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

Trial characteristics:
study objectives
inclusion and exclusion criteria
definition of SAPS
number of patients allocated to intervention and control groups
follow-up time
sample size estimations
study sponsorships and conflict of interest statements and trial registry identifiers.

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

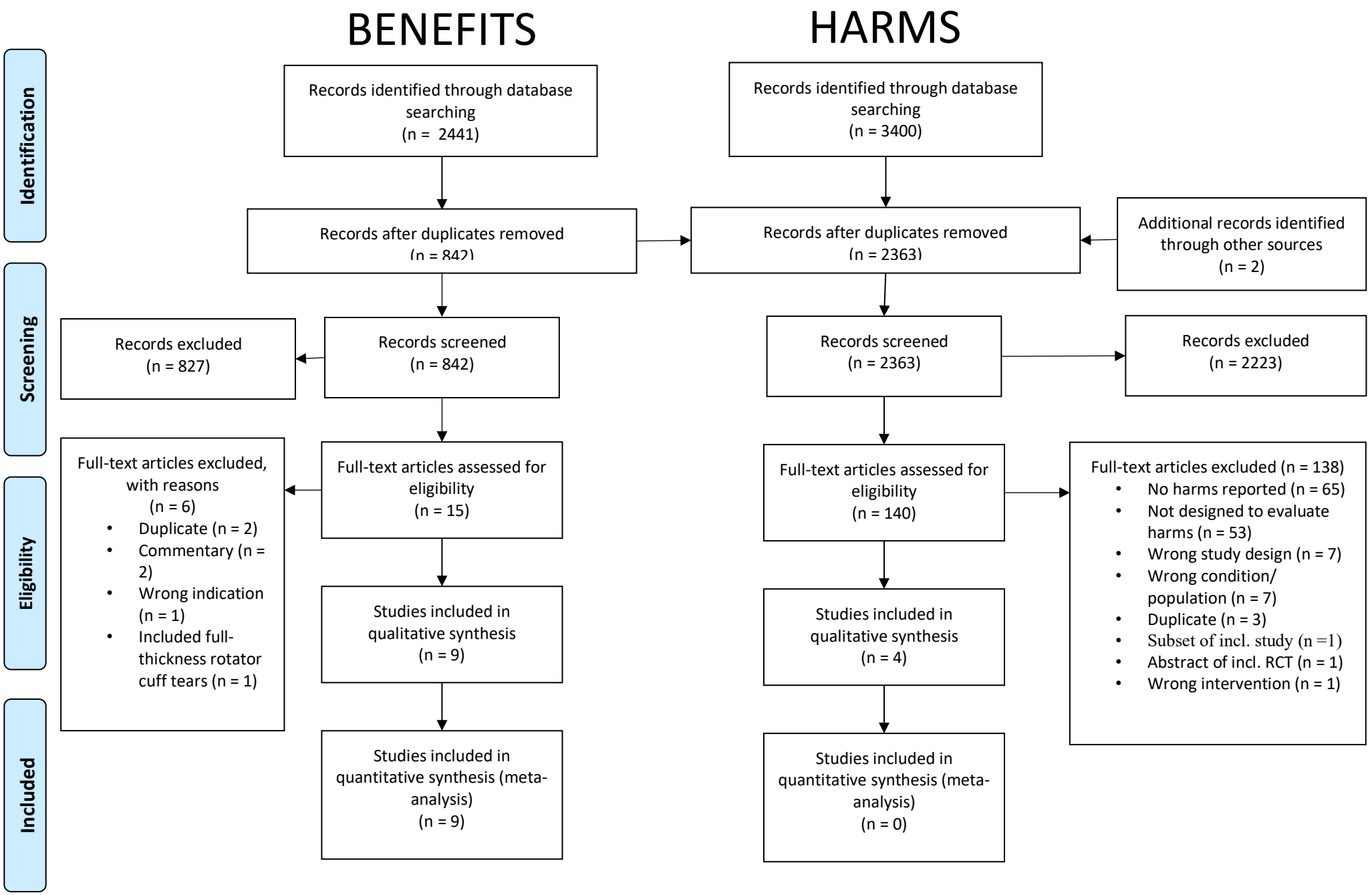
Pain
overall pain
average pain in a preceding period
unspecified pain
pain with activity in a preceding period
worst/highest pain in a preceding period
night pain in a preceding period
rest pain in a preceding period
current pain

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



Appendix table 3: Study characteristics

Trial	Interventions	Minimum duration of symptoms for eligibility	Required treatments for eligibility	Pain measure	Mean baseline pain§	Function measure	Mean baseline function †*	HRQoL measure	Mean baseline HRQoL
Paavola et al. 2018	ASAD (n = 59) DA (n = 63) ET (71)	3 months	No relief from non-operative means (including physiotherapy, non-steroidal anti-inflammatory medication, corticosteroid injections, rest)	Pain on activity during previous 24 hours (VAS 0-100)	7.12 (2.36) 7.23 (2.17) 7.24 (2.08)	Constant score	32.2 (28.2-36.2) 31.7 (28.2-35.2) 35.2 (31.4-39.0)	15D	0.89 (0.87-0.91) 0.89 (0.87-0.91) 0.88 (0.86-0.90)
Beard et al. 2017	ASAD (n = 106) DA (n = 103) WaS (n = 104)	3 months	Completed non-op management programme that included exercise therapy *and* at least 1 steroid injection	Average pain during previous 4 weeks (VAS 0-10)	6.0 (1.9) 5.8 (2.0) 6.6 (1.7)	Constant score	39.4 (13.9) 43.1 (15.5) 38.3 (14.2)	EQ-15D-3L	0.52 (0.3) 0.55 (0.29) 0.50 (0.3)
Farfaras et al. 2016	ASAD (n = 29) OSAD (n = 24) ET (n = 34)	6 months	None reported	Not measured		Constant score	56 (11.3) 48 (15.7) 56 (13.1)		
Ketola et al. 2009	ASAD (n = 70) ET (n = 70)	3 months	Chronic symptoms not relieved by rest, anti-inflammatory medication, subacromial glucocorticoid injection and physiotherapy (physiotherapy included exercise, massage, heat and transcutaneous electrical stimulation)	Pain unspecified (VAS 0-10)	6.4 6.5	Shoulder Disability Questionnaire	22.0 17.5		
Henkus et al. 2009	ASAD (n = 30) BT (n= 26)		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	Pain unspecified (VAS 1-10)	7.9 6.8	Constant score	57 56		

Taverna et al. 2007	ASAD (n = 30) MT (n = 30)	6 months	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	Pain unspecified (VAS 0-10)	8.2 (0.8) 8.4 (0.9)	Constant score	54 (4) 51 (4)	
Haahr et al. 2005	ASAD (n = 41) ET (n = 43)	6 months	None required; previous treatment (within the preceding 3 years) with rest, non-steroidal anti-inflammatory medication, subacromial injection and physiotherapy were permitted	Highest pain within previous 24 hours (VAS 0-15 at 3 and 6 months follow-up) Average pain over previous 7 days (VAS 0-9 at 1 and 5 years follow-up)	6.56 (5.78-7.33) 7.22 (6.56-7.78)	Constant score	33.7 (29.2-38.2) 34.7 (30.4-39.0)	
Peters & Kohn 1997	SAD (n = 32) CT (n = 40)	Unclear; patients in the SAD group had completed conservative treatment of approximately 6 months duration prior to surgery	None reported	Not measured				54 59
Brox et al. 1993	ASAD (n = 45) ET (n = 50) Laser (n = 30)	3 months	None reported	Pain on activity during the previous 7 days (VAS 1-9)	7.25 (1.9) 6.89 (2.3) 6.96 (2.5)	Neer shoulder score	63.4 (10.8) 66.3 (8.8) 64.7 (10.6)	

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

Trial	Identical care for operative and non-operative groups?	Description of post-operative care and non-operative treatment
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.*
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 ("seven were generally required").
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

Haahr et al. 2005	No	POST-OPERATIVE REHABILITATION: at 10 days post-operative, patients received instructions from a physiotherapist on how to perform a progressive muscle strengthening programme. 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.
Peters & Kohn 1997	No	POST-OPERATIVE REHABILITATION: range of motion exercises commenced on the day of the surgery, progressive strengthening commenced from the fourth post-operative week. 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.
Brox et al. 1993	No	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. 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.

Appendix table 4: Risk of Bias assessments of the trials

	Comparison: ASAD vs placebo surgery	
	Publication:	**Beard 2017**	**Paavola 2018**
Selection bias	All outcomes	Low	Low
Performance bias	Subjective	Low	Low
	Harms	Low	Low
Detection bias	Subjective	Low	Low
	Harms	Low	Low
Attrition bias	All outcomes	Low	Low
Reporting bias	All outcomes	Low	Low
Other biases	All outcomes	Low	Low

	Comparison: (A)SAD vs nonoperative treatment							
	Publication:	**Beard 2017**	**Brox 1993**	**Farfaras 2016**	**Haahr 2005**	**Ketola 2009**	**Paavola 2018**	**Peters 1997**
Selection bias	All outcomes	Low	Unclear	High	Low	Low	Low	Unclear
Performance bias	Subjective	High	High	High	High	High	High	High
	Harms	Low					Low	
Detection bias	Subjective	High	High	High	High	High	High	High
	Harms	Low					Low	
Attrition bias	All outcomes	Low	Low	High	Low	High	Low	Unclear
Reporting bias	All outcomes	Low	Unclear	Unclear	High	Unclear	Low	High
Other biases	All outcomes	Low	High	High	Low	Unclear	Unclear	Low

Appendix table 5: Summary of Findings for outcomes with data from one study in the primary comparison and serious harms in the RCTs

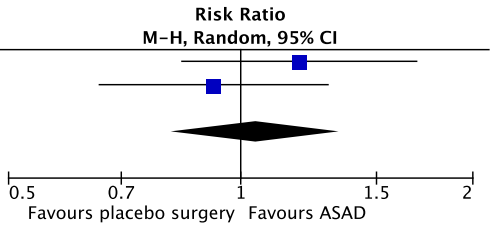
Outcome Timeframe	**Measurement instruments and relative effects**	**Absolute effect estimates** Placebo Surgery Surgery	**Certainty in effect estimates** (Quality of evidence)	**Plain text summary**
Global perceived effect at 2 years	Relative risk: 0.98 (CI 95% 0.81 - 1.18) Based on data from 116 patients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

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);

a:

Study or Subgroup	(A)SAD Events	(A)SAD Total	Placebo Surgery Events	Placebo Surgery Total	Weight	Risk Ratio M-H, Random, 95% CI
Beard 2018	39	87	35	93	48.8%	1.19 [0.84, 1.69]
Paavola 2018	29	56	32	57	51.2%	0.92 [0.66, 1.30]
Total (95% CI)		**143**		**150**	**100.0%**	**1.04 [0.81, 1.34]**
Total events	68		67			

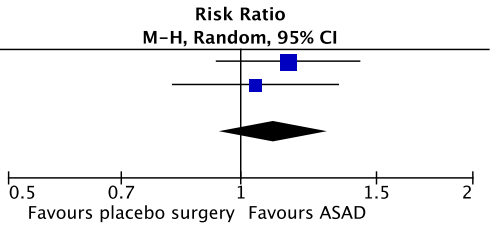
Heterogeneity: Tau² = 0.00; Chi² = 1.06, df = 1 (P = 0.30); I² = 6%
Test for overall effect: Z = 0.34 (P = 0.73)



b:

Study or Subgroup	(A)SAD Events	(A)SAD Total	Placebo Surgery Events	Placebo Surgery Total	Weight	Risk Ratio M-H, Random, 95% CI
Beard 2018	61	87	56	92	57.2%	1.15 [0.93, 1.43]
Paavola 2018	39	55	38	56	42.8%	1.04 [0.82, 1.34]
Total (95% CI)		**142**		**148**	**100.0%**	**1.10 [0.94, 1.30]**
Total events	100		94			

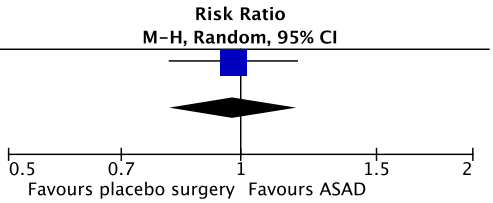
Heterogeneity: Tau² = 0.00; Chi² = 0.34, df = 1 (P = 0.56); I² = 0%
Test for overall effect: Z = 1.21 (P = 0.23)



c:

Study or Subgroup	(A)SAD Events	(A)SAD Total	Placebo Surgery Events	Placebo Surgery Total	Weight	Risk Ratio M-H, Random, 95% CI
Paavola 2018	45	58	46	58	100.0%	0.98 [0.81, 1.18]
Total (95% CI)		**58**		**58**	**100.0%**	**0.98 [0.81, 1.18]**
Total events	45		46			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.23 (P = 0.82)

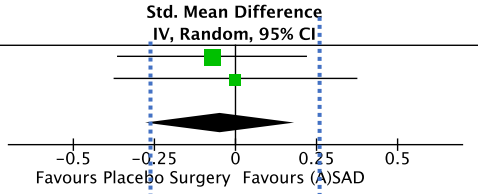


Appendix fig 2: Forest plots for global perceived effect in the primary comparison. **a:** 6 months, **b:** 1 year, **c:** 2 years

a:

Study or Subgroup	(A)SAD Mean	(A)SAD SD	(A)SAD Total	Placebo Surgery Mean	Placebo Surgery SD	Placebo Surgery Total	Weight	Std. Mean Difference IV, Random, 95% CI
Beard 2018	0.65	0.29	89	0.67	0.26	93	62.3%	-0.07 [-0.36, 0.22]
Paavola 2018	0.92	0.074	55	0.92	0.037	55	37.7%	0.00 [-0.37, 0.37]
Total (95% CI)			**144**			**148**	**100.0%**	**-0.05 [-0.27, 0.18]**

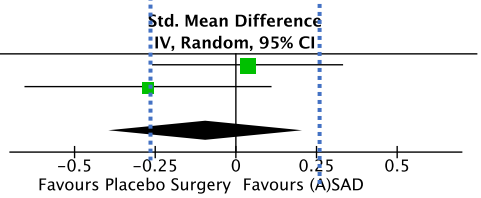
Heterogeneity: Tau² = 0.00; Chi² = 0.09, df = 1 (P = 0.76); I² = 0%
Test for overall effect: Z = 0.39 (P = 0.70)



b:

Study or Subgroup	(A)SAD Mean	(A)SAD SD	(A)SAD Total	Placebo Surgery Mean	Placebo Surgery SD	Placebo Surgery Total	Weight	Std. Mean Difference IV, Random, 95% CI
Beard 2018	0.74	0.28	86	0.73	0.27	92	58.0%	0.04 [-0.26, 0.33]
Paavola 2018	0.92	0.0366	54	0.93	0.0363	53	42.0%	-0.27 [-0.65, 0.11]
Total (95% CI)			**140**			**145**	**100.0%**	**-0.09 [-0.39, 0.21]**

Heterogeneity: Tau² = 0.02; Chi² = 1.58, df = 1 (P = 0.21); I² = 37%
Test for overall effect: Z = 0.61 (P = 0.54)



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

Outcome Timeframe	**Study results and measurements**	**Absolute effect estimates** Exercise Therapy	Surgery	**Certainty in effect estimates** (Quality of evidence)	**Plain text summary**
Pain at 3 months	Measured by: VAS and NRS scaled to 0-10 Scale: 0-10 Lower better Based on data from 361 patients in 4 studies	**4.5** Mean	**3.9** Mean Difference: **MD 0.55 lower** (CI 95% 1.24 lower - 0.14 higher)	**Moderate** Due to serious risk of bias[1]	SAD surgery probably has little or no effect on pain at 3 months
Pain at 6 months	Measured by: VAS and NRS scaled to 0-10 Scale: 0-10 Lower better Based on data from 399 patients in 4 studies	**3.7** Mean	**3.1** Mean Difference: **MD 0.56 lower** (CI 95% 1.09 lower - 0.02 lower)	**Moderate** Due to serious risk of bias[1]	SAD surgery probably has little or no effect on pain at 6 months
Pain at 1 year	Measured by: VAS and NRS scaled to 0-10 Scale: 0-10 Lower better Based on data from 316 patients in 3 studies	**3.7** Mean	**2.7** Mean Difference: **MD 1.01 lower** (CI 95% 1.60 lower - 0.42 lower)	**Low** Due to serious risk of bias and serious imprecision[2]	SAD surgery may have little or no effect on pain at 1 year
Pain at 2 years	Measured by: VAS and NRS scaled to 0-10 Scale: 0-10 Lower better Based on data from 352 patients in 3 studies	**2.8** Mean	**2.4** Mean Difference: **MD 0.44 lower** (CI 95% 1.37 lower - 0.48 higher)	**Moderate** Due to serious risk of bias[1]	SAD surgery probably has little or no effect on pain at 2 years
Pain 5 years	Measured by: VAS and NRS scaled to 0-10 Scale: 0-10 Lower better Based on data from 188 patients in 2 studies	**2.2** Mean	**2.6** Mean Difference: **MD 0.36 higher** (CI 95% 1.17 lower - 1.89 higher)	**Low** Due to serious risk of bias and serious imprecision[2]	SAD surgery may have little or no effect on pain 5 years
Function at 3 months	Measured by: CS, SDQ, NS, SSRS scaled to 0-100 Scale: 0-100 High better Based on data from 257 patients in 3 studies	**55** Mean	**61** Mean Difference: **MD 6.11 higher** (CI 95% 5.57 lower - 17.79 higher)	**Low** Due to serious risk of bias and serious imprecision[2]	SAD surgery may have little or no effect on function at 3 months
Function at 6 months	Measured by: CS, SDQ, NS, SSRS scaled to 0-100 Scale: 0-100 High better Based on data from 398 patients in 4 studies	**57** Mean	**61** Mean Difference: **MD 3.66 higher** (CI 95% 2.25 lower - 9.58 higher)	**Low** Due to serious risk of bias and serious imprecision[2]	SAD surgery may have little or no effect on function at 6 months
Function at 1 year	Measured by: CS, SDQ, NS, SSRS scaled to 0-100 Scale: 0-100 High better Based on data from 259 patients in 3 studies	**66** Mean	**69** Mean Difference: **MD 3.24 higher** (CI 95% 8.08 lower - 14.55 higher)	**Low** Due to serious risk of bias and serious imprecision[2]	SAD surgery may have little or no effect on function at 1 year
Function at 2 years	Measured by: CS, SDQ, NS, SSRS scaled to 0-100 Scale: 0-100 High better Based on data from 467 patients in 5 studies	**71** Mean	**76** Mean Difference: **MD 4.94 higher** (CI 95% 0.77 higher - 9.11 higher)	**Low** Due to serious risk of bias and serious imprecision[2]	SAD surgery may have little or no effect on function at 2 years
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Function at 5 years	Measured by: CS, SDQ, NS, SSRS scaled to 0-100 Scale: 0-100 High better Based on data from 157 patients in 2 studies	**76** Mean **84** Mean Difference: **MD 7.63 higher** (CI 95% 0.17 higher - 15.09 higher)	**Low** Due to serious risk of bias and serious imprecision[2]	SAD surgery may have little or no effect on function at 5 years
Function at 10 years	Measured by: CS, SDQ, NS, SSRS scaled to 0-100 Scale: 0-100 High better Based on data from 156 patients in 2 studies	**69** Mean **79** Mean Difference: **MD 9.54 higher** (CI 95% 1.93 higher - 17.15 higher)	**Low** Due to serious risk of bias and serious imprecision[2]	SAD surgery may improve function at 10 years slightly
Global perceived effect at 6 months	Relative risk: 1.27 (CI 95% 0.86 - 1.86) Based on data from 122 patients in 1 study	**409** per 1000 **519** per 1000 Difference: **110 more per 1000** (CI 95% 57 fewer - 352 more)	**Very Low** Due to serious risk of bias and very serious imprecision[3]	We are uncertain whether SAD surgery has an global perceived effect at 6 months
Global perceived effect at 1 year	Relative risk: 1.13 (CI 95% 0.87 - 1.46) Based on data from 117 patients in 1 study	**629** per 1000 **711** per 1000 Difference: **82 more per 1000** (CI 95% 82 fewer - 289 more)	**Very Low** Due to serious risk of bias and very serious imprecision[3]	We are uncertain whether SAD surgery has an global perceived effect at 1 year
Global perceived effect at 2 years	Relative risk: 1.23 (CI 95% 0.98 - 1.56) Based on data from 127 patients in 1 study	**618** per 1000 **760** per 1000 Difference: **142 more per 1000** (CI 95% 12 fewer - 346 more)	**Very Low** Due to serious risk of bias and very serious imprecision[3]	We are uncertain whether SAD surgery has an global perceived effect at 2 years
Number at work 3 months	Relative risk: 0.96 (CI 95% 0.75 - 1.22) Based on data from 127 patients in 1 study	**691** per 1000 **663** per 1000 Difference: **28 fewer per 1000** (CI 95% 173 fewer - 152 more)	**Low** Due to very serious imprecision[4]	SAD Surgery may have little or no difference on number at work at 3 months
Number at work 6 months	Relative risk: 1.05 (CI 95% 0.81 - 1.36) Based on data from 187 patients in 2 studies	**730** per 1000 **766** per 1000 Difference: **36 more per 1000** (CI 95% 139 fewer - 263 more)	**Moderate** Due to serious imprecision[5]	SAD Surgery probably has little or no difference on number at work at 6 months
Number at work 1 year	Relative risk: 0.98 (CI 95% 0.85 - 1.13) Based on data from 119 patients in 1 study	**873** per 1000 **856** per 1000 Difference: **17 fewer per 1000** (CI 95% 131 fewer - 113 more)	**Low** Due to very serious imprecision[4]	SAD Surgery may have little or no difference on number at work at 1 year
Number at work 2 years	Relative risk: 0.87 (CI 95% 0.7 - 1.07) Based on data from 183 patients in 2 studies	**860** per 1000 **748** per 1000 Difference: **112 fewer per 1000** (CI 95% 258 fewer - 60 more)	**Moderate** Due to serious imprecision[5]	SAD Surgery probably has little or no difference on number at work at 2 years
Number at work 5 years	Relative risk: 1.13 (CI 95% 0.97 - 1.32) Based on data from 188 patients in 2 studies	**674** per 1000 **762** per 1000 Difference: **88 more per 1000** (CI 95% 20 fewer - 216 more)	**Low** Due to very serious imprecision[4]	SAD Surgery may have little or no difference on number at work at 5 years
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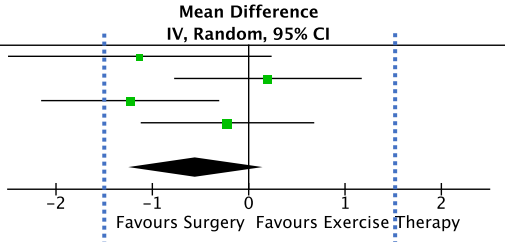
Number at work 10 years	Relative risk: 1.1 (CI 95% 0.7 - 1.72) Based on data from 90 patients in 1 study	**435** per 1000 **479** per 1000 Difference: **44 more per 1000** (CI 95% 131 fewer - 313 more)	**Low** Due to very serious imprecision[4]	SAD Surgery may have little or no difference on number at work at 10 years
Sport/leisure activities at 3 months	Relative risk: 1.31 (CI 95% 0.91 - 1.88) Based on data from 120 patients in 1 study	**431** per 1000 **565** per 1000 Difference: **134 more per 1000** (CI 95% 39 fewer - 379 more)	**Low** Due to very serious imprecision[4]	SAD surgery may have little or no difference on sport/leisure activities at 3 months
Sport/leisure activities at 6 months	Relative risk: 1.12 (CI 95% 0.83 - 1.5) Based on data from 116 patients in 1 study	**565** per 1000 **633** per 1000 Difference: **68 more per 1000** (CI 95% 96 fewer - 283 more)	**Low** Due to very serious imprecision[4]	SAD surgery may have little or no difference on sport/leisure activities at 6 months
Sport/leisure activities at 1 year	Relative risk: 1.08 (CI 95% 0.88 - 1.33) Based on data from 118 patients in 1 study	**719** per 1000 **777** per 1000 Difference: **58 more per 1000** (CI 95% 86 fewer - 237 more)	**Low** Due to very serious imprecision[4]	SAD surgery may have little or no difference on sport/leisure activities at 1 year
Sport/leisure activities at 2 years	Relative risk: 1.06 (CI 95% 0.88 - 1.27) Based on data from 118 patients in 1 study	**774** per 1000 **820** per 1000 Difference: **46 more per 1000** (CI 95% 93 fewer - 209 more)	**Low** Due to very serious imprecision[4]	SAD surgery may have little or no difference on sport/leisure activities at 2 years
Full thickness rotator cuff tear at 5 years (MRI)	Relative risk: 1.0 (CI 95% 0.4 - 2.52) Based on data from 90 patients in 1 study	**167** per 1000 **167** per 1000 Difference: **0 fewer per 1000** (CI 95% 100 fewer - 254 more)	**Low** Due to very serious imprecision[4]	SAD surgery may have little or no effect on incidence of full thickness rotator cuff tears at 5 years
Full thickness rotator cuff tear at 10 years (ultrasound)	Relative risk: 0.37 (CI 95% 0.07 - 1.87) Based on data from 66 patients in 1 study	**143** per 1000 **53** per 1000 Difference: **90 fewer per 1000** (CI 95% 133 fewer - 124 more)	**Very Low** Due to serious risk of bias and very serious imprecision[6]	We are uncertain whether SAD surgery increases or decreases the incidence of full thickness rotator cuff tears at 10 years

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.;
   Imprecision: Serious. Confidence interval overlaps MID
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
   Imprecision: Very Serious. Only data from one study, Wide confidence intervals

a:

Study or Subgroup	(A)SAD Mean	SD	Total	Nonoperative Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Brox 1993	3.63	2.65	31	4.76	2.86	32	17.5%	−1.13 [−2.49, 0.23]
Haahr 2005	−1.87	2.34	41	−2.07	2.12	41	26.3%	0.20 [−0.77, 1.17]
Ketola 2009	3.19	2.38	43	4.42	2.23	57	27.7%	−1.23 [−2.15, −0.31]
Paavola 2018	4.23	2.49	54	4.45	2.4	62	28.4%	−0.22 [−1.11, 0.67]
Total (95% CI)			**169**			**192**	**100.0%**	**−0.55 [−1.24, 0.14]**

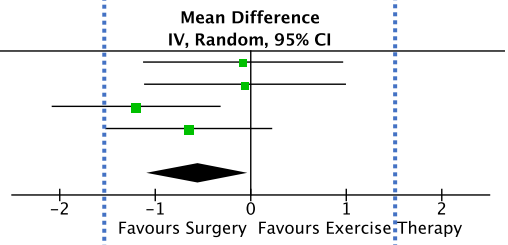
Heterogeneity: Tau² = 0.23; Chi² = 5.64, df = 3 (P = 0.13); I² = 47%
Test for overall effect: Z = 1.55 (P = 0.12)



b:

Study or Subgroup	(A)SAD Mean	SD	Total	Nonoperative Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Brox 1993	3.38	2.5	42	3.46	2.5	47	21.6%	−0.08 [−1.12, 0.96]
Haahr 2005	−2.53	2.53	41	−2.47	2.37	43	21.3%	−0.06 [−1.11, 0.99]
Ketola 2009	2.48	2.07	44	3.68	2.4	56	28.3%	−1.20 [−2.08, −0.32]
Paavola 2018	3.81	2.46	59	4.46	2.5	67	28.8%	−0.65 [−1.52, 0.22]
Total (95% CI)			**186**			**213**	**100.0%**	**−0.56 [−1.09, −0.02]**

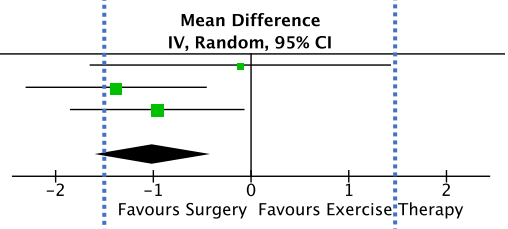
Heterogeneity: Tau² = 0.06; Chi² = 3.77, df = 3 (P = 0.29); I² = 21%
Test for overall effect: Z = 2.05 (P = 0.04)



c:

Study or Subgroup	(A)SAD Mean	SD	Total	Nonoperative Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Haahr 2005	4.56	3.89	41	4.67	3.24	43	14.7%	−0.11 [−1.64, 1.42]
Ketola 2009	2.33	2.28	51	3.71	2.71	62	41.0%	−1.38 [−2.30, −0.46]
Paavola 2018	2.35	2.44	55	3.31	2.48	64	44.2%	−0.96 [−1.85, −0.07]
Total (95% CI)			**147**			**169**	**100.0%**	**−1.01 [−1.60, −0.42]**

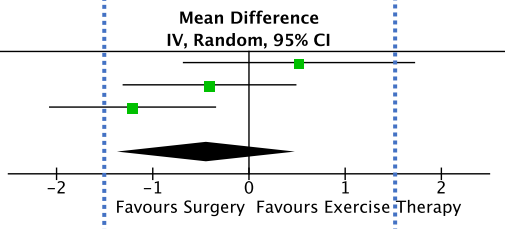
Heterogeneity: Tau² = 0.00; Chi² = 1.95, df = 2 (P = 0.38); I² = 0%
Test for overall effect: Z = 3.35 (P = 0.0008)



d:

Study or Subgroup	(A)SAD Mean	SD	Total	Nonoperative Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Brox 1993	2.8	2.97	46	2.28	2.87	45	28.1%	0.52 [−0.68, 1.72]
Ketola 2009	2.47	2.6	68	2.88	2.69	66	35.5%	−0.41 [−1.31, 0.49]
Paavola 2018	1.6	2.46	59	2.81	2.48	68	36.4%	−1.21 [−2.07, −0.35]
Total (95% CI)			**173**			**179**	**100.0%**	**−0.44 [−1.37, 0.48]**

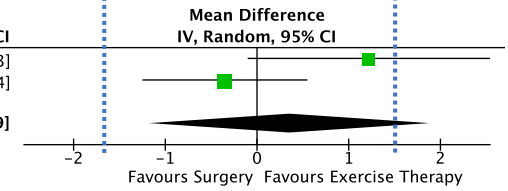
Heterogeneity: Tau² = 0.42; Chi² = 5.40, df = 2 (P = 0.07); I² = 63%
Test for overall effect: Z = 0.93 (P = 0.35)



e:

Study or Subgroup	(A)SAD Mean	SD	Total	Nonoperative Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Haahr 2005	−2.11	3.4242	39	−3.33	2.4389	40	45.1%	1.22 [−0.09, 2.53]
Ketola 2009	1.88	2.48	57	2.23	2.27	52	54.9%	−0.35 [−1.24, 0.54]
Total (95% CI)			**96**			**92**	**100.0%**	**0.36 [−1.17, 1.89]**

Heterogeneity: Tau² = 0.90; Chi² = 3.76, df = 1 (P = 0.05); I² = 73%
Test for overall effect: Z = 0.46 (P = 0.65)

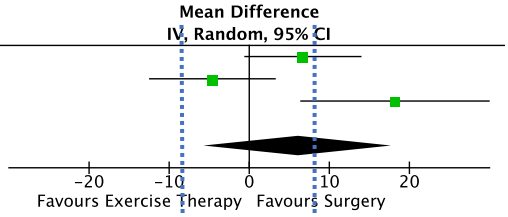


Appendix fig 4: Forest plots for pain in the secondary comparison. **a:** 3 months, **b:** 6 months, **c:** one year, **d:** two years, **e:** five years. Vertical lines denote MID (1,5 units)

a:

Study or Subgroup	(A)SAD Mean	SD	Total	Nonoperative Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Brox 1993	79.4	15.7	31	72.7	15.4	42	35.8%	6.70 [-0.53, 13.93]
Haahr 2005	15.5	20.3	41	20.1	15.9	43	35.0%	-4.60 [-12.42, 3.22]
Ketola 2009	62.6	29.4	43	44.4	30	57	29.2%	18.20 [6.46, 29.94]
Total (95% CI)			**115**			**142**	**100.0%**	**6.11 [-5.57, 17.79]**

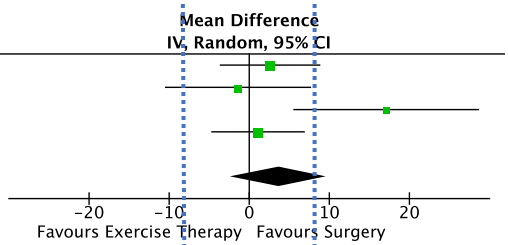
Heterogeneity: Tau² = 85.64; Chi² = 10.78, df = 2 (P = 0.005); I² = 81%
Test for overall effect: Z = 1.03 (P = 0.31)



b:

Study or Subgroup	(A)SAD Mean	SD	Total	Nonoperative Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Brox 1993	82.6	15.5	40	80	13.8	48	30.0%	2.60 [-3.59, 8.79]
Haahr 2005	19.9	22.8	41	21.3	19.2	43	21.9%	-1.40 [-10.44, 7.64]
Ketola 2009	73.4	26.3	44	56.3	32.4	56	16.6%	17.10 [5.59, 28.61]
Paavola 2018	59.2	16.5	59	58.1	16.4	67	31.4%	1.10 [-4.66, 6.86]
Total (95% CI)			**184**			**214**	**100.0%**	**3.66 [-2.25, 9.58]**

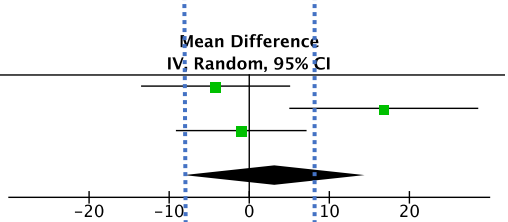
Heterogeneity: Tau² = 20.37; Chi² = 7.10, df = 3 (P = 0.07); I² = 58%
Test for overall effect: Z = 1.21 (P = 0.23)



c:

Study or Subgroup	(A)SAD Mean	SD	Total	Nonoperative Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Haahr 2005	18.8	23.1	41	23	19.8	43	34.1%	-4.20 [-13.42, 5.02]
Ketola 2009	75.2	28	51	58.4	35.5	62	29.9%	16.80 [5.09, 28.51]
Peters 1997	74	16	26	75	16	36	36.0%	-1.00 [-9.07, 7.07]
Total (95% CI)			**118**			**141**	**100.0%**	**3.24 [-8.08, 14.55]**

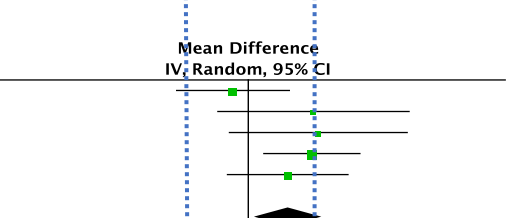
Heterogeneity: Tau² = 75.64; Chi² = 8.39, df = 2 (P = 0.02); I² = 76%
Test for overall effect: Z = 0.56 (P = 0.57)



d:

Study or Subgroup	(A)SAD Mean	SD	Total	Nonoperative Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Brox 1993	84.7	17.3	40	86.6	15.2	44	24.6%	-1.90 [-8.89, 5.09]
Farfaras 2016 combined	69.1	21.2	34	61	22.2	21	10.7%	8.10 [-3.77, 19.97]
Ketola 2009	75.8	28.9	68	67.1	35.8	66	12.1%	8.70 [-2.34, 19.74]
Paavola 2018	79.1	16.7341	58	71.2	16.95	65	30.3%	7.90 [1.94, 13.86]
Peters 1997	78.9	16	32	74	16	39	22.3%	4.90 [-2.58, 12.38]
Total (95% CI)			**232**			**235**	**100.0%**	**4.94 [0.77, 9.11]**

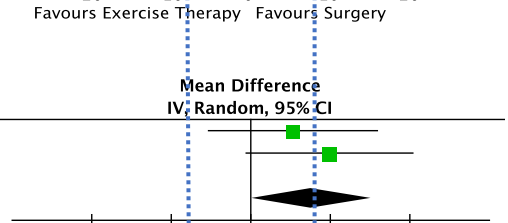
Heterogeneity: Tau² = 5.66; Chi² = 5.34, df = 4 (P = 0.25); I² = 25%
Test for overall effect: Z = 2.32 (P = 0.02)



e:

Study or Subgroup	(A)SAD Mean	SD	Total	Nonoperative Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Ketola 2009	83.1	28.6	57	77.8	27.9	52	49.3%	5.30 [-5.31, 15.91]
Peters 1997	84	17	23	74.1	20	25	50.7%	9.90 [-0.58, 20.38]
Total (95% CI)			**80**			**77**	**100.0%**	**7.63 [0.17, 15.09]**

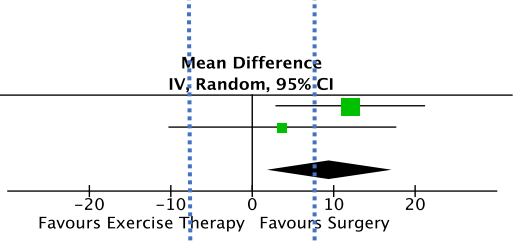
Heterogeneity: Tau² = 0.00; Chi² = 0.37, df = 1 (P = 0.55); I² = 0%
Test for overall effect: Z = 2.01 (P = 0.04)



f:

Study or Subgroup	(A)SAD Mean	SD	Total	Nonoperative Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Farfaras 2016 combined	77.64	17.24	38	65.6	19.6	28	70.0%	12.04 [2.94, 21.14]
Ketola 2009	77	33.1	44	73.3	34.2	46	30.0%	3.70 [-10.20, 17.60]
Total (95% CI)			**82**			**74**	**100.0%**	**9.54 [1.93, 17.15]**

Heterogeneity: Tau² = 0.00; Chi² = 0.97, df = 1 (P = 0.33); I² = 0%
Test for overall effect: Z = 2.46 (P = 0.01)

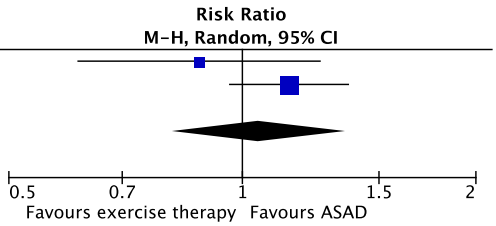


Appendix fig 5: Forest plots for function in the secondary comparison **a:** 3 months, **b:** 6 months, **c:** one year, **d:** two years, **e:** five years, **f:** 10+ years. Vertical lines denote MID (8.3 points)

a:

Study or Subgroup	(A)SAD Events	(A)SAD Total	Placebo Surgery Events	Placebo Surgery Total	Weight	Risk Ratio M-H, Random, 95% CI
Brox 1993	19	31	23	33	33.3%	0.88 [0.61, 1.26]
Paavola 2018	48	56	50	67	66.7%	1.15 [0.96, 1.37]
Total (95% CI)		**87**		**100**	**100.0%**	**1.05 [0.81, 1.36]**
Total events	67		73			

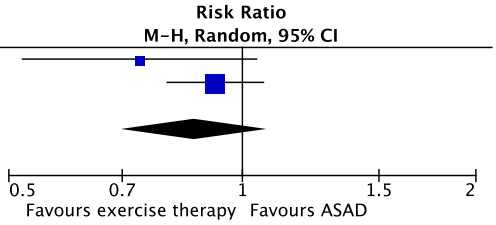
Heterogeneity: $Tau^2 = 0.02$; $Chi^2 = 1.84$, df = 1 (P = 0.18); $I^2 = 46\%$
Test for overall effect: Z = 0.38 (P = 0.70)



b:

Study or Subgroup	(A)SAD Events	(A)SAD Total	Placebo Surgery Events	Placebo Surgery Total	Weight	Risk Ratio M-H, Random, 95% CI
Brox 1993	18	31	26	33	28.2%	0.74 [0.52, 1.04]
Paavola 2018	49	59	54	60	71.8%	0.92 [0.80, 1.06]
Total (95% CI)		**90**		**93**	**100.0%**	**0.87 [0.70, 1.07]**
Total events	67		80			

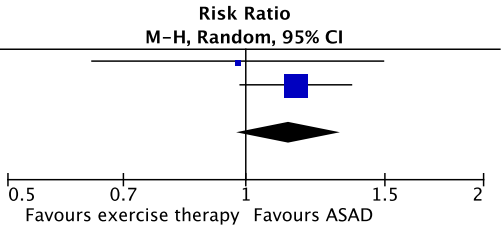
Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 1.63$, df = 1 (P = 0.20); $I^2 = 39\%$
Test for overall effect: Z = 1.30 (P = 0.19)



c:

Study or Subgroup	(A)SAD Events	(A)SAD Total	Nonoperative Events	Nonoperative Total	Weight	Risk Ratio M-H, Random, 95% CI
Haahr 2005	20	39	21	40	12.7%	0.98 [0.64, 1.49]
Ketola 2009	52	57	41	52	87.3%	1.16 [0.98, 1.36]
Total (95% CI)		**96**		**92**	**100.0%**	**1.13 [0.97, 1.32]**
Total events	72		62			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.69$, df = 1 (P = 0.41); $I^2 = 0\%$
Test for overall effect: Z = 1.61 (P = 0.11)



Appendix fig 6: Forest plots for work in the secondary comparison when two studies contributed data **a:** 6 months **b:** two years, **c:** five yeas

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

Author and year of publication	**HILL 2017**	**SHIELDS 2015**	**Both**
Biases	**Rating of reporting**	**Rating of reporting**	**Rating of "Risk of bias"**
1. Study Participation	**Unsure**, but judged unlikely to incur significant bias.	**Yes** (large number of centres, judged likely to be representative)	**Unclear ROB**, not likely to affect results in a problematic way
2. Study Attrition	**Probably low risk** given the tracking of patients who went elsewhere for care, and given follow-up was 30 days	**Probably low risk** given the tracking of patients who went elsewhere for care, and given follow-up was 30 days	**Low** RoB
3. Prognostic Factor Measurement	**Yes** – arthroscopic procedure is the prognostic factor	**Yes** – arthroscopic procedure is the prognostic factor	**Low** RoB
4. Outcome Measurement	**Yes** – based on hospital record + patient contact call	**Yes** – based on hospital record + patient contact call	**Low** RoB
5. Study Confounding	**Yes** - total harms are of interest, no proper confounders	**Yes** - total harms are of interest, no proper confounders	**Low** RoB
6. Statistical Analysis and Reporting	**Unclear**, judged not likely to lead to overestimation of harms	**Unclear**, judged not likely to lead to overestimation of harms	**Low** RoB

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).

	Hill[48]		Shields[49]	
	number	**IP %**	number	**IP %**
Total patients	15015		10225	
Serious harms:				
Mortality	2	0,01	4	0,04
Bleeding transfusion	7	0,05	5	0,05
Sepsis	0	0,00	1	0,01
Septic shock	3	0,02	2	0,02
Deep infection	1	0,01	1	0,01
Organ/space surgical site infection	3	0,02	2	0,02
Wound dehiscence	1	0,01	1	0,01
Deep vein thrombosis	21	0,14	8	0,08
Pulmonary embolism	20	0,13	7	0,07
Myocardial infarction	3	0,02	4	0,04
Cardiac arrest requiring CPR	1	0,01	2	0,02
Cerebral vascular accident	4	0,03	2	0,02
Acute renal failure	2	0,01	1	0,01
Pneumonia	13	0,09	7	0,07
Unplanned intubation	7	0,05	3	0,03
Ventilator >48 hours	2	0,01	1	0,01
Peripheral nerve injury	2	0,01	2	0,02
Other harms				
Superficial infection	24	0,16	17	0,17
Urinary tract infection	19	0,13	15	0,15
Re-operations	40	0,27	34	0,33

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)*[1] 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] Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision). In: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.handbook.cochrane.org.

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
https://www.ncbi.nlm.nih.gov/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)
http://www.pedro.org.au/
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)

4 Rotator cuff disease.ti,ab,kw. (514)
5 or/1-4 (4049)
6 side effect/ (255218)
7 exp postoperative complication/ (615989)
8 peroperative complication/ (36248)
9 treatment failure/ (99694)
10 adverse outcome/ (39587)
11 reoperation/ (72392)
12 surgical infection/ (39515)
13 (infection or infections or infected).ti,ab. (1755077)
14 (reoperation or reoperations or reoperated or re-operation or re-operations or re-operated).ti,ab. (49566)
15 ((nerve or nerves) adj3 (injury or injuries or injured)).ti,ab. (31047)
16 (shoulder adj3 (stiff or stiffness)).ti,ab. (744)
17 ((failed or failure) adj3 (surgery or operation$ or treatment$ or rate$1)).ti,ab. (102815)
18 (safe or safety or risk or risks or harm or harms or complication$).ti,ab. (4227057)
19 ((adverse or undesirable or serious or fatal or harmful) adj3 (effect$ or reaction$ or event$ or outcome$ or incident$)).ti,ab. (631605)
20 side effect$.ti,ab. (323943)
21 (ae or co).fs. (2818947)
22 or/6-21 (7901730)
23 5 and 22 (1265)
24 (animal/ or animal experiment/ or animal model/ or animal tissue/ or nonhuman/) not exp human/ (5938340)
25 (editorial or letter).pt. (1601120)
26 23 not (24 or 25) (1244)
27 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

#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

2.4 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 Trials 157

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
https://www.ncbi.nlm.nih.gov/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

adverse outcome[Title/Abstract] OR adverse outcomes[Title/Abstract] OR adverse incident[Title/Abstract] OR adverse incidents[Title/Abstract] OR undesirable effect[Title/Abstract] OR undesirable effects[Title/Abstract] OR undesirable reaction[Title/Abstract] OR undesirable reactions[Title/Abstract] OR undesirable event[Title/Abstract] OR undesirable events[Title/Abstract] OR undesirable outcome[Title/Abstract] OR undesirable outcomes[Title/Abstract] OR serious incident[Title/Abstract] OR serious incidents[Title/Abstract] OR fatal reaction[Title/Abstract] OR fatal reactions[Title/Abstract] OR fatal outcome[Title/Abstract] OR fatal outcomes[Title/Abstract] OR fatal incident[Title/Abstract] OR fatal incidents[Title/Abstract] OR harmful effect[Title/Abstract] OR harmful effects[Title/Abstract] OR harmful outcome[Title/Abstract] OR harmful outcomes[Title/Abstract] OR harmful incident[Title/Abstract] OR harmful incidents[Title/Abstract] 209180

#18 Search safe[Title/Abstract] OR safety[Title/Abstract] OR risk[Title/Abstract] OR risks[Title/Abstract] OR harm[Title/Abstract] OR harms[Title/Abstract] OR complication[Title/Abstract] OR complications[Title/Abstract] 3041624

#17 Search failed surgery[Title/Abstract] OR failed operation[Title/Abstract] OR failed treatment[Title/Abstract] OR treatment failure[Title/Abstract] OR failure rate[Title/Abstract] OR failure rates[Title/Abstract] 34839

#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/ae[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 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 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 (shoulder N3 (stiff or stiffness)) OR AB (shoulder N3 (stiff or stiffness))	226
S16	TI ((nerve or nerves) N3 (injury or injuries or injured)) OR AB ((nerve or nerves) N3 (injury or injuries or injured))	4,068
S15	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
S14	TI (infection or infections or infected) OR AB (infection or infections or infected)	172,486
S13	(MH “Surgical Wound Infection”)	8,405
S12	(MH "Reoperation")	13,462
S11	(MH "Decompression, Surgical/AE")	445
S10	(MH “Treatment Failure”)	11,242
S9	(MH "Treatment Complications, Delayed")	2,001
S8	(MH "Postoperative Complications+")	87,604
S7	(MH "Intraoperative Complications+")	9,545

S6	(MH “Adverse Health Care Event”)	5,599
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	1,123

2.9 Physiotherapy Evidence Database (PEDro)
http://www.pedro.org.au/
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)