Title: A systematic review of reverse total shoulder arthroplasty clinical and patient-reported outcomes and complications stratified by pre-operative diagnosis

Authors:
June Kennedy, PT, MS, transitional doctorate of physical therapy candidate, University of North Carolina at Chapel Hill, Chapel Hill, NC

Garrett S. Bullock, PT, DPT, D.Phil Candidate, Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences, University of Oxford, Oxford, United Kingdom

Christopher S. Klifto, MD; Orthopedic surgeon, North Carolina Orthopedic Clinic, Durham, NC

Leila Ledbetter, MLIS, Duke University Health Systems, Durham, NC

Steph Hedron, MLIS, Duke University Health Systems, Durham, NC

Capstone advisor to June Kennedy: Michael Gross, PT, PhD, University of North Carolina at Chapel Hill

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Lead author email: junetex5@gmail.com; June.kennedy@duke.edu

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Introduction

Reverse total shoulder arthroplasty (RTSA) was approved for use in the United States in 2003 for the treatment of rotator cuff tear arthropathy (CTA).[1] The prosthetic implant design employs fixed fulcrum mechanics that medialize the glenohumeral joint center of rotation such that the deltoid functions as both an elevator and compressor to the joint, thereby compensating for rotator cuff deficiency.[2] The prosthesis utility has expanded to include management of primary glenohumeral osteoarthritis with excessive glenoid erosion with an intact rotator cuff (OA),[3] massive irreparable rotator cuff tear without arthritis (MIRCT),[4] rheumatoid arthritis (RA),[5] proximal humeral fracture (PHFx),[6,7] revision of anatomic total shoulder arthroplasty (Rev),[8,9] and other complicated shoulder conditions such as tumors.[10] RTSA was reported to be the most common primary form of shoulder arthroplasty in one registry increasing from 27% in 2005 to 52% in 2015, and the rise was attributed to the use for varied pre-operative diagnoses.[11] Clinical and patient reported outcomes may vary following RTSA dependent on the pre-operative diagnosis due to differences in the status of the rotator cuff and pre-operative functional mobility. Anatomic shoulder arthroplasty is reported as having better clinical outcome of range of motion for the pre-operative diagnoses of OA and osteonecrosis compared to the procedure being performed for rheumatoid arthritis, post-traumatic arthritis, or dislocation arthropathy.[12] RTSA may also result in varied outcomes depending on variable pre-operative diagnosis.

Post-operative outcome differences following RTSA according to etiology was previously investigated in 2007 with poorer outcomes for Rev compared to CTA, MIRCT and OA groups.[13] This study does not include analysis of acute PHFx or RA pre-operative diagnoses, and furthermore, RTSA prosthetic design has evolved with numerous studies reporting results since this report. Inferior results for revision RTSA compared to the procedure employed for CTA was also reported in 2013, however comparison amongst

other pre-operative diagnoses is not analyzed in this study.[14] A more recent cohort study investigates the outcome of RTSA stratified by 7 pre-operative diagnoses and did not include revision, however this paper reflects outcomes for one practice which may not be generalizable.[15]

Knowledge about outcomes for RTSA for variable diagnoses can assist clinicians in setting appropriate patient goals, and also aid in helping patients develop realistic expectations for recovery. Expectation is closely linked to patient satisfaction,[16,17] therefore establishing differences in outcomes following RTSA for different pre-operative diagnoses is impactful so that clinicians can help patients develop realistic goals for recovery. Younger patients may have different functional demands than elderly which impact RTSA performance and longevity, thereby influencing expectation and outcome following RTSA.[18] Therefore, the purpose of this systematic review was to 1) investigate differences in clinical and patient reported outcomes for different pre-operative diagnoses (CTA, OA, MIRCT, PHFx, RA, and Rev) following RTSA in patients at least 60 years old, and 2) to compare the type and rate of complications following RTSA for each pre-operative diagnostic indications.

Methods

Study Design

This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines.[19] This systematic review was prospectively registered in Prospero (identification number 166957). Clinical trials.gov and Prospero were queried and did not have systematic reviews registered regarding this research question.

Search strategy and eligibility

A literature search was conducted by professional medical librarians (SH and LL) in New Pub Med, Embase, and Web of Science from the inception of each database through January 20, 2020. Search keywords included “reverse” combined with “shoulder joint” combined with “arthroplasty, replacement”

and limited to studies performed with humans and published in the English language. The search strategy and outcome are summarized in Appendix A. Specific criteria for consideration in the literature search are outlined the Population Intervention Comparison Outcome Time (PICOT) chart in Table 1. Inclusion criteria were (1) patients with RTSA over 60 years of age with a pre-operative diagnosis of CTA, OA, MIRCT, PHFx, RA, or Rev; (2) a minimum of 2 year follow-up; (3) pre- and post-operative values for clinical (shoulder range of motion) and patient reported outcomes (PRO) (pain, American Shoulder and Elbow Society score, Constant score, Disability of Arm Shoulder and Hand score, Single assessment numeric evaluation, or other) measures. Exclusion criteria were (1) RTSA for pre-operative diagnoses other than those stated; (3) studies which reported results for combined pre-operative diagnoses; (3) RTSA which included additional muscle transfer, such as a latissimus dorsi transfer; (4) studies with less than 20 subjects; and (5) subjects reporting on anatomic shoulder arthroplasty (including hemiarthroplasty or anatomic total shoulder arthroplasty).

Table 1. The elements for consideration in the search strategy for the systematic review.

Terms used to guide the search strategy				
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)	**T**ime
Patients with reverse total shoulder arthroplasty greater than or equal to 60 years of age	Reverse total shoulder arthroplasty (RTSA) for: ·Rotator cuff tear arthropathy ·Primary osteoarthritis Massive irreparable rotator cuff tear without arthritis Proximal humeral fracture Rheumatoid arthritis Revision of anatomic TSA	Pre-operative to post-operative measures (delta values) at a minimum of 2 years follow-up for each diagnosis Final outcome variables as well as the delta value compared across diagnoses	Clinical and patient reported outcome measures including: ·pain active range of motion ·ASES, Constant, DASH, Sane or other patient reported outcome measures Quality of life scores Complications (rate and type)	Minimum 2 year follow up

Further delineation of each pre-operative diagnosis warranting RTSA as follows:

- Rotator cuff tear arthropathy (CTA): rotator cuff tear with concomitant arthritis of the glenohumeral joint confirmed by radiologic studies including radiographs, magnetic resonance imaging (MRI), and/or computed topography (CT) scan demonstrating superior migration of the humeral head.[13,15]
- Primary osteoarthritis with an intact rotator cuff (OA): osteoarthritis of the glenohumeral joint with an intact rotator cuff as shown by imaging studies demonstrating no proximal migration of the humeral head.[13]
- Massive irreparable rotator cuff tear without arthritis (MIRCT): radiographs demonstrating elevation of the humeral head on the glenoid without evidence of cartilage erosion.[4,15]
- Acute proximal humeral fracture (PHFx): fractures managed within 6 weeks of injury[7,15]
- Rheumatoid arthritis (RA): established diagnosis of this condition with erosion of glenohumeral articular cartilage and/or rotator cuff deficiecy.[5,15]
- Revision of anatomic shoulder arthroplasty (Rev): revision of either a hemiarthroplasty or anatomic total shoulder arthroplasty.[13]

Study selection

Two reviewers (JK and GB) used Covidence systematic review software (Veritas Health Innovation Ltd, Melbourne, Australia) to independently screen titles and abstracts that were identified in the literature search, and the same reviewers screened articles selected for full-text review. Disagreement at the title and abstract review stage as well as the full-text review stage was reached by a third party (CK) who was blinded to the two voters' selections. Following screening, a hand search was performed to identify articles which may have been missed in the preliminary literature search.

Quality assessment of the included studies

Two reviewers independently determined the study design using the Oxford Centre for Evidence-Based Medicine levels of evidence from I to V.[20] Leve I studies are high quality diagnostic, prospective or randomized controlled trials, Level II evidence is from lesser-quality diagnostic, prospective or randomized controlled trials (weaker diagnostic criteria and reference standards, improper randomization, no blinding, and less than 80% follow-up), Level III are case-control or retrospective studies, Level IV are case series, and Level V is expert opinion. Two reviewers also independently scored the risk of bias for non-randomized studies using the Methodological Index for Non-randomized Studies (MINORS) tool.[21] The Modified Downs and Black tool was used to assess risk of bias for randomized controlled studies.[22] Consensus on disagreements in score was reached by discussion. The MINORS appraisal tool assigns a score of 0 (not reported), 1 (inadequately reported), or 2 (adequately reported) to 8 items for non-comparative studies, and an additional 4 items for comparative studies. The scores are categorized regarding the level of evidence in the following manner: 0-6 is very low; 7-10 is low, 11-16 is moderate, and >16 is strong. The Modified Downs and Black employs a checklist of 15 items for assessment of the quality of evidence, and studies scored 12 to 15 are regarded as high quality, those scored 10 or 11 are regarded as moderate quality, and those scored 9 or lower are regarded as low quality.[22]

Data extraction

A custom data extraction sheet was developed using Microsoft Excel (Microsoft Corporation, Redmond, WA), and extraction was shared amongst three of the investigators (40% by GB; 40% by JK, and 20% by CK). Twenty percent (11/53) of the articles were randomly selected for a second assessment of data extraction amongst the investigators to determine agreeability of the data pull. The majority of the data

(75%) was found to be extracted correctly in this comparison. Due to the percentage of agreement being 75%, all data was hand checked for agreement and discrepancies were corrected by referring to the included studies.

Extracted data included study characteristics (lead author, year of publication, time to final end point for follow-up, and sample size) and patient information (gender, age, and pre-operative diagnosis indicating RTSA procedure). Clinical outcomes for range of motion including shoulder flexion, abduction, external rotation with the arm at the side (ER0), external rotation with the arm at 90 degrees of abduction (ER90), and internal rotation (IR) were extracted from studies. Patient-reported outcomes extracted included pain level using the 0-10 Numeric Pain Rating Scale (NPRS), American Society of Shoulder and Elbow Surgeons (ASES) score, total unadjusted Constant Score, Disability of Arm Shoulder Hand (DASH) score, Single Assessment Numeric Evaluation (SANE) score, and other PROs. These clinical and PROs were extracted from studies at pre-operative and final post-operative measure, and the delta values of pre- to post-operative change were recorded. The mean value of each variable was recorded as available in the studies, and the standard deviation and range were also recorded if available. The rate and type of complications were extracted from each paper. Only the final outcome measures were extracted for the PHFx group as this is an unanticipated injury; therefore, pre-operative values are not commonly obtained. Upon completion of data extraction for all papers, the data was sorted by pre-operative diagnosis for aggregation and comparison amongst groups.

Statistical analysis

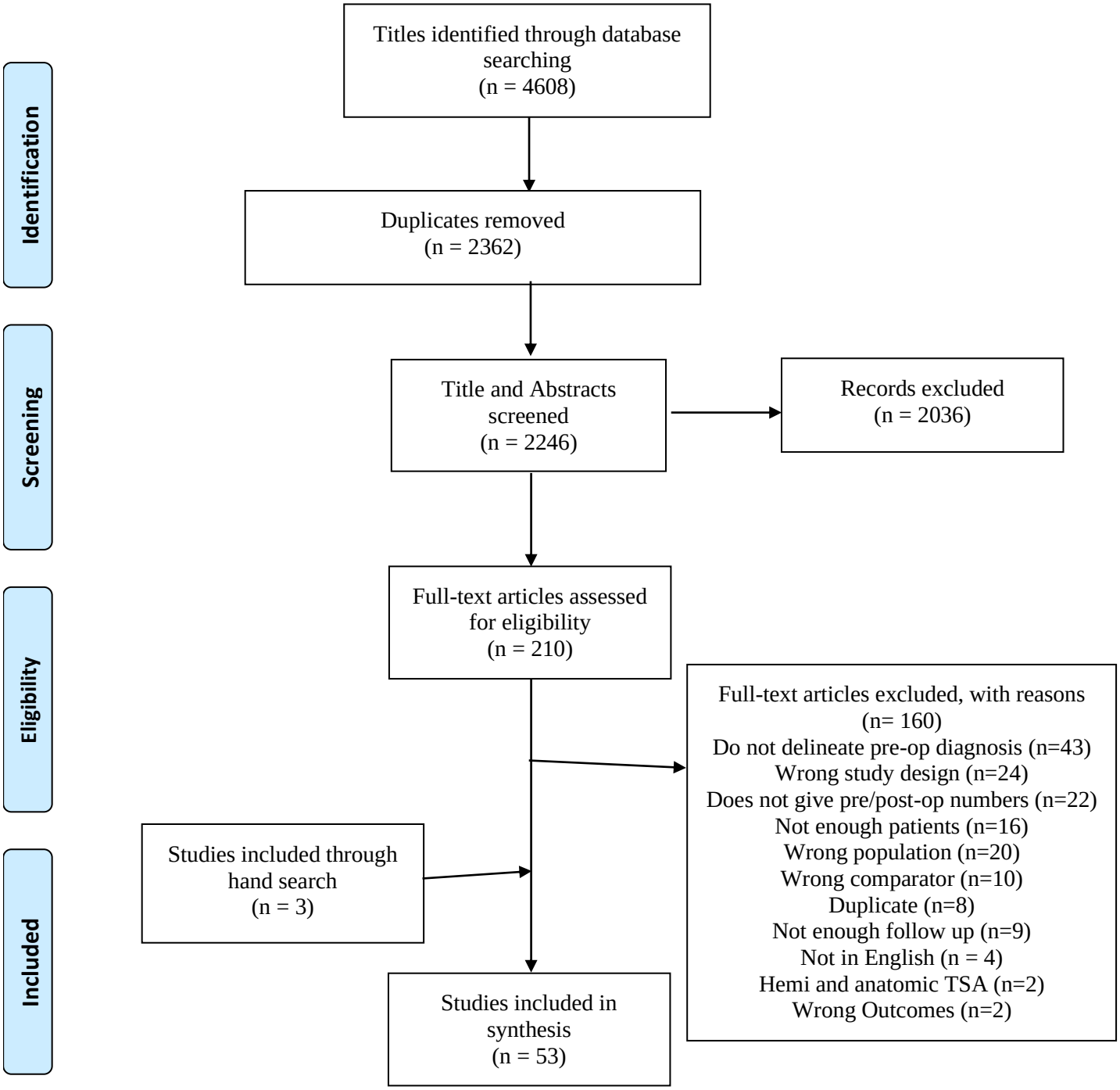
Descriptive analysis was performed due to high variance and risk of bias and low quality of evidence for the majority of the studies. The weighted mean by study sample size was calculated for aggregated

patient specific (age and time to follow-up), delta values, and final end point measures for all clinical and patient reported variables for each pre-operative diagnosis. The variance for the weighted means was recorded as the range from lowest to highest reported across studies for each diagnostic classification. Microsoft Excel was used to calculate the weighted means and range.

Results

The literature search identified 4608 articles amongst the three databases, and 2362 duplicate articles were removed leaving 2246 articles for title and abstract review. Upon exclusion of 2036 titles and abstracts, completion of full-text review of 210 articles, and hand searching, a total of 53 articles were included in this systematic review.[4–9,13,15,23–70] Figure 1 summarizes the PRISMA process from initial search to final article selection.

Figure 1. PRISMA flow chart


Identification
Screening
Eligibility
Included
Titles identified through database searching (n = 4608)
Duplicates removed (n = 2362)
Title and Abstracts screened (n = 2246)
Records excluded (n = 2036)
Full-text articles assessed for eligibility (n = 210)
Full-text articles excluded, with reasons (n= 160)
Do not delineate pre-op diagnosis (n=43)
Wrong study design (n=24)
Does not give pre/post-op numbers (n=22)
Not enough patients (n=16)
Wrong population (n=20)
Wrong comparator (n=10)
Duplicate (n=8)
Not enough follow up (n=9)
Not in English (n = 4)
Hemi and anatomic TSA (n=2)
Wrong Outcomes (n=2)
Studies included through hand search (n = 3)
Studies included in synthesis (n = 53)

Quality of evidence

There were 36 level IV retrospective non-comparative case series;[5,6,8,9,23–25,27,30,33–37,39,40,42–44,46–48,50–53,55,56,59,60,63,64,67–70] 12 level III retrospective comparative studies,[4,7,15,26,29,31,32,38,49,65,66,71] two level II prognostic studies,[13,28] and three level I randomized controlled trials.[41,57,61]

The MINORS score for the 36 noncomparative case series was a mean of 8.91, which is an overall low quality of evidence. In these non-comparative trials 3 studies were very low quality,[37,56,64] 26 were low quality,[5,6,8,9,23–25,30,34,35,39,40,43,46,47,50–53,55,59,63,67–70] and 7 were moderate quality.[27,33,36,42,44,48,60] The MINORS score for the 14 comparative studies was a mean of 14.5, which is a moderate level of evidence. In these comparative studies 4 were low quality,[7,13,15,26] 7 were moderate quality,[4,7,26,29,32,38,62,65,66] and three were strong quality.[31,49,65] The mean Modified Downs and Black score for the three randomized controlled trials was 12.3 which is a high level of evidence. In these three studies, two were high quality[57,61] and one was moderate quality.[41] A table summarizing the Oxford Level of Evidence, Minors Scores, and Modified Downs and Black Scores for all studies is provided in Appendix B.

Pre-operative diagnoses

There were a total of 24 CTA,[13,15,23–26,28,32–34,36,38,39,41,42,47,49,50,53,57,60,64,66,70] 8 OA;[13,15,25,30,35,48,51,65] 6 MIRCT;[4,13,15,25,42,52] 12 PHFx;[6,7,26,27,29,31,40,46,55,59,61,63] 3 RA;[5,44,47] and 15 Rev[8,9,13,25,26,33,37,42,43,47,56,62,68,69,72] pre-operative diagnoses cohorts included in this review, Table 2 summarizes the study and patient characteristics for each pre-operative diagnosis. The majority of studies reported outcomes for CTA, revision of anatomic arthroplasty, and acute proximal humeral fracture. There were very few studies which isolated outcomes for patients with MIRCT[4,52] and RA.[5,44,47] Two studies reported outcomes exclusively for RA.[5,47]

The Rev pre-operative diagnosis had the youngest patients with a weighted mean of 69 years (range 68-83), and the PHFx group were the oldest patients with a weighted mean of 77.5 (72-80). The age of the CTA, OA, MIRCT and RA groups was similar from 71-74 years of age. There was a higher prevalence of RTSA in women than men amongst all pre-operative diagnoses: CTA: 529 men, 1206 women; OA 82 men, 117 women; MIRCT 1141 men, 211 women; and PHFx 62 men, 344 women; RA 7 men, 30 women; and Rev 122 men, 243 women.

The time to final follow-up amongst all pre-operative diagnoses ranged from 36 months for the PHFx group to 52 months for the OA group. One study contained final end point analysis at greater than 10 years for the CTA, OA, MIRCT and Rev groups.[25]

Table 2. Study and patient characteristics according to pre-operative diagnosis.

	CTA	**OA**	**MIRCT**	**PHFx**	**RA**	**Rev**
Number of studies	24	8	6	12	3	15
Total number of subjects	1524	376	470	856	52	435
Age	74.2 (67-82.6)	71.8 (71-85)	72.4 (71-84)	77.5 (72-80)	71.3 (70.1-74.4)	68.9 (64-83)
Male	529	82	141	62	7	122
Female	1206	117	211	344	30	243
Time to follow-up	41.2 (22-150)	52.2 (36-150)	48 (24-150)	35.6 (24-59)	42.8 (36-50)	49.3 (24-150)

Age, gender and time to follow-up in months represent the weighted mean by sample size for all studies included in each pre-operative diagnostic group. Number of males and female represents the number included in final follow-up. CTA = cuff tear arthropathy; OA = osteoarthritis; MIRCT = massive irreparable rotator cuff tear; PHFx = acute proximal humeral fracture; Rev = Revision

Clinical Outcomes

The number of studies and the weighted means and range for the delta value and final post-operative measures of range of are summarized in Table 3. Twenty-three studies reported flexion/elevation, and

external rotation with the arm at the side for CTA in comparison to only 16 studies reporting abduction and ER90 for the same pre-operative diagnosis. Internal rotation was not included in the data analysis because the method of reporting this motion did not employ discrete numbers.

The greatest improvement in flexion/elevation was observed in the RA group and the least in the OA group, with delta values of 68 (61-74) and 54 (28-81) degrees, respectively. Abduction delta values were within 2-7 degrees of flexion/elevation gains, with the exception of the Rev group which gained 10 more degrees of elevation than abduction. External rotation with the arm at the side (ER0) was improved most in the OA group with an increase of 21 degrees, but also with the largest range from 2-46 degrees. Across all of the other groups, ER0 improved from 10-17 degrees and the range for the MIRCT and Rev groups contained negative values (-6-24, MIRCT range, and -14-37 Rev range) indicating that some patients had a decrease in ER0 range of motion following RTSA.

The final end point for flexion/elevation was 130-134 degrees for CTA, OA, MIRCT and RA groups, and there was a large range in this variable for CTA (80 degrees), OA (38 degrees) and Rev (40 degrees). In comparison, the final end point for PHFx and Rev was 122 and 110 degrees, respectively. Abduction end points followed a similar trend as flexion across groups with CTA, OA, MIRCT and RA reaching better mobility (116-125 degrees) compared to PHFx and Rev (110 and 94 degrees, respectively). The final ER0 mobility attained was very similar across all pre-operative diagnoses ranging from 20-27 degrees, with the exception of MIRCT which was 36 degrees. All of the groups had a large range (30-40 degrees) for final ER0. External rotation at 90 degrees of abduction (ER90) at final follow up was greatest in the OA group (58 degrees) and least in the Rev group (24 degrees).

Table 3. Clinical outcomes of range of motion according to pre-operative diagnoses.

	CTA	OA	MIRCT	PHFx	RA	Rev
Flexion						
Number of Studies	23 studies	7 studies	5 studies	12 studies	2 studies	12 studies
Delta	62 (61-74)	54 (28-81)	65 (31-84)	NA	68 (61-74)	60 (44-80)
Final	130 (78-158)	134 (115-153.)	132 (122-143)	122 (115-130)	132 (126-139)	110 (90-130)
Abduction						
Number of Studies	16 studies	2 studies	3 studies	5 studies	2 studies	6 studies
Delta	60 (37-130)	58 (24-80)	63 (39-76)	NA	61 (no range)	50 (43-55)
Final	116 (90-145	125 (116-140)	122 (109-129)	110 (101-113)	116 (no range)	94 (85-101)
ER (0)						
Number of Studies	23 studies	6 studies	4 studies	9 studies	2 studies	9 studies
Delta	17 (2-32)	21 (2-46)	16 (-6-24)	NA	10 (5-14)	9 (-14-37)
Final	26 (7-40)	27 (9-47)	36 (8-51)	20 (5-37)	27 (20-33)	27 (1-50)
ER (90)						
Number of Studies	3 studies	3 studies	2 studies	2 studies	1 study	2 studies
Delta	27 (14-61)	25 (8-37)	19 (1-25)	NA	29 (no range)	-0.5 (-6-2)
Final	44 (40-63)	58 (39-64)	53 (41-57)	32 (32-36)	46 (no range)	24 (18-26)

Delta value = pre- to post-RTSA change; Final = range of motion reported at final time point; ER(0) is External rotation with the arm at the side; ER(90) is external rotation at 90 degrees of abduction. CTA = cuff tear arthropathy; OA = osteoarthritis; MIRCT = massive irreparable rotator cuff tear; PHFx = acute proximal humeral fracture; Rev = Revision

Patient Reported Outcomes

Table 4 summarizes the PROs stratified by pre-operative diagnoses as well as the number of studies reported for each variable. The DASH and SANE scores were not often reported therefore were not included in analysis, and in the "other PRO" category, the SST was most commonly reported, and therefore was included in the analysis. The final PROs included for analysis were pain level (0-10), ASES score, Constant Score, and the SST value which all are validated for measures of functional outcomes in patients after shoulder arthroplasty.[73,74] Pain was improved across all pre-operative diagnoses 5-6 points. The final pain rating was lowest in the CTA group (0.4) and highest in the Rev group (1.8). The ASES score improved the least in the MIRCT group (35 points) and the most in the RA group (54 points). ASES score improvement was very similar for CTA, OA, and Rev (42-43 points). The final ASES score was similar for all groups ranging 78-81 points, with the exception of the Rev group which was a final score of 69 with little variance in the range (68-74). Constant score improvement was very similar across all groups ranging from 36 to 44 points with small variance, with the exception of the Rev group, which had a variance range of 30 points. The final Constant score was highest in the OA group (76) and lowest in the Rev group (51) and similar for the other groups (59-67). The SST improved 4-6 points across all pre-operative groups, though a large variance in the Rev group (3-11) was observed. The final SST score was 7-9 in all groups with the exception of the Rev group which was 6 with a range of 5-11.

Table 4. Patient reported outcomes of range of motion according to pre-operative diagnoses**.**

	CTA	OA	MIRCT	PHFx	RA	Rev
Pain						
Number of studies	8 studies	1 study	2 studies	1 study	1 study	4 studies
Delta	5.3 (3.8-7.2)	6.4	4.5 (4.4-4.6)	NA	6 (no range)	5.2 (3.5-6)
Final	0.4 (0.8-3.5)	0.4 (no range)	1.4 (1-2.9)	1.4 (no range)	1 (no range)	1.8 (1-3)
ASES						
Number of studies	13 studies	3 studies	4 studies	4 studies	1 study	5 studies
Delta	42 (32-56)	43 (37-48)	35 (29-42)	NA	54 (no range)	42 (32-55)
Final	81 (65-90)	80 (73-84)	78 ((75-83)	78 (68-89)	82 (no range)	69 (68-74)
Constant						
Number of studies	20 studies	5 studies	1 study	10 studies	2 studies	8 studies
Delta	44 (35-52)	36 (33-45)	36 (no range)	NA	41 (40-42)	37 (25-55)
Final	67 (60-74)	76 (65-88)	63 (no range)	59 (57-71)	60 (54-65)	51 (39-56)
SST						
Number of studies	4 studies	2 studies	4 studies	3 studies	1 study	6 studies
Delta	5 (3-8)	4 (4-6)	4 (3-5)	NA	6 (no range)	4 (3-11)
Final	9 (8-10)	7.8 (7.7-7.9	7.3 (6.5-8.3)	8.5 (7.4-9.2)	7 (no range)	6.3 (5-11.2)

Delta value = pre-to post-RTSA change; Final = patient reported outcome at final time point; ASES is the American Shoulder and Elbow Society score; Constant score is the total unadjusted value; SST is the Simple Shoulder Test. CTA = cuff tear arthropathy; OA = osteoarthritis; MIRCT = massive irreparable rotator cuff tear; PHFx = acute proximal humeral fracture; Rev = Revision

Complications

Table 5 summarizes the rate and type of complications according to the pre-diagnosis. The highest overall rate of complications was seen in the RA group with a rate of 28%. This group also had the highest rate of each type of complication with 41% having acromial or scapular spine fractures, 28% infections, 26% dislocations, and 10% nerve palsy. The rate of complications should be interpreted with caution in the RA group as it contained the lowest number of subjects. The lowest overall complication rate was seen in the OA group (1.4%) followed by the CTA group (7.4%). The PHFx aggregated data included one study with a very large sample size of 898 patients which increased that data pool, therefore higher overall numbers of complications are observed, however the rate for each category of complications is less than 2%. The most frequently occurring complication in the Rev and MIRCT groups was glenoid loosening (4% and 6.7%, respectively). Dislocation was reported as a complication in less than 2% for all pre-operative diagnoses with the exception of RA.

Table 5. Complications according to pre-operative diagnosis – most common 8 complications extracted from literature.

	CTA	**OA**	**MIRCT**	**PHFx**	**RA**	**Rev**
Number of studies reporting	13	5	1	10	3	10
Number of subjects pooled	668	213	60	1303	39	384
Number of complications	50	3	12	142	11	73
Complication rate	7.4%	1.4%	20%	11%	28%	19%
Hematoma	0	0	1 (1.7%)	4 (0%)	0	8 (2%)
Peri-prostheric fracture	1 (0%)	2 (1%)	0	11 (0.8%)	1 (2.5%)	5 (1.3%)
Glenoid loosening	1 (0%)	1 (0%)	4 (6.7%)	24 (1.8%)	1 (2.5%)	15 (4%)
Instability	2 (0%)	0	0	22 (1.7%)	2 (5%)	7 (1.8%)

Dislocation	10 (1.5%)	0	1 (1.7%)	3 (0%)	10 (26%)	7 (1.8%)
Infection	11 (1.6%)	4 (2%)	1 (1.7%)	16 (1.2%)	11 (28%)	11 (3%)
Nerve palsy	4 (0.6%)	5 (2.3%)	0	6 (0.4%)	4 (10%)	6 (1.6%)
Acromial or scapular spine fracture	16 (2%)	3 (1.4%)	4 (6.7%)	1 (0%)	16 (41%)	3 (0.8%)

The number in parenthesis is the rate of complication occurrence relative to the total number of subjects in the pooled data for studies reporting complications. CTA = cuff tear arthropathy; OA = osteoarthritis; MIRCT = massive irreparable rotator cuff tear; PHFx = acute proximal humeral fracture; Rev = Revision

Discussion

The purpose of this systematic review was to assess differences in the clinical and patient reported outcomes at a minimum of a two year follow up period for six different pre-operative indications and to compare the rate and type of complications amongst groups. All 6 pre-operative diagnoses obtained improved shoulder elevation and abduction of at least 50 degrees, ER0 of approximately 10 degrees, a reduction in pain of 5-6 on the 0-10 NPRS, and an improvement of function of 4-6 on the SST score as reflected by the delta values. All groups demonstrated improved ASES and Constant scores of at least 35 points, and the minimally clinically important difference (MCID) for these PROs after RTSA has been reported as 13-20 and 5.7, respectively.[75,76] The MCID for improvement in pain has been reported as 1.6 and for the SST 1.5, which was demonstrated by all of the pre-operative diagnoses.[73,76] Therefore, RTSA is advantageous to patients who have pre-operative diagnoses of CTA, OA, MIRCT, PHFx, RA and Rev.

There was a preponderance of low quality evidence to inform this systematic review with 36/53 (68%) of the studies being level IV retrospective case series, and 34/53 (64%) being low quality evidence. Case series are a lower quality of evidence as they do not allow for a comparison of outcomes. The 12 (23%) case controlled studies were of moderate quality of evidence, which allowed for more direct comparison of outcomes. The dearth of randomized controlled trials (3/53, 6%) reported increases bias in the interpretation of the results. The original indication for RTSA was CTA which is reflected in the majority of the studies in this review reporting outcomes for this population. The age of the subjects was comparable across all pre-operative diagnoses, therefore subject age does not preclude comparison amongst the aggregated group data. The observation of more women than men across all pre-operative diagnoses has been reported in prior studies,[13,15,77] and the higher incidence in women with PHFx reflects that elderly females are more prone to PHFx injury due to osteoporosis.[78]

Patients who had RTSA for OA had a lower delta value for flexion, which may reflect a higher level of mobility prior to the procedure, however there was much range in this group's flexion outcome measure. Patients can expect to have better outcomes following RTSA when they have higher levels of range of motion and function prior to surgery,[79] therefore clinicians can counsel RTSA patients regarding expectations based on pre-operative status. Patients with OA attained the highest ER0 delta value and final ER90 which reflects the intact rotator cuff in this population and better pre-operative status for this motion. This result conflicts with that of Wall et al. who demonstrated decreased range of motion for all values as well as lower Constant scores in the OA group compared to other pre-operative diagnoses.[13] The surgical procedure in the Wall et al. study utilized a medialized Grammont prosthesis. This systematic review includes studies with a variety of prosthetic designs, including lateralized implants, which have been shown to provide increased range of motion, and thereby may impact functional

outcome. CTA and MIRCT groups were often combined in studies reviewed for this systematic review, which therefore were not included in this analysis. Flexion and abduction range of motion, and ASES and Constant scores are comparable for these two groups, therefore expectations for outcomes for RTSA are similar for CTA and MIRCT. Lindbloom et al. recently published outcomes for RTSA stratified by pre-operative diagnosis, and concluded that CTA, MIRCT, and OA patients all demonstrated clinically significant improvement in range of motion, ASES, SST and pain scores.[15] The PHFx group did not have pre-operative data due to the nature of the injury, however the final range of motion for flexion, abduction, ER0 and ER90 was lower than all other groups with the exception of the Rev group. RTSA is employed for acute 3 and 4 part PHFx which often involve the tuberosities.[80] Patients with RTSA and greater tuberosity repair have been reported to demonstrate better flexion and external rotation than when the greater tuberosity is not repaired.[80] This systematic review analyzed all PHFx data aggregated together without stratifying tuberosity repair which may have resulted in the lower mobility scores. Clinicians should be aware of the impact of tuberosity repair on outcomes for this population. The PHFx group had comparable (ASES, Constant and SST scores) to the other pre-operative diagnoses in this study. The reported ASES and Constant scores,76 and 59, respectively. were comparable to results in a previous systematic review of RTSA outcomes for PHFX, which reported 74 and 56, respectively.[80]

Patients who had RTSA for a revision of an anatomic arthroplasty (hemi or total) attained a lower final end point of range of motion for flexion, abduction, and ER90, and had higher post-operative pain and lower satisfaction as compared to the other groups. Though the Rev group had a poorer outcome overall, the differential between the Rev and CTA final pain scores was 1.4 (1.8 and 0.4, respectively) which did not reach the MCID value of 1.6.[76] A report of short and midterm results following RTSA according to pre-operative etiology for CTA and Rev demonstrated that the Rev group patients had lower Constant

scores.[77] Wall et al. reported on results for RTSA for CTA, OA, MIRCT, acute fracture Rev and RA, and also determined that Rev patients have poorer outcomes on the Constant score and that overall the procedure is less predictable for this population.[13] Clinicians can expect that although patients who have RTSA for a revision of a failed anatomic shoulder replacement will improve following surgery, the amount of motion and function will be less than when surgery is performed for other pre-operative indications. The rationale for the inferior result is likely related to soft tissue attrition and scarring from repeated surgery, as well as poor bone quality.[69]

Complications are reported for all pre-operative indications for RTSA in this systematic review. The complication rate was highest in the RA group, which may reflect the bone and soft tissue degeneration surrounding the shoulder in this population.[81] This group also contained the lowest number of subjects, therefore the rate of complications should be interpreted with caution. Acromial or scapular spine fractures occurred at a high rate in the RA group, and these patients are reported to demonstrate a high rate of osteoporosis.[82] Dislocation was higher in this population which may be related to subscapularis insufficiency, which is associated with dislocation following RTSA,[83] and rotator cuff compromise is common in RA.[84] The infection rate was highest in the RA population, which may reflect the immunocompromised status of these patients.[85] Complication rates were also comparatively elevated in the MIRCT, Rev and PHFx groups, and were most prevalent for acromial/scapular spine fractures, glenoid loosening and infection. Lengthening of the deltoid in RTSA places strain on the acromion and scapular spine which likely have decreased bone density in this elderly population. Awareness and identification of this complication is important so that patients can rest sufficiently if stress fractures occur, in order to recover and attain successful outcomes after RTSA.[86] Glenoid loosening, dislocation, and infection are reported in prior comparative studies of RTSA for varied pre-operative etiologies,[13,15]

with one author reporting a higher rate of complications in the Rev group.[14] The rate of dislocation amongst the pre-operative diagnoses in this systematic review, excluding the RA population, ranged from 0-1.8% which is lower than other reports of 9% or higher,[87,88] therefore the risk of dislocation after RTSA may not be as high as implicated in some studies. Dislocation rate is higher in the male population, patients who have RTSA for fracture sequelae, and when the subscapularis is not repaired.[87] All of the pre-operative diagnoses in this systematic review had a larger proportion of females than males, did not include fracture sequelae, and did not stratify results with consideration of subscapularis repair which may account for the lower reported dislocation rate.

Future research

Future research is needed which utilizes randomized controlled trials or high quality case controlled series to inform outcomes for varied pre-operative diagnoses following RTSA. Globally applied methods of collecting clinical and patient reported outcome measures would allow for more robust comparison of studies and aggregation of data. The trend in reporting results is for European studies to use the Constant or Oxford Scores for patient reported outcomes, as compared to the United States reporting the ASES score.[89] The variability in reporting patient outcomes precludes pooling data which creates a less robust analysis. The American Shoulder and Elbow Surgeons society participates in a global registry which allows surgeons to collect and analyze patient outcomes in a unified manner.[90] Standardized data aggregation at this level would be advantageous for informing outcomes after RTSA.

Limitations

A significant limitation of this study was that varied prosthetic implants and surgical procedures were aggregated and analyzed together. Studies have shown differences between medialized and lateralized

centers of rotation for the prosthetic implant,[89] and variance in the neck-shaft angle.[91] The status of the teres minor and infraspinatus were not included in data extraction, and posterior rotator cuff integrity may impact motion and function following RTSA.[92] There was much variance in the reported PROs, with the ASES score utilized in American studies, and the Constant score often utilized in the European based literature. When the Constant score was reported, the pain level extracted from this data, which precluded the use of pain as a data point for these studies. The complication rate was not described for all studies included in this systematic review, therefore there may be a difference in the expected rate and type of complications for each pre-operative diagnosis. Also, not all studies are equally represented in the aggregated data, therefore the results cannot be weighed equally amongst the pre-operative diagnoses. Though an attempt to manage this was made through the calculation of weighted means, there were more studies and therefore more robust data regarding CTA, PHFx and Rev than OA, MIRCT, and RA. Across all studies, there was a preponderance of low quality level IV studies which limits the interpretation of the data. Finally, only English language studies were included which may have led to omission of studies which could have contributed meaningful results.

Conclusion

Reverse total shoulder arthroplasty is a reliable solution for improving clinical and patient reported outcomes for varied pre-operative indications including rotator cuff tear arthropathy, primary osteoarthritis without rotator cuff tear, massive irreparable rotator cuff tear without osteoarthritis, acute proximal humeral fracture, rheumatoid arthritis, and revision of anatomic shoulder arthroplasty. The majority of studies reporting outcomes following RTSA are level IV and have a low quality of evidence. Patients with OA may expect greater improvement in ER0 and final ER90 ROM and decreased shoulder flexion ROM improvement compared to other groups, depending on pre-operative status. Rev and PHFx

may expect decreased ROM and lower functional scores than other groups While RA patients demonstrate good clinical and patient reported outcomes, there are higher complication rates in this population. Other complications which occurred amongst all pre-operative diagnoses included acromial/scapular spine stress fractures, glenoid loosening, and infection. Understanding the differences in outcomes for RTSA according to pre-operative diagnosis can assist clinicians in establishing patient expectations regarding recovery.

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Appendix A. Search strategy

Database·(including·vendor/platform):·New·Pubmed¶

Set¤	Terms¤	Results¤
1¤	reverse[tw]¤	387,692¤
2¤	"Shoulder·Joint"[Mesh]·OR·"shoulder·fractures"[MeSH·Terms]·OR·"Shoulder"[Mesh]·OR·shoulder[tw]·OR·shoulders[tw]·OR·glenohumeral[tw]·OR·humeral[tw]·OR·"rotator·cuff"[tw]·OR·"Rotator·Cuff"[Mesh]·OR·"Rotator·Cuff·Tear·Arthropathy"[Mesh]¤	92,646¤
3¤	"Arthroplasty,·Replacement"[MeSH·Terms]·OR·"arthroplasty,·replacement,·shoulder"[MeSH·Terms]·OR·arthroplasty[tw]·OR·arthroplasties[tw]·OR·arthroplastic[tw]·OR·((joint[tw])·AND·(replacement[tw]·OR·reconstruction[tw]·OR·"Shoulder·Prosthesis"[Mesh]·OR·prostheses[tw]·OR·prosthesis[tw]·OR·prosthetic[tw]·OR·prosthetics[tw]·OR·endoprostheses[tw]·OR·endoprosthesis[tw]·OR·endoprosthesoplasty[tw]·OR·endoprosthetic[tw]·OR·endoprosthetics[tw]·OR·endoprosthetoplasty[tw]·OR·implant[tw]·OR·implants[tw]))¤	122,083¤
4¤	1·AND·2·AND·3·¤	1,734¤
5¤	NOT·(animals[mh]·NOT·humans[mh])·NOT·(Editorial[ptyp]·OR·Letter[ptyp]·OR·Case·Reports[ptyp]·OR·Comment[ptyp])¤	1611¤

Database·(including·vendor/platform):·Embase¶

Set¤	Terms¤	Results¤
1¤	reverse:ti,ab,kw¤	324,396¤
2¤	'shoulder'/exp·OR·'shoulder·fracture'/exp·OR·shoulder:ti,ab,kw·OR·shoulders:ti,ab,kw·OR·glenohumeral:ti,ab,kw·OR·humeral:ti,ab,kw·OR·'rotator·cuff':ti,ab,kw·OR·'rotator·cuff·injury'/exp¤	141,631¤

3¤	'reverse·shoulder·arthroplasty'/exp·OR·'replacement·arthroplasty'/exp·OR·'shoulder·replacement'/exp·OR·arthroplasty:ti,ab,kw·OR·arthroplasties:ti,ab,kw·OR·arthroplastic:ti,ab,kw·OR·(joint:ti,ab,kw·AND·(replacement:ti,ab,kw·OR·reconstruction:ti,ab,kw·OR·'shoulder·prosthesis'/exp·OR·prostheses:ti,ab,kw·OR·prosthesis:ti,ab,kw·OR·prosthetic:ti,ab,kw·OR·prosthetics:ti,ab,kw·OR·endoprostheses:ti,ab,kw·OR·endoprosthesis:ti,ab,kw·OR·endoprosthesoplasty:ti,ab,kw·OR·endoprosthetic:ti,ab,kw·OR·endoprosthetics:ti,ab,kw·OR·endoprosthetoplasty:ti,ab,kw·OR·implant:ti,ab,kw·OR·implants:ti,ab,kw))¤	123,965¤
4¤	1·AND·2·AND·3·¤	2,057¤
5¤	NOT·('case·report'/exp·OR·'case·study'/exp·OR·'editorial'/exp·OR·'letter'/exp·OR·'note'/exp·OR·[conference·abstract]/lim)¤	1613¤

Database·(including·vendor/platform):·Web·of·Science¶

Indexes=SCI-EXPANDED,·SSCI,·A&HCI,·CPCI-S,·CPCI-SSH,·BKCI-S,·BKCI-SSH,·ESCI,·CCR-EXPANDED,·IC·Timespan=All·years¶

Set¤	Terms¤	Results¤
1¤	TS=(reverse)¤	612,189¤
2¤	TS=("shoulder"·OR·"shoulder·fracture"·OR·shoulder·OR·shoulders·OR·glenohumeral·OR·humeral·OR·"rotator·cuff"·OR·"rotator·cuff·injury")·¤	93,282¤
3¤	TS=("reverse·shoulder·arthroplasty"·OR·"replacement·arthroplasty"·OR·"shoulder·replacement"·OR·arthroplasty·OR·arthroplasties·OR·arthroplastic·OR·((joint)·AND·(replacement·OR·reconstruction·OR·"shoulder·prosthesis"·OR·prostheses·OR·prosthesis·OR·prosthetic·OR·prosthetics·OR·endoprostheses·OR·endoprosthesis·OR·endoprosthesoplasty·OR·endoprosthetic·OR·endoprosthetics·OR·endoprosthetoplasty·OR·implant·OR·implants)))¤	113,070¤
4¤	1·AND·2·AND·3·¤	1679¤
5¤	AND·DOCUMENT·TYPES:·(Article)¤	1384¤

4608 total records
2246 studies added to Title and abstract screening
2362 duplicates were removed

*List*ing of Oxford, MINORS, a*nd Modified Downs an*d Black score*s*

*Appendix B. Ox*ford L*evel of evidence, Met*hodological Index for Non-randomized Studies (MINORS) and Modified Downs and Black scores.

Author	Year	Oxford Level	MINORS Score	Modified Downs and Black
Al-Hadithy	2014	4	9	
Alcobia-Diaz	2017	4	7	
Bacle	2017	4	9	
Bonnevialle	2019	4	12	
Collin	2019	4	7	
Cuff	2008	4	12	
DeBiase	2012	4	10	
Dukan	2019	4	6	
Flurin	2013	4	12	
Flury	2011	4	5	
Gallinet	2019	4	8	
Gianotti 2014	2014	4	7	
Giardella	2017	4	8	
Hasan	2019	4	12	
Hernandez	2017	4	8	
Holcomb	2010	4	11	
Klein	2008	4	9	
Levy	2016	4	12	
McFarland	2016	4	11	
Middleton	2014	4	8	
Mizuno	2013	4	11	
Mulieri	2010	4	8	
Naveed	2011	4	7	
Obert	2016	4	9	
Patel	2012	4	6	
Ross	2010	4	10	
Saier	2015	4	14	
Simovitch	2019	4	8	
Stetchel	2010	4	6	
Velenti	2014	4	8	
Walker	2012	4	8	
Werner	2005	4	9	
Young	2011	4	8	
Ortmaier (hand search)	2013	4	9	
Melis (hand search)	2012	4	8	
Sirveaux (hand search)	2004	4	7	
Allert	2018	3	12	
Boileau	2019	3	11	
Boileau	2006	3	10	

Chivot	2019	3	15	
Cuff	2013	3	21	
Cuff	2018	3	13	
Francescheti	2020	3	12	
Lindenbloom	2019	3	21	
Merolla	2018	3	11	
Shields	2019	3	17	
Steen	2015	3	17	
Triplett	2015	3	14	
Boutsiadis	2018	2	14	
Wall	2007	2	9	
Granier	2015	1		11
Poon	2014	1		12
Sebastia-Forcada	2014	1		14