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Put a Patch on It!: When and How to Perform Soft-Tissue Augmentation in Rotator Cuff Surgery

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Despite advancements in arthroscopic and surgical techniques, successful management of large to massive rotator cuff tears remains challenging. Risk factors including advanced age, significant retraction, reduced bone mineral density, and high physical demand have previously been shown to be negative prognostic indicators of good outcomes in rotator cuff repair. In order to increase healing rates, mechanical strength, and favorable biologic conditions, multiple patch augmentation and interposition techniques using tissue scaffolds have been developed. Numerous patch grafts are commercially available, including tissue scaffolds from autogenic, allogenic, synthetic, and xenogenic sources, although the quantity of literature varies widely between grafts. This review aims to present current indications, outcomes of patch interposition and augmentation, and surgical techniques for both primary and revision rotator cuff tears.
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Introduction

Rotator cuff tears are one of the most prevalent causes of shoulder discomfort and impaired mobility, with a population prevalence of 5% to 40%.[1,2] Massive rotator cuff tears, generally defined to be 5 cm or greater in length or involving 2 or more rotator cuff tendons, comprise 20% of all rotator cuff tears. Retear rates following massive primary rotator cuff repair can range from 40% to 90%, which imposes significant challenges for further management.[3,4]

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Disclosure

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Many factors contribute to the high rate of failure after primary repair, including poor tissue quality, fatty infiltration, increased tear size, patient age, and accompanying medical comorbidities.[3,5-11] Advanced rotator cuff pathology imposes significant pain, weakness, upper extremity limitations,[12] and retearing after primary rotator cuff repair is associated with persistent symptoms and reduced functional outcomes.[3,4,13,14] Current surgical techniques in the treatment of massive rotator cuff tears include primary arthroscopic or open repair,[3,5,15] partial repairs with or without footprint medialization,[16] rotator cuff tear debridement and decompression,[17] superior capsular reconstructions,[18] latissimus dorsi and/or lower trapezius tendon transfer,[19] subacromial balloon spacer,[20,21] and ultimately, reverse total shoulder arthroplasty.[22] Among the options to prevent structural failure and improve biological incorporation, rotator cuff patch augmentation for repairable tears has emerged as a viable adjunctive tool for operative management. Patch augmentation refers to integrating a graft over a reparable tear, whereas graft extension (or interposition grafting) describes a bridge application to connect the native tendon to the desired footprint, most commonly in irreparable tears. Patches optimize healing by providing increased biomechanical support via an extracellular matrix (ECM) scaffold, allowing for host cell integration, angiogenesis, and subsequent tissue remodeling. Graft options include allografts, xenografts, synthetic polymers, and, less commonly, autografts. This review details the current surgical indications, techniques, and outcomes of patch augmentation and extension for large-to-massive rotator cuff tear pathology.

Surgical Indications

Indications for Patch Augmentation and Patch Interposition (Extension)

(1) Persistent pain and shoulder dysfunction despite at least 6-months of conservative treatment with physical therapy, oral medication, or periarticular injections.
(2) Symptomatic primary or revision rotator cuff tear documented by preoperative imaging and intraoperative assessment (Fig. 1).
(3) A repairable tear was demonstrated by intraoperative assessment (patch augmentation).
   (a) an irreparable tear would indicate the need for patch interposition.
(4) A patient with additional risk factors that might predict failure following nonaugmented rotator cuff repair such as advanced age, significant retraction, infraspinatus fatty infiltration, reduced bone mineral density, and anticipated high physical demands.[2]
(5) Reliable patient was able to participate in the postoperative rehabilitation regimen.

Contraindications

(1) Glenohumeral arthritis or inflammatory arthropathy.
(2) Active infection.

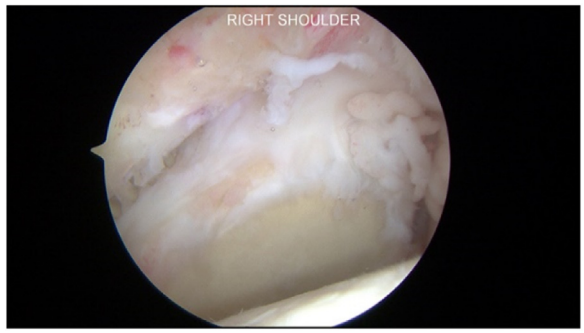

Figure 1 Arthroscopic image demonstrating the lateral subacromial view of a massive, 3 tendon retracted rotator cuff tear. (Color version of figure is available online.)

(3) Patient is not likely or unwilling to be compliant with rehabilitation protocols.
(4) Previous adverse reaction to graft products or materials.

Outcomes of Patch Augmentation Techniques

Allograft

Multiple studies have evaluated the outcomes of both allograft augmentation and interposition for massive rotator cuff tears. This section will focus on those investigations in which patients underwent allograft augmentation of a repairable tear. Several options are currently commercially available in the United States, with acellular dermal allografts most utilized. Commercially available products include GraftJacket (Wright Medical Group, Memphis, TN), Arthroflex (Arthrex Inc, Naples, FL), and Allopatch (MTFBiologics, Edison, NJ), although GraftJacket has been most extensively studied historically (Table 3). Treated human dermal tissue forms an acellular collagen ECM scaffold to provide an organized framework for host cell infiltration and vascular ingrowth.[23] Barber et al. performed a randomized, multicenter prospective level II clinical trial comparing arthroscopic GraftJacket augmentation ($n = 22$) of chronic 2-tendon rotator cuff tears with a group receiving arthroscopic repair alone ($n = 20$).[23] Arthrogram-enhanced magnetic resonance imaging (MRI) at 12-month follow-up showed intact cuffs in 85% of the augmented group, and only 40% of the nonaugmented repairs, and no adverse reactions were recorded. Burkhead et al. followed 17 consecutive patients who underwent open massive rotator cuff repair with Graft Jacket augmentation and found similar results.[24] Gilot et al. prospectively compared patients ($n = 20$) who underwent repair of massive rotator cuff tears using Arthroflex (Arthrex, Naples, FL) augmentation with patients who received a rotator cuff repair alone ($n = 15$).[25] There was a significantly greater improvement in functional scores at a mean of 24.9 months in subjects who underwent patch augmentation. Retear rates were also lower in the augmentation group, with 10% experiencing a tear vs 26% of participants in the control group.[25]

Xenograft

The premise behind xenograft technology for augmentation of rotator cuff repairs is that the acellularized ECM will serve as a scaffold to stimulate host inflammatory response and collagen deposition, thereby strengthening tendon healing. Multiple products have been studied over the past decade, with results varying widely. Iannotti et al. performed a level II, randomized controlled trial comparing the effectiveness of the porcine small intestine submucosal xenograft ($n = 15$) (Restore Orthobiologic Implant, Warsaw, IN) vs a control group without augmentation ($n = 15$) in chronic 2-tendon rotator cuff tears.[26] The rotator cuff healed in only 4 of the 15 shoulders in the open augmentation group as compared to 9 of the 15 in the control group ($P = 0.11$). Clinical outcome scores were inferior in the augmentation group.[26] Similar results were found in another randomized controlled trial conducted by Bryant et al., who ultimately concluded submucosal grafting is unlikely to provide superior outcomes vs rotator cuff repair alone.[27] Laboratory analysis has found significant quantities of residual porcine DNA along with the presence of GAL-α1,3 antigenic epitope in the xenografts derived from small intestine submucosal patches.[28,29] Importantly, the Restore Orthobiologic implant has since been removed from the market due to the theoretical immunogenic response leading to failure. However, porcine dermal collagen patches are another alternative which has been evaluated in the literature. These grafts have a higher tensile strength than porcine intestinal submucosa, which may be due to increased collagen cross-linking in dermal tissue.[30,31] Furthermore, acellular dermal collagen patches have not elicited the same inflammatory reaction seen in repairs augmented with porcine small intestine submucosa grafts.[26,32,33] Avanzi et al. conducted a level II randomized controlled trial comparing porcine dermal patch augmentation (Conexa, Tornier Inc, Bloomington, MN) vs a control group without augmentation in patients with degenerative small to medium rotator cuff tears.[34] Patients underwent an MRI and clinical outcome surveys at 2-year follow-up. The healing rate was 97.6% for the augmented group and 59.6% for the control group. Additionally, footprint coverage increased to a greater extent in the augmentation group (mean value of 9.5 mm vs 6.1 mm in the control group (measured via MRI), $P = 0.0002$). Both groups demonstrated statistically significant improvement in clinical and functional outcome scores, although there was no significant difference between the2 groups.[34] Lamas et al. conducted a level I randomized controlled trial comparing outcomes of patients with full-thickness rotator cuff tears who either received a type I collagen membrane (OrthADAPT, Pegasus Biologics, Inc., Irvine, CA) or bone marrow—mesenchymal stem cells (BM — MSCs) in combination with a type I collagen membrane.[35] The study was prematurely stopped due to adverse outcomes in both groups as a result of a severe immunopathologic response consisting of chronic synovitis and granulomatous lesions.

Bioinductive Xenografts

Emerging evidence suggests that bioinductive xenograft options may be beneficial for not only the augmentation of massive rotator cuff tears but also for the management of partial rotator cuff tears.[36-39] One such product, REGENETEN, a purified, porous bovine collagen patch that is implanted on the bursal side of the rotator cuff with PLLA bioabsorbable staples as an augmentation device (Smith and Nephew, Andover, MA) has shown promising short-term results mostly used for partial thickness rotator cuff tears offering little time zero biomechanical strength.[40,41] Thon et al conducted a case series of 23 patients undergoing repair of full-thickness large (2-tendon) or massive (3-tendon) rotator cuff tears augmented with the REGENETEN bioinductive collagen patch.[41] MRI scan was used to confirm tendon healing and thickness at a minimum of 6 months postoperatively, and ultrasound (US) was utilized by the treating surgeon to assess tendon thickness at 3-, 6-, 12-, and 24-month intervals. American Shoulder and Elbow Surgeons (ASES) scores were collected at the final follow-up. Overall, 96% (22 of 23) of rotator cuff repairs healed and were confirmed on US and MRI. There were no adverse events, and the mean ASES score at the final follow-up was 82.8 ± 16.7 (range, 53-100). The authors concluded that arthroscopic application of this bioinductive collagen scaffold when combined with rotator cuff repair is a safe and effective treatment for the healing of large and massive rotator cuff repairs.[41] Further mid to long-term studies are needed to determine the efficacy of these bioinductive collagen patches.[37,42]

Synthetic

The theoretical benefit of synthetic patch augmentation of rotator cuff repairs is that the graft is immunocompatable, able to serve as an ECM scaffold to allow for a host tissue response and connective tissue in-growth, and provide some degree of mechanical strength.[43,44] Many synthetic patches are available with a range of characteristics. Multiple studies have evaluated various synthetic patch augmentations, although few large studies have been conducted in the United States despite FDA approval of these devices.[45] A list of commercially available synthetic devices can be found in Table 3. The outcomes after synthetic patch augmentation, summarized in Table 1, are variable with retear rates ranging from 10% to 62%.[46-49] The practical utility of these grafts is limited by a lack of large, high-quality comparative studies.

Outcomes of Patch Interposition (Extension) Techniques

In contrast to patch augmentation, interpositional (extension) grafts are used to bridge the residual space between the leading edge of the torn rotator cuff and its native insertion on the humerus, often in irreparable tears.[50,51] This must also be distinguished from contemporary descriptions of

Table 1 Studies Evaluating Outcomes of Rotator Cuff Repair With Patch Augmentation

	Study	Level of Evidence	Inclusion Criteria	Number of Patients	Surgical Technique	Graft Used	Retear Rate and Outcomes	Imaging Assessment
Allograft	Barber et al.	II	Large, massive RCTs	Aug-22, control-20	Arthroscopic	Acellular human dermal matrix; GraftJacket (Wright Medical Technology, Arlington, TN)	Retear rate: aug group-15%, control group- 60%; significant improvement in outcome scores (ASES, Constant)	MRI at mean 14.5 mo
	Burkhead et al.	IV	Massive RCTs	Aug-17	Open	Acellular human dermal matrix; GraftJacket (Wright Medical Technology, Arlington, TN)	25% Retear rate (3/12). Significant improvement in pain scores, UCLA scores, and active forward flexion	MRI, CTA at 1 y
Xenograft	Avanzi et al.	II	Small, medium RCTs	Aug-46, control-46	Arthroscopic	Porcine acellular dermal matrix; Conexa (Tornier, Inc., Edina, MN)	Healing rate: Aug-97.6%, Control-59.6%; No signifigant difference in functional scores between the 2 groups	MRI 2 y
	Iannotti et al.	II	Large, massive RCTs	Aug-15, control-15	Open	Porcine small intestine submucosa; Restore Orthobiologic Implant	Retear rate: aug group-73%, control group- 40%; inferior outcomes in augmentation group	MRI at 1 y
	Castagna et al.	III	Large, massive RCTs	Aug-35, control-35	Arthroscopic	Porcine acellular dermal matrix; Conexa (Tornier, Inc., Edina, MN)	Retear rate: aug- 21.9, control- 33.3%; signifigantly higher functional scores in augmentation group	MRI at 2 y
	Walton et al.	III	Large, massive RCTs	Aug-10, control-12	Open	Porcine small intestine submucosa; Restore Orthobiologic Implant (DePuy, Warsaw, Indiana)	Retear rate: aug group-60%, control group- 58%; xenograft group had worse objective outcomes	MRI at 2 y
	Ciampi et al.	III	Massive RCTs	Aug (syn)-52, aug (xeno)-49, control-51	Mini-Open	Collagen bovine pericardium (TUTOPATCH, Tutogen Medical GmbH, Neunkirchen am Brand, Germany)	Retear rate: aug group-51%, control group-41%; no significant difference	Ultrasound at 1 y
	Cho et al.	IV	Massive RCTs	Aug-5	Mini-Open	Porcine dermal collagen (Permacol, Covidien, Mansfield, MA)	20% Retear rate. Significant improvement in clinical outcome scores (VAS/UCLA/ASES)	MRI at 6 mo
	Bokor et al.	IV	Partial thickness RCTs	Aug-13	Arthroscopic	Bovine collagen bioinductive patch (Rotation Medical, Plymouth, MN)	No tear progression in any patients at 24 mo; significant improvement in scores (ASES/ Constant)	MRI at 12 and 24 mo
	Giannotti et al.	IV	Massive RCTs	Aug-3	Mini-Open	Porcine dermal collagen (Zimmer, Warsaw, IN)	No failures. Improvement in pain, ROM, and strength	MRI
Synthetic graft	Ciampi et al.	III	Massive RCTs	Aug (syn)-52, aug (xeno)- 49, control-51	Mini-Open	Polypropylene (Repol Angimesh, ANGIOLOGICA BM Srl, Pavia,	Retear rate: aug synthetic group-17%, control group-41%; significant improvement in function,	Ultrasound at 1 y
	Flury et al.	III	Massive RCTs	Aug-10; control- 10	Arthroscopic	DX Reinforcement Matrix (Athrex, INC., Naples, FL)	strength at 3-y follow-up	MRI at 2 y
	Proctor et al.	IV	Large, massive RCTs	Aug-18	Arthroscopic	poly-L-lactic acid; X-Repair	17% Retear rate at 12 mo, 22% at 42 mo, significant functional improvement	Ultrasound at 1 y
	Lenart et al.	IV	Large, massive RCTs	Aug-13	Open	poly-L-lactic acid (X-Repair; Synthasome Inc, San Diego, CA	62% Retear rate. Significant improvement in clinical outcome scores (PENN/ASES)	MRI at 1 y
	Burkhard et al.	IV	Full-Thickness RCTs	Aug-16	Arthroscopic	Biofiber Patch (Athrex, INC., Naples, FL)		MRI at 1 y

Table 1 (*Continued*)

	Study	Level of Evidence	Inclusion Criteria	Number of Patients	Surgical Technique	Graft Used	Retear Rate and Outcomes	Imaging Assessment
							6.7% Retear rate. Signifigant improvements in Constant-Murley, SST and ISP strength	
	Encalada-Diaz et al.	IV	Small, medium RCTs	Aug-10	Mini-Open	Polycarbonate polyurethane (Biomerix, Fremont, CA)	10% Retear rate; significant improvement in VAS, SST, ASES, and ROM	MRI at 1 y
Bioinductive Xenografts	Thon et al.	IV	Large, Massive RCTs	Aug-23	Arthroscopic	Porous bovine collagen patch	Clinical failure rate of 9%, ASES improved signifigantly postoperatively for both large and massice RCTs	MRI at mean of 13 mo
	Bokor et al.	IV	Partial thickness RCTs	Aug-13	Arthroscopic	Porous collagen patch	Signifigantly improve functional scores at 2 and 5-years (ASES, Constant)	MRI at 5 y
	Schlegel et al.	IV	Partial thickness RCTs	Aug-33	Arthroscopic	Bioinductive collagen implant	70% demonstrated decreased tear size on MRI, 24% showed no defect on MRI, signifigant improvement in ASES at 1 year	MRI at 1-y
	McIntyre et al.	IV	Full and partial thickness RCTs	Aug-203	Arthroscopic	Highly porous collagen scaffold (Regeneten, Smith and nephew, Andover, MA	Partial thickness – significant improvement in VAS, SANE, VR-12, ASES, and WORC scores; Full-thickness tear – statistically significant improvement in VAS, SANE, VR-12, ASES, and WORC scores	None

ASES, American Shoulder and Elbow Surgeons score; Aug, augmentation group; RCTs, rotator cuff tears; ROM, range of motion; SST, simple shoulder test; UCLA, University of California, Los Angeles; VAS, visual analog scale.

superior capsular reconstruction, which is rigidly fixed to both the glenoid and humerus to statically resist superior humeral head migration during motion.

Allograft

Several studies have evaluated the role of allograft interposition for massive irreparable rotator cuff tears with good short-term outcomes and minimal complications.[52-55] Wong et al. conducted a level I randomized controlled trial evaluating outcomes of chronic, massive rotator cuff tears treated with either bridging reconstruction using an acellular, dermal allograft vs maximal repair.[53] Fifteen patients were randomized to each group and followed for 2 years postoperatively. At the final follow-up, the bridging reconstruction group demonstrated a significantly better improvement in DASH scores and WORC scores. Retear rates were significantly lower in the study group with only 3 of 14 patients demonstrating a retear on MRI vs 13 of 15 patients in the control group. Modi et al. demonstrated good results with improvements in Oxford Shoulder Score and visual analog scale pain scores at a mean of 9.1 years follow-up in a cohort of 53 patients treated with acellular, dermal allograft interposition for irreparable rotator cuff tears.[56] In 45 patients with long-term follow-up, 39 had positive improvement and no patients required revision surgery.[56] Despite these series demonstrating favorable subjective and objective outcome measurements and low retear rates with acellular dermal allograft interposition, anecdotal results and clinical outcomes have varied widely.[53, 54, 57-60]

Xenograft

There are few studies investigating interpositional grafting using xenograft during rotator cuff repair. Neumann et al. performed a level IV case series of 61 patients who underwent porcine dermal matrix xenograft interposition for massive rotator cuff tears.[55] At a mean of 50.3 months, patients had significant improvement in pain, range of motion, and manual muscle strength. Postoperative ultrasound demonstrated that 91.8% of repairs were intact at final follow-up.[55] Additionally, Badhe et al. studied the effect of porcine dermal collagen (Zimmer Patch, formerly known as Permacol; Tissue Science Laboratories plc, Aldershot, Hampshire, UK) interposition for irreparable massive rotator cuff tears, and similarly found low retear rates.[61] Christian et al. analyzed the histologic appearance of tissue biopsied at 4 distinct time intervals following porcine interposition for irreparable rotator cuff tears.[28] Four patients underwent biopsy at either 18 days, 3 months, 7 months, or 10.5 months, demonstrating progressive remodeling, a relative absence of inflammation, and collagen that resembled normal tendon at the final time point.

Synthetic

Several studies have evaluated the clinical outcomes of synthetic patch extension devices. These patches are all made of nonabsorbable material. Petrie et al. performed a single surgeon prospective evaluation of 29 patients with 31 symptomatic irreparable massive rotator cuff tears with grade 3 or 4 Goutallier fatty degeneration who underwent open repair with an interpositional polyester ligament augmentation reconstruction system patch (Arc-sur-Tille, France) with a mean follow-up period of 3 years.[62] Postoperative Oxford shoulder score and visual analog score results demonstrated a statistically significant improvement at follow-up, compared with preoperative values ($P = 0.0001$). Two patients required revision with good postoperative results.[62] Several other series have evaluated the outcomes of various synthetic devices. Ranebo et al. conducted a long-term retrospective evaluation of 12 eligible patients who underwent rotator cuff repair with graft interposition using a synthetic polyester, Dacron (DuPont, Wilmington, DE), at an average follow-up of 18 years.[63] Upon radiologic evaluation, cuff tear arthropathy was present in 75% of patients and the graft was no longer intact in 70% of patients. The mean postoperative man Constant-Murley score was 61 and they found the mean Western Ontario Rotator Cuff (WORK) score to be 59. The conflicting results present in the literature are further compounded by the small sample size and the lack of large randomized comparative trials. Table 2 lists the published series evaluating synthetic interpositional devices.[63-67]

Autograft

There have been limited studies investigating autograft patch interposition or augmentation as donor site morbidity can largely be mitigated by the use of commercially available allograft, xenograft, and synthetic options. Mori et al. conducted a level III retrospective study comparing an arthroscopic autograft fascia lata patch graft procedure ($n = 24$) and partial repair ($n = 24$) for irreparable large or massive rotator cuff tears in shoulders with low-grade (1 or 2) fatty degeneration of the infraspinatus.[68] The fascia lata patch graft procedure showed an 8.3% retear rate with both improved clinical scores and recovery of muscle strength, whereas the partial repair group had a retear rate of 41.7%. Further, a clinical study is needed to determine the benefit of this procedure in the setting of donor site morbidity. Scheibel et al. also reported good results of open rotator cuff repair with a proximal humeral rotational periosteal flap augmentation, including 26% with large to massive tears. A total of 4 patients (20%) demonstrated a retear of the tendon on postoperative MRI, and ectopic ossifications of the supraspinatus tendon were found in 4 patients (20%), although this had no impact on the final clinical results. Other autografts have been described including rotator cuff repair with the iliotibial band.[69,70] Zhou et al. recently led a retrospective study evaluating autologous iliotibial band with intact Gerdy's tubercle for irreparable rotator cuff tears.[69] In 16 patients who underwent the procedure, they found significantly improved functional outcome scores, and significantly improved range of motion, and 14 patients demonstrated an intact graft on MRI at a mean follow-up of 24 months.[69] A novel approach to autograft augmentation is the use of the biceps tendon which

Table 2 Studies Evaluating Outcomes of Rotator Cuff Repair with Graft Interposition

	Study	Level of Evidence	Inclusion Criteria	No. of Patients	Surgical Technique	Graft Used	Retear Rate/Outcomes	Imaging Assessment
Allograft	Venouziou et al.	IV	Massive RCTs	Interpos-14	Open	Acellular human dermal matrix; GraftJacket (Wright Medical Technology, Arlington, TN)	Significant improvement in ASES, pain, and ROM.	None
	Modi et al.	IV	Massive RCTs	Interpos-61	Open	Acellular human dermal matrix; GraftJacket	No retears. Significant improvement in clinical outcome scores	MRI - mean follow-up 3.6 y
	Gupta et al.	IV	Massive RCTs	Interpos-24	Mini-open	Acellular human dermal matrix; GraftJacket	24% retear rate (all partial tears); significant improvement in pain, ROM, outcome scores and strength	Ultrasound at 3 y
	Wong et al.	IV	Large, massive RCTs	Interpos-45	Arthroscopic	Acellular human dermal matrix; GraftJacket	Significant improvement in mean clinical outcome scores (UCLA, ASES, WORC)	None
	Modi et al.	IV	Massive RCTs	Interpos-61	Open	Acellular human dermal matrix; GraftJacket	Significant improvement in mean OSS, VAS pain score, ROM, and patient reported satisfaction	
	Awad et al.	IV	Large, massive RCTs	Interpos-49	Arthroscopic	Acellular human dermal matrix; GraftJacket	27.5% retear rate; significant improvement in WORC and DASH Scores	MRI 2 y
Xenograft	Neumann et al.	IV	Massive RCTs	Interpos-61	Mini-Open	Porcine acellular dermal matrix; Conexa (Tornier, Inc., Edina, MN, USA)	8.2% retear rate; significant improvement in pain, ROM, and strength	Ultrasound at mean 50.3 mo
	Badhe et al.	IV	Massive RCTs	Interpos-10	Open	Porcine dermal collagen (Zimmer Patch, formerly known as Permacol; Tissue Science Laboratories plc, Aldershot, Hampshire, UK)	20% retear rate; significant improvement in pain, Constant scores, ROM, and abduction strength	MRI, Ultrasound at mean 4.5 y
Synthetic graft	Petrie et al.	IV	Massive RCTs	Interpos-29	Open	Polyester ligament augmentation reconstruction system (LARS) patch (Arc-sur-Tille, France)	2 Patients required revision with good results; significant improvement in pain and subjective outcome scores	None
	Nada et al.	IV	Massive RCTs	Interpos-21	Mini-Open	Polyethylene terephthalate (Dacron Xiros, Leeds, United Kingdom)	12% Retear rate; significant improvement in Constant scores	MRI at 3 y
	Audenaert et al.	IV	Massive RCTs	Interpos-41	Open		7.3% retear rate; significant improvement in pain,	Ultrasound at mean 43-mo

Table 2 (*Continued*)

	Study	Level of Evidence	Inclusion Criteria	No. of Patients	Surgical Technique	Graft Used	Retear Rate/Outcomes	Imaging Assessment
						Polyethylene terephthalate Mersilene mesh (Ethicon, Inc., Somerville, NJ)	Constant scores, and performance of daily activities	
	Hirooka et al.	IV	Small, medium, large, massive RCTs	Interpos-27	Open	Gore-Tex patch (W.L. Gore & Associates, Flagstaff, AZ)	Significant improvement in mean subjective outcome scores and pain relief	None
	Visuri et al.	IV	medium, large, massive RCTs	Interpos-14	Open	Carbon fiber tow device (Integraft; Hexcel Medical, Dublin, CA)	11 Patients had excellent results, and 3 (fair/poor) results	None
	Ozaki et al.	IV	Massive RCTs	Interpos-25	Open	Polytetrafluoroethylene (Teflon; Dupont Company, Wilmington, DE)	23 of 25 Patients had satisfactory results	None
	Ranebo et al.	IV	Irreparable cuff tear	Interpos-13	Open	Dacron patch (Science Et Medicine; Acropole Group, Creteil, France)v	Retear in aug- 70%, cuff tear arthropathy in 75%	Ultrasound at mean 18 y
Autograft	Mori et al.	III	Large, massive RCTs	Interpos-24, partial repair-24	Arthroscopic	Fascia lata autograft	Retear rate: interpos group-8.3%, partial repair group-41.7%; significant improvement in outcome scores (ASES, Constant)	MRI at a mean of 3 y
	Scheibel et al.	III	Small, medium RCTs	Interpos-20	Open	Autologous humeral periosteal flap	0% Retear rate. Significant improvement in clinical outcomes (SST/Constant)	MRI at 1 y

ASES, American Shoulder and Elbow Surgeons Score; interpos, interposition group; RCT, rotator cuff tear; ROM, range of motion; SST, simple shoulder test; UCLA, University of California, Los Angeles; WORC, Western Ontario Rotator Cuff.

Table 3 Commercial Patch Matrices for Rotator Cuff Repair

	Scaffold Material Composition	Patch Name	Supplier
Synthetic	Polyethylene Terephthalate	Poly-Tape	Neoligaments, Leeds, UK
	Polyethylene Terephthalate	LARS	LARS Company, Arc sur Tille, France
	Polyethylene Terephthalate	Mersilene Mesh	Ethicon, Inc., Somerville, NJ)
	Polyethylene Terephthalate	Dacron Xiros	Leeds, UK
	Polypropylene	Repol Angimesh	Angiologica, Siccomario, Italy
	Poly-L-lactic-acid (PLLA)	X-Repair	Synthasome, San Diego, CA
	Carbon filament polylactic Acid Filament	Intergraft	Hexcel Corp., Dublin, CA
	Polytetrafluoroethylene	Teflon	Dupont Company Wilmington, DE
	Poly-4-hydroxybutyrate (P4HB)	Biofiber	Tornier, Edina, MN
Allograft	Acellular human dermal matrix	GraftJacket	Wright Medical Group, Memphis, TN
	Acellular human dermal matrix	AlloPatch HD	MTF Biologics, Edison, NJ
	Acellular human dermal matrix	Arthroflex	Arthrex Inc., Naples, FL
Xenograft	Porcine dermis	Biotape XM	Wright Medical Technology, Inc., Arlington, TN
	Porcine dermis	Permacol	Medtronic, Minneapolis, MN
	Porcine dermis	Conexa	Tornier, Edina, MN
	Bovine dermis	BioBlanket	Kensey Nash, Exton, PA
	Fetal bovine dermis	TissueMend	TEI Biosciences, Boston, MA; Licensed to Stryker
	Equine pericardium	OrthoADAPT	Pegasus Biologics, Irvine, CA
Bioinductive Xenografts	Porous bovine collagen patch	Regeneten	Smith and Nephew, Andover, MA
	Porous type I collagen and bio-reabsorbale Poly-L-lactic acid	BioBrace	Biorez, New Haven, CT

has excellent mechanical properties and offers a local low-cost source of tissue.[71-73] Additionally, recent laboratory studies have demonstrated the ability of autologous biceps tendon scaffolds to be a viable source of tenocytes and produce bioactive signals which promote a favorable healing environment.[71] Various types of autografts have demonstrated promising results but continue to be limited by small, nonrandomized studies, and the risk of donor site morbidity.[51,69,70]

Summary of Studies

Steinhaus et al. performed a systematic review of clinical outcomes and retear rates after patch use in rotator cuff repair surgery between 1986 and January 2015.[74] Twenty-four studies (level of evidence II-IV) met inclusion criteria (Tables 1 and 2). The frequency-weighted mean age was 61.9 years with 35.4 months of follow-up. Patch augmentation and interposition techniques demonstrated similar improvements in patient-reported outcome measures, range of motion, and strength. However, xenografts showed less favorable improvement in outcome scores and activities of daily living as compared to other graft types. The overall retear rate was 25% (patch augmentation—34%, patch interposition—12%), whereas rates of retearing by graft were 44%, 23%, and 15% for xenografts, allografts, and synthetic grafts, respectively. The authors concluded that retear rates may be lower with patch interposition techniques, or in patients with allograft or synthetics. More recently, de Andrade et al. conducted a systematic review of 7 interventional, comparative studies published between 2012 and 2019 to better evaluate the effect of a patch augmentation in rotator cuff repair.[75] Patch augmentation, regardless of the graft utilized, resulted in lower retear rates although only 2 studies showed significance. Shoulder function assessed with the UCLA score demonstrated significant improvements although this was not repeated across other functional measures. In the pooled analysis of comparative studies, they found no improvement in the American Shoulder and Elbow Surgeons (ASES) score, Simple Shoulder Test (SST), or range of motion in the patch augmentation groups when compared to rotator cuff repair alone.[75] These results emphasize the need for more long-term, adequately powered, randomized controlled trials in order to confirm the improvement in outcome measures offered by patch augmentation.

Complications

The systematic review by Steinhaus et al. reported a relatively low pooled complication rate of 3.5% (12 of 340). The most common complication was a severe noninfectious or pseudo-septic inflammatory reaction seen in 7 patients treated with porcine small intestine submucosa (Restore) patch augmentation.[26,32,74] Five of these patients required formal debridement and irrigation. Several authors have hypothesized that the inflammatory reactions to residual porcine DNA material may be the causative factor.[76-78] Other complications included 1

deep infection in an immunocompromised patient who underwent allograft augmentation[57] and 1 case of recurrent bursitis.[23] Additional complications were related to asymptomatic cystic changes of the greater tuberosity after carbon fiber patch interposition,[67] although these radiographic changes had no or indeterminate repercussions on overall patient function.

Preferred Surgical Technique

The authors prefer to use rotator cuff repair augmentation with an acellular human dermal matrix allograft for patients with repairable rotator cuff tears, suboptimal tissue quality or tendon attenuation, and younger patient age or higher functional demands.[79] Most commonly, patients receive a regional nerve block in the preoperative holding area and undergo general endotracheal anesthesia in the operating room. The patient is placed in the beach chair position. Examination under anesthesia is performed to assess the shoulder range of motion with the scapula stabilized. After standard prepping, draping, and marking of relevant anatomic landmarks, a standard posterior viewing portal is created to perform a diagnostic arthroscopy of the glenohumeral joint. An anterior portal is established via an outside-in technique with a spinal needle and concurrent intra-articular pathologies, such as biceps tenosynovitis, may be addressed. The arthroscope is then placed into the subacromial space and 2 additional portals are established: 1) a lateral viewing portal located 3 cm lateral to the acromial edge, in line with the posterior border of the clavicle; and 2) an anterolateral portal with a screw-in 8.25 mm cannula (Arthrex, Inc., Naples, FL) inserted. A subacromial bursectomy and acromioplasty are performed to aid visualization from the lateral portal and global access of the rotator cuff. A thorough bursectomy is critical to provide sufficient space to perform patch augmentation. Rotator cuff mobilization is performed to confirm footprint restoration can be achieved without undue tension. Then, the rotator cuff tendon is repaired in a standard fashion according to tear morphology, tissue mobility, and surgeon preference. The senior surgeon's preference is to perform a transosseous-equivalent repair when feasible. If required due to poor tissue mobility, the articular margin can be medialized up to 5mm to facilitate direct rotator cuff repair.

The senior author's most commonly used dermal allograft (AFLEX 201 graft, Arthrex, Inc., Naples, FL), is available in 2 sizes and the more appropriate size is selected based on rotator cuff tear size and morphology. Once the acellular dermal allograft patch is on the surgical field, the smooth, bursal side of the patch is marked with a pen to differentiate it from its interlaced, articular side. The medial side of the patch is prepared with 2 simple stitches of nonabsorbable, ultra-high tensile strength suture (#0 FiberWire, Arthrex, Inc., Naples, FL). SutureTape TigerLink sutures (Arthrex, Inc., Naples, FL) are used to create 2 luggage-tag stitches on the lateral side of the graft, approximately 5 mm from its edge. Sutures from the medial side of the patch are loaded onto an arthroscopic delivery device (Graft Spreader, Arthrex, Inc) in a crossed fashion (Fig. 2). Before loading the graft, we recommend trialing the delivery device to ensure it deploys appropriately. Following placement of a lateral cannula (10 mm x 4 cm PassPort, Arthrex, Inc), the Graft Spreader is passed through the lateral cannula into the subacromial space. A lateral cannula at least 10 mm in diameter is necessary to accommodate the passage of a patch. Once the desired position of the graft over the rotator cuff repair construct is achieved, the Graft Spreader is deployed. Six to 8 polylactic staples (TissueTak tendon staples, Arthrex, Inc., Naples, FL) are placed medially and peripherally to secure the graft to the rotator cuff tendon construct. Medial patch sutures are cut, and the Graft Spreader is removed from the lateral portal. Sutures from the lateral edge of the patch are loaded into 3.5 mm biocomposite PushLock anchors (Arthrex, Inc., Naples, FL), tensioned, and secured in the lateral greater tuberosity footprint for a transosseous-equivalent repair (Fig. 3). Optional orthobiologic adjuncts, such as platelet-rich plasma or bone marrow aspirate concentrate, may be added to theoretically enhance biologic incorporation at the site of repair and augmentation. The use of patch augmentation does not alter the senior surgeon's postoperative rehabilitation protocol.

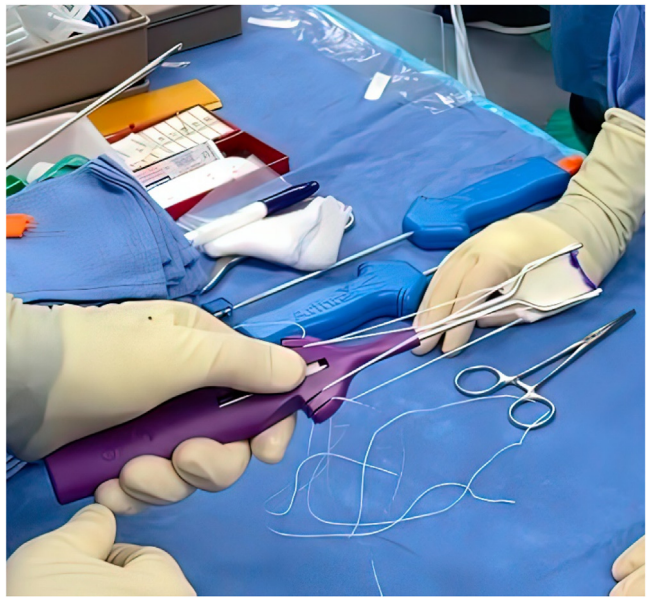

Figure 2 Intraoperative photo of the premeasured AFLEX graft (Arthrex, Inc., Naples, FL) in the Graft Spreader. The smooth, bursal side of the graft is marked with a pen. The medial side is prepared 2 simple stitches of nonabsorbable, ultra-high tensile strength (FiberWire, Arthrex, Inc., Naples, FL). SutureTape TigerLink (Arthrex, Inc., Naples, FL) sutures are used to create 2 luggage tag stitches on the lateral side of the graft. (Color version of figure is available online.)

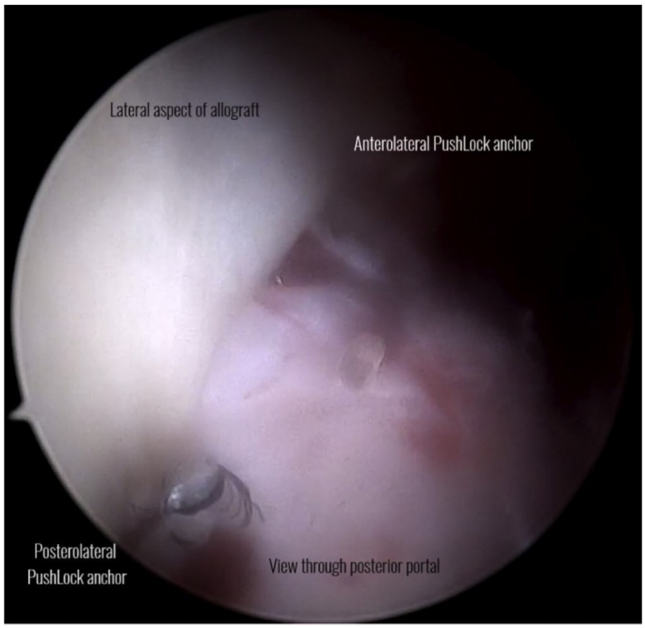

Figure 3 Arthroscopic image taken after the sutures on the lateral side of the graft have been secured into the lateral greater tuberosity using 3.5 biocomposite pushlock anchors (Arthrex, Inc., Naples, FL). Permission to use requested from Arthroscopy Techniques, awaiting response. (Color version of figure is available online.)

Conclusion

Treatment of large-to-massive rotator cuff has continued to be challenging. Patch augmentation and interposition are indicated in patients whose rotator cuff pathology, intrinsic patient factors, and/or history of failed rotator cuff surgery suggest an impaired ability for native tendon-to-bone healing with isolated rotator cuff repair. Patch augmentation of large-to-massive repairable rotator cuff tears improves clinical and functional outcomes with an acceptable retear rate and low complication risk. Based on the current literature, synthetic grafts and allografts have shown greater improvement than xenografts; however, future clinical trials are required in the setting of newer xenograft devices. Furthermore, patch interposition with synthetic, allograft, and xenograft tissue for irreparable tears is a viable surgical option for this difficult problem. Studies have shown similar improvements in clinical and functional outcomes, with a trend toward lower retear rates when compared to augmentation, although surgical indications may vary. Despite the fact that there are numerous options available, the best graft for augmentation or interposition with advanced rotator cuff tears has yet to be determined.

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