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Use of implantable meshes for augmented rotator cuff repair: a systematic review and meta-analysis

Mathew Baldwin ,[1] N S Nagra,[1] Gemma Greenall,[1] Andrew J Carr,[1] David Beard,[1] J L Rees,[1] Amar Rangan,[1,2] Naomi Merritt,[1] Melina Dritsaki,[3] Sally Hopewell,[3] Jonathan Alistair Cook [1]

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[1]Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Oxford University, Oxford, UK
[2]Department of Orthopaedics, James Cook University Hospital, Middlesbrough, UK
[3]Centre for Statistics in Medicine, Oxford University, Oxford, UK

Correspondence to
Dr Mathew Baldwin; matthew.baldwin@ndorms.ox.ac.uk

ABSTRACT

Objective To appraise studies reporting on clinical effectiveness and safety of surgical meshes used to augment rotator cuff repairs (RCRs).

Design Systematic review and meta-analysis.

Data sources MEDLINE, Embase and Cochrane databases were searched between April 2006 and April 2020.

Eligibility criteria All studies evaluating adults (≥18 years) undergoing RCR were considered. There were no language restrictions.

Data extraction and synthesis Screening, data extraction and quality appraisal were conducted by two independent reviewers. Meta-analysis was conducted using a random-effects models if ≥2 comparative studies reported the same outcome measure. Risk of bias assessment was undertaken for randomised (RoB2, Cochrane) and comparative studies (ROBINS-I, Cochrane).

Results We included 60 studies, consisting of 7 randomised controlled trials, 13 observational comparative studies and 40 observational case series. All comparative studies reported on shoulder-specific functional outcome scores, 18 on the radiographic occurrence of re-tear and 14 on pain score metrics. All studies contained some risk of bias.

Compared with non-augmented repair, a small improvement in shoulder-specific function or pain scores was observed for synthetic patches with a mean improvement of 6.7 points on the University of California Los Angles (UCLA) shoulder score (95% CI 0.1 to 13.4) and 0.46 point reduction on the Visual Analogue Scale (95% CI −0.74 to −0.17), respectively. A reduced likelihood of radiologically observed re-tear was observed for synthetic (risk ratio (RR) 0.41, 95% CI 0.27 to 0.61) and allograft (RR 0.34, 95% CI 0.18 to 0.65) patches. A total of 49 studies reported on the occurrence of complications. Slightly higher crude complication rates were observed following patch-augmented repair (2.1%) than standard repair (1.6%).

Conclusions While several studies suggest a decreased failure rate and small improvements in shoulder function and pain following augmented RCR, a paucity of rigorous clinical evaluation, for both effectiveness and safety, prevents firm recommendations.

Prospero registration number CRD42017057908.

Strengths and limitations of this study

- ► The largest systematic appraisal of the clinical effectiveness and safety of implantable meshes for augmented rotator cuff repair.
- ► Thorough searching of three major electronic databases and reporting as per Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines. The study protocol was published a priori, with inclusion of all non-English language articles.
- ► Study bias and substantial heterogeneity between studies means that our meta-analysis results must be interpreted very cautiously, seriously limiting our ability to draw firm recommendations.
- ► The observed differences in outcomes between patch types could reflect, to some degree, chance findings given the limited numbers of studies and small typical study size. Confirmation of findings by further trials is warranted.

INTRODUCTION

Shoulder pain is the third most prevalent musculoskeletal disorder and is responsible for prolonged periods of disability, absence from work and a significant health-economic burden.[1–3] Rotator cuff problems account for a large proportion of shoulder pain and results in pain, weakness, reduced shoulder mobility and sleep disturbance.[4] It is estimated that the overall prevalence of full-thickness tears is between 15% and 20% with the rate set to increase as populations age.[5 6] While some are asymptomatic, many symptomatic full-thickness tears will often require surgical repair, with successful repair correlating with symptom resolution.[7] Indeed, 9000 rotator cuff repairs (RCRs) are performed each year in the NHS in England alone, at a cost of £6500 per operation.[8] Unfortunately, randomised controlled trials (RCTs) have demonstrated a failure rate of up to 40%, with increasing patient age and tear size, both predictive of failure.[7 9] While various surgical techniques have attempted to

improve the outcome of RCR, there remains a real need to improve healing rates.

One approach is the use of an implant called a surgical mesh, or patch, to augment the repair. A patch made from Teflon was first described over 30 years ago,[10] but recently, the number and types of patch specifically for rotator cuff surgery have increased significantly. These can broadly be divided into categories based on the materials used; xenograft or allograft are decellularised extracellular matrix derived from animal or human cadaveric tissues, respectively; synthetic grafts are materials derived from a variety of bio-inert polymers; and autografts are patient's own whole tendon harvested from various anatomical sites. Patch augmentation can also be classified based on the method of application into 'on-lay' or 'bridging'. The former refers to the application of a synthetic or biological patch over the top of a standard repair to provide mechanical stability and biological stimulation, reducing the likelihood of failure and improving patient outcomes.[11 12] In contrast, 'bridging' refers to the use of a patch as an interposition graft to fill any residual defect of an otherwise irreparable tear, providing a scaffold for the regeneration of tendon and/or scar tissue formation.[13]

Recent and important debate surrounding medical device regulation has emphasised the need for robust evaluations of safety, efficacy and surveillence.[14] Unfortunately, in the context of patch augmentation, the growing number of available patches, mixed results and recent concerns over safety, including adverse immunological responses,[15] have generated a clouded and uncertain landscape.

The aim of this systematic review is to identify and critically appraise those studies reporting on the clinical effectiveness and safety of patch-augmented surgical repair in adults with rotator cuff tears.

METHODS

Protocol and registration

The review protocol and search strategy has been previously been registered (PROSPERO Registration: CRD42017057908) and published in full.[16]

Eligibility criteria

Population

The review incorporated studies of adult (≥18 years) patients who required surgical repair of a rotator cuff tear. No restrictions were applied to tear type (partial or full thickness), size (small through to massive), tendon involvement (supraspinatus, infraspinatus, teres minor or subscapularis), primary or recurrent tears, or the presence of medical comorbidities. For the purpose of this review small (<1 cm), medium (1–3 cm) and large (3–5 cm) tears were classified according to the DeOrio and Cofield classification.[17] Due to the large number of classification systems available, tears were considered massive if they met one of following criteria: (1) Measured >5 cm in the anterior-posterior dimension,[17] (2) Involved ≥2 tendons,[18] or were (3) Described as being massive by the study authors.

Interventions

All studies where at least one treatment arm included the use of patches to augment rotator cuff surgery were included. A patch was defined as an implantable human, synthetic or animal material which is used with the aim of improving tissue healing and/or patient outcome via some form of mechanical support. Patches were grouped into xenograft, allograft, autograft or synthetic. There was no restriction placed on the type of surgery received or the experience of the surgeon. The type of patch surgery was classified as either (1) 'on-lay' or (2) 'bridging' in accordance with previously reported definitions.[19] We excluded studies that investigated the use of sutures or anchors in isolation, or studies investigating drug therapy or physiotherapy, except when used as a comparator group or in addition to patch augmentation.

Comparators

No restriction was placed on the type or number of control groups.

Outcomes

The primary outcomes of interest in this review were: (1) Shoulder-specific function and pain scores—measured using a previously validated scale. (2) Patch-related adverse events (complications). (3) Shoulder pain outcomes—measured using validated tools such as the Visual Analogue Scale (VAS) or other scales. (4) Health-related quality life—measured using tools such as Short Form-36 (SF-36), EuroQol 5-dimension (EQ-5D) Questionnaires or other assessment measures. The main secondary outcome was the radiological assessment of postoperative rotator cuff integrity (re-tear).

Study types

We considered all relevant RCTs and observational studies (comparative and single group) involving at least five patients. No language restrictions were applied. In vitro studies, animal studies, review articles, editorials and studies involving up to five patients were all excluded.

Search strategy

A previous Cochrane review had carried out a comprehensive search prior to April 2006.[20] We searched the following databases between the dates of April 2006 and February 2017 (and updated our search in April 2020): (1) MEDLINE, (2) Embase, (3) The Cochrane Library. In addition, the reference list of all identified articles and reviews identified were checked for relevant articles.[19 21–24]

Study selection

Two authors (MB and NSN) independently screened all titles and abstracts identified from the search strategy. Full reports for all relevant studies identified were then reviewed and assessed against the eligibility criteria. A

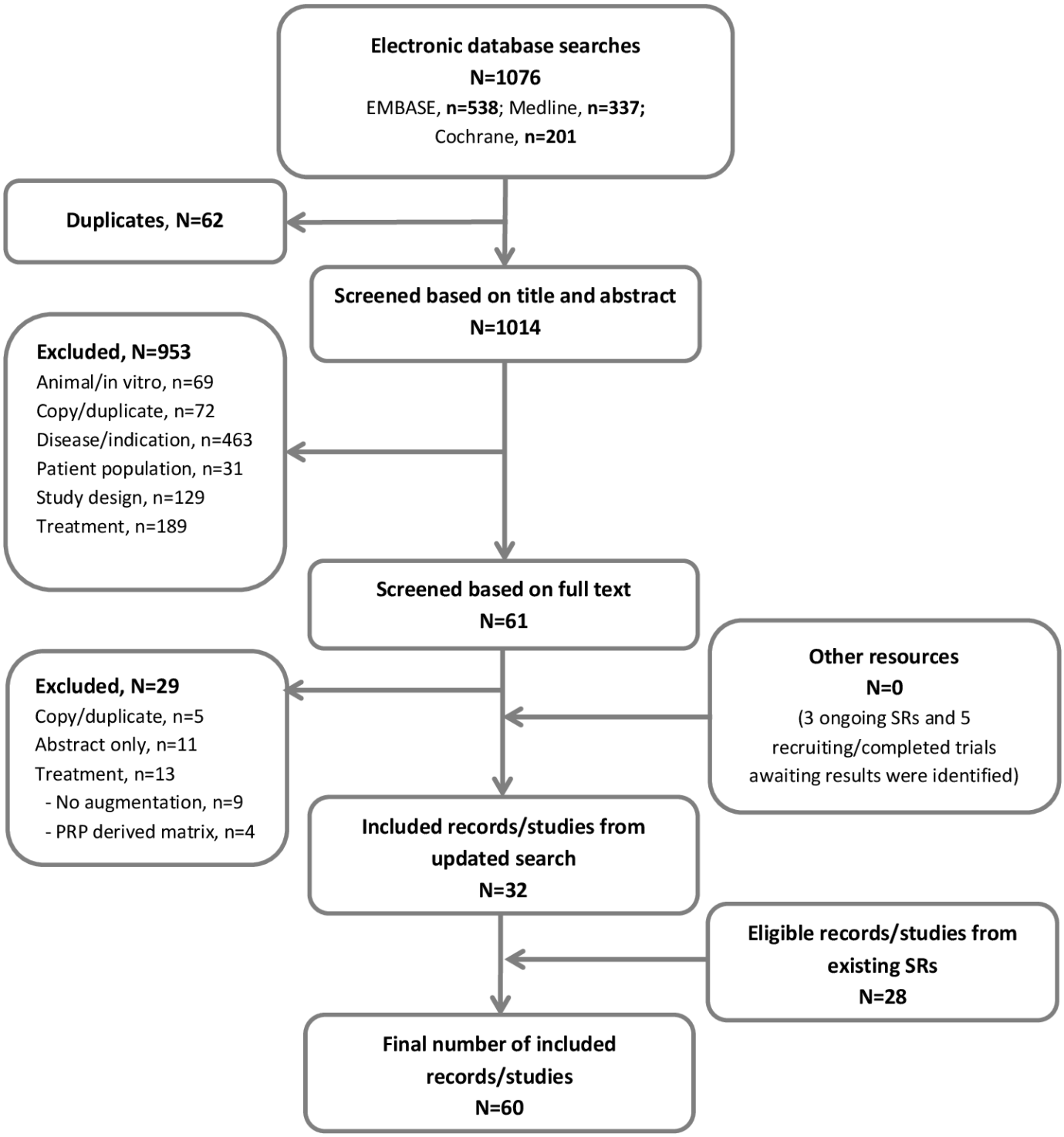

Figure 1 PRISMA flow chart of study selection. N, number; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; SR, systematic review.

third independent reviewer (GG) was available to resolve any disagreements regarding study inclusion. Reasons for exclusion are detailed in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flow diagram (figure 1).

Data extraction

Two authors (MB and NSN) extracted the following data from all eligible studies: general study information (authors, publication year, study location), study population (sample size, age, gender, tear size), study characteristics (study design, inclusion/exclusion criteria, duration of clinical and radiological follow-up, surgical technique, patch characteristics), all primary and secondary outcomes for each study, and adverse events or complications. Each reviewer independently checked the results of the data extraction process.

Risk of bias assessment

The risk of bias was independently assessed by two authors (MB and NSN) and discrepancies discussed with a third reviewer (GG) allowing resolution based on unanimous decision. RCTs were assessed using the isk-of-bias tool for randomized trials (RoB2) provided by the Cochrane Collaboration.[25] Observational comparative studies were assessed using the ROBINS-I tool (Risk Of Bias In Non-randomised Studies - of Interventions).[26]

Data analysis

Identified studies were stratified (RCTs, observational comparative studies, single-arm studies) and a narrative summary of results from RCTs and observational comparative studies reported in accordance with the standards set out in the PRISMA-P checklist.[27] Data from single-arm studies were only used in the quantification of complications. All studies that compared the outcomes of RCR with graft augmentation versus standard RCR were considered for meta-analysis. A meta-analysis was conducted only for outcomes consistently reported across studies and forest plots constructed using the R (V.3.2.4) packages 'meta' and 'metafor'. Regardless of the observed statistical heterogeneity, we conducted an analysis for each patch type (xenograft, allograft, autograft or synthetic) when each type was represented by at least two studies. Given the known controversy surrounding xenograft isolated from small intestinal submucosa (SIS), the analysis for xenografts was further divided into SIS-derived and non-SIS. There were insufficient study numbers to permit subgrouping based on graft configuration (on-lay or bridging).

Statistical analysis

For dichotomous parameters included in the meta-analysis the risk ratio (RR) with 95% CI was calculated for each graft type. For continuous variables, such as shoulder-specific functional outcome scores, the effect was reported as the mean difference with 95% CI. Due to significant heterogeneity in the specific functional shoulder scores used between studies, a meta-analysis was conducted using the most frequently used score across all studies at final follow-up. Within each patch type, if no single functional outcome score was consistently used, we combined scores and the standardised mean difference was meta-analysed (95% CI). Studies in which no SD was calculable, or where only subcomponents of functional outcome scores were reported, were excluded. Heterogeneity was characterised by use of the I^2 statistic and a random-effect analysis was used to allow for heterogeneity among studies. Meta-analyses were conducted on available data across all comparative studies; sensitivity meta-analyses were then performed to assess the impact of restricting to only one study design where two or more studies of the same design were available.

Patient involvement

Patient representatives were full members of the PARCS Study[28] steering committee and provided critical feedback on the systematic review protocol.

RESULTS

Study selection

The search strategy identified 1076 articles, of which 62 were duplicates (figure 1). A total of 1014 abstracts were reviewed in detail with 61 appearing to meet inclusion criteria. After full-text review 29 articles were excluded (details in figure 1). A further 28 articles were identified from existing systematic reviews, generating a total of 60 studies for inclusion, including 2 non-English language articles. The summaries below focus predominantly on the comparative (RCTs and observational) studies.

Study characteristics

Seven RCTs and 13 observational comparative studies analysing 1128 patient events were identified. Most comparative studies assessed a single patch against standard repair, with some studies having up to three treatment arms.[29–31] A single study compared autograft patch augmentation to conservative therapy,[32] while a further study assessed the effect of xenograft patch with or without mesenchymal stem cell augmentation.[33] The trial of mesenchymal stem cell augmentation by Lamas *et al* was terminated early due to safety concerns[33] as was the study by Walton *et al* which assessed the RESTORE patch.[34] Study population sizes ranged from 13 to 105 patients for RCTs (age range 29–85 years), and 9 to 152 patients (age range 36–83 years) among observational comparative studies, with a predominance of male participants across all studies. Only two studies included the full spectrum of full thickness tear sizes, with most studies instead restricting recruitment to large or massive tears of the supraspinatus and infraspinatus (table 1). Other eligibility criteria were highly heterogeneous (online supplemental table 1).

Surgical characteristics

Across all the comparative studies a total of 15 different patches was used. Decellularised xenograft patches were the most commonly investigated (n=9; Restore n=4). Surgical techniques could be classified as fully arthroscopic (55%, n=11), open (35%, n=7) or a mixture of both (10%, n=2). Regarding the method of patch utilisation, a larger proportion of studies investigated an 'on-lay' (60%, n=12) rather than a 'bridging' (40%, n=8) technique.

Risk of bias

Assessment of bias was conducted for all RCTs and comparative studies (online supplemental tables 2 and 3). For the study by Bryant *et al*[35] some concerns over bias were identified but with the remaining RCTs assessed as having a high risk. These findings are based

Table 1 Patch type and population demographics

	Patch type										Patient demographics		
	Xenograft			Human		Synthetic							
Study	Dermal	Intestinal	Other	Allograft*	Autograft	Resorbable	Non-resorbable	Brand	Surgical approach	Surgical patch technique	Age at surgery, mean (range or ±SD)	Gender, n male (%)	Tear size
Randomised comparative studies													
Avanzi[37]	✓							Conexa	Arthroscopic	On-lay	68 (58–78)	14 (30)	Small to medium†
								Control			66 (54–76)	22 (48)	Small to medium†
Barber[36]				✓				Graftjacket	Arthroscopic	On-lay	56 (43–69)	18 (82)	Small to massive‡
								Control			56 (34–72)	13 (65)	Small to large‡
Byrant[35]		✓						Restore	Open	On-lay	55 (29–40)	29 (85)	Small to massive‡
								Control			58 (40–81)	22 (79)	Small to massive‡
Cai[38]	NR							Collagen matrix	Arthroscopic	On-lay	62 (50–85)	24 (47)	Large to massive†
								Control			61 (50–80)	32 (60)	Large to massive†
Ianotti[39]		✓						Restore	Open	On-lay	58 (NR)	11 (73)	Large to massive‡
								Control			57 (NR)	12 (80)	Large to massive‡
Lamas[33]			✓§					MSCs+OrthADAPT	Open	On-lay	57 (±6.5)	6 (75)	NR
			✓§					OrthADAPT			61 (±3.8)	2 (40)	
Leuzinger[29]				✓				Graftjacket	Arthroscopic	On-lay	66 (51–81)	20 (71)	Massive¶
						✓		Artelon			68 (52–79)	23 (22)	Massive¶
		✓						Restore			68 (50–82)	20 (69)	Massive¶
Non-randomised comparative studies													
Ciampi[30]							✓	Repol Angimesh	Open	On-lay	66 (57–77)	41 (79)	Massive¶
			✓**					Tutopatch			66 (58–76)	38 (78)	Massive¶
								Control			67 (58–77)	35 (69)	Massive¶
Flury[41]	✓							DX reinforcement matrix + PRP	Arthroscopic	On-lay	67 (±3.1)	6 (30)	NR
								Control			65 (±3.3)	6 (30)	
Gilot[40]				✓				Arthroflex	Arthroscopic	On-lay	58 (±6.2)	8 (60)	Large to massive‡
								Control			62 (±4.6)	7 (47)	Large to massive‡

Continued

Table 1 Continued

	Patch type										Patient demographics		
	Xenograft			Human		Synthetic							
Study	Dermal	Intestinal	Other	Allograft*	Autograft	Resorbable	Non-resorbable	Brand	Surgical approach	Surgical patch technique	Age at surgery, mean (range or ±SD)	Gender, n male (%)	Tear size
Ito[42]				✓‡‡				Fascia lata (cadaveric)	Open	Bridging	63 (49–70)	6 (67)	Large to massive‡
								Control			52 (36–66)	10 (83)	Large to massive‡
Jeon[43]					✓			Biceps (long head)	Arthroscopic	Bridging	62 (46–82)	14 (45)	Medium‡
								Control			63 (46–82)	16 (48)	Medium to large‡
Maillot[31]	✓							Conexa	Open	On-lay	56 (46–63)	5 (45)	Medium to massive‡
								Standard repair	Arthroscopic		58 (45–71)	5 (42)	Medium to massive‡
								Debridement	Arthroscopic		60 (54–76)	3 (33)	Medium to massive‡
Mori[13]					✓			Fascia lata	Arthroscopic	Bridging	65 (±8.9)	17 (71)	Medium to massive‡
								Control			65 (±9.2)	10 (42)	Medium to massive‡
Mori[56]					✓			Fascia lata + grade 1–2 atrophy	Arthroscopic	Bridging	65 (±9.0)	18 (69)	Large to massive‡
					✓			Fascia lata + grade 3–4 atrophy			67 (±6.2)	11 (58)	Large to massive‡
Tempelaere[44]					✓			Quadriceps tendon	Open	Bridging	NR	18 (78)	Massive††
								Control	Arthroscopic		NR	15 (56)	Massive††
Veen[32]					✓			Biceps (long head)	Arthroscopic	Bridging	64 (61–67)	3 (75)	Massive¶††
								Control			65 (57–72)	1 (3)	Massive¶††
Vitali[46]					✓		✓	Repol Angimesh + biceps (long head)	Open	Bridging	66 (55–78)	15 (25)	Massive¶
								Control			67 (56–77)	18 (30)	Massive¶
Walton[34]		✓						Restore	Open	On-lay	60 (±3.5)	10 (67)	Large to massive†
								Control			59 (±3.1)	11 (69)	Large to massive†
Yoon[45]				✓				Allocover	Arthroscopic	Bridging	64 (±8.7)	9 (43)	Large to massive‡
								Control			62 (±6.7)	26 (48)	Large to massive‡
Non-comparative studies													

Continued

Table 1 Continued

	Patch type										Patient demographics		
	Xenograft			Human		Synthetic							
Study	Dermal	Intestinal	Other	Allograft*	Autograft	Resorbable	Non-resorbable	Brand	Surgical approach	Surgical patch technique	Age at surgery, mean (range or ±SD)	Gender, n male (%)	Tear size
Agrawal[57]				✓				Allopatch HD	Arthroscopic	On-lay	54 (47–69)	10 (71)	Large to massive‡
Audenaert[58]							✓	Mersilene	Open	Bridging	67 (51–80)	23 (56)	Massive¶
Badhe[59]	✓							Zimmer collagen repair patch	Open	Bridging	66 (46–80)	5 (50)	Massive‡¶
Bektaser[60]					✓			**Coracoacromial** ligament	Open	On-lay	54.3 (39–66)	4 (8.6)	Medium to massive‡
Bond[61]				✓				Graftjacket	Arthroscopic	Bridging	54 (39–74)	13 (81)	Massive‡¶
Burkhead[62]				✓				Graftjacket	Open	On-lay	56 (NR)	12 (71)	Massive¶
Cho[63]	✓							Permacol	Open	On-lay	53 (45–57)	3 (60)	Massive‡¶
Consigliere[64]	✓							DX reinforcement matrix	Arthroscopic	On-lay	74 (65–82)	6 (40)	Large to massive¶
Encalada-Diaz[65]							✓	Polycarbonate polyurethane patch	Open	On-lay	56 (44–65)	0	Small to large‡
Flury[66]				✓				Graftjacket or Arthroflex	Arthroscopic	On-lay	57 (50–68)	5 (63)	Medium to large‡
Giannotti[67]	✓							Zimmer collagen repair patch	Open	Mixed	66 (50–80)	4 (44)	Massive†
Gouk[68]				✓				Graftjacket	Open	Bridging	54 (44–59)	6 (86)	Massive‡¶
Gupta[69]				✓				Graftjacket	Open	Bridging	63 (45–83)	12 (50)	Massive†
Gupta[70]	✓							Conexa	Open	Bridging	60 (45–77)	12 (46)	Massive¶
Hirooka[71]							✓	Gore-tex PTFE	Open	Bridging	62 (44–75)	20 (74)	Small to massive‡
Johnson[72]				✓				Graftjacket	Open	Bridging	63 (31–77)	NR	Large to massive‡¶
Lederman[73]	✓							Conexa	Open	On-lay	56 (40–69)	NR	Large‡
Lenart[74]						✓		X-repair	Open	On-lay	57 (42–68)	9 (69)	Massive¶
Malcarney[15]		✓						Restore	Open	Mixed	NR	NR	NR
Marberry[75]						✓		Artelon	Open	On-lay	65 (45–76)	5 (29)	Massive¶
Metcalf[76]		✓						Restore	Open	On-lay	NR	NR	Massive†
Modi[77]				✓				Graftjacket	Open	Bridging	62 (47–72)	41 (67)	Large to massive‡
Moore[50]				✓‡‡				Cadaveric	Open	Bridging	59 (34–81)	23 (72)	Massive¶
Nada[78]							✓	Dacron	Arthroscopic	Bridging	66 (55–85)	14 (67)	Massive‡¶
Neumann[79]	✓							Conexa	Open	Bridging	62 (38–82)	21 (35)	Massive‡§

Continued

Table 1 Continued

	Patch type										Patient demographics		
	Xenograft			Human		Synthetic							
Study	Dermal	Intestinal	Other	Allograft*	Autograft	Resorbable	Non-resorbable	Brand	Surgical approach	Surgical patch technique	Age at surgery, mean (range or ±SD)	Gender, n male (%)	Tear size
Petrie[80]							✓	LARS	Open	Bridging	67 (NR)	21 (70)	Massive†
Petri[81]				✓				Arthroflex	Open	On-lay	57 (26–68)	11 (85)	Large to massive†
Petricciolo[82]						✓		SportMesh	Open	On-lay	61 (51–68)	8 (80)	Subscapularis tears
Phipatanakul[47]		✓						Restore	Open	On-lay	48 (31–62)	9 (82)	Massive†
Proctor[83]						✓		X-Repair	Arthroscopic	On-lay	66 (52–89)	NR	Massive¶
Rhee[84]					✓			Biceps (long head)	Mixed	Bridging	61 (46–79)	11 (35)	Massive‡¶
Rotini[85]				✓				Acellular human dermal matrix	Mixed	On-lay	48 (37–55)	5 (100)	Large to massive†
Sano[86]					✓			Biceps (long head)	Open	Bridging	64 (48–79)	12 (86)	Massive¶
Scheibel[48]					✓			Periosteum	Open	On-lay	59 (44–71)	16 (70)	NR
Schlegel[49]			✓§§					Collagen sheet	Arthroscopic	On-lay	54 (34–75)	19 (58)	N/A—partial thickness
Sclamberg[87]		✓						Restore	Open	Mixed	67 (52–79)	7 (64)	Large to massive‡
Sears[88]				✓				Graftjacket	Arthroscopic	On-lay			
	✓							Tissuemend			50 (37–70)	NR	NR
	✓							Conexa					
Smolen[89]							✓	Pitch-Patch	Arthroscopic	On-lay	64 (41–75)	34 (68)	Massive¶
Venouziou[90]				✓				Graftjacket	Open	Bridging	54 (33–64)	9 (64)	Massive†
Wong[91]				✓				Graftjacket	Arthroscopic	Bridging	53 (39–67)	36 (80)	Massive†

Control refers to rotator cuff repair without augmentation. For definitions of 'On-lay' and 'Bridging' see the Methods section.
*Allograft patches constructed from decellularised human dermis.
†Size of tear as reported by study authors—no details provided on classification used and insufficient detail to enable post hoc classification by review authors (MB and NSN).
‡DeOrio *et al*[17] (J Bone Joint Surg Am 1984:66:563–7).
§Patch derived from equine pericardium.
¶Gerber *et al*[18] (J Bone Joint Surg Am 2000;82:505–15).
**Patch constructed from decellularised bovine pericardium.
††Defined as grade 3 retraction according to Patte classification[92] (Clin Orthop Relat Res 1990;254:81–6).
‡‡Cadaveric source of allograft, irradiated but not decellularised.
§§Patch derived from bovine achilles.
DX, dermal xenograft ; HD, Human Dermis; LARS, Ligament Augmentation Reconstruction System; MSC, mesenchymal stem cells; NA, Not applicable; NR, not reported; PRP, Platelet-Rich Plasma; PTFE, polytetrafluoroethylene.

on inadequate randomisation methodologies and a lack of study methodology detail, in particular surrounding blinding of patients and outcome assessors. All observational comparative studies had a serious risk of bias, centring around the potential for confounding, bias in patient selection and outcome measurement.

Outcomes summaries

Shoulder-specific function and pain scores

Eleven different outcomes scores were used to assess shoulder-specific function and pain (online supplemental table 1). The Constant Scale (70%), American Shoulder and Elbow Surgeons (ASES) Score (40%) and University of California Los Angles (UCLA) Scale (30%) were most commonly reported in the comparative studies with most studies reporting multiple functional scores.

Among RCTs, only one study found a sustained, statistically meaningful improvement in ASES and Constant Scores, but not UCLA Scale, 2 years after implantation of an allograft patch (online supplemental table 4).[36] A further two studies, investigating a dermal xenograft (DX)[37] and an unspecified non-proprietary patch,[38] reported initial improvements in Constant Scores at 12 months, but this was not sustained at longer (2 years) follow-up. The two RCTs investigating decellularised porcine small intestine submucosa (Restore)[35 39] failed to demonstrate an improvement in patient-reported outcomes at 1–2 years follow-up, while the study by Leuzinger *et al*[29] only undertook intragroup comparisons between preoperative and postoperative Constant Scores, reporting similar improvements following implantation of an allograft, xenograft or synthetic patch.

For the non-randomised comparative studies, only three reported a significant improvement in functional shoulder scores for synthetic,[30] human allograft[40] and fascia lata autografts.[13] The remaining studies found no significant improvement,[31 34 41–45] while the studies by Ito *et al*,[42] Veen *et al*[32] and Vitali *et al*[46] did not undertake intergroup comparisons.

Repair failure

Integrity of the surgical repair was assessed by all RCTs and 11 (84%) observational comparative studies, with a re-tear rate ranging from 2% to 100% following patch implantation and 13% to 65% following a standard RCR (online supplemental table 5). MRI was the the most common imaging modality (72%) used to diagnose re-tears, with an MR arthrogram used in a further 17% of studies. The majority of studies (72%) undertook postoperative imaging after 1–2 years but with considerable heterogeneity existing in the radiological classification of re-tears and with seven studies[30 32 33 38 40 42 46] not providing any details. While the RCTs investigating human allograft (Graftjacket),[36] DX (Conexa)[37] and an unspecified collagen patch,[38] each demonstrated a significantly lower failure rate in the augmentation arm, neither of the RCTs investigating the small-intestine submucosa xenograft patch (Restore)[35 39] found any reduction in re-tear rate. In conflict with these findings, a multipatch comparative study[29] found no difference in failure rate between xenograft (Restore) and two different patches; human allograft (Graftjacket) or synthetic (Artelon). Among the observational comparative studies, significantly lower rates of re-tears were reported with augmentation using synthetic (Repol Angimesh),[30] autograft (fascia lata)[13] or allograft patches (Arthroflex and Allocover),[40 45] while no improvement in re-tears was observed following augmentation with DX (reinforcement matrix),[41] long head of biceps tendon autograft[43] or for the Restore[34] patch.

Pain scores

Only two studies (Gilot *et al*, Athroflex;[41] Mori *et al*, fascia lata[13]) reported significant reduction in pain when compared against standard repair (online supplemental table 6). Interestingly, the study by Walton *et al*, who used a 'mean activity pain score', found an increase in pain for the first 3 months following implantation of the Restore patch, which subsequently normalised by 6 months.[34] The remaining 10 studies either did not report intergroup comparisons (n=5),[30 32 33 42 46] or found no significant difference in pain scores between treatment arms (n=5).[39 43–45]

Quality of life

Only five comparative trials reported the use of either the SF-12, SF-36 or EQ-5D Scores (online supplemental table 7). When compared with standard repair, two RCTs investigating porcine SIS xenograft (Restore) found no difference in the physical or mental components of SF-36.[35 39] Similarly, an RCT (Avanzi *et al*)[37] and an observational comparative study (Flury *et al*)[41] assessing different DXs did not find an improved EQ-5D at 2-year follow-up. Conversely, a comparative study using human allograft (Athroflex) reported a significant improvement in all components of SF-12 at 6 months and 2 years postoperatively (though not at 3 months).[40]

Complications

Forty-nine studies provided data on complications, of which 24 studies reported the occurrence of 83 complications in a total population of 1567 patients undergoing any form of augmentative surgery and 488 patients receiving a standard RCR (online supplemental table 5). The overall crude complications rates were 4.5% for patients undergoing any form of patch augmentation and 1.6% following non-augmentative surgery. However, by excluding six studies in the augmentation group which had particularly high rates of complications (20%–74%) following quadriceps tendon, MSC seeded xenograft, Restore patch or humeral periosteal augmented repair,[33 34 39 44 47 48] the overall rate of complications following patch augmentation was 2.6%. An inflammatory response was recorded in 18 patients (all reported complications are detailed in online supplemental table 5). The majority of these events (n=11) occurred in patients who received an SIS xenograft (Restore) patch, but with reactions also

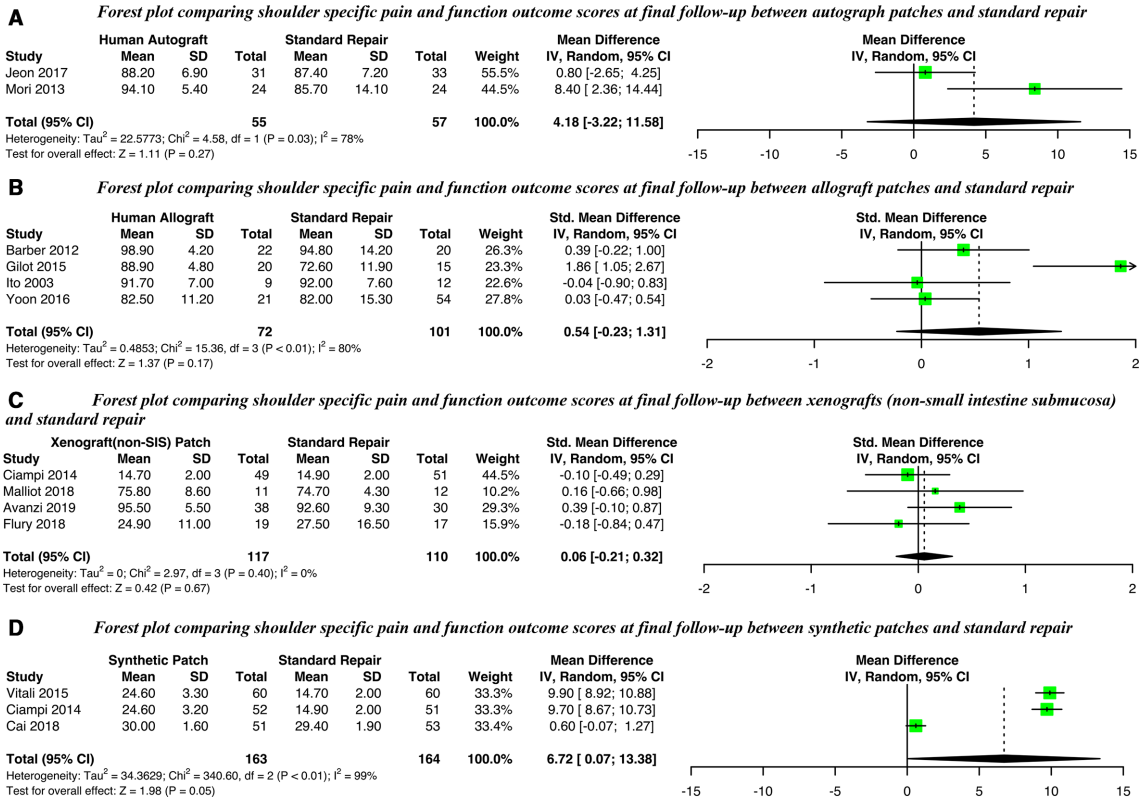

Figure 2 Forest plots comparing shoulder-specific functional outcomes scores at final follow-up for (A) Autografts, (B) Allografts, (C) Xenografts (non-SIS) or (D) Synthetic patches against standard repair alone. SIS, small intestine submucosa; IV, Random, a random-effects meta-analysis is applied, with weights based on inverse variances.

reported after implantation of bovine-derived,[49] equine-derived,[33] irradiated[50] or decellularised[29] human allograft and synthetic patches.[29] Excluding all adverse events concerning the Restore patch, which has been withdrawn from the marketplace, the crude complication rate for patches in current clinical use was 2.1%.

Meta-analysis

Shoulder-specific function and pain

Of the 20 comparative studies, 12 provided sufficient data on postoperative functional outcome scores to be included in the meta-analysis (figure 2). An improvement on the UCLA shoulder scale was observed for synthetic patches at long-term (range 24–36 months) follow-up (mean difference 6.72, 95% CI 0.07 to 13.38) but not in the ASES Score of studies of autografts (mean difference 4.18, 95% CI −3.22 to 11.58). Studies of allografts or xenografts derived from dermis or pericardium (non-SIS) used differing measures but with no significant standardised mean differences observed for either. Level of heterogeneity, across all patch types, was generally very high (I^2 >70%). Insufficient data were available for xenografts derived from intestinal submucosa (SIS). Sensitivity analyses did not find any impact of study design (randomised vs observational) except for synthetic patches where the sole RCT differed from the observational studies (online supplemental figure 1).

Re-tear rate

Fourteen studies were included in a meta-analysis for re-tear rate (figure 3). A significantly lower re-tear rate was seen for allograft patches (RR 0.34, 95% CI 0.18 to 0.65) and synthetic patches (RR 0.41, 95% CI 0.27 to 0.61) but not for autografts, SIS-derived or non-SIS-derived xenografts (there was substantial heterogeneity for the latter, I^2=67%). Meta-analysis results were not influenced by study design (online supplemental figure 2).

Pain

Eight observational comparative studies had sufficient data for a meta-analysis of postoperative pain (figure 4). A small, possibly non-clinically significant,[51] improvement in postoperative pain was only observed for synthetic patches (mean difference −0.46, 95% CI −0.74 to −0.17, I^2=0%). Meta-analyses of allograft, autograph and xenograph (non-SIS) patches did not show any statistically significant differences. Level of heterogeneity was generally very high (I^2 >70%). Insufficient data were available for a meta-analysis of postoperative pain following augmentation with xenograft patches derived from SIS.

Health-related quality of life

There were insufficient data available to meta-analyse the effect of patch augmentation on quality of life.

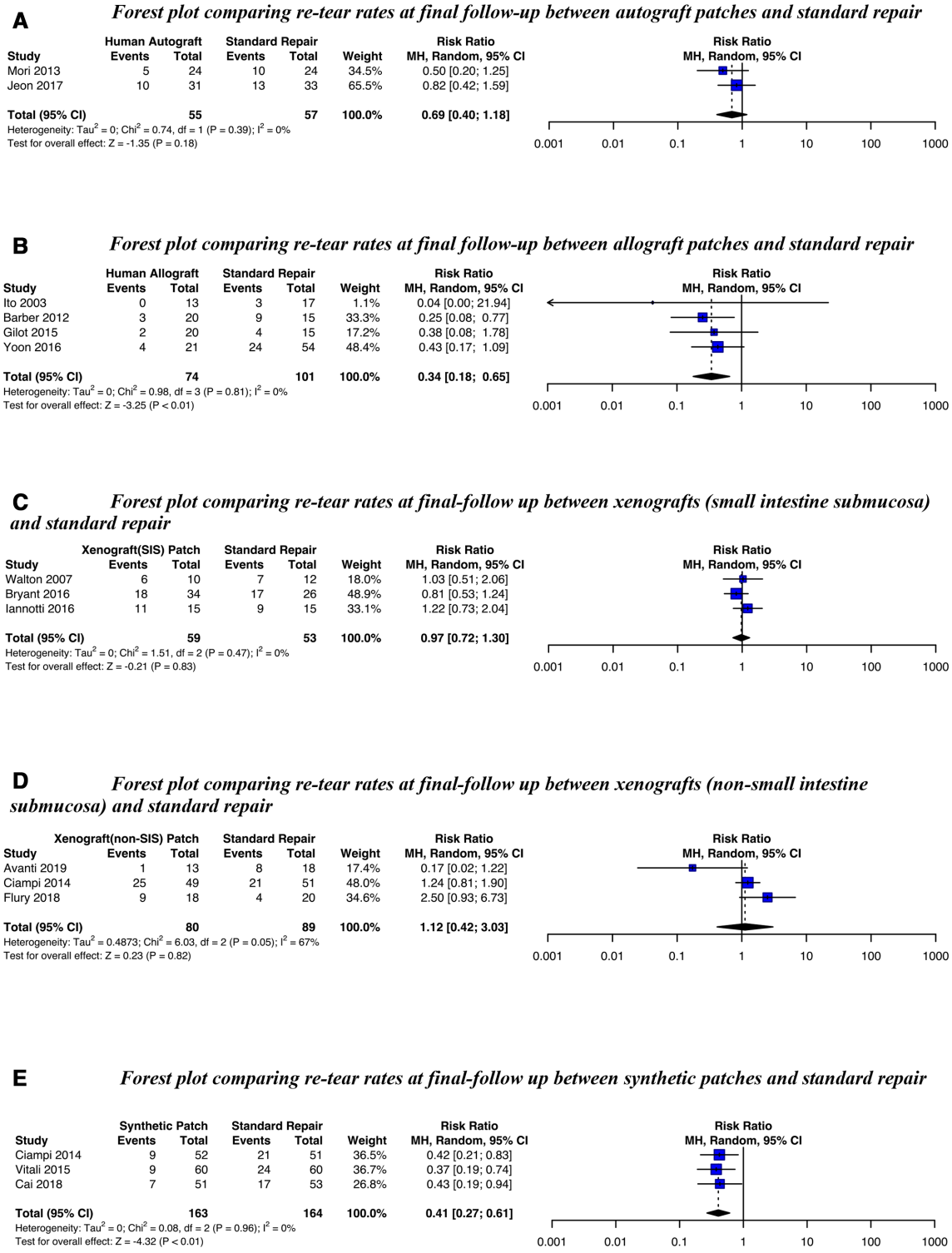

Figure 3 Forest plots comparing re-tear rates at final follow-up for (A) Autografts, (B) Allografts, (C) Xenografts (SIS) (D) Xenografts (non-SIS) or (E) Synthetic patches against standard repair alone. SIS, small intestine submucosa; MH, Random, a random-effects meta-analysis is applied, with weights based on the Mantel-Haenszel method.

DISCUSSION

The use of medical implants has recently come under increasing scrutiny. Surgical repair of the rotator cuff with patch augmentation has been proposed as a method of improving rates of tendon healing and patient outcomes. This systematic review is the largest and most comprehensive systematic appraisal of the clinical effectiveness and safety of such implants to date. Overall, the current evidence is not sufficiently robust to determine the effectiveness of patch-augmented RCR compared with standard repair alone. While this meta-analysis suggests a small improvement in pain and patient reported outcome measures (PROMS) for synthetic patches, and a moderate reduction in re-tear rate for synthetic and human allograft

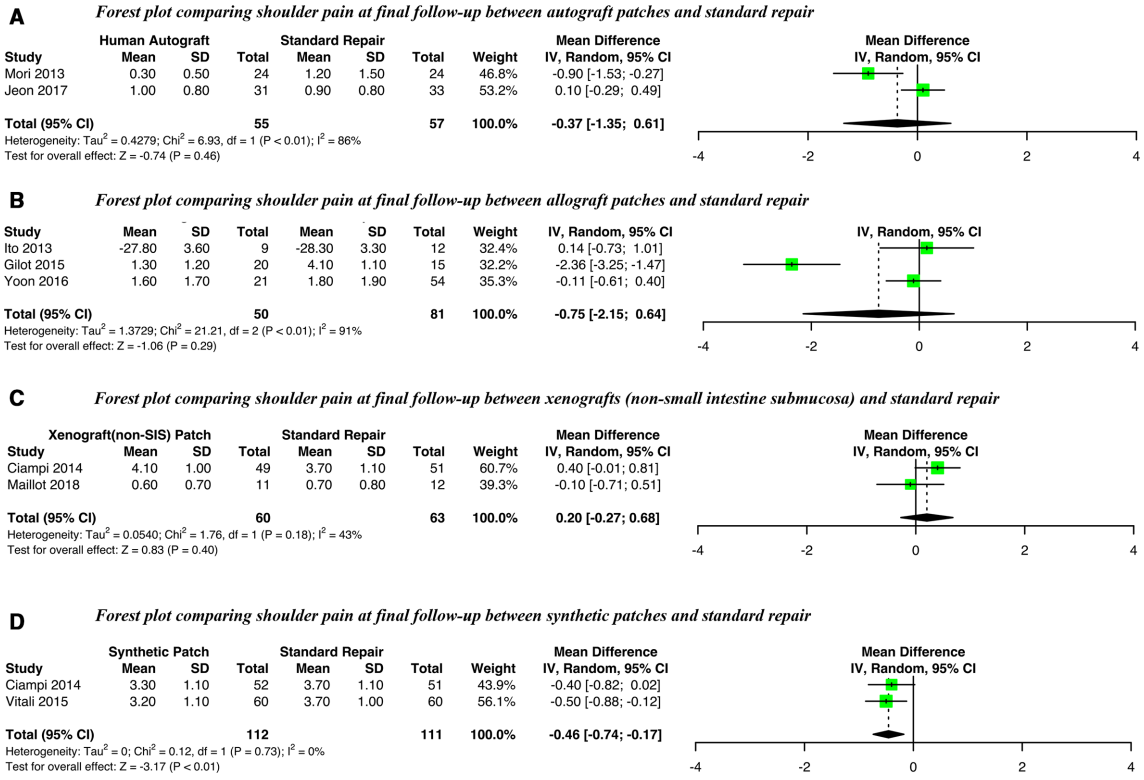

Figure 4 Forest plots comparing postoperative pain at final follow-up for (A) Autografts, (B) Allografts, (C) Xenografts (non-SIS) or (D) Synthetic patches against standard repair alone. SIS, small intestine submucosa; IV, Random, a random-effects meta-analysis is applied, with weights based on inverse variances.

patches, study bias and heterogeneity mean that these results need to be interpreted very cautiously. Further, it is unclear if the observed 6-point improvement in UCLA Score for synthetic patches is clinically meaningful. To date, the minimal clinically importance difference for UCLA shoulder score following RCR has not been established.[52] However, a threshold of 30 UCLA points after 2 years has been proposed as an absolute cut-off signifying treatment success following RCR.[53] In the studies investigating synthetic polypropylene patches, augmentation failed to meet this threshold.[30 46] Similarly, the 0.46-point reduction in VAS pain scores is unlikely to be clinically meaningful.[51]

Across 49 studies reporting complications (adverse events) with a combined population of 2055 participants, the crude complication rate was marginally higher for augmented (2.1%) than standard (1.6%) repairs, with specific safety concerns associated with certain patches (Restore)[39] or techniques (Quadriceps allograft, Humeral Periosteal allograft, MSCs embedded in decellularised bovine pericardium).[33 44 48]

Strengths and limitations of the study

Strengths of this this review include an *a priori published* protocol;[16] a comprehensive search strategy; inclusion of non-English language articles and duplicate assessment of eligibility, risk of bias and data extraction. Nonetheless, there remain several limitations to the current review, which are mainly a reflection of the quality of published primary research available. Only seven RCTs have been published, of which three refer to a product (Restore) that has now been withdrawn from the market due to safety concerns,[29 36 39] and the study by Lamas *et al* was terminated due to excessive adverse events.[33] Second, substantial heterogeneity between studies was observed with the majority of studies also judged to have a high risk of bias, seriously limiting our ability to draw firm recommendations. An exhaustive exploration of the heterogeneity has not been undertaken and indeed such an analysis was not declared a priori in our protocol paper.[16] However, separating studies by patch type did influence the degree of heterogeneity and we would therefore recommend patch type should be considered in the design of future reviews. Finally, it should be noted that given the limited number of studies for the different patch types and the relatively small typical size of studies, the observed effects identified could reflect, to a degree, chance findings. With this in mind, the observed differences in outcomes between patch types should be interpreted cautiously and warrant confirmation by further trials.

In comparison with previous systematic reviews,[19 22 23] we have included four additional RCTs[29 33 37 38] and five observational comparative studies,[32 41–43 45] representing 324 patients, not otherwise identified. Results from our meta-analysis are, in part, consistent with a previous analysis which found an overall reduction in re-tear rate and improved ASES Scores following patch augmentation.[22] The substantial number of additional studies included in this current review provide greater precision and, while

a subgroup analysis was not originally specified in our protocol, they have allowed us to hypothesise that patch type may have an effect on patient outcomes. The occurrence of adverse events with only certain patch types adds some credibility to this notion. Previous reviews of augmented RCR have, on the basis of a presumed effect on patient outcome, excluded studies based on the size of rotator cuff tear or surgical technique (on-lay or bridging).[19] It is possible that each technique reflects different patient cohorts, for example, the use of bridging scaffolds may represent larger, more chronic or even recurrent rotator cuff tears. However, we were unable to detect any overall difference in patient-reported outcomes, re-tear rate or pain scores between studies reporting on-lay or bridging techniques. It should be noted that differences in terminology makes comparison of these surgical techniques challenging—many studies use the terms *irreparable*, *bridging*, *interposition* or *reconstruction* interchangeably. To help facilitate the future interrogation of the relationship between surgical technique and outcomes we would suggest that only the terms *on-lay augmentation* or *bridging reconstruction* be used in accordance with previously published definitions.[19] Similarly, a frequent lack of detail on how tear size was determined impedes any examination of tear size on treatment effectiveness. Trials should clearly describe, in a reproducible way, the classification system used when determining rotator cuff tear size.

There are a growing number of patches available for the augmentation of RCR. Despite the safety-related withdrawal of certain patches,[34] as well as wider concerns surrounding medical device[54] and mesh implantation,[54] rigorous clinical evaluation of patch augmentation is lacking. We were particularly concerned by the absence of publicly available research for several patches currently in clinical use (eg, d-cell and Leeds-Kuff). While some studies have indicated promise for specific patches, firm recommendations in terms of patch type or surgical technique cannot be made at present. There remains a need for well-designed comparative (preferably multicentre RCTs) studies that are capable of robustly evaluating the effectiveness and safety of multiple patch types. Furthermore, routine reporting of registry data patch could address the current lack of robust safety data for cuff-augmented rotated cuff repair.[55]

Twitter Mathew Baldwin @mathewbaldwin3 and Jonathan Alistair Cook @ProfJACook

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ORCID iDs
Mathew Baldwin http://orcid.org/0000-0002-8790-9975
Jonathan Alistair Cook http://orcid.org/0000-0002-4156-6989

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