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Shoulder replacement surgery for osteoarthritis and rotator cuff tear arthropathy (Protocol)

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Shoulder replacement surgery for osteoarthritis and rotator cuff tear arthropathy

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To determine the benefits and harms of shoulder arthroplasty in adults with osteoarthritis (OA) of the shoulder, including rotator cuff tear arthropathy (RCTA).

BACKGROUND

Description of the condition

Shoulder osteoarthritis (OA) typically results in narrowing of the glenohumeral (shoulder) joint due to degeneration of the articular cartilage and subchondral bone. The rotator cuff is an important group of four small muscles and associated tendons around the shoulder which are vital for shoulder stability, shoulder rotation, initiation of movement and fine control. People with advanced damage to the rotator cuff tendons around the shoulder commonly develop a specific pattern of arthritis, termed rotator cuff tear arthropathy (RCTA) (Neer 1983; Walch 2005). Shoulder OA and RCTA present primarily with shoulder pain, stiffness, limitation of shoulder function and disability. These symptoms are common, affecting 5% to 21% of adults in the USA and Western countries (Bergnudd 1988; Chakravarty 1990; Chard 1991;

Breivik 2006; National Center for Health Statistics 2011). Shoulder OA is the underlying cause of shoulder pain in 2% to 5% of this group (Meislin 2005), although few truly population-based studies have been done. Shoulder pain is associated with shoulder-related disability in more than half of the people reporting this pain (Chard 1991; Croft 1996; Pope 1997), and causes increased use of healthcare resources (Wofford 1997). Thus, shoulder OA leads to significant morbidity, especially in the ageing population.

Description of the intervention

Current non-surgical treatment options for chronic shoulder pain associated with shoulder OA include oral analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), intra-articular injections (corticosteroids and hyaluronic acid), physical therapy and acupuncture (Green 2005). NSAIDs can help to alleviate the pain, but may cause systemic side-effects, including renal insuf-

iciency and gastrointestinal problems, especially in the elderly (ACR 2000; Shamoony 2000). Intra-articular corticosteroid injections, electrotherapies (including transcutaneous electrical nerve stimulation), exercise and physiotherapy may provide benefits as they do for other shoulder conditions (Buchbinder 2003; van der Windt 2003; Page 2016a; Page 2016b), but their benefits in shoulder OA have not been proven. Intra-articular hyaluronic acid injections have been recently investigated for treatment of persistent shoulder pain, including - but not limited to - people with shoulder OA (Blaine 2008). If non-operative treatments fail, and there is disabling pain and loss of function, then surgery is usually undertaken.

Arthroplasty surgery is joint replacement surgery, and is now the main surgical treatment for shoulder OA. It involves replacement of either the humeral head (hemiarthroplasty (Smith 1998)), or the humeral head and the glenoid (total shoulder arthroplasty (Fenlin 1998)) with implants, or replacement of the humeral head and the glenoid with components in a reversed configuration, that is, insertion of a metal ball where the native socket was, and a plastic cup on a metal stem where the native head was (reverse total shoulder arthroplasty (RTSA) (Grammont 1993)). These procedures are now performed more often, in younger people and for earlier degrees of OA.

The surgical arthroplasty treatment options for shoulder OA and RCTA are the focus of this review and will include all types of hemiarthroplasty, total shoulder replacement and RTSA.

How the intervention might work

Arthroplasty surgery involves the removal of damaged bone and cartilage, with release of soft tissues that are causing contractures, where necessary. These damaged tissues and the inflammation associated with them contribute to the painful symptoms of arthritis. The bone and cartilage that has been removed is replaced with new, smooth, prosthetic (man-made) materials which try to recreate the anatomy and function of the shoulder joint. The new joint is designed to glide smoothly and restore the centre of rotation of the shoulder joint. The result should be a joint with improved mechanical properties, allowing the muscles to work more easily to move the arm.

The specific reversed geometry design of the RTSA is intended to provide the maximum mechanical advantage to the deltoid muscle to move the shoulder and arm in people who do not have intact or functioning rotator cuff muscles.

Why it is important to do this review

Shoulder pain due to OA is a painful, disabling and common condition. Surgical treatment of shoulder OA with arthroplasty has been reported to be associated with a significant improvement in pain, function, and quality of life (Fehring 2002). There has

been a rapid expansion in both the number of shoulder replacements available and the number of procedures performed annually for shoulder OA (AOA NJR 2016). Therefore, a new up to date synthesis of the available evidence is needed to assess the effectiveness and safety of different arthroplasty approaches when compared to each other, to placebo, or to other conservative options. A National Institute of Health Research and national surgical society funded priority setting partnership has identified the optimal type of shoulder replacement for OA as an ongoing research uncertainty (JLA 2015), and it appears within its top 10 research priorities.

OBJECTIVES

To determine the benefits and harms of shoulder arthroplasty in adults with osteoarthritis (OA) of the shoulder, including rotator cuff tear arthropathy (RCTA).

METHODS

Criteria for considering studies for this review

Types of studies

We will consider all randomised controlled trials (RCTs) for inclusion. Non-randomised and quasi-randomised studies will be excluded to minimise the risk of patient selection bias. There will be no language restrictions on included studies and we will translate non-English articles.

Types of participants

We will include studies of adults (aged 18 years and over) with arthritis of the shoulder joint, confirmed by radiographic examination. We will include participants with primary osteoarthritis and osteoarthritis secondary to rotator cuff tear arthropathy (RCTA). We will exclude studies of adults undergoing surgery for inflammatory arthritis such as rheumatoid arthritis, benign or malignant tumours, adhesive capsulitis, shoulder instability or fractures.

Types of interventions

We will include studies that compare any type of shoulder arthroplasty (replacement) surgery to any other treatment modality. We will specifically include studies that compare shoulder arthroplasty to placebo (i.e. sham surgery), other surgical modalities (e.g. arthroscopic debridement), non-surgical modalities (e.g. intra-articular corticosteroid injections, physiotherapy, acupuncture, etc.)

or no treatment. In addition, we will include studies that compare one type of shoulder arthroplasty to another type of shoulder arthroplasty (e.g. conventional total shoulder arthroplasty (TSA) versus reverse total shoulder arthroplasty (RTSA)) or one type of arthroplasty surgical technique to another (e.g. cemented TSA versus uncemented TSA).

Types of outcome measures

Based on the preliminary core domain set described by the OMERACT (Outcome Measures in Rheumatology) Special Interest Group (Buchbinder 2017), we will measure the following major outcomes.

Major outcomes

1. Pain measured using a visual analogue scale (VAS), numeric rating scale (NRS) or semi-quantitative descriptive scales (e.g. short-form McGill scale (Melzack 1987), or other instruments
2. Disability/function measured using shoulder-specific instruments and analysed according to the following hierarchy:
 - i) Western Ontario Osteoarthritis of the Shoulder Index (WOOS)
 - ii) American Shoulder and Elbow Surgeons Scale (ASES)
 - iii) Oxford Shoulder Score (OSS)
 - iv) Constant Score
 - v) Shoulder Pain and Disability Index (SPADI)
 - vi) Disability of the arm, shoulder and hand (DASH) questionnaire
3. Adverse events: assessed as either serious (death, or requiring hospitalisation) or specific (including shoulder stiffness, instability, infection, and nerve damage)
4. Quality of life measured using a generic instrument such as Short-Form 36 (SF-36) and other similar instruments
5. Revision or other re-operation, including treatment failure
6. Patient-perceived success of treatment, including patient satisfaction
7. Physician-evaluated outcomes, including radiographic assessment of lucency

Death is a rare event in shoulder surgery and therefore will be measured within the domain of serious adverse events. Measured range of motion and strength is considered to be of low utility (Buchbinder 2017), and we will not analyse these outcomes separately. These outcomes, however, will be assessed with some of the functional tools that we will use (major outcome 2).

We will collect outcome data for the following time points: short-term (less than one year), intermediate (one to three years) and long-term (more than three years). We will consider the intermediate time point to be the primary time point for comparisons.

Search methods for identification of studies

Electronic searches

We will search the following databases, from inception, with no date or language restrictions:

1. The Cochrane Central Register of Controlled Trials (CENTRAL), via the Cochrane Library, Wiley InterScience (www.thecochranelibrary.com);
2. MEDLINE (1966 to present)
3. EMBASE (1988 to present)
4. CINAHL (1937 to present)
5. SportDiscus (1985 to present)
6. Web of Science (1945 to present)

We will also conduct searches of ClinicalTrials.gov (www.ClinicalTrials.gov) and the WHO International Clinical Trials Registry Platform (www.who.int/ictrp/en/).

See Appendix 1, Appendix 2, Appendix 3, Appendix 4, Appendix 5, Appendix 6, Appendix 7, and Appendix 8 for detailed search strategies.

Searching other resources

We will check reference lists of all primary studies and review articles for additional references. In addition, we will search for published congress abstracts from, but not limited to, the American Academy of Orthopedic Surgeons (AAOS), the British Orthopaedic Association (BOA), the American Society of Shoulder and Elbow Surgeons, the British Elbow and Shoulder Society (BESS), the European Society of Shoulder and Elbow Surgery (SECEC) and the European Federation of National Associations of Orthopaedics and Traumatology (EFORT), using the available archives on the relevant society websites. We will search relevant manufacturers' websites for trial information and contact individuals or organisations where appropriate. We will search for errata or retractions from included studies.

Data collection and analysis

Selection of studies

Independently, two review authors (RC, HG) will review the titles and abstracts of studies identified by the searches according to the 'Criteria for considering studies for this review', and discard those that are clearly not relevant. We will then retrieve the full text of those remaining potentially eligible studies. Independently, the same authors (RC, HG) will repeat the selection process by screening the full text versions of these studies, to determine which studies should be included and have data extracted. We will resolve any disagreements by consensus. Where consensus is not achieved initially, a third author (SH or JR) will act as an adjudicator. We will identify and exclude duplicates and collate multiple reports of the same study so that each study, rather than each report, is the unit of interest in the review. We will record the selection process

in sufficient detail to complete a PRISMA flow diagram (PRISMA Group 2009), and 'Characteristics of excluded studies' table.

Data extraction and management

We will use the online review manager 'Covidence' to create a data collection form for study characteristics and outcome data, which will be piloted on at least one study in the review (Covidence). Independently, two review authors (RC, HG) will extract study characteristics from included studies. Consensus for the final data extraction will be reached by discussion. We will extract the following study characteristics.

1. Methods: study design, total duration of study, details of any 'run-in' period, number of study centres and location, study setting, description of eligibility criteria for centres and surgeons, withdrawals, and date of study.

2. Participants: N, mean age, age range, sex, sociodemographics, ethnicity, disease duration, severity of condition, diagnostic criteria, important condition-specific baseline data; inclusion criteria, and exclusion criteria.

3. Interventions: the total number of intervention groups within each trial, specific details of each intervention and comparator (e.g. details of the surgery including number of surgeons in the trial, their experience and duration of operation, descriptions of the procedure for tailoring the interventions to individual participants), any co-interventions and details of rehabilitation following surgery.

4. Outcomes: relevant primary and secondary outcomes specified and collected in the trials, and time points reported.

5. Characteristics of the design of the trial as outlined below in the 'Assessment of risk of bias in included studies' section.

6. Notes: funding for trial, and notable declarations of interest of trial authors.

Independently, two review authors (RC, HG) will extract outcome data from included studies using Covidence. We will extract the number of events and number of participants per treatment group for dichotomous outcomes, and means and standard deviations and number of participants per treatment group for continuous outcomes. We will note in the 'Characteristics of included studies' table whether outcome data were not reported in a usable way and when data were transformed or estimated from a graph. We will resolve disagreements by consensus or by involving a third person (SH or JR). One review author (RC) will transfer data into Review Manager 5 (RevMan 5) (RevMan 2014). We will double-check that data are entered correctly by comparing the data presented in the systematic review with the study reports.

For numerical data presented only in figures or graphs, we will contact the authors of the original report and request data. Where this is not possible, we will use software for extraction from graphs (e.g. PlotDigitizer) to extract data from the graphs or figures. These data will also be extracted in duplicate.

Where both final and change from baseline values are reported for

a given outcome, we will extract the final value; if both unadjusted and adjusted values for the same outcome are reported, we will extract the unadjusted value. If more than one outcome measure is reported in a trial, we will prioritise outcomes based on the hierarchy of major outcomes listed above. Where possible, we will extract data based on intention-to-treat analysis.

Main planned comparisons

Our main planned comparisons will be:

1. Any type of arthroplasty versus placebo (sham-surgery)
 2. Any type of arthroplasty surgery versus any other type of surgery
 3. Any type of arthroplasty versus any type of non-surgical treatment
 4. Any one type of arthroplasty surgery versus any other type of arthroplasty surgery
 5. Any one type of surgical technique versus any other type of surgical technique (e.g. cemented versus uncemented implants)
- For comparisons 1, 2 and 3 we plan to pool studies of different arthroplasty types as a single analysis versus a common comparator.

Assessment of risk of bias in included studies

Independently, two review authors (RC, HG) will assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). We will resolve any disagreements by discussion or by involving another author (SH). We will assess the risk of bias according to the following domains.

1. Random sequence generation
2. Allocation concealment
3. Blinding of participants and personnel
4. Blinding of outcome assessment - self-reported outcomes
5. Blinding of outcome assessment - physician-reported outcomes
6. Incomplete outcome data
7. Selective outcome reporting
8. Major baseline imbalance
9. Differences in rehabilitation regime

We will grade each potential source of bias as high, low or unclear, and provide a quote from the study report together with a justification for our judgement in the 'Risk of bias' table. We will summarise the 'Risk of bias' judgements across different studies for each of the domains listed. In addition, we will consider the impact of missing data by key outcomes.

Where information about risk of bias relates to unpublished data or correspondence with a trialist, we will note this in the 'Risk of bias' table. When considering treatment effects, we will take into account the risk of bias for the studies that contribute to that outcome. We will present the figures generated by the 'Risk of bias' tool to provide summary assessments of the risk of bias.

Assessment of bias in conducting the systematic review

We will conduct the review according to this published protocol and report any deviations from it in the 'Differences between protocol and review' section of the systematic review.

Measures of treatment effect

We will analyse dichotomous data as risk ratios or Peto odds ratios when the outcome is a rare event (approximately less than 10%), and use 95% confidence intervals (CI).

We will analyse continuous data as mean difference (MD) or standardised mean difference (SMD), with 95% CIs, depending on whether the outcome is measured using the same scale or different scales. We will enter data presented as a scale with a consistent direction of effect across studies. When different scales are used to measure the same conceptual outcome, we will back-translate SMD to a typical scale (e.g. 0 to 10 for pain) as described in Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011a).

In the 'Effects of intervention' results section and the 'Comments' column of the 'Summary of findings' table, we will provide the absolute per cent difference, the relative per cent change from baseline, and the number needed to treat for an additional beneficial outcome (NNTB). We will provide the NNTB only when the outcome shows a statistically significant difference.

For dichotomous outcomes, such as serious adverse events, we will calculate the NNTB and number needed to treat for an additional harmful outcome (NNTH) from the control group event rate and the risk ratio using the Visual Rx NNT calculator (Cates 2008). We will calculate the NNTB for continuous measures using the Wells calculator (available at the Cochrane Musculoskeletal Group (CMSG) Editorial office, musculoskeletal.cochrane.org). The minimal clinical important difference (MCID) will be used in the calculation of NNTB or NNTH for continuous outcomes; we will assume an MCID of 1.5 points in a 10-point scale for pain; and 10 points on a 100-point scale for function or disability for input into the calculator.

For dichotomous outcomes, we will calculate the absolute risk difference using the risk difference statistic in RevMan 5 and express the result as a percentage. For continuous outcomes, we will calculate the absolute benefit as the improvement in the intervention group minus the improvement in the control group, in the original units.

We will calculate the relative per cent change for dichotomous data as the risk ratio $- 1$ and express this as a percentage. For continuous outcomes, we will calculate the relative difference in the change from baseline as the absolute benefit divided by the baseline mean of the control group.

Unit of analysis issues

Where multiple trial arms are reported in a single trial, we will include only the relevant arms. If two comparisons (e.g. surgical intervention A versus non-surgical intervention and surgical intervention B versus non-surgical intervention) are combined in the same meta-analysis, we will halve the control group to avoid double-counting.

If multiple time points are reported, we will group them into short- (less than one year), intermediate- (one to three years), and long-term (more than three years) follow-up. If a single trial reports multiple time points within one of these groups, then we will extract the data that relate to the latest time point.

Dealing with missing data

We will contact investigators or study sponsors in order to verify key study characteristics and obtain missing numerical outcome data where possible (e.g. when a study is identified as an abstract only or when data are not available for all participants). Where this is not possible, and the missing data are thought to introduce serious bias, we will explore the impact of including such studies in the overall assessment of results by a sensitivity analysis. We will describe any assumptions and imputations we make to handle missing data clearly, and we will explore the effect of imputation by sensitivity analyses.

For dichotomous outcomes (e.g. number of withdrawals due to adverse events), we will calculate the withdrawal rate using the number of participants randomised in the group as the denominator.

For continuous outcomes (e.g. mean change in pain score), we will calculate the mean difference or SMD based on the number of participants analysed at that time point. If the number of participants analysed is not presented for each time point, we will use the number of randomised participants in each group at baseline. Where possible, we will compute missing standard deviations from other statistics such as standard errors, confidence intervals or P values, according to the methods recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b). If standard deviations cannot be calculated, they will be imputed (e.g. from other studies in the meta-analysis).

Assessment of heterogeneity

We will assess clinical and methodological diversity in terms of participants, interventions, outcomes and study characteristics for the included studies to determine whether a meta-analysis is appropriate. We will conduct this by observing these data from the data extraction tables. We will assess statistical heterogeneity by visual inspection of forest plots to assess for obvious differences in results between the studies, and using the I^2 and χ^2 statistical tests.

As recommended in the *Cochrane Handbook for systematic Reviews of Interventions* (Deeks 2011), the interpretation of an I^2 value of

0% to 40% might 'not be important'; 30% to 60% may represent 'moderate' heterogeneity; 50% to 90% may represent 'substantial' heterogeneity; and 75% to 100% represent 'considerable' heterogeneity. As noted in the *Cochrane Handbook for systematic Reviews of Interventions*, we will keep in mind that the importance of I^2 depends on: 1) magnitude and direction of effects; and 2) strength of evidence for heterogeneity.

We will interpret a Chi^2 test P value ≤ 0.10 as indicative of statistical heterogeneity.

If we identify substantial heterogeneity we will report it and investigate possible causes by following the recommendations in section 9.6 of the *Cochrane Handbook for systematic Reviews of Interventions* (Deeks 2011).

Assessment of reporting biases

We will create and examine a funnel plot to explore possible small study biases. In interpreting funnel plots, we will examine the different reasons possible for funnel plot asymmetry as outlined in section 10.4 of the *Cochrane Handbook for systematic Reviews of Interventions* and relate this to the results of the review. If we are able to pool more than 10 trials, we will undertake formal statistical tests to investigate funnel plot asymmetry, and will follow the recommendations in section 10.4 of the *Cochrane Handbook for systematic Reviews of Interventions* (Sterne 2011).

To assess outcome reporting bias, we will check trial protocols against their published reports. For studies published after 1 July 2005, we will screen the Clinical Trial Register at the International Clinical Trials Registry Platform of the World Health Organization (apps.who.int/trialssearch) for the a priori trial protocol. We will evaluate whether selective reporting of outcomes is present.

Data synthesis

We will undertake meta-analyses only where this is meaningful, that is, if the treatments, participants and the underlying clinical question are similar enough for pooling to make sense. For clinically homogeneous studies, we will pool outcomes in a meta-analysis using the random-effects model as a default. We will also examine the results from the fixed-effect model as sensitivity analyses, to evaluate any bias from smaller studies.

We will restrict the primary analysis for our main outcome measures reported in the 'Summary of findings' table to trials at low risk of detection and selection bias.

GRADE and 'Summary of findings' tables

We will include 'Summary of findings' (SoF) tables based on the following main comparisons.

1. Any type of arthroplasty versus placebo (sham-surgery)
2. Any type of arthroplasty surgery versus any other type of surgery

3. Any type of arthroplasty versus any type of non-surgical treatment

4. Any one type of arthroplasty surgery versus any other type of arthroplasty surgery

5. Any one type of surgical technique versus any other type of surgical technique (e.g. cemented versus uncemented implants)

We will include the following seven major outcomes in the SoF tables.

1. Pain
2. Disability and function
3. Adverse effects: total
4. Quality of life
5. Revision or re-operation
6. Participant-perceived success of treatment
7. Physician-evaluated outcomes

Where multiple time points are reported, the SoF will report intermediate outcomes (one to three years post surgery). Where multiple time points are recorded within this range by the same study, the latest time point will be used.

Two people (RC, HG) will independently assess the quality of the evidence. We will use the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of a body of evidence as it relates to the studies which contribute data to the meta-analyses for the prespecified outcomes, and report the quality of evidence as high, moderate, low, or very low. We will use methods and recommendations described in section 8.5 and 8.7, and chapters 11 and 12, of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a; Schünemann 2011a; Schünemann 2011b). We will use GRADEpro software to prepare the SoF tables (GRADEpro GDT 2015). We will justify all decisions to downgrade the quality of studies using footnotes and we will make comments to aid the reader's understanding of the review where necessary. We will provide the NNTB or NNTH, and the absolute and relative per cent change in the Comments column of the SoF tables as described in the 'Measures of treatment effect' section above.

Subgroup analysis and investigation of heterogeneity

We plan to carry out the following subgroup analyses, where data are available, for the following factors thought to influence outcomes (Muh 2013; Simone 2014):

1. age of participant divided into groups: < 55 years, 55 to 64 years, 65 to 74 years, 75 to 84 years, ≥ 85 ;
2. presence or absence of significant rotator cuff tear.

We will use our seven main outcomes ('Types of outcome measures') in the sub-group analyses.

We will use the formal test for subgroup interactions in RevMan 5 (RevMan 2014), and will use caution in the interpretation of subgroup analyses as advised in section 9.6 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011).

Sensitivity analysis

We plan to carry out the following sensitivity analyses to investigate the robustness of the treatment effect of pain, disability and function.

1. Inclusion of missing data
2. Inclusion of trials identified at risk of selection bias
3. Inclusion of trials with unclear or inadequate blinding of the outcome assessor
4. The choice of statistical method for pooled data (fixed-effect versus random-effects model)

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* Indicates the major publication for the study

APPENDICES**Appendix I. MEDLINE (Ovid) search strategy**

- 1 randomized controlled trial.pt.
- 2 controlled clinical trial.pt.
- 3 randomized.ab.
- 4 placebo.ab.
- 5 drug therapy.fs.
- 6 randomly.ab.
- 7 trial.ab.
- 8 groups.ab.
- 9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
- 10 exp animals/ not humans.sh.
- 11 9 not 10
- 12 exp osteoarthritis/
- 13 osteoarthr\$.tw.
- 14 (degenerative adj2 arthritis).tw.
- 15 arthrosis.tw.
- 16 arthropat\$.tw.
- 17 rotator cuff arthro\$.tw.
- 18 or/12-17
- 19 Shoulder/
- 20 shoulder joint/
- 21 shoulder pain/
- 22 shoulder\$.tw.
- 23 or/19-22
- 24 exp surgical Procedures, Operative/
- 25 su.fs.
- 26 (surgery\$ or surgeries or surgical or operat\$).tw.
- 27 (arthroplast\$ or hemiarthroplast\$ or (joint\$ adj2 replace\$)).tw.
- 28 (surface\$ adj replace\$).tw.
- 29 resurfac\$.tw.
- 30 RTSA.tw.
- 31 glenoid.tw.

32 glenosphere.tw.
 33 exp "Prostheses and Implants"/
 34 (glenoid adj2 component).tw.
 35 (humor\$ adj2 component).tw.
 36 endopro\$.tw.
 37 reverse.tw.
 38 or/24-37
 39 and/11,18,23,38

Appendix 2. EMBASE (Ovid) search strategy

1 random\$.ti,ab.
 2 factorial\$.ti,ab.
 3 (crossover\$ or cross over\$ or cross-over\$).ti,ab.
 4 placebo\$.ti,ab.
 5 (doubl\$ adj blind\$).ti,ab.
 6 (singl\$ adj blind\$).ti,ab.
 7 assign\$.ti,ab.
 8 allocat\$.ti,ab.
 9 volunteer\$.ti,ab.
 10 crossover procedure.sh.
 11 double blind procedure.sh.
 12 randomized controlled trial.sh.
 13 single blind procedure.sh.
 14 or/1-13
 15 exp osteoarthritis/
 16 osteoarthr\$.tw.
 17 (degenerative adj2 arthritis).tw.
 18 arthrosis.tw.
 19 arthropat\$.tw.
 20 rotator cuff arthro\$.tw.
 21 or/15-20
 22 Shoulder/
 23 Shoulder Pain/
 24 shoulder\$.tw.
 25 or/22-24
 26 exp Surgery/
 27 su.fs.
 28 (surgery\$ or surgeries or surgical or operat\$).tw.
 29 RTSA.tw.
 30 (arthroplast\$ or hemiarthroplast\$ or (joint\$ adj2 replace\$)).tw.
 31 (surface\$ adj replace\$).tw.
 32 resurfac\$.tw.
 33 glenoid.tw.
 34 glenosphere.tw.
 35 (glenoid adj2 component).tw.
 36 (humor\$ adj2 component).tw.
 37 endopro\$.tw.
 38 reverse.tw.
 39 or/26-38
 40 14 and 21 and 25 and 39

Appendix 3. CENTRAL search strategy

1 MeSH descriptor: [Osteoarthritis] explode all trees
2 osteoarth*:ti,ab
3 degenerative near/2 arthritis:ti,ab
4 arthrosis:ti,ab
5 arthropat*:ti,ab
6 (#1 or #2 or #3 or #4 or #5)
7 MeSH descriptor: [Shoulder] explode all trees
8 MeSH descriptor: [Shoulder Joint] explode all trees
9 MeSH descriptor: [Shoulder Pain] explode all trees
10 shoulder*:ti,ab
11 (#7 or #8 or #9 or #10)
12 MeSH descriptor: [Surgical Procedures, Operative] explode all trees
13 Any MeSH descriptor with qualifier(s): [Surgery - SU]
14 RTSA or reverse or glenoid or glenosphere:ti,ab
15 (surgery* or surgeries or surgical or operat*):ti,ab
16 (arthroplast* or hemiarthroplast* or (joint* near/2 replace*)):ti,ab
17 (glenoid near/2 component) or (humor* near/2 component):ti,ab
18 surface* replace*:ti,ab
19 resurfac*:ti,ab
20 endopro*:ti,ab
21 reverse:ti,ab
22 (#12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21)
23 (#6 and #11 and #22)

Appendix 4. CINAHL search strategy

S1 (MH "Osteoarthritis+")
S2 TI osteoarthr* OR AB osteoarthr*
S3 TI (degenerative n2 arthritis) OR AB (degenerative n2 arthritis)
S4 TI arthrosis OR AB arthrosis
S5 TI arthropat* OR AB arthropat*
S6 TI "rotator cuff arthro*" OR AB "rotator cuff arthro*"
S7 S1 OR S2 OR S3 OR S4 OR S5 OR S6
S8 (MH "Shoulder")
S9 (MH "Shoulder Joint")
S10 (MH "Shoulder Pain")
S11 TI shoulder* OR AB shoulder*
S12 S8 OR S9 OR S10 OR S11
S13 (MH "Surgery, Operative+")
S14 TI (surgery* OR surgeries OR surgical OR operat*) OR AB (surgery* OR surgeries OR surgical OR operat*)
S15 TI (RTSA OR reverse) OR AB (RTSA OR reverse)
S16 TI (arthroplast* OR hemiarthroplast* OR (joint* N2 replace*)) OR
AB (arthroplast* OR hemiarthroplast* OR (joint* N2 replace*))
S17 TI surface* replace* OR AB surface* replace*
S18 TI resurfac* OR AB resurfac*
S19 TI glenoid OR AB glenoid
S20 TI glenosphere OR AB glenosphere
S21 (MH "Prostheses and Implants+")
S22 TI (glenoid N2 component) OR AB (glenoid N2 component)
S23 TI (humor* N2 component) OR AB (humor* N2 component)
S24 TI endopro* OR AB endopro*
S25 S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24

S26 (MH "Clinical Trials+")
 S27 PT Clinical Trial
 S28 TI clinical* trial* OR AB clinical* trial*
 S29 TI singl* blind* or singl* mask* or doub* blind* or doubl* mask* or trebl* blind* or trebl* mask* or tripl* blind* or tripl* mask*
 S30 AB singl* blind* or singl* mask* or doub* blind* or doubl* mask* or trebl* blind* or trebl* mask* or tripl* blind* or tripl* mask*
 S31 TI randomi?ed control* trial* OR AB randomi?ed control* trial*
 S32 (MH "Random Assignment")
 S33 TI random* allocat* OR AB random* allocat*
 S34 TI placebo* OR AB placebo*
 S35 (MH "Placebos")
 S36 (MH "Quantitative Studies")
 S37 TI allocat* random* OR AB allocat* random*
 S38 S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37
 S39 S7 AND S12 AND S25 AND S38

Appendix 5. SportDiscus search strategy

S1 TI (osteoarthr* OR (degenerative n2 arthritis) OR arthrosis OR arthopat* OR "rotator cuff arthro*") OR AB (osteoarthr* OR (degenerative n2 arthritis) OR arthrosis OR arthopat* OR "rotator cuff arthro*") OR SU (osteoarthr* OR (degenerative n2 arthritis) OR arthrosis OR arthopat* OR "rotator cuff arthro*") OR KW (osteoarthr* OR (degenerative n2 arthritis) OR arthrosis OR arthopat* OR "rotator cuff arthro*")
 S2 TI shoulder* OR AB shoulder* OR SU shoulder* OR KW shoulder*
 S3 TI (surgery* OR surgeries OR surgical OR operat* OR arthroplast* OR hemiarthroplast* OR joint* replace* OR surface* replace* OR resurfac* OR RTSA OR reverse OR glenoid OR glenosphere OR (glenoid n2 component) OR (humor* n2 component) OR endopro*) OR AB (surgery* OR surgeries OR surgical OR operat* OR arthroplast* OR hemiarthroplast* OR joint* replace* OR surface* replace* OR resurfac* OR RTSA OR reverse OR glenoid OR glenosphere OR (glenoid n2 component) OR (humor* n2 component) OR endopro*) OR SU (surgery* OR surgeries OR surgical OR operat* OR arthroplast* OR hemiarthroplast* OR joint* replace* OR surface* replace* OR resurfac* OR RTSA OR reverse OR glenoid OR glenosphere OR (glenoid n2 component) OR (humor* n2 component) OR endopro*) OR KW (surgery* OR surgeries OR surgical OR operat* OR arthroplast* OR hemiarthroplast* OR joint* replace* OR surface* replace* OR resurfac* OR RTSA OR reverse OR glenoid OR glenosphere OR (glenoid n2 component) OR (humor* n2 component) OR endopro*)
 S5 S1 AND S2 AND S3 AND S4 (24)

Appendix 6. Web of Science search strategy

#1 TOPIC: (osteoarthr*)
 #2 TOPIC: (degenerative near/2 arthritis)
 #3 TOPIC: (arthrosis OR arthopat* OR "rotator cuff arthro*")
 #4 #1 or #2 or #3
 #5 TOPIC: (shoulder*)
 #6 TOPIC: (surgery* OR surgeries OR surgical OR operat* OR arthroplast* OR hemiarthroplast* OR joint* replace* OR surface* replace* OR resurfac* OR RTSA OR reverse OR glenoid OR glenosphere OR (glenoid near/2 component) OR (humor* near/2 component) OR endopro*)
 #7 TOPIC: (trial* or random* or placebo* or control* or double or treble or triple or blind* or mask* or allocat* or prospective* or volunteer* or comparative or evaluation or follow-up or followup)
 #8 #4 and #5 and #6 and #7

Appendix 7. clinicaltrials.org search strategy

shoulder AND (arthroplasty OR hemiarthroplasty OR replacement OR resurfacing OR surface)

Appendix 8. WHO ICTRP search strategy

- 1 shoulder AND replacement
- 2 shoulder AND arthroplasty
- 3 shoulder and hemiarthroplasty
- 4 shoulder AND reverse
- 5 shoulder and surface

WHAT'S NEW

Date	Event	Description
9 March 2017	Amended	Change of scope

HISTORY

Protocol first published: Issue 11, 2017

Date	Event	Description
8 April 2009	Amended	CMSG ID A044-P

CONTRIBUTIONS OF AUTHORS

RC, SH, JR - title registration and review concept

RC,HG, SH, JR - protocol development and editing

JS - author of original review, protocol editing

DECLARATIONS OF INTEREST

RC: none known

HG: none known

JS:none known

SH: none known

JR:none known

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Research Fellowship (RC)

NOTES

This is an update of a previous review ([Singh 2010](#)). The original review sought to assess the benefits and harms of any surgical treatment for shoulder OA, but only identified eligible studies looking at arthroplasty surgery. The focus of this updated review has been narrowed to assess the effects of surgical arthroplasty treatments only. The scope of the review has been explicitly expanded to ensure that patients with OA secondary to rotator cuff tear arthropathy and patients treated with reverse total shoulder arthroplasty are captured by the inclusion criteria.