Systematic Review

Outcomes After Patch Use in Rotator Cuff Repair

Michael E. Steinhaus, M.D., Eric C. Makhni, M.D., M.B.A., Brian J. Cole, M.D., M.B.A., Anthony A. Romeo, M.D., and Nikhil N. Verma, M.D.

Purpose: To provide a comprehensive review of clinical outcomes and retear rates after patch use in rotator cuff repair, and to determine the differences between available graft types and techniques. **Methods:** A systematic review was conducted from database (PubMed, Medline, Scopus, Embase) inception to January 2015 for English-language articles reporting outcome data with 9 months' minimum follow-up. Studies were assessed by 2 reviewers who collected pertinent data, with outcomes combined to generate frequency-weighted means. **Results:** Twenty-four studies met the inclusion criteria. The frequency-weighted mean age was 61.9 years with 35.4 months' follow-up. The mean improvements in postoperative range of motion in the forward elevation, abduction, external rotation, and internal rotation planes were 58.6°, 66.2°, 16.6°, and 16.1°, respectively, and postoperative abduction strength improved by 3.84 kg. American Shoulder and Elbow Surgeons, University of California—Los Angeles, Constant, Penn, and Oxford scores improved by 39.3, 10.7, 40.8, 34.4, and 17.6, respectively. Augmentation and interposition techniques showed similar improvements in range of motion, strength, and patient-reported outcomes (PROs), whereas xenografts showed less improvement in PROs compared with other graft types. Studies reported improvements in pain and activities of daily living (ADLs), with greater than 90% overall satisfaction, although few patients (13%) were able to return to preinjury activity. Whereas interposition and augmentation techniques showed similar improvements in pain and ADLs, xenografts showed less improvement in ADLs than other graft types. The overall retear rate was 25%, with rates of 34% and 12% for augmentation and interposition, respectively, and rates of 44%, 23%, and 15% for xenografts, allografts, and synthetic grafts, respectively. **Conclusions:** We report improvements in clinical and functional outcomes, with similar results for augmentation and interposition techniques, whereas xenografts showed less improvement than synthetic grafts and allografts in PROs and ADLs. Retear rates may be lower with the interposition technique or in patients with synthetic grafts or allografts. **Level of Evidence:** Level IV, systematic review of Level II through IV studies.

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From the Hospital For Special Surgery (M.E.S.), New York, New York; and Department of Orthopaedics, Rush University Medical Center (E.C.M., B.J.C., A.A.R., N.N.V.), Chicago, Illinois, U.S.A.

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Address correspondence to Eric C. Makhni, M.D., M.B.A., Department of Orthopaedics, Rush University Medical Center, 1611 W Harrison St, Ste 300, Chicago, IL 60612, U.S.A. E-mail: ericmakhnimd@gmail.com

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Successful management of large or massive rotator cuff tears continues to present a clinical challenge. Because of the size and chronicity of tears, which contribute to poor soft-tissue quality, as well as advanced patient age and medical comorbidities, primary repair attempts are accompanied by high rates of tendon retearing.[1-6] Interestingly, patients who undergo a repair attempt with subsequent failure still show improved functional outcomes postoperatively.[7-9] However, those with a successful repair have the highest likelihood of subsequent clinical success and functional improvement, particularly regarding strength recovery.[10]

Several treatment attempts have been described for surgical management of chronic and massive rotator cuff tears. These techniques have ranged from simple debridement and decompression[11,12] to primary reverse total shoulder arthroplasty.[13] Although rotator cuff repair reliably improves patient functional outcomes and satisfaction, it is accompanied by retear rates of 34% to 94%.[14] One technique to improve tendon healing has been the use of synthetic or biologic patch reinforcement. These grafts are composed of a variety of materials, including synthetic graft,[15] allograft,[16] and xenograft options.[17] The procedure can be performed either as augmentation (onlay) of a cuff repair,[15] in which the patch is used to reinforce an anatomically reparable tear, or as interposition (intercalary),[18] wherein the graft bridges the gap between the irreparable cuff and the humerus. However, studies have reported conflicting evidence regarding the success of this technique.[17,19-22]

Our knowledge of outcomes associated with patch use is primarily based on Level III or IV studies that have reported on a variety of different outcome measures and other findings in small groups of patients. Moreover, each of these studies typically represents the experience of one surgeon or one institution and therefore, when taken alone, may not be an accurate reflection of patch use more broadly. A comprehensive review of these studies will help provide clinicians with the necessary data for counseling patients with large to massive rotator cuff tears and give patients and clinicians a better understanding of expected outcomes associated with these procedures.

The purposes of this study were to provide a comprehensive review of clinical outcomes and retear rates after patch use in rotator cuff repair and to determine the differences between available graft types and techniques. We hypothesized that incorporation of a patch graft at the time of rotator cuff repair would lead to improved clinical outcomes, with few complications and retears, after surgery.

Methods

This systematic review was performed in accordance with the guidelines laid out by the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement[23] and included studies retrieved from the PubMed, Medline, Scopus, and Embase computerized literature databases. Searches were executed comprising all years from database inception through January 2015. Articles were retrieved by an electronic search of Medical Subject Headings and keyword terms and their respective combinations (Table 1). The inclusion criteria for studies in this systematic review were studies that (1) were written in the English language, (2) followed up patients for a minimum of 9 months, and (3) reported explicit outcome data. The exclusion criteria were (1) studies using autologous grafts (e.g., biceps augmentation, periosteal flap, triceps flap, coracoacromial ligament graft) or biologics (e.g., stem cells, growth factors, platelet-rich plasma); (2) review articles, meta-analyses, case reports, conference papers, comments and letters, or technique articles without reported patient data; and (3) basic research, biomechanics, or animal or cadaveric studies without reported patient data.

The literature search is outlined in Figure 1. The initial title search yielded a subset of possible articles that were then further included or excluded based on the contents of the article's abstract, wherein articles were again selected based on the aforementioned inclusion and exclusion criteria. Articles selected in both the title and abstract phases underwent full-text review, during which the full text of each qualifying article was reviewed. In addition, the reference sections from articles undergoing full-text review were scanned to identify any additional studies that were not identified from the original literature search. Appropriate studies for final inclusion were then selected at this stage. The title, abstract, and full-text selection process was performed independently by 2 of the study authors (M.E.S. and E.C.M.), with any discrepancies discussed and resolved by mutual agreement.

For all 24 included studies,[15-18,24-43] data were collected regarding the type of study, patients included, and outcomes measured in the study. The source of funding and level of evidence, as well as the number of patients included in the study at baseline and at final follow-up, were noted. Patient information included mean age, sex, arm dominance, history of repair, history of trauma to the injured shoulder, mean duration of symptoms, and mean follow-up time. In addition, operative and device details were collected, including muscles torn, tear size, acromiohumeral interval, fatty infiltration grade, surgical technique, graft source, device used, and reinforcement technique (augmentation *v* interposition). Of note, the terms "augmentation" (i.e., onlay), in which the patch reinforces an anatomically reparable tear, and "interposition" (i.e., intercalary), in which the patch bridges a gap between the cuff and humerus, are used in this review. Patient outcomes included objective data (range of motion [ROM] and

Table 1. Search Terms Entered Into PubMed, Medline, Scopus, and Embase Computerized Literature Databases to Identify English-Language Studies Through January 2015

Database	Search Terms
PubMed, Scopus	Keywords: ((augmentation) AND "rotator cuff") OR ((synthetic augmentation) AND "rotator cuff") OR ((graft augmentation) AND "rotator cuff") OR ((patch augmentation) AND "rotator cuff") OR ((scaffold) AND "rotator cuff") OR ((bridge) AND "rotator cuff") OR ((interposition) AND "rotator cuff")
Medline	MeSH: ("rotator cuff") AND (("prostheses and implants") OR ("tissue scaffolds") OR ("biocompatible materials") OR ("reconstructive procedures") OR keywords ("augmentation") OR ("synthetic augmentation") OR ("graft augmentation") OR ("patch augmentation") OR ("scaffold") OR ("bridge") OR ("interposition"))
Embase	Emtree: ("rotator cuff") AND (("implants") OR ("tissue scaffold") OR ("biomaterial") OR ("repair") OR keywords ("augmentation") OR ("synthetic augmentation") OR ("graft augmentation") OR ("patch augmentation") OR ("scaffold") OR ("bridge") OR ("interposition"))

strength) and subjective data (validated outcome scores, as well as patient-reported pain, satisfaction, and ability to complete activities of daily living [ADLs] and return to sport or activity). Outcomes with more than 2 studies reporting an identical measure were noted in our review. Finally, we recorded any reported complications in the studies, including retear rates. When possible, weighted averages of these outcomes were then calculated across all studies to obtain aggregate outcomes, reflecting only studies reporting each of these outcomes.

Results

Study Inclusion

Twenty-four studies, published between 1986 and 2014, fulfilled all the inclusion and exclusion criteria and were included in this systematic review (Table 2). Most of the studies (16) were investigator driven, whereas 2 were industry sponsored[15,30] and 6 did not report the source of funding. Two studies were published as Level II evidence, 3 studies as Level III evidence, and 19 studies as Level IV evidence. Of note, one study included 2 treatment groups that fit the criteria for this review, with one group undergoing open rotator cuff repair with collagen patch augmentation (49 patients) and the other undergoing open repair with polypropylene patch augmentation (52 patients)[25]; both groups were analyzed separately in this review. Two studies reported data[19,44] from the same group of patients from a study included in this review[35] and were therefore excluded.

Demographic Data

Demographic data from the included studies are presented in Table 2. There were a total of 566 patients included at baseline in these studies'

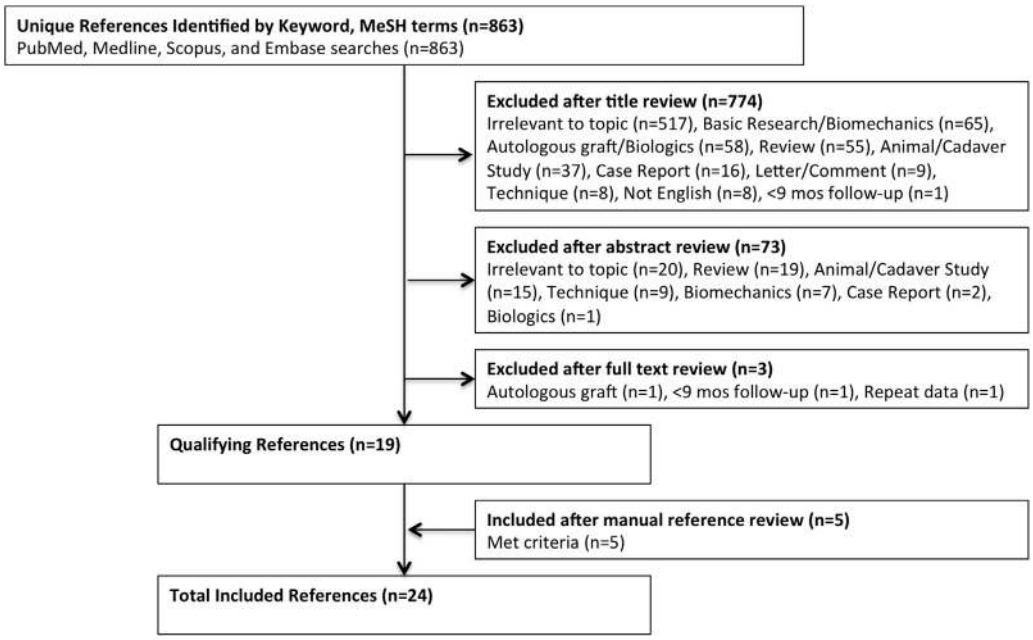

Fig 1. Flow diagram representing systematic review process used in study. A total of 24 studies were included for final analysis.

Table 2. Demographic Details of Included Studies

Authors, Year	Level of Evidence	No. of Patients		Age, yr		Sex, n		Arm Dominance, n		Prior Repair, n	Trauma History, n	Duration of Symptoms, mo		Follow-Up Duration, mo	
		Baseline	Final	Mean	Range/SD	M	F	D	ND			Mean	Range	Mean	Range
Cho et al.,[24] 2014	IV*	5	5	53.4	Range, 45-57	3	2	4	1	NR	NR	34.4	12-72	20.6	14-27
Ciampi et al.,[25] 2014 (synthetic)	III	52	52	66.2	Range, 57-77	41	11	NR	NR	NR	NR	NR	NR	36	NR
Ciampi et al., 2014 (collagen)	III	49	49	66.53	SD, 5.17	38	11	NR	NR	NR	NR	NR	NR	36	NR
Giannotti et al.,[26] 2014	IV*	9	9	66.88	Range, 50-80	4	5	NR	NR	NR	NR	NR	NR	36	30-45
Lenart et al.,[15] 2014	IV	13	13	57.3	Range, 42-68	9	4	11	2	9 of 13	2 of 13	NR	NR	18	14.4-20.4
Proctor,[27] 2014	IV	18	18	66	Range, 52-89	NR	NR	NR	NR	5 of 18	NR	NR	NR	42	NR
Petrie and Ismaiel,[28] 2013	IV*	29	29	67.1	NR	21	8	NR	NR	NR	NR	NR	NR	40	24-72
Venouziou et al.,[29] 2013	IV*	14	14	54.6	Range, 33-64	9	5	9	5	9 of 14	8 of 14	10.1	3-24	30.2	18-52
Modi et al.,[18] 2013	IV*	61	61	62.7	Range, 47-72	41	20	NR	NR	NR	14 of 61	NR	NR	43.2	12-72
Barber et al.,[30] 2012	II	22	22	56	Range, 43-69	18	4	20	2	NR	NR	NR	NR	24	12-38
Gupta et al.,[31] 2012	IV	24	24	63	Range, 45-83	12	12	NR	NR	NR	NR	NR	NR	36	29-42
Encalada-Diaz et al.,[32] 2011	IV	10	10	56.2	Range, 44-65	0	10	8	2	NR	NR	16.2	NR	12	NR
Rotini et al.,[33] 2011	IV*	5	5	48	Range, 37-55	5	0	NR	NR	NR	4 of 5	NR	NR	13.6	12-18
Nada et al.,[34] 2010	IV*	21	21	66.5	Range, 55.0-85.0	14	7	16	5	3 of 21	NR	20.8	6.0-48.0	36	30-46
Wong et al.,[35] 2010	IV*	45	45	53.6	Range, 39-67	36	9	NR	NR	NR	NR	NR	NR	48	24-68
Phipatanakul and Petersen,[36] 2009	IV*	11	11	48	Range, 31-62	9	2	NR	NR	7 of 11	NR	NR	NR	26	14-38
Badhe et al.,[37] 2008	IV*	10	10	65.7	Range, 46-80	5	5	8	2	2 of 10	NR	NR	NR	54	36-60
Walton et al.,[38] 2007	III	16	16	60.2	SD, 3.5	11	5	NR	NR	NR	NR	NR	NR	24	NR
Burkhead et al.,[16] 2007	IV*	17	17	56.9	NR	12	5	9	8	6 of 17	NR	NR	NR	14.4	NR
Audenaert et al.,[39] 2006	IV*	41	39	67	Range, 51-80	23	18	24	17	NR	16 of 39	11.5	3-54	43	24-86
Iannotti et al.,[17] 2006	II	15	15	58	Range, 41-70	11	4	NR	NR	NR	NR	NR	NR	14	12-26.5
Hirooka et al.,[40] 2002	IV*	28	28	62	Range, 44-75	20	8	16	12	NR	11 of 28	16	NR	44	24-72
Metcalf et al.,[41] 2002	IV*	12	12	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	24	NR
Visuri et al.,[42] 1991	IV*	14	14	54	Range, 48-77	12	2	NR	NR	NR	7 of 14	36.3	3-120	48.9	25-85
Ozaki et al.,[43] 1986	IV*	25	25	67.3	Range, 47-79	17	8	NR	NR	NR	25 of 25	33.6	1-120	25	12-42
Frequency-weighted data		566	564	61.9	Range, 31-89	371	165	114	56	41 of 104	87 of 199	20.2	1-120	35.4	12-86

D, dominant; F, female; M, male; ND, nondominant; NR, not reported.
*The level of evidence was not reported in the article and was assigned by us.

analyses. A total of 564 patients (range, 5 to 61 patients per study) were noted in the final postoperative analyses among all 24 studies. The frequency-weighted mean age at surgery was 61.9 years (range, 31 to 89 years) across all 24 studies. Twenty-two studies reported a total of 371 male patients (69.2%) and 165 female patients (30.8%). Arm dominance was noted in 10 studies, with the dominant arm being involved in 114 cases (67.1%) and the nondominant arm in 56 cases (32.9%). Seven studies observed 41 of 104 patients (39.4%) with a history of rotator cuff repair, whereas eight studies reported 87 of 199 patients (43.7%) noting a history of traumatic injury to the affected shoulder. Nine studies collected the mean duration of symptoms before patients underwent repair, with a frequency-weighted mean duration of 20.2 months (range, 1 to 120 months). All 24 studies reported follow-up data, with a frequency-weighted mean follow-up period of 35.4 months (range, 12 to 86 months).

Operative and Device Details

The operative and device details for each of these studies were noted. Tear pattern was reported in 11 studies (195 total patients), with combined supraspinatus and infraspinatus tears representing the majority of reported tears (72.3%, 141 of 195), followed by 3-tendon tears (subscapularis, supraspinatus, and infraspinatus) in 31 cases, a supraspinatus tear alone in 12 cases, and subscapularis and supraspinatus tears in 11 cases. Six studies (151 patients) reported explicit data on tear size, with a frequency-weighted mean tear size of 4.55 cm (range, 1 to 8 cm). The preoperative acromiohumeral interval was examined in 3 studies (84 patients), with a frequency-weighted mean of 6.06 mm (range, 4.2 to 11.3 mm). The frequency-weighted mean fatty infiltration grade, as defined by Goutallier et al.,[45] was 1.58 (range, 0 to 4), noted in 7 studies (160 patients). Inclusion criteria, surgical technique, graft source, device used, and reinforcement technique are presented in Table 3. Most of the studies included patients with large and/or massive tears, with the exception of 3 studies that included patients with smaller tears.[32,40,42] Nine studies excluded patients with osteoarthritis and/or inflammatory or autoimmune disease,[15,17,18,25,30,31,33-35] whereas 4 studies explicitly excluded patients undergoing revision procedures.[17,24,30,39] The most common surgical technique used across the 24 studies was open, representing 54.6% of cases (309 of 566), followed by mini-open in 170 cases and arthroscopic in 87 cases. The most common graft source was synthetic, representing 44.3% of grafts (251 of 566), followed by allograft in 188 cases and xenograft in 127 cases. The graft was used to bridge the gap between the retracted cuff and humerus (interposition) in 56.3% of patients (319 of 566), whereas it was used to augment the repair in 43.6% (247 of 566).

Clinical Outcomes

Clinical outcomes after patch use in rotator cuff tears are summarized in Tables 4 through 6. ROM was reported as preoperative and postoperative values in 4 different planes (forward elevation [FE], abduction, external rotation [ER], and internal rotation [IR]) and is depicted in Table 4. Overall, studies observed improvements in ROM in each of these planes, with mean improvements of 58.6°, 66.2°, 16.6°, and 16.1° for FE, abduction, ER, and IR, respectively. When ROM was analyzed by augmentation group versus interposition group, there were no substantial differences in the mean improvements for FE (57.9° for augmentation *v* 59.3° for interposition), abduction (70.8° for augmentation *v* 65.7° for interposition), or ER (16.9° for augmentation *v* 16.5° for interposition). The mean improvements for IR were considerably different (37° for augmentation *v* 4.2° for interposition), although each of these figures reflects data from only one study. When ROM was analyzed by graft type, synthetic grafts showed the greatest improvement in FE (66.3°) compared with allografts (57.7°) and xenografts (45.4°) and in abduction (72.4°, compared with 58.5° for allografts and 59.0° for xenografts). Improvements in ER were 10.8° for synthetic grafts, 20.7° for allografts, and 16.6° for xenografts.

Strength was reported as preoperative and postoperative values in 2 different planes (abduction and ER) and is depicted in Table 5. For the 3 studies that examined both preoperative and postoperative abduction strength, the mean improvement was 3.84 kg (3.88 kg for augmentation and 3.5 kg for interposition). In addition, Walton et al.[38] measured postoperative abduction strength in patients undergoing open repair with and without augmentation devices, noting that those without augmentation had a mean abduction strength 21 N greater than that in those with augmentation. No studies reported objective preoperative and postoperative ER strength. Several studies found improvements in ER strength using subjective measures that were unable to be input into the frequency-weighted mean calculation.[18,29,39,43] Walton et al. noted a mean postoperative ER strength 20 N greater in patients undergoing open repair without augmentation compared with those with an augmentation device.

The results of outcome score reporting are summarized in Table 6. Overall, studies found improvements in these measures, with mean improvements from preoperatively to postoperatively in American Shoulder and Elbow Surgeons Evaluation Form (ASES), University of California—Los Angeles (UCLA), Constant, Penn, and Oxford scores of 39.3, 10.7, 40.8, 34.4, and 17.6, respectively. When score improvements were analyzed

Table 3. Operative and Device Details

Authors, Year	Inclusion Criteria	Surgical Technique	Graft Source	Device Used	Reinforcement Technique
Cho et al.,[24] 2014	R, M (posterosuperior), unable to reattach tendons, age ≤60 yr; no prior surgery, static superior migration of humeral head, or G >50%	Mini-open	Xenograft	Porcine dermal collagen (Permacol; Covidien, Mansfield, MA)	Augmentation
Ciampi et al.,[25] 2014 (synthetic)	R, M, postoperative residual retraction <2 cm, G stage 1/2; no	Mini-open	Synthetic	Polypropylene (Repol Angimesh; Angiologica, Pavia, Italy)	Augmentation
Ciampi et al., 2014 (collagen)	OA, inflammatory/rheumatic condition, labral lesions, biceps tenodesis, cortisone injection within 12 wk, or contralateral shoulder injury	Mini-open	Xenograft	Bovine pericardium–derived collagen (Tutopatch; Tutogen Medical BmbH, Neunkirhen am Brand, Germany)	Augmentation
Giannotti et al.,[26] 2014	M	Mini-open	Xenograft	Porcine dermal collagen patch (Zimmer, Warsaw, IN)	Augmentation (3), interposition (6)
Lenart et al.,[15] 2014	M or recurrent L/M; no instability, OA, or revision surgery in follow-up period	Open	Synthetic	Poly-L-lactide polymer (X-Repair; Synthasome, San Diego, CA)	Augmentation
Proctor,[27] 2014	L, M (including supraspinatus) with retraction ≥3 cm	Arthroscopic	Synthetic	Poly-L-lactide polymer (X-Repair)	Augmentation
Petrie and Ismaiel,[28] 2013	I, M, G grade 3/4	Open	Synthetic	Ligament augmentation reconstruction system (LARS, Arc-sur-Tille, France)	Interposition
Venouziou et al.,[29] 2013	I, M, follow-up ≥18 mo	Open	Allograft	Human dermal matrix (GraftJacket; Wright Medical Technology, Arlington, TN)	Interposition
Modi et al.,[18] 2013	I, >3 cm; no prior TSA or inflammatory/autoimmune disease	Open	Allograft	Human dermal matrix (GraftJacket)	Interposition
Barber et al.,[30] 2012	R, L/M, age 18-75 yr, >90° elevation; no I + M, subscapularis tendon tear, revision, inflammatory/ autoimmune/cancer/ communicable disease, infection, or smoker	Arthroscopic	Allograft	Human dermal matrix (GraftJacket)	Augmentation
Gupta et al.,[31] 2012	I, retraction >5 cm; no OA, cuff tear arthropathy, or G >50%	Mini-open	Allograft	Human dermal matrix (GraftJacket)	Interposition
Encalada-Diaz et al.,[32] 2011	Small/medium, FT (supraspinatus or infraspinatus), intact subscapularis	Mini-open	Synthetic	Polyurethane polymer	Augmentation
Rotini et al.,[33] 2011	R, L/M, age <55 yr, tendon retraction of grade 3 or lower (Thomazeau), G <3, follow-up ≥1 yr; no OA, frozen shoulder, AC arthritis, autoimmune/connective tissue disease	Open (3), arthroscopic (2)	Allograft	Human dermal matrix	Augmentation

(continued)

Table 3. Continued

Authors, Year	Inclusion Criteria	Surgical Technique	Graft Source	Device Used	Reinforcement Technique
Nada et al.,[34] 2010	M, functional deltoid, compliance with rehabilitation; no cuff tear arthropathy with stiffness, infection, or neurologic condition affecting shoulder girdle function	Mini-open	Synthetic	Polyethylene terephthalate (Dacron; Dacron Xiros, Leeds, England)	Interposition
Wong et al.,[35] 2010	L/M, ideally intact biceps, good motion, functioning subscapularis, younger patients; relative contraindications—OA, immunocompromised, or heavy smoker	Arthroscopic	Allograft	Human dermal matrix (GraftJacket)	Interposition
Phipatanakul and Petersen,[36] 2009	M	Open	Xenograft	Porcine small intestine submucosa (Restore Orthobiologic Implant; DuPuy Orthopaedics, Warsaw, IN)	Augmentation (10), interposition (1)
Badhe et al.,[37] 2008	M (supraspinatus + infraspinatus)	Open	Xenograft	Porcine dermal collagen (Permacol)	Interposition
Walton et al.,[38] 2007	R, L/M or poor-quality tendon, intact subscapularis	Open	Xenograft	Porcine small intestine submucosa (Restore Orthobiologic Implant)	Augmentation
Burkhead et al.,[16] 2007	R, M; no active infection	Open	Allograft	Human dermal matrix (GraftJacket)	Augmentation
Audenaert et al.,[39] 2006	I, M, unable to elevate >90°; no revision	Open	Synthetic	Mersilene mesh (Ethicaon, Somerville, NJ)	Interposition
Iannotti et al.,[17] 2006	R, L/M (chronic, supraspinatus + infraspinatus), age >18 yr; no prior surgery, cervical spine disease, frozen shoulder, or OA	Open	Xenograft	Porcine small intestine submucosa (Restore Orthobiologic Implant)	Augmentation
Hirooka et al.,[40] 2002	I, small, medium, L, M	Open	Synthetic	Gore-Tex patch (W.L. Gore & Associates, Flagstaff, AZ)	Interposition
Metcalf et al.,[41] 2002	M (chronic), "significant" atrophy of supraspinatus + infraspinatus	Open	Xenograft	Porcine small intestine submucosa	Augmentation
Visuri et al.,[42] 1991	Medium, L, M	Open	Synthetic	Carbon fiber tow (Integraft; Hexcel Medical, Dublin, CA)	Interposition
Ozaki et al.,[43] 1986	I, M (chronic)	Open	Synthetic	Polytetrafluoroethylene (Teflon; Dupont Company, Wilmington, DE) felt (4), fabric (6), high-density polyethylene (Marlex; C.R. Bard; Mullayhill, NJ) mesh (15)	Interposition
Total patients		Open: 309 Mini-open: 170 Arthroscopic: 87	Synthetic: 251 Allograft: 188 Xenograft: 127		Interposition: 319 Augmentation: 247

AC, acromioclavicular; FT, full thickness; G, Goutallier fatty degeneration; I, irreparable; L, large tear; M, massive tear; OA, osteoarthritis; R, reparable; TSA, total shoulder arthroplasty.

Table 4. Objective Outcome Measures: Range of Motion

	FE, °					Abduction, °					ER, °					IR, °				
	Preop		Postop			Preop		Postop			Preop		Postop			Preop		Postop		
Authors, Year	Mean	Range/SD/SEM	Mean	Range/SD/SEM	Mean Δ	Mean	Range	Mean	Range/SD	Mean Δ	Mean	Range	Mean	Range/SD	Mean Δ	Mean	Range	Mean	Range	Mean Δ
Ciampi et al.,[25] 2014 (synthetic)	92.0	SD, 6.9	174.71	SD, 8.18	82.71	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Ciampi et al., 2014 (collagen)	92.4	SD, 8.4	140.61	SD, 12.48	48.2	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Lenart et al.,[15] 2014	145	SEM, 11.5	160	SEM, 7.3	15	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Venouziou et al.,[29] 2013	73.6	Range, 20-130	129.3	Range, 60-180	55.7	67.5	20-100	117.9	Range, 60-180	50.4	7.9	0-35	43.2	Range, 20-75	35.3	NR	NR	NR	NR	NR
Modi et al.,[18] 2013	97	Range, 10-180	160	Range, 60-180	63	90	10-180	155	Range, 30-180	65	42	0-70	60	Range, 15-80	18	Sacrum*	NR	Upper lumbar*	NR	IC*
Gupta et al.,[31] 2012	111.7	NR	157.3	SD, 21.7	45.6	105	NR	151.7	SD, 22.2	46.7	46.2	NR	65.1	SD, 23.0	18.9	NR	NR	NR	NR	NR
Encalada-Diaz et al.,[32] 2011	90	NR	160	NR	70	70	NR	155	NR	85	15	NR	30	NR	15	Sacrum*	NR	T12*	NR	IC*
Nada et al.,[34] 2010	65	Range, 55-85	120	Range, 90-160	55	60	50-70	120	Range, 90-140	60	39	30-50	57	Range, 30-70	18	4.2	4-6	8.4	6-10	4.2
Phipatanakul and Petersen,[36] 2009	109	Range, 30-160	126	Range, 40-160	17	NR	NR	NR	NR	NR	37	10-65	28	Range, 10-65	−9	NR	NR	NR	NR	NR
Badhe et al.,[37] 2008	NR	NR	NR	NR	NR	NR	NR	89	NR	NR	NR	NR	50	NR	NR	NR	NR	T12*	NR	NR
Audenaert et al.,[39] 2006	69.2	NR	136	NR	66.8	68.4	NR	133.7	NR	65.3	32.4	NR	38.3	NR	5.9	3.4 of 10 points*	NR	7.5 of 10 points*	NR	4.1 points
Iannotti et al.,[17] 2006	125	Range, 45-180	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Metcalf et al.,[41] 2002	30	NR	90	NR	60	27	NR	86	NR	59	0	NR	40	NR	40	3	NR	40	NR	37
Visuri et al.,[42] 1991	NR	NR	NR	NR	NR	72.9	30-90	157.1	Range, 60-180	84.2	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Ozaki et al.,[43] 1986	NR	NR	NR	NR	NR	44.16	15-135	133.2	Range, 45-150	89.04	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Frequency-weighted data	91.0	Range, 10-180	148.0	Range, 40-180	58.6	72.9	0-180	136.9	Range, 30-180	66.2	33.4	0-70	50.0	Range, 10-80	16.6	3.8	3-6	19.9	6-40	16.1

ER, external rotation; FE, forward elevation; IC, incalculable; IR, internal rotation; NR, not reported; Postop, postoperative; Preop, preoperative.
*Incalculable from information provided.

Table 5. Objective Outcome Measures: Strength

	Abduction, kg					ER, kg				
	Preop		Postop			Preop		Postop		
Authors, Year	Mean	Range/SD	Mean	Range/SD	Mean Δ	Mean	Range	Mean	Range/SD	Mean Δ
Ciampi et al.,[25] 2014 (synthetic)	7.7	SD, 0.6	13.79	SD, 0.64	6.09	NR	NR	NR	NR	NR
Ciampi et al., 2014 (collagen)	7.5	SD, 0.5	9.03	SD, 0.60	1.53	NR	NR	NR	NR	NR
Venouziou et al.,[29] 2013	NR	NR	3/5*	Range, 0 to 5*	NR	NR	NR	2.9/5*	Range, 0 to 5*	NR
Modi et al.,[18] 2013	4/5*	Range, 3 to 4*	5/5*	Range, 3 to 5*	1*	4/5*	3 to 5*	5/5*	Range, 3 to 5*	1*
Gupta et al.,[31] 2012	7.2/10†	NR	9.4/10†	SD, 1.21†	2.2†	7.8/10†	NR	9.3/10†	SD, 0.91†	1.5†
Nada et al.,[34] 2010	3.9/5*	Range, 3 to 5*	5/5*	NR	1.1*	NR	NR	NR	NR	NR
Badhe et al.,[37] 2008	6.3	NR	9.8	NR	3.5	NR	NR	NR	NR	NR
Walton et al.,[38] 2007	NR	NR	37 N	SD, 7 N	−21 N‡	NR	NR	47 N	SD, 5 N	−20 N‡
Audenaert et al.,[39] 2006	0 points§	NR	7.9 points§	NR	7.9 points§	NR	NR	NR	NR	NR
Hirooka et al.,[40] 2002	IC	NR	3.5	NR	NR	NR	NR	NR	NR	NR
Metcalf et al.,[41] 2002	0.8/5*	NR	3.1/5*	NR	2.3*	NR	NR	NR	NR	NR
Ozaki et al.,[43] 1986	3+ of 5*	Range, 3− to 4*	4 of 5*	Range, 3 to 5*	IC	3+ of 5*	3− to 4*	4+ of 5*	Range, 3 to 5*	IC
Frequency-weighted data	7.49	IC	9.75	IC	3.84	IC	IC	IC	IC	IC

ER, external rotation; IC, incalculable from information provided; NR, not reported; Postop, postoperative; Preop, preoperative.

*Based on 5-point Medical Research Council Scale (not calculated in total).

†Based on 10-point Modified Medical Research Council Scale (not calculated in total).

‡Mean difference between test subjects and control group (not calculated in total).

§Power assessed as part of Constant-Murley score (not calculated in total).

Table 6. Validated Outcome Scores

	ASES Score					UCLA Score					Constant Score				
	Preop		Postop			Preop		Postop			Preop		Postop		
Authors, Year	Mean	Range/SEM	Mean	Range/SD/SEM	Mean Δ	Mean	Range/SD	Mean	Range/SD	Mean Δ	Mean	Range	Mean	Range/SD	Mean Δ
Cho et al.,[24] 2014	39.4	Range, 20.0-56.7	86.4	Range, 62.0-100.0	47	15.4	Range, 10-21	31.2	Range, 26-35	15.8	NR	NR	NR	NR	NR
Ciampi et al.,[25] 2014 (synthetic)	NR	NR	NR	NR	NR	10.9	SD, 1.5	24.61	SD, 3.22	13.71	NR	NR	NR	NR	NR
Ciampi et al., 2014 (collagen)	NR	NR	NR	NR	NR	10.4	SD, 1.2	14.69	SD, 1.99	4.29	NR	NR	NR	NR	NR
Giannotti et al.,[26] 2014	38	NR	79	NR	41	NR	NR	NR	NR	NR	42	NR	73	NR	31
Lenart et al.,[15] 2014	32.8	SEM, 9.5	74.2	SEM, 5.0	41.4	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Proctor,[27] 2014	25	NR	70	NR	45	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Venouziou et al.,[29] 2013	23.8	Range, 15-34	72.3	Range, 52-94	48.5	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Barber et al.,[30] 2012	48.5	NR	98.9	SD, 4.2	50.4	13.3	NR	28.2	SD, 2.1	14.9	41	NR	91.9	SD, 9.2	50.9
Gupta et al.,[31] 2012	66.6	NR	88.7	SD, 17.7	22.1	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Encalada-Diaz et al.,[32] 2011	44	NR	73.3	NR	29.3	NR	NR	29.2	NR	NR	NR	NR	NR	NR	NR
Rotini et al.,[33] 2011	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	64	55-75	88	Range, 77-95	24
Nada et al.,[34] 2010	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	46.7	39-61	84.5	Range, 52-96	37.8
Wong et al.,[35] 2010	NR	NR	84.1	NR	NR	18.4	NR	27.5	NR	9.1	NR	NR	NR	NR	NR
Phipatanakul and Petersen,[36] 2009	36.3	NR	71.8	NR	35.5	13.9	NR	25.7	NR	11.8	NR	NR	NR	NR	NR
Badhe et al.,[37] 2008	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	41.5	NR	62.2	NR	20.7
Burkhead et al.,[16] 2007	NR	NR	NR	NR	NR	9.06	NR	26.12	NR	17.06	NR	NR	NR	NR	NR
Audenaert et al.,[39] 2006	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	25.7	20-39	72.1	Range, 34-89	46.4
Metcalf et al.,[41] 2002	NR	NR	NR	NR	NR	9.3	NR	19.9	NR	10.6	NR	NR	NR	NR	NR
Frequency-weighted data	41.7	Range, 15-56.7	81.8	Range, 52-100.0	39.3	12.6	Range, 9-21	23.6	Range, 14-35	10.7	37.7	20-75	78.6	Range, 34-96	40.8

ASES, American Shoulder and Elbow Surgeons Evaluation Form; NR, not reported; Postop, postoperative; Preop, preoperative; UCLA, University of California—Los Angeles.

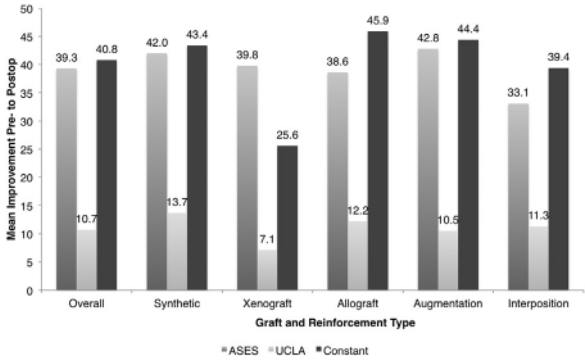

Fig 2. Improvement in clinical outcome scores by graft and repair type. The overall improvement in American Shoulder and Elbow Surgeons (ASES) score from preoperatively (Pre) to postoperatively (Postop) was 39.3, with similar improvements by graft and reinforcement type. The overall improvement in the University of California–Los Angeles (UCLA) score was 10.7, with similar improvements for augmentation (10.5) and interposition (11.3) and with improvements varying by graft type from xenograft (7.1) to synthetic graft (13.7). The overall improvement in the Constant score was 40.8, with similar improvements by graft and reinforcement type, with the exception of xenograft, which only showed improvement of 25.6. Penn and Oxford scores were only reported by studies examining one technique and are not included.

by reinforcement technique, augmentation and interposition showed similar improvements for ASES (42.8 for augmentation *v* 33.1 for interposition), UCLA (10.5 for augmentation *v* 11.3 for interposition), and Constant (44.4 for augmentation *v* 39.4 for interposition) scores. Similarly, various graft types showed similar outcome improvements, with xenograft showing lower improvements on the UCLA and Constant scales (ASES scores of 42.0, 39.8, and 38.6 for synthetic graft, xenograft, and allograft, respectively; UCLA scores of 13.7, 7.1, and 12.2 for synthetic graft, xenograft, and allograft, respectively; and Constant scores of 43.4, 25.6, and 45.9 for synthetic graft, xenograft, and allograft, respectively). Outcome score reporting by graft type and reinforcement technique is shown in Figure 2. Penn and Oxford scores were only reported by studies examining one technique and therefore could not be analyzed for such differences.

Patient-reported data on pain, satisfaction, and ability to perform ADLs and return to sport or activity were noted for each of these studies. Ten studies reported preoperative and postoperative visual analog scale (VAS) pain scores, with a mean reduction in pain score of 5.0 points (4.6 points for augmentation and 5.3 points for interposition; 4.6 points for synthetic graft, 5.7 points for allograft, and 4.4 points for xenograft). Four studies examined general outcomes of patient satisfaction, with overall, 67 of 73 patients reporting satisfaction with the operation. Two studies noted whether patients said they would undergo the surgical procedure again (24 of 24 patients[31] and 10 of 11 patients[36]) and 2 reported on general satisfaction (19 of 21 patients[34] and 14 of 17 patients[16]). The low number and heterogeneity of studies reporting on satisfaction precluded analysis by reinforcement and graft type. Four studies observed ability to perform ADLs as a subset of the Constant score, with a mean improvement of 7.0 points (6.1 points for augmentation and 7.1 points for interposition; 7.9 points for synthetic graft and 0.9 points for xenograft).[32,34,37,39] Two studies reported on patients' abilities to return to sport and/or activity, with a total of 4 of 30 patients being able to return to their preinjury levels of activity.[38,42]

Retears and Complications

Rotator cuff retear or tendon failure rates were noted in 22 studies, with findings presented in Figure 3. Overall, the rate of complete retears was 22.0% (90 of 410 patients) and the rate of partial retears was 2.7% (11 of 410). When categorized by graft type, the rates of complete retears were 15.0% (33 of 220), 42.0% (50 of 119), and 9.9% (7 of 71) for synthetic graft, xenograft, and allograft, respectively, and the rates of partial retears were 0% (0 of 220), 1.7% (2 of 119), and 12.7% (9 of 71), respectively. When categorized by reinforcement technique, the rates of complete retears were 33.2% (77 of 232) and 7.3% (13 of 178) for augmentation and interposition, respectively, and the rates of partial retears were 1.3% (3 of 232) and 4.5% (8 of 178), respectively.

Fifteen studies noted other complications associated with the operations. Overall, the complication rate was 3.5% (12 of 340). In 9 of these studies, there were no reported complications associated with rotator cuff repair. Six other studies found 12 total cases with complications: 1 case of bursitis,[30] 1 case of deep infection,[35] 1 case of infection and 2 skin reactions,[36] 4

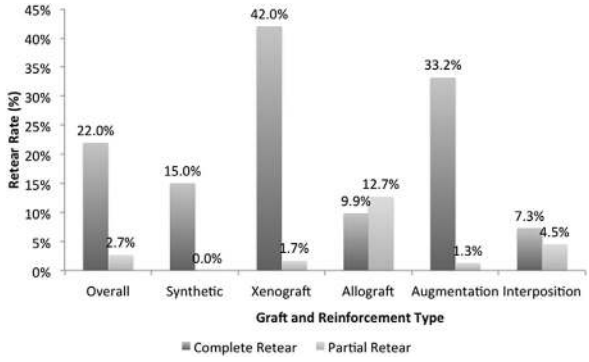

Fig 3. Retear rate (percentage) by graft and repair type. The overall retear rate was 25%, with retear rates for synthetic graft, xenograft, and allograft of 15%, 44%, and 23%, respectively. Retear rates for augmentation and interposition were 34% and 12%, respectively. If unspecified, retears were assumed to be complete.

cases of severe inflammatory reaction,[38] 1 proximal humeral shaft fracture,[39] and 2 cases of cystic changes of the humeral head seen on imaging.[42]

Discussion

Patch reinforcement is one option for patients with large or massive rotator cuff tears, which present a major treatment challenge for the orthopaedic surgeon, given uncertainty surrounding reparability and appropriate intervention. This study indicates that patients undergoing patch grafting benefit in terms of ROM, clinical outcome scores, pain, satisfaction, and ability to perform ADLs and can anticipate few complications, although they exhibit low rates of return to sport or activity. These outcomes are similar for both augmentation and interposition techniques, with interposition showing lower retear rates, and for graft types, with the exception of xenograft, which shows lower improvements in clinical outcomes and ADLs and higher retear rates than other grafts. After the procedure, complete graft retear occurred in 22% of patients, with 2.7% having a partial retear and few other complications.

Despite many studies reporting on patch reinforcement for rotator cuff tears, we could not identify any existing comprehensive review providing analysis of procedure details and clinical outcomes among these patients. There are several existing reviews, but these typically lacked stringent inclusion and exclusion criteria (as well as comprehensive extraction from existing literature) and did not focus on clinical outcomes,[46,47] whereas others focused on biologic (e.g., platelet-rich plasma, growth factors, gene therapy, mesenchymal stem cells) augmentation in rotator cuff repair,[48-50] which was not the subject of our review. One systematic review was comprehensive in its study inclusion but simply re-reported data without aggregating results or synthesizing findings.[51] Our study, on the other hand, analyzes data from across the 24 included studies to provide aggregate estimates. Clinical outcomes and retear data are of particular importance because they will provide clinicians and patients with a better understanding of the anticipated benefits associated with this procedure.

In terms of objective clinical outcome measures, notable findings from our study include improvements in ROM and strength after patch use for rotator cuff repair. The gains in FE (58.6°) and ER (16.6°) were similar but smaller than those reported by Bigliani et al.,[52] who studied patients undergoing primary repair of massive cuff tears without augmentation, with patients in their study gaining 76° of FE and 30° of ER. Another study of long-term outcomes after primary repair of large or massive chronic rotator cuff tears showed similar gains in active FE, with an increase in the UCLA score to 4.6 points, which corresponds to 120° to 150° and above, similar to the postoperative FE reported in our study (148.0°).[53] In that same study, peak abduction torque increased by 79% postoperatively, whereas abduction strength in our study increased by 51%. In one of the studies included in our review, Walton et al.[38] compared postoperative strength in patients undergoing open repair with and without augmentation and found that those without augmentation showed mean abduction and ER strengths 21 N and 20 N greater, respectively, than those with augmentation. In terms of graft and reinforcement type, similar improvements were seen for the augmentation and interposition groups, with synthetic grafts showing greater FE and abduction to allografts and xenografts.

In addition to objective measures after patch use, this systematic review reports on a variety of validated shoulder outcome scores, with improvements in ASES (from 41.7 to 81.8), UCLA (from 12.6 to 23.6), and Constant (from 37.7 to 78.6) scores. In another study, Rokito et al.[53] reported on patients undergoing repair of large or massive chronic rotator cuff tears without a patch and found preoperative and postoperative UCLA scores of 12.3 and 31.0, respectively. Park et al.[54] noted postoperative ASES scores of 89.67 and 93.24 in patients with large to massive tears undergoing single- and double-row repairs, respectively, and postoperative Constant scores of 72.07 and 79.82, respectively. They did not report preoperative scores for the large to massive group but mentioned overall preoperative ASES scores of 42.79 and 40.82 and Constant scores of 41.63 and 44.16 for single- and double-row repairs, respectively. These results indicate that, although relatively similar, patients undergoing repair without patch use may have improved function postoperatively compared with those undergoing repair with a patch, although selection bias may play a role in this difference. When we considered reinforcement and graft type, augmentation and interposition grafts showed similar improvements in patient-reported outcomes whereas xenograft showed lower improvements in UCLA and Constant scores than other graft types.

Furthermore, we noted improvements in several other patient-reported subjective outcomes, including ability to perform ADLs and pain level (mean reduction of 5 points on VAS) and high overall satisfaction of greater than 90%. Despite improvements across these measures, patients reported a low rate of return to preinjury level of sport or activity (13%). In their study, Rokito et al.[53] found that most patients undergoing repair without augmentation (57%) were able to perform all normal activities without limitation, there were significant improvements in pain (8.5 points on the UCLA scale), and all patients were satisfied with their results. Bigliani et al.[52] noted a satisfaction rate of 85% in their study of patients with massive rotator cuff repairs, similar to the rate reported in our study.

Improvements in VAS pain score and ability to perform ADLs were similar for all graft types and reinforcement techniques, with the exception of xenograft, which showed a lower improvement in ADLs compared with other graft types.

Finally, regarding failure, we found an overall retear rate of 25%. In terms of graft source, xenograft showed the highest rate of retear of 44%, followed by allograft (23%) and synthetic graft (15%) devices; in terms of reinforcement technique, augmentation showed a higher retear rate (34%) than interposition (12%). Overall, these retear rates appear lower than in prior studies of repair without patch use. Several studies of arthroscopic and open repair of large or massive tears have shown retear rates of greater than 40%,[2,4,6,55] with others reporting much higher retear rates of 79% to 100%.[56,57]

Limitations

Our study does contain a number of limitations. Most of the studies included in this review are Level III or IV, and therefore our study is limited by any bias or heterogeneity introduced in recruitment, patient selection, variability of technique, data collection, and analysis in these studies. In addition, several different outcome measures were reported across the 24 studies used in this review, which decreased the relevance of any one particular clinical outcome.

Conclusions

We report improvements in clinical and functional outcomes, with similar results for augmentation and interposition techniques, whereas xenografts showed less improvement than synthetic grafts and allografts in patient-reported outcomes and ADLs. Retear rates may be lower with the interposition technique or in patients with synthetic grafts or allografts.

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