Subacromial decompression surgery for adults with shoulder pain – a systematic review with meta-analysis

Appendix tables and figures and literature search description

**Appendix table 1: The full list of extracted data items**

<table>
<thead>
<tr>
<th><strong>Trial characteristics:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>study objectives</td>
<td></td>
</tr>
<tr>
<td>inclusion and exclusion criteria</td>
<td></td>
</tr>
<tr>
<td>definition of SAPS</td>
<td></td>
</tr>
<tr>
<td>number of patients allocated to intervention and control groups</td>
<td></td>
</tr>
<tr>
<td>follow-up time</td>
<td></td>
</tr>
<tr>
<td>sample size estimations</td>
<td></td>
</tr>
<tr>
<td>study sponsorships and conflict of interest statements and trial registry identifiers.</td>
<td></td>
</tr>
</tbody>
</table>

**Patient demographic-related variables:**

- sex distribution
- age
- duration of symptoms
- severity of symptoms at baseline
- shape of acromion
- employment and physical activity participation.

**Diagnosis or treatment-related data:**

- indications for surgery
- indications for other treatments
- treatments administered (key details)
- concomitant pathology (for example subacromial bursitis) and the method of diagnosis of the concomitant pathology, especially imaging.

**Trial methodology:**

- information on sequence generation
- allocation concealment
- degrees and success of blinding
- completeness of data (loss to follow-up
- handling of missing data and possible effects
- intention-to-treat analysis
- selective reporting and other sources of bias
  - dissimilarity of patient groups
  - co-interventions not evenly distributed among groups
  - compliance differences
  - differences in timing of the outcome assessment(s)
**Appendix table 2: Outcome hierarchy**

<table>
<thead>
<tr>
<th>Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>overall pain</td>
</tr>
<tr>
<td>average pain in a preceding period</td>
</tr>
<tr>
<td>unspecified pain</td>
</tr>
<tr>
<td>pain with activity in a preceding period</td>
</tr>
<tr>
<td>worst/highest pain in a preceding period</td>
</tr>
<tr>
<td>night pain in a preceding period</td>
</tr>
<tr>
<td>rest pain in a preceding period</td>
</tr>
<tr>
<td>current pain</td>
</tr>
</tbody>
</table>

If multiple periods during which the pain was evaluated were available, the shortest was chosen.

**Function PROs and mixed function-capacity-pain scores:**

- Oxford Shoulder Score (OSS)
- Constant-Murley Score (CS)
- American Shoulder and Elbow Surgeons Standardized Form (ASES-SF)
- UCLA Shoulder Score
- Simple Shoulder Test (SST)
- Shoulder Disability Questionnaire (SDQ)
- Neer Score
- Watson-Sonnabend score

**Health-related quality of life:**

- EQ-5D
- 15D
- EQ-VAS
- SF-36
Appendix fig 1: PRISMA flowchart

**BENEFITS**

- Records identified through database searching (n = 2441)
  - Records after duplicates removed (n = 842)
    - Records excluded (n = 827)
      - Full-text articles excluded, with reasons
        - Duplicate (n = 2)
        - Commentary (n = 2)
        - Wrong indication (n = 1)
        - Included full-thickness rotator cuff tears (n = 1)
    - Records screened (n = 842)
      - Full-text articles assessed for eligibility (n = 15)
        - Studies included in qualitative synthesis (n = 9)
        - Studies included in quantitative synthesis (meta-analysis) (n = 9)

**HARMS**

- Records identified through database searching (n = 3400)
  - Records after duplicates removed (n = 2363)
    - Records screened (n = 2363)
      - Full-text articles assessed for eligibility (n = 140)
        - Studies included in qualitative synthesis (n = 4)
        - Studies included in quantitative synthesis (meta-analysis) (n = 0)
    - Additional records identified through other sources (n = 2)
      - Records excluded (n = 2223)
        - Full-text articles excluded (n = 138)
          - No harms reported (n = 65)
          - Not designed to evaluate harms (n = 53)
          - Wrong study design (n = 7)
          - Wrong condition/population (n = 7)
          - Duplicate (n = 3)
          - Subset of incl. study (n = 1)
          - Abstract of incl. RCT (n = 1)
          - Wrong intervention (n = 1)
### Appendix table 3: Study characteristics

<table>
<thead>
<tr>
<th>Trial</th>
<th>Interventions</th>
<th>Minimum duration of symptoms for eligibility</th>
<th>Required treatments for eligibility</th>
<th>Pain measure</th>
<th>Mean baseline pain§</th>
<th>Function measure</th>
<th>Mean baseline function †*</th>
<th>HRQoL measure</th>
<th>Mean baseline HRQoL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paavola et al. 2018</td>
<td>ASAD (n = 59)</td>
<td>3 months</td>
<td>No relief from non-operative means (including physiotherapy, non-steroidal anti-inflammatory medication, corticosteroid injections, rest)</td>
<td>Pain on activity during previous 24 hours (VAS 0-100)</td>
<td>7.12 (2.36)</td>
<td>Constant score</td>
<td>32.2 (28.2-36.2)</td>
<td>15D</td>
<td>0.89 (0.87-0.91)</td>
</tr>
<tr>
<td></td>
<td>DA (n = 63)</td>
<td></td>
<td></td>
<td></td>
<td>7.23 (2.17)</td>
<td></td>
<td>31.7 (28.2-35.2)</td>
<td>0.89</td>
<td>0.87-0.91</td>
</tr>
<tr>
<td></td>
<td>ET (n = 71)</td>
<td></td>
<td></td>
<td></td>
<td>7.24 (2.08)</td>
<td></td>
<td>35.2 (31.4-39.0)</td>
<td>0.88</td>
<td>0.86-0.90</td>
</tr>
<tr>
<td>Beard et al. 2017</td>
<td>ASAD (n = 106)</td>
<td>3 months</td>
<td>Completed non-op management programme that included exercise therapy and at least 1 steroid injection</td>
<td>Average pain during previous 4 weeks (VAS 0-10)</td>
<td>6.0 (1.9)</td>
<td>Constant score</td>
<td>39.4 (13.9)</td>
<td>EQ-15D-3L</td>
<td>0.52 (0.3)</td>
</tr>
<tr>
<td></td>
<td>DA (n = 103)</td>
<td></td>
<td></td>
<td></td>
<td>5.8 (2.0)</td>
<td></td>
<td>43.1 (15.5)</td>
<td>0.55</td>
<td>0.29</td>
</tr>
<tr>
<td></td>
<td>WaS (n = 104)</td>
<td></td>
<td></td>
<td></td>
<td>6.6 (1.7)</td>
<td></td>
<td>38.3 (14.2)</td>
<td>0.50</td>
<td>0.3</td>
</tr>
<tr>
<td>Farfaras et al. 2016</td>
<td>ASAD (n = 29)</td>
<td>6 months</td>
<td>None reported</td>
<td>Not measured</td>
<td>Constant score</td>
<td>56 (11.3)</td>
<td>48 (15.7)</td>
<td>56</td>
<td>13.1</td>
</tr>
<tr>
<td></td>
<td>OSAD (n = 24)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ET (n = 34)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ketola et al. 2009</td>
<td>ASAD (n = 70)</td>
<td>3 months</td>
<td>Chronic symptoms not relieved by rest, anti-inflammatory medication, subacromial glucocorticoid injection and physiotherapy (physiotherapy included exercise, massage, heat and transcutaneous electrical stimulation)</td>
<td>Pain unspecified (VAS 0-10)</td>
<td>6.4</td>
<td>Shoulder Disability Questionnaire</td>
<td>22.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ET (n = 70)</td>
<td></td>
<td></td>
<td></td>
<td>6.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Henkus et al. 2009</td>
<td>ASAD (n = 30)</td>
<td></td>
<td>Three lidocaine and hydrocortisone injections into the subacromial space at 4-week intervals, combined with non-steroidal anti-inflammatory medication and a minimum 6-week exercise programme</td>
<td>Pain unspecified (VAS 1-10)</td>
<td>7.9</td>
<td>Constant score</td>
<td>57</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BT (n = 26)</td>
<td></td>
<td></td>
<td></td>
<td>6.8</td>
<td></td>
<td>56</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Group</td>
<td>Treatment</td>
<td>Outcome Measures</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>-------</td>
<td>---------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Taverna et al. 2007</td>
<td>ASAD (n = 30)</td>
<td>6 months&lt;br&gt;Any combination of physiotherapy (including range of motion and strength exercises), subacromial corticosteroid injection(s), non-steroidal anti-inflammatory medication, activity modification, rest and ice</td>
<td>Pain unspecified (VAS 0-10)&lt;br&gt;Pain 8.2 (0.8) Constant score 54 (4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>MT (n = 30)</td>
<td>6 months&lt;br&gt;None required; previous treatment (within the preceding 3 years) with rest, non-steroidal anti-inflammatory medication, subacromial injection and physiotherapy were permitted</td>
<td>Highest pain within previous 24 hours (VAS 0-15 at 3 and 6 months follow-up) Constant score 33.7 (29.2-38.2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haahr et al. 2005</td>
<td>ASAD (n = 41)</td>
<td>6 months&lt;br&gt;Unclear; patients in the SAD group had completed conservative treatment of approximately 6 months duration prior to surgery</td>
<td>Highest pain within previous 24 hours (VAS 0-15 at 3 and 6 months follow-up) Constant score 6.56 (5.78-7.33)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ET (n = 43)</td>
<td>6 months&lt;br&gt;None reported</td>
<td>Average pain over previous 7 days (VAS 0-9 at 1 and 5 years follow-up) Constant score 7.22 (6.56-7.78)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peters &amp; Kohn 1997</td>
<td>SAD (n = 32)</td>
<td>6 months&lt;br&gt;None reported</td>
<td>Pain on activity during the previous 7 days (VAS 1-9) Neer shoulder score 63.4 (10.8)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>CT (n = 40)</td>
<td>6 months&lt;br&gt;None reported</td>
<td>Pain 7.25 (1.9) Neer shoulder score 66.3 (8.8)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Laser (n = 30)</td>
<td>6 months&lt;br&gt;None reported</td>
<td>Pain 6.89 (2.3) Neer shoulder score 64.7 (10.6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note. ASAD, arthroscopic subacromial decompression surgery; DA, diagnostic arthroscopy; WaS, wait and see; ET, exercise therapy; OSAD, open subacromial decompression surgery; SAD, subacromial decompression surgery; CT, conservative therapy; *Medians reported by Peters & Kolk 1997; †Measures were transformed to a 0-10 scale, a higher score indicates less pain; ††Measures were transformed to a 0-100 scale, a higher score indicates superior function.
### Appendix Table 3 continued: Study characteristics: post-operative rehabilitation and nonoperative management in the included trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Identical care for operative and non-operative groups?</th>
<th>Description of post-operative care and non-operative treatment</th>
</tr>
</thead>
</table>
| Paavola et al. 2018 | No                                                    | POST-OPERATIVE REHABILITATION: one visit to an independent physiotherapist for guidance and instructions for home exercises. Subsequent rehabilitation according to standardised rehabilitation protocol at the treatment site.  
EXERCISE THERAPY: supervised, progressive loading programme, individually designed physiotherapy that was started within 2 weeks of randomisation - daily home exercise programme plus 15 visits to independent physiotherapist. The aim of the programme was to restore pain-free normal mobility of the shoulder girdle, eliminate capsular tightness and increase dynamic stability of the glenohumeral joint and scapula. Detailed protocol described in Paavola et al. appendix. |
<p>| Beard et al. 2017   | No                                                    | Standardised post-operative care and rehabilitation (post-operative physiotherapy involved advice and up to 4 treatment sessions, not described in detail); non-surgical group did not receive physiotherapy                                                                                                                                     |
| Farfaras et al. 2016| Yes                                                   | POST-OPERATIVE REHABILITATION AND EXERCISE THERAPY: commenced as soon as pain permitted and was supervised by 5 local physiotherapists using the method described by Böhmer. The aim of the progressive range of motion and loading programme was to strengthen rotator cuff and scapula-stabilising muscles, to restore normal, pain-free shoulder kinematics. The programme was performed twice a week under the supervision of a physiotherapist and the rest of the days at home for a period of three to six months. In the final stage of the programme, patients replaced some exercises with corresponding leisure activities. |
| Ketola et al. 2009  | Yes                                                   | POST-OPERATIVE REHABILITATION AND EXERCISE THERAPY: an individualised progressive loading home exercise programme aiming to restore normal, pain-free shoulder mobility, and increase dynamic stability of the glenohumeral joint and scapula. Exercise sessions were performed at least 4 times per week until discharge (discharge criteria not described). Exercises were monitored and progressed by a physiotherapist during a series of follow-up visits (&quot;seven were generally required&quot;). |
| Henkus et al. 2009  | N/A                                                   | POST-OPERATIVE REHABILITATION: all patients completed the same physiotherapy-guided exercise programme (no further information reported)                                                                                                                                                                                                            |
| Taverna et al. 2007 | N/A                                                   | POST-OPERATIVE REHABILITATION: one or two days after the procedure, patients began passive range of motion exercises. Between the first and second postoperative month, patients started an exercise program designed to strengthen the rotator cuff and other scapula girdle muscles |</p>
<table>
<thead>
<tr>
<th>Authors</th>
<th>Intervention</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haahr et al. 2005</td>
<td>POST-OPERATIVE REHABILITATION: at 10 days post-operative, patients received instructions from a physiotherapist on how to perform a progressive muscle strengthening programme.</td>
<td>EXERCISE THERAPY: 19 sessions of physiotherapy (each session lasted for up to 60 minutes) focusing on progressive muscle strengthening within pain limits. Patients were instructed to complete a daily home exercise programme. At conclusion of 12-week intervention period, patients were encouraged to continue the programme at least twice per week.</td>
</tr>
<tr>
<td>Peters &amp; Kohn 1997</td>
<td>POST-OPERATIVE REHABILITATION: range of motion exercises commenced on the day of the surgery, progressive strengthening commenced from the fourth post-operative week.</td>
<td>CONSERVATIVE THERAPY: all patients were hospitalised for 2 weeks to receive treatment including physiotherapy. Up to 3 corticosteroid injections were administered. Initial physiotherapy focused on reducing pain (using electrotherapy, thermal therapy, and manual therapy or massage). Intensive exercise therapy began with exercises to restore full range of motion and dynamic shoulder and scapular stability, based on progressive loading principles. Participants received instruction on how to complete a home-based rehabilitation programme.</td>
</tr>
<tr>
<td>Brox et al. 1993</td>
<td>POST-OPERATIVE REHABILITATION: commenced on the first post-operative day. The exercises prescribed by the surgeon were performed against low resistance and repeated many times. Patients visited a physiotherapist where they lived. Unrestricted activities were usually allowed after 4 to 6 weeks.</td>
<td>EXERCISE THERAPY: a progressive loading program lasting 3 to 6 months, supervised twice weekly (plus daily home exercise programme), which focused on normalising dysfunctional neuromuscular patterns and increasing the nutrition of the rotator cuff collagen tissue. There were an additional 3 lessons on shoulder anatomy and function, pain management, ergonomic advice. Patients completed a training diary for motivation and to guide load progression. PLACEBO LASER: administered for 12 sessions (two sessions per week). Patients who were randomised to supervised exercises and placebo laser all were treated by the same physiotherapist.</td>
</tr>
</tbody>
</table>
### Appendix table 4: Risk of Bias assessments of the trials

#### Comparison: ASAD vs placebo surgery

<table>
<thead>
<tr>
<th>Publication</th>
<th>Beard 2017</th>
<th>Paavola 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Selection bias</strong></td>
<td>All outcomes</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Performance bias</strong></td>
<td>Subjective</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Harms</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Detection bias</strong></td>
<td>Subjective</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Harms</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Attrition bias</strong></td>
<td>All outcomes</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Reporting bias</strong></td>
<td>All outcomes</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Other biases</strong></td>
<td>All outcomes</td>
<td>Low</td>
</tr>
</tbody>
</table>

#### Comparison: (A)SAD vs nonoperative treatment

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Selection bias</strong></td>
<td>All outcomes</td>
<td>Low</td>
<td>Unclear</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Performance bias</strong></td>
<td>Subjective</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td></td>
<td>Harms</td>
<td>Low</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td><strong>Detection bias</strong></td>
<td>Subjective</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td></td>
<td>Harms</td>
<td>Low</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td><strong>Attrition bias</strong></td>
<td>All outcomes</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Reporting bias</strong></td>
<td>All outcomes</td>
<td>Low</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Other biases</strong></td>
<td>All outcomes</td>
<td>Low</td>
<td>High</td>
<td>High</td>
<td>Low</td>
<td>Unclear</td>
<td>Unclear</td>
</tr>
</tbody>
</table>
## Appendix table 5: Summary of Findings for outcomes with data from one study in the primary comparison and serious harms in the RCTs

<table>
<thead>
<tr>
<th>Outcome Timeframe</th>
<th>Measurement instruments and relative effects</th>
<th>Absolute effect estimates</th>
<th>Certainty in effect estimates (Quality of evidence)</th>
<th>Plain text summary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Global perceived effect at 2 years</strong></td>
<td>Relative risk: 0.98 (CI 95% 0.81 - 1.18) Based on data from 116 patients in 1 study</td>
<td>Placebo Surgery: 793 per 1000 Surgery: 777 per 1000 Difference: 16 fewer per 1000 (CI 95% 151 fewer - 143 more)</td>
<td>Low Due to very serious imprecision¹</td>
<td>SAD surgery may have little or no global perceived effect at 2 years</td>
</tr>
<tr>
<td><strong>Number at work 3 months</strong></td>
<td>Relative risk: 0.94 (CI 95% 0.74 - 1.21) Based on data from 119 patients in 1 study</td>
<td>Placebo Surgery: 700 per 1000 Surgery: 658 per 1000 Difference: 42 fewer per 1000 (CI 95% 182 fewer - 147 more)</td>
<td>Low Due to very serious imprecision¹</td>
<td>SAD surgery may have little or no effect on number at work 3 months</td>
</tr>
<tr>
<td><strong>Number at work 6 months</strong></td>
<td>Relative risk: 1.08 (CI 95% 0.91 - 1.28) Based on data from 114 patients in 1 study</td>
<td>Placebo Surgery: 793 per 1000 Surgery: 856 per 1000 Difference: 63 more per 1000 (CI 95% 71 fewer - 222 more)</td>
<td>Low Due to very serious imprecision¹</td>
<td>SAD surgery may have little or no effect on number at work 6 months</td>
</tr>
<tr>
<td><strong>Number at work 1 year</strong></td>
<td>Relative risk: 1.05 (CI 95% 0.89 - 1.23) Based on data from 111 patients in 1 study</td>
<td>Placebo Surgery: 818 per 1000 Surgery: 859 per 1000 Difference: 41 more per 1000 (CI 95% 90 fewer - 188 more)</td>
<td>Low Due to very serious imprecision¹</td>
<td>SAD surgery may have little or no effect on number at work 1 year</td>
</tr>
<tr>
<td><strong>Number at work 2 years</strong></td>
<td>Relative risk: 0.98 (CI 95% 0.83 - 1.15) Based on data from 112 patients in 1 study</td>
<td>Placebo Surgery: 849 per 1000 Surgery: 832 per 1000 Difference: 17 fewer per 1000 (CI 95% 144 fewer - 127 more)</td>
<td>Low Due to very serious imprecision¹</td>
<td>SAD surgery may have little or no effect on number at work 2 years</td>
</tr>
<tr>
<td><strong>Pain - 3 months</strong></td>
<td>Measured by: VAS and NRS scaled to 0-10 Scale: 0-10 Lower better MID: 1.5 units Based on data from 109 patients in 1 study</td>
<td>Placebo Surgery: 3.7 per 1000 Surgery: 4.2 per 1000 Difference: MD 0.47 higher (CI 95% 0.43 lower - 1.37 higher)</td>
<td>High</td>
<td>Surgery has little or no effect on pain at 6 months</td>
</tr>
<tr>
<td><strong>Pain - 2 years</strong></td>
<td>Measured by: VAS and NRS scaled to 0-10 Scale: 0-10 Lower better MID: 1.5 units Based on data from 284 patients in 1 study</td>
<td>Placebo Surgery: 2.5 per 1000 Surgery: 1.6 per 1000 Difference: MD 0.90 lower (CI 95% 1.80 lower - 0.00 higher)</td>
<td>Moderate Due to serious imprecision²</td>
<td>Surgery probably has little or no effect on pain at 1 year</td>
</tr>
<tr>
<td><strong>Other harms (randomised trial data)</strong></td>
<td>Based on data from 331 patients in 2 studies Follow up 1-2 years</td>
<td>The trials did not capture serious harms</td>
<td>Low Due to very serious imprecision (lack of power to detect low incidence rate events)³</td>
<td>There were too few who experienced harms to determine whether surgery is associated with a difference in risk</td>
</tr>
</tbody>
</table>

¹ Imprecision: Very Serious. Wide confidence intervals, Only data from one study

² Imprecision: Serious. Wide confidence intervals;

³ Imprecision: Very Serious. No events (observational studies report rare complications);
Appendix fig 2: Forest plots for global perceived effect in the primary comparison. a: 6 months, b: 1 year, c: 2 years

Appendix fig 3: Forest plots for health-related quality of life in the primary comparison. a: 6 months, b: 1 year. Vertical lines denote MID (0.07 units, converted to SMD of 0.26)
### Appendix table 6: Summary of Findings in the secondary comparison

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Timeframe</th>
<th>Study results and measurements</th>
<th>Absolute effect estimates</th>
<th>Certainty in effect estimates (Quality of evidence)</th>
<th>Plain text summary</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Exercise Therapy</td>
<td>Surgery</td>
<td></td>
</tr>
<tr>
<td>Pain at 3 months</td>
<td></td>
<td>Measured by: VAS and NRS scaled to 0-10 Scale: 0-10 Lower better Based on data from 361 patients in 4 studies</td>
<td><strong>4.5</strong> Mean</td>
<td><strong>3.9</strong> Mean</td>
<td>Moderate</td>
</tr>
<tr>
<td>Pain at 6 months</td>
<td></td>
<td>Measured by: VAS and NRS scaled to 0-10 Scale: 0-10 Lower better Based on data from 399 patients in 4 studies</td>
<td><strong>3.7</strong> Mean</td>
<td><strong>3.1</strong> Mean</td>
<td>Moderate</td>
</tr>
<tr>
<td>Pain at 1 year</td>
<td></td>
<td>Measured by: VAS and NRS scaled to 0-10 Scale: 0-10 Lower better Based on data from 316 patients in 3 studies</td>
<td><strong>3.7</strong> Mean</td>
<td><strong>2.7</strong> Mean</td>
<td>Low</td>
</tr>
<tr>
<td>Pain at 2 years</td>
<td></td>
<td>Measured by: VAS and NRS scaled to 0-10 Scale: 0-10 Lower better Based on data from 352 patients in 3 studies</td>
<td><strong>2.8</strong> Mean</td>
<td><strong>2.4</strong> Mean</td>
<td>Moderate</td>
</tr>
<tr>
<td>Pain 5 years</td>
<td></td>
<td>Measured by: VAS and NRS scaled to 0-10 Scale: 0-10 Lower better Based on data from 188 patients in 2 studies</td>
<td><strong>2.2</strong> Mean</td>
<td><strong>2.6</strong> Mean</td>
<td>Low</td>
</tr>
<tr>
<td>Function at 3 months</td>
<td></td>
<td>Measured by: CS, SDQ, NS, SSRS scaled to 0-100 Scale: 0-100 High better Based on data from 257 patients in 3 studies</td>
<td><strong>55</strong> Mean</td>
<td><strong>61</strong> Mean</td>
<td>Low</td>
</tr>
<tr>
<td>Function at 6 months</td>
<td></td>
<td>Measured by: CS, SDQ, NS, SSRS scaled to 0-100 Scale: 0-100 High better Based on data from 398 patients in 4 studies</td>
<td><strong>57</strong> Mean</td>
<td><strong>61</strong> Mean</td>
<td>Low</td>
</tr>
<tr>
<td>Function at 1 year</td>
<td></td>
<td>Measured by: CS, SDQ, NS, SSRS scaled to 0-100 Scale: 0-100 High better Based on data from 259 patients in 3 studies</td>
<td><strong>66</strong> Mean</td>
<td><strong>69</strong> Mean</td>
<td>Low</td>
</tr>
<tr>
<td>Function at 2 years</td>
<td></td>
<td>Measured by: CS, SDQ, NS, SSRS scaled to 0-100 Scale: 0-100 High better Based on data from 467 patients in 5 studies</td>
<td><strong>71</strong> Mean</td>
<td><strong>76</strong> Mean</td>
<td>Low</td>
</tr>
</tbody>
</table>

continued on next page
<table>
<thead>
<tr>
<th>Function at 5 years</th>
<th>Measured by: CS, SDQ, NS, SSRS scaled to 0-100 Scale: 0-100 High better Based on data from 157 patients in 2 studies</th>
<th>76</th>
<th>84</th>
<th>Low</th>
<th>Due to serious risk of bias and serious imprecision&lt;sup&gt;2&lt;/sup&gt;</th>
<th>SAD surgery may have little or no effect on function at 5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function at 10 years</td>
<td>Measured by: CS, SDQ, NS, SSRS scaled to 0-100 Scale: 0-100 High better Based on data from 156 patients in 2 studies</td>
<td>69</td>
<td>79</td>
<td>Low</td>
<td>Due to serious risk of bias and serious imprecision&lt;sup&gt;2&lt;/sup&gt;</td>
<td>SAD surgery may improve function at 10 years slightly</td>
</tr>
<tr>
<td>Global perceived effect at 6 months</td>
<td>Relative risk: 1.27 (CI 95% 0.86 - 1.86) Based on data from 122 patients in 1 study</td>
<td>409</td>
<td>519</td>
<td>Very Low</td>
<td>Due to serious risk of bias and very serious imprecision&lt;sup&gt;3&lt;/sup&gt;</td>
<td>We are uncertain whether SAD surgery has a global perceived effect at 6 months</td>
</tr>
<tr>
<td>Global perceived effect at 1 year</td>
<td>Relative risk: 1.13 (CI 95% 0.87 - 1.46) Based on data from 117 patients in 1 study</td>
<td>629</td>
<td>711</td>
<td>Very Low</td>
<td>Due to serious risk of bias and very serious imprecision&lt;sup&gt;3&lt;/sup&gt;</td>
<td>We are uncertain whether SAD surgery has a global perceived effect at 1 year</td>
</tr>
<tr>
<td>Global perceived effect at 2 years</td>
<td>Relative risk: 1.23 (CI 95% 0.98 - 1.56) Based on data from 127 patients in 1 study</td>
<td>618</td>
<td>760</td>
<td>Very Low</td>
<td>Due to serious risk of bias and very serious imprecision&lt;sup&gt;3&lt;/sup&gt;</td>
<td>We are uncertain whether SAD surgery has a global perceived effect at 2 years</td>
</tr>
<tr>
<td>Number at work 3 months</td>
<td>Relative risk: 0.96 (CI 95% 0.75 - 1.22) Based on data from 127 patients in 1 study</td>
<td>691</td>
<td>663</td>
<td>Low</td>
<td>Due to very serious imprecision&lt;sup&gt;4&lt;/sup&gt;</td>
<td>SAD Surgery may have little or no difference on number at work at 3 months</td>
</tr>
<tr>
<td>Number at work 6 months</td>
<td>Relative risk: 1.05 (CI 95% 0.81 - 1.36) Based on data from 187 patients in 2 studies</td>
<td>730</td>
<td>766</td>
<td>Moderate</td>
<td>Due to serious imprecision&lt;sup&gt;5&lt;/sup&gt;</td>
<td>SAD Surgery probably has little or no difference on number at work at 6 months</td>
</tr>
<tr>
<td>Number at work 1 year</td>
<td>Relative risk: 0.98 (CI 95% 0.85 - 1.13) Based on data from 119 patients in 1 study</td>
<td>873</td>
<td>856</td>
<td>Low</td>
<td>Due to very serious imprecision&lt;sup&gt;4&lt;/sup&gt;</td>
<td>SAD Surgery may have little or no difference on number at work at 1 year</td>
</tr>
<tr>
<td>Number at work 2 years</td>
<td>Relative risk: 0.87 (CI 95% 0.7 - 1.07) Based on data from 183 patients in 2 studies</td>
<td>860</td>
<td>748</td>
<td>Moderate</td>
<td>Due to serious imprecision&lt;sup&gt;5&lt;/sup&gt;</td>
<td>SAD Surgery probably has little or no difference on number at work at 2 years</td>
</tr>
<tr>
<td>Number at work 5 years</td>
<td>Relative risk: 1.13 (CI 95% 0.97 - 1.32) Based on data from 188 patients in 2 studies</td>
<td>674</td>
<td>762</td>
<td>Low</td>
<td>Due to very serious imprecision&lt;sup&gt;4&lt;/sup&gt;</td>
<td>SAD Surgery may have little or no difference on number at work at 5 years</td>
</tr>
</tbody>
</table>

Continued On next page
<table>
<thead>
<tr>
<th>Activity</th>
<th>Relative Risk</th>
<th>Confidence Interval</th>
<th>Risk of Bias</th>
<th>Imprecision</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number at work 10 years</td>
<td>1.1 (CI 0.7 - 1.72)</td>
<td>44 more per 1000 (CI 131 fewer - 313 more)</td>
<td>Low</td>
<td>Very Serious</td>
<td>Due to very serious imprecision due to number at work at 10 years</td>
</tr>
<tr>
<td>Sport/leisure activities at 3 months</td>
<td>1.31 (CI 0.91 - 1.88)</td>
<td>134 more per 1000 (CI 39 fewer - 379 more)</td>
<td>Low</td>
<td>Very Serious</td>
<td>Due to very serious imprecision due to sport/leisure activities at 3 months</td>
</tr>
<tr>
<td>Sport/leisure activities at 6 months</td>
<td>1.12 (CI 0.83 - 1.5)</td>
<td>68 more per 1000 (CI 96 fewer - 283 more)</td>
<td>Low</td>
<td>Very Serious</td>
<td>Due to very serious imprecision due to sport/leisure activities at 6 months</td>
</tr>
<tr>
<td>Sport/leisure activities at 1 year</td>
<td>1.08 (CI 0.88 - 1.33)</td>
<td>58 more per 1000 (CI 86 fewer - 237 more)</td>
<td>Low</td>
<td>Very Serious</td>
<td>Due to very serious imprecision due to sport/leisure activities at 1 year</td>
</tr>
<tr>
<td>Sport/leisure activities at 2 years</td>
<td>1.06 (CI 0.88 - 1.27)</td>
<td>46 more per 1000 (CI 93 fewer - 209 more)</td>
<td>Low</td>
<td>Very Serious</td>
<td>Due to very serious imprecision due to sport/leisure activities at 2 years</td>
</tr>
<tr>
<td>Full thickness rotator cuff tear at 5 years (MRI)</td>
<td>1.0 (CI 0.4 - 2.52)</td>
<td>0 fewer per 1000 (CI 100 fewer - 254 more)</td>
<td>Low</td>
<td>Very Serious</td>
<td>Due to very serious imprecision due to incidence of full thickness rotator cuff tears at 5 years</td>
</tr>
<tr>
<td>Full thickness rotator cuff tear at 10 years (ultrasound)</td>
<td>0.37 (CI 0.07 - 1.87)</td>
<td>90 fewer per 1000 (CI 133 fewer - 124 more)</td>
<td>Very Low</td>
<td>Serious</td>
<td>We are uncertain whether SAD surgery increases or decreases the incidence of full thickness rotator cuff tears at 10 years</td>
</tr>
</tbody>
</table>

1. **Risk of bias: Serious.** Lack of blinding of participants and personnel, resulting in potential for performance bias. Lack of blinding of outcome assessors, resulting in potential for detection bias. Individual studies have additional domains at high risk of bias: interim analysis, no ITT, stopped early, co-interventions, compliance bias, group imbalance.
2. **Risk of bias: Serious.** Lack of blinding of participants and personnel, resulting in potential for performance bias. Lack of blinding of outcome assessors, resulting in potential for detection bias. Individual studies have additional domains at high risk of bias: interim analysis, no ITT, stopped early, co-interventions, compliance bias, group imbalance.
3. **Imprecision: Very Serious.** Only data from one study, wide confidence intervals
4. **Imprecision: Very Serious.** Only data from one study, wide confidence intervals
5. **Imprecision: Serious.** Wide confidence intervals
6. **Risk of bias: Serious.** No ITT
7. **Imprecision: Very Serious.** Only data from one study, wide confidence intervals
### Appendix fig 4: Forest plots for pain in the secondary comparison

**a:** 3 months, **b:** 6 months, **c:** one year, **d:** two years, **e:** five years. Vertical lines denote MID (1.5 units)

#### a:

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>(A)SAD</th>
<th>Nonoperative</th>
<th>Mean Difference IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brox 1993</td>
<td>3.63</td>
<td>31</td>
<td>-1.13 [-2.49, 0.23]</td>
</tr>
<tr>
<td>Haahr 2005</td>
<td>-1.37</td>
<td>41</td>
<td>0.20 [-0.77, 1.17]</td>
</tr>
<tr>
<td>Ketola 2009</td>
<td>3.19</td>
<td>43</td>
<td>-1.23 [-2.15, -0.31]</td>
</tr>
<tr>
<td>Paavola 2018</td>
<td>4.25</td>
<td>44</td>
<td>-0.22 [-1.11, 0.67]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>169</td>
<td>192</td>
<td>100.0% [-0.55 [-1.24, 0.14]]</td>
</tr>
<tr>
<td><strong>Test for overall effect:</strong> Z = 1.55 (P = 0.12)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### b:

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>(A)SAD</th>
<th>Nonoperative</th>
<th>Mean Difference IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brox 1993</td>
<td>3.38</td>
<td>42</td>
<td>-0.06 [-1.12, 0.96]</td>
</tr>
<tr>
<td>Haahr 2005</td>
<td>-2.53</td>
<td>43</td>
<td>-0.06 [-1.11, 0.99]</td>
</tr>
<tr>
<td>Ketola 2009</td>
<td>2.48</td>
<td>44</td>
<td>-1.20 [-2.08, -0.32]</td>
</tr>
<tr>
<td>Paavola 2018</td>
<td>3.81</td>
<td>59</td>
<td>-0.65 [-1.52, 0.22]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>186</td>
<td>213</td>
<td>100.0% [-0.56 [-1.09, 0.02]]</td>
</tr>
<tr>
<td><strong>Heterogeneity:</strong> Tau² = 0.06; Chi² = 3.77, df = 3 (P = 0.29); I² = 21%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for overall effect:</strong> Z = 2.05 (P = 0.04)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### c:

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>(A)SAD</th>
<th>Nonoperative</th>
<th>Mean Difference IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haahr 2005</td>
<td>4.56</td>
<td>41</td>
<td>-0.11 [-1.64, 1.42]</td>
</tr>
<tr>
<td>Ketola 2009</td>
<td>2.33</td>
<td>51</td>
<td>-1.38 [-2.30, -0.46]</td>
</tr>
<tr>
<td>Paavola 2018</td>
<td>2.44</td>
<td>55</td>
<td>-0.96 [-1.85, -0.07]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>147</td>
<td>169</td>
<td>100.0% [-1.01 [-1.60, -0.42]]</td>
</tr>
<tr>
<td><strong>Heterogeneity:</strong> Tau² = 0.00; Chi² = 1.95, df = 2 (P = 0.38); I² = 0%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for overall effect:</strong> Z = 3.35 (P = 0.0008)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### d:

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>(A)SAD</th>
<th>Nonoperative</th>
<th>Mean Difference IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brox 1993</td>
<td>2.8</td>
<td>46</td>
<td>0.52 [-0.68, 1.72]</td>
</tr>
<tr>
<td>Ketola 2009</td>
<td>2.47</td>
<td>68</td>
<td>-0.41 [-1.31, 0.49]</td>
</tr>
<tr>
<td>Paavola 2018</td>
<td>1.6</td>
<td>59</td>
<td>-1.21 [-2.07, -0.35]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>173</td>
<td>179</td>
<td>100.0% [-0.44 [-1.37, 0.48]]</td>
</tr>
<tr>
<td><strong>Heterogeneity:</strong> Tau² = 0.42; Chi² = 5.40, df = 2 (P = 0.07); I² = 63%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for overall effect:</strong> Z = 0.93 (P = 0.35)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### e:

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>(A)SAD</th>
<th>Nonoperative</th>
<th>Mean Difference IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haahr 2005</td>
<td>-2.11</td>
<td>39</td>
<td>1.22 [-0.09, 2.53]</td>
</tr>
<tr>
<td>Ketola 2009</td>
<td>1.88</td>
<td>57</td>
<td>-0.35 [-1.24, 0.54]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>96</td>
<td>92</td>
<td>100.0% [0.36 [-1.17, 1.89]]</td>
</tr>
<tr>
<td><strong>Heterogeneity:</strong> Tau² = 0.90; Chi² = 3.76, df = 1 (P = 0.05); I² = 73%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for overall effect:</strong> Z = 0.46 (P = 0.65)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix fig 5: Forest plots for function in the secondary comparison: a: 3 months, b: 6 months, c: one year, d: two years, e: five years, f: 10+ years. Vertical lines denote MID (8.3 points).
Appendix fig 6: Forest plots for work in the secondary comparison when two studies contributed data a: 6 months b: two years, c: five years

Appendix table 7: QUIPS summary of studies providing serious harms data

<table>
<thead>
<tr>
<th></th>
<th>Author and year of publication</th>
<th>HILL 2017</th>
<th>SHIELDS 2015</th>
<th>Both</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Biases</td>
<td>Rating of reporting</td>
<td>Rating of reporting</td>
<td>Rating of &quot;Risk of bias&quot;</td>
</tr>
<tr>
<td>1.</td>
<td>Study Participation</td>
<td>Unsure, but judged unlikely to incur significant bias.</td>
<td>Yes (large number of centres, judged likely to be representative)</td>
<td>Unclear ROB, not likely to affect results in a problematic way</td>
</tr>
<tr>
<td>2.</td>
<td>Study Attrition</td>
<td>Probably low risk given the tracking of patients who went elsewhere for care, and given follow-up was 30 days</td>
<td>Probably low risk given the tracking of patients who went elsewhere for care, and given follow-up was 30 days</td>
<td>Low RoB</td>
</tr>
<tr>
<td>3.</td>
<td>Prognostic Factor Measurement</td>
<td>Yes – arthroscopic procedure is the prognostic factor</td>
<td>Yes – arthroscopic procedure is the prognostic factor</td>
<td>Low RoB</td>
</tr>
<tr>
<td>4.</td>
<td>Outcome Measurement</td>
<td>Yes – based on hospital record + patient contact call</td>
<td>Yes – based on hospital record + patient contact call</td>
<td>Low RoB</td>
</tr>
<tr>
<td>5.</td>
<td>Study Confounding</td>
<td>Yes – total harms are of interest, no proper confounders</td>
<td>Yes – total harms are of interest, no proper confounders</td>
<td>Low RoB</td>
</tr>
<tr>
<td>6.</td>
<td>Statistical Analysis and Reporting</td>
<td>Unclear, judged not likely to lead to overestimation of harms</td>
<td>Unclear, judged not likely to lead to overestimation of harms</td>
<td>Low RoB</td>
</tr>
</tbody>
</table>
**Appendix table 8:** Harms by event type in the studies providing data. IP = incidence proportion point estimate (CIs were not calculated for the individual harms).

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Hill</th>
<th>IP %</th>
<th>Shields</th>
<th>IP %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total patients</strong></td>
<td>15015</td>
<td></td>
<td>10225</td>
<td></td>
</tr>
<tr>
<td><strong>Serious harms:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>2</td>
<td>0,01</td>
<td>4</td>
<td>0,04</td>
</tr>
<tr>
<td>Bleeding transfusion</td>
<td>7</td>
<td>0,05</td>
<td>5</td>
<td>0,05</td>
</tr>
<tr>
<td>Sepsis</td>
<td>0</td>
<td>0,00</td>
<td>1</td>
<td>0,01</td>
</tr>
<tr>
<td>Septic shock</td>
<td>3</td>
<td>0,02</td>
<td>2</td>
<td>0,02</td>
</tr>
<tr>
<td>Deep infection</td>
<td>1</td>
<td>0,01</td>
<td>1</td>
<td>0,01</td>
</tr>
<tr>
<td>Organ/space surgical site infection</td>
<td>3</td>
<td>0,02</td>
<td>2</td>
<td>0,02</td>
</tr>
<tr>
<td>Wound dehiscence</td>
<td>1</td>
<td>0,01</td>
<td>1</td>
<td>0,01</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>21</td>
<td>0,14</td>
<td>8</td>
<td>0,08</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>20</td>
<td>0,13</td>
<td>7</td>
<td>0,07</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>3</td>
<td>0,02</td>
<td>4</td>
<td>0,04</td>
</tr>
<tr>
<td>Cardiac arrest requiring CPR</td>
<td>1</td>
<td>0,01</td>
<td>2</td>
<td>0,02</td>
</tr>
<tr>
<td>Cerebral vascular accident</td>
<td>4</td>
<td>0,03</td>
<td>2</td>
<td>0,02</td>
</tr>
<tr>
<td>Acute renal failure</td>
<td>2</td>
<td>0,01</td>
<td>1</td>
<td>0,01</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>13</td>
<td>0,09</td>
<td>7</td>
<td>0,07</td>
</tr>
<tr>
<td>Unplanned intubation</td>
<td>7</td>
<td>0,05</td>
<td>3</td>
<td>0,03</td>
</tr>
<tr>
<td>Ventilator &gt;48 hours</td>
<td>2</td>
<td>0,01</td>
<td>1</td>
<td>0,01</td>
</tr>
<tr>
<td>Peripheral nerve injury</td>
<td>2</td>
<td>0,01</td>
<td>2</td>
<td>0,02</td>
</tr>
<tr>
<td><strong>Other harms</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Superficial infection</td>
<td>24</td>
<td>0,16</td>
<td>17</td>
<td>0,17</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>19</td>
<td>0,13</td>
<td>15</td>
<td>0,15</td>
</tr>
<tr>
<td>Re-operations</td>
<td>40</td>
<td>0,27</td>
<td>34</td>
<td>0,33</td>
</tr>
</tbody>
</table>
**Literature search description**

Searches for randomised controlled trials were conducted in MEDLINE, Embase, PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), CINAHL, Physiotherapy Evidence Database (PEDro), ClinicalTrials.gov and WHO International Clinical Trials Registry Platform (WHO ICTRP). The *Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision)* was used in MEDLINE and PubMed, and adapted for other sources where needed.

Searches for studies reporting adverse effects were conducted in MEDLINE, Embase, PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment (HTA), CINAHL and Physiotherapy Evidence Database (PEDro).

Animal studies and publication types unlikely to contain relevant information (such as news, comments, letters to the editor and editorials) were removed. No other limits were applied.

Two sets of searches were undertaken on 12-14 July 2017. Searches for randomised controlled trials retrieved 2441 records in total, and 695 records remained for assessment after deduplication. Searches for adverse effects retrieved 3400 records in total, and 1597 records remained for assessment after deduplication.

The searches were updated on 23 July 2018 by rerunning the original searches and deduplicating the results against the original search results. This resulted in 147 new records being retrieved by the searches for randomised controlled trials, and 166 new records by the searches for adverse effects.

---

1. Full search strategies for randomised controlled trials

1.1 Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to July 20,2018>

OvidSP

Date of search: 23 July 2018 (first search: 12 July 2017)
Number of records retrieved: 414

Search strategy:
1 Shoulder Impingement Syndrome/ (1604)
2 ((coracohumeral or coracoid or internal or outlet or posterosuperior glenoid or rotator cuff or subacromial or shoulder) adj5 impinge$).ti,ab,kf. (1899)
3 (Subacromial adj3 (pain or bursitis)).ti,ab,kf. (322)
4 Rotator cuff disease.ti,ab,kf. (425)
5 or/1-4 (3140)
6 Randomized Controlled Trial.pt. (464603)
7 Controlled Clinical Trial.pt. (92507)
8 placebo.ab. (190294)
9 randomized.ab. (416440)
10 Clinical Trials as Topic/ (184192)
11 randomly.ab. (293862)
12 trial.ti. (184782)
13 or/6-12 (1161270)
14 5 and 13 (427)
15 exp Animals/ not Humans/ (4475707)
16 (news or comment or letter or editorial or case report).pt. or case report.ti. (2021865)
17 14 not (15 or 16) (414)
1.2. Embase <1974 to 2018 July 20>

OvidSP
Date of search: 23 July 2018 (first search: 12 July 2017)
Number of records retrieved: 544
Search Strategy:

1. shoulder impingement syndrome/ (2470)
2. ((coracohumeral or coracoid or internal or outlet or posterosuperior glenoid or rotator cuff or subacromial or shoulder) adj5 impinge$).ti,ab,kw. (2383)
3. (Subacromial adj3 (pain or bursitis)).ti,ab,kw. (400)
4. Rotator cuff disease.ti,ab,kw. (514)
5. or/1-4 (4049)
6. randomized controlled trial/ (511016)
7. controlled clinical trial/ (460066)
8. randomized.ab. (594320)
9. placebo.ab. (267572)
10. "clinical trial (topic)/ (94494)
11. randomly.ab. (384315)
12. trial.ti. (253486)
13. or/6-12 (1516450)
14. 5 and 13 (569)
15. (animal/ or animal experiment/ or animal model/ or animal tissue/ or nonhuman/) not exp human/ (5938340)
16. (editorial or letter).pt. or case report.ti. (1859737)
17. 14 not (15 or 16) (555)
18. remove duplicates from 17 (544)

1.3. Cochrane Central Register of Controlled Trials (CENTRAL)

Issue 6 of 12, June 2018
Wiley Cochrane Library
Date of search: 23 July 2018 (first search: 12 July 2017)
Number of records retrieved: 530
Search strategy:

#1 [mh "Shoulder Impingement Syndrome"] 295
#2 ((coracohumeral or coracoid or internal or outlet or posterosuperior glenoid or rotator cuff or subacromial or shoulder) near/5 impinge*) 526
#3 Subacromial near/3 (pain or bursitis) 114
#4 Rotator next cuff next disease 72
#5 {or #1-#4} 618
#6 {or #1-#4} in Trials 530

1.4. PubMed

Date of search: 23 July 2018 (first search: 12 July 2017)
Number of records retrieved: 396
Search strategy:

#16 (#14 NOT #15) 396
#15 animals [mh] NOT humans [mh] 4476713
#14 #5 AND #13 400
#13 (#6 or #7 or #8 or #9 or #10 or #11 or #12) 1169407
#12 trial[Title] 184630
#11 randomly[Title/Abstract] 294498
#10 clinical trials as topic [mesh: noexp] 184219
#9 placebo[Title/Abstract] 195492
#8 randomized[Title/Abstract] 449425
#7 controlled clinical trial[Publication Type] 552820
#6 randomized controlled trial[Publication Type] 465155
#5 (#1 OR #2 OR #3 OR #4) 2690
#4 rotator cuff disease[Title/Abstract] 425
#3 (subacromial pain[Title/Abstract] OR subacromial bursitis[Title/Abstract] OR subacromial impingement[Title/Abstract]) 886
#2 (coracohumeral impingement[Title/Abstract] OR coracoid impingement[Title/Abstract] OR internal impingement[Title/Abstract] OR outlet impingement[Title/Abstract] OR posterosuperior glenoid impingement[Title/Abstract] OR rotator cuff impingement[Title/Abstract] OR shoulder impingement[Title/Abstract]) 760
#1 Shoulder Impingement Syndrome[MeSH Terms] 1605
1.5 Physiotherapy Evidence Database (PEDro)
Date of search: 23 July 2018 (first search: 12 July 2017)
Number of records retrieved: 328
Search strategy:
Advanced search option was used and terms were searched separately. Due to limited
database search functionality only the most relevant search terms were used.

Abstract & Title:
shoulder impingement
subacromial impingement
subacromial pain
rotator cuff impingement
rotator cuff disease
Method:
clinical trial

1.6. CINAHL Plus
EBSCOhost
Date of search: 23 July 2018 (first search: 12 July 2017)
Number of records retrieved: 252
Search strategy:
S13 S5 AND S12 252
S12 S6 OR S7 OR S8 OR S9 OR S10 OR S11 294,191
S11 TI trial 80,768
S10 AB randomly 64,841
S9 AB placebo 41,049
S8 AB randomized 117,050
S7 PT clinical trial 86,303
S6 PT randomized controlled trial 84,311
S5 S1 OR S2 OR S3 OR S4 1,675
S4 TI rotator cuff disease OR AB rotator cuff disease 217
S3 TI ( Subacromial N3 (pain OR bursitis) ) OR AB ( Subacromial N3 (pain OR bursitis) ) 159
S2 TI ( (coracohumeral OR coracoid OR internal OR outlet OR posterosuperior glenoid OR rotator cuff OR subacromial OR shoulder) N5 impinge*) ) OR
AB ( (coracohumeral OR coracoid OR internal OR outlet OR posterosuperior glenoid OR rotator cuff OR subacromial OR shoulder) N5 impinge*)) 981
S1 MH shoulder impingement syndrome 1,12
1.7. ClinicalTrials.gov
https://www.clinicaltrials.gov/ct
Date of search: 23 July 2018 (first search: 13 July 2017)
Number of records retrieved: 272
Search strategy:
Advanced search option was used. Terms were entered into the “Other Terms” field on the search page.
coracohumeral OR coracoid OR internal OR outlet OR posterosuperior glenoid OR rotator cuff OR subacromial OR shoulder) AND impingement
subacromial AND (pain OR bursitis)

1.8. WHO International Clinical Trials Registry Platform (WHO ICTRP)
http://www.who.int/ictrp/en/
Date of search: 23 July 2018 (first search: 13 July 2017)
Number of records retrieved: 206
Search strategy:
Basic search option was used.
coracohumeral impingement OR coracoid impingement OR internal impingement OR outlet impingement OR posterosuperior glenoid impingement OR rotator cuff impingement OR subacromial impingement OR shoulder impingement OR subacromial pain OR subacromial bursitis
2. Full search strategies for adverse events

2.1. Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to July 20,2018>

OvidSP
Date of search: 23 July 2018 (first search: 14 July 2017)
Number of records retrieved: 1002
Search strategy:

1 Shoulder Impingement Syndrome/ (1604)
2 ((coracohumeral or coracoid or internal or outlet or posterosuperior glenoid or rotator cuff or subacromial or shoulder) adj5 impinge$).ti,ab,kf. (1899)
3 (Subacromial adj3 (pain or bursitis)).ti,ab,kf. (322)
4 Rotator cuff disease.ti,ab,kf. (425)
5 or/1-4 (3140)
6 Long Term Adverse Effects/ (348)
7 exp Intraoperative Complications/ (48517)
8 exp Postoperative Complications/ (497299)
9 Treatment Failure/ (32130)
10 Decompression, Surgical/ae (1404)
11 Reoperation/ (78861)
12 Surgical Wound Infection/ (33502)
13 (reoperation or reoperations or reoperated or re-operation or re-operations or re-operated).ti,ab. (35631)
14 (infection or infections or infected).ti,ab. (1393846)
15 ((nerve or nerves) adj3 (injury or injuries or injured)).ti,ab. (24436)
16 (shoulder adj3 (stiff or stiffness)).ti,ab. (565)
17 ((failed or failure) adj3 (surgery or operation$ or treatment$ or rate$1)).ti,ab. (69601)
18 (safe or safety or risk or risks or harm or harms or complication$).ti,ab. (2962276)
19 ((adverse or undesirable or serious or fatal or harmful) adj3 (effect$ or reaction$ or event$ or outcome$ or incident$)).ti,ab. (413613)
20 side effect$.ti,ab. (221873)
21 (ae or co).fs. (3231492)
22 or/6-21 (6705778)
23 5 and 22 (1030)
24 exp Animals/ not Humans/ (4475707)
25 (news or letter or comment or editorial).pt. (1819745)
26 23 not (24 or 25) (1004)
27 remove duplicates from 26 (1002)

2.2 Embase <1974 to 2018 July 20>

OvidSP
Date of search: 23 July 2018 (first search: 14 July 2017)
Number of records retrieved: 1222
Search strategy:

1 shoulder impingement syndrome/ (2470)
2 ((coracohumeral or coracoid or internal or outlet or posterosuperior glenoid or rotator cuff or subacromial or shoulder) adj5 impinge$).ti,ab,kw. (2383)
3 (Subacromial adj3 (pain or bursitis)).ti,ab,kw. (400)
Rotator cuff disease. (514)
or/1-4 (4049)
side effect/ (255218)
exp postoperative complication/ (615989)
peroperative complication/ (36248)
treatment failure/ (99694)
adverse outcome/ (39587)
reoperation/ (72392)
surgical infection/ (39515)
(infection or infections or infected).ti,ab. (1755077)
(reoperation or reoperations or reoperated or re-operation or re-operations or re-operated).ti,ab. (49566)
((nerve or nerves) adj3 (injury or injuries or injured)).ti,ab. (31047)
(shoulder adj3 (stiff or stiffness)).ti,ab. (744)
((failed or failure) adj3 (surgery or operation$ or treatment$ or rate$1)).ti,ab. (102815)
(safe or safety or risk or risks or harm or harms or complication$).ti,ab. (4227057)
((adverse or undesirable or serious or fatal or harmful) adj3 (effect$ or reaction$ or event$ or outcome$ or incident$)).ti,ab. (631605)
side effect$.ti,ab. (323943)
(ae or co).fs. (2818947)
or/6-21 (7901730)
5 and 22 (1265)
(animal/ or animal experiment/ or animal model/ or animal tissue/ or nonhuman/) not exp human/ (5938340)
editorial or letter).pt. (1601120)
23 not (24 or 25) (1244)
remove duplicates from 26 (1222)

2.3 Cochrane Database of Systematic Reviews (CDSR)
Issue 7 of 12, July 2018
Wiley Cochrane Library
Date of search: 23 July 2018 (first search: 14 July 2017)
Number of records retrieved: 39
Search strategy:
#1 [mh "Shoulder Impingement Syndrome"] 295
#2 ((coracohumeral or coracoid or internal or outlet or posterosuperior glenoid or rotator cuff or subacromial or shoulder) near/5 impinge*) 526
#3 Subacromial near/3 (pain or bursitis) 114
#4 Rotator next cuff next disease 72
#5 {or #1-#4} 618
#6 [mh ^"Long Term Adverse Effects"] 15
#7 [mh "Intraoperative Complications"] 4374
#8 [mh "Postoperative Complications"] 38013
#9 [mh ^"Treatment Failure"] 3294
#10 [mh "Decompression, Surgical"/AE] 166
#11 [mh ^Reoperation] 2022
#12 [mh ^"Surgical Wound Infection"] 3472
#13 (infection or infections or infected) 99364
2.4 Cochrane Central Register of Controlled Trials (CENTRAL)
Issue 6 of 12, June 2018
Wiley Cochrane Library
Date of search: 23 July 2018 (first search: 14 July 2017)
Number of records retrieved: 157
Search strategy:

#1 [mh "Shoulder Impingement Syndrome"] 295
#2 ((coracohumeral or coracoid or internal or outlet or posterosuperior glenoid or rotator cuff or subacromial or shoulder) near/5 impinge*) 526
#3 Subacromial near/3 (pain or bursitis) 114
#4 Rotator next cuff next disease 72
#5 {or #1-#4} 618
#6 [mh ^"Long Term Adverse Effects"] 15
#7 [mh "Intraoperative Complications"] 4374
#8 [mh "Postoperative Complications"] 38013
#9 [mh ^"Treatment Failure"] 3294
#10 [mh "Decompression, Surgical"/AE] 166
#11 [mh ^Reoperation] 2022
#12 [mh ^"Surgical Wound Infection"] 3472
#13 (infection or infections or infected) 99364
#14 (reoperation or reoperations or reoperated or re-operation or re-operations or re-operated) 5171
#15 (nerve or nerves) near/3 (injury or injuries or injured) 1419
#16 shoulder near/3 (stiff or stiffness) 130
#17 (failed or failure) near/3 (surgery or operation* or treatment* or rate or rates) 21362
#18 (safe or safety or risk or risks or harm or harms or complication or complications) 442757
#19 ((adverse or undesirable or serious or fatal or harmful) near/3 (effect or effects or reaction or reactions or event or events or outcome or outcomes or incident or incidents)) 250445

#20 ("side effect" or "side effects") 111109
#21 [mh /CO] 52977
#22 [mh /AE] 126563
#23 {or #6-#22} 602737
#24 #5 and #23 220
#25 #5 and #23 in Cochrane Reviews (Reviews and Protocols) 39
2.5 Database of Abstracts of Reviews of Effect (DARE)
Issue 2 of 4, April 2015
Wiley Cochrane Library
Date of search: 23 July 2018 (first search: 14 July 2017)
Number of records retrieved: 20
Search strategy:

#1 [mh "Shoulder Impingement Syndrome"] 295
#2 ((coracohumeral or coracoid or internal or outlet or posterosuperior glenoid or rotator cuff or subacromial or shoulder) near/5 impinge*) 526
#3 Subacromial near/3 (pain or bursitis) 114
#4 Rotator next cuff next disease 72
#5 {or #1-#4} 618
#6 [mh "^"Long Term Adverse Effects"] 15
#7 [mh "Intraoperative Complications"] 4374
#8 [mh "Postoperative Complications"] 38013
#9 [mh "^"Treatment Failure"] 3294
#10 [mh "Decompression, Surgical"/AE] 166
#11 [mh ^Reoperation] 2022
#12 [mh "^"Surgical Wound Infection"] 3472
#13 (infection or infections or infected) 99364
#14 (reoperation or reoperations or reoperated or re-operation or re-operations or re-operated) 5171
#15 (nerve or nerves) near/3 (injury or injuries or injured) 1419
#16 shoulder near/3 (stiff or stiffness) 130
#17 (failed or failure) near/3 (surgery or operation* or treatment* or rate or rates) 21362
#18 (safe or safety or risk or risks or harm or harms or complication or complications) 442757
#19 ((adverse or undesirable or serious or fatal or harmful) near/3 (effect or effects or reaction or reactions or event or events or outcome or outcomes or incident or incidents)) 250445
#20 ("side effect" or "side effects") 111109
#21 [mh /CO] 52977
#22 [mh /AE] 126563
#23 {or #6-#22} 602737
#24 #5 and #23 220
#25 #5 and #23 in Other Reviews 20

2.6 Health Technology Assessment Database (HTA)
Issue 4 of 4, October 2016
Wiley Cochrane Library
Date of search: 23 July 2018 (first search: 14 July 2017)
Number of records retrieved: 1
Search strategy:

#1 [mh "Shoulder Impingement Syndrome"] 295
#2 ((coracohumeral or coracoid or internal or outlet or posterosuperior glenoid or rotator cuff or subacromial or shoulder) near/5 impinge*) 526
#3 Subacromial near/3 (pain or bursitis) 114
#4 Rotator next cuff next disease 72
#5 {or #1-#4} 618
#6 [mh ^"Long Term Adverse Effects"] 15
#7 [mh "Intraoperative Complications"] 4374
#8 [mh "Postoperative Complications"] 38013
#9 [mh ^"Treatment Failure"] 3294
#10 [mh "Decompression, Surgical"/AE] 166
#11 [mh ^Reoperation] 2022
#12 [mh ^"Surgical Wound Infection"] 3472
#13 (infection or infections or infected) 99364
#14 (reoperation or reoperations or reoperated or re-operation or re-operations or re-operated) 5171
#15 (nerve or nerves) near/3 (injury or injuries or injured) 1419
#16 shoulder near/3 (stiff or stiffness) 130
#17 (failed or failure) near/3 (surgery or operation* or treatment* or rate or rates) 21362
#18 (safe or safety or risk or risks or harm or harms or complication or complications) 442757
#19 ((adverse or undesirable or serious or fatal or harmful) near/3 (effect or effects or reaction or reactions or event or events or outcome or outcomes or incident or incidents)) 250445
#20 ("side effect" or "side effects") 111109
#21 [mh /CO] 52977
#22 [mh /AE] 126563
#23 {or #6-#22} 602737
#24 #5 and #23 220
#25 #5 and #23 in Technology Assessments 1

2.7 PubMed
Date of search: 23 July 2018 (first search: 14 July 2017)
Number of records retrieved: 847
Search strategy:

#25 Search #23 NOT #24 847
#24 Search animals [mh] NOT humans [mh] 4476713
#23 Search #5 and #22 851
#22 Search #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 7134497
#21 Search ae[MeSH Subheading] OR co[MeSH Subheading] 3764616
#20 Search side effect[Title/Abstract] OR side effects[Title/Abstract] 226984
#19 Search adverse effect[Title/Abstract] OR adverse effects[Title/Abstract] OR adverse reaction[Title/Abstract] OR adverse reactions[Title/Abstract] OR
#16 Search stiff shoulder[Title/Abstract] OR shoulder stiffness[Title/Abstract] 386
#15 Search nerve injury[Title/Abstract] OR nerve injuries[Title/Abstract] OR injured nerves[Title/Abstract] 20027
#14 Search infection[Title/Abstract] OR infections[Title/Abstract] OR infected[Title/Abstract] 1421552
#13 Search reoperation[Title/Abstract] OR reoperations[Title/Abstract] OR reoperated[Title/Abstract] OR re-operation[Title/Abstract] OR re-operations[Title/Abstract] OR re-operated[Title/Abstract] 35876
#12 Search Surgical Wound Infection[MeSH Terms] 33512
#11 Search Reoperation[MeSH Terms] 79461
#10 Search Decompression, Surgical/a[MeSH Terms] 3596
#9 Search Treatment Failure[MeSH Terms] 32194
#8 Search Postoperative Complications[MeSH Terms] 497480
#7 Search Intraoperative Complications[MeSH Terms] 48536
#6 Search Long Term Adverse Effects[MeSH Terms] 348
#5 Search #1 or #2 or #3 or #4 2690
#4 Search rotator cuff disease[Title/Abstract] 425
#3 Search subacromial pain[Title/Abstract] OR subacromial bursitis[Title/Abstract] OR subacromial impingement[Title/Abstract] 886
#2 Search coracoacromial impingement[Title/Abstract] OR coracoid impingement[Title/Abstract] OR internal impingement[Title/Abstract] OR outlet impingement[Title/Abstract] OR posterosuperior glenoid impingement[Title/Abstract] OR rotator cuff impingement[Title/Abstract] OR shoulder impingement[Title/Abstract] 760
#1 Search Shoulder Impingement Syndrome[MeSH Terms] 1605

2.8 CINAHL Plus
EBSCOhost
Date of search: 23 July 2018 (first search: 14 July 2017)
Number of records retrieved: 406
Search strategy:
S24 S5 AND S23 406
S23 S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 1,388,464
S22 MW "ae" OR MW "co" 649,078
S21 TI side effect* OR AB side effect* 31,229
S20 TI ( (adverse or undesirable or serious or fatal or harmful) N3 (effect* or reaction* or event* or outcome* or incident*) ) OR AB ( (adverse or undesirable or serious or fatal or harmful) N3 (effect* or reaction* or event* or outcome* or incident*) ) 97,292
S19 TI ( safe or safety or risk or risks or harm or harms or complication or complications ) OR AB ( safe or safety or risk or risks or harm or harms or complication or complications ) 747,649
S18 TI ( (failed or failure) N3 (surgery or operation* or treatment* or rate*) ) OR AB ( (failed or failure) N3 (surgery or operation* or treatment* or rate*) ) 15,249
S17 TI ( (nerve or nerves) N3 (injury or injuries or injured) ) OR AB ( (nerve or nerves) N3 (injury or injuries or injured) ) 226
S16 TI ( (reoperation or reoperations or reoperated or re-operation or re-operations or re-operated ) OR AB ( reoperation or reoperations or reoperated or re-operation or re-operations or re-operated ) 4,493
S15 TI ( infection or infections or infected ) OR AB ( infection or infections or infected ) 172,486
S14 (MH “Surgical Wound Infection”) 8,405
S13 (MH "Reoperation") 13,462
S12 (MH "Decompression, Surgical/AE") 445
S11 (MH "Treatment Failure") 11,242
S10 (MH "Treatment Complications, Delayed") 2,001
S9 (MH "Postoperative Complications+") 87,604
S8 (MH "Intraoperative Complications+") 9,545
2.9 Physiotherapy Evidence Database (PEDro)
Date of search: 23 July 2018 (first search: 14 July 2017)
Number of records retrieved: 28
Search strategy:
Advanced search option was used and terms were searched separately. Due to limited database search functionality only the most relevant search terms were used.

Title & Abstract:
adverse shoulder impingement
adverse subacromial
adverse rotator cuff
complication* shoulder impingement
complication* subacromial
complication* rotator cuff

When searching:
Match all search terms (AND)