NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of superior capsular augmentation for massive rotator cuff tears

The rotator cuff is a group of muscles and tendons that surround the shoulder joint and help to keep it stable. A tear in a rotator cuff tendon can cause pain, limit arm movement and may lead to arthritis. This procedure involves using a graft to fix the top of the shoulder socket to the top of the upper arm bone when the muscles and tendons are no longer repairable. The aims are to stabilise the shoulder joint, reduce pain and improve shoulder function.

Contents

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety

and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in November 2017.

Procedure name

- Superior capsular augmentation for massive rotator cuff tears

Specialist societies

- British Elbow and Shoulder Society (subgroup of the British Orthopaedic Association)
- Royal College of Surgeons.

Description of the procedure

Indications and current treatment

Patients with rotator cuff tears may have shoulder pain and weakness accompanied by functional limitation 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 physiotherapy, pharmacological treatments (including pain relief and topical or oral non-steroidal anti-inflammatory drugs) and corticosteroid injections. If the tear is severe or has not responded to other treatments, surgical interventions such as debridement, rotator cuff repair, bridging rotator cuff reconstruction, subacromial smoothing, tendon transfer, or shoulder arthroplasty may be needed.

What the procedure involves

Superior capsular augmentation aims to improve pain symptoms and shoulder function in patients with massive and otherwise irreparable rotator cuff tears. The intention is to reduce superior gleno-humeral translation and restore superior stability with minimal re-tear rates. The optimal repair uses the patient's own rotator cuff muscles and tendons, but if the tear is too large augmentation with other tissue may be needed.

Superior capsular augmentation is done arthroscopically or by open surgery with the patient either in the lateral decubitus position, or the 'beach-chair' position, and under general anaesthesia. It involves using a fascia lata autograft, an allograft or a regenerative tissue matrix. The arm of the patient is kept in neutral abduction and in neutral rotation. The supraspinatus and infraspinatus are repaired as much as possible and a biceps tenotomy or tendonesis are done on any biceps tear or instability. The superior glenoid and greater tuberosity are debrided to prepare for reconstruction. Using suture anchors, the graft is attached medially to the glenoid superior tubercle and laterally to the greater tuberosity. Side-to-side sutures between the graft and the infraspinatus tendon, as well as between the graft and the residual anterior supraspinatus/subscapularis may also be added to improve force coupling. Post-operative rehabilitation is essential and can be long and difficult.

Efficacy summary

Procedure success

In a prospective case series of 59 patients, the rate of procedure success (defined as final American shoulder and elbow surgeons score [ASES] greater than 50, combined with a 17-point postoperative improvement in the ASES and no need for reverse shoulder arthroplasty or revision superior capsular reconstruction) was 68% (40/59). [1]

Improvement in shoulder function

In a retrospective case series of 23 patients (24 shoulders), the mean (± standard deviation [SD]) ASES improved statistically significantly from 23.5±14.4 before the procedure to 92.9±11.3 after a mean follow-up of 34 months ($p<0.00001$, scale from 0 to 100 points). In the same study, the Japanese orthopaedic association score (scale from 0 to 100 points) and the University of California, Los Angeles score (scale from 0 to 35 points) also improved statistically significantly from 48.3±13.0 to 92.6±9.0 and from 9.9±4.7 to 32.4±4.3 respectively ($p<0.00001$). The mean shoulder active range of motion improved statistically significantly for elevation from 84º±52.2º to 148º±33.4º ($p<0.001$), for external rotation from 26º±14.1º to 40º±17.2º ($p<0.01$) and for internal rotation from L3 to L1 ($p<0.01$). The shoulder muscle strength improved statistically significantly for abduction and external rotation from grade 5 to 9 on a 10-grade scale and from grade 8 to 10 for internal rotation ($p<0.001$ for all measures). There was no further change for the range of motion and the muscle strength beyond 2 years after the procedure.[2]

In the prospective case series of 59 patients, the mean (±SD) shoulder active range of motion improved statistically significantly for active forward flexion from 130º±48º before the procedure to 158º±32º at a mean 18-month follow-up ($p<0.001$), for active external rotation from 36º±18º to 45º±17º ($p=0.008$) and for internal rotation from L3 to L1 ($p<0.001$). In the same study, the shoulder

functional scores also improved statistically significantly after a mean follow-up of 18 months, from 43.6±18.6 to 77.5±22.0 for the ASES and from 35.0±19.9 to 76.3±25.2 for the subjective shoulder value ($p<0.001$). [1]

Improvement in pain symptoms

In the prospective case series of 59 patients, the mean (±SD) visual analogue scale score (score ranges from 1 to 10 from best to worst) improved statistically significantly from 5.8±2.2 before the procedure to 1.7±2.1 at a mean 18-month follow-up ($p<0.001$).[1]

Patient satisfaction

In the prospective case series of 59 patients, 73% (43/59) of patients were satisfied with the procedure. [1]

Return to normal activities

In the prospective case series of 59 patients, 69% (41/59) of patients returned to normal activity. [1]

Re-tear rate

In the retrospective case series of 23 patients, 83% (20/24) of shoulders had no graft tears or no re-tears of the repaired rotator cuff tendon during the mean follow-up of 34 months, 12.5% (3/24) of shoulders with severe fatty degeneration of the infraspinatus tendon had re-tears of the repaired infraspinatus tendon at 3 months after surgery and 1 patient whose surgery was a revision procedure, had a postoperative graft tear 3 months after surgery.[2]

Secondary procedures

In the prospective case series of 59 patients, 19% (11/59) of patients had revision procedures: 12% (7/59) had a reverse shoulder arthroplasty, 3% (2/59) had a revision superior capsular reconstruction, 2% (1/59) had a debridement and placement of an antibiotic spacer and 2% (1/59) had an open subpectoral tenodesis. [1]

Safety summary

Detachment of the allograft

Detachment of the allograft from the glenoid was reported 8 months after the procedure in a single case report. The graft was reattached with new suture anchors and additional side-to-side anastomosis between the posterior portion of the graft and the infraspinatus tendon was done using multiple sutures.[3]

Infection

An infection was reported in 1 patient after the procedure in a case series of 59 patients; it needed debridement and placement of an antibiotic spacer.[1]

A mild infection was reported in 3% (2/70) of patients after the procedure in a case series of 70 patients (72 shoulders). It was treated with antibiotics and arthroscopic debridement without removal of the reconstructed superior capsule.[4]

Pain

Persistent biceps pain after a proximal tenodesis was reported in 1 patient after the procedure in the case series of 59 patients; it was treated with an open subpectoral tenodesis.[1]

Contracture of the shoulder

A severe contracture of the shoulder was reported in 3% (2/70) of patients after the procedure in the case series of 70 patients. It was treated with arthroscopic capsular release in the inferior glenohumeral joint.[4]

Suture anchor pull-out

Pull-out of the suture anchor was reported in 6% (4/70) of patients after the procedure in the case series of 70 patients. There were no consequences on the procedure clinical outcomes.[4]

Fall

A fall was reported in 3% (2/59) of patients after the procedure in the case series of 59 patients (no further details provided).[1]

Anecdotal and theoretical adverse events

As well as safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, the specialist advisers did not list any anecdotal adverse events. They considered that the following were theoretical adverse events: compartment syndrome from prolonged procedure, failure of the graft used to perform capsular reconstruction and swelling.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to superior capsular augmentation for massive rotator cuff tears. The following

databases were searched, covering the period from their start to 21 November 2017: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with massive rotator cuff tears.
Intervention/test	Superior capsular augmentation.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 153 patients from 3 case series[1,2,4] and 1 case report[3].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on superior capsular augmentation for massive rotator cuff tears

Study 1 Denard P J (2018)

Details

Study type	**Prospective case series**
Country	US (4 centres)
Recruitment period	2014–16
Study population and number	n=**59** patients with irreparable massive rotator cuff tears
Age and sex	Mean 62 years; 66% (39/59) male
Patient selection criteria	Inclusion criteria: arthroscopic SCR done with a dermal allograft. Exclusion criteria: revision SCR, an irreparable subscapularis tear, active infection, or neurologic pathology limiting shoulder function.
Technique	Arthroscopic superior capsular reconstruction with dermal allograft. The decision to do SCR was made intraoperatively based on the inability to achieve a complete repair following mobilisation. Graft thickness was 1 mm in 5 patients, 2 mm in 2 patients, and 3 mm in all other patients. Postoperatively, patients were immobilised in a sling for 6 weeks without dedicated physical therapy. At 6 weeks postoperatively, the sling was discontinued, and passive forward flexion and passive external rotation were allowed. At 3 to 4 months postoperatively, active forward flexion and passive internal rotation were allowed and strengthening was initiated. Return to full activity was allowed at 6 to 12 months, including all sports activities without restriction.
Follow-up	**Minimum 1 year (mean 18 months)**
Conflict of interest/source of funding	The authors reported the following potential conflicts of interest or sources of funding: PJD receives support from Arthrex; PCB receives support from Arthrex; CRA receives support from Arthrex; JMT receives support from Arthrex, DePuy, and Mitek; SSB receives support from Arthrex and Wolters-Kluwer.

Analysis
Follow-up issues:

- Sixty-seven patients met the study criteria. No patient declined to participate in the study. Eight patients were lost to follow-up, leaving 88% (59/67) of patients available for the analysis.
- 59% (35/59) of patients had radiographs at 2 weeks postoperatively, and 75% (44/59) had radiographs at 1 year postoperatively.
- Only 20 patients had postoperative MRIs to evaluate graft healing.

Study design issues:

- Range of motion and functional outcome according to visual analogue scale (VAS) pain, American Shoulder and Elbow Surgeons (ASES) score, and subjective shoulder value (SSV) score were assessed preoperatively and at final follow-up. Radiographs were used to evaluate the acromiohumeral interval (AHI).
- For final analysis, postoperative functional scores and range of motion were excluded in patients who were converted to reverse shoulder arthroplasty.
- At final follow-up patient satisfaction (yes or no), return to normal activities (yes or no), and any complications or revision surgery were recorded.
- All MRIs and radiographs were reviewed by a single author.

Study population issues: 42% (25/59) of patients had had a range of 1 to 3 previous rotator cuff repairs.

Other issues Radiographs were not fluoroscopically controlled, which limited the evaluation of the AHI.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **59**

Shoulder range of motion

	Preoperative status (mean±SD)	Postoperative status (mean±SD)	p value
Active forward flexion	130º± 48º	158º±32º	<0.001
Active external rotation	36º±18º	45º±17º	0.008
Internal rotation, spinal level	L3	L1	<0.001

Pain

	Preoperative status (mean±SD)	Postoperative status (mean±SD)	p value
VAS pain	5.8 ± 2.2	1.7± 2.1	<0.001

Shoulder functional scores

	Preoperative status (mean±SD)	Postoperative status (mean±SD)	p value
ASES	43.6±18.6	77.5±22.0	<0.001
SSV	35.0±19.9	76.3±25.2	<0.001

AHI

	Preoperative status (mean ±SD)	Postoperative status (mean±SD)	p value
AHI	6.6±3.0 mm	6.7±3.0 mm	0.889

Patient satisfaction: 73% (43/59)

% return to normal activities: 69% (41/59)

Complete healing of the graft (based on MRI): 45% (9/20) of the grafts

Secondary procedures: 19% (11/59)

12% (7/59) had a reverse shoulder arthroplasty, 3% (2/59) had a revision SCR, 2% (1/59) had a debridement and placement of an antibiotic spacer and 2% (1/59) had an open subpectoral tenodesis.

Successful procedure: 68% (40/59)

The outcome was categorised as successful if the final ASES score was >50 based on a previous study combined with a 17-point postoperative improvement in the ASES to meet a minimal clinically important difference for rotator cuff tears and if the patient did not need reverse shoulder arthroplasty or revision SCR.

Safety

- **Fall**: 3% (2/59).
- **Infection**: 2% (1/59). It needed debridement and placement of an antibiotic spacer.
- Persistent **biceps pain** after a proximal tenodesis: 2% (1/59). It was treated with an open subpectoral tenodesis.

Abbreviations used: AHI, acromiohumeral interval; ASES, American Shoulder and Elbow Surgeons; SCR, superior capsular reconstruction; SD, standard deviation; SSV, subjective shoulder value; VAS, visual analogue scale.

Study 2 Mihata T (2013)

Details

Study type	**Retrospective case series**
Country	Japan (1 centre)
Recruitment period	2007–09
Study population and number	n=**23** consecutive patients (24 shoulders) with symptomatic irreparable rotator cuff tears (11 large [3 to 5 cm], 13 massive [>5cm])
Age and sex	Mean 65 years; 52% (12/23) male
Patient selection criteria	Inclusion criteria: irreparable rotator cuff tear (defined as a torn tendon that cannot reach the original footprint) that was evaluated during shoulder arthroscopy. Exclusion criteria: severe bone deformity such as Hamada classification type V, severe superior migration of the humeral head that does not move by traction of the arm, cervical nerve palsy, axillary nerve palsy, deltoid muscle dysfunction, and infection.
Technique	Arthroscopic superior capsule reconstruction using fascia lata. The use of an abduction pillow was recommended for 4 weeks after the procedure. After the immobilisation period, passive- and active-assisted exercises were started to promote 'scaption' (scapular plane elevation). 8 weeks after surgery, the patients began to do exercises to strengthen the rotator cuff and the scapula stabilisers. Physical therapists assisted all patients.
Follow-up	**Mean 34 months (range 24 to 51 months)**
Conflict of interest/source of funding	None

Analysis
Follow-up issues:
- From 2007 to 2009, 223 consecutive patients had arthroscopic surgery done by a single surgeon. Twenty-five patients with irreparable rotator cuff tears had arthroscopic superior capsule reconstruction, 24 had partial-thickness tears and 174 with full-thickness tears had arthroscopic rotator cuff repair.
- Among the 25 patients who had arthroscopic superior capsule reconstruction, 2 patients moved away and were lost to follow-up.
- Physical examination, radiography and MRI were done before surgery, at 3, 6 and 12 months after surgery, and yearly thereafter.

Study design issues:
- The objective of the study was to investigate the clinical outcomes and radiographic findings after use of arthroscopic superior capsule reconstruction on irreparable postero-superior rotator cuff tears.

Study population issues:
- One patient had the procedure in both shoulders.
- Mean duration of symptoms before surgery was 21.8 months (3 to 120 months).

Other issues: The patients are likely to be included in the Mihata (2015) abstract also included in table 2.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **23 patients (24 shoulders)**

Shoulder functional scores (n=24 shoulders)

	ASES score		JOA score		UCLA score	
	Preoperative	At final follow-up	Preoperative	At final follow-up	Preoperative	At final follow-up
Mean	23.5	92.9	48.3	92.6	9.9	32.4
SD	14.4	11.3	13.0	9.0	4.7	4.3

All scores improved statistically significantly from the preoperative to the final assessment (p<0.00001).

- ASES and JOA scores: scale of 0 (minimum) to 100 points (maximum); UCLA score: scale of 0 to 35 points.

Shoulder range of motion (n=24 shoulders)

	Active elevation (º)		Active external rotation (º)		Active internal rotation (º)	
	Preoperative	At final follow-up	Preoperative	At final follow-up	Preoperative	At final follow-up
Mean	84	148	26	40	L3	L1
SD	52.2	33.4	14.1	17.2	-	-

The shoulder active range of motion improved statistically significantly at the final follow-up for elevation (p <0.001), for external rotation (p < 0.01) and by 2 vertebral bodies for internal rotation (p < 0.01). There was no further change beyond 2 years after the procedure.

- Internal rotation decreased in 3 patients after surgery.

Shoulder muscle strength (n=24 shoulders)

	Abduction (Grade)				External Rotation (Grade)				Internal Rotation (Grade)			
	Preoperative		At final follow-up		Preoperative		At final follow-up		Preoperative		At final follow-up	
	MMT	10 scale	MMT	10 scale	MMT	10 scale	MMT	10 scale	MMT	10 scale	MMT	10 scale
Mean	3+	5	5-	9	3+	5	5-	9	4+	8	5	10

MMT is on a scale of 0 to 5; 10 scale is converted MMT grade to a scale of 0 to 10, where MMT 5 =10, MMT 5- = 9, MMT 4+ = 8, MMT 4 =7, MMT 4- = 6, MMT 3+ = 5, MMT 3 = 4, MMT 3- = 3, MMT 2 =2, MMT 1 = 1, and MMT 0 = 0.

The shoulder muscle strength improved statistically significantly from the preoperative assessment to the final assessment (p <0 .001 for abduction, external and internal rotation). There was no further change beyond 2 years after the procedure.

Acromiohumeral distance (radiographic evaluation, n=24 shoulders)

	AHD (mm)		
	Preoperative	At final follow-up	p
Mean	4.6	8.7	0.00001
SD	2.2	2.6	

The AHD in 58% (14/24) of shoulders was 5 mm or less before surgery. At final follow-up, the AHD was more than 5 mm in 92% (22/24) of shoulders.

MRI findings

- 83% (20/24) of shoulders had no graft tears or no re-tears of the repaired rotator cuff tendon during the follow-up.
- 12.5% (3/24) of shoulders with severe fatty degeneration of the infraspinatus tendon had re-tears of the repaired infraspinatus tendon at 3 months after surgery.
- 1 patient whose surgery was a revision procedure, had a postoperative graft tear 3 months after surgery.

Safety

There were no surgical complications or complications with the harvest site.

Abbreviations used: AHD, acromiohumeral distance; ASES, American Shoulder and Elbow Surgeons; JOA, Japanese Orthopaedic Association; MMT, manual muscle testing; SD, standard deviation; UCLA, University of California, Los Angeles.

Study 3 Zerr J (2017)

Details

Study type	**Case report**
Country	US
Recruitment period	Not reported
Study population and number	n= **1** patient with massive rotator cuff tear
Age and sex	55.5 years; male
Patient selection criteria	Not reported
Technique	Superior capsular reconstruction using a dermal patch allograft along with revision rotator cuff repair of the subscapularis
Follow-up	**8 months**
Conflict of interest/source of funding	None

Analysis

Study population issues: The patient had previously had rotator cuff repair and a revision of rotator cuff repair.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **1**

Examination findings

	pre-SCR	**post-SCR**	**post-SCR when graft had failed**	**7 weeks post-SCR revision**
Forward elevation	70º	130º	100º	100º
Abduction	60º	95º	80º	80º
External rotation	55º	40º	50º	40º
Strength	4/5	4/5	4/5	-

Safety

Detachment of the allograft from the glenoid

After returning to work about 6 months after the procedure, the patient noticed some mild shoulder pain and limitation in motion. Symptoms gradually progressed and a shoulder magnetic resonance (MR) arthrogram was done 8 months after the procedure.

Detachment of the allograft from the **glenoid** and anterior aspect of the rotator cuff was seen on the MR arthrogram. Repeat shoulder arthroscopy confirmed the partial detachment of the superior capsule graft from the posterior glenoid, although it remained fixed on the humeral side.

The graft was reattached with new suture anchors. Additional side-to-side anastomosis between the posterior portion of the graft and the infraspinatus tendon was done using multiple sutures.

The patient was doing reasonably well 7 weeks after the superior capsular reconstruction revision, with minimal improvement in his physical examination findings, complaining of some pain, and having physiotherapy.

Abbreviations used: SCR, superior capsular reconstruction.

Study 4 Mihata T (2015) [conference abstract only]

Details

Study type	**Case series**
Country	Japan
Recruitment period	2007–13
Study population and number	n=**70** consecutive patients (72 shoulders) with irreparable rotator cuff tears
Age and sex	Mean 65.5 years; gender not stated
Patient selection criteria	Patients with irreparable rotator cuff tears for whom conservative treatment had failed.
Technique	Arthroscopic superior capsule reconstruction using fascia lata.
Follow-up	**Mean 30.5 months (range 12 to 76 months)**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues:

- Physical examination, radiography and MRI were done before surgery, at 3, 6 and 12 months after surgery, and yearly thereafter.

Study design issues:

- The objective of the study was to investigate the clinical outcomes and radiographic findings after use of arthroscopic superior capsule reconstruction on irreparable postero-superior rotator cuff tears.

Study population issues:

- 2 patients had the procedure in both shoulders.

Other issues: Some of the patients included in this study are also likely to be included in the Mihata (2013) paper also included in table 2.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **70 patients (72 shoulders)** Efficacy findings from conference abstracts are not normally considered adequate to support decisions on efficacy and are not generally selected for presentation in the overview.	**Mild infection**: 3% (2/70) It was treated with antibiotics and arthroscopic debridement without removal of the reconstructed superior capsule. **Suture anchor pull-out**: 6% (4/70) There were no consequences on the procedure clinical outcomes. **Severe contracture of the shoulder**: 3% (2/70) It was treated with arthroscopic capsular release in the inferior glenohumeral joint. There were no complications with the harvest site.

Validity and generalisability of the studies

- The evidence base was limited to 2 case series of 59 and 23 patients with a mean follow-up of 18[1] and 34 months[2], 1 case report[3] and 1 abstract[4] included for the safety data.

- There seems to be a learning curve associated with this procedure.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- Biodegradable subacromial spacer insertion for rotator cuff tears. NICE interventional procedures guidance 558 (2016). Available from http://www.nice.org.uk/guidance/ipg558.
- Shoulder resurfacing arthroplasty. NICE interventional procedures guidance 354 (2010). Available from http://www.nice.org.uk/guidance/ipg354.
- Extracorporeal shockwave lithotripsy for calcific tendonitis (tendinopathy) of the shoulder. NICE interventional procedures guidance 21 (2003). Available from http://www.nice.org.uk/guidance/ipg21.

Additional information considered by IPAC

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Two

Specialist Advisor Questionnaires for superior capsular augmentation for massive rotator cuff tears were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme will send questionnaires to NHS trusts for distribution to patients who had the procedure (or their carers). When NICE has received the completed questionnaires, these will be discussed by the committee.

Issues for consideration by IPAC

There was no ongoing trial.

References

1. Denard P J, Brady P C, Adams C R et al. (2018) Preliminary Results of Arthroscopic Superior Capsule Reconstruction with Dermal Allograft. Arthroscopy: The Journal of Arthroscopic and Related Surgery, Vol 34, No 1: pp 93-99
2. Mihata T, Lee T Q, Watanabe C et al. (2013) Clinical results of arthroscopic superior capsule reconstruction for irreparable rotator cuff tears. Arthroscopy 29(3), 459-70
3. Zerr J, McDermott J D, Beckmann N M et al. (2017) Case study: failure of superior capsular reconstruction using dermal allograft. Skeletal Radiology 46(11), 1585-1589
4. Mihata T and Lee T Q (2015) Clinical Outcomes of Superior Capsule Reconstruction for Irreparable Rotator Cuff Tears without Osteoarthritis in the Glenohumeral Joint. Journal of shoulder and elbow surgery 24(4) e107–e109

Appendix A - Additional relevant papers

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Roberson T A, and Tokish J M (2017) Superior Capsular Reconstruction for Irreparable Rotator Cuff Tears. Techniques in Shoulder and Elbow Surgery 18(1), 8-14	Single case report	Superior capsular reconstruction does offer great promise to fill a previously unmet need and as such further investigation is warranted to define the nuances of technique and supporting clinical outcomes.	Description of the procedure technique.

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	21/11/2017	Issue 11 of 12, November 2017
HTA database (Cochrane)	21/11/2017	Issue 4 of 4, October 2016
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane)	21/11/2017	Issue 10 of 12, October 2017
MEDLINE (Ovid)	21/11/2017	1946 to November Week 2 2017
MEDLINE In-Process (Ovid)	21/11/2017	November 20, 2017
EMBASE (Ovid)	21/11/2017	1974 to 2017 Week 47
PubMed	21/11/2017	n/a
BLIC (British Library)	21/11/2017	n/a

Trial sources searched

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

Websites searched

- National Institute for Health and Care Excellence (NICE)
- 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)
- EuroScan
- 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.

1 Rotator Cuff/

2 Shoulder Impingement Syndrome/

3 Shoulder Joint/

4 Shoulder Pain/

5 Acromion/

6	(shoulder* or rotat* or rotor* or rotar* or cuff* or humer* or abcromi* or subabcromi* or sub-abcromi* or acromion* or arthroscop* or supraspinatus* or infraspinatus* or "teres minor*" or teres-minor* or subscapularis*).tw.
7	or/1-6
8	((scar* or tear* or torn* or rip* or ruptur* or absenc* or irrepair* or irreparab* or imping* or fullthick* or full-thick* or non-funct* or nonfunct* or ruptur*) adj4 (lesion* or large* or partial* or massive* or tendon* or ligament* or muscle*)).tw.
9	7 and 8
10	Rotator cuff injuries/
11	(rotat* adj4 cuff* adj4 injur*).tw.
12	or/9-11
13	Reconstructive Surgical Procedures/
14	(superior adj4 capsul*).tw.
15	((dermis or dermal or tissue* or fascia lata*) adj4 (matri* or scaffold* or autograft* or autotransplant* or allograft* or graft* or patch*)).tw.
16	SCR.tw.
17	or/13-16
18	12 and 17
19	(arthroflex or graftjacket).tw.
20	18 or 19
21	animals/ not humans/
22	20 not 21