Rotator Cuff Matrix Augmentation and Interposition

CME

A Systematic Review and Meta-analysis

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Background: Surgical management of rotator cuff tears is controversial and complex, ranging from nonoperative management to reverse shoulder arthroplasty.

Purpose: To systematically review and evaluate the outcomes of graft augmentation or interposition versus rotator cuff repair (RCR) alone and evaluate via meta-analysis whether the use of a graft leads to superior outcomes versus RCR alone.

Study Design: Systematic review and meta-analysis.

Methods: An electronic literature search (Medline, Embase, CINAHL) was conducted. Studies with a minimum follow-up of 1 year and minimum sample size of 10 that provided clinical results of RCR or rotator cuff reconstruction using any type of augmentation tissue or matrix were included. Methodological quality was evaluated by assessment of the risk of bias in the included studies. Studies comparing outcomes of RCR with graft augmentation or interposition versus repair alone (control group) were subjected to meta-analysis.

Results: The authors identified 774 articles and included 36 in the systematic review; 5 of the 36 studies underwent meta-analysis. Except for one outcome measure in a single study, all surgical interventions (RCR alone, RCR with augmentation, and RCR with interposition) improved clinical scores and outcome measures. Because of variability in study outcomes, no graft option was found to be superior. Compared with RCR alone, graft augmentation or interposition provided significantly lower retear rates (P = .05) and higher American Shoulder and Elbow Surgeons (ASES) scores (P = .005), but improvements in UCLA (University of California, Los Angeles) scores (P = .29) and pain scores (P = .1) did not reach statistical significance.

Conclusion: In the meta-analysis, graft augmentation or interposition appeared to provide a lower retear rate and improved ASES scores when compared with RCR alone. Future prospective, randomized, controlled, and appropriately powered trials are needed for more definitive recommendations.

Keywords: allograft; augmentation; autograft; patch; rotator cuff tear; xenograft; shoulder; repair; graft

Rotator cuff disease is a leading cause of shoulder disability.[81,82] Surgical management of symptomatic large and massive rotator cuff tears is controversial and complex, and treatment recommendations span a spectrum that includes nonoperative treatment, debridement,[9,24,62] primary rotator cuff repair (RCR), tendon transfers,[11,25,45,46] tendon augmentation or interposition,‖ superior capsular reconstruction,[44] and reverse shoulder arthroplasty.[77] Many factors contribute to surgical decision making, including chronicity of the tear,[16] age of patient,[7,15,21,32] status of muscle atrophy or fatty degeneration,[23] degree of tear retraction and size of tear,[7,15,32,42] and presence or absence of rotator cuff arthropathy. The goal of RCR is to provide a low-tension repair of the tendon to its native footprint on the humerus while promoting bone-tendon integration and reestablishing appropriate tension mechanics.[63] Achievement of these goals is made more difficult by tendon retraction, large and massive tendon tears, and tendon degeneration, which can lead to inferior clinical outcomes.[26,35]

Primary RCR continues to be a challenge to surgeons; retear rates range from 20% to 40%,[7,15,18,21,38,71] with more difficult and challenging (ie, massive and significantly retracted) tears yielding retear rates of up to 94%.¶ Tendon augmentation and interposition have been proposed as improvements over simple repair of the rotator

‖References 1-5, 8, 10, 12, 14, 19, 27, 29, 30, 33, 34, 40, 41, 43, 48-50, 52, 54, 57-61, 65-67, 73-76, 80.

¶References 6, 13, 23, 26, 31, 37, 51, 55, 78, 81, 84.

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cuff tendon to the bone, with potential benefits of avoiding an overtensioned repair, augmenting friable, degenerative tissue, and providing a biological scaffold for long-term incorporation.[#] RCR augmentation refers to the use of a synthetic, xenograft, allograft, or autograft patch over the repair site in efforts to bolster the mechanical stability. The tendon is attached to the tuberosity bone and the patch is laid over the tendon in efforts to augment the strength of the repair.** RCR with interposition grafting entails using the graft in a "bridge" configuration where the tendon is sewn to the patch medially and the patch is then repaired to the tuberosity laterally.[††] This configuration is typically used to treat cases that entail tendon loss and/or to decrease the tension on the repair for significantly retracted tendons. The use of grafts for tendon augmentation is approved by the US Food and Drug Administration, but bridging is not.

Many different types of augmentation and interposition grafting have been described and results have been mixed, leaving the clinician without clear recommendations. The purpose of this study was to evaluate the usefulness of graft augmentation or interposition during RCR by conducting a comprehensive literature review. A secondary goal of this study was to perform a meta-analysis to compare the outcomes of RCR with graft augmentation or interposition versus RCR alone (control group). It was hypothesized that the use of a graft to augment the repair construct would lead to superior outcomes compared with RCR alone.

METHODS

This systematic review followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines.[48]

Search Strategy

Identification and Selection of the Literature. A systematic, computerized search of the literature in Medline, CINAHL, and Embase using controlled vocabulary and keywords was performed on September 22, 2015, by a medical librarian with a master's degree in library and information science (L.L.). An updated search was performed on October 29, 2017. The search terms were related to "rotator cuff, tissue engineering, grafts, tissue scaffolds, bridges and patches, augmentation, or synthetic biology." Database-specific subject headings and common keywords were used. A modified Cochrane filter was used to focus results on research articles while ignoring animal studies, editorials, letters, and commentary. The inclusion criteria were peer-reviewed research articles published in English between 2000 and 2017. Studies using animals and studies in which the scaffold played no structural role (eg, carriers for platelet-rich plasma [PRP] with no structural effect) were excluded. Our search terms are presented in Table 1, and the results of the search strategy are summarized in Figure 1. We then reviewed the reference lists of each selected publication for relevant publications that had not been identified in the computerized search.

Eligibility Criteria. All prospective, cross-sectional, or retrospective human studies investigating RCR or rotator cuff reconstruction with augmentation that used any type of graft were evaluated for inclusion. A study was included in this qualitative analysis if it met the following criteria: (1) had a level of evidence of 1 to 4, (2) was written in English, (3) clearly defined the type of augmentation used, (4) had a minimum follow-up of 1 year, and (5) had a minimum sample size of 10 patients. Review articles, systematic reviews, and meta-analyses were not included; reference lists of excluded articles were examined to ensure completeness of relevant studies.

Study Selection. All abstracts were read and the full text of articles of potential interest were reviewed in detail by 2 co-authors (J.R.B., C.K.) for final decision on inclusion or exclusion from this systematic review. In cases of disagreement, both authors reviewed and discussed the study together and a final consensus decision was achieved. All cases of initial disagreement between the 2 primary reviewers were reviewed by the senior author (G.E.G.) to confirm that the final consensus decision was correct.

Data Collection and Analysis

Data Collection Process. The same 2 co-authors performed all data extraction from the included studies. This

[#]References 1-5, 8, 10, 12, 14, 19, 27, 29, 30, 33, 34, 41, 43, 48-50, 54, 58-61, 65-67, 73-76, 80.

**References 1, 4, 5, 10, 14, 19, 27, 34, 41, 43, 50, 58-60, 66, 67, 76.

[††]References 2, 3, 8, 12, 29, 30, 36, 48, 49, 54, 61, 65, 73, 75, 80.

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TABLE 1
Search Strategy Used for the Electronic Literature Search

PubMed Search	Query	Results
#1	"Rotator Cuff"[Mesh] OR rotator cuff OR supraspinatus[tiab] OR infraspinatus[tiab] OR teres minor[tiab] OR subscapularis[tiab]	
#2	graft[tiab] OR "Tissue Scaffolds"[Mesh] OR scaffold[tiab] OR xenograft[tiab] OR synthetic[tiab] OR matrix[tiab] OR augment[tiab] OR augmentation[tiab] OR augmented[tiab] OR bridge[tiab] OR patch[tiab] OR "Heterografts"[Mesh] OR "Synthetic Biology"[Mesh] OR "Tissue Engineering"[Mesh]	
#3	#1 AND #2	
#4	#3 AND (randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR randomised[tiab] OR randomization[tiab] OR randomisation[tiab] OR placebo[tiab] OR drug therapy[sh] OR randomly[tiab] OR trial[tiab] OR groups[tiab] OR Clinical trial[pt] OR "clinical trial"[tiab] OR "clinical trials"[tiab] OR "evaluation studies"[Publication Type] OR "evaluation studies as topic"[MeSH Terms] OR "evaluation study"[tiab] OR evaluation studies[tiab] OR "intervention studies"[MeSH Terms] OR "intervention study"[tiab] OR "intervention studies"[tiab] OR "case-control studies"[MeSH Terms] OR "case-control"[tiab] OR "cohort studies"[MeSH Terms] OR cohort[tiab] OR "longitudinal studies"[MeSH Terms] OR "longitudinal"[tiab] OR longitudinally[tiab] OR "prospective"[tiab] OR prospectively[tiab] OR "retrospective studies"[MeSH Terms] OR "retrospective"[tiab] OR "follow up"[tiab] OR "comparative study"[Publication Type] OR "comparative study"[tiab]) NOT (Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp] OR Comment[ptyp]) NOT (animals[mh] NOT humans[mh])	
#5	#4 AND English	679

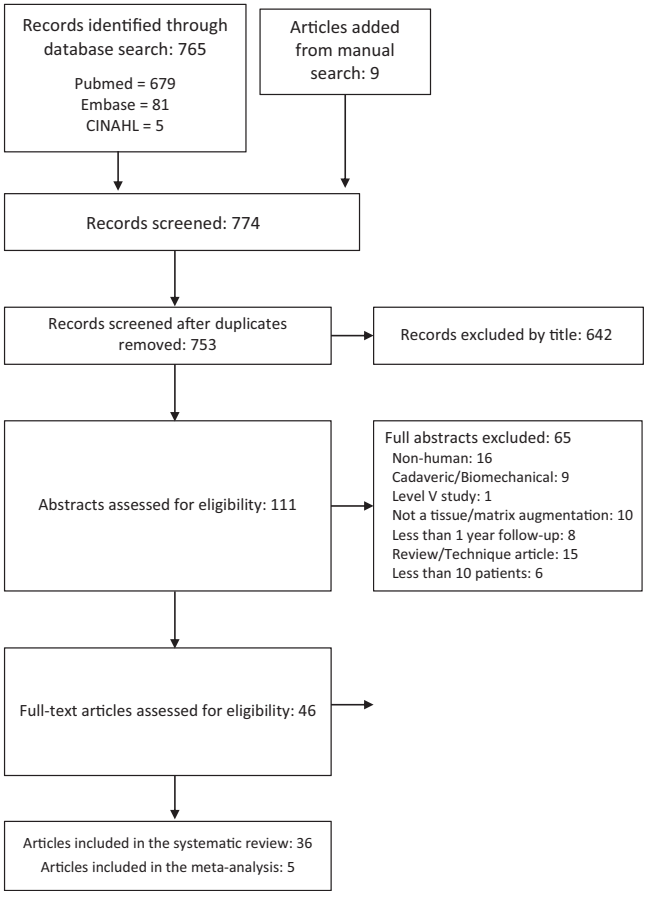

Figure 1. PRISMA flowchart of study selection.

included data regarding study type, patient characteristics, graft type, reported outcomes, and conclusions.

Data Analysis. A systematic review and qualitative analysis was performed for all included studies. When possible, frequency-weighted means were calculated for key demographic data and reported outcomes. Studies that compared the outcomes of RCR with graft augmentation or interposition versus RCR alone were considered for meta-analysis. The number of studies that met the meta-analysis inclusion criteria was small (n = 5), and thus for the meta-analysis portion we could not separate by graft type (autograft, allograft, xenograft, or synthetic) or by graft configuration (augmentation or interposition). Therefore, we combined all 5 studies into an "augmentation or interposition" group that was compared with RCR alone. The meta-analysis was conducted only for those parameters reported by most of the studies. This ensured the maximum sample size for the meta-analysis of each included outcome.

Assessment of the Risk of Bias. All studies that met inclusion criteria were assessed for risk of bias by 2 independent reviewers (J.R.B., C.K.) (Appendix Table A2, available in the online version of this article). Risk of bias was determined by use of the scale from van Tulder et al,[72] an appraisal tool used by the Cochrane Group. This scale focuses on several methodological criteria including randomization adequacy, concealment of treatment, similarity of groups, blinding, minimization of cointerventions, compliance, drop-out rates, timing of outcome assessment, and intention to treat.

Statistical Analysis

For dichotomous parameters included in the meta-analysis, the odds ratio (OR) with 95% CI was calculated based on the number of individuals with and without the event in both

groups. The overall prevalence was calculated for both groups by use of the Wilson procedure with correction for continuity.[79] A meta-analysis for dichotomous parameters was conducted within each group to produce combined estimates of measures of effect using the OR with 95% CI. For continuous variables, routine descriptive statistics (mean, SD and total number of patients) for both groups were used to conduct the meta-analysis. The effect measure was reported as the mean difference (95% CI). For both dichotomous and continuous parameters, an inverse variance weighted random effects model with 95% CIs was used. Heterogeneity was characterized by use of the I^2 statistic. Random effects analysis was used because the overall heterogeneity was moderate.[64] The meta-analysis was conducted by use of RevMan v5.3 (The Nordic Cochrane Centre, The Cochrane Collaboration).

RESULTS

Study Selection

The initial literature search identified a total of 765 references, of which 21 were duplicates and another 642 were excluded by title alone (Figure 1). In addition, 9 articles were added during the review process. A total of 111 abstracts were reviewed in detail; 46 appeared to meet our inclusion and exclusion criteria. The full texts of these 46 studies were reviewed. After full-text review, 10 manuscripts were deleted based on the following criteria: included an abstract only (n = 1), discussed PRP carrier matrix without any structural properties of augmentation (n = 5), entailed isolated subscapularis repairs (n = 1), and did not meet the inclusion/exclusion criteria after full text review (n = 3). Therefore, 36 articles involving 1291 shoulders (1217 at final follow-up) met the final inclusion criteria for the current systematic review.[‡‡]

Eight of the 36 studies compared the outcomes of RCR plus graft augmentation or interposition and repair alone[4,12,14,27,34,48,75,76]; however, 3 studies were discarded from further meta-analysis: 1 study did not include SDs for quantitative outcomes[12] and 2 studies used grafts that have subsequently been removed from the market for failure.[34,76] Therefore, 5 studies (involving 397 shoulders at final follow-up) were included in the quantitative analysis (meta-analysis).[4,14,27,48,75] The limited number of operative shoulders meant that the meta-analysis could be carried out only for the following outcomes: retear rate (all 5 studies), postoperative American Shoulder and Elbow Surgeons (ASES) score (3 studies), postoperative UCLA (University of California, Los Angeles) score (4 studies), and postoperative visual analog scale (VAS) score for pain (4 studies).

Study Characteristics and Demographic Data

Of the 36 studies, 2 were prospective comparative studies, 6 were case-control or cross-sectional studies, and 28 were case series. The results of the assessment of the risk of bias are summarized in Appendix Table A2, showing that most of the studies had a high risk of bias for most of the evaluated parameters, with the average score of all 36 studies being 3.36 out of 11 points (higher scores mean less risk for bias). Appendix Table A3 summarizes the study characteristics and demographic data of the 36 studies and the 1291 shoulders. At final follow-up, 1217 shoulders were available for analysis (10-152 shoulders per study). Of these, 985 were grafts and 232 were controls. The frequency-weighted mean patient age at the time of surgery was 61.6 years (range of means was 48.0-67.3 years). Thirty-one studies recorded a total of 652 men (57%) and 485 women (43%); 5 studies did not report sex. Fatty infiltration, as described by Goutallier et al[28] and modified for magnetic resonance imaging (MRI) by Fuchs et al,[22] was documented in 16 of the 36 studies (727 shoulders) and noted in Appendix Table A3. Goutallier grades ranged from 0 to 4. Only 1 study[27] reported level of activity (35 shoulders).

Treatment Characteristics

Appendix Table A4 summarizes the treatment characteristics of the included studies. Nine studies used a synthetic graft (197 shoulders, 20.0%), 9 studies used allograft (184 shoulders, 18.7%), 8 studies used xenograft (202 shoulders, 20.5%), 7 studies used autograft (217 shoulders, 22.0%), 2 studies compared 2 different types of grafts (125 shoulders, 12.7%), and 1 study used a hybrid of synthetic and autograft (60 shoulders, 6.1%). One of these graft comparison studies[67] used either xenografts or allografts (24 shoulders at final follow-up) but did not break down how many were in each group, prompting exclusion from certain frequency-weighted means requiring graft numbers. Excluding controls, an open approach was the most common procedure performed (378 shoulders) followed by mini-open approach (350 shoulders) and arthroscopic approach (257 shoulders). Fifty percent (18/36) used grafts as augmentation, 47% (17/36) used an interposition technique, and 1 study used a mix of both techniques.

Clinical Outcomes

Outcomes and principal findings of the 36 studies are summarized in Appendix Table A5. In studies that provided mean preoperative and postoperative outcome scores and ranges of motion, the mean difference was calculated by simply subtracting preoperative from postoperative measures. From these data, frequency-weighted mean outcome scores were obtained based on the number of participants at final follow-up per group.

Functional Outcome Scores. Functional outcome scores were reported in all 36 studies; however, 3 studies did not report preoperative scores.[67,74,76] The most commonly reported outcome scores were VAS, ASES, and the UCLA shoulder scale. All studies that reported both pre- and postoperative evaluations reported improved functional outcome scores. Of the 8 studies that compared RCR

[‡‡]References 1-5, 8, 10, 12, 14, 19, 27, 29, 30, 33, 34, 40, 41, 43, 48-50, 52, 54, 57-61, 65-67, 73-76, 80.

augmentation or interposition versus RCR alone, 6 studies favored augmentation or interposition and 2 studies favored RCR alone. The 2 studies favoring RCR alone[34,76] compared repairs that used xenograft tissue, which has since been recalled from the market (Restore; DePuy). A total of 4 studies in this review used the Restore patch.[34,43,59,76] One study[49] looked at interposition of fascia lata autograft between 2 groups of differing fatty atrophy (low grade vs high grade). Both of those 2 study arms are included in the calculations for the autograft group.

Pain scores were reported in 22 of the 36 studies (61%), and all showed improvement. VAS pain scores were measured in 13 of the 36 studies (36%), with all studies showing improvement in all groups. The overall improvement in the frequency-weighted mean VAS pain score was 3.9 points (620 patients, 13 studies with 19 groups). One study[12] measured pain at rest and activity, so these were averaged in all groups of this study for aggregate analysis. Broken down by graft type, VAS pain scores improved most in the allograft groups (5.3 points, range 4.5-5.9 points, 58 patients, 3 studies), followed by autograft combined with synthetic (5.0 points, 60 patients, 1 study), synthetic (4.5 points, range 3.3-6.0 points, 112 patients, 4 studies), autograft (4.4 points, range 2.9-6.7 points, 61 patients, 2 studies), nonaugmented (4.2 points, range 2.1-5.8 points, 181 patients, 5 studies), xenograft (3.8 points, range 3-4.7 points, 148 patients, 4 studies), and xenograft with the recalled xenograft studies removed[59] (3.78 points, range 3-4.7 points, 137 patients, 3 studies). For studies comparing augmentation versus interposition, the frequency-weighted mean VAS decreases were 4.6 and 4.3, respectively, favoring augmentation.

Constant-Murley scores[17] were reported in 13 of the 36 (36%) studies, with all studies showing improvement in all groups. The overall frequency-weighted mean improvement in Constant-Murley score was 37.6 points (448 patients, 13 studies with 17 groups). By graft type, Constant-Murley scores improved most in the synthetic groups (43.9 points, range 38.7-46.4 points, 58 patients, 2 studies), followed by nonaugmented (40.0 points, range 33.6-45.2 points, 75 patients, 3 studies), allograft (39.3 points, range 30.2-50.9 points, 52 patients, 3 studies), autograft (38.2 points, range 23.2-54.1 points, 203 patients, 6 studies [one of which had 2 autograft arms]), and xenograft (25.4 points, 60 patients, 2 studies). None of the xenograft studies used the recalled xenograft that needed to be removed from this outcome measure calculation. When we looked independently at the studies comparing augmentation versus interposition, the frequency-weighted mean increases in Constant-Murley scores were 33.9 and 39.9, respectively, favoring interposition.

ASES scores were reported in 13 of the 36 studies (36%), with all studies showing improvement in all groups. The overall frequency-weighted mean improvement in ASES score was 38.5 points (349 patients, 13 studies with 17 groups). By graft type, ASES scores improved most in the autograft groups (46.6 points, range 33.7-53.3 points, 69 patients, 2 studies [one of which had 2 autograft study arms]), followed by synthetic (39.6 points, range 29.3-44.0 points, 41 patients, 3 studies), xenograft with recalled xenograft studies removed[59] (37.3 points, range 29.1-41.7 points, 77 patients, 2 studies), xenograft (37.1 points, range 29.1-41.7 points, 88 patients, 3 studies), nonaugmented (36.5 points, range 9.9-48.8 points, 59 patients, 3 studies), and allograft (34.5 points, range 22.5-50.4 points, 92 patients, 5 studies). When the studies using augmentation versus interposition techniques were assessed independently, the frequency-weighted mean increase in ASES scores was identical at 38.9 points.

UCLA scores were noted in 11 of the 36 studies (31%), with all studies showing improvement in all groups. The overall frequency-weighted mean improvement in UCLA scores was 11.9 points (562 patients, 11 studies with 18 groups). By graft type, UCLA scores improved most in the autograft groups (18.5 points, range 18.3-18.6 points, 92 patients, 3 studies), followed by autograft combined with synthetic (13.8 points, 60 patients, 1 study), synthetic (13.7 points, 52 patients, 1 study), allograft (12.2 points, range 9.1-17.1 points, 100 patients, 4 studies), nonaugmented (9.3 points, range 4.2-16.4, 186 patients, 5 studies), xenograft (6.6 points, range 4.5-11.8 points, 72 patients, 3 studies), and xenograft with recalled xenograft studies removed[43,59] (4.5 points, 49 patients, 1 study). When the studies using augmentation versus interposition techniques were assessed independently, the frequency-weighted mean increases in UCLA scores were 11.1 and 14.7, respectively, favoring interposition.

Range of Motion. Range of motion and relative changes were noted in 24 of the 36 studies (67%), with all studies showing improvement in all groups, except for 1 study showing decreases in both external and internal rotation in a nonaugmented control group.[12] Measurable changes in degrees in at least 1 plane were noted in 19 of the 36 studies (53%) and are discussed below. The overall frequency-weighted mean improvement in forward flexion was 42.3° (463 patients, 14 studies with 18 groups). By graft type, forward flexion improved most in the synthetic group (53.9°, range 15.0°-66.8°, 52 patients, 2 studies), followed by autograft (50.8°, range 24.6°-80.0°, 152 patients, 5 studies), allograft (45.4°, range 36.0°-55.7°, 54 patients, 3 studies), nonaugmented (34.6°, range 21.4°-51.7°, 55 patients, 2 studies), xenograft (31.3°, range 19.7°-60.0°, 150 patients, 4 studies), and xenograft with recalled xenograft studies removed[43] (28.8°, range 19.7°-40°, 138 patients, 3 studies). When the studies using augmentation versus interposition techniques were assessed independently, the frequency-weighted mean degree increases in forward flexion were 52.6 and 39.4 degrees, respectively, favoring augmentation.

The overall frequency-weighted mean improvement in abduction (including studies measuring elevation in the scapular plane) was 50.4° (617 patients, 13 studies with 19 groups). By graft type, abduction improved most in the autograft combined with synthetic group (82.1°, 60 patients, 1 study), followed by synthetic (75.2°, range 65.3°-82.7°, 91 patients, 2 studies), allograft (49.3°, range 46.7°-52.8°, 52 patients, 3 studies), autograft (43.9°, range 22°-74°, 134 patients, 4 studies), xenograft (40.4°, range 31.4°-59.0°, 138 patients, 4 studies), xenograft with recalled xenograft studies removed[43] (38.6°, range 31.4°-48.2°, 126 patients, 3 studies), and nonaugmented (37.4°, range 1.0°-47.8°, 142 patients, 3 studies). When the studies

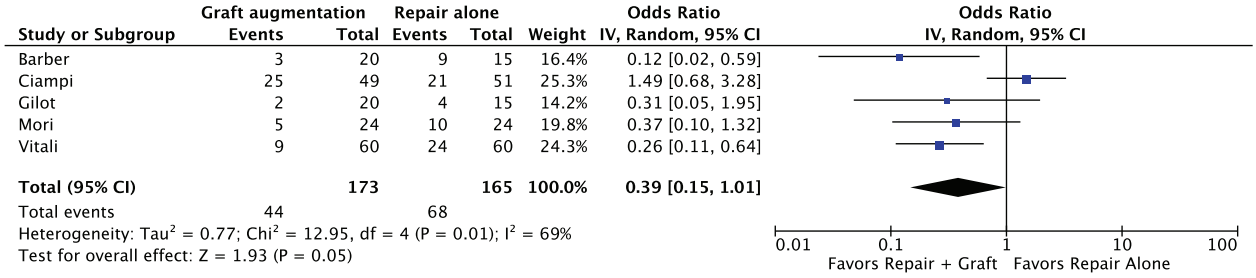

Figure 2. Forest plot comparing retear rates between graft augmentation and repair-alone groups.

using augmentation versus interposition techniques were assessed independently, the frequency-weighted mean increases in abduction were 56.7° and 51.8°, respectively, favoring augmentation.

The overall frequency-weighted mean improvement in external rotation was 11.7° (435 patients, 12 studies with 17 groups). To help standardize measurements, external rotation with the arm at 0° of abduction was chosen if multiple options were given. By graft type, external rotation improved most in the allograft groups (18.8°, range 4.2°-35.3°, 54 patients, 3 studies), followed by xenograft (14.0°, range 7°-40°, 150 patients, 4 studies), xenograft with recalled xenograft studies removed[43] (16.4°, range 7°-14.5°, 138 patients, 3 studies), autograft (11.2°, range 3.4°-18.7°, 137 patients, 4 studies), synthetic (5.9°, 39 patients, 1 study), and nonaugmented (4.2°, 55 patients, 2 studies). When the studies using augmentation versus interposition techniques were assessed independently, the frequency-weighted mean increases in external rotation were 16.6° and 12.1°, respectively, favoring augmentation.

Eight of the 36 studies (22.2%; 11 groups total) assessed some measure of internal rotation. Multiple different measurement techniques were used, so an accurate direct comparison could not be made; however, there was an increase in internal rotation in 10 of these 11 groups with a decrease of internal rotation (by 1 spinal level behind the back) in a nonaugmented comparison group.[12]

Strength Testing. Seventeen of the 36 studies (47.2%; 23 groups total) assessed strength in raising the elbow away from the side. The specific plane of motion varied with measures of forward flexion, elevation in the scapular plane, and abduction. In addition, multiple different measures were used to document change (ie, kilograms, newtons, manual muscle testing, point scale, good/poor), so a direct comparison could not be made. However, an increase in strength was noted in all groups (allograft, autograft, xenograft, and nonaugmented repairs). Eight of the 36 studies (22.2%; 9 groups total) assessed some measure of external rotation strength. Again, multiple different measurement techniques were used, so an accurate direct comparison could not be made, but an increase in strength was noted in all groups (allograft, autograft, synthetic, xenograft, and nonaugmented repairs).

Graft and Repair Integrity. Graft/repair integrity as measured by MRI, ultrasonography, or computed tomography arthrogram was noted in 24 of the 36 studies (66.7%) with 34 groups. The overall rate of intact grafts and repairs was 66.9%. This includes both grafted and nonaugmented repair groups. When we assessed grafted and nonaugmented repairs independently, the repair integrity rates were 72.9% and 49.3%, respectively. By graft type, graft/repair integrity percentage was highest in the autograft combined with synthetic groups (85.0%, 1 study), followed by allograft (82.2%, range 74.0%-90.0%, 6 studies), synthetic (78.2%, range 38.5%-90.0%, 5 studies), xenograft with recalled xenograft studies removed[34,43,76] (70.7%, range 49.0%-80.0%, 5 studies), xenograft (67.7%, range 26.7%-91.7%, 8 studies), autograft (63.7%, range 10.6%-80.0%, 4 studies), and nonaugmented repairs (49.3%, range 26.3%-73.3%, 8 studies). When the studies using augmentation versus interposition techniques were assessed independently, the graft integrity percentages were 70.4% and 75.8%, respectively, favoring interposition.

Meta-analysis

Retear Rate. Of the 5 studies included in the meta-analysis,[4,14,27,48,75] all reported retear rates; 3 studies used MRI to evaluate rotator cuff integrity,[4,48,75] and 2 studies used ultrasonography.[14,27] The overall prevalence of retear in the treatment and control groups was 0.38 (95% CI, 0.30-0.46) and 0.43 (95% CI, 0.35-0.52), respectively. A significantly lower retear rate was found in the treatment groups (repair plus graft augmentation/interposition) compared with control groups (Figure 2; $P = .05$).

Postoperative ASES and UCLA Scores. Of the 5 studies included in the meta-analysis, 3 reported postoperative ASES scores in both groups.[4,27,48] Even with the limited number of studies included (n = 3), the treatment group (RCR with graft augmentation or interposition) demonstrated significantly higher postoperative ASES scores compared with the control group (Figure 3A; $P = .005$). Four studies reported postoperative UCLA scores in both groups.[4,14,48,75] No statistically significant differences were found in the postoperative UCLA scores between both groups (Figure 3B; $P = .29$).

Postoperative VAS Score for Pain. Of the 5 studies included in the meta-analysis, 4 reported postoperative VAS score for pain.[14,27,48,75] No statistically significant differences were found in postoperative VAS scores for pain between both groups (Figure 4; $P = .1$).

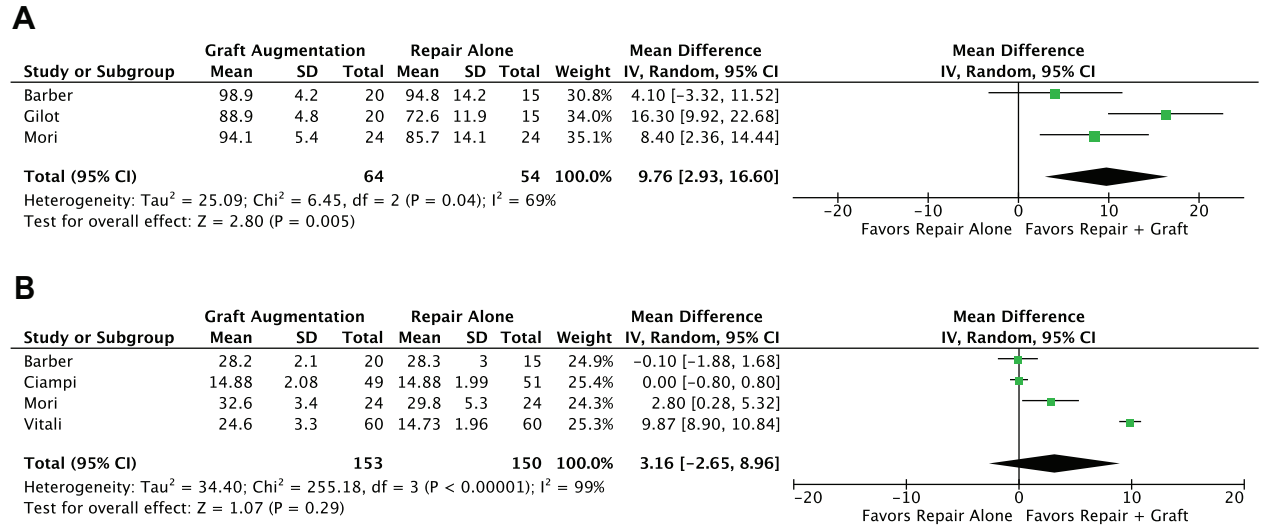

Figure 3. Forest plots comparing postoperative (A) American Shoulder and Elbow Surgeons and (B) University of California, Los Angeles scores between graft augmentation and repair-alone groups.

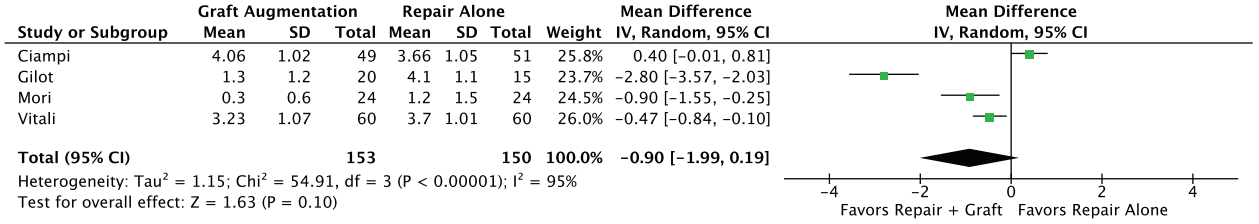

Figure 4. Forest plot comparing visual analog scale scores between graft augmentation and repair-alone groups.

DISCUSSION

Our systematic review of the available literature focused on levels of evidence 1 through 4, 1-year minimum follow-up, and a minimum sample size of at least 10 patients; data from a total of 1217 shoulders were available at final follow-up. We further performed a meta-analysis on those articles that compared the outcomes between RCR with graft augmentation or interposition and a control group consisting of RCR alone; the meta-analysis included 397 shoulders at final follow-up.

Overall, clinical and functional outcomes improved for all repair types, including RCR with augmentation, RCR with interposition, and RCR alone. Only 1 study reported decreases in external rotation and internal rotation in a nonaugmented control group.[12]

Regarding the types of grafts used, autograft had the best results for the ASES score and the UCLA score, while allograft had the best results for the VAS pain scale and postoperative external rotation. Synthetic graft had the best results regarding the Constant-Murley score and postoperative forward flexion, while synthetic graft plus autograft had the best results for postoperative abduction/elevation in scapular plane and graft integrity. The poorest results were largely split between xenograft, xenograft with recalled xenograft studies removed, and nonaugmented repairs. Given the heterogeneity of these findings, it is difficult to recommend for or against a single graft type, although xenografts in general showed the least favorable results. This finding is in keeping with another recent review looking at retear rates of patch augmentation in RCR[68] in which xenografts showed less improvement than synthetic and allografts.

We chose to assess the results of xenograft use with and without inclusion of studies that involved a porcine small intestine submucosa graft (Restore patch). The Restore patch was removed from the market due to safety concerns with the implant. In retrospect, the presence of porcine DNA[83] and the Galα1,3 epitope[39,69,70] in the Restore patch may have caused the inflammatory reactions observed with this graft. Since the recognition of these issues with the Restore patch, results with the new xenografts may differ from the Restore patch because currently available xenografts have been processed to remove DNA and the Galα1,3 epitope.

Determining whether augmentation or interposition was more efficacious is difficult since the ASES score, VAS score, postoperative forward flexion, abduction/elevation in scapular plane, and external rotation all favored augmentation,

while the Constant-Murley score, UCLA score, and graft integrity all favored interposition. In addition, as mentioned below in the discussion of limitations, the indications for each of these techniques are not clear and thus the clinical scenarios for their use may not always be consistent. Caution is warranted when comparing these groups. Steinhaus et al,[68] in reviewing 24 studies, reported retear rates of 12% and 34% after bridging and augmentation, respectively, thus suggesting lower retear rates with interposition. Similarly, in a systematic review by Ono et al[53] of 12 studies, healing rates favored bridging over augmentation (77.9% vs 64.0%, respectively), although the differences were not statistically significant. The current study cannot suggest superiority of one technique over the other.

Meta-analysis of the included studies showed that graft augmentation or interposition during RCR seems to provide lower retear rates and better ASES, UCLA, and pain scores compared with RCR alone. But the differences were only statistically significant for retear rate and ASES score. The use of different assessment tools (ultrasonography or MRI) and the radiologist's experience in evaluating the rotator cuff after graft use may influence the results. One could also argue that differences in ASES scores were not clinically relevant (between-group score differences ranged from 4 to 17 on a 100-point scale). UCLA scores were quite similar between studies. It is possible that the inclusion of more studies in the meta-analysis would have had no influence on the between-group differences for ASES and UCLA scores. Similarly, both surgical procedures (repair alone and repair with a graft) seem to elicit similar pain reduction according to VAS pain scores. Still, the inclusion of a higher number of studies in the meta-analysis likely would have provided more reliable results. Unfortunately, only 8 of the 36 studies compared the outcomes between RCR with augmentation and repair alone, and not all of them reported the outcomes using the same parameters. Therefore, results from our meta-analysis need to be confirmed in further studies. Despite these limitations, this meta-analysis provides valuable information for orthopaedic surgeons planning the use of graft augmentation or interposition for RCR.

Several recent systematic reviews have evaluated augmentation techniques for RCR, but the current report is unique in several aspects. In 2013, Papalia et al[56] reviewed 32 articles published from 1978 to 2012. We reviewed a total of 36 papers including 16 not analyzed in Papalia's review (13 of which were published between 2012 and 2015) while choosing to not include studies looking at PRP alone as an augmentation to RCR. Our focus was on studies that used a medium with solid structural properties for augmentation or interposition. Papalia and colleagues concluded that no augmentation technique was flawless and there was no meaningful increase in clinical or functional assessment after augmented procedures when compared with control groups treated with conventional surgical procedures. Those authors did identify significant heterogeneity of both objective data and clinical outcomes scores, making definite recommendations difficult. Despite this, the authors believed that given the high costs and technical difficulty of the procedure, more high-quality scientific evidence was needed to support the routine use of augmentation procedures.

The 2016 systematic review by Steinhaus et al[68] provided an excellent review of outcomes from 24 studies that met their strict inclusion criteria. There were some key differences between their report and our review. Steinhaus et al excluded autograft augmentations from their review, their minimum follow-up was 9 months (ours was 12 months), they did not perform a risk bias assessment, and they did not include a meta-analysis of their comparative studies. They reported that augmentation and interposition techniques showed overall improvements in clinical and functional outcomes, whereas xenograft showed less improvement than other grafts. It is important to note, however, that Steinhaus et al did not include the 2013 study by Gupta et al[30] that reported promising results using xenograft. This study was included in our systematic review.

Another systematic review published in 2016, this by Ferguson et al,[20] detailed data on 10 studies of graft augmentation to treat large to massive RCRs; in contrast, our current study looked at augmentation and interposition of all tear sizes. All but 2 of the studies reviewed by Ferguson et al are included in our more inclusive review. The 2 studies not included in our study failed to meet our minimum case requirement ($n \geq 10$). Ferguson et al concluded that allograft augmentation was associated with superior function and structural outcome when compared with primary repair. Xenograft augmentation, however, did not demonstrate superiority, but synthetic grafts showed promising initial results. Ultimately, Ferguson et al concluded that research in this field was limited and higher quality studies were needed; a meta-analysis was not included.

The present study has its own limitations. First, the bulk of studies meeting the inclusion criteria for this review were level of evidence 3 and 4 with high risk of bias. Of all papers included in this study, none entailed level 1 evidence, two studies were level 2, six studies were level 3, and 28 studies were level 4. Our average methodologic risk score was 3.4 of 11 possible points. It is difficult to make data-driven recommendations without high-quality studies to support recommendations. A second limitation is the heterogeneity of data included in this systematic review. Although we present a comprehensive review of the literature on rotator cuff augmentation and interposition, the heterogeneity of data makes comparisons difficult and potentially problematic. Tear size is probably the best example in this review. Although the majority of studies in this review involve massive or "irreparable" cuff tears, one study discussed retears that were 0 to 1 cm.[73] The amount of rotator cuff muscle fatty infiltration and atrophy also varied greatly among these studies. In addition, the indications for primary repair versus augmentation or interposition may not be easily comparable, and so the variability in the patients included should be considered. For example, when clinically confronted with a massive, retracted rotator cuff tear, some surgeons might accept more tension in the repair and then use a graft to augment this increased tension on the deficient tissues. Other surgeons might prefer to use an interpositional bridge technique to decrease the tension at the

repair site while introducing a separate interface required for healing. Nevertheless, this represents a review of the outcomes reported by other authors who thought the indications were appropriately comparable. Third, the number of studies included in the meta-analysis portion of this review is low and the studies are heterogeneous in type of treatment and outcomes reported. In addition, the evaluation methods for retear rate were not the same across all studies. Considerable inter- and intraobserver differences should be expected when determining the presence or absence of retear using ultrasonography or MRI. The large heterogeneity between studies was also evidenced by high values of the I^2 statistic. Thus, the use of a random effects model can, in some instances, inappropriately weight smaller studies.

CONCLUSION

We have reviewed the growing body of clinical data on the use of grafts for augmentation and interposition in RCRs. The systematic review showed improvements in clinical and functional outcomes in all treatment groups, including augmentation, interposition, and RCR alone. In the studies that met criteria for the meta-analysis, retear rates and ASES scores were significantly better in patients who received augmentation or interposition compared with RCR alone.

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