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Joint replacement (primary): hip, knee and shoulder title

[N] Evidence review for shoulder replacement – intact rotator cuff

NICE guideline

Intervention evidence review

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1 Hemiarthroplasty versus conventional versus reverse total shoulder arthroplasty

1.1 Review question: In adults having primary elective shoulder replacement for osteoarthritis with an intact rotator cuff, what is the clinical and cost effectiveness of humeral hemiarthroplasty versus conventional total shoulder arthroplasty versus reverse total shoulder arthroplasty?

1.2 Introduction

The number of people having shoulder replacement surgery is increasing year on year with 6,526 detailed in the national joint registry in 2017.[30] Most of these are elective procedures. There have been recent changes and variations in practice about which type of shoulder replacement might offer the best outcomes for different patient groups. For people with osteoarthritis with intact rotator cuffs, current practice now seems to be favour conventional total shoulder replacement (TSA), although previously humeral hemiarthoplasty was a common procedure. In addition many more reverse total joint replacements (RSAs) are being undertaken in this population though RSAs are not strictly indicated for people with intact rotator cuffs. This review aims to assess the clinical and cost effectiveness of all 3 types of surgery in a population of people with osteoarthritis and intact rotator cuffs.

In 2015 a James Lind Alliance Priority Setting Partnership brought together people who have had a shoulder replacement, carers and clinicians to identify important research priorities where uncertainty still existed. This review question is based on one of these important top 10 priorities which highlighted little published evidence for choosing between these procedure types.

1.3 PICO table

For full details, see the review protocol in appendix A.

Table 1: PICO characteristics of review question

Population	Adults with osteoarthritis with an intact (or attenuated) rotator cuff, who are indicated for shoulder arthroplasty
Intervention	• Humeral hemiarthroplasty • Conventional total shoulder arthroplasty • Reverse total shoulder arthroplasty
Comparison	Comparison of interventions
Outcomes	**Critical** • Mortality: life expectancy (time to event) • Mortality: 30 day (dichotomous) • Quality of life at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (continuous) • Patient Reported Outcome Measures (PROMs) at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (continuous) • Revision of joint replacement (time to event) • Reoperation at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2

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	years (dichotomous) **Important** • Component failure (dichotomous) • Dislocations within 1 year, after 1 year (dichotomous) • Return to activity/sports (time to event) • Deep surgical site Infection (dichotomous) • Superficial surgical site infection (dichotomous) • Length of stay (continuous) • Major adverse events (including nerve injury, MI, VTE) Where multiple time points are reported that meet the protocol outcomes, the latest will be used.
Study design	Randomised controlled trials If no well-conducted RCTs are available, then observational studies with multivariate analysis will be investigated.

1.4 Clinical evidence

1.4.1 Included studies

A search was conducted for randomised trials comparing adults with osteoarthritis and an intact rotator cuff, who are can be treated with humeral hemiarthroplasty, conventional total shoulder arthroplasty or reverse total shoulder arthroplasty. Three randomised controlled trials were included in the review;[16, 25, 38] these address the humeral hemiarthroplasty versus conventional total shoulder arthroplasty comparison and are summarised in Table 2 below. Evidence from these studies is summarised in the clinical evidence summary below (Table 3).

See also the study selection flow chart in appendix C, study evidence tables in appendix D, forest plots in appendix E and GRADE tables in appendix H.

1.4.2 Excluded studies

See the excluded studies list in appendix I.

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1.4.3 Summary of clinical studies included in the evidence review

Table 2: Summary of studies included in the evidence review

Study	Intervention and comparison	Population	Outcomes	Comments
Conventional total shoulder arthroplasty versus humeral hemiarthroplasty				
Gartsman 2000[16]	Total shoulder arthroplasty (n=25) Versus Humeral hemiarthroplasty (n=22)	Adults with osteoarthritis and an intact rotator cuff, indicated for shoulder arthroplasty	• Dislocations after 1 year • After at least 2 years: PROMS: University of California, Los Angeles (UCLA) • PROMS: American Shoulder and Elbow Surgeons (ASES) • Infection • Major adverse events: neurological complications • Reoperation	Mean follow up of 35 months used to classify outcome timing. USA
Lo 2005[25]	Total shoulder arthroplasty (n=20) Versus Humeral hemiarthroplasty (n=21)	Adults with osteoarthritis and an intact rotator cuff, indicated for shoulder arthroplasty	**After at least 2 years:** PROMS shoulder index • Western Ontario Osteoarthritis of the Shoulder (WOOS) • UCLA • ASES • Constant and Murley Quality of life (SF-36 scale) Revision of joint replacement Fractures Infection	Canada
Sandow 2013[38]	Total shoulder arthroplasty	Adults with osteoarthritis and	**later than 6 weeks up to 1**	Australia

Study	Intervention and comparison	Population	Outcomes	Comments
	(n=20) Versus Humeral hemiarthroplasty (n=13)	an intact rotator cuff, indicated for shoulder arthroplasty	**year and after at least 2 years:** PROMS shoulder index • UCLA • Constant and Murley **After at least 2 years:** Revision of joint replacement Fractures Infection Major adverse events	Study followed participants for 10 years. Before recruitment of sufficient patients to achieve the number identified in the sample size calculation, post-operative reviews noted that 2 HA patients required early revision and 2 further patients were experiencing a deterioration of their pain levels. The institutional review board independently assessed the outcomes to that stage and recommended that recruitment of patients be suspended until all of those patients within the study had reached the 2 year mark post-operatively, at which time the results were again analysed. Because a significant difference was identified at that review, the study was terminated. The study has been downgraded due to this.

1 See appendix D for full evidence tables.

1.4.4 2 Quality assessment of clinical studies included in the evidence review

3 **Table 3: Clinical evidence summary: Conventional total shoulder arthroplasty versus humeral hemiarthroplasty**

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Total shoulder arthroplasty versus hemiarthroplasty (95% CI)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Total shoulder arthroplasty versus hemiarthroplasty (95% CI)
Mortality	Not reported				
Quality of life after at least 2 SF-36 - mental scale. Scale from 0 to 100	41 (1 study) 2 years	LOW[1,2] due to risk of bias, imprecision		The mean quality of life in the control groups was 57.4	The mean quality of life in the intervention groups was 1 higher (5.14 lower to 7.14 higher)
Quality of life after at least 2 years SF-36 - physical scale. Scale from 0 to 100	41 (1 study) 2 years	VERY LOW[1,2] due to risk of bias, imprecision		The mean quality of life in the control groups was 42.9	The mean quality of life in the intervention groups was 0.8 lower (8.23 lower to 6.63 higher)
ASES shoulder index after at least 2 years ASES. Scale from 0 to 100	88 (2 studies) 24-35 months	LOW[1,2] due to risk of bias, imprecision		The mean ASES shoulder index in the control groups was 74.15	The mean ASES shoulder index in the intervention groups was 10.05 higher (1.13 to 18.97 higher)
UCLA shoulder score after at least 2 years UCLA. Scale from 0 to 35	88 (2 studies) 24-35 months	LOW[1,2] due to risk of bias, imprecision		The mean UCLA shoulder score in the control groups was 23.7	The mean UCLA shoulder score in the intervention groups was 3.23 higher (1.18 to 5.28 higher)
WOOS index after at least 2 years WOOS. Scale from 0 to 100	41 (1 study) 2 years	LOW[1,2] due to risk of bias, imprecision		The mean WOOS index in the control groups was 81.5	The mean WOOS index in the intervention groups was 9.1 higher (2.72 lower to 20.92 higher)
Constant and Murley shoulder score after at least 2 years. Scale from 0 to 100	41 (1 study) 2 years	LOW[1,2] due to risk of bias, imprecision		The mean Constant and Murley index in the control groups was 67.1	The mean Constant and Murley index in the intervention groups was 3.70 higher (7.57 lower to 14.97 higher)
Reoperation of joint replacement - (within 4 years)	47 (1 study) 4 years	LOW[2] due to risk of bias, imprecision	RR 0.13 (0.01 to 2.32)	136 per 1,000	118 fewer per 1,000 (from 135 fewer to 180 more)

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Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Total shoulder arthroplasty versus hemiarthroplasty (95% CI)
Revision of joint replacement - (within 19 months)	41 (1 study) 19 months	LOW[2] due to imprecision	Peto OR 0.14 (0.01 to 2.24)	95 per 1,000	100 fewer per 1000 (from 240 fewer to 50 more)[4]
Revision of joint replacement - (within 7 years)	33 (1 study) 7 years	VERY LOW[1,2] due to risk of bias, imprecision	RR 0.32 (0.07 to 1.53)	308 per 1,000	209 fewer per 1,000 (from 286 fewer to 163 more)
Fracture	74 (2 studies) 2-10 years	LOW[1,2] due to risk of bias, inconsistency	RD 0.00 (-0.12 to 0.11)	60 per 1,000	0 fewer per 1,000 (from 120 fewer to 110 more)
Dislocations	47 (1 study) 4 years	HIGH	RD 0.00 (-0.08 to 0.08)		0 fewer per 1,000 (from 80 fewer to 80 more)
Major adverse events (neurological injuries)	80 (2 studies) 2-10 years	HIGH	RD 0.00 (-0.07 to 0.07)		0 fewer per 1,000 (from 70 fewer to 70 more)

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Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Total shoulder arthroplasty versus hemiarthroplasty (95% CI)
Infection (not specified as deep or superficial)	121 (3 studies) 2-10 years	LOW[1,3] due to risk of bias, inconsistency	RD 0.02 (-0.05 to 0.08)		20 fewer per 1000 (from 50 fewer to 80 more)

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
[2] Downgraded by 1 increment if the confidence interval crossed 1 MID or by 2 increments if the confidence interval crossed both MIDs.
[3] Downgraded by 1 or 2 increments because the point estimate and or the confidence intervals varied widely across studies, unexplained by subgroup analysis
[4] Absolute effect manually calculated due to zero event in one arm.

1 See appendix F for full GRADE tables.

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1.5 Economic evidence

1.5.1 Included studies

No relevant health economic studies were identified.

1.5.2 Excluded studies

No health economic studies that were relevant to this question were excluded due to assessment of limited applicability or methodological limitations.

See also the health economic study selection flow chart in appendix G.

1.5.3 Summary of studies included in the economic evidence review

None

1.5.4 Unit costs

Relevant unit costs are provided below to aid consideration of cost effectiveness. All three procedures map the same healthcare resource group (HRG HB61) suggesting similar resource use. However, there may be some difference in implant cost as illustrated in Table 4.

Table 4: Unit costs for different shoulder implants

Type of shoulder procedure	Implant cost (£)
Reverse total shoulder arthroplasty	£2,996
Conventional total shoulder arthroplasty	£2,307
Hemiarthroplasty	£1,013

Source: Implant costs are taken from a private provider supplied by a committee member. The magnitude of difference may differ for other providers.

1.6 Evidence statements

1.6.1 Clinical evidence statements

Evidence from 3 studies comparing conventional total shoulder arthroplasty to humeral hemiarthroplasty in adults with osteoarthritis with an intact (or attenuated) rotator cuff who are indicated for shoulder joint replacement. Evidence from studies showed no clinically important difference for 2 quality of life outcomes, 4 PROMs outcomes and 3 adverse event outcomes. The quality ranged from high to very low with most outcomes sitting at the lower end of that range (n=41 to88). Evidence indicated a clinically important benefit for total shoulder arthroplasty in reoperation, 2 PROMs outcomes and 2 revision outcomes (low to very low quality, n=10 to88). Evidence showed a clinically important benefit for hemiarthroplasty in infection (low quality, n=121). No evidence was identified for mortality.

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1.6.2 Health economic evidence statements

No relevant economic evaluations were identified.

1.7 The committee's discussion of the evidence

1.7.1 Interpreting the evidence

1.7.1.1 The outcomes that matter most

This review sought to assess whether the most effective form of shoulder replacement is conventional total arthroplasty, reverse total arthroplasty or hemiarthroplasty in people with osteoarthritis and no rotator cuff pathology. The critical outcomes were mortality, quality of life, patient reported outcomes (PROMs), revision of joint replacement and reoperation.

The important outcomes were component failure, dislocations, return to activity or sports, deep surgical site infection, superficial surgical site infection, length of stay and major adverse events.

PROMs and quality of life are critical outcome measurements, as they are a true representation of a person's subjective experience of joint replacement, which differentiates them from harder objective outcomes and end points such as revision surgery. It was discussed how it is easier to revise a hemiarthroplasty than a conventional total shoulder arthroplasty (TSA) or reverse shoulder arthroplasty (RSA). Therefore, not all people in need of a TSA revised have the surgery because it is complex with more associated risks. Thus, people may decide to live with discomfort and a failing implant. The outcome of such people would not be identified by revision surgery end points but would be highlighted through PROMs. Revision is a critical outcome as it is a significant operation; the lengthier the period of time before one is in need of a revision, the better the primary replacement has performed. Return to activity or a sport is important, as people in need of shoulder replacements surgery tend to be younger and more physically active than those receiving hip or knee replacements. Length of stay is important in terms of economics and people tend to prefer leaving hospital sooner.

1.7.1.2 The quality of the evidence

3 RCTs were found for the humeral hemiarthroplasty versus conventional total shoulder arthroplasty comparison and were included in the evidence review. No studies were included comparing humeral hemiarthroplasty to reverse total shoulder arthroplasty or comparing conventional total shoulder arthroplasty to reverse total shoulder arthroplasty. The quality of the outcomes in the review ranged from high to very low, commonly due to a risk of bias from a lack of blinding and/or allocation concealment, imprecision or inconsistency. The majority of the evidence was rated at low quality. Two outcomes were downgraded for inconsistency due to 1 or more studies reporting 0 events.

It is important to note that 1 of the included studies was downgraded for risk of bias due to early termination of the study after suspension of recruitment due to adverse effects reported in the humeral hemiarthroplasty arm.

1.7.1.3 Benefits and harms

No evidence was found for 2 of the 3 possible comparisons; those comparing either humeral hemiarthroplasty or conventional TSA to RSA.

RSA is not a strictly indicated form of joint replacement for this population but has emerged in practice over recent years. RSAs were designed for people with cuff tear arthropathy; a condition with a large rotator cuff tear, superior migration of the humeral head and arthritis. This is because the procedure does not require a functioning rotator cuff. This population, by definition, does have an intact rotator cuff but there are cases where the surgeon believes the rotator cuff might fail during the lifetime of the joint replacement. Thus an RSA is utilised as the initial joint replacement to remove the possibility of rotator cuff failure followed by necessary revision surgery. A committee member noted that conventional TSA would potentially provide better results and fewer adverse events, and if the cuff could be guaranteed to remain intact it would be the preferred option. One advantage of conventional TSA over RSA is the rotation benefit provided. This can have an impact on people's activities of daily living.

At the moment there is variation in the utilisation of RSAs in this population. There are surgeons who undertake an RSA even if there are no obvious signs the rotator cuff will fail because at present it is not possible to accurately predict people's risk of rotator cuff failure.

The committee did not make a recommendation for or against RSA because there was no published evidence that met our inclusion criteria in this population and the committee did not feel a consensus recommendation was appropriate. In light of this uncertainty the committee agreed that there is a need for investigations of this intervention in this population and made a research recommendation to inform future decision-making.

The comparison for which evidence was found was the conventional TSA versus humeral hemiarthroplasty comparison. 3 randomised controlled trials (RCTs) with small sample sizes were found. A clinically important benefit in favour of conventional TSA was found for reoperation, revision of joint replacement, and several PROMs outcomes using the UCLA and Constant Murley score scales. A clinically important benefit for hemiarthroplasty was found in 1 of the infection outcomes. No clinically important difference was found for all other outcomes which including mortality, dislocations, return to activity or sports, deep and superficial site infection, and length of stay.

Overall, the committee noted that all but 1 outcome either favoured conventional TSA or indicated no clinical difference. The outcomes tended to show a benefit in favour of conventional TSA when assessed at longer time points such as 2 years, whereas the outcomes reported at 6 months tended not to show a difference, indicating a divergence in the outcomes between the 2 types of replacement as time with the joint replacement advances. The committee stated that problems might not appear in the early stages of joint replacement and the advantages of conventional TSA may be more apparent after a year with the joint replacement has passed. A lay member highlighted that it takes 6 months to grow into a new joint, so the varying benefits of different surgeries before that may be harder to pinpoint at early stages and later improvements in PROMs scores may be a truer assessment of the surgery. The committee suggested the later time points are more relevant and accurate as they are more indicative of the person's overall joint replacement experience.

The committee agreed that conventional TSA should be offered to this population. It was noted that the people in the RCTs necessarily had adequate glenoid bone stock to allow a TSR to be performed. For people without adequate glenoid bone stock then some other solution, such as RSA or other major surgery, would be required. The committee considered this to be such an important characteristic that it warranted inclusion in the recommendation. The committee noted that modern imaging now offers further information to surgeons when assessing the adequacy of glenoid bone stock. It was not possible to make a specific recommendation for people with inadequate glenoid bone stock as there were no suitable studies included in the review in this population and the committee did not feel a consensus recommendation was appropriate.

The population in the evidence review protocol was people with osteoarthritis with an intact or attenuated rotator cuff. The committee decided that this should be simplified to 'no rotator cuff tear' in the recommendation. A rotator cuff is either attached to the humerus and therefore intact or not attached and therefore torn. The range of this attachment can span a spectrum, and this is something that the surgeon can assess at surgery

The committee commented that the people in the RCTs were mainly over 60 years of age. However younger people are considered for shoulder replacement surgery at the moment and the committee did not feel the people included in the RCTs accurately reflected the modern people undergoing surgery. Due to this lack of evidence people aged under 60, a research recommendation was made to give more definitive guidance for future recommendations for this growing group of younger people having shoulder replacement surgery.

1.7.2 Cost effectiveness and resource use

No published cost effectiveness studies were found. The implant costs for reverse TSA and conventional TSA may be more than for hemiarthroplasty given that their prosthesis consists of 2 parts. However, implant costs are variable depending on the manufacturer. The operation time for conventional TSA takes longer than a hemiarthroplasty, although, in practice, this would not affect resource use as operating theatres are booked for the same amount of time in case a hemiarthroplasty needs to be changed to a TSA during the operation. Other costs and resources for all 3 interventions, such as length of stay, are similar as indicated by the 3 procedures mapping to the same healthcare resource group (HRG HN52) code.

TSA is the most prominent procedure given that roughly only 10% of elective primary shoulder replacement surgeries are hemiarthroplasties according to NJR data. Therefore, offering TSA over hemiarthroplasty for those who have adequate glenoid bone stock will not alter current practice nor have a substantial resource impact. Similarly, doing a reverse TSA will not have a large resource impact, as the overall costs for the procedures are similar. For these reasons, the committee decided they were able to make a recommendation without the need for economic modelling.

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Appendix A: Review protocols

Table 5: Review protocol: Humeral hemiarthroplasty versus conventional total shoulder arthroplasty versus reverse total shoulder arthroplasty

ID	Field	Content
0.	PROSPERO registration number	Not registered
1.	Review title	Humeral hemiarthroplasty versus conventional total shoulder arthroplasty versus reverse total shoulder arthroplasty
2.	Review question	In adults having primary elective shoulder replacement for osteoarthritis with an intact rotator cuff, what is the clinical and cost effectiveness of humeral hemiarthroplasty versus conventional total shoulder arthroplasty versus reverse total shoulder arthroplasty?
3.	Objective	To assess whether the most effective form of shoulder replacement is conventional total arthroplasty or hemiarthroplasty in people with osteoarthritis with an intact (or attenuated) rotator cuff.
4.	Searches	The following databases will be searched: Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Database of Systematic Reviews (CDSR) Embase MEDLINE Searches will be restricted by: English language Human studies Letters and comments are excluded. Other searches: Inclusion lists of relevant systematic reviews will be checked by the reviewer. The searches may be re-run 6 weeks before final committee meeting and further studies retrieved for inclusion if relevant. The full search strategies will be published in the final review.

ISBN

ID	Field	Content
5.	Condition or domain being studied	Shoulder joint replacement
6.	Population	Inclusion: • Adults with osteoarthritis with an intact (or attenuated) rotator cuff, who are indicated for shoulder arthroplasty Exclusion: • Adults having joint replacement as immediate treatment following fracture. • Adults having revision joint replacement. • Adults having joint replacement as treatment for primary or secondary cancer affecting the bones.
7.	Intervention/Exposure/Test	Humeral hemiarthroplasty Conventional total shoulder arthroplasty Reverse total shoulder arthroplasty
8.	Comparator/Reference standard/Confounding factors	Comparison of interventions
9.	Types of study to be included	Randomised controlled trials If no well-conducted RCTs are available, then observational studies with multivariate analysis will be investigated.
10.	Other exclusion criteria	Non-English language studies. Abstracts will be excluded as it is expected there will be sufficient full text published studies available.
11.	Context	N/A
12.	Primary outcomes (critical outcomes)	Mortality: life expectancy (time to event) Mortality: 30 day (dichotomous) Quality of life at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (continuous) Patient Reported Outcome Measures (PROMs) at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (continuous) Revision of joint replacement (time to event) Reoperation at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (dichotomous)

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ID	Field	Content
13.	Secondary outcomes (important outcomes)	Component failure (dichotomous) Dislocation within 1 year, after 1 year (dichotomous) Return to activity/sports (time to event) Deep surgical site Infection (dichotomous) Superficial surgical site infection (dichotomous) Length of stay (continuous) Major adverse events (including nerve injury, MI, VTE) Where multiple time points are reported that meet the protocol outcomes, the latest will be used. To be extracted when not included within a PROM: • Function at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (continuous) • Pain at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (continuous)
14.	Data extraction (selection and coding)	EndNote will be used for reference management, sifting, citations and bibliographies. Titles and/or abstracts of studies retrieved using the search strategy and those from additional sources will be screened for inclusion. The full text of potentially eligible studies will be retrieved and will be assessed for eligibility in line with the criteria outlined above. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. An in-house developed database; EviBase, will be used for data extraction. A standardised form is followed to extract data from studies (see Developing NICE guidelines: the manual section 6.4) and for undertaking assessment of study quality. Summary evidence tables will be produced including information on: study setting; study population and participant demographics and baseline characteristics; details of the intervention and control interventions; study methodology' recruitment and missing data rates; outcomes and times of measurement; critical appraisal ratings. A second reviewer will quality assure the extracted data. Discrepancies will be identified and resolved through discussion (with a third reviewer where necessary).
15.	Risk of bias (quality) assessment	Risk of bias will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual. For Intervention reviews the following checklist will be used according to study design being assessed:

ISBN

ID	Field	Content
		Systematic reviews: Risk of Bias in Systematic Reviews (ROBIS) Randomised Controlled Trial: Cochrane RoB (2.0) Disagreements between the review authors over the risk of bias in particular studies will be resolved by discussion, with involvement of a third review author where necessary.
16.	Strategy for data synthesis	Where possible, data will be meta-analysed. Pairwise meta-analyses will be performed using Cochrane Review Manager (RevMan5) to combine the data given in all studies for each of the outcomes stated above. A fixed effect meta-analysis, with weighted mean differences for continuous outcomes and risk ratios for binary outcomes will be used, and 95% confidence intervals will be calculated for each outcome. Heterogeneity between the studies in effect measures will be assessed using the I^2 statistic and visually inspected. We will consider an I^2 value greater than 50% indicative of substantial heterogeneity. Sensitivity analyses will be conducted based on pre-specified subgroups using stratified meta-analysis to explore the heterogeneity in effect estimates. If this does not explain the heterogeneity, the results will be presented using random-effects. GRADE pro will be used to assess the quality of each outcome, taking into account individual study quality and the meta-analysis results. The 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) will be appraised for each outcome. If the population included in an individual study includes children aged under 12, it will be included if the majority of the population is aged over 12, and downgraded for indirectness if the overlap into those aged less than 12 is greater than 20%. Publication bias is tested for when there are more than 5 studies for an outcome. Other bias will only be taken into consideration in the quality assessment if it is apparent. Where meta-analysis is not possible, data will be presented and quality assessed individually per outcome. If sufficient data is available to make a network of treatments, WinBUGS will be used for network meta-analysis.
17.	Analysis of sub-groups	Age: working age non-working age Humeral component:

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ID	Field	Content			
		stemmed versus stemless Resurfacing in hemiarthroplasty: resurfaced versus not resurfaced Surgical fixation: cemented versus uncemented			
18.	Type and method of review	☒	Intervention		
		☐	Diagnostic		
		☐	Prognostic		
		☐	Qualitative		
		☐	Epidemiologic		
		☐	Service Delivery		
		☐	Other (please specify)		
19.	Language	English			
20.	Country	England			
21.	Anticipated or actual start date	03/10/18			
22.	Anticipated completion date	20/03/20			
23.	Stage of review at time of this submission	Review stage		Started	Completed
		Preliminary searches		☐	☑
		Piloting of the study selection process		☐	☑
		Formal screening of search results against eligibility criteria		☐	☑
		Data extraction		☐	☑
		Risk of bias (quality) assessment		☐	☑
		Data analysis		☐	☑

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ID	Field	Content
24.	Named contact	5a. Named contact National Guideline Centre 5b Named contact e-mail TBC 5e Organisational affiliation of the review National Institute for Health and Care Excellence (NICE) and the National Guideline Centre
25.	Review team members	From the National Guideline Centre: Mr Carlos Sharpin [Guideline lead] Mr Alex Allen [Senior Systematic Reviewer] Ms Rafina Yarde [Systematic reviewer] Mr Robert King [Health economist] Ms Agnès Cuyàs [Information specialist] Ms Eleanor Priestnall [Project Manager]
26.	Funding sources/sponsor	This systematic review is being completed by the National Guideline Centre which receives funding from NICE.
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: [NICE guideline webpage].
29.	Other registration details	
30.	Reference/URL for published protocol	

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ID	Field	Content	
31.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: notifying registered stakeholders of publication publicising the guideline through NICE's newsletter and alerts issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.	
32.	Keywords	Shoulder, joint replacement, humeral hemiarthroplasty, conventional total shoulder arthroplasty, reverse total shoulder arthroplasty	
33.	Details of existing review of same topic by same authors	N/A	
34.	Current review status	☐	Ongoing
		☒	Completed but not published
		☐	Completed and published
		☐	Completed, published and being updated
		☐	Discontinued
35..	Additional information	N/A	
36.	Details of final publication	www.nice.org.uk	

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1 **Table 6: Health economic review protocol**

Review question	All questions – health economic evidence
Objectives	To identify health economic studies relevant to any of the review questions.
Search criteria	• Populations, interventions and comparators must be as specified in the clinical review protocol above. • Studies must be of a relevant health economic study design (cost–utility analysis, cost-effectiveness analysis, cost–benefit analysis, cost–consequences analysis, comparative cost analysis). • Studies must not be a letter, editorial or commentary, or a review of health economic evaluations. (Recent reviews will be ordered although not reviewed. The bibliographies will be checked for relevant studies, which will then be ordered.) • Unpublished reports will not be considered unless submitted as part of a call for evidence. • Studies must be in English.
Search strategy	A health economic study search will be undertaken using population-specific terms and a health economic study filter – see appendix B below.
Review strategy	Studies not meeting any of the search criteria above will be excluded. Studies published before 2003, abstract-only studies and studies from low or middle-income countries (for example, most non-OECD countries) or the USA will also be excluded. Each remaining study will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist which can be found in appendix H of Developing NICE guidelines: the manual (2014).[29] **Inclusion and exclusion criteria** • If a study is rated as both 'Directly applicable' and with 'Minor limitations', then it will be included in the guideline. A health economic evidence table will be completed and it will be included in the health economic evidence profile. • If a study is rated as either 'Not applicable' or with 'Very serious limitations' then it will usually be excluded from the guideline. If it is excluded then a health economic evidence table will not be completed and it will not be included in the health economic evidence profile. • If a study is rated as 'Partially applicable', with 'Potentially serious limitations' or both then there is discretion over whether it should be included. **Where there is discretion** The health economist will make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the guideline committee if required. The ultimate aim is to include health economic studies that are helpful for decision-making in the context of the guideline and the current NHS setting. If several studies are considered of sufficiently high applicability and methodological quality that they could all be included, then the health economist, in discussion with the committee if required, may decide to include only the most applicable studies and to exclude selectively the remaining studies. All studies excluded based on applicability or methodological limitations will be listed with explanation in the excluded health economic studies appendix below. The health economist will be guided by the following hierarchies. *Setting:* • UK NHS (most applicable). • OECD countries with predominantly public health insurance systems (for example, France, Germany, Sweden). • OECD countries with predominantly private health insurance systems (for example,

	Switzerland). • Studies set in non-OECD countries or in the USA will be excluded before being assessed for applicability and methodological limitations. *Health economic study type:* • Cost–utility analysis (most applicable). • Other type of full economic evaluation (cost–benefit analysis, cost-effectiveness analysis, cost–consequences analysis). • Comparative cost analysis. • Non-comparative cost analyses including cost-of-illness studies will be excluded before being assessed for applicability and methodological limitations. *Year of analysis:* • The more recent the study, the more applicable it will be. • Studies published in 2003 or later but that depend on unit costs and resource data entirely or predominantly before 2003 will be rated as 'Not applicable'. • Studies published before 2003 will be excluded before being assessed for applicability and methodological limitations. *Quality and relevance of effectiveness data used in the health economic analysis:* • The more closely the clinical effectiveness data used in the health economic analysis match with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline.

Appendix B: Literature search strategies

The literature searches for this review are detailed below and complied with the methodology outlined in Developing NICE guidelines: the manual.[29]

For more detailed information, please see the Methodology Review.

B.1 Clinical search literature search strategy

Searches were constructed using a PICO framework where population (P) terms were combined with Intervention (I) and in some cases Comparison (C) terms. Outcomes (O) are rarely used in search strategies for interventions as these concepts may not be well described in title, abstract or indexes and therefore difficult to retrieve. Search filters were applied to the searches where appropriate.

Due to the size of retrieval, only the population was used in this search.

Table 7: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline (OVID)	1946 – 01 May 2019	Exclusions Randomised controlled trials Systematic review studies Observational studies
Embase (OVID)	1974 – 01 May 2019	Exclusions Randomised controlled trials Systematic review studies Observational studies
The Cochrane Library (Wiley)	Cochrane Reviews to 2019 Issue 5 of 12 CENTRAL to 2019 Issue 5 of 12	None

1 Medline (Ovid) search terms

1.	arthroplasty, replacement, shoulder/
2.	shoulder prosthesis/
3.	(shoulder* adj4 (replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast* or reverse)).ti,ab.
4.	or/1-3
5.	letter/
6.	editorial/
7.	news/
8.	exp historical article/
9.	Anecdotes as Topic/
10.	comment/
11.	case report/
12.	(letter or comment*).ti.
13.	or/5-12
14.	randomized controlled trial/ or random*.ti,ab.
15.	13 not 14
16.	animals/ not humans/
17.	exp Animals, Laboratory/
18.	exp Animal Experimentation/
19.	exp Models, Animal/
20.	exp Rodentia/
21.	(rat or rats or mouse or mice).ti.
22.	or/15-21
23.	4 not 22
24.	limit 23 to English language
25.	randomized controlled trial.pt.
26.	controlled clinical trial.pt.
27.	randomi#ed.ti,ab.
28.	placebo.ab.
29.	randomly.ti,ab.
30.	Clinical Trials as topic.sh.
31.	trial.ti.
32.	or/25-31
33.	Meta-Analysis/
34.	exp Meta-Analysis as Topic/
35.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
36.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
37.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
38.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
39.	(search* adj4 literature).ab.
40.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
41.	cochrane.jw.

42.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
43.	or/33-42
44.	Epidemiologic studies/
45.	Observational study/
46.	exp Cohort studies/
47.	(cohort adj (study or studies or analys* or data)).ti,ab.
48.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
49.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
50.	Controlled Before-After Studies/
51.	Historically Controlled Study/
52.	Interrupted Time Series Analysis/
53.	(before adj2 after adj2 (study or studies or data)).ti,ab.
54.	or/45-54
55.	exp case control study/
56.	case control*.ti,ab.
57.	or/56-57
58.	55 or 58
59.	Cross-sectional studies/
60.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
61.	or/60-61
62.	55 or 62
63.	55 or 58 or 62
64.	24 and (32 or 43 or 63)

1 **Embase (Ovid) search terms**

1.	shoulder replacement/
2.	shoulder prosthesis/
3.	(shoulder* adj4 (replac* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast* or reverse)).ti,ab.
4.	or/1-3
5.	letter.pt. or letter/
6.	note.pt.
7.	editorial.pt.
8.	case report/ or case study/
9.	(letter or comment*).ti.
10.	or/5-9
11.	randomized controlled trial/ or random*.ti,ab.
12.	10 not 11
13.	animal/ not human/
14.	nonhuman/
15.	exp Animal Experiment/
16.	exp Experimental Animal/
17.	animal model/
18.	exp Rodent/

19.	(rat or rats or mouse or mice).ti.
20.	or/12-19
21.	4 not 20
22.	limit 21 to English language
23.	random*.ti,ab.
24.	factorial*.ti,ab.
25.	(crossover* or cross over*).ti,ab.
26.	((doubl* or singl*) adj blind*).ti,ab.
27.	(assign* or allocat* or volunteer* or placebo*).ti,ab.
28.	crossover procedure/
29.	single blind procedure/
30.	randomized controlled trial/
31.	double blind procedure/
32.	or/23-31
33.	systematic review/
34.	meta-analysis/
35.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
36.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
37.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
38.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
39.	(search* adj4 literature).ab.
40.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
41.	cochrane.jw.
42.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
43.	or/33-42
44.	Clinical study/
45.	Observational study/
46.	family study/
47.	longitudinal study/
48.	retrospective study/
49.	prospective study/
50.	cohort analysis/
51.	follow-up/
52.	cohort*.ti,ab.
53.	52 and 53
54.	(cohort adj (study or studies or analys* or data)).ti,ab.
55.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
56.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
57.	(before adj2 after adj2 (study or studies or data)).ti,ab.
58.	or/45-51,54-58
59.	exp case control study/
60.	case control*.ti,ab.

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61.	or/60-61
62.	59 or 62
63.	cross-sectional study/
64.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
65.	or/64-65
66.	59 or 66
67.	59 or 62 or 66
68.	22 and (32 or 43 or 67)

Cochrane Library (Wiley) search terms

#1.	MeSH descriptor: [Arthroplasty, Replacement, Shoulder] this term only
#2.	MeSH descriptor: [Shoulder Prosthesis] this term only
#3.	(shoulder* near/4 (replac* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast* or reverse)):ti,ab
#4.	(OR #1-#3)

B.2 Health Economics literature search strategy

Health economic evidence was identified by conducting a broad search relating to the joint replacement population in NHS Economic Evaluation Database (NHS EED – this ceased to be updated after March 2015) and the Health Technology Assessment database (HTA) with no date restrictions. NHS EED and HTA databases are hosted by the Centre for Research and Dissemination (CRD). Additional health economics searches were run in Medline and Embase..

Table 8: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline	2014 – 01 May 2019	Exclusions Health economics studies
Embase	2014 – 01 May 2019	Exclusions Health economics studies
Centre for Research and Dissemination (CRD)	HTA - Inception – 01 May 2019 NHSEED - Inception to March 2015	None

Medline (Ovid) search terms

1.	arthroplasty/ or arthroplasty, replacement/ or arthroplasty, replacement, hip/ or arthroplasty, replacement, knee/ or arthroplasty, replacement, shoulder/ or hemiarthroplasty/
2.	joint prosthesis/ or hip prosthesis/ or knee prosthesis/ or shoulder prosthesis/
3.	((joint* or knee* or shoulder* or hip*) adj5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*)).ti,ab.
4.	or/1-3
5.	letter/
6.	editorial/
7.	news/

8.	exp historical article/
9.	Anecdotes as Topic/
10.	comment/
11.	case report/
12.	(letter or comment*).ti.
13.	or/5-12
14.	randomized controlled trial/ or random*.ti,ab.
15.	13 not 14
16.	animals/ not humans/
17.	exp Animals, Laboratory/
18.	exp Animal Experimentation/
19.	exp Models, Animal/
20.	exp Rodentia/
21.	(rat or rats or mouse or mice).ti.
22.	or/15-21
23.	4 not 22
24.	limit 23 to English language
25.	Economics/
26.	Value of life/
27.	exp "Costs and Cost Analysis"/
28.	exp Economics, Hospital/
29.	exp Economics, Medical/
30.	Economics, Nursing/
31.	Economics, Pharmaceutical/
32.	exp "Fees and Charges"/
33.	exp Budgets/
34.	budget*.ti,ab.
35.	cost*.ti.
36.	(economic* or pharmaco?economic*).ti.
37.	(price* or pricing*).ti,ab.
38.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
39.	(financ* or fee or fees).ti,ab.
40.	(value adj2 (money or monetary)).ti,ab.
41.	or/25-40
42.	24 and 41

1 **Embase (Ovid) search terms**

1.	*arthroplasty/ or *replacement arthroplasty/ or *hip replacement/ or *knee replacement/ or *shoulder replacement/ or *hemiarthroplasty/
2.	*joint prosthesis/ or *hip prosthesis/ or *knee prosthesis/ or *shoulder prosthesis/
3.	((joint* or knee* or shoulder* or hip*) adj5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*)).ti,ab.
4.	or/1-3
5.	letter.pt. or letter/
6.	note.pt.

7.	editorial.pt.
8.	case report/ or case study/
9.	(letter or comment*).ti.
10.	or/5-9
11.	randomized controlled trial/ or random*.ti,ab.
12.	10 not 11
13.	animal/ not human/
14.	nonhuman/
15.	exp Animal Experiment/
16.	exp Experimental Animal/
17.	animal model/
18.	exp Rodent/
19.	(rat or rats or mouse or mice).ti.
20.	or/12-19
21.	4 not 20
22.	limit 21 to English language
23.	health economics/
24.	exp economic evaluation/
25.	exp health care cost/
26.	exp fee/
27.	budget/
28.	funding/
29.	budget*.ti,ab.
30.	cost*.ti.
31.	(economic* or pharmaco?economic*).ti.
32.	(price* or pricing*).ti,ab.
33.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
34.	(financ* or fee or fees).ti,ab.
35.	(value adj2 (money or monetary)).ti,ab.
36.	or/23-35
37.	22 and 36

1 NHS EED and HTA (CRD) search terms

#1.	MeSH DESCRIPTOR arthroplasty
#2.	MeSH DESCRIPTOR arthroplasty, replacement
#3.	MeSH DESCRIPTOR arthroplasty, replacement, hip
#4.	MeSH DESCRIPTOR arthroplasty, replacement, knee
#5.	MeSH DESCRIPTOR arthroplasty, replacement, shoulder
#6.	MeSH DESCRIPTOR hemiarthroplasty
#7.	MeSH DESCRIPTOR joint prosthesis
#8.	MeSH DESCRIPTOR hip prosthesis

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#9.	MeSH DESCRIPTOR knee prosthesis
#10.	MeSH DESCRIPTOR shoulder prosthesis
#11.	(((joint* or knee* or shoulder* or hip*) adj5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*)))
#12.	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11) IN NHSEED
#13.	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11) IN HTA

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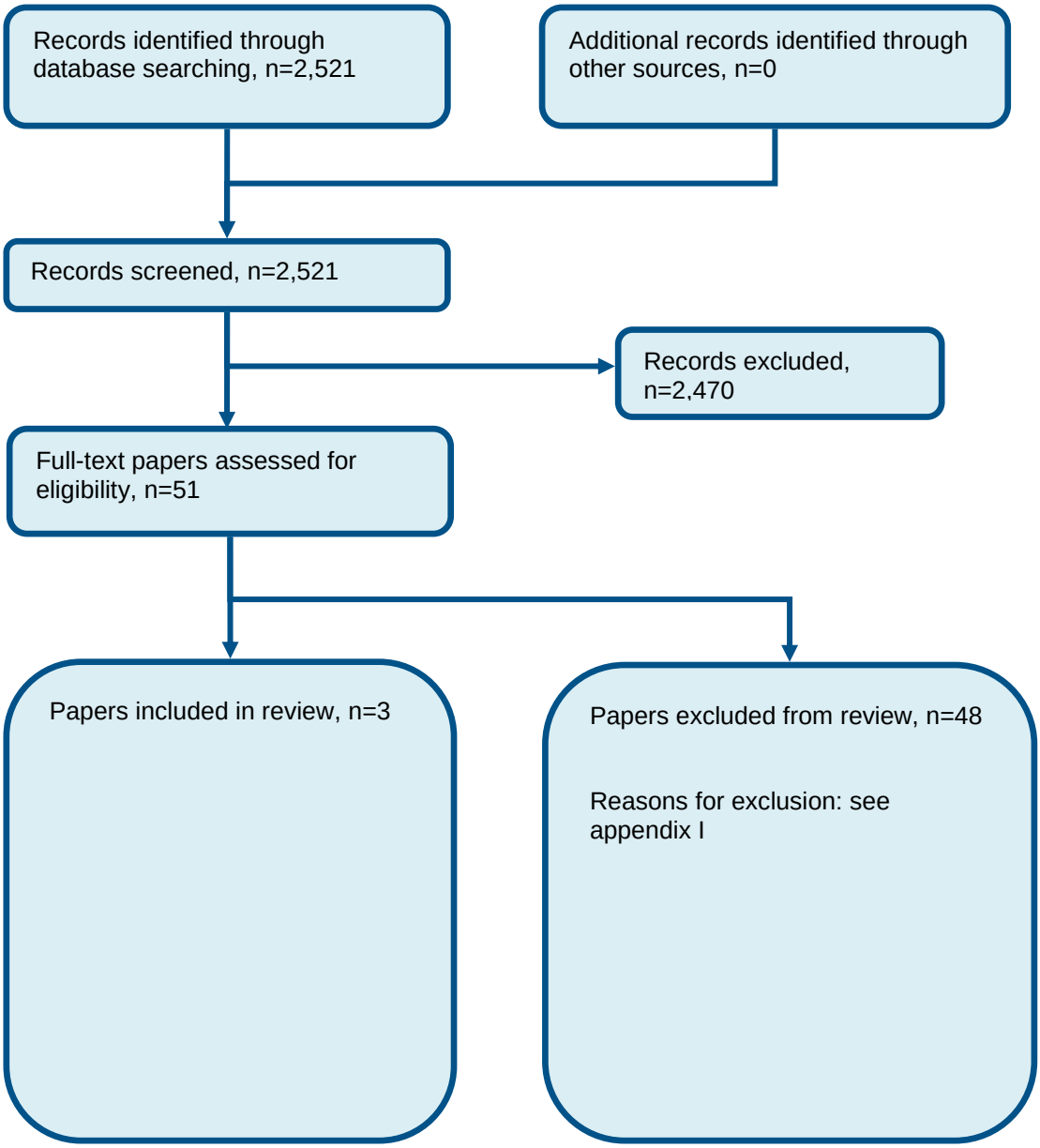
Appendix C: Clinical evidence selection

Figure 1: Flow chart of clinical study selection for the review of shoulder replacement



Appendix D: Clinical evidence tables

Study	Gartsman 2000[16]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=47)
Countries and setting	Conducted in USA
Line of therapy	First line
Duration of study	Follow up (post intervention): ranged from 24 to 72 months, mean 35 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	All patients who were to have a shoulder arthroplasty between December 1992 and December 1996 were evaluated for inclusion in this study. The criteria for inclusion in the study were a diagnosis of osteoarthritis, an intact rotator cuff, and a concentric glenoid. In order to increase the uniformity of the study group, the criteria for inclusion required that, at the time of the operation, the glenoid demonstrate degeneration of the cartilage of the articular surface and a concentric osseous surface with no flattening or bone loss.
Exclusion criteria	A diagnosis other than osteoarthritis was a criterion for exclusion.
Age, sex and family origin	Age - Mean (SD): 64.95 (7.35). Sex (M: F): 19 female, 28 male. Family origin: N/A
Further population details	1. Age: Working age
Indirectness of population	No indirectness
Interventions	(n=22) Intervention 1: Shoulder arthroplasty - Shoulder humeral hemiarthroplasty. Hemiarthroplasty - replacement of the humeral head without resurfacing of the glenoid. Duration 35 months FU. Concurrent medication/care: All patients received the same type of humeral component, and all operations were performed by or under the direct supervision of the same surgeon. All patients were managed with the same postoperative regimen, including administration of antibiotics and physical therapy. The physical therapist instructed the patients in a home exercise program, according to a protocol provided by the surgeon. . Indirectness: No indirectness Further details: 1. Humeral component: Not stated / Unclear 2. Resurfacing in hemiarthroplasty: Not resurfaced 3. Surgical fixation:

	(n=25) Intervention 2: Shoulder arthroplasty - Conventional total shoulder arthroplasty. Total shoulder arthroplasty - replacement of the humeral head with resurfacing of the glenoid with a polyethylene component with cement. Duration 35 months FU. Concurrent medication/care: All patients received the same type of humeral component, and all operations were performed by or under the direct supervision of the same surgeon. All patients were managed with the same postoperative regimen, including administration of antibiotics and physical therapy. The physical therapist instructed the patients in a home exercise program, according to a protocol provided by the surgeon. . Indirectness: No indirectness Further details: 1. Humeral component: Not stated / Unclear 2. Resurfacing in hemiarthroplasty: Resurfaced 3. Surgical fixation: Cemented
Funding	Academic or government funding (The funding source was a research fellowship provided by HCA/Columbia and Texas Orthopaedic Hospital (T.S.R))

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SHOULDER HUMERAL HEMIARTHROPLASTY versus CONVENTIONAL TOTAL SHOULDER ARTHROPLASTY

Protocol outcome 1: Patient Reported Outcome Measures (PROMs) at later than 2 years

- Actual outcome: Total score at 35 months - American shoulder and elbow surgeons shoulder index at 35 months ; Group 1: mean 65.2 (SD 24.9); n=22, Group 2: mean 77.3 (SD 18.2); n=25

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: 22.7 - TSA, 22.6 - HA; Group 1 Number missing: 0; Group 2 Number missing: 0

- Actual outcome: Total score at 35 months - University of California at Los Angeles Shoulder Score at 35 months ; Group 1: mean 23.2 (SD 5.9); n=22, Group 2: mean 27.4 (SD 4.9); n=25

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: 8.1 - TSA, 8.3 - HA; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 2: Reoperation at later than 2 years

- Actual outcome: Resurfacing at 19, 39 and 48 months at 48 months latest; Group 1: 3/22, Group 2: 0/25

Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 3: Dislocation at after 1 year

- Actual outcome: No dislocations at 35 months ; Group 1: 0/22, Group 2: 0/25

Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover

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- Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0 Protocol outcome 4: Superficial surgical site infection at before JR is revised - Actual outcome: No infection at 35 months ; Group 1: 0/22, Group 2: 0/25 Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0 Protocol outcome 5: Major adverse events (including nerve injury, MI, VTE) at before JR is revised - Actual outcome: No neurological complications at 35 months ; Group 1: 0/22, Group 2: 0/25 Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Mortality: life expectancy at time to event; Mortality at within 30 days; Quality of life at 6 weeks or earlier; Quality of life at later than 6 weeks up to 1 year; Quality of life at later than 2 years ; Patient Reported Outcome Measures (PROMs) at 6 weeks or earlier; Patient Reported Outcome Measures (PROMs) at later than 6 weeks up to 1 year; Revision of joint replacement at time to event; Reoperation at 6 weeks or earlier; Reoperation at later than 6 weeks up to 1 year; Component failure at before JR is revised; Dislocation at within 1 year; Return to activity/sports at time to event; Deep surgical site Infection at before JR is revised; Length of stay at in hospital; Function at 6 weeks or earlier; Function at later than 6 weeks up to 1 year; Function at later than 2 years ; Pain at 6 weeks or earlier; Pain at later than 6 weeks up to 1 year; Pain at later than 2 years

ISBN

Study	Lo 2005[25]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=42)
Countries and setting	Conducted in Canada; Setting: A single university centre with 3 orthopaedic surgeons.
Line of therapy	First line
Duration of study	Intervention + follow up: 24 months FU
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	The patients included had a diagnosis of primary osteoarthritis of the shoulder, had a failure of a minimum of 6 months of non-operative treatment (including analgesics, anti-inflammatory medication and physiotherapy), and wished to have surgical intervention. Primary osteoarthritis of the shoulder was defined as shoulder pain; no history of major trauma, infection, osteonecrosis, cuff tear arthropathy, chronic dislocation, or a secondary cause of osteoarthritis; and radiographic evidence of joint space narrowing, osteophyte formation, and/or subchondral sclerosis.
Exclusion criteria	Exclusion criteria included a condition other than shoulder osteoarthritis that would substantially contribute to shoulder dysfunction (e.g., cervical spine disease), a rotator cuff tear (>1cm), inflammatory arthritis, post-capsulorrhaphy osteoarthritis, a major medical illness that would substantially influence quality of life (e.g., unstable angina), an active infection, substantial muscle paralysis, and a lack of fitness for surgery or an unwillingness to be followed for 2 years.
Age, sex and family origin	Age - Mean (SD): 70.35 (8.15). Sex (M:F): 18 male, 23 female. Family origin: N/A
Further population details	1. Age: Above working age
Indirectness of population	No indirectness
Interventions	(n=21) Intervention 1: Shoulder arthroplasty - Shoulder humeral hemiarthroplasty. Hemiarthroplasty - the humerus was prepared, according to the manufacturer's instructions, with progressive intramedullary reaming. The humeral osteotomy was performed with the use of an intramedullary guide at approximately 30 degrees of retroversion. In each patient, the glenoid was exposed and the severity of glenoid arthritis was documented. The version of the glenoid and the amount of posterior erosion were confirmed intraoperatively, were compared with their appearance on preoperative radiographs, and computed tomography scans. No attempt was made to alter the glenoid anatomy in the patients being treated with a hemiarthroplasty. . Duration 24 months. Concurrent medication/care: Radiographic templating was performed preoperatively for all patients to estimate the size of the prosthesis, but the final implant was determined intraoperatively with the use of trial implants. Preoperative prophylactic antibiotics were given to all patients, and all procedures

	were performed with the patient under general anaesthesia. Postoperatively a sling was applied with the arm at the side. Active-assisted range of motion exercises were begun on the first postoperative day in the hospital, with emphasis on forward elevation and external rotation. . Indirectness: No indirectness Further details: 1. Humeral component: Not stated / Unclear 2. Resurfacing in hemiarthroplasty: Not stated / Unclear 3. Surgical fixation: Not stated / Unclear (n=20) Intervention 2: Shoulder arthroplasty - Conventional total shoulder arthroplasty. Total shoulder arthroplasty - eccentric reaming was performed as necessary to allow the implantation of the glenoid component in the centre of the glenoid, parallel to the neck and in the appropriate version. A slot was made in the glenoid to accommodate the glenoid component and to allow for cement interlock. Next, the glenoid was irrigated and was dried with thrombin-soaked gauze and the component was cemented into place with thumb pressurisation. . Duration 24 months. Concurrent medication/care: Radiographic templating was performed preoperatively for all patients to estimate the size of the prosthesis, but the final implant was determined intraoperatively with the use of trial implants. Preoperative prophylactic antibiotics were given to all patients, and all procedures were performed with the patient under general anaesthesia. Postoperatively a sling was applied with the arm at the side. Active-assisted range of motion exercises were begun on the first postoperative day in the hospital, with emphasis on forward elevation and external rotation. Indirectness: No indirectness Further details: 1. Humeral component: Not stated / Unclear 2. Resurfacing in hemiarthroplasty: Not stated / Unclear 3. Surgical fixation: Not applicable
Funding	Other author(s) funded by industry (One or more of the authors received grants or outside funding from 3M Canada.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SHOULDER HUMERAL HEMIARTHROPLASTY versus CONVENTIONAL TOTAL SHOULDER ARTHROPLASTY

Protocol outcome 1: Quality of life at later than 2 years

- Actual outcome: Short form-36 (mental component) at 2 years at 2 years; Group 1: mean 57.4 (SD 10.9); n=21, Group 2: mean 58.4 (SD 9.1); n=20

Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: hemi - 55.5, TSA - 51.4; Group 1 Number missing: 0; Group 2 Number missing: 0

- Actual outcome: Short form-36 (physical component) at 2 years at 2 years; Group 1: mean 42.9 (SD 10.9); n=21, Group 2: mean 42.1 (SD 13.2); n=20

Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: hemi - 29.5, TSA - 31.3; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 2: Patient Reported Outcome Measures (PROMs) at later than 2 years

- Actual outcome: WOOS total quality of life at 2 years (Western Ontario Osteoarthritis of the Shoulder index) at 2 years; Group 1: mean 81.5 (SD 24.1); n=21, Group 2: mean 90.6 (SD 13.2); n=20

Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: hemi - 33.5, TSA - 31.4; Group 1 Number missing: 0; Group 2 Number missing: 0

- Actual outcome: American Shoulder and Elbow Surgeons (ASES) at 2 years at 2 years; Group 1: mean 83.1 (SD 25.6); n=21, Group 2: mean 91.1 (SD 14.3); n=20

Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: hemi - 31.1, TSA - 30.7; Group 1 Number missing: 0; Group 2 Number missing: 0

- Actual outcome: University of California at Los Angeles (UCLA) at 2 years at 2 years; Group 1: mean 24.2 (SD 5); n=21, Group 2: mean 26.7 (SD 3.8); n=20

Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: hemi - 12.6, TSA - 13.2; Group 1 Number missing: 0; Group 2 Number missing: 0

- Actual outcome: Constant score quality of life at 2 years at 2 years; Group 1: mean 67.1 (SD 19.6); n=21, Group 2: mean 70.8 (SD 17.2); n=20

Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: hemi -30.7, TSA - 28.7; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 3: Revision of joint replacement at time to event

- Actual outcome: Revision of joint replacement at 2 years; Group 1: 2/21, Group 2: 0/20; Comments: 1 - 19 months after surgery

1 - 16 months after surgery

Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 4: Component failure at before JR is revised

- Actual outcome: Fracture at 2 years; Group 1: 2/21, Group 2: 2/20

Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 5: Major adverse events (including nerve injury, MI, VTE) at before JR is revised

- Actual outcome: Infection after 2 weeks at 2 years; Group 1: 0/21, Group 2: 1/20

Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low,

Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Mortality: life expectancy at time to event; Mortality at within 30 days; Quality of life at 6 weeks or earlier; Quality of life at later than 6 weeks up to 1 year; Patient Reported Outcome Measures (PROMs) at 6 weeks or earlier; Patient Reported Outcome Measures (PROMs) at later than 6 weeks up to 1 year; Reoperation at 6 weeks or earlier; Reoperation at later than 6 weeks up to 1 year; Reoperation at later than 2 years ; Dislocation at within 1 year; Dislocation at after 1 year; Return to activity/sports at time to event; Deep surgical site Infection at before JR is revised; Superficial surgical site infection at before JR is revised; Length of stay at in hospital; Function at 6 weeks or earlier; Function at later than 6 weeks up to 1 year; Function at later than 2 years ; Pain at 6 weeks or earlier; Pain at later than 6 weeks up to 1 year; Pain at later than 2 years

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Study	Sandow 2013[38]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=33)
Countries and setting	Conducted in Australia; Setting:
Line of therapy	First line
Duration of study	Intervention + follow up: 10 years FU
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Inclusion in the study and randomisation to a study group only occurred after satisfactory exposure and visualisation of the glenoid had been achieved and where there was clinical equipoise regarding the best option based on existing contemporaneous surgical indications.
Exclusion criteria	Patients who had excessive glenoid erosion, a very flat glenoid shape, or major glenoid cysts, all of which are regarded as a contraindication to HA, did not constitute an appropriate comparative group because the performance of a HA in this particular patient would prejudice the results of HA. They were therefore not entered into the study. When there was inadequate surgical exposure, an apparent inflammatory process, significant rotator cuff tear, or proximal humeral or glenoid deformity, an accurate comparison between HA and TSR was not deemed appropriate and such patients were also not entered into the study.
Recruitment/selection of patients	Patients were identified who might be suitable for the study where there was a reasonable expectation that the rotator cuff was intact; there was obvious advanced osteoarthritis of the shoulder, and no evidence of infection, inflammatory disease or previous fracture.
Age, sex and family origin	Age - Median (range): 68 - hemi, 72 - tsr. Sex (M: F): 11 male, 22 female. Family origin: N/A
Further population details	1. Age: Working age
Indirectness of population	No indirectness
Interventions	(n=13) Intervention 1: Shoulder arthroplasty - Shoulder humeral hemiarthroplasty. Hemiarthroplasty - The surgical technique used a standard deltopectoral approach, without osteotomy of the lesser tuberosity, using the Global Shoulder Arthroplasty system. To ensure a similar degree of soft tissue mobilisation, the glenoid was exposed and the glenoid reamer was position over the glenoid as if to commence reaming. All glenoid components, when used, were cemented using polymethyl methacrylate and were of the pegged design. All humeral components were inserted using a press-fit technique. . Duration 2 years. Concurrent medication/care: Postoperative mobilisation for the 2 groups was identical. The study participants therefore consisted of a group of patients with an identical surgeon, approach, soft tissue release, rehabilitation, and,

	apart from the glenoid component implantation or not, the same surgical prosthesis. Further details: 1. Humeral component: 2. Resurfacing in hemiarthroplasty: 3. Surgical fixation: (n=20) Intervention 2: Shoulder arthroplasty - Conventional total shoulder arthroplasty. TSR (total shoulder replacement) - The surgical technique used a standard deltopectoral approach, without osteotomy of the lesser tuberosity, using the Global Shoulder Arthroplasty system. To ensure a similar degree of soft tissue mobilisation, the glenoid was exposed and the glenoid reamer was position over the glenoid as if to commence reaming. All glenoid components, when used, were cemented using polymethyl methacrylate and were of the pegged design. All humeral components were inserted using a press-fit technique. Duration 2 years. Concurrent medication/care: Postoperative mobilisation for the 2 groups was identical. The study participants therefore consisted of a group of patients with an identical surgeon, approach, soft tissue release, rehabilitation, and, apart from the glenoid component implantation or not, the same surgical prosthesis. Further details: 1. Humeral component: 2. Resurfacing in hemiarthroplasty: 3. Surgical fixation:
Funding	Academic or government funding (An educational grant was received from DePuy to initiate the study in 1994. No other funding has been received.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SHOULDER HUMERAL HEMIARTHROPLASTY versus CONVENTIONAL TOTAL SHOULDER ARTHROPLASTY

Protocol outcome 1: Patient Reported Outcome Measures (PROMs) at later than 6 weeks up to 1 year

- Actual outcome: Constant and Murley Shoulder score at 6 months at 6 months; median (range)

hemi - 55.5 (17-86) 10 people with complete data

TSR - 61 (34-84) 15 people with complete data;

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - High; Indirectness of outcome: No indirectness ; Baseline details: hemi - 31, TSR - 25.5; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: University of California, Los Angeles (UCLA) shoulder score at 6 months at 6 months; median (range)

hemi - 24 (21-29) 9 people with complete data

TSR - 28 (8-34) 17 people with complete data;

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - High; Indirectness of outcome: No indirectness ; Baseline details: hemi - 12, TSR - 10; Group 1 Number missing: ; Group 2 Number missing: 0

Protocol outcome 2: Patient Reported Outcome Measures (PROMs) at later than 2 years

- Actual outcome: Constant and Murley Shoulder score at 3 years at 3 years; median (range)

hemi - 54.5 (43-59) 4 people with complete data TSR - 77 (67-95) 6 people with complete data; Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - High; Indirectness of outcome: No indirectness ; Baseline details: hemi - 31, TSR - 25.5; Group 1 Number missing: ; Group 2 Number missing: 0 - Actual outcome: University of California, Los Angeles (UCLA) shoulder score at 3 years at 3 years; median (range) hemi - 18.5 (10-25) 6 people with complete data TSR - 33 (24-34) 11 people with complete data; Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - High; Indirectness of outcome: No indirectness ; Baseline details: hemi - 12, TSR - 10; Group 1 Number missing: ; Group 2 Number missing: 0 Protocol outcome 3: Revision of joint replacement at time to event - Actual outcome: Revision at 10 years at 10 years; Group 1: 4/13, Group 2: 2/20; Comments: hemi - 1 at 2 yrs, 2 at 3 yrs, 1 at 4 yrs TSR - 1 at 5 yrs, 1 at 7 yrs Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - High; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing:	
Protocol outcomes not reported by the study	Mortality at within 30 days; Quality of life at 6 weeks or earlier; Quality of life at later than 6 weeks up to 1 year; Quality of life at later than 2 years ; Patient Reported Outcome Measures (PROMs) at 6 weeks or earlier; Reoperation at 6 weeks or earlier; Reoperation at later than 6 weeks up to 1 year; Reoperation at later than 2 years ; Component failure at before JR is revised; Dislocation at within 1 year; Dislocation at after 1 year; Return to activity/sports at time to event; Deep surgical site Infection at before JR is revised; Superficial surgical site infection at before JR is revised; Length of stay at in hospital; Major adverse events (including nerve injury, MI, VTE) at before JR is revised; Function at 6 weeks or earlier; Function at later than 6 weeks up to 1 year; Function at later than 2 years ; Pain at 6 weeks or earlier; Pain at later than 6 weeks up to 1 year; Pain at later than 2 years

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Appendix E: Forest plots

E.1 Total shoulder arthroplasty versus hemiarthroplasty

Figure 2: Quality of life after at least 2 years , SF-36 mental scale, 0-100

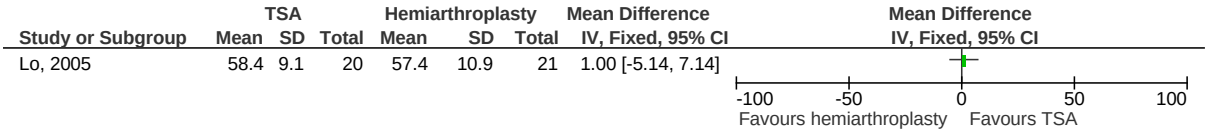


Figure 3: Quality of life after at least 2 years, SF-36 physical scale, 0-100

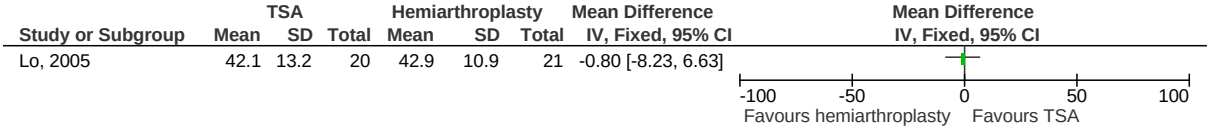


Figure 4: ASES shoulder index after at least 2 years, 0-100

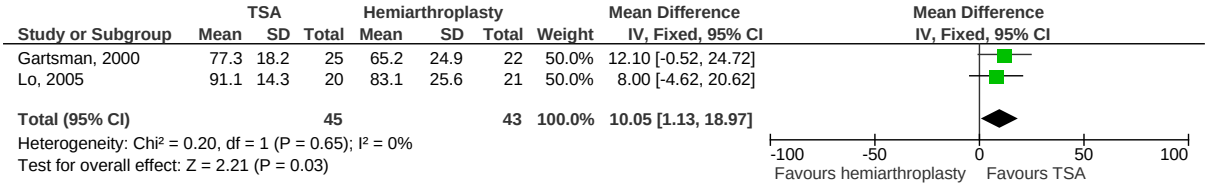


Figure 5: UCLA shoulder score after at least 2 years, 0-35

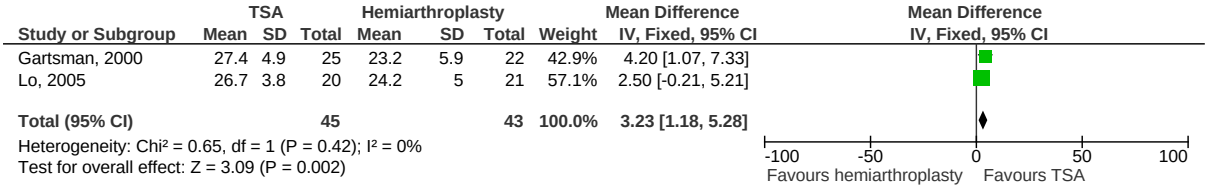


Figure 6: WOOS index, after at least 2 years, 0-100

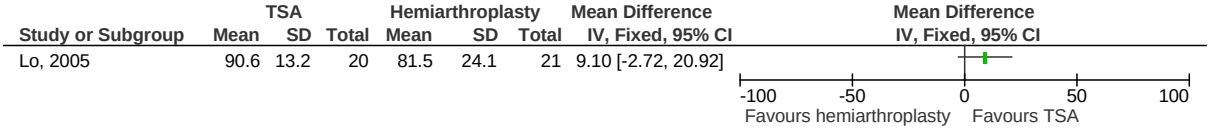
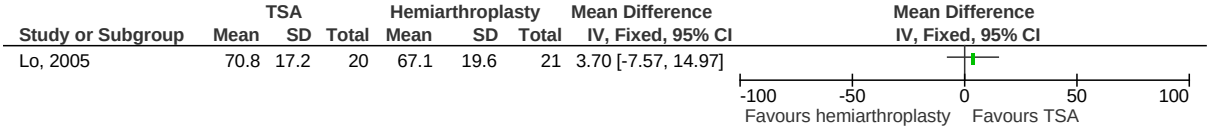
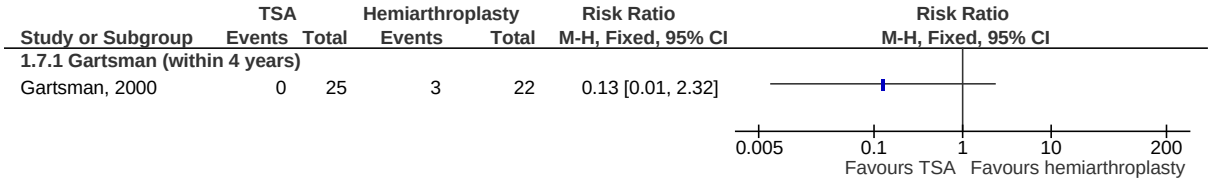


Figure 7: Constant and Murley index after at least 2 years, 0-100



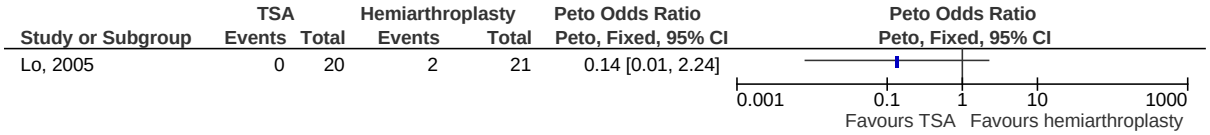
1

Figure 8: Reoperation of joint replacement, within 4 years



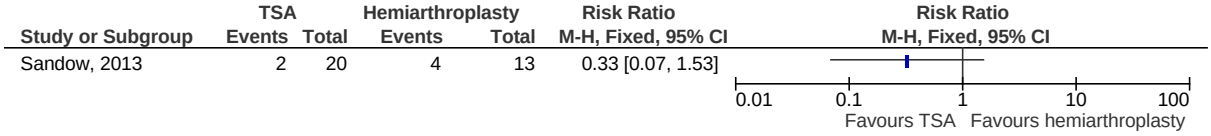
2

Figure 9: Revision of joint replacement within 19 months



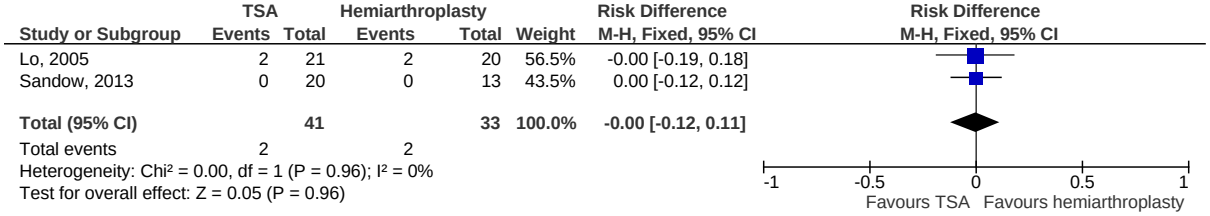
3

Figure 10: Revision of joint replacement after at least 2 years



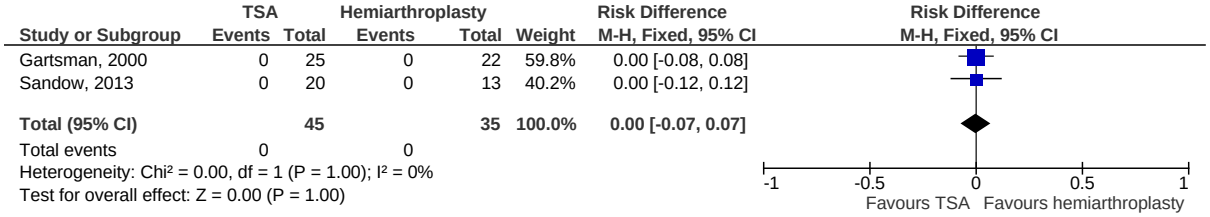
4

Figure 11: Fracture after at least 2 years



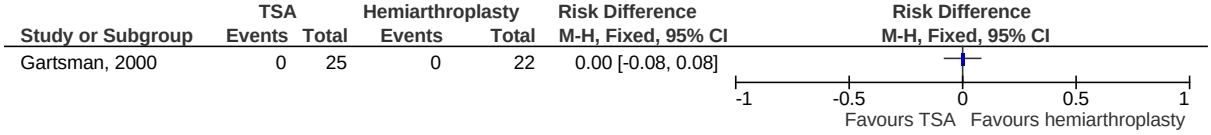
5

Figure 12: Major adverse events (neurological complications)



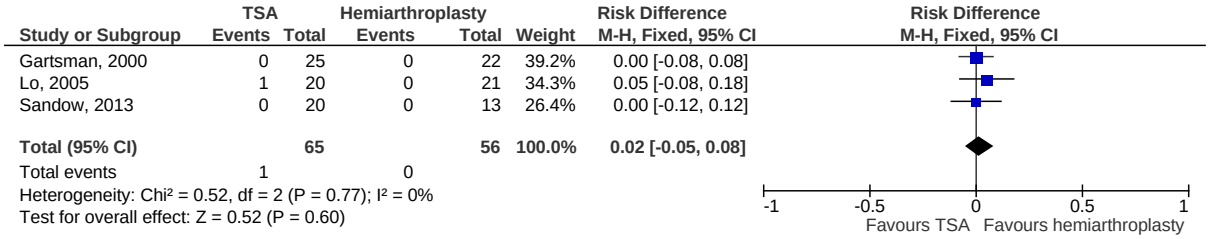
6

Figure 13: Dislocations after at least 2 years



1

Figure 14: Infection after at least 2 years2-10 years



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Appendix F: GRADE tables

Table 9: Clinical evidence profile: Total shoulder arthroplasty versus hemiarthroplasty

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Total shoulder arthroplasty versus hemiarthroplasty	Control	Relative (95% CI)	Absolute		
Quality of life (follow-up 2 years; measured with: SF-36 - mental scale; range of scores: 0-100; Better indicated by higher values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	20	21	-	MD 1 higher (5.14 lower to 7.14 higher)	⊕⊕OO LOW	CRITICAL
Quality of life (follow-up 2 years; measured with: SF-36 - physical scale; range of scores: 0-100; Better indicated by higher values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[2]	none	20	21	-	MD 0.8 lower (8.23 lower to 6.63 higher)	⊕⊕OO LOW	CRITICAL
ASES shoulder index (follow-up 24-35 months; measured with: ASES; range of scores: 0-100; Better indicated by higher values)												
2	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	45	43	-	MD 10.05 higher (1.13 to 18.97 higher)	⊕⊕OO LOW	CRITICAL
UCLA shoulder score (follow-up 24-35 months; measured with: UCLA; range of scores: 0-35; Better indicated by higher values)												
2	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	45	43	-	MD 3.23 higher (1.18 to 5.28 higher)	⊕⊕OO LOW	CRITICAL
WOOS index (follow-up 2 years; measured with: WOOS; range of scores: 0-100; Better indicated by higher values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[2]	none	20	21	-	MD 9.1 higher (2.72 lower to 20.92 higher)	⊕⊕⊕O MODERATE	CRITICAL

Constant and Murley shoulder index (follow-up 2 years; measured with: Constant and Murley scale; range of scores: 0-100; Better indicated by higher values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	20	21	-	MD 3.70 higher (7.57 lower to 14.97 higher)	⊕⊕OO LOW	CRITICAL
Reoperation of joint replacement - Gartsman (within 4 years) (follow-up 4 years)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[2]	none	0/25 (0%)	13.6%	RR 0.13 (0.01 to 2.32)	118 fewer per 1000 (from 135 fewer to 180 more)	⊕OOO LOW	CRITICAL
Revision of joint replacement - (within 19 months) (follow-up 19 months)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[2]	none	0/20 (0%)	2/21 (9.5%)	Peto OR 0.14 (0.01 to 2.24)	100 fewer per 1000 (from 240 fewer to 50 more)	⊕⊕OO LOW	CRITICAL
Revision of joint replacement - (within 7 years) (follow-up 7 years)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	2/20 (10%)	30.8%	RR 0.32 (0.07 to 1.53)	209 fewer per 1000 (from 286 fewer to 163 more)	⊕OOO VERY LOW	CRITICAL
Fracture (follow-up 2 years)												
2	randomised trials	serious[1]	serious[3]	no serious indirectness	no serious imprecision	none	2/41 (4.9%)	6%	RD 0.00 (-0.12 to 0.11)	0 fewer per 1000 (from 120 fewer to 110 more)	⊕⊕OO LOW	IMPORTANT
Dislocations - not reported												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/25 (0%)	0%	RD 0.00 (-0.08 to 0.08)	0 fewer per 1000 (from 80 fewer to 80 more)	⊕⊕⊕⊕ HIGH	IMPORTANT
Major adverse events (including nerve injury, MI, VTE) - not reported												

2	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/45 (0%)	0%	RD 0.00 (-0.07 to 0.07)	0 fewer per 1000 (from 70 fewer to 70 more)	⊕⊕⊕⊕ HIGH	IMPORTANT
Infection (follow up 2-10 years)												
3	randomised trials	serious[1]	no serious inconsistency	serious[3]	no serious imprecision	none	1/65 (1.5%)	0%	RD 0.02 (-0.05 to 0.08)	20 fewer per 1000 (from 50 fewer to 80 more)	⊕⊕OO LOW	IMPORTANT

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
[2] Downgraded by 1 increment if the confidence interval crossed 1 MID or by 2 increments if the confidence interval crossed both MIDs.
[3] Downgraded by 1 or 2 increments because the point estimate and or the confidence intervals varied widely across studies, unexplained by subgroup analysis.

Appendix G: Health economic evidence selection

Figure 15: Flow chart of health economic study selection for the guideline

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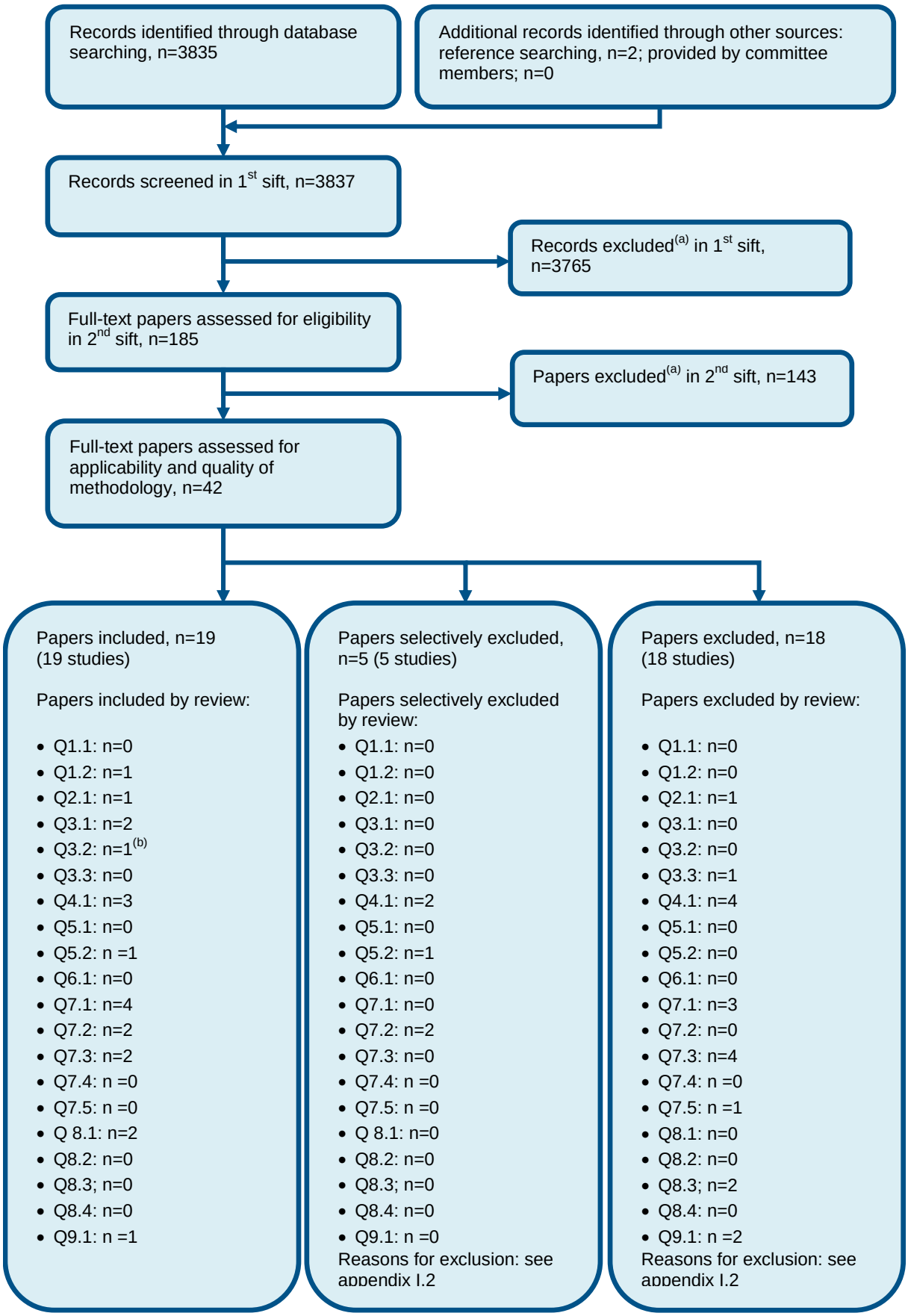

a) Non-relevant population, intervention, comparison, design or setting; non-English language
b) One study was applicable to both Q3.1 and Q3.2

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Appendix H: Health economic evidence tables

None

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1 Appendix I: Excluded studies

I.1 2 Excluded clinical studies

3 **Table 10: Studies excluded from the clinical review**

Study	Exclusion reason
Aibinder 2018[1]	Inclusion criteria did not match those of this evidence review. Included studies were checked for inclusion in this evidence review.
Aim 2018[2]	Inclusion criteria did not match those of this evidence review. Included studies were checked for inclusion in this evidence review.
Alentorn-Geli 2014[3]	Observational study without adjustment for confounding factors
Alentorn-Geli 2018[4]	Incorrect population
Allen 2014[5]	Observational study without adjustment for confounding factors
Anakwenze 2017[6]	Incorrect population
Anakwenze 2017[7]	Incorrect population
Beazley 2018[8]	Incorrect population
Bryant 2005[9]	Systematic review – references checked, each paper included separately
Craig 2017[10]	Protocol
Dillon 2015[11]	Incorrect population
Duan 2013[12]	Systematic review – references checked, each paper included separately
Flurin 2013[13]	Incorrect population
Flurin 2015[14]	Incorrect population
Gallusser 2014[15]	Observational study without adjustment for confounding factors
Jiang 2014[17]	Incorrect population
Johnson 2016[18]	Systematic review – references checked, incorrect comparisons
Khair 2015[19]	Incorrect study design
Kirkley 2001[20]	Incorrect study design. No reported usable outcomes
Kurowicki 2018[21]	Incorrect population
Latif 2012[22]	Observational study without adjustment for confounding factors
Levy 2014[23]	Unable to obtain
Liu 2018[24]	Inclusion criteria did not match those of this evidence review. Included studies were checked for inclusion in this evidence review.
Lowe 2018[26]	Incorrect population
Mansat 2015[27]	Incorrect review population
Merolla 2019[28]	Incorrect population
Navarro 2013[31]	Incorrect population
Nct 2013[32]	Unable to obtain
Parisien 2016[33]	Incorrect population
Ponce 2015[34]	Incorrect population
Radnay 2007[35]	Inclusion criteria did not match those of this evidence review. Included studies were checked for inclusion in this evidence review.

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Study	Exclusion reason
Rasmussen 2014[36]	Incorrect comparison
Saleh 2013[37]	Systematic review – references checked, incorrect population and interventions
Schnetzke 2017[39]	Incorrect population
Simovitch 2015[40]	Incorrect population
Simovitch 2017[41]	Incorrect population
Singh 2011[44]	Incorrect comparison
Singh 2010[42]	Systematic review – references checked, different objective
Singh 2011[43]	Systematic review – references checked, incorrect interventions
Steen 2015[45]	Observational study without adjustment for confounding factors
Streubel 2014[46]	Incorrect population
Triplet 2015[47]	Incorrect population
Triplet 2015[48]	Incorrect population
van den Bekerom 2013[49]	Systematic review – references checked, incorrect study designs
Villacis 2016[50]	Incorrect population
Westermann 2015[51]	Incorrect population
Wong 2018[52]	Incorrect population

I.2 Excluded health economic studies

None.

Appendix J: Research recommendations

J.1 Conventional total shoulder replacement compared with humeral hemiarthroplasty for people aged under 60

Research question: What is the clinical and cost effectiveness of humeral hemiarthroplasty compared with conventional total shoulder replacement for adults aged under 60 having primary elective shoulder replacement for osteoarthritis with no rotator cuff tear?

Why this is important:

The number of people having shoulder replacement surgery is increasing year on year with over 6,500 people having their shoulder replaced in the UK in 2017. Most of these are elective procedures. There have been recent changes and variations in practice around which type of shoulder replacement might offer the best outcomes for different patient groups. For people with osteoarthritis and no rotator cuff tears, surgical practice has involved either conventional total shoulder replacement or humeral hemiarthroplasty, although in recent years conventional total shoulder replacement has been favoured. In this NICE review, evidence was found to favour conventional total shoulder replacement over humeral hemiarthroplasty leading to an 'offer' recommendation, however the evidence was made up of studies that were dominated by the people over 60 years age. There is a gap in the evidence for people who are younger than 60 years, and consequently the committee have made a research recommendation.

PICO question	**Population:** People under the age of 60 with shoulder osteoarthritis and no rotator cuff tear who require a shoulder replacement procedure and have adequate glenoid bone stock to be suitable for a conventional total shoulder replacement **Intervention(s**): Conventional Total Shoulder replacement **Comparison:** Humeral Hemiarthroplasty **Outcome(s):** Quality of life and Patient Reported Outcome Measues (PROMs) 2 year after surgery. Cost outcomes to enable cost-effectiveness analysis. Time to event data for revision surgery after 5 and 10 years.
Study design	Randomised controlled trial nested in NJR for longer term follow up
Other details	This was within one of the priorities in the 2015 James Lind Alliance PSP.

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Appendix K: Research recommendations

K.1 Conventional compared with reverse total shoulder arthroplasty

Research question: What is the clinical and cost effectiveness of conventional total shoulder arthroplasty compared with reverse total shoulder arthroplasty for adults having primary elective shoulder replacement for osteoarthritis with no rotator cuff tear?

Why this is important:

The number of people having shoulder replacement surgery is increasing year on year with over 6,500 people having their shoulder replaced in the UK in 2017. Most of these are elective procedures. There have been recent changes and variations in practice around which type of shoulder replacement might offer the best outcomes for different patient groups.

For people with osteoarthritis, surgical practice has always favoured either conventional total shoulder replacement or humeral hemiarthroplasty. National Joint Registry (NJR) data now indicates that a rapidly increasing number of people are being treated with a different type of replacement called a reverse total shoulder replacement. This type of replacement was not originally designed to be used in people with osteoarthritis and intact rotator cuff tendons (no tears), however the year on year NJR figures confirm an annual increase in its use for this indication. This NICE review was unable to find any evidence to justify anything other than a research recommendation. In view of the increasing numbers being performed, this was considered a high priority research recommendation

Criteria for selecting high-priority research recommendations:

PICO question	**Population:** People with osteoarthritis and no rotator cuff tear who are offered shoulder replacement for pain relief. **Intervention(s**): Reverse Total Shoulder Replacement **Comparison:** Conventional Total Shoulder Replacement **Outcome(s):** Quality of life and Patient Reported Outcome Measues (PROMs) 2 year after surgery. Cost outcomes to enable cost-effectiveness analysis. Time to event data for clinical (PROM) and cost outcomes. revision surgery after 5 and 10 years.
Importance to patients or the population	People want a shoulder replacement that will provide the best clinical outcomes with minimal risk of further surgery. This is clear from the 2015 James Lind Alliance PSP for Surgery for Common Shoulder Problems.
Relevance to NICE guidance	It will allow an update of recommendations on reverse total shoulder replacements in this population
Relevance to the NHS	While the initial costs of both these procedures in the NHS are effectively the same, it is unknown what the consequences are in patient outcome, the longevity of these implants and the potential need for revision surgery.
National priorities	This question is relevant to the 2015 James Lind Alliance PSP for Surgery for Common Shoulder Conditions and is part of one of the top 10 research priorities for patients, carers and clinicians.
Current evidence base	This guideline did not identify any acceptable evidence to support or restrict the use of Reverse Total Shoulder Replacement in patients with osteoarthritis and no rotator cuff tears
Equality	All patient groups suffer with pain and disability from shoulder osteoarthritis. There is no evidence that any UK ethnic groups suffer more

	or less with this condition.
Study design	RCT nested in the National Joint Registry
Feasibility	The two year outcomes would be similar to other 5 year funded NIHR HTA trials, but we recommend that this one also be nested in a national registry as a key component of any successful application to ensure monitoring for longer term revision outcomes that would keep the funding cost down if this trial was funded.
Other comments	
Importance	• High: the research is essential to inform future updates of key recommendations in the guideline.

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