Interventional procedure overview of biodegradable subacromial spacer insertion for rotator cuff tears.

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Table 1 Abbreviations

Abbreviation	Definition
ADL	Activities of Daily Living
ASCR	Arthroscopic Superior Capsular Repair
ASES	American Shoulder and Elbow Society
EQ-5D-5L	EuroQol-5 Dimensions-5 Level
MCID	Minimal Clinically Important Difference
NS	Non-significant
OSS	Oxford Shoulder Score
RCT	Randomised Controlled Trial
ROM	Range of Motion
RTSA	Reverse Total Shoulder Arthroplasty
VAS	Visual Analog Scale
WORC	Western Ontario Rotator Cuff

Indications and current treatment

People who have rotator cuff tears may have shoulder pain and weakness with reduced shoulder function leading to a reduced quality of life. Rotator cuff tears can be caused by an injury or can develop gradually. They can be minor or severe depending on the degree of damage to the tendon. Minor tears to the rotator cuff are very common and may not cause any symptoms at all. Diagnosis is usually by ultrasound or MRI.

Conservative treatment may include physical therapy, pharmacological treatments (including pain relief and topical or oral non-steroidal anti-inflammatory medicines) and corticosteroid injections. If the tear is severe or has not responded to other treatments, surgical interventions such as debridement, rotator cuff repair, subacromial smoothing, tendon transfer or shoulder arthroplasty may be needed.

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What the procedure involves

Inserting a biodegradable subacromial spacer aims to improve pain and restore shoulder function in people who have irreparable rotator cuff tears. The aim is to reduce subacromial friction by lowering the humeral head during shoulder abduction. It is a less invasive and potentially safer alternative to reverse shoulder arthroplasty or tendon transfer, and has shorter procedure and rehabilitation times.

The procedure is done with the person under general or regional anaesthetic. The subacromial space is visualised using either arthroscopy or mini-open surgery. The damaged area is surgically cleared. Measurements are taken to determine the size of biodegradable spacer needed. The balloon-like spacer is then inserted into the subacromial space and inflated with saline solution. Once a sufficient volume is reached, the balloon is sealed and left in situ. The balloon spacer is made from a biodegradable polymer and resorbs over a period of about one year.

Outcome measures

The main outcomes included are OSS, the ASES score, the Constant Score, the WORC index score, VAS for pain, EQ-5D-5L quality of life score, active ROM and patient satisfaction. The measures used are detailed in the following paragraphs.

The OSS is a 12-item participant-reported measure (scored 0 to 48; where 48 is the best score) of shoulder-related pain and function. Its published MCID is 6.

The ASES score is a mixed outcome reporting measure, divided into pain and Activities of Daily Living (ADL) domains, for use in a variety of shoulder

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pathologies. Results are in the 0 to 100 range, where 100 indicates the best shoulder condition. The MCID in ASES score is 17.

The Constant (or Constant-Murley) score consists of four variables that are used to assess the function of the shoulder. The objective variables are ROM and strength which give a total of 65 points. The subjective variables are pain and ADL (sleep, work, recreation or sport), which give a total of 35 points. These can be combined to give a score out of 100, with 0 as the worst shoulder function and 100 as the best. The MCID in Constant Score has been shown to be 10.4 points.

The WORC Index is a disease-specific quality of life questionnaire, evaluating symptoms and functional ability. It is self-administered and has 21-items relating to 5 domains (physical symptoms, sports or recreation, work, social function, emotions). The maximum score is 2100 (worst possible symptoms) and 0 represents no symptoms. Its MCID is 245 points of the total score.

The VAS score is an unidimensional measure of pain intensity, used to record patients' pain progression or to compare pain severity between patients with similar conditions. Pain is shown spatially as distance along a straight line, usually 10 cm, anchored by 2 verbal descriptors, one for each symptom extreme. The score is determined by measuring the distance on the line between the 'no pain' anchor and the patient's mark. The MCID has been found to be 1.4.

The EQ-5D-5L is a self-reported survey that measures quality of life across 5 domains: mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. Each dimension is scored on a 5-level severity ranking that ranges from 'no problems' through to 'extreme problems'. It is assessed on a scale of 1 to 5 with a lower score indicating better quality of life.

Active ROM measures the totality of movement the shoulder is capable of doing. Active (as opposed to passive) ROM assesses independent movement. The

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movements that are most commonly assessed are: abduction, forward flexion, forward elevation and external rotation.

Evidence summary

Population and studies description

This interventional procedures overview is based on approximately 1500 patients from 2 RCTs, 2 systematic reviews, 1 case-control study, 1 retrospective comparative study and 3 case series. Of these patients, approximately 675 patients had the procedure. This is a rapid review of the literature, and a flow chart of the complete selection process is shown in figure 1. This overview presents 9 studies as the key evidence in table 2 and table 3, and lists other relevant studies in table 5.

Of those studies included which are not systematic reviews, 1 was from the United Kingdom, 1 from US and Canada, 1 from Italy, 1 from Greece, 1 from Israel, 1 from Turkey, 1 from Ireland and 1 from Slovenia. The mean follow-up ranged from 12 months to 5 years, and the mean age of participants ranged from 65.7 to 70.3 years. All 9 studies had inclusion and exclusion criteria, which had some small differences between studies. The majority stated that the rotator cuff tear had to be irreparable for a patient to be eligible, however this is a highly variable definition. But, 1 case series (Senekovic 2017) included patients with irreparable and reparable rotator cuff tears. Furthermore, 7 of the 9 studies stated that to be eligible the rotator cuff tear had to be defined as ‘massive’. This is defined as a rotator cuff tear with retraction of the tendon to the glenoid rim or exposing two-thirds of the greater tuberosity.

Of those studies comparing spacer implantation with another group of patients, one RCT compared debridement with spacer implantation with debridement only as the control group (Metcalfe 2022). The other RCT compared InSpace

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implantation without repair with partial repair (Verma 2022). The case-control study and the comparative study both compared partial repair with spacer implantation with partial repair only (Malahias 2021 and Bisel 2022). Meanwhile, the systematic review by Osti et al. 2021 collated evidence from studies on patients who had been implanted with a spacer and compared outcomes to those patients who had undergone ASCR. Table 2 presents study details.

Figure 1 Flow chart of study selection

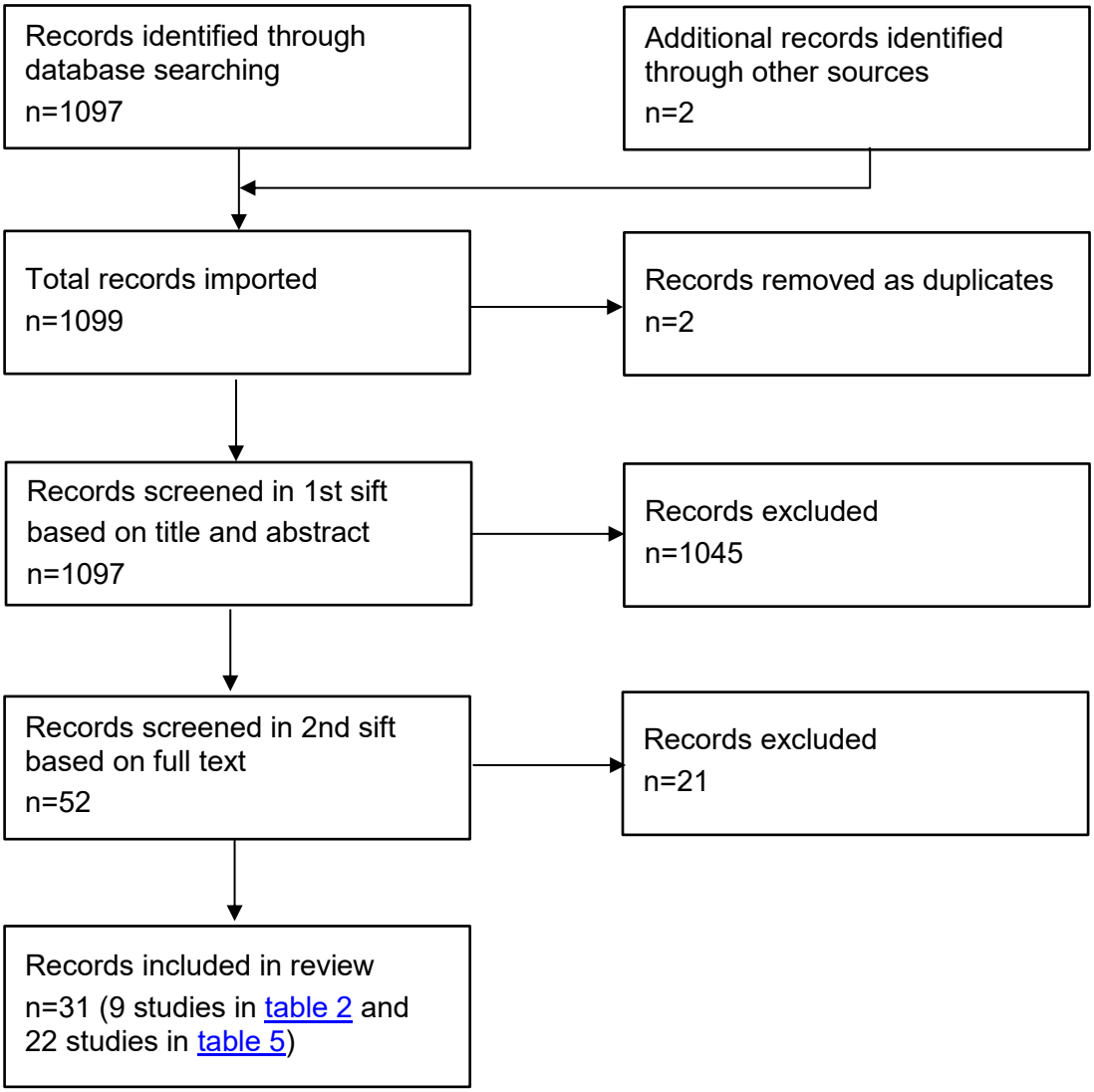

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Table 2 Study details

Study no.	First author, date Country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
1	Metcalfe et al, 2022. United Kingdom	117 (67:50)	Mean 66.9 years	RCT	Irreparable rotator cuff tear, which had not resolved with conservative treatment and had symptoms warranting surgery.	Debridement with spacer (56 patients) versus debridement-only (61 patients).	3, 6 and 12 months
2	Verma et al, 2022. United States and Canada	184 patients (100:84)	Mean age 66.8yrs (Inspace group), 64.7yrs (partial repair group)	RCT	Patients ≥40 years of age with symptomatic, irreparable, posterosuperior, massive rotator cuff tears and an intact subscapularis who underwent failed non-operative management. **Further details:** 1. Male or female subject ≥40 years of age 2. Within 9 months before study enrolment, positive diagnostic imaging by MRI of the index shoulder indicating a full-thickness massive rotator cuff tear:	InSpace implant insertion (with no rotator cuff repair) (93 patients) versus partial repair (suture anchor repair) (91 patients) as a primary surgical treatment for posterosuperior, massive rotator cuff tears.	10 days, 6 weeks, 3, 6, 12 and 24 months

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Study no.	First author, date Country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
					a. Measuring ≥5 cm in diameter (Cofield classification) b. Involving ≥2 tendons 3. Functional deltoid muscle and preserved passive ROM on physical examination 4. Documented VAS pain score >30 mm 5. Underwent failed nonoperative treatment of at least 4 months' duration (time elapsed since the initial treatment) using ≥1 of the following: a. Oral analgesics b. Anti-inflammatory medication (e.g., ibuprofen, naproxen) c. Corticosteroid injection(s) d. Physical therapy e. Activity modification f. Rest (sling used)		
3	Osti et al, 2021 Italy	998. Gender specified in 25 studies	Mean 67.9 years	Systematic review	Studies reporting clinical and functional outcomes following the use of a subacromial spacer for	Subacromial spacer implantation (375	Mean 27.6 months (range 4-

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Study no.	First author, date Country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
		(756 patients, 438:318).			massive irreparable rotator cuff tear, comparing them with ASCR.	patients) versus ASCR (623 patients)	110). For Spacer group: mean 27.0 months (range 4-60).
4	Johns, 2020 USA	337 patients and 343 shoulders. Where gender specified: 158:143	Mean 68 years	Systematic review	All studies assessing the use of implantable subacromial balloon spacers for management of massive, irreparable rotator cuff tears, reporting outcomes relating to biomechanics, clinical function, shoulder ROM, patient satisfaction, costs and complications. Published in the English language.	Insertion of implantable subacromial balloon spacer for massive, irreparable rotator cuff tear.	Mean 33 months
5	Malahias, 2021 Greece	32 (13:19)	Mean group A: 65.7 years, group B 69.7 years	Retrospective case-control study	A diagnosis of symptomatic massive rotator cuff tear confirmed clinically, radiologically and intra-operatively in patients >50 years undergoing arthroscopic	Arthroscopic partial repair with (16 patients) or without (16 patients) InSpace Balloon implanation.	12 months

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Study no.	First author, date Country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
					treatment either as combined spacer and partial repair or isolated partial repair with follow-up after 12-months post-op.		
6	Maman and Kazum, 2022 Israel	78 (37:41)	Mean age 70 years	Retrospective case series	Massive rotator cuff tear treated with InSpace device implantation, a minimum of 1 year follow-up, failure of at least 3 months of conservative treatment,	Balloon implantation performed arthroscopically.	Mean 56 months
7	Bilsel, 2022 Turkey	32 (8:24)	Median age partial repair group: 68 years. Median age partial repair with spacer group: 68.5 years	Retrospective comparative study	Patients with a symptomatic and irreparable massive rotator cuff tear with tension retraction > stage 2, according to the Patte classification, without significant osteoarthritis and minimum 1-year follow-up	Patients who had undergone arthroscopic partial cuff repair only compared with patients who had additional implantation of a subacromial spacer	Partial repair group median follow-up: 28 months. Spacer group median follow-up: 17 months

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Study no.	First author, date Country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
8	Davey, 2021. Ireland	45 (31: 14)	Mean age 70.3 years	Retrospective case series	Patients with a massive rotator cuff tear who underwent subacromial balloon spacer insertion alone with a minimum of 12 months follow-up.	Subacromial balloon spacer insertion	Mean 37.1 months
9	Senekovic, 2017. Slovenia	24 (12:12)	Mean age 68.8 years	Prospective case series	People with persistent pain and functional disability for at least 6 months, imaging confirmation of a rotator cuff tear and failed conservative therapy.	Insertion of a biodegradable inflatable InSpace system in patients with massive reparable or irreparable rotator cuff tear.	5 years

Table 3 Study outcomes (option 1)

First author, date	Efficacy outcomes	Safety outcomes
Metcalfe, 2022	**Adjusted mean difference debridement only versus debridement with device:** **OSS at 12 months:** -4.2 (95% CI: -8.2 to -0.26) **Constant score at 12 months:** -13.8 (95%CI: -24.0 to -3.6) **Abduction angle at 12 months:**	There were no clear differences in safety events between the two groups. **Adverse events in debridement with device group:** Overall: 11/56 (20%) participants had any adverse event: 6/56 exacerbation/persistence of shoulder pain

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First author, date	Efficacy outcomes	Safety outcomes
	-34.1 (-77.1 to 8.8) **Flexion angle at 12 months:** -56.8 (-91.1 to -22.5) **Abduction strength at 12 months:** -2.3 (-3.8 to -0.8) **WORC Index at 12 months:** -8.4 (-16.8 to -0.1) **EQ-5D-5L at 12 months:** -0.056 (-0.150 to 0.035)	or restrictive ROM, 3/56 injection into the shoulder region, 2/56 adhesive capsulitis, 1/56 persistent muscle soreness or muscle injury. 4/56 (7%) had a serious adverse event – 2 deemed related to the surgery (1 persistent pain or disability at 12 months, 1 further surgery required). **Adverse events in debridement only group:** Overall: 9/61 (15%) had any adverse event: 5/61 exacerbation/persistence of shoulder pain, 1/61 injection into shoulder region. 2/61 (3%) had a serious adverse event – 1 deemed related to the surgery (persistent pain or disability at 12 months).
Verma, 2022	Outcomes of InSpace implant were comparable with those of partial repair at Month 24. Mean operative time: InSpace implant group 44.6 mins versus Partial repair group 71.2 mins (p<0.0001). There was earlier recovery of outcome in the InSpace group compared with partial repair group. **ASES score (primary outcome):** **Improvement from baseline to month 24:**	No device related surgical complications were noted. 4/93 (4%) re-operations required after InSpace implantation versus 3/91 (3%) re-operations after partial repair.

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First author, date	Efficacy outcomes	Safety outcomes
	InSpace group: 46.22±20.89, p<0.0001 versus partial repair group: 42.53±20.54, p<0.0001. **Patients achieving MCID at 24 months:** 83% InSpace group versus 81% partial repair (NS). **Secondary outcomes:** • **Constant score:** Statistically significant difference between groups in improvement from BL to Week 6 and Month 24, favouring InSpace. • **WORC score:** Statistically significant difference between groups in improvement from BL to Day 10, favouring InSpace. • **Forward elevation:** Statistically significant difference between groups in improvement from BL to Day 10, Week 6, Month 12, Month 24, favouring InSpace. • **VAS pain:** NS difference between groups at all post-operative time-points. • **EQ-5D-5L:** NS difference between groups at all post-operative time-points.	
Osti, 2021	**Subacromial Spacer Implantation pre-op to post-op:** **Constant score:** Mean improved from 35.8 to 64.8. **ASES:** Mean increased from 45 to 84. **VAS:** Mean improved from 6.1 to 3.5 **OSS:** Mean improved from 30.8 to 33.0 **ROM forward elevation:** Mean increased from 94° to 150°.	**Subacromial Spacer Implantation:** Complications reported in 25 (6.7%) patients post-op: in 3 patients the balloon migrated, 18 patients pain persisted (12 underwent reverse total shoulder arthroplasty, in 3 the balloon was reimplanted), 1 patient transient neural damage with forearm dysesthesia, 1

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First author, date	Efficacy outcomes	Safety outcomes
	UCLA: Mean increased from 10.9 to 15.9 **Patient satisfaction:** 80.3% overall satisfaction rate. **ASCR pre-op to post-op:** **Constant score:** Mean improved from 41.8 to 70.4. **ASES:** Mean increased from 44 to 86. **VAS:** Mean improved from 5.2 to 1. **OSS:** Mean improved from 17.9 to 38.5. **ROM forward elevation:** Mean increased from 105° to 133°. **UCLA:** Mean increased from 9.9 to 32.4. **Patient satisfaction:** 76.2% overall satisfaction rate.	patient superficial wound infection, 1 patient deep wound infection treated with balloon removal, 1 patient a persistent limited motion treated with latissimus dorsi tendon transfer. **ASCR:** Complications reported in 92 (14.8%) patients post-op: 34 graft tears, 7 suture anchor pull-out, 6 severe shoulder contracture, 5 deep infections, 33 graft failures, 2 persistent shoulder pain, 1 anterior shoulder escape.
Johns, 2020	**Constant score** (assessed by 11 studies) All reported statistically significant improvement in Constant Score from pre-op to post-op at all timepoints. Pre-op range 22.5-41.8, post-op range 51.4-72.3. **OSS** (assessed by 3 studies) Pre-op range 21.3-26, post-op range 34.39-48.2 **ASES score** (assessed by 4 studies) All showed statistically significant improvement from pre-op to post-op. **VAS pain score (**assessed by 3 studies) 1 study showed statistically significant improvement at 3, 6, 12 and 24 months. 24-month result: 6.6-2.8, p=0.0019.	• Transient forearm dysesthesia in the lateral cutaneous nerve: 1/350 (0.29%) patients. • Superficial wound infection: 1/350 (0.29%) patients. • Deep wound infection: 1/350 (0.29%) patients. • Remnants of deflated balloon transforming into scar tissue in subacromial space: 1/350 (0.29%) patients. • Re-operation required in 11/350 (3.14%) patients, including 5 (1.42%) for balloon migration, 1

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First author, date	Efficacy outcomes	Safety outcomes
	1 study showed statistically significant improvement at 12 and 24 months. 24-month result: 7.1-2.1, p<0.0001). 1 study showed statistically significant improvement following both partial repair with spacer and spacer alone, with no statistically significant difference between groups. **UCLA shoulder score** (assessed by 1 study) Improved from 10.9±3.24 pre-op to 15.9±6.87 post-op, p=0.001 **Shoulder ROM** (assessed by 4 studies) Statistically significant improvement of shoulder abduction (pre-op range: 70-113°, post-op range: 110-165°), shoulder flexion (pre-op range: 80-130°, post-op range: 106.5°-161°) and external rotation (pre-op range: 25-44.5°, post-op range: 35-63.7°). **Patient satisfaction** (assessed by 4 studies) Mean of 3.7 on the 4-point Likert satisfaction scale. 13 of 15 patients rated their satisfaction from 8-10 on a 10-point scale, with 10 representing 'very satisfied'. 1 study: 25/31 patients (80.6%) were fully or almost satisfied, 3/31 (9.6%) reported moderate satisfaction, 3/31 (9.6%) no satisfaction. 1 study: 11/24 (46%) of patient's satisfied.	(0.29%) for synovitis, 6 (1.71%) underwent reverse total shoulder arthroplasty due to absence of or worsening symptoms. • Synovitis on MRI at 3-years post-implantation, 4 patients. • Shoulder dislocation secondary to acute trauma, 1/350 (0.29%) patients.
Malahias, 2021	All mean post-operative clinical and functional scores of both groups statistically significantly improved in comparison to the mean pre-operative value. Patients treated with partial repair and spacer implantation had a propensity toward better functional outcomes	**Spacer only group:** No re-operations or major complications. **Partial repair only group:** 1 patient suffered a deep infection requiring a revision shoulder arthroscopy.

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First author, date	Efficacy outcomes	Safety outcomes
	compared to partial repair alone, but these were statistically non-significant differences. **Partial repair and spacer group pre-op to post-op changes:** **Constant score:** Increased from mean 38.8 (SD 19.9) to mean 75.8 (SD 12.1), p<0.001. **ASES score:** Increased from mean 47.7 (SD 19.1) to mean 89.8 (SD 10.9), p<0.001. **VAS pain:** Decreased from mean 53.8/100 (SD 29.4) to mean 16.9/100 (SD 23.0), p<0.001. **ROM:** **Shoulder forward flexion:** Improved from mean 128.8° (SD 56.0) to mean 175.6° (SD 7.3), p=0.02. **% achieving MCID of Constant score:** 93.8%. **% achieving MCID of ASES score:** 93.8%. **Partial repair only pre-op to post-op changes:** **Constant score:** Increased from mean 41.7 (SD 15.6) to mean 69.6 (SD 19.7), p<0.001. **ASES score:** Increased from mean 51.0 (SD 16.5) to mean 79.8 (SD 18.8), p<0.001. **VAS pain:** Decreased from mean 41.3/100 (SD 30.9) to 8.7/100 (SD 15.5), p<0.001. **ROM** **Shoulder forward flexion:** Increased from mean 140.7° (SD 50.9) to 171.6° (SD 23.7), p<0.05.	

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First author, date	Efficacy outcomes	Safety outcomes
	% achieving MCID of Constant score: 87.5% **% achieving MCID of ASES score:** 87.5%	
Maman and Kazum, 2022	**ROM:** **Forward flexion:** Mean improvement of 13° (from a mean of 107° pre-op to 120° post-op). **Abduction:** Mean improvement of 14° (from a mean of 106 pre-op to 120°). **External rotation:** Mean improvement of 2° (from a mean of 36 pre-op to 38°). **Patient report of a positive effect on their conditions:** 51 (65%). **Patient reported they would repeat the procedure in hindsight:** 45 (58%)	• 2/78 (2.5%) patients experienced superficial wound infection. • 9/78 (11.5%) patients underwent reverse total shoulder arthroplasty (RTSA) subsequently, average time to RTSA was 17 months.
Bilsel, 2022	**Pre-op & post-op outcome scores. Value (range)** **Pre-op median ASES (range)** Partial repair 30.0 (20-37.5) Partial repair + spacer 30.8 (20-42) p-value 0.4 **Post-op median ASES (range)** Partial repair 55.0 (37.5-65) Partial repair + spacer 75.5 (55-88.3) P-value **<0.001** **Δ median ASES** Partial repair 28.0 (7-40) Partial repair + spacer 40.2 (26.7-63.3)	Not assessed

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First author, date	Efficacy outcomes	Safety outcomes
	P-value **<0.001** **% achieving MCID ASES** Partial repair 70 Partial repair + spacer 100 P-value **0.04** **Pre-op median Constant score (range)** Partial repair 26.0 (20-38) Partial repair + spacer 28.5 (20-40) P-value 0.6 **Post-op median Constant score (range)** Partial repair 55.0 (31-79) Partial repair + spacer 40.0 (43-79) P-value **0.01** **Δ median Constant score (range)** Partial repair 29.0 (8-53) Partial repair + spacer 39.0 (23-53) P-value **0.01** **% achieving MCID constant score** Partial repair 95 Partial repair + spacer 100 P-value 0.6 **Pre-op median VAS (range)** Partial repair 8.0 (7-9) Partial repair + spacer 7.5 (6-9)	

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First author, date	Efficacy outcomes	Safety outcomes
	P-value 0.6 **Post-op median VAS (range)** Partial repair 2.0 (0-4) Partial repair + spacer 1.0 (0-3) P-value **0.04** **Δ median VAS (range)** Partial repair 5.5 (3-8) Partial repair + spacer P-value 0.1 **% achieving MCID VAS** Partial repair 100 Partial repair + spacer 100 P-value n/a **Pre-op median forward flexion (range)** Partial repair 100.0° (75-120°) Partial repair + spacer 105.0° (75-120°) P-value 0.5 **Post-op median forward flexion (range)** Partial repair 120.0° (80-153°) Partial repair + spacer 140.0 (90-150°) P-value **0.01** **Δ median forward flexion (range)** Partial repair 17.5° (-10, 33°) Partial repair + spacer 30.0 (15-40°)	

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First author, date	Efficacy outcomes	Safety outcomes
	P-value **<0.001** **Pre-op median abduction (range)** Partial repair 80.0° (60-100°) Partial repair + spacer 85.0 (60-100°) P-value 0.5 **Post-op median abduction (range)** Partial repair 90.0° (70-110°) Partial repair + spacer 100.0° (70-130°) P-value **0.03** **Δ median abduction (range)** Partial repair 10.0° (-10-30°) Partial repair + spacer 20.0° (0-40°) P-value 0.05 **Pre-op median external rotation** Partial repair 3.0° (2-3°) Partial repair + spacer 3.0° (2-3°) P-value 0.9 **Post-op median external rotation** Partial repair 3.0° (2-4°) Partial repair + spacer 3.0° (2-5°) P-value 0.4 **Δ median external rotation** Partial repair 0.0° (-1-2°) Partial repair + spacer 1.0° (-1-2°)	

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First author, date	Efficacy outcomes	Safety outcomes
	P-value 0.5	
Davey, 2021	**Final follow-up: (NB no pre-op values measured)** **Mean ASES score:** 73.4 ± 21.8 **Mean Subjective Shoulder Value (SSV):** 76.4 ± 16.0 **Patient satisfaction:** **% relatively satisfied:** 40 (88.9%) **% very satisfied:** 37 (82.2%) **% that would opt to have procedure again:** 40 (88.9%)	• 3 (6.6%) patients required subsequent procedure to the ipsilateral shoulder • 2 (4.4%) patients underwent removal of balloon following plateau in rehabilitation alongside ongoing pain. • 1 (2.2%) patients underwent removal of suture anchor for residual pain.
Senekovic, 2017	**Change between pre-op and 3, 4 and 5-year follow-up:** **Total Constant Score:** **3 years:** +23.28 (19.42), p<0.0001 **4 years:** +26.55 (19.51), p<0.0001 **5 years:** +28.56 (17.65), p<0.0001 At 5 year follow-up, 84.6% showed improvement of 15 points, 61.5% showed improvement of 25 points.	• No complications or unexpected device-related adverse events were recorded. • 1 patient diagnosed with a recurrent rotator cuff tear at 4.5 years follow-up. • 2 patients presented with synovitis. It is unclear if this was related to the device.

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Procedure technique

All 9 studies detailed the procedure technique and devices used. All used the InSpace implant (Stryker, US) as the surgical device for insertion.

As outlined previously, there have been some differences in the surgical technique used whilst inserting the InSpace device. Of the studies comparing spacer implantation with another group of patients, 1 RCT compared debridement with spacer implantation with debridement only as the control group (Metcalfe 2022). It has been proposed by a recent review that extensive debridement in addition to spacer implantation may theoretically lead to balloon migration and therefore inferior outcomes (Mease 2023). The other RCT compared InSpace implantation without repair with partial repair (Verma 2022). The case-control study and the comparative study both compared partial repair with spacer implantation with partial repair only (Malahias 2021 and Bisel 2022). Meanwhile, the systematic review by Osti et al. collated evidence from studies on patients who had a spacer implanted and compared outcomes to those patients who had ASCR.

Efficacy

Oxford Shoulder Score

The OSS was assessed by 1 RCT and 2 systematic reviews. The RCT found a statistically significantly higher OSS in the control group (debridement only) compared with the intervention group (debridement with spacer) at 12 months follow up (OSS of 34.3 [SD 11.1] in the debridement group versus 30.3 [10.9] in the debridement plus device group, mean difference -4.2 [95% CI -8.2 to -0.26; Metcalfe 2022]. A systematic review comparing spacer implantation with ASCR found a higher post-operative OSS in patients having ASCR compared with those treated with spacer implantation (mean increase in OSS from pre-operation to post-operation of 30.8 to 33.0 in the spacer implantation group versus 17.9 to

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38.5 in the ASCR group). The spacer implantation group consisted of 128 patients from 4 studies while the ASCR group consisted of 25 patients from 1 study (Osti, 2021). Another systematic review found a statistically significant increase in OSS in patients having spacer implantation at a mean follow up of 33 months (pre-operative range 21.3 to 26; post-operative range 34.4 to 48.2; Johns 2020).

ASES

ASES was examined by 1 RCT, 2 systematic reviews, 1 case-control study, 1 retrospective comparative study and 1 case series. The RCT found statistically significant and comparable improvements in ASES from baseline to month 24 in both the spacer and partial repair groups. (The InSpace group improvement from baseline to month 24 was 46.2 [SD 20.9], $p<0.001$ compared with 42.5 [SD 20.5], $p<0.001$.) There was no statistically significant difference in the percentage of patients achieving MCID in ASES at 24 months (83% for the InSpace group versus 81% for the partial repair group; Verma 2022). In contrast, a comparative study found the percentage achieving MCID in ASES was statistically significantly higher in the partial repair with spacer group compared with the partial repair only group (100% compared with 70%, $p=0.04$; Bilsel, 2022). A systematic review found a slightly greater increase in ASES in the ASCR group compared with the spacer group (mean increase in the spacer group of 45 to 84 compared with a mean increase from 44 to 86 in the ASCR group; Osti 2021). A case-control study found statistically significant improvements in ASES in both the partial repair with spacer and partial repair only group at 12 months follow up (mean improved from 47.7 [SD 19.1] to 89.8 [SD 10.9], $p<0.001$ in the partial repair plus spacer group compared with mean improvement from 51.0 [SD 16.5] to 79.8 [SD 18.8] in the partial repair group, $p<0.001$; Malahias 2021). A systematic review with mean follow up of 33 months, which included 4 studies examining ASES found a statistically significant improvement in ASES score after

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spacer insertion, with a pre-operative range of 24.5 to 59.1 and a post-operative range of 72.5 to 85.7.

Constant Score

Constant Score was examined by 2 RCTs, 2 systematic reviews, 1 case-control study, 1 comparative study and 1 case series. The 2 RCTs had conflicting results, with one finding a mean difference at 12 months follow up in Constant Score between the debridement only and debridement with device groups of -13.8 (95% CI -24.0 to -3.6 favouring the debridement only group; Metcalfe 2022). In contrast, another RCT found a statistically significant difference in the improvement in Constant Score between the InSpace and partial repair groups at both the 6-week and 24-month follow-up points, favouring the InSpace group (no figures available; Verma 2022). The comparative study also found a statistically significant difference between the spacer with partial repair and partial repair only groups, favouring the spacer group (change in median Constant Score of 29.0 for partial repair compared with 39.0 for partial repair with spacer, p=0.01; Bilsel 2022). All 11 studies assessing Constant Score in the systematic review by Johns et al. reported a statistically significant improvement in Constant Score after spacer insertion (pre-operative range 22.5 to 41.8 and post-operative range 51.4 to 72.3). One case series examined change in Constant Score between pre-operation and post-operation at 3, 4 and 5 years follow up. At all follow-up points, there continued to be a statistically significant improvement compared with baseline. At 5 years follow up, the mean improvement in Constant Score was 28.6 (SD 17.7), p<0.0001.

WORC score

WORC score was assessed by the 2 RCTs. One RCT found a mean difference in WORC score between the debridement only compared with the debridement with device group which favoured debridement only (mean difference -8.4 [95% CI -16.8 to -0.1] Metcalfe 2022). The other RCT showed no statistically significant

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difference in improvement between baseline and all follow-up points between the InSpace and partial repair groups, apart from at day 10 which favoured the InSpace group (figures not available).

VAS pain score

VAS pain score was assessed by 1 RCT, 2 systematic reviews, 1 case-control study and 1 comparative study. The RCT found no statistically significant difference between the InSpace and partial repair groups in terms of improvement in VAS at any follow-up time point (Verma 2022). A systematic review found a mean improvement in VAS after spacer implantation to be 6.1 to 3.5 (98 patients) compared with 5.2 to 1 in ASCR (340 patients; Osti 2021). Another systematic review included 3 studies assessing improvement in VAS after spacer implantation, all 3 of which showed statistically significant improvements compared with the pre-operation VAS pain value. The comparative study found that 100% of patients in both the partial repair and partial repair plus spacer groups had an MCID in VAS pain score after their procedure (Bilsel 2022). The case-control study showed statistically significant improvements in VAS in both the partial with spacer and partial only groups (reduction in mean VAS of 53.8 of 100 [SD 29.4] to 16.9 of 100 [23.0] $p<0.001$ in the partial and spacer group compared with mean reduction from 41.3 of 100 [30.9] to 8.7 of 100 [15.5], $p<0.001$ in the partial only group; Malahias 2021).

EQ-5D-5L

EQ-5D-5L was investigated by the 2 RCTs. Both found no statistically significant difference between the spacer and control groups in terms of improvement in EQ-5D-5L between baseline and any follow-up time point. One found a mean difference between the debridement only and debridement plus device group of -0.056 (95% CI -0.150 to 0.035).

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ROM

Active ROM was assessed by 2 RCTs, 2 systematic reviews, 1 case series and 1 comparative study. It is important to note that not all studies examined the same movements. 1 RCT and 1 comparative study had conflicting results in terms of forward flexion. The RCT found that at 12 months follow up, the control group had a statistically significantly greater increase in flexion compared with the spacer group (mean difference -56.8, 95% CI -91.1 to -22.5; Metcalfe 2022). In contrast, the comparative study found a statistically significantly greater median change in forward flexion angle in the spacer group compared with the partial repair group (median increase of 17.5 degrees versus 30.0 degrees, $p<0.001$; Bilsel 2022).

There was a statistically significantly greater improvement in forward elevation from baseline to all follow-up time points (day 10, week 6, month 12 and month 24) in the spacer group compared with the partial repair group in 1 RCT (Verma 2022). A systematic review found that mean forward elevation in 288 patients with a spacer implant increased from 94 degrees pre-operation to 150 degrees post-operation, compared with the mean increase in the ASCR group which was from 105 degrees to 133 degrees.

In the 4 studies which examined abduction in a systematic review, all showed statistically significant improvement in abduction between pre-operation and post-operation (pre-operation range 70 to 113 degrees compared with post-operation range 80 to 130 degrees; Osti 2021). But the comparative study found no statistically significant difference in the change in abduction angle between the partial repair only and InSpace implantation groups (Bilsel 2022).

Patient satisfaction

Patient satisfaction was assessed in 2 systematic reviews and 1 case series. One systematic review found an overall satisfaction rate of spacer implantation to

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be 80% compared with 76% for those who had ASCR (Osti 2021). Another systematic review found that in 1 study, 13 of 15 patients rated their satisfaction after spacer implantation between 8 and 10 on a 10-point scale, with 10 representing very satisfied while another study found that 81% were fully or almost satisfied, 10% reported moderate satisfaction and 10% no satisfaction. However, a further study included in the systematic review found that only 46% were satisfied (Johns 2020). In the case series, 82% were very satisfied after spacer implantation.

Safety

Deep wound infection

One out of 350 patients in a systematic review had a deep wound infection which needed a 1-week course of intravenous antibiotics followed by 2 weeks of oral antibiotics.

Persistence or exacerbation of shoulder pain, or persistent limited motion

Three studies (1 systematic review, 1 RCT and 1 case series) reported patients who had persistent worsening of their shoulder pain or continued limited ROM. The systematic review by Osti et al. noted that 19 of 373 (5%) patients experienced this after balloon implantation. The RCT found that 6 of 56 (11%) patients were experiencing these symptoms by 12 months follow up, with 1 further patient experiencing persistent muscle soreness or muscle injury (Metcalfe 2022). In the case series, 1 out of 45 patients experienced persistent symptoms and required removal of suture anchor for residual pain within the 37 month follow-up period (Davey 2021).

Re-operations

Several studies noted the risk of a further operation being needed. In an RCT, 4 of 93 (4%) patients required a re-operation by 24 months follow up (1

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arthroscopy for persistent pain, 2 conversions to RTSA for failure, 1 conversion to RTSA for fracture non-union after a fall). A systematic review found that at mean follow up of 33 months, re-operation was required in 11 of 350 (3%) patients, including 5 of 350 (1%) for balloon migration, 1 of 350 for synovitis and 6 of 350 (2%) underwent RTSA because of absence of or worsening symptoms (Johns 2020). In a case series, 3 (7%) needed a subsequent procedure, including 2 (4%) for removal of the balloon (Davey 2021).

Superficial wound infection

Superficial wound infection was documented in 1 of 350 patients in a systematic review. This resolved after a course of antibiotics. Furthermore, 2 of 78 (3%) in a case-control study experienced a superficial wound infection.

Synovitis

Synovitis was documented in 4 patients included in a systematic review (Johns 2020). This was found on MRI at 3 years post implantation of the spacer device. Two of 24 patients in a case series presented within the 5-year follow-up period with synovitis (Senekovic 2017). But because there was no pre-operative imaging available, it was unclear if this was related to the device.

Recurrent rotator cuff tear

Recurrent rotator cuff tear was experienced by 1 of 24 patients in a case series with 5-years follow up (Senekovic 2017).

Transient neural damage with forearm dysesthesia

One of 373 patients experienced transient neural damage with forearm dysesthesia in a systematic review with mean follow up of 27 months (Osti 2021).

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Shoulder dislocation

One of 350 patients experienced shoulder dislocation in a systematic review with mean follow up 33 months. It was documented as being secondary to acute trauma. (Johns 2020).

Remnants of deflated balloon transforming into scar tissue

Remnants of deflated balloon transforming into scar tissue was documented in 1 of 350 patients in a systematic review with mean follow-up time of 33 months (Johns 2020).

Anecdotal and theoretical adverse events

Expert advice was sought from consultants who have been nominated or ratified by their professional society or royal college. They were asked if they knew of any other adverse events for this procedure that they had heard about (anecdotal), which were not reported in the literature. They were also asked if they thought there were other adverse events that might possibly occur, even if they had never happened (theoretical).

They listed the following anecdotal adverse events:

- anterior escape of the balloon in the shoulder leading to pain
- inserting a balloon which is too large and overfilling the device
- failure to ensure that the device is appropriately sited
- balloon bursting.

Four professional expert questionnaires for this procedure were submitted. Find full details of what the professional experts said about the procedure in the specialist advice questionnaires for this procedure.

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Validity and generalisability

Overall, results from studies which have simply compared shoulder functioning and pain before and after insertion of a biodegradable spacer have mostly shown improved shoulder functioning and reduced pain after biodegradable subacromial spacer insertion. The procedure also appears to have a low rate of complications. But the 2 recent RCTs have conflicting findings, with 1 showing non-inferiority to partial rotator cuff repair and the other finding inferiority to debridement alone.

Pre-operative patient selection may have contributed to these conflicting results. The 2 RCTs had a difference in their study population's pre-operative active forward flexion (74.1 in the UK study by Metcalfe et al. and 115 in the US/Canada study by Verma et al.). It has been proposed that pre-operative ROM may influence final outcomes (Mease 2023). In the Verma et al. study, participants were screened by MRI to identify tears ≥ 5 cm and involving greater than or equal to 2 tendons. In comparison, in the Metcalfe et al. study there was no cut-off for tear size (Mease 2023). Furthermore, the 2 RCTs had differing post-operative rehabilitation protocols. An important finding from both RCTs was that male participants performed better than females (although subgroup comparison was based on small numbers). Finally, it is important to note that the study by Verma et al. was funded by OrthoSpace (now Stryker), the manufacturer of the InSpace device, and 2 of the authors are Stryker or OrthoSpace employees.

The systematic reviews on this topic are limited by most of the studies being case series with small numbers of patients and relatively short follow up.

Related NICE guidance

Interventional procedures

- NICE's interventional procedures guidance on superior capsular augmentation for massive rotator cuff tears (Recommendation: research only).

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- NICE's interventional procedures guidance on shoulder resurfacing arthroplasty (Recommendation: normal arrangements).

Professional societies

- British Elbow & Shoulder Society (subgroup of the British Orthopaedic Association)

Company engagement

NICE asked companies who manufacture a device potentially relevant to this procedure for information on it. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

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2. Verma N, Srikumaran MD, Roden CM et al. (2022) InSpace implant compared with partial repair for the treatment of full-thickness massive rotator cuff tears. J Bone Joint Surg Am. 104;1250-62.
3. Osti L, Milani L, Ferrari S, Maffulli N. (2021) Subacromial spacer implantation: an alternative to arthroscopic superior capsular reconstruction. A systematic review. British Medical Bulletin, 139:59-72.
4. Johns WL, Ailaney N, Lacy K et al. (2020) Implantable subacromial balloon spacers in patients with massive rotator cuff tears: a systematic review of clinical, biomechanical, and financial implications. Arthroscopy, Sports Medicine, and Rehabilitation. Vol 2, No 6 (December), pp e855-e872.
5. Malahias, M-A, Brilakis E, Avramidis G et al. (2021) Arthroscopic partial repair with versus without biodegradable subacromial spacer for patients with massive rotator cuff tears: a case-control study. Musculoskeletal surgery. 105:247-255.
6. Maman E, Kazum E, Abboud JA et al. (2022) Biodegradable balloon spacer for massive irreparable rotator cuff tears is associated with improved

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functional outcomes, low revisions, and complications rate at minimum one year follow-up. International Orthopaedics 46:573-579.

7. Bilsel K, Aliyev O, Atlintas B et al. (2022) Subacromial spacer implantation during arthroscopic partial repair in patients with massive irreparable rotator cuff tears provides satisfactory clinical and radiographic outcomes: a retrospective comparative study. Arthroscopy, Sports Medicine, and Rehabilitation. Vol 4, No 3, pp e1051-e1057.
8. Davey MS, Kaar K. (2021) Clinical outcomes at medium-term follow-up of sub-acromial balloon spacer insertion in the operative management of massive rotator cuff tears. Irish Journal of Medical Science 191:1687-1691.
9. Senekovic V, Poberaj B, Kovacic L et al. (2017) The biodegradable spacer as a novel treatment modality for massive rotator cuff tears: a prospective study with 5-year follow-up. Archives of Orthopaedic and Trauma Surgery 137, 95-103.

Methods

NICE identified studies and reviews relevant to biodegradable subacromial spacer insertion for rotator cuff tears from the medical literature. The following databases were searched between the date they started to 12/12/22: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the internet were also searched (see the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following inclusion criteria were applied to the abstracts identified by the literature search.

- Publication type: clinical studies were included with emphasis on identifying good quality studies. Abstracts were excluded if they did not report clinical outcomes. Reviews, editorials, and laboratory or animal studies, were also excluded and so were conference abstracts, because of the difficulty of appraising study methodology, unless they reported specific adverse events that not available in the published literature.
- Patients with rotator cuff tears.

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- Intervention or test: biodegradable subacromial spacer insertion.
- Outcome: articles were retrieved if the abstract contained information relevant to the safety, efficacy, or both.

If selection criteria could not be determined from the abstracts the full paper was retrieved.

Potentially relevant studies not included in the main evidence summary are listed in the section on other relevant studies.

Find out more about how NICE selects the evidence for the committee.

Table 4 literature search strategy

Databases	Date searched	Version/files
MEDLINE (Ovid)	12/12/2022	1946 to December 07, 2022
MEDLINE In-Process (Ovid)	12/12/2022	1946 to December 06, 2022
MEDLINE Epubs ahead of print (Ovid)	12/12/2022	December 06, 2022
EMBASE (Ovid)	12/12/2022	1974 to 2022 December 09
EMBASE Conference (Ovid)	12/12/2022	1974 to 2022 December 09
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	12/12/2022	Issue 12 of 12, December 2022
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	12/12/2022	Issue 11 of 12, November 2022
International HTA database (INAHTA)	12/12/2022	-

Trial sources searched:

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry.

Websites searched:

- National Institute for Health and Care Excellence (NICE)

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- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search.

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

MEDLINE search strategy

Strategy used:
1 Rotator Cuff/
2 Shoulder Impingement Syndrome/
3 Shoulder Pain/
4 Shoulder Joint/
5 Acromion/
6 (shoulder* or rotat* or rotor* or rotar* or cuff* or humer* or abcromi* or subacromi* or sub-acromi* or arthroscop* or supraspinatus* or infraspinatus* or "teres minor*" or teres-minor* or subscapularis*).ti,ab.
7 ((scar* or tear* or torn* or rip* or ruptur* or absenc* or irrepair* or irreparab* or imping* or non-funct* or nonfunct* or ruptur*) adj4 (lesion* or large* or partial* or massive* or tendon* or tendin* or ligament* or muscle* or coracohumeral* or coracoid* or internal* or posterosuperio* or outlet* or glenohumeral* or fullthick* or full-thick* or glenoid*)).ti,ab.
8 or/1-6
9 7 and 8
10 Arthroplasty, Replacement, Shoulder/ or Arthroplasty, Replacement/ or Arthroplasty/
11 (arthroplast* or arthroscop* or fluoroscop*).tw.
12 Video-Assisted Surgery/
13 Surgery, Computer-Assisted/
14 Therapy, Computer-Assisted/
15 ((minimal* or non*) adj4 invasiv* adj4 (surg* or tech* or treat* or therap* or device* or procedure*)).tw.
16 ((video* or comput*) adj4 (surg* or tech* or treat* or therap* or device* or pocedure*)).tw.
17 or/10-16
18 Polymers/

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19 Biodegradable Plastics/
20 (compostab*or copolymer* or co-polymer* or polymer* or biodegrad* or biograd* or saline* or fluid* or absorb*).ti,ab.
21 joint prosthesis/ or shoulder prosthesis/
22 Absorbable Implants/
23 (implant* or space* or balloon*).ti,ab.
24 or/18-23
25 9 and 17 and 24
26 (Inspace or inspaceTM or Orthospace).ti,ab.
27 25 or 26
28 animals/ not humans/
29 27 not 28

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Other relevant studies

Other potentially relevant studies to the IP overview that were not included in the main evidence summary (tables 2 and 3) are listed in table 5.

Table 5 additional studies identified

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
[Moon AS, Harshadkumar A, Patel MD et al. (2019) Subacromial spacer implantation for the treatment of massive irreparable rotator cuff tears: A systematic review. Arthroscopy, Vol 35, No 2]	Systematic review n=200 patients, 204 shoulders mean 19.4 months follow up	Patients have satisfactory outcomes at 2-3 years follow-up with a low rate of complications after subacromial spacer implantation.	More recent systematic review included.
Stewart RK, Kaplin L, Parada SA et al. (2019) Outcomes of subacromial balloon spacer implantation for massive and irreparable rotator cuff tears. OJSM, 7(10).	Systematic review N= 284 patients (291 shoulders). Mean 22.9 months follow-up	Subacromial balloon spacer has favourable patient-reported outcomes at limited short-term follow-up.	More recent systematic review included.
Vecchini E, Gulmini M, Peluso A et al. The treatment of irreparable massive rotator cuff tears with inspace balloon: rational and medium-term results	Case series N=79 patients Mean follow-up 56 months.	Improvement in function and ROM following InSpace implantation.	Small case series
Gervasi E, Maman E et al. Fluoroscopically guided subacromial spacer implantation	Case series N=46 patients Follow-up 2 years	87.5% of patients saw statistically significant improvement in	Case series

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for massive rotator cuff tears.		Constant and ASES scores. Low rates of complications	
Malahias M-A, Brilakis E et al. Satisfactory mid-term outcome of subacromial balloon spacer for the treatment of irreparable rotator cuff tears.	Case series N=31 Mean follow-up 22.1 months	InSpace implanation leads to statistically significantly improved mid-term outcomes and high patient satisfaction	Small case series
Yallapragada RK, Apostolopoulos A et al. The use of a subacromial spacer-inspace balloon in managing patients with irreparable rotator cuff tears.	Non-randomised study. N=14 Mean follow-up 12.6 months	Spacer implantation resulted in improved shoulder function and pain.	Small case series
Iban MAR, Moreno RL et al. The absorbable subacromial spacer for irreparable posterosuperior cuff tears has inconsistent results	Case series N=16 Follow-up: 12 and 24 months	Outcomes after implantation of subacromial spacer at 2-year follow-up are not satisfactory. Only 40% of patients clearly benefit from surgery.	Small case series
Piekaar RSM, Bouman ICE et al. Early promising outcome following arthroscopic implantation of the subacromial balloon spacer for treating massive rotator cuff tear.	Case series N=44 patients, 46 shoulders Follow-up: 1 year	Biodegradable balloon spacer statistically significantly reduces pain and improves ADL at 1 year follow-up.	Included in systematic reviews already in overview
Ricci M, Vecchini E et al. A clinical and radiological study of biodegradable subacromial spacer	Case series N=30 Follow-up: 3, 6, 12 and 24 months	Results support biodegradable spacer implantation for shoulder function	Already included in systematic review within overview.

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in the treatment of massive irreparable rotator cuff tears		improvement and reduction of pain.	
Basat HC, Kircil C et al. Treatment alternative for irreparable rotator cuff ruptures: Arthroscopic biodegradable balloon	Case series N=12	Biodegradable balloon yields improvement in function, ROM and all patients were satisfied.	Small case series already included in systematic review in overview.
Gervasi E, Maman E et al. Fluroscopy-guided biodegradable spacer implantation using local anaesthesia: safety and efficacy study in patients with massive rotator cuff tears	Case series N=15 Follow-up: 6 weeks and 12 months	All patients demonstrated an improvement in constant score and ASES.	Small case series, already included in systematic review within overview.
Kooistra B, Gurnani N et al. Low level of evidence for all treatment modalities for irreparable posterosuperior rotator cuff tears.	Systematic review N=2000 (including all treatments for rotator cuff tears). Minimum 2 years follow-up	The weighted mean improvement in constant score following subacromial spacer was 32.5.	More recent systematic review with the same studies included.
Moreno JG, Bellido PC et al. Results after the application of biodegradable spacer balloons as therapeutic option in non-repairable massive ruptures of the shoulder rotator cuff.	Case series N=25 Follow-up: 1 year	Results are in favour of the use of subacromial balloon.	Small case series
Garofalo R, De Crescenzo AD et al. 2022. Rotator cuff repair protected with subacromial balloon spacer	Case series N=32 Mean follow-up 27 months	Clinical outcomes and pain scores improved statistically significantly without	Small case series

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shows low rate of non-healing		severe complications.	
Familiari F, Nayar SK et al. 2021 Subacromial balloon spacer for massive, irreparable rotator cuff tears is associated with improved shoulder function and high patient satisfaction	Case series N=51 Mean follow-up 36 months	At mean 3-years follow-up, subacromial spacer placement was associated with statistically significant improvement in shoulder function, limited need for revision surgery and high patient satisfaction.	Case series
Piekaar RSM, Bouman ICE et al. 2019. The subacromial balloon spacer for massive irreparable rotator cuff tears: approximately 3 years of prospective follow-up.	Case series N=44 patients, 46 shoulders. Follow-up: 3 years	Biodegradable balloon spacer leads to statistically significant reduction in pain and improvement of function.	Already included in systematic review included within overview.
Deranlot J, Herisson O et al. 2017. Arthroscopic subacromial spacer implantation in patients with massive irreparable rotator cuff tears: clinical and radiographic results of 39 retrospective cases	Case series N=37 patients, 39 shoulders. Follow-up: min 1 year	Biodegradable spacer implantation leads to statistically significant improvement in shoulder function at a minimum of 1 year postoperatively.	Case series already included in systematic review.
Senekovic V, Poberaj B. 2013. Prospective clinical study of a novel biodegradable subacromial spacer in treatment of	Case series N=20 Follow-up: 3 years	Biodegradable spacer is a low risk procedure associated with improvement in shoulder function and low complications	Case series already included within systematic reviews.

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massive irreparable rotator cuff tears.			
Hughes JD, Davis B et al. 2022. Nonarthroplasty options for massive, irreparable rotator cuff tears have improvement in ROM and patient-reported outcomes as short-term follow-up: a systematic review	Systematic review N=3363 (assessing multiple options for treating rotator cuff tear). Follow-up: minimum 1 year	All treatment options (including spacer insertion) resulted in statistically significant improvements in ROM and patient-reported outcomes.	Other systematic reviews selected instead.
Oderuth ENH, Morris DLJ et al. 2021. The balloon spacer improves outcomes in only a minority of patients with an irreparable rotator cuff tear.	Case series N=22 Mean follow-up: 31.4 months	The balloon spacer is effective in a minority (32%) of patients in the medium term. The majority convert to reverse total shoulder replacement or remain symptomatic.	Small case series
Mease SJ, Wang KC et al. (2023) Tendon transfers, balloon spacers, and bursal acromial reconstruction for massive rotator cuff tears.	Review	N/A : discusses reasons for conflicting results in the 2 RCTs within overview.	No results.
Oh JH, Park, JH et al. (2019) Comparing clinical outcomes after subacromial spacer insertion versus other reconstruction methods in the treatment of irreparable massive rotator cuff tears	Cohort study N=17 patients (spacer) versus 36 patients (other techniques) Follow-up: Min 2 years	No difference in outcomes between subacromial spacer and other techniques, but other techniques have high retear rate.	Small number of patients treated with spacer.
Kunze KN, Moran J et al. (2023) High	Systematic review and meta-analysis	Patients who underwent isolated	Other systematic reviews included

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rate of clinically meaningful achievement in outcomes after subacromial balloon spacer implantation for massive irreparable rotator cuff tears: a systematic review and meta-analysis	N=748 (of which 379 underwent subacromial balloon spacer implantation) Follow-up: 1-3 years depending on outcome measure.	subacromial balloon spacer implantation for massive irreparable rotator cuff tears demonstrated a high rate of clinically significant improvement in Constant-Murley score, ASES and OSS.	similar studies. This paper was published after literature search was completed.

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