Systematic Review

Patient-Reported Outcome Measures Show No Relevant Change Between 1-Year and 2-Year Follow-Up After Treatment for Anterior Shoulder Instability: A Systematic Review

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Purpose: To compare patient-reported outcome measures (PROMs) at 1-year and 2-year follow-up after treatment for anterior shoulder instability. **Methods:** Randomized controlled trials and prospective studies that evaluated and reported PROMs after a capsulolabral repair (with or without remplissage), bone augmentation, or nonoperative treatment to treat anterior shoulder instability at both 1-year and 2-year follow-up were included. PROMs were compared between 1-year and 2-year follow-up; forest plots with mean difference were created to compare baseline, 1-year, and 2-year follow-up; and scatterplots were created to visualize clinical improvement over time. **Results:** Fourteen studies, comprising 923 patients, with levels of evidence Level I and II were included. Nine PROMs, of which predominantly were the Western Ontario Shoulder Instability Index (WOSI; 11 studies; 79%), were evaluated. Minimal to no statistically significant change in WOSI, Oxford Shoulder Instability Score, American Shoulder and Elbow Surgeons (ASES), Subjective Shoulder Value, Simple Shoulder Test, Disabilities of Arm, Shoulder, and Hand (DASH), Quick DASH, Single Assessment Numeric Evaluation, or visual analog scale was observed between 1-year and 2-year follow-up. Pooling of the WOSI, Oxford Shoulder Instability Score, ASES, and Single Assessment Numeric Evaluation demonstrated improvement from baseline to 1-year follow-up and minimal to no change between 1-year and 2-year follow-up. Scatterplots of the WOSI and ASES demonstrated the most improvement within 6 months and no clear improvement after 1-year follow-up. Recurrence rates increased with time but varied between studies. **Conclusions:** In contrast to recurrence rates, which have been shown to increase with time, minimal to no statistically significant change was observed for any of the included PROMs between 1-year and 2-year follow-up. This finding raises the question as to whether it is necessary to evaluate PROMs in long-term follow-up of patients after shoulder stabilization treatment. **Level of Evidence:** Level II, systematic review of Level I and II studies.

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The shoulder is the most frequently dislocated joint in the human body, showing an incidence ranging from 12.3 to 26.2 per 100,000 person-years annually for first-time dislocations.[1,2] More than 70% of shoulder dislocations occur in male patients, and more than 95% of these dislocations occur in the anterior

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direction. A shoulder dislocation can limit patients in sports and daily life and result in instability complaints of the shoulder that might warrant treatment.[3] Nonoperative treatment of this injury usually consists of physical therapy focused on improving muscle strength and coordination to improve (a feeling of) stability and prevent redislocation.[4] However, redislocation rates of up to 60% are observed after a first-time dislocation in young individuals.[5] To reduce the risk of a redislocation, operative treatment can be performed.

A widely performed surgical procedure to treat anterior shoulder instability is a capsulolabral repair.[6] If a large Hill-Sachs lesions is present, this procedure can be combined with a capsulotenomyodesis of the infraspinatus tendon in the Hill-Sachs lesion (remplissage).[7] For patients with significant glenoid bone loss, bone-augmentation procedures, in which a bone graft is used to reconstruct the anterior glenoid, have proven to be successful in preventing redislocation.[8-10]

In shoulder instability research, the primary outcome to measure the efficacy of treatment in clinical trials or cohort studies is often redislocation rate, or recurrent instability, referring to redislocation, subluxation, and sometimes apprehension. These are often combined with patient-reported outcome measures (PROMs), which can be used to assess patient-centered therapeutic responses after treatment. Many different PROMs are used in shoulder instability research, which can lead to difficulties when comparing results between studies. The most frequently used PROMs in shoulder instability research are the Western Ontario Shoulder Instability Index (WOSI) and the American Shoulder and Elbow Surgeons (ASES) scores.[11] Randomized controlled trials (RCTs) in which PROMs are used to evaluate patients with shoulder instability often show that the maximum improvement of the cohort is reached far before the point of final follow-up.[12,13] These clinical trials generally complete a 2-year follow-up period in which PROMs and the redislocation rate are measured at the same time points. However, 2 prospective cohort studies that followed patients until 10 years after treatment demonstrated that a significant number of redislocations do not occur within 2 years, meaning that a follow-up of 2 years could lead to an underestimation of the true redislocation rate.[14,15] Considering that redislocation requires a long follow-up to prevent underestimation and maximum improvement in PROMs is reached much earlier, it can be questioned whether they should be evaluated at the same time points to retrieve the desired information in clinical studies.

It remains unclear whether patients with shoulder instability demonstrate further clinical improvement beyond 1 year after treatment in clinical studies and whether there is a difference between PROMs that are used to measure this clinical improvement. A systematic review by Sahoo et al.[16] on rotator cuff tears and Piuzzi[17] on total hip and knee replacement demonstrated no difference in average PROMs between 1-year and 2-year follow-up. It remains unknown whether these effects occur in patients with anterior shoulder instability as well. Therefore, the primary aim of this study was to compare PROMs at 1-year and 2-year follow-up after treatment for anterior shoulder instability. It was hypothesized that mean PROM values would not improve the second year (1-year to 2-year follow-up) after treatment.

Methods

A review protocol was developed on the basis of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis statement (www.prisma-statement.org) and was submitted to PROSPERO under review ID: CRD42022372096.[18]

Literature Search

Relevant studies were identified by searching PubMed, Embase/Ovid, Cochrane Central Register of Controlled Trials/Wiley, Web of Science/Clarivate Analytics, CINAHL/EBSCO and SportDiscus/EBSCO from inception up to July 14, 2022, and rerun on September 13, 2023 (by P.J.S., L.P.E.V. and S.P.V., information specialist). The following terms, including synonyms and closely related words, were used as index terms or free-text words: “shoulder,” “dislocation,” “patient reported outcome measures”[19] and “trials.”[20] Full search strategies for all databases are shown in Appendix 1, available at www.arthroscopyjournal.org. The search strategies were informally peer reviewed by a second clinical librarian. Duplicate articles were excluded by the information specialist (S.P.V.) using EndNote X8 (Analytics Clarivate, 2018). After removing duplicate articles, the remaining studies were individually screened on title and abstract by 2 authors (P.J.S. and L.P.E.V.) with the use of Rayyan.[21] Studies that met the inclusion criteria underwent full-text screening until a final selection was made. Any disagreement was resolved by discussion and consensus. If the authors were unable to reach a consensus, a third author (M.P.J.B.) would provide final judgment.

Inclusion and Exclusion Criteria

RCTs, prospective cohort studies, and prospective case series that reported PROMs after nonoperative treatment, a capsulolabral repair (with or without remplissage), or glenoid augmentation to treat anterior glenohumeral instability caused by a traumatic anterior shoulder dislocation with a 1-year and 2-year follow-up evaluation were included. Only unique patient populations were included. The definition of traumatic was adopted as reported by the authors. Furthermore, only articles written in the English, Dutch, or German language with a sample size greater than 5 were included. To reduce selection bias, studies involving patients with a mean age younger than 18 years were excluded, as patients younger than the age of 18 years possibly have underdeveloped skeletons. Furthermore, systematic reviews, case reports, abstracts, and cadaveric or animal studies were excluded.

Quality Appraisal

The quality of included randomized studies was assessed using the Cochrane Risk of Bias Tool for Randomized Trials (RoB 2). Nonrandomized studies were assessed using the Risk Of Bias In Non-randomized Studies − of Interventions (ROBINS-I) tool.[22,23] All studies received a risk of bias rating of "low," "some concerns," or "high." The quality control was independently performed by 2 authors (P.J.S. and L.P.E.V.). After the individual assessment, the authors compared results to create a final rating. If the authors were unable to reach a consensus, a third author (M.P.J.B.) would give final judgment. A GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) assessment was not performed to determine the certainty of the evidence. The GRADE approach is typically used to evaluate studies with a PICO (patient, intervention, comparison, outcome)-formulated research question according to the handbook.[24] As this study compared 2 follow-up moments rather than a PICO-formulated question, the GRADE approach was deemed not applicable.

Data Extraction

Baseline characteristics of all patients were extracted from the included studies and included total number of patients and shoulders evaluated, age, sex, and follow-up time. The primary outcome was any PROM used to evaluate the functional outcome of any treatment for shoulder instability. These included nonoperative treatment, a capsulolabral repair with or without remplissage and glenoid augmentation. The rate of recurrence was extracted from the included studies and the definition of the authors was adopted in this review. The following PROMs were extracted: the WOSI, ASES, Oxford Shoulder Instability Score (OSIS), Subjective Shoulder Value (SSV), visual analog scale (VAS) for pain, Simple Shoulder Test (SST), Single Assessment Numeric Evaluation (SANE), Disabilities of Arm, Shoulder, and Hand (DASH) and Quick Disabilities of Arm, Shoulder, and Hand (Quick DASH). The WOSI and OSIS are instability-specific PROMs; the ASES, SSV, and SST are shoulder-specific PROMs; the DASH and Quick DASH are upper extremity-specific PROMs; and the SANE and VAS pain scale are single-component PROMs. In case the WOSI was reported on the scale of 0 to 2100, it was converted to a scale of 0 to 100 according to Kirkley et al.[25] For the WOSI, DASH, and Quick DASH, a decrease in score meant a clinical improvement in the patient. For all other PROMs, an increase in score meant a clinical improvement. In case of strong suspicion of an incorrectly reported PROM with exceptionally low baseline scores and serious scale deviation, authors were contacted for clarification and studies were excluded if the inconsistencies remained unresolved. If the follow-up at a specific time point was evaluated but not reported in the manuscript, the lead author (P.J.S.) sent an e-mail to the authors of the manuscript to acquire the data. If data could not be acquired, the study was excluded.

Statistical Analysis

Mean changes (with 95% confidence intervals [CIs]) of the PROMs in the first and second year of follow-up were calculated and pooled using a random effect model with inverse variance weighting. Pooling of data of each PROM was only performed in case 3 or more samples were available considering risk of bias. Studies with high risk of bias (RoB) were excluded with the exception of RCTs exhibiting high RoB that was solely attributable to a positive awareness of the intervention (domain 2 of RoB 2), as the comparison in this systematic review does not focus on comparing interventions but on comparing different time points for the same cohort. If an article did not report a standard deviation, an estimate was made using the range and sample size according to Walter et al.[26] Moreover, if an article did not report the mean, an estimate was made according to Hozo et al.[27] Heterogeneity between studies was assessed with the use of the I^2 statistic.[28] An I^2 statistic of more than 50% was considered substantial heterogeneity. Sensitivity analyses were performed in case $I^2 > 50\%$ by excluding articles with extreme values. Statistical significance was considered in case the 95% CI did not include the value 0. Forest plots were created to compare the improvement in PROMs in the first year (baseline to 1-year) to the second year (1-year to 2-year) of follow-up in case PROMs were reported at baseline, 1-year and 2-year follow-up. Analyses were performed using R, version 4.3.2 (R Foundation for Statistical Computing, Vienna, Austria) with R package "Meta."[29] To visualize clinical improvement over time, scatterplots of the WOSI and ASES were created when studies reported 3 or more follow-up moments. Scatter plots were created using Excel (Microsoft Corp., Redmond, WA).

Results

Screening and Study Characteristics

The literature search resulted in 14,919 studies. After 8,024 duplicates were removed, the title and abstract of 6,895 studies were screened (Fig 1). After title and abstract screening, 189 studies were selected for full-text screening for eligibility and 29 studies met the

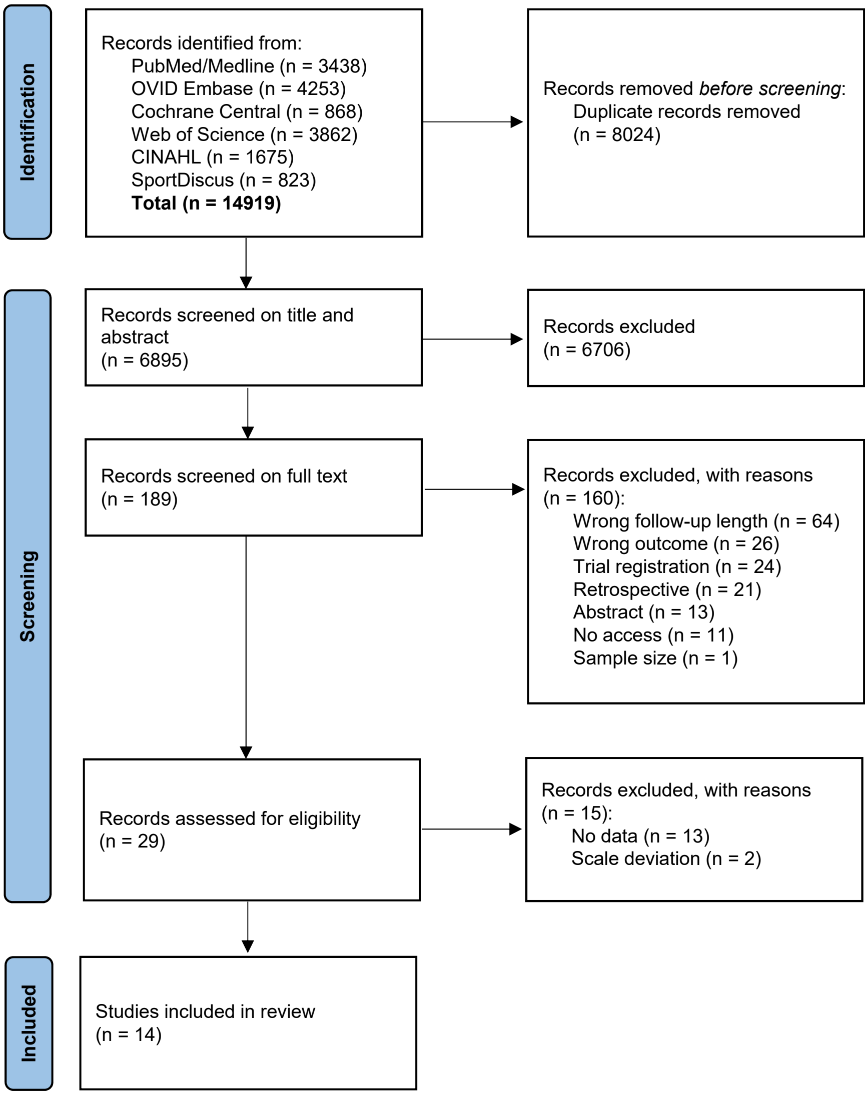

Fig 1. Preferred Reporting Items for Systematic Reviews and Meta-Analysis flow diagram. Wrong outcome = an alternative to patient-reported outcome measures was used to evaluate patient improvement, Trial registration = published information about a trial, not a full article.

inclusion criteria. Reasons for exclusion during and after full-text screening are shown in Figure 1. Data could not be extracted in 16 of the 29 studies that met the criteria. After sending an e-mail to all authors of manuscripts with missing data, the data of 3 additional studies were acquired.[30-32] Two additional e-mails were sent to authors of manuscript with extremely low baseline values of the WOSI (less than half of what other authors reported) and serious scale deviation. These 2 studies were excluded; one because of nonresponse[33] and one because of persisting scale deviation and baseline values that could not be explained, despite the response of the authors.[34] Therefore, a total of 14 studies (25 unique samples) were included, of which 4 were prospective cohort studies[35-38] and 10 RCTs[6,9,30-32,39-43] (Table 1)[44] Included studies were published between 2008 and 2022.

The quality assessment showed a "low" risk of bias rating in 4 randomized studies and 3 nonrandomized studies, "high" risk of bias in 6 randomized studies and "some concerns" for risk of bias in 1 nonrandomized study (Appendix Tables 1 and 2, available at www.arthroscopyjournal.org). The high RoB was attributed to domain 2 for all 6 randomized studies, as both the patient and caregiver were aware of the participants' assigned intervention during the trial.[9,31,32,41-43] In the nonrandomized study with a greater risk of bias, only participants who completed the 2-year follow-up were included, possibly causing selection bias.[38] Therefore, all study data were considered suitable for use in the analysis. In total, 9 PROMs were used to evaluate patient improvement in the included studies, of which the WOSI score was most frequently used (11 studies; 79%). Other PROMs included the OSIS (4 studies;

Table 1. Study Characteristics

Author	Year	Design (LOE)	Sample size, n	Male, %	Mean age at operation ± SD, yr	Mean follow-up ± SD, yr	PROMs	Intervention
Robinson et al.[6]	2008	RCT (I)	80	93	*24.8 ± 4.6*	*2*	WOSI, DASH	A. Lavage, A. Bankart
Kemp et al.[35]	2012	PC (II)	43	74	26 ± 8.2	2 ± 0	WOSI, ASES	A. Bankart
Mohtadi et al.[42]	2014	RCT (I)	162	82	27.5 ± 8.4	2 ± 0	WOSI, ASES	A. Bankart, O. Bankart
McRae et al.[40]	2015	RCT (II)	40	83	25.8 ± 8.1	2 ± 0	WOSI, ASES	A. Bankart, ETAC
Koyonos et al.[36]	2016	PC (II)	34	82	23.2	2 ± 0	WOSI, SST, SANE	A. Bankart
Saier et al.[37]	2017	PC (II)	44	70	29.4 ± 6.1	2 ± 0.1	OSIS	A. Bankart
Zhu et al.[38]	2018	PC (II)	61	93	22.2 ± 1.6	2 ± 0	OSIS	A. Bankart
Moroder et al.[31]	2019	RCT (I)	54	93	29.9 ± 8.4	2 ± 0	WOSI, SSV	O. Latarjet, ICBGT
Murray et al.[43]	2020	RCT (II)	47	85	27 ± 7.5	2 ± 0	OSIS	Nonoperative IR, ER
Kukkonen et al.[9]	2021	RCT (II)	91	100	21.4 ± 2.7	2 ± 0	WOSI, OSIS, SSV	A. Bankart, O. Latarjet
MacDonald et al.[39]	2021	RCT (I)	87	86	*27.5 ± 8.7*	*2.1 ± 0.7*	WOSI, ASES, SST	A. Bankart, Remplissage
Minkus et al.[41]	2021	RCT (I)	91	92	*26.2 ± 5.9*	2 ± 0	WOSI, SSV	Nonoperative ER, A. Bankart
Pouges et al.[32]	2021	RCT (I)	38	82	*21.4 ± 0.6*	>2	WOSI, Quick DASH	Nonoperative IR, A. Bankart
Lobo et al.[30]	2022	RCT (I)	51	71	*31.9 ± 10.4*	2 ± 0	WOSI, VAS, SANE	A. Bankart

NOTE. The level of evidence was determined according to Poehling and Jenkins.[44]

A., arthroscopic; ASES, American Shoulder and Elbow Surgeons; DASH, Disabilities of Arm, Shoulder, and Hand; EETAC, electrothermally assisted capsulorrhaphy; ICBGT, iliac crest bone graft transfer; IR, immobilization in internal rotation; LOE, level of evidence; O., open; OSIS, Oxford Shoulder Instability Score; PC, prospective cohort; PROM, patient-reported outcome measure; R, immobilization in external rotation; RCT, randomized controlled trial; SANE, Single Assessment Numeric Evaluation; SD, standard deviation; SST, Simple Shoulder Test; SSV, Subjective Shoulder Value; VAS, visual analog scale; WOSI, Western Ontario Shoulder Instability Index.

29%), ASES (4 studies; 29%), SSV (3 studies; 21%), SST (2 studies; 14%), SANE (2 studies; 14%), VAS pain scale (1 study; 7%), DASH (1 study; 7%), and Quick DASH (1 study; 7%). The included studies comprised a total of 923 patients (86% male), ranging from 34 to 162 patients. The weighted mean age at operation was 26.1 years (range 21.4-31.9), and the weighted mean follow-up time was 2.2 years (range 2-5). The most commonly used treatment in the included studies was the arthroscopic capsulolabral (Bankart) repair, which was used in treating 584 (63%) patients.

Instability-specific PROMs

The WOSI score was used in 11 studies and the OSIS score was used in 4 studies. Almost all patient groups demonstrated no statistically significant change between 1-year and 2-year follow-up for both scores (Table 2). Only 2 patient groups treated with the arthroscopic capsulolabral repair showed a significant but minimal change in WOSI between 1-year and 2-year follow-up (Table 2). The pooled WOSI after arthroscopic capsulolabral repair showed a statistically significant improvement between baseline and 1-year follow-up (mean difference [MD] = −35.0; 95% CI = −39.3 to −30.8; I^2 = 65%) and a significant but substantially smaller change between 1-year and 2-year follow-up (MD = −2.9; 95% CI = −5.3 to−0.5; I^2 = 9%; Fig 2). A sensitivity analysis of the WOSI excluding Robinson et al.[6] showed comparable results between baseline and 1-year follow-up (MD = −33.8; 95% CI = −37.6 to −30.1; I^2 = 32%) and no change between 1-year and 2-year follow-up (MD = −1.7; 95% CI = −4.3 to 1.0; I^2 = 0%; Appendix Fig 1, available at www.arthroscopyjournal.org). The pooled OSIS after the arthroscopic capsulolabral repair showed a statistically significant improvement between baseline and 1-year follow-up (MD = 16.2; 95% CI = 14.1-18.2; I^2 = 0%) and no change between 1-year and 2-year follow-up (MD = 0.9; 95% CI = −1.1 to 3.0; I^2 = 0%; Fig 3). Varying recurrence rates were observed between studies at 1-year and 2-year follow-up (Table 2).

Shoulder-specific PROMs

The ASES score was used in 4 studies, the SSV score in 3 studies and the SST score in 2 studies. Almost all patient groups demonstrated no statistically significant change between 1-year and 2-year follow-up for the ASES, SSV, or SST (Table 2). Only one patient group treated with the arthroscopic capsulolabral repair showed a minimal but significant change in SST between 1-year and 2-year follow-up (Table 2). The pooled ASES after the arthroscopic capsulolabral repair showed a statistically significant improvement between baseline and 1-year follow-up (MD = 17.8; 95%

Table 2. All Samples of the Included Studies With Each PROM That Was Used To Evaluate Treatment Options For Shoulder Instability

Treatment Type	Treatment	Patients, n	Baseline, mean ± SD	1-Year FU, mean ± SD	2-Year FU, mean ± SD	MD First Year, 95% CI	MD Second Year, 95% CI	Recurrence, n	Months to Recurrence, mean ± SD
WOSI									
N	Immobilization IR (32)	19	–	16.9 ± 17.8	17.7 ± 18.4	–	0.8 (−10.7 to 12.3)	14 (70%)	–
N	Immobilization ER (41)	47	–	8.9 ± 4.3	10.5 ± 5.4	–	1.6 (−0.4 to 3.6)	9 (19%)	9.8 ± 4.4
A	Lavage (6)	40	57.7 ± 11.6	15.6 ± 10.7	18.3 ± 13.8	−42.1 (−47.0 to − 37.2)	2.7 (−2.7 to 8.1)	16 (40%)	13.6
A	Capsulolabral repair (6)	40	58.0 ± 12.7	13.2 ± 7.1	7.8 ± 5.1	−44.8 (−49.3 to −40.3)	−5.4 (−8.1 to −2.7)	3 (8%)	11.3
A	Capsulolabral repair (35)	40	51.9 ± 19.8	15.9 ± 14.6	14.9 ± 14.6	−36.0 (−43.6 to −28.4)	−1.0 (−7.4 to 5.4)	8 (20%)	–
A	Capsulolabral repair (42)	83	59.4 ± 18.4	18.4 ± 19.1	18.1 ± 19.8	−41.0 (−46.7 to −35.3)	−0.3 (−6.2 to 5.6)	20 (24%)	–
A	Capsulolabral repair (40)	22	56.3 ± 20.0	20.6 ± 21.6	20.5 ± 23.2	−35.7 (−48.0 to −23.4)	−0.1 (−13.3 to 13.1)	5 (22%)	–
A	Capsulolabral repair (40)	18	50.9 ± 16.3	18.4 ± 18.6	16.6 ± 14.5	−32.5 (−43.9 to −21.1)	−1.8 (−12.7 to 9.1)	3 (18%)	–
A	Capsulolabral repair (36)	16	54.3 ± 12.0	27.0 ± 30.1	11.7 ± 12.3	−27.3 (−43.2 to −11.4)	−15.3 (−32.1 to 0.6)	4 (25%)	–
A	Capsulolabral repair (39)	41	56.4 ± 13.3	20.3 ± 12.5	15.6 ± 12.1	−36.1 (−41.7 to −30.5)	−4.7 (−10.0 to 0.6)	9 (22%)	12.4 ± 7.7
A	Capsulolabral repair (41)	44	-	8.0 ± 4.1	11.7 ± 4.1	–	3.7 (2.0-5.4)	1 (2%)	12
A	Capsulolabral repair (9)	48	42.2 ± 20.3	12.7 ± 22.5	11.6 ± 10.1	−29.5 (−38.1 to −20.9)	−1.1 (−8.1 to 5.9)	10 (21%)	–
A	Capsulolabral repair (32)	19	-	12.5 ± 16.4	11.5 ± 18.6	–	-1.0 (−12.2 to 10.2)	2 (10%)	–
A	Capsulolabral repair (30)	24	49.4 ± 15.8	21.4 ± 21.5	24.2 ± 22.9	−28.0 (−38.7 to −17.3)	2.8 (−9.8 to 15.4)	4 (17%)	–
A	Capsulolabral repair (30)	27	47.7 ± 17.1	21.8 ± 16.2	26.5 ± 18.7	−25.9 (−34.8 to −17.0)	4.7 (−4.6 to 14.0)	4 (19%)	–
A	Bankart w/ remplissage (39)	46	57.0 ± 13.1	17.2 ± 12.5	15.6 ± 11.3	−39.8 (−45.0 to −34.6)	−1.6 (−6.5 to 3.3)	2 (4%)	9.5 ± 2.1
A	Capsulolabral repair (H) (36)	12	61 ± 10	15.8 ± 18.4	10.8 ± 8.3	−45 (−57 to −33)	−5.0 (−16.4 to 6.4)	2 (17%)	–
O	Capsulolabral repair (42)	79	58.3 ± 19.0	13.6 ± 15.2	14.8 ± 20.4	−44.7 (−50.1 to −39.3)	1.2 (−4.4 to 6.8)	9 (11%)	–
O	Latarjet (9)	43	44.3 ± 20.3	14.4 ± 22.9	14.6 ± 12.3	−29.9 (−39.0 to −20.8)	0.2 (−7.6 to 8.0)	1 (2%)	–
O	Latarjet (31)	25	45.7 ± 17.1	14.4 ± 11.9	11.1 ± 11.1	−31.3 (−39.5 to −23.1)	−3.3 (−9.7 to 3.1)	1 (3%)	–
O	Iliac crest bone augmentation (31)	29	52.3 ± 18.6	14.7 ± 10.5	12.0 ± 13.2	−37.6 (−45.4 to −29.8)	−2.7 (−8.8 to 3.4)	2 (7%)	–
ASES									
A	Capsulolabral repair (35)	40	84.7 ± 7.8	94.4 ± 4.9	94.2 ± 7.7	9.7 (6.8-12.6)	−0.2 (−3.0 to 2.6)	8 (20%)	–
A	Capsulolabral repair (42)	83	64.0 ± 21.6	89.5 ± 12.6	88.2 ± 15.9	25.5 (20.1-30.9)	-1.3 (−5.7 to 3.1)	20 (24%)	–
A	Capsulolabral repair (40)	22	72.5 ± 22.4	93.3 ± 8.1	88.2 ± 19.2	20.8 (10.8-30.8)	-5.1 (−13.8 to 3.6)	5 (22%)	–
A	Capsulolabral repair (40)	18	77.1 ± 15.7	91.9 ± 8.6	87.7 ± 17.0	14.8 (6.5-23.1)	-4.2 (−13.0 to 4.6)	3 (18%)	–
A	Capsulolabral repair (39)	41	69.8 ± 15.1	89.5 ± 8.8	91.6 ± 8.6	19.7 (14.4-25.0)	2.1 (−1.7 to 5.9)	9 (22%)	12.4 ± 7.7
A	Bankart w/ remplissage (39)	46	72.5 ± 13.4	91.4 ± 8.7	93.3 ± 8.1	18.9 (14.3-23.5)	1.9 (−1.5 to 5.3)	2 (4%)	9.5 ± 2.1
O	Capsulolabral repair (42)	79	67.3 ± 18.7	91.9 ± 11.6	91.4 ± 12.7	24.6 (19.7-29.5)	−0.5 (−4.3 to 3.3)	9 (11%)	–
OSIS									
N	Immobilization IR (43)	23	–	42.2 ± 6.5	45.3 ± 4.3	–	3.1 (−0.1 to 6.3)	11 (48%)	9.3 ± 6.8
N	Immobilization ER (43)	24	–	44.9 ± 4.7	46.1 ± 2.5	–	1.2 (−0.9 to 3.3)	7 (29%)	8.9 ± 5.7
A	Capsulolabral repair (37)	44	25.9 ± 8.2	42.4 ± 6.6	43.5 ± 7.4	16.5 (13.4-19.6)	1.1 (−1.8 to 4.0)	5 (11%)	–
A	Capsulolabral repair (38)	61	15 ± 10	30 ± 10	31 ± 9	15 (12-18)	1 (−2 to 4)	6 (10%)	–
A	Capsulolabral repair (9)	48	22.8 ± 6.0	40.1 ± 13.7	40.3 ± 12.7	17.3 (13.1-21.5)	0.2 (−5.1 to 5.5)	10 (21%)	–
O	Latarjet (9)	43	23.1 ± 6.3	39.9 ± 12.3	41.3 ± 12.0	16.8 (12.7 to 20.9)	1.4 (−3.7 to 6.5)	1 (2%)	–
SSV									
N	Immobilization ER (41)	47	–	90.3 ± 7.9	91.6 ± 8.9	–	1.3 (−2.1 to 4.7)	9 (19%)	9.8 ± 4.4
A	Capsulolabral repair (41)	44	–	90.8 ± 7.4	92.7 ± 6.6	–	1.9 (−1.0 to 4.8)	1 (2%)	12
A	Capsulolabral repair (9)	48	50.3 ± 18.0	86.6 ± 24.1	90.0 ± 23.6	36.3 (27.8; 44.8)	3.4 (−6.1 to 12.9)	10 (21%)	–
O	Latarjet (9)	43	51.3 ± 17.5	84.0 ± 23.7	82.2 ± 24.5	32.7 (23.9; 41.5)	−1.8 (−12.0 to 8.4)	1 (2%)	–
O	Latarjet (31)	25	44 ± 21	90 ± 11	89 ± 12	46 (37; 55)	−1 (−7 to 5)	1 (3%)	–
O	Iliac crest bone augmentation (31)	29	44 ± 18	88 ± 11	90 ± 14	44 (36; 52)	2 (−4 to 8)	2 (7%)	–

(continued)

Table 2 . Continued

Treatment Type	Treatment	Patients, n	Baseline, mean ± SD	1-Year FU, mean ± SD	2-Year FU, mean ± SD	MD First Year, 95% CI	MD Second Year, 95% CI	Recurrence, n	Months to Recurrence, mean ± SD
VAS									
A	Capsulolabral repair (30)	24	–	1.4 ± 2.2	1.7 ± 2.5	–	0.3 (−1.0 to 1.6)	4 (17%)	–
A	Capsulolabral repair (30)	27	–	1.7 ± 2.5	2.5 ± 2.7	–	0.8 (−0.6 to 2.2)	4 (19%)	–
SST									
A	Capsulolabral repair (36)	16	8.8 ± 2.6	11.7 ± 0.5	11.1 ± 1.0	2.9 (1.6; 4.2)	−0.6 (−1.1 to −0.1)	4 (25%)	–
A	Capsulolabral repair (39)	41	9.1 ± 1.9	11.3 ± 0.8	11.5 ± 1.1	2.2 (1.6; 2.8)	0.2 (−0.2 to 0.6)	9 (22%)	12.4 ± 7.7
A	Bankart w/ remplissage (39)	46	8.9 ± 1.8	11.6 ± 0.8	11.3 ± 1.0	2.7 (2.1; 3.3)	−0.3 (−0.7 to 0.1)	2 (4%)	9.5 ± 2.1
A	Capsulolabral repair (H) (36)	12	7.6 ± 3.8	11.8 ± 0.4	11.2 ± 1.3	4.2 (2.0; 6.4)	−0.6 (−1.4 to 0.2)	2 (17%)	–
SANE									
A	Capsulolabral repair (36)	16	62.0 ± 22.0	89.0 ± 7.8	91.0 ± 8.4	27.0 (15.6-38.4)	2.0 (−3.6 to 7.6)	4 (25%)	–
A	Capsulolabral repair (30)	24	65.4 ± 21.2	89.1 ± 19.3	90.7 ± 18.7	23.7 (12.2-35.2)	1.6 (−9.2 to 12.4)	4 (17%)	–
A	Capsulolabral repair (30)	27	62.6 ± 27.4	88.6 ± 15.6	89.2 ± 14.8	26.0 (14.1-37.9)	0.6 (−7.5 to 8.7)	4 (19%)	–
A	Capsulolabral repair (H) (36)	12	60 ± 20	89.5 ± 12.0	90.0 ± 8.8	29 (16-43)	0.5 (−7.9 to 8.9)	2 (17%)	–
DASH									
A	Lavage (6)	40	48.6 ± 13.2	3.1 ± 3.7	4.6 ± 4.6	-45.5 (−29.7 to −41.3)	1.5 (−0.3 to 3.3)	16 (40%)	13.6
A	Capsulolabral repair (6)	40	47.1 ± 10.4	3.4 ± 4.0	1.7 ± 1.8	-43.7 (−47.2 to −40.2)	-1.7 (−3.1 to −0.3)	3 (8%)	11.3
Quick DASH									
N	Immobilization IR (32)	19	–	7.9 ± 12.0	11.2 ± 13.0	–	3.3 (−4.7 to 11.3)	14 (70%)	–
A	Capsulolabral repair (32)	19	–	11.3 ± 19.2	6.5 ± 10.6	–	-4.8 (−14.7 to 5.1)	2 (10%)	–

NOTE. Each sample is presented with the available PROM outcome at baseline, 1-year and 2-year follow-up and also includes the mean difference (MD) in the first year and second year of follow-up.

“Recurrence” indicates the number of patients from each sample with recurrent instability, subluxation or dislocation within the 2-year follow-up period. “Months to recurrence” indicates the duration from treatment to first episode of recurrence.

A, arthroscopic; ASES, American Shoulder and Elbow Surgeons; DASH, Disabilities of Arm, Shoulder, and Hand; ER, external rotation; FU, follow-up; H, hyperlaxity patients; IR, internal rotation; N, nonoperative; O, open; OSIS, Oxford Shoulder Instability Score; PROM, patient-reported outcome measure; SANE, Single Assessment Numeric Evaluation; SD, standard deviation; SST, Simple Shoulder Test; SSV, Subjective Shoulder Value; VAS, visual analog scale; WOSI, Western Ontario Shoulder Instability Index.

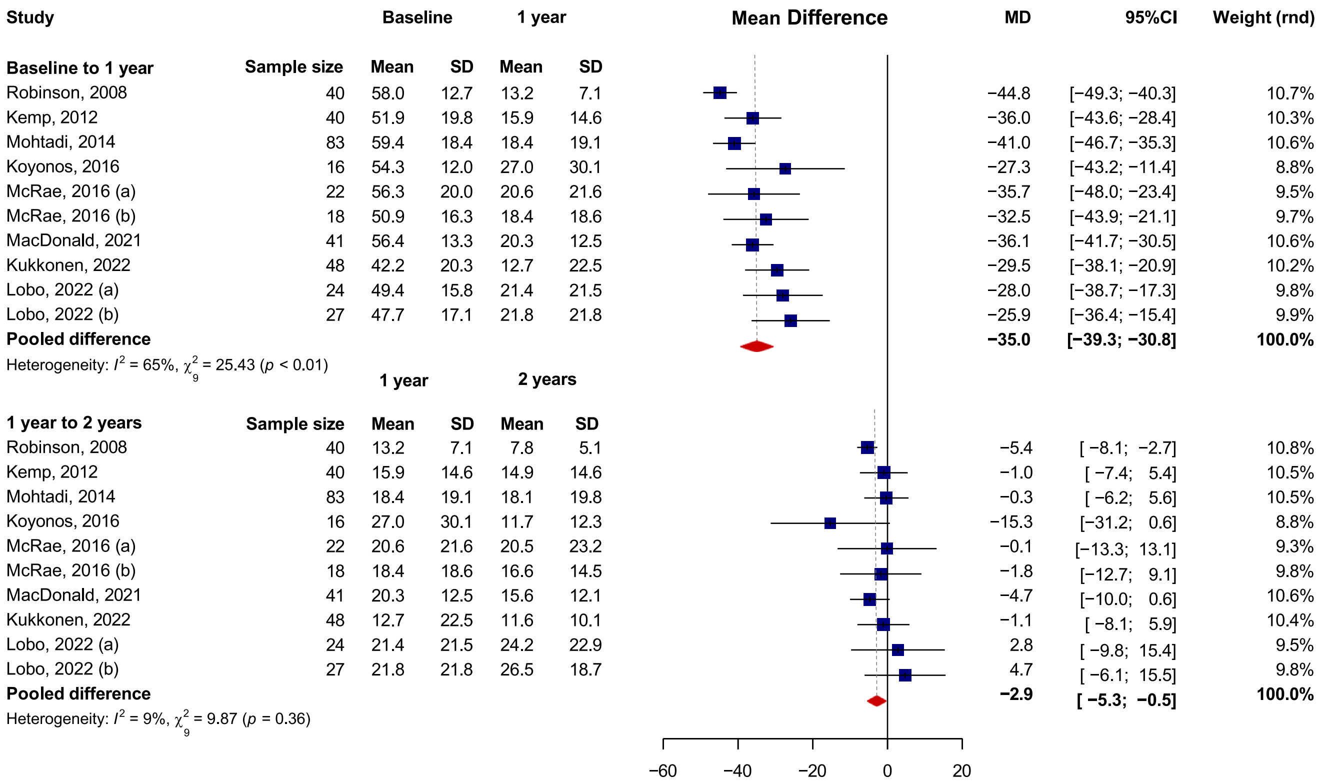

Fig 2. Forest plot of studies that reported the Western Ontario Shoulder Instability Index (WOSI) for the arthroscopic capsulolabral repair to assess treatment effectiveness between baseline and 1-year follow-up and between 1-year and 2-year follow-up. The upper part of the forest plot demonstrates the mean difference between baseline and 1-year follow-up, and the lower part of the forest plot demonstrates the mean difference between 1-year and 2-year follow-up. Whenever a study had 2 samples of unique patients that could be used in the forest plot, (a) refers to the first sample and (b) refers to the second sample. (CI, confidence interval; MD, mean difference; SD, standard deviation.)

CI = 11.8, 23.8; I^2 = 88%) and no change between 1-year and 2-year follow-up (MD = −0.2; 95% CI = −2.2, 1.7; I^2 = 0%; Fig 4). A sensitivity analysis of the ASES excluding Kemp et al.[35] showed comparable results between baseline and 1-year follow-up (MD = 20.8; 95% CI = 16.2-25.3; I^2 = 41%) and between 1-year and 2-year follow-up (MD = −0.7; 95% CI = −3.9 to 2.5; I^2 = 19%; Appendix Fig 2,

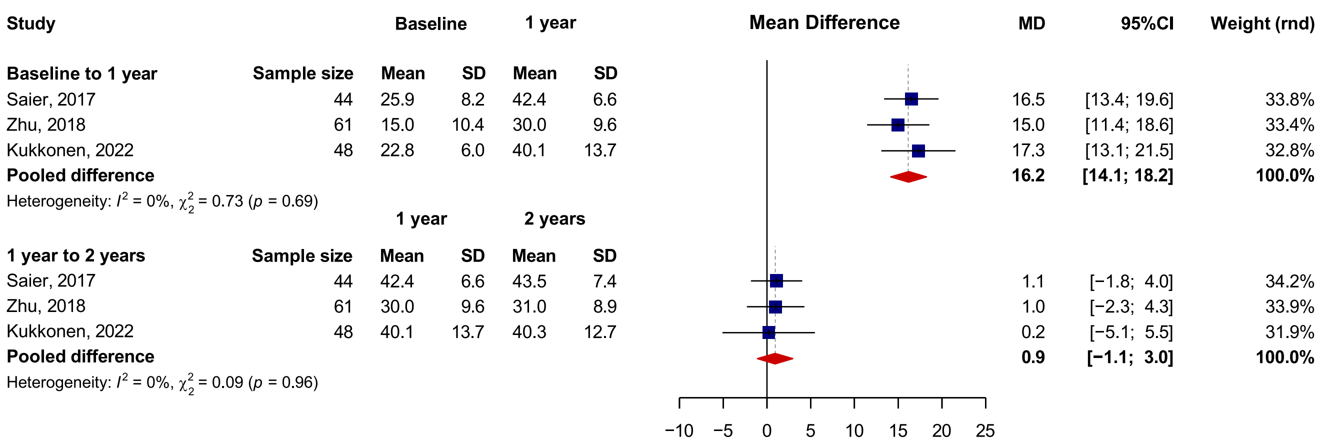

Fig 3. Forest plot of studies that reported the Oxford Shoulder Instability Score (OSIS) for the arthroscopic capsulolabral repair to assess treatment effectiveness at 1-year and 2-year follow-up. The upper part of the forest plot demonstrates the mean difference between baseline and 1-year follow-up, and the lower part of the forest plot demonstrates the mean difference between 1-year and 2-year follow-up. (CI, confidence interval; MD, mean difference; SD, standard deviation.)

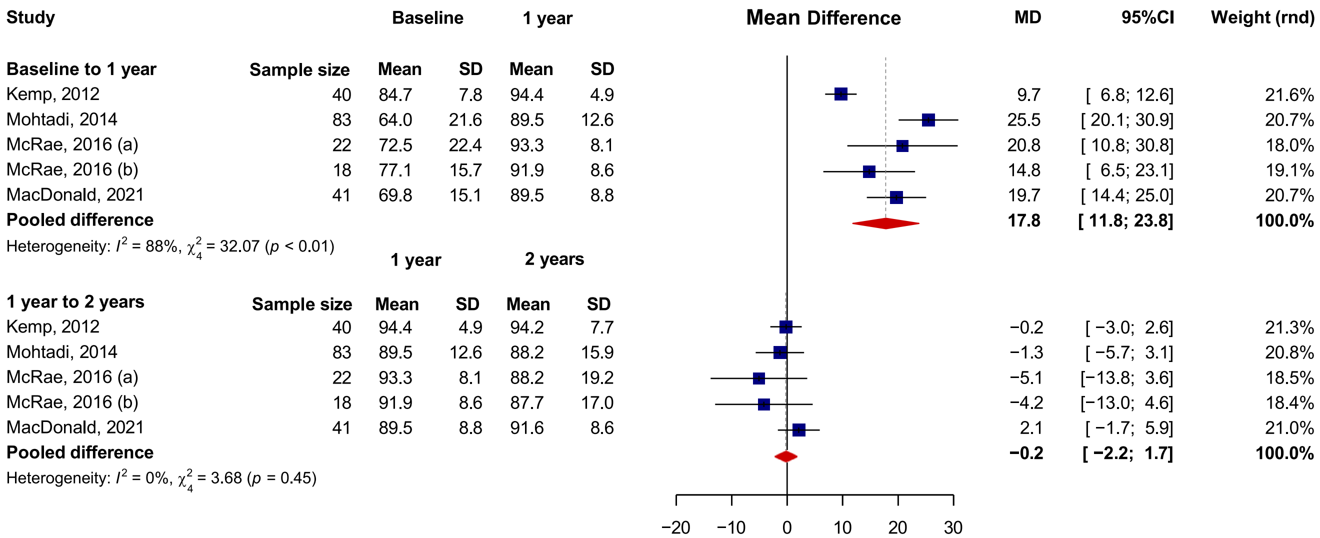

Fig 4. Forest plot of studies that reported on the American Shoulder and Elbow Surgeons (ASES) score for the arthroscopic capsulolabral repair to assess treatment effectiveness at 1-year and 2-year follow-up. The upper part of the forest plot demonstrates the mean difference between baseline and 1-year follow-up, and the lower part of the forest plot demonstrates the mean difference between 1-year and 2-year follow-up. Whenever a study had 2 samples of unique patients that could be used in the forest plot, (a) refers to the first sample and (b) refers to the second sample. (CI, confidence interval; MD, mean difference; SD, standard deviation.)

available at www.arthroscopyjournal.org). Varying recurrence rates were observed between studies at 1-year and 2-year follow-up (Table 2).

Upper Extremity-Specific PROMs

The DASH score was used in 1 study and the Quick DASH score was used in 1 study. Almost all patient groups demonstrated no statistically significant change between 1-year and 2-year follow-up for both scores (Table 2). Only one patient group treated with the arthroscopic capsulolabral repair showed a minimal but significant change in DASH between 1-year and 2-year follow-up (Table 2).

Single-Component PROMs

The SANE score was used in 2 studies, and the VAS pain scale was used in 1 study. None of the patient groups demonstrated a statistically significant change between 1-year and 2-year follow-up for both scores (Table 2). The pooled SANE after arthroscopic capsulolabral repair showed a statistically significant improvement between baseline and 1-year follow-up

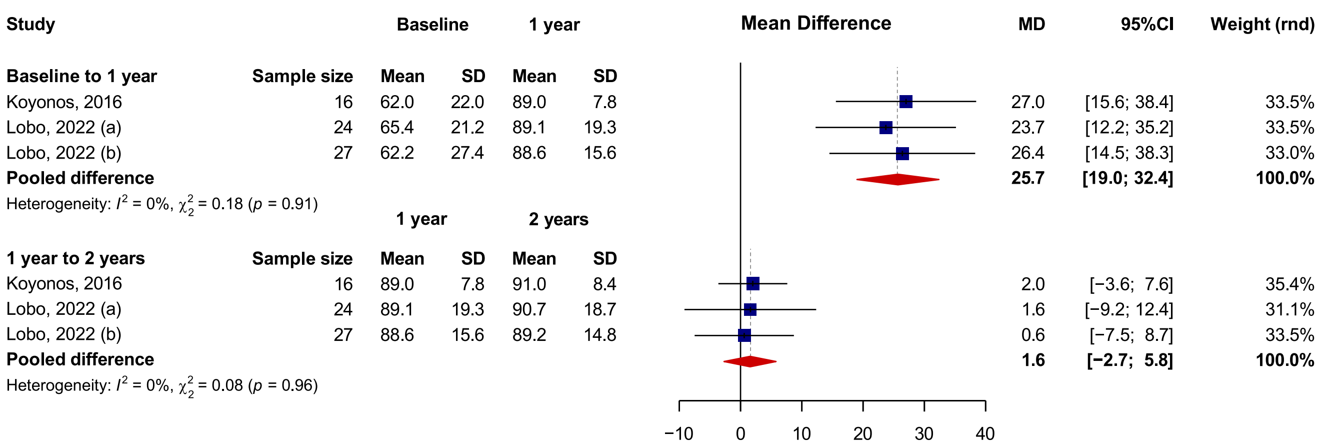

Fig 5. Forest plot of studies that reported on the Single Assessment Numeric Evaluation (SANE) for the arthroscopic capsulolabral repair to assess treatment effectiveness at 1-year and 2-year follow-up. The upper part of the forest plot demonstrates the mean difference between baseline and 1-year follow-up, and the lower part of the forest plot demonstrates the mean difference between 1-year and 2-year follow-up. Whenever a study had 2 samples of unique patients that could be used in the forest plot, (a) refers to the first sample and (b) refers to the second sample. (CI, confidence interval; MD, mean difference; SD, standard deviation.)

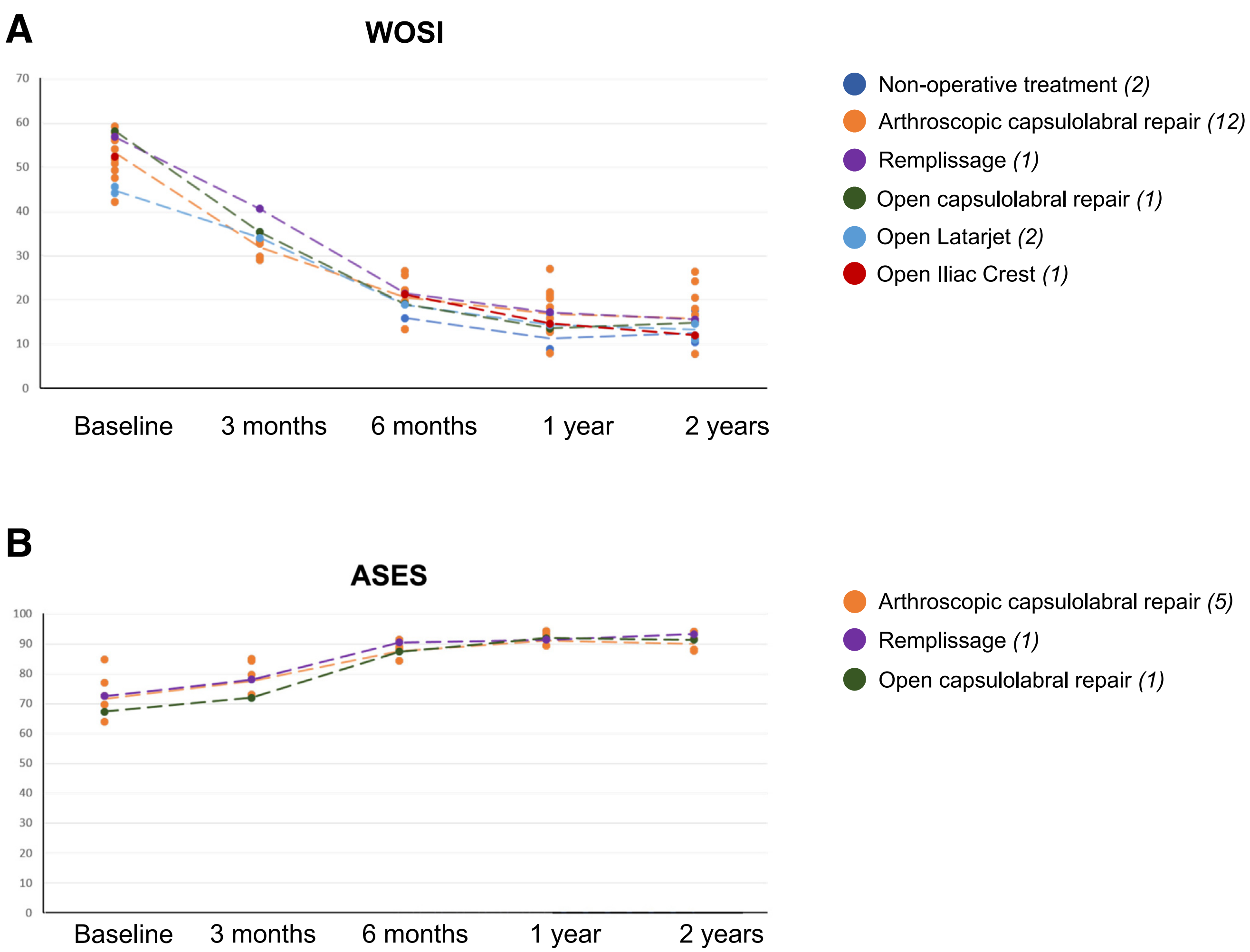

Fig 6. Scatterplots of studies that reported 3 or more follow-up moments for the Western Ontario Shoulder Instability Index (WOSI; A) and the American Shoulder and Elbow Surgeons (ASES) score (B) were used to assess the clinical improvement over time. Each colored dot represents an average patient-reported outcome measure value for a treatment at a specific time point that was extracted from the studies, and the dotted lines follow the average of these values. The number in parentheses indicates the number of samples for each treatment.

(MD = 25.7; 95% CI = 19.0-32.4; I^2 = 0%) and no change between 1-year and 2-year follow-up (MD = 1.6; 95% CI = −2.7 to 5.8; I^2 = 0%; Fig 5). Varying recurrence rates were observed between studies at 1-year and 2-year follow-up (Table 2).

Clinical Improvement Over Time

Scatterplots of the WOSI and ASES did not show a clinically relevant improvement after 1 year of follow-up in the average patient (Fig 6). The majority of improvement seemed to occur between baseline and 6 months follow-up and the WOSI seemed to capture a greater difference between baseline and 6 months follow-up than the ASES.

Discussion

The most important finding of this study was that almost all patient groups showed no significant change in PROMS values between 1-year and 2-year follow-up after treatment for shoulder instability. Only 3 patient groups treated with the arthroscopic capsulolabral repair showed a minimal change in PROM values during the second year, but these changes are unlikely to be clinically relevant. Forest plots with pooled values of the WOSI, OSIS, ASES, and SANE scores demonstrated that most improvement is observed between baseline and 1-year follow-up after arthroscopic capsulolabral repair and minimal to no change is observed in the second year of follow-up. Scatterplots indicated that the WOSI and ASES scores showed most improvement within the first 6 months and no clear improvement was observed after 1 year of follow-up. Varying recurrence rates were observed between the included studies at all time points but generally increased with time. A formal statistical analysis to evaluate the relationship between PROM and recurrence could not be performed without individual patient data.

The WOSI, OSIS, ASES, and SANE demonstrated mean differences close to 0 between the 1-year and 2-year follow-up. The close proximity to 0, coupled with the fact that the 95% CIs contained 0 in most cases, indicates that there is, on average, no clear change in PROMs in the second year of follow-up. Furthermore, the heterogeneity in the forest plots was only observed in the first year of follow-up and not in the second year. This heterogeneity can possibly be explained by the different patient populations included in the trials. For example, some studies only included patients suffering from recurrent anterior shoulder instability, whereas others included patients after a first-time shoulder dislocation and some studies had restrictions on (young) age. Despite these differences in included patients, substantial heterogeneity was only observed in the first year of follow-up in forest plots of the WOSI and ASES. This demonstrates that on average, the rate of recovery varies between patients and different patient populations. However, despite the differences in patient populations and rates of recovery, no differences in PROMs were observed in the second year of follow-up. These findings are concurrent with the results of studies that evaluate treatment of other orthopedic pathologies.[16,17] This all shows that a follow-up period of 2 years could be excessive to successfully evaluate clinical improvement of the average patient using PROMs following treatment for anterior glenohumeral instability. However, monitoring patients at individual level during 2 years by use of PROMs could be useful to identify outliers due to complications or delayed recovery. Even though average PROMs do not demonstrate any differences, the standard deviations are high, indicating that there are patients that follow a different clinical improvement pattern.

The study findings indicate that a follow-up of 1 year might be sufficient to successfully evaluate overall clinical improvement for the average patient treated for anterior shoulder instability using PROMs. However, recent studies have shown that the standard 2-year follow-up in shoulder instability research leads to underestimations of the amount of redislocations.[14,15] Redislocation is a cumulative outcome and will increase with a longer follow-up. Therefore, the follow-up for clinical trials in general should not be 1 year, as this is too short when evaluating redislocation. PROMs seem to reach maximum values between 6 months to 1 year and can worsen again due to a redislocation event. Patient often feel better between episodes of instability and therefore measuring PROMs at the same time points as redislocation can be misleading. It is important to consider the timing and methodology of incorporating PROMs in the design of future clinical studies. Future evaluations could benefit from separately evaluating redislocation and PROM scores. For example, PROMs could be measured up until 1 year after treatment, with more frequent measurements within the first 6 months, whereas patients are evaluated for redislocation at longer intervals after treatment. This approach could lead to a better understanding of the patient's clinical improvement after treatment for anterior shoulder instability, while preventing the underestimation of the true number of recurrent dislocations.

Currently, the best tool for evaluating patients in shoulder instability research is unknown. A consensus has not been reached, and therefore many different PROMs are used to evaluate treatment success in shoulder instability research, hampering the comparison of different treatments and studies. The use of a Core Outcome Set, a standardized set of outcomes in a specific clinical area, could be implemented in shoulder instability research to increase the homogeneity of studies, leading to an easier comparison.[45] This could be developed using the most effective or well-constructed elements from existing PROMs. However, whether the development of a Core Outcome Set in shoulder instability research is possible and beneficial will need to be determined. Therefore, future studies should bring stakeholders together to select the most suitable way of using PROMs or to identify the possibilities in developing an alternative to PROMs for evaluating patients in shoulder instability research.

This review has some important strengths. First, the literature search was constructed in cooperation with an information specialist and performed systematically to avoid overlooking studies with data relevant to this review. Second, this review only included RCTs and studies with prospectively collected data, ensuring the use of high-quality data.

Limitations

This review should be interpreted in the light of the following limitations. First, of the 14 included studies, 6 were considered high RoB as the result of patients being aware of which treatment they received in the RCTs. The inclusion of studies with a high risk of bias could increase the likelihood of skewed results, which could lead to an inaccurate conclusion. Second, an I^2 statistic of more than 50% was observed in 2 forest plots, in the first year of follow-up for the WOSI (Fig 2) and the ASES (Fig 4). This can be attributable to variation in study design, indications, variations in how treatment was performed, or type of patient that was included. Third, the forest plots were created with pooled averages and not individual patient data. Therefore, samples were treated as independent groups. Furthermore, by using pooled averages the potentially false assumption was made that data was distributed normally. Fourth, 2 of the included studies excluded patients from further follow-up if they experienced recurrent instability. In the study by Saier et al.,[37] 9% of the included patients experienced recurrent instability, in the study by Murray et al.,[43] this was 38%. The exclusion of these patients could overestimate the mean PROM values reported at following follow-up moments, particularly when the percentage of exclusions is high. Fifth, while the current study included recurrence rates, the relationship between recurrence and PROMs was not statistically evaluated as this was not possible without individual patient data. Last, there was a lack of clarity concerning revision surgeries in the included studies. Only the study by Saier et al.[37] reported that 12 patients had undergone revision surgery and were therefore excluded. Eight of 14 included studies were unclear about whether patients requiring revision surgery were included or excluded from further follow-up, while the remaining 6 studies provided no information on revision surgeries.

Conclusions

In contrast to recurrence rates, which have been shown to increase with time, minimal to no statistically significant change was observed for any of the included PROMs between 1-year and 2-year follow-up. This finding questions whether it is necessary to evaluate PROMs in long term follow-up of patients following shoulder stabilization treatment.

Disclosures

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44. Poehling GG, Jenkins CB. Levels of evidence and your therapeutic study: What's the difference with cohorts, controls, and cases? [Editorial]. *Arthroscopy* 2004;20:563.
45. Williamson PR, Altman DG, Bagley H, et al. The COMET Handbook: version 1.0. *Trials* 2017;18:280 (suppl 3).

Appendix Table 1. Quality Control of Randomized Studies Using the Cochrane Risk of Bias Tool for Randomized Trials (RoB 2)

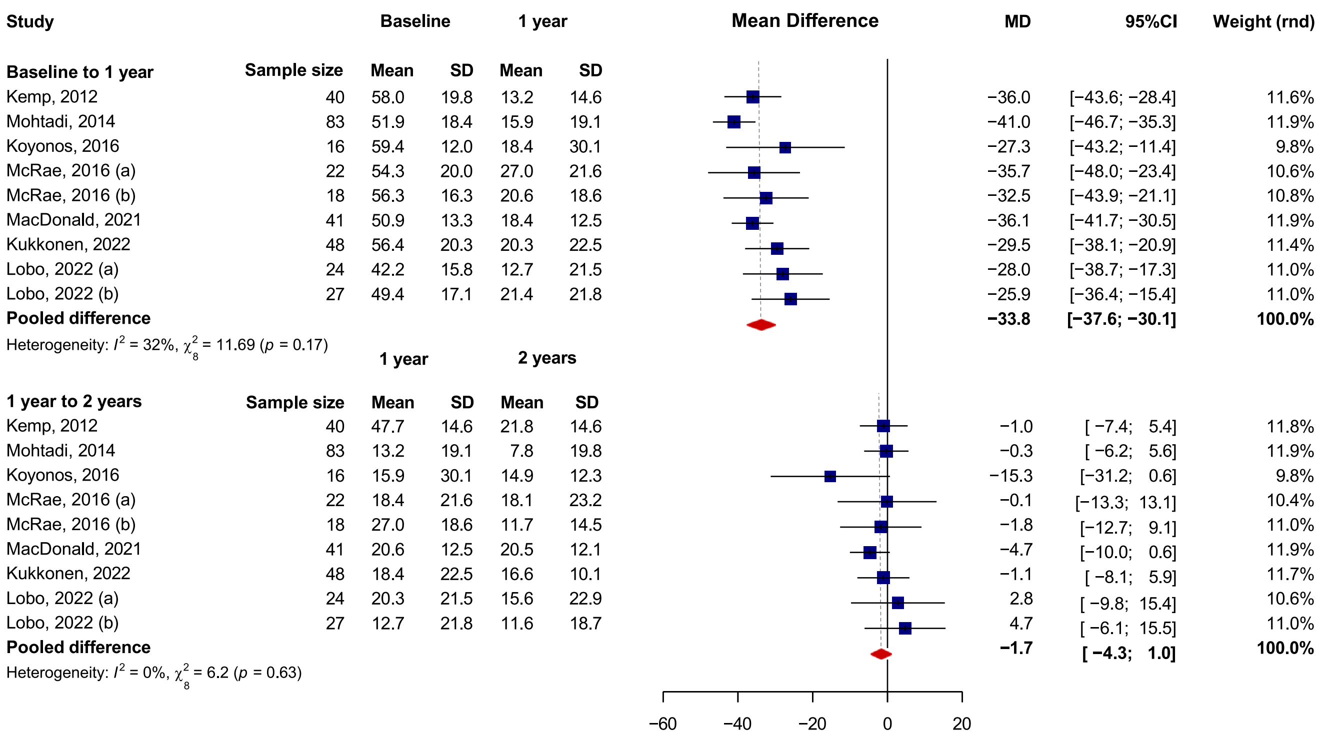
Author	Domain 1 RoB	Domain 2 RoB	Domain 3 RoB	Domain 4 RoB	Domain 5 RoB	Overall RoB
Robinson et al.[6]	Low	Low	Low	Low	Low	Low
Mohtadi et al.[42]	Low	High	Low	Low	Low	High
McRae et al.[40]	Low	Low	Low	Low	Low	Low
Moroder et al.[31]	Low	High	Low	Low	Low	High
Murray et al.[43]	Low	High	Low	Low	Low	High
Kukkonen et al.[9]	Low	High	Low	Low	Low	High
MacDonald et al.[39]	Low	Low	Low	Low	Low	Low
Minkus et al.[41]	Low	High	Low	Low	Low	High
Pouges et al.[32]	Low	High	Low	Low	Low	High
Lobo et al.[30]	Low	Low	Low	Low	Low	Low

RoB, risk of bias.

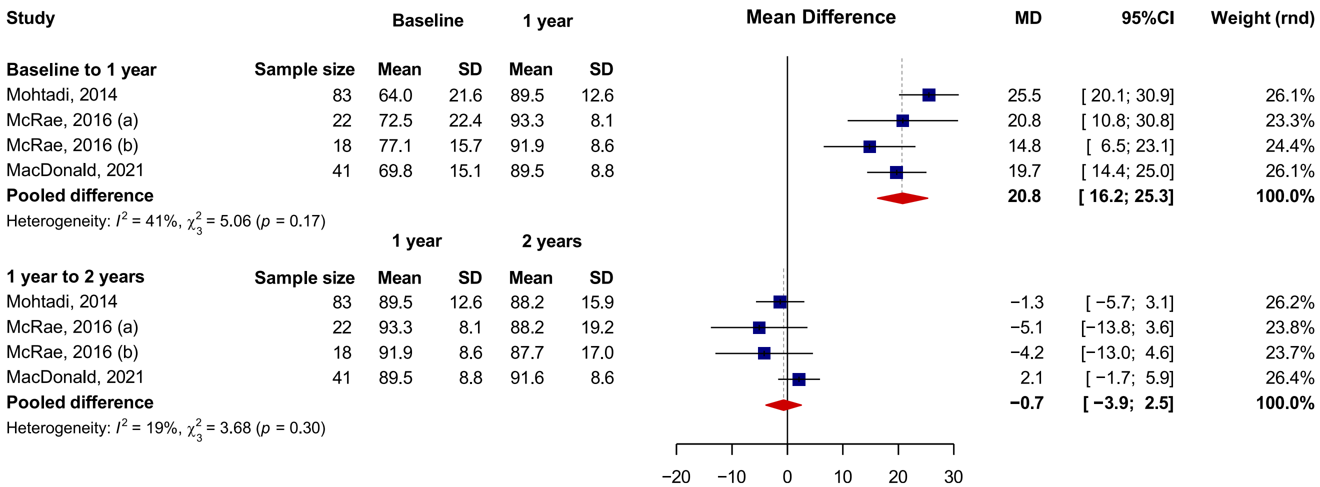
Appendix Table 2. Quality Control of Nonrandomized Studies Using the Risk of Bias in Nonrandomized Studies – of Interventions (ROBINS-I) Tool

Author	Domain 1 RoB	Domain 2 RoB	Domain 3 RoB	Domain 4 RoB	Domain 5 RoB	Domain 6 RoB	Domain 7 RoB	Overall RoB
Kemp et al.[35]	Low	Low	Low	Low	Low	Low	Low	Low
Koyonos et al.[36]	Low	Low	Low	Low	Low	Low	Low	Low
Saier et al.[37]	Low	Low	Low	Low	Low	Low	Low	Low
Zhu et al.[38]	Low	Low	Low	Low	Some concerns	Low	Low	Some concerns

RoB, risk of bias.



Appendix Fig 1. Sensitivity analysis of the WOSI score forest plot (Figure 2) performed by removing Robinson et al. (CI, confidence interval; MD, mean difference; SD, standard deviation.)



Appendix Fig 2. Sensitivity analysis of the ASES score forest plot (Figure 4) performed by removing Kemp et al. (CI, confidence interval; MD, mean difference; SD, standard deviation.)

Appendix 1

Searching and deduplication were performed on July 14, 2022, and rerun on September 13, 2023. All search strategies are based on the update in 2023. No filters were applied.

PubMed

Search	Query	Results
#1	("Shoulder Dislocation"[Mesh] OR (("Shoulder"[Mesh] OR "Shoulder Joint"[Mesh] OR shoulder*[tiab] OR glenohumeral[tiab] OR labr*[tiab]) AND ("Joint Dislocations"[Mesh] OR "Joint Instability"[Mesh] OR dislocat*[tiab] OR luxat*[tiab] OR subluxat*[tiab] OR instabilit*[tiab] OR unstable[tiab] OR instable[tiab])))	17,461
#2	("Randomized Controlled Trial"[pt] OR "Controlled Clinical Trial"[pt] OR "Pragmatic Clinical Trial"[pt] OR "Comparative Study"[PT] OR "Equivalence Trial"[pt] OR "Evaluation study"[PT] OR "Cross-Over Studies"[MeSH] OR "Clinical Trial, Phase III"[pt] OR "Randomized Controlled Trials as Topic"[mh] OR "Controlled Clinical Trials as Topic"[mh] OR "Clinical Studies as Topic"[Mesh] OR "Random Allocation"[mh] OR "Double-Blind Method"[mh] OR "Single-Blind Method"[mh] OR Placebos[Mesh:NoExp] OR "Control Groups"[mh] OR (random*[tiab] OR sham [tiab] OR placebo*[tiab]) OR ((singl*[tiab] OR doubl*[tiab]) AND (blind*[tiab] OR dumm*[tiab] OR mask*[tiab])) OR ((tripl*[tiab] OR trebl*[tiab]) AND (blind*[tiab] OR dumm*[tiab] OR mask*[tiab])) OR (control*[tiab] AND (study[tiab] OR studies [tiab] OR trial*[tiab] OR group*[tiab])) OR (Nonrandom*[tiab] OR "non random*"[tiab] OR "non-random*"[tiab] OR "quasi-random*"[tiab] OR quasirandom*[tiab]) OR allocated[tiab] OR (("open label"[tiab] OR "open-label"[tiab]) AND (study[tiab] OR studies[tiab] OR trial*[tiab])) OR ((equivalence [tiab] OR superiority[tiab] OR "non-inferiority"[tiab] OR noninferiority[tiab]) AND (study[tiab] OR studies[tiab] OR trial*[tiab])) OR ("pragmatic study"[tiab] OR "pragmatic studies"[tiab]) OR ((pragmatic[tiab] OR practical[tiab]) AND trial*[tiab]) OR ((quasiexperimental[tiab] OR "quasi-experimental"[tiab]) AND (study[tiab] OR studies[tiab] OR trial*[tiab])) OR (phase[ti] AND (III[ti] OR 3[ti]) AND (study[ti] OR studies[ti] OR trial*[ti])) OR (phase[ot] AND (III[ot] OR 3[ot]) AND (study[ot] OR studies[ot] OR trial*[ot])) OR "comparative study"[TIAB] OR "cohort study"[TIAB] OR "cohort analysis"[TIAB] OR "follow up study"[TIAB] OR "follow-up study"[TIAB] OR "followup study"[TIAB] OR "observational study"[TIAB] OR longitudinal[TIAB] OR retrospective[TIAB] OR prospective[tiab] OR questionnaire [TIAB] OR questionnaires[TIAB] OR survey[TIAB] OR randomly [tiab] OR trial [ti]) NOT ("Animals"[MeSH] NOT (Animals[MeSH] AND "Humans"[MeSH]))	7,047,401

(continued)

Continued

Search	Query	Results
#3	Western Ontario Shoulder Index[tiab] OR WOSI[tiab] OR American Shoulder and Elbow Surgeons score[tiab] OR ASES[tiab] OR Walch-Duplay score[tiab] OR University of California-Los Angeles score[tiab] OR UCLA[tiab] OR Disabilities of Arm Shoulder and Hand[tiab] OR DASH[tiab] OR Simple Shoulder Test[tiab] OR SST[tiab] OR Subjective shoulder value[tiab] OR SSV[tiab] OR Single Assessment Numeric Evaluation[tiab] OR SANE[tiab] OR Oxford Instability Shoulder Score [tiab] OR OISS[tiab] OR Oxford Shoulder Instability Score[tiab] OR OSIS[tiab] OR "Recurrence"[Mesh] OR recur*[tiab] OR "Patient Outcome Assessment"[Mesh] OR patient outcome assessment*[tiab] OR patient centered outcome*[tiab] OR patientcentred outcome*[tiab] OR patient reported outcome*[tiab] OR prom[tiab] OR proms[tiab] OR hr pro[tiab] OR hrpro[tiab] OR health index*[tiab] OR health indices[tiab] OR health profile*[tiab] OR health status[tw] OR ((patient[tiab] OR self[tiab] OR child[tiab] OR parent[tiab] OR carer[tiab] OR proxy[tiab]) AND ((report[tiab] OR reported[tiab] OR reporting[tiab]) OR (rated[tiab] OR rating[tiab] OR ratings[tiab]) OR based[tiab] OR (assessed[tiab] OR assessment[tiab] OR assessments[tiab]))) OR ((disability[tiab] OR function[tiab] OR functional[tiab] OR functions[tiab] OR subjective[tiab] OR utility[tiab] OR utilities[tiab] OR wellbeing [tiab] OR well being[tiab]) AND (outcome[tiab] OR outcomes[tiab] OR index[tiab] OR indices[tiab] OR instrument[tiab] OR instruments[tiab] OR measure[tiab] OR measures[tiab] OR questionnaire[tiab] OR questionnaires[tiab] OR profile[tiab] OR profiles[tiab] OR scale[tiab] OR scales[tiab] OR score[tiab] OR scores[tiab] OR status[tiab] OR survey[tiab] OR surveys[tiab]))	4,157,443
#4	#1 AND #2 AND #3	3,438
OVID Embase		
1	shoulder dislocation/	6647
2	exp shoulder/	87131
3	(shoulder* or glenohumeral or labr*).ti,ab,kw.	126204
4	2 or 3	162585
5	exp joint dislocation/ or exp joint instability/	23502
6	(dislocat* or luxat* or subluxat* or instabilit* or unstable or instable).ti,ab,kw.	353496
7	5 or 6	361799
8	4 and 7	18727
9	1 or 8	20375
10	exp randomized controlled trial/ or exp controlled clinical trial/ or exp pragmatic trial/ or exp comparative study/ or exp equivalence trial/ or exp evaluation study/ or exp crossover procedure/ or exp phase 3 clinical trial/ or exp "controlled clinical trial (topic)"/ or exp "randomized controlled trial (topic)"/ or exp randomization/ or exp double blind procedure/ or placebo/ or exp control group/	3227548
11	(random* or sham or placebo* or ((singl* or doubl*) and (blind* or dumm* or mask*)) or ((tripl* or trebl*) and (blind* or dumm* or mask*)) or (control* and (study or studies or trial* or group*)) or (Nonrandom* or "non random*" or "non-random*" or "quasi-random*" or quasirandom*) or allocated or (("open label" or "open-label") and (study or studies or trial*)) or ((equivalence or superiority or "non-inferiority" or noninferiority) and (study or studies or trial*)) or ("pragmatic study" or "pragmatic studies") or ((pragmatic or practical) and trial*) or ((quasiexperimental or "quasi-experimental") and (study or studies or trial*)) or (phase and (III or (shoulder* or glenohumeral or labr*)) and (study or studies or trial*)) or "comparative study" or "cohort study" or "cohort analysis" or "follow up study" or "follow-up study" or "followup study" or "observational study" or longitudinal or retrospective or prospective or questionnaire or questionnaires or survey or randomly or trial).ti,ab,kw.	9235443
12	10 or 11	10644914
13	12 not ((exp animal/ or nonhuman/) not exp human/)	9101635

(continued)

Continued

Search	Query	Results
14	(((((Western Ontario Shoulder Index or WOSI or American Shoulder) and Elbow Surgeons score) or ASES or Walch-Duplay score or University of California-Los Angeles score or UCLA or Disabilities of Arm Shoulder) and Hand) or DASH or Simple Shoulder Test or SST or Subjective shoulder value or SSV or Single Assessment Numeric Evaluation or SANE or Oxford Instability Shoulder Score or OISS or Oxford Shoulder Instability Score or OSIS or recur* or patient outcome assessment* or patient centered outcome* or patientcentred outcome* or patient reported outcome* or prom or proms or hr pro or hrpro or health index* or health indices or health profile* or health status or ((patient or self or child or parent or carer or proxy) and (report or reported or reporting or (rated or rating or ratings) or based or (assessed or assessment or assessments))) or ((disability or function or functional or functions or subjective or utility or utilities or wellbeing or well being) and (outcome or outcomes or index or indices or instrument or instruments or measure or measures or questionnaire or questionnaires or profile or profiles or scale or scales or score or scores or status or survey or surveys))).ti,ab,kw.	5692931
15	exp outcome assessment/ or exp patient-reported outcome/	914977
16	exp recurrent disease/	213791
17	14 or 15 or 16	6297844
18	9 and 13 and 17	4253

Cochrane Central Register of Controlled Trials

868 Trials matching ((shoulder* OR glenohumeral OR labr*) AND (dislocat* OR luxat* OR subluxat* OR instabilit* OR unstable OR instable)) AND (random* OR sham OR placebo* OR ((singl* OR doubl*) AND (blind* OR dumm* OR mask*)) OR ((tripl* OR trebl*) AND (blind* OR dumm* OR mask*)) OR (control* AND (study OR studies OR trial* OR group*)) OR (Nonrandom* OR "non random*" OR "non-random*" OR "quasi-random*" OR quasirandom*) OR allocated OR (("open label" OR "open-label") AND (study OR studies OR trial*)) OR ((equivalence OR superiority OR "non-inferiority" OR noninferiority) AND (study OR studies OR trial*)) OR ("pragmatic study" OR "pragmatic studies") OR ((pragmatic OR practical) AND trial*) OR ((quasiexperimental OR "quasi-experimental") AND (study OR studies OR trial*)) OR (phase AND (III OR 3) AND (study OR studies OR trial*)) OR "comparative study" OR "cohort study" OR "cohort analysis" OR "follow up study" OR "follow-up study" OR "followup study" OR "observational study" OR longitudinal OR retrospective OR prospective OR questionnaire OR questionnaires OR survey OR randomly OR trial) AND (Western Ontario Shoulder Index OR WOSI OR “American Shoulder and Elbow Surgeons score” OR ASES OR Walch-Duplay score OR University of California-Los Angeles score OR UCLA OR Disabilities of “Arm Shoulder and Hand” OR DASH OR Simple Shoulder Test OR SST OR Subjective shoulder value OR SSV OR Single Assessment Numeric Evaluation OR SANE OR Oxford Instability Shoulder Score OR OISS OR Oxford Shoulder Instability Score OR OSIS OR recur* OR patient outcome assessment* OR patient centered outcome* OR patientcentred outcome* OR patient reported outcome* OR prom OR proms OR hr pro OR hrpro OR health index* OR health indices OR health profile* OR health status OR ((patient OR self OR child OR parent OR carer OR proxy) AND ((report OR reported OR reporting) OR (rated OR rating OR ratings) OR based OR (assessed OR assessment OR assessments))) OR ((disability OR function OR functional OR functions OR subjective OR utility OR utilities OR wellbeing OR well being) AND (outcome OR outcomes OR index OR indices OR instrument OR instruments OR measure OR measures OR questionnaire OR questionnaires OR profile OR profiles OR scale OR scales OR score OR scores OR status OR survey OR surveys))) *in Title Abstract Keyword*

Web of Science (Clarative), Core collection (SCI-EXPANDED, SSCI, AHCI, ESCI)

TOPIC: ((shoulder* OR glenohumeral OR labr*) AND (dislocat* OR luxat* OR subluxat* OR instabilit* OR unstable OR instable)) AND (random* OR sham OR placebo* OR ((singl* OR doubl*) AND (blind* OR dumm* OR mask*)) OR ((tripl* OR trebl*) AND (blind* OR dumm* OR mask*)) OR (control* AND (study OR studies OR trial* OR group*)) OR (Nonrandom* OR "non random*" OR "non-random*" OR "quasi-random*" OR quasirandom*) OR allocated OR (("open label" OR "open-label") AND (study OR studies OR trial*)) OR ((equivalence OR superiority OR "non-inferiority" OR noninferiority) AND (study OR studies OR trial*)) OR ("pragmatic study" OR "pragmatic studies") OR ((pragmatic OR practical) AND trial*) OR ((quasiexperimental OR "quasi-experimental") AND (study OR studies OR trial*)) OR (phase AND (III OR 3) AND (study OR studies OR trial*)) OR "comparative study" OR "cohort study" OR "cohort analysis" OR "follow up study" OR "follow-up study" OR "followup study" OR "observational study" OR longitudinal OR retrospective OR prospective OR questionnaire OR questionnaires OR survey OR randomly OR trial) AND (Western Ontario Shoulder Index OR WOSI OR “American Shoulder and Elbow Surgeons score” OR ASES OR Walch-Duplay score OR University of California-Los Angeles score OR UCLA OR Disabilities of “Arm Shoulder and Hand” OR DASH OR Simple Shoulder Test OR SST OR Subjective shoulder value OR SSV OR Single Assessment Numeric Evaluation OR SANE OR Oxford Instability Shoulder Score OR OISS OR Oxford Shoulder Instability Score OR OSIS OR recur* OR patient outcome assessment* OR patient centered outcome* OR patientcentred outcome* OR patient reported outcome* OR prom OR proms OR hr pro OR hrpro OR health index* OR health indices OR health profile* OR health status OR ((patient OR self OR child OR parent OR carer OR proxy) AND ((report OR reported OR reporting) OR (rated OR rating OR ratings) OR based OR (assessed OR assessment OR assessments))) OR ((disability OR function OR functional OR functions OR subjective OR utility OR utilities OR wellbeing OR well being) AND (outcome OR outcomes OR index OR indices OR instrument OR instruments OR measure OR measures OR questionnaire OR questionnaires OR profile OR profiles OR scale OR scales OR score OR scores OR status OR survey OR surveys)))

3862 results

CINAHL (EBSCO)

#	Query	Results
S1	(MH "Shoulder Dislocation")	1,834
S2	(MH "Shoulder")	7,608
S3	TI ((shoulder* or glenohumeral or labr*)) OR AB ((shoulder* or glenohumeral or labr*))	37,185
S4	S2 OR S3	38,635
S5	(MH "Dislocations+")	9,488
S6	(MH "Joint Instability+")	11,751
S7	TI ((dislocat* or luxat* or subluxat* or instabilit* or unstable or instable)) OR AB ((dislocat* or luxat* or subluxat* or instabilit* or unstable or instable))	54,021
S8	S5 OR S6 OR S7	61,247
S9	S1 OR (S4 AND S8)	6,447
S10	TI ((random* or sham or placebo* or ((singl* or doubl*) and (blind* or dumm* or mask*)) or ((tripl* or trebl*) and (blind* or dumm* or mask*)) or (control* and (study or studies or trial* or group*)) or (Nonrandom* or "non random*" or "non-random*" or "quasi-random*" or quasirandom*) or allocated or (("open label" or "open-label") and (study or studies or trial*)) or ((equivalence or superiority or "non-inferiority" or noninferiority) and (study or studies or trial*)) or ("pragmatic study" or "pragmatic studies") or ((pragmatic or practical) and trial*) or ((quasiexperimental or "quasi-experimental") and (study or studies or trial*)) or (phase and (III or (shoulder* or glenohumeral or labr*)) and (study or studies or trial*)) or "comparative study" or "cohort study" or "cohort analysis" or "follow up study" or "follow-up study" or "followup study" or "observational study" or longitudinal or retrospective or prospective or questionnaire or questionnaires or survey or randomly or trial)) OR AB ((random* or sham or placebo* or ((singl* or doubl*) and (blind* or dumm* or mask*)) or ((tripl* or trebl*) and (blind* or dumm* or mask*)) or (control* and (study or studies or trial* or group*)) or (Nonrandom* or "non random*" or "non-random*" or "quasi-random*" or quasirandom*) or allocated or (("open label" or "open-label") and (study or studies or trial*)) or ((equivalence or superiority or "non-inferiority" or noninferiority) and (study or studies or trial*)) or ("pragmatic study" or "pragmatic studies") or ((pragmatic or practical) and trial*) or ((quasiexperimental or "quasi-experimental") and (study or studies or trial*)) or (phase and (III or (shoulder* or glenohumeral or labr*)) and (study or studies or trial*)) or "comparative study" or "cohort study" or "cohort analysis" or "follow up study" or "follow-up study" or "followup study" or "observational study" or longitudinal or retrospective or prospective or questionnaire or questionnaires or survey or randomly or trial))	1,842,952
S11	(MH "Randomized Controlled Trials+") OR (MH "Equivalence Trials") OR (MH "Comparative Studies+") OR (MH "Crossover Design") OR (MH "Single-Blind Studies") OR (MH "Double-Blind Studies") OR (MH "Random Assignment") OR (MH "Placebos") OR (MH "Control Group")	626,599
S12	S10 OR S11	2,086,440
S13	S12 NOT (MH "Animals" NOT MH "Human)	2,070,501

(continued)

Continued

#	Query	Results
S14	TI ((Western Ontario Shoulder Index OR WOSI OR "American Shoulder and Elbow Surgeons score" OR ASES OR Walch-Duplay score OR University of California-Los Angeles score OR UCLA OR Disabilities of "Arm Shoulder and Hand" OR DASH OR Simple Shoulder Test OR SST OR Subjective shoulder value OR SSV OR Single Assessment Numeric Evaluation OR SANE OR Oxford Instability Shoulder Score OR OISS OR Oxford Shoulder Instability Score OR OSIS OR recur* OR patient outcome assessment* OR patient centered outcome* OR patientcentred outcome* OR patient reported outcome* OR prom OR proms OR hr pro OR hrpro OR health index* OR health indices OR health profile* OR health status OR ((patient OR self OR child OR parent OR carer OR proxy) AND ((report OR reported OR reporting) OR (rated OR rating OR ratings) OR based OR (assessed OR assessment OR assessments))) OR ((disability OR function OR functional OR functions OR subjective OR utility OR utilities OR wellbeing OR well being) AND (outcome OR outcomes OR index OR indices OR instrument OR instruments OR measure OR measures OR questionnaire OR questionnaires OR profile OR profiles OR scale OR scales OR score OR scores OR status OR survey OR surveys)))) OR AB ((Western Ontario Shoulder Index OR WOSI OR "American Shoulder and Elbow Surgeons score" OR ASES OR Walch-Duplay score OR University of California-Los Angeles score OR UCLA OR Disabilities of "Arm Shoulder and Hand" OR DASH OR Simple Shoulder Test OR SST OR Subjective shoulder value OR SSV OR Single Assessment Numeric Evaluation OR SANE OR Oxford Instability Shoulder Score OR OISS OR Oxford Shoulder Instability Score OR OSIS OR recur* OR patient outcome assessment* OR patient centered outcome* OR patientcentred outcome* OR patient reported outcome* OR prom OR proms OR hr pro OR hrpro OR health index* OR health indices OR health profile* OR health status OR ((patient OR self OR child OR parent OR carer OR proxy) AND ((report OR reported OR reporting) OR (rated OR rating OR ratings) OR based OR (assessed OR assessment OR assessments))) OR ((disability OR function OR functional OR functions OR subjective OR utility OR utilities OR wellbeing OR well being) AND (outcome OR outcomes OR index OR indices OR instrument OR instruments OR measure OR measures OR questionnaire OR questionnaires OR profile OR profiles OR scale OR scales OR score OR scores OR status OR survey OR surveys))))	1,522,149
S15	(MH "Patient-Reported Outcomes+") OR (MH "Outcome Assessment") OR (MH "Recurrence+")	112,187
S16	S14 OR S15	1,573,986
S17	S9 AND S13 AND S16	1,675

SportDiscus (EBSCO)

#	Query	Results
S1	DE "SHOULDER" OR DE "SHOULDER joint"	6,345
S2	TI ((shoulder* or glenohumeral or labr*)) OR AB ((shoulder* or glenohumeral or labr*))	25,853
S3	DE "JOINT dislocations" OR DE "SUBLUXATION"	1,149
S4	DE "JOINT instability"	168
S5	TI ((dislocat* or luxat* or subluxat* or instabilit* or unstable or instable)) OR AB ((dislocat* or luxat* or subluxat* or instabilit* or unstable or instable))	17,351
S6	(S1 OR S2) AND (S3 OR S4 OR S5)	3,388
S7	TI ((random* or sham or placebo* or ((singl* or doubl*) and (blind* or dumm* or mask*)) or ((tripl* or trebl*) and (blind* or dumm* or mask*)) or (control* and (study or studies or trial* or group*)) or (Nonrandom* or "non random*" or "non-random*" or "quasi-random*" or quasirandom*) or allocated or (("open label" or "open-label") and (study or studies or trial*)) or ((equivalence or superiority or "non-inferiority" or noninferiority) and (study or studies or trial*)) or ("pragmatic study" or "pragmatic studies") or ((pragmatic or practical) and trial*) or ((quasiexperimental or "quasi-experimental") and (study or studies or trial*)) or (phase and (III or (shoulder* or glenohumeral or labr*)) and (study or studies or trial*)) or "comparative study" or "cohort study" or "cohort analysis" or "follow up study" or "follow-up study" or "followup study" or "observational study" or longitudinal or retrospective or prospective or questionnaire or questionnaires or survey or randomly or trial)) OR AB ((random* or sham or placebo* or ((singl* or doubl*) and (blind* or dumm* or mask*)) or ((tripl* or trebl*) and (blind* or dumm* or mask*)) or (control* and (study or studies or trial* or group*)) or (Nonrandom* or "non random*" or "non-random*" or "quasi-random*" or quasirandom*) or allocated or (("open label" or "open-label") and (study or studies or trial*)) or ((equivalence or superiority or "non-inferiority" or noninferiority) and (study or studies or trial*)) or ("pragmatic study" or "pragmatic studies") or ((pragmatic or practical) and trial*) or ((quasiexperimental or "quasi-experimental") and (study or studies or trial*)) or (phase and (III or (shoulder* or glenohumeral or labr*)) and (study or studies or trial*)) or "comparative study" or "cohort study" or "cohort analysis" or "follow up study" or "follow-up study" or "followup study" or "observational study" or longitudinal or retrospective or prospective or questionnaire or questionnaires or survey or randomly or trial))	295,867
S8	DE "PLACEBOS"	2,774
S9	S7 OR S8	295,952

(continued)

Continued

#	Query	Results
S10	TI ((Western Ontario Shoulder Index OR WOSI OR "American Shoulder and Elbow Surgeons score" OR ASES OR Walch-Duplay score OR University of California-Los Angeles score OR UCLA OR Disabilities of "Arm Shoulder and Hand" OR DASH OR Simple Shoulder Test OR SST OR Subjective shoulder value OR SSV OR Single Assessment Numeric Evaluation OR SANE OR Oxford Instability Shoulder Score OR OISS OR Oxford Shoulder Instability Score OR OSIS OR recur* OR patient outcome assessment* OR patient centered outcome* OR patientcentred outcome* OR patient reported outcome* OR prom OR proms OR hr pro OR hrpro OR health index* OR health indices OR health profile* OR health status OR ((patient OR self OR child OR parent OR carer OR proxy) AND ((report OR reported OR reporting) OR (rated OR rating OR ratings) OR based OR (assessed OR assessment OR assessments))) OR ((disability OR function OR functional OR functions OR subjective OR utility OR utilities OR wellbeing OR well being) AND (outcome OR outcomes OR index OR indices OR instrument OR instruments OR measure OR measures OR questionnaire OR questionnaires OR profile OR profiles OR scale OR scales OR score OR scores OR status OR survey OR surveys)))) OR AB ((Western Ontario Shoulder Index OR WOSI OR "American Shoulder and Elbow Surgeons score" OR ASES OR Walch-Duplay score OR University of California-Los Angeles score OR UCLA OR Disabilities of "Arm Shoulder and Hand" OR DASH OR Simple Shoulder Test OR SST OR Subjective shoulder value OR SSV OR Single Assessment Numeric Evaluation OR SANE OR Oxford Instability Shoulder Score OR OISS OR Oxford Shoulder Instability Score OR OSIS OR recur* OR patient outcome assessment* OR patient centered outcome* OR patientcentred outcome* OR patient reported outcome* OR prom OR proms OR hr pro OR hrpro OR health index* OR health indices OR health profile* OR health status OR ((patient OR self OR child OR parent OR carer OR proxy) AND ((report OR reported OR reporting) OR (rated OR rating OR ratings) OR based OR (assessed OR assessment OR assessments))) OR ((disability OR function OR functional OR functions OR subjective OR utility OR utilities OR wellbeing OR well being) AND (outcome OR outcomes OR index OR indices OR instrument OR instruments OR measure OR measures OR questionnaire OR questionnaires OR profile OR profiles OR scale OR scales OR score OR scores OR status OR survey OR surveys))))	185,627
S11	S6 AND S9 AND S10	823

Database	Before Deduplication	After Deduplication
PubMed	3,438	3,427
OVID Embase	4,253	1,513
Cochrane central	868	443
Web of Science	3,862	1,293
CINAHL	1,675	184
SportDiscus	823	35
Total	14,919	6,895