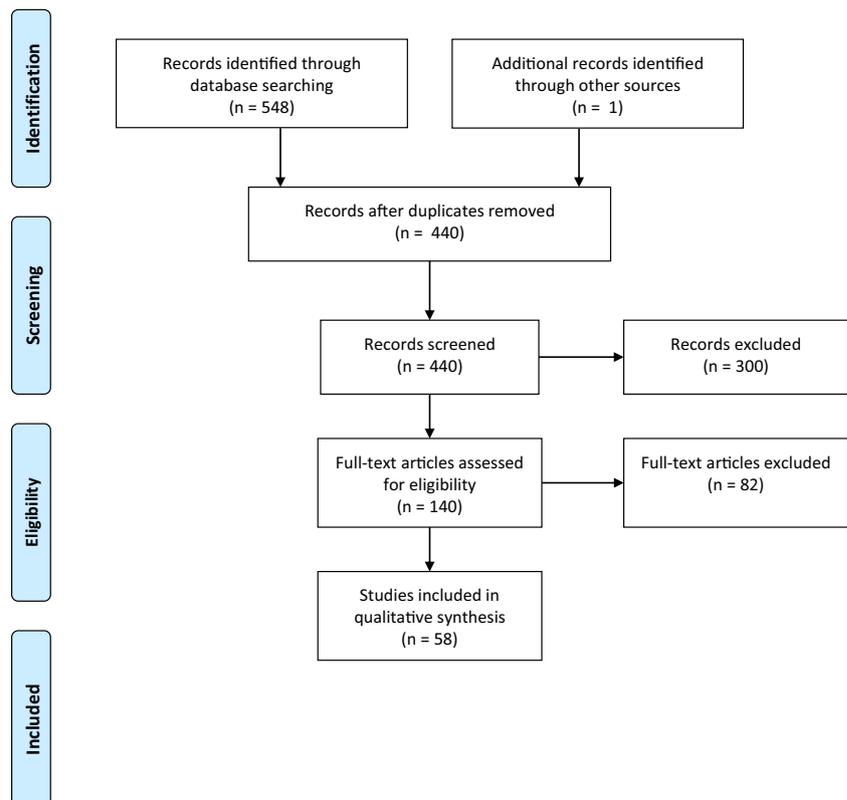
(range 12–48 months). Six studies ($N = 156$) used acellular dermal allograft, five studies ($N = 116$) used tensor fascia lata autograft, and one study ($N = 32$) used both types of graft.

Quality of Literature and Temporal Trends

Between 1993 and 2018, there was an increasing number of SCR-related publications. The most dramatic single-year increase was noted from 2017 to 2018, when there was a 175% increase in the number of publications (Fig. 2). There were no Level 1 studies present in the literature. Articles that were of Levels II and III evidence were only published in 2017 and 2018. Ninety-five percent ($N = 55/58$) of all included studies were of Levels IV and V quality evidence. Specifically, there were two Level II studies (3.5%), one Level III study (1.7%), nine level IV studies (15.5%), and 46 level V studies (79.3%).

The most common study designs published were Level V technique articles ($N = 20$, 34.5%), followed by clinical articles of various quality ($N = 14$, 24.1%), and finally Level V review articles ($N = 12$, 20.7%). Though the limited number of high-level studies makes it difficult to assess the overall trend in the quality of literature, clinical studies (Level IV or higher) made up 25.0% of all studies published in 2018 as compared to 16.7% the year before (Fig. 3).

Fig. 1 PRISMA flow diagram



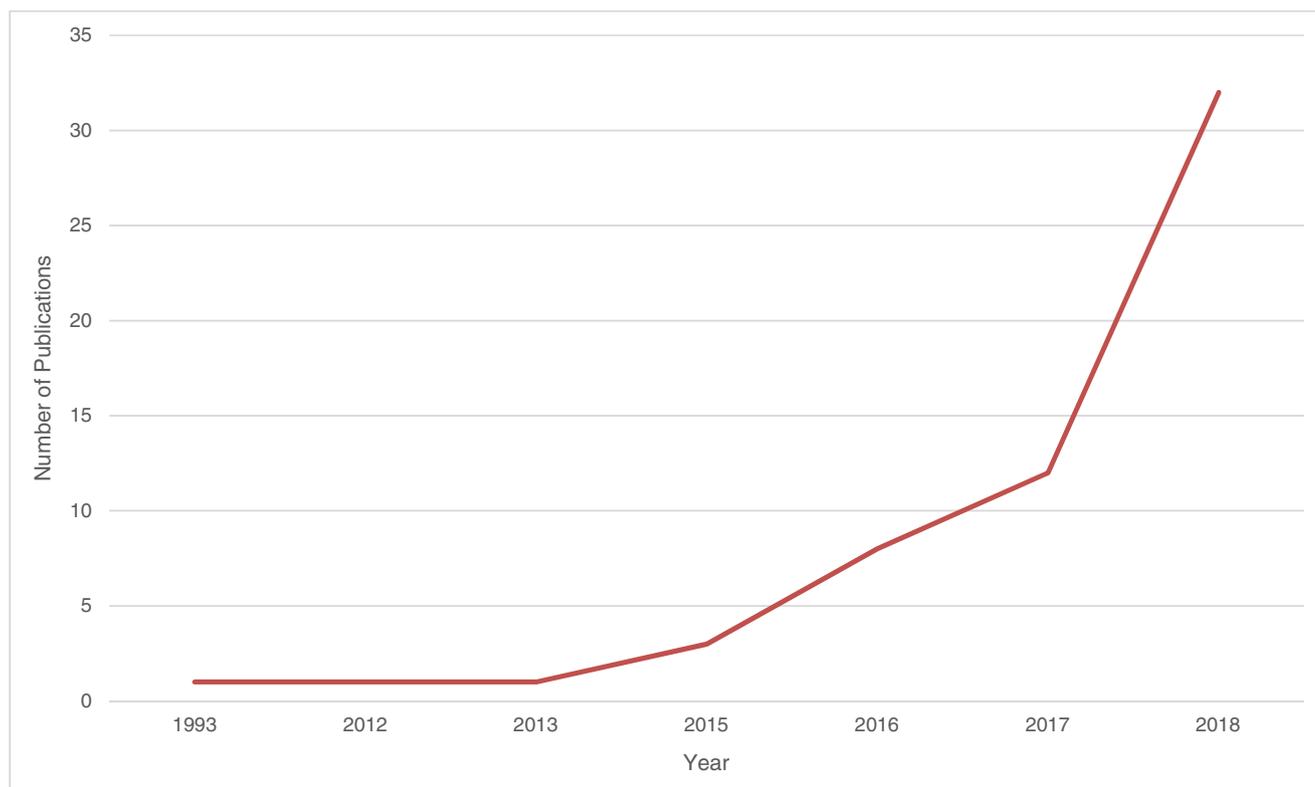


Fig. 2 Number of publications per year

Sources of Literature

Of the 12 review articles identified, none were systematic in nature. There were nearly twice as many clinical review articles published in 2018 ($N = 10$) compared to all previous years combined ($N = 6$). The majority of publications were in orthopedic and sports medicine journals ($N = 55$, 94.8%), with the remaining in radiology journals (3, 5.2%). The journal with the greatest number of SCR-related publications was *The Journal of Arthroscopy* and its companion *Arthroscopy Techniques*, which has published 23 SCR articles (39.7%) followed by the *Journal of Shoulder and Elbow Surgery* ($N = 5$, 8.6%). The majority of publications were based in the USA ($N = 31$, 53.4%) followed by the Netherlands (18, 31.0%), Germany (4, 6.9%), France and Japan (2 each, 3.4%), and England (1, 1.7%).

Clinical and Radiographic Outcomes

Overall, 12 studies ($N = 304$) reported on some combination of clinical and/or radiographic outcomes [12, 14, 18•, 19–24, 25•, 26, 27•, 28•, 29]. Three of these studies reported on various subgroups of the same cohort of patients [12, 18•, 19]; thus, for each outcome, only the study with the largest and most up-to-date results was used for quantitative analysis. Eight studies ($N = 286$) reported on one or more patient-reported outcome score [12, 14, 19–24, 25•, 26, 27•, 28•,

29, 30]. The most commonly reported functional outcome scores were the American Shoulder and Elbow Surgeons score (ASES) (8/12 studies, 66.7%, 286 patients) [12, 14, 19, 23, 24, 27, 31, 32] and the Japanese Orthopedic Association scale (JOA) (3/12 studies, 25.0%, 100 patients) [12, 19, 31]. The pooled weighted mean ASES score improved from 44.2 pre-operatively (range 36.0–52.0) to 84.8 post-operatively (range 77.5–92.0) with a weighted mean follow-up of 41.6 months (range 12–48 months). The JOA scores, only reported for one cohort of patients, improved from a pre-operative mean of 53 ± 13 to 91 ± 11 post-operatively at a mean follow-up of 48 months (range 24–88).

Of the 12 studies reporting outcomes, six studies reported on the Visual Analogue Score (VAS) (50%, 186 patients) [14, 22–24, 27, 32]. The pooled weighted mean VAS pre-operatively was 5.0 (range 4–6.3), compared to 1.5 post-operatively (range 0.4–1.7) at a weighted mean follow-up of 26.0 months (range 12–32 months).

Range of motion was (ROM) was reported on in nine of 14 studies (75.0%, 280 patients) [12, 19, 20, 23, 24, 26, 27, 31, 32]. Pre-operatively, forward elevation was reported at a weighted mean of 111° (range 91° – 175°), compared to 152° post-operatively (range 140° – 160°). External rotation increased from 32° pre-operatively (range 26° – 80°) to 44° post-operatively (range 30° – 80°). Internal rotation improved from a median vertebral level of L4 pre-operatively (range L3–L5) to L1 reported by all studies post-operatively.

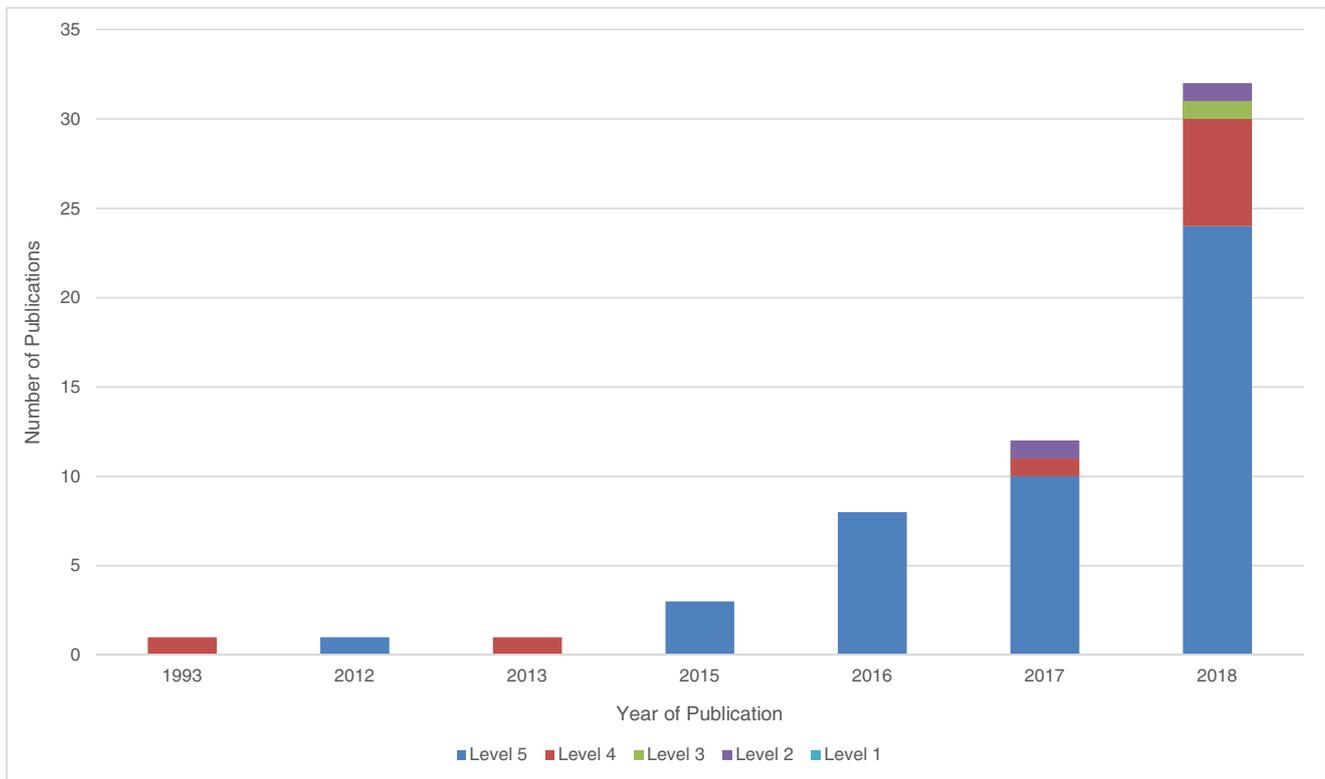


Fig. 3 Distribution of levels of evidence by year of publication

Weighted mean follow-up for studies reporting ROM was 40.7 months (range 12–48 months).

Five of 14 studies (41.7%, 185 patients) reported on acromiohumeral distance (AHD), measured radiographically [12, 14, 23, 30]. The weighted mean AHD increased from 6.5 mm pre-operatively (range 4.5–7.1) to 8.4 mm post-operatively (range 6.7–9.7) at a weighted mean follow-up of 26.3 months (range 25 to 32 months).

Eight studies (66.7%, $N=186$ patients) reported on complications. Overall, 25 patients (13.4%) had complications, with graft rupture being the most common ($N=7$, 3.8%). Eight patients (4.3%) required revision surgery following SCR.

Discussion

Key Findings

This systematic review of SCR literature identified a rapid growth in the number of SCR-related publications over time, particularly over the past 3 years. Specifically, there was an increase in the annual publication rate of SCR literature by over 300% in the year 2018 as compared to 2016 in orthopedic and sports medicine journals. Overall, significantly improved functional outcome scores, range of motion, and pain levels

across studies after treatment with SCR. However, the vast majority of articles are level 4 or 5 evidence with no Level-I literature present to guide management decisions.

The majority of clinical studies reviewed in this study used some combination of ASES, VAS, ROM, and AHD as their functional outcome measures. Pooled analysis identified a sizeable improvement in ASES scores of over 40 points. The minimal clinically important difference (MCID) for the ASES has been reported as between 6 and 14 points in previous studies [33]. Similarly, VAS scores decreased by 3.5 points, which is just above the established MCID of 3 for this scale [34]. Range of motion in all measured planes was improved by the SCR procedure: in forward elevation (from 111° to 152°), external rotation (from 32° to 44°), and internal rotation (from L4 to L1). The MCID has been reported as 18° for forward elevation and 15° for external rotation [35]. Finally, SCR improved AHD radiographically from 6.5 to 8.4 mm; however, the clinical relevance of this finding is not fully known. These outcomes are comparable, and in some cases better than other surgical treatments in this patient population. A recent systematic review on latissimus dorsi tendon transfer found that forward elevation improved from 114° pre-operatively to 155° post-operatively, while VAS score decreased from 5.9 to 1.5 [36]. Similarly, a systematic review on arthroscopic repair of massive rotator cuff tears found improvement of forward elevation from 125° to 169° and

reduction of VAS from 5.9 to 1.7 [37]. More clinical comparative studies are required to establish the optimal treatment choice for this subset of patients.

The SCR literature identified in this systematic review was predominantly comprised of low-level evidence, with 95% of included studies being level 4 or 5 evidence. Furthermore, the sample sizes of the included studies were small, with a median sample size of 19 subjects. These important findings highlight that the current literature is prone to the bias that accompanies low-level observational and non-comparative studies. Additionally, with small sample sizes, the studies may not be adequately powered to identify statistically significant trends within the data. As such, the state of the literature provides information that may be hypothesis generating as opposed to providing definitive conclusions.

However, this review found that the Level II and Level III evidence studies were published most recently between 2017 and 2018, suggesting that efforts at improving the quality of evidence are underway. In addition, one randomized controlled trial has been prospectively registered [38]. At this time of preparation for this manuscript, there were no systematic reviews identified on the SCR procedure.

In addition to an improvement in the quality of SCR literature noted over time, this review also identified a nearly two-fold increase in the number of clinical studies focusing on patient important outcomes in the year 2018 compared to all previous years combined. In association with the fact that the majority of all studies are technique protocols on SCR surgery, these findings highlight that the focus of the previous literature has been on improving surgical technique, while more recently the focus has been on assessing patient outcomes.

Finally, this review found that while the original description of the SCR procedure came from Japan, the majority of studies published in the last 5 years were performed in centers in the USA, with many other studies being conducted in Europe. As other studies have identified, these trends may be related to a growing interest in this procedure in those regions, but this trend may also be related to other factors, such as accessibility to research funding and English language proficiency [39]. From the studies available for review, the true extent of the global proliferation of the SCR procedure could not be determined.

Strengths and Limitations

This systematic review utilized duplicate screening by reviewers and broad search terms to evaluate the literature of SCR. A piloted data extraction form was used to ensure comprehensiveness and found moderate agreement regarding study selection between reviewers. Prior to statistical analysis, the primary author reviewed all data for accuracy.

This systematic review does have some limitations. There is the potential for language and publication bias to exist in this review, as only publications in the English language were

included. This may explain why the majority of the countries of publication were English speaking, possibly excluding countries in which literature is predominantly published in another language. Additionally, there is the possibility that our review excluded studies published in journals that are not indexed by PubMed. Finally, the limited amount of clinical data precludes the ability to make any comparisons between different graft types.

Finally, as with all systematic reviews, the strength of the findings and conclusions presented regarding clinical outcomes are only a reflection of those properties of the articles included for review. Since the majority of the clinical articles reviewed were rated as Level IV evidence, there exists significant inherent potential bias in the clinical outcome findings reported in this systematic review. When interpreting these results, surgeons should be cognizant of the associated potential issues pertaining to validity and reproducibility of these results when endeavoring to adopt SCR into their own practice.

Conclusion

Over the past 3 years there has been a significant increase in the number of publications related to SCR, as well as a trend towards higher-quality evidence being published. Preliminary available evidence does suggest promising and significant improvement in function, pain, and range of motion. In order to build on the current SCR literature and to justify the rapid proliferation of this technique, more high-quality research is needed, in particular a large-scale randomized controlled trial.

Compliance with Ethical Standards

Conflict of Interest Seper Ekhtiari, Anthony Adili, Muzammil Memon, Tim Leroux, Patrick Henry, and Moin Khan each declare no potential conflicts of interest.

Asheesh Bedi is a consultant and received personal fees from Arthrex.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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