SYSTEMATIC REVIEW

Rotator Cuff Repair With Patch Augmentation: What Do We Know?

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Abstract

Background: Repair of massive rotator cuff tears remains a challenging process with mixed success. There is a growing interest in the use of patches to augment the repair construct and the potential to enhance the strength, healing, and associated clinical outcomes. Such patches may be synthetic, xenograft, or autograft/allograft, and a variety of techniques have been tried to biologically enhance their integration and performance. The materials used are rapidly advancing, as is our understanding of their effects on rotator cuff tissue. This article aims to evaluate what we currently know about patch augmentation through a comprehensive review of the available literature.

Methods: We explore the results of existing clinical trials for each graft type, new manufacturing methods, novel techniques for biological enhancement, and the histological and biomechanical impact of patch augmentation.

Results: There are promising results in short-term studies, which suggest that patch augmentation has great potential to improve the success rate. In particular, this appears to be true for human dermal allograft, while porcine dermal grafts and some synthetic grafts have also had promising results.

Conclusion: However, there remains a need for high-quality, prospective clinical trials directly comparing each type of graft and the effect that they have on the clinical and radiological outcomes of rotator cuff repair.

Level of evidence: IV

Keywords: Biological enhancement, Extracellular matrix, Patch augmentation, Rotator cuff, Rotator cuff repair, Rotator cuff tear, Tissue scaffolds

Introduction

Repair of massive rotator cuff tears remains a challenging process with variable healing rates despite new advances in technology and surgical techniques.[1] The overall aim is to improve patients' symptoms and the structural integrity of the rotator cuff. While patient satisfaction and cuff function appear to improve even with failed repair, high rates of recurrent tears have been reported.[2-8] This is particularly true for large and massive tears, with some studies reporting recurrent tearing in as many as 94% of these cases.[5-9] A meta-analysis in 2015 addressed the outcomes of over 8,000 patients with rotator cuff repair and demonstrated that around 26.6% of these cases fail to heal, with roughly a quarter of all repairs failing.[9] Patients who suffer from rotator cuff tears often have poor quality, degenerative tendons with an inadequate blood supply. Healing outcomes are even worse in elderly patients, with inferior rates of both healing and recurrence.[8,10]

However, there is substantial evidence that those with healed rotator cuff repair have better clinical outcomes.[1]

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Cuff repair has been consistently shown to have superior outcomes when accompanied by conservative management, provided it is used in appropriate patients. Most recreational athletes can return to their previous level of competition following arthroscopic repair. In addition, several studies have shown improved function, lower pain scores, reduced sleep disturbance, and a higher rate of overall patient satisfaction.[11-15] When healing is successful and repair integrity is maintained, the long-term outcomes are highly positive.[3,16-18] The focus has therefore been shifted toward developing novel techniques and materials that promote healing. Patch augmentation has been used increasingly in recent years, particularly for large and massive tears, hoping that this can both mechanically enhance the repair construct and encourage healing with advantageous tissue properties. This study aims to evaluate what we currently know about rotator cuff repair with patch augmentation and identify potential future research directions.

Materials and Methods

Literature Search

A comprehensive literature search was performed in Nov 2020 using Medline, CINAHL, and PubMed search engines. A search strategy was formulated using the following keywords: "Shoulder", "Rotator cuff", "Rotator cuff tear", "Rotator cuff repair", "Augmentation", "Augmented rotator cuff repair", "Rotator cuff repair patch augmentation", "Patch rotator cuff repair", "Biologics", "Rotator cuff repair and biologics", and "Rotator cuff repair with graft". In order to ensure the maximum number of articles were considered, the references of the included studies were also manually checked and included.

The primary focus was given to recent articles, particularly human clinical trials examining each augmentation type. The main aim of this study is to explore the outcomes of primary rotator cuff repair with patch augmentation; therefore, focus was not given to the cases in which the graft had been utilized as a "bridging" structure. We chose not to dwell on results from animal or in vitro studies and do not explain in detail the underlying biological mechanisms of each graft type. Extensive work has been done in these areas that is beyond the scope of this study.

Results

Graft Material

The graft material is generally of three types, namely animal, human, or synthetic, including the recently developed "nano-scaffolds".[19-21] It is important to mention that patch augmentation of rotator cuff repairs is not a new concept.[22-24] The issue until recently has been the profound inflammatory reaction against the animal and synthetic patches, which lead to the achievement of poor outcomes.[25,26]

However, newer animal extracellular matrix (ECM) patches undergo more modern and complete DNA extracting procedures than the earlier models. Therefore, the resulting inflammatory response appears to be less and in most patients is subclinical.[27,28] These advances in patch technology have resulted in a renewed interest in rotator cuff repair with patch augmentation. In addition to the increasing popularity of other shoulder procedures that utilize patches, improved instrumentation in arthroscopic surgery has also been a contributing factor. A notable example of this is superior capsular reconstruction (SCR), which has been strongly endorsed by the industry.[29,30]

Each method has variable outcomes, which may be improved by future research. Recent advancements have given rise to biological augmentations (e.g. platelet-rich plasma [PRP], bone marrow aspirate [BMA], bio-engineered patches).[31-33] The use of biologics themselves, such as PRP, mesenchymal stem cells, cytokines, and growth factors has also been investigated. However, a considerable amount of work is still to be done in this area.[34] The "belt and braces" technique that combines patch augmentation with SCR has also been proposed to improve the chance of healing and functional outcomes. However, clinical trials have yet to be completed.[35]

Biomechanics

The aim of using patch augments in rotator cuff repair is to induce native tissue growth, providing biomechanical support and an optimal environment for rotator cuff healing. While it is still too early to conclude that the augment directly induces native tissue growth, there is a strong argument advocating the indirect involvement of the patch by reducing (but not eliminating) the load on the repaired tendon in its initial healing phase. Synthetic, allograft, and dermal xenograft patches have all been shown to significantly increase construct strength and load-to-failure rates, while small intestine submucosa has had less favorable outcomes.[16,36-41]

Crucially, however, effective augmentation is not as simple as creating the most robust possible graft. On the one hand, if the patch is too strong, it may prevent tissue in-growth or underlying tendon healing due to stress shielding. On the other hand, if it is weak, it may fail prematurely.[42] The other consideration is to what degree the patch encourages tissue infiltration and subsequent incorporation with desirable properties more similar to the native rotator cuff.[43] In addition, the patch itself will exert shear forces on local structures. There is significant variation between products and their tensile properties that should be carefully considered.[44] As a result, most new techniques attempt to create a graft that is indistinguishable from a native tendon while examining biological enhancements to better incorporate it into that tendon, such as use of electrospun scaffolds and nanofiber technology.[19,33]

Histology

There are limited histological studies investigating patch use for rotator cuff repair in humans, though comparative animal studies do exist.[45] Existing studies show variable healing outcomes with patch augmentation, depending on the type of graft used. There is a disagreement among studies using the same material; furthermore, the evidence base is not large enough to recommend any single graft type. The most common xenografts are porcine dermal or small intestinal submucosa (SIS) grafts, though a recent study has also reported promising

outcomes using ovine foregut matrix.[46] The porcine dermal grafts have yielded encouraging outcomes in animal studies and these may yet prove to be a reliable option for augmentation of cuff repairs.[47] However, despite initial optimism about the potential of porcine SIS from animal studies, unsatisfactory outcomes have since been reported in humans.[41,48-50] Bovine grafts are also used in some centers, and good results have been achieved both with the graft alone and biological augmentation.[51,52] However, we are not aware of any histological studies comparing them to other graft types.

Human dermal allograft has performed well in histological studies, with good cellular infiltration, revascularisation, and new tendon formation.[53] Autografts have also had encouraging histological outcomes in animal models, with improved tendon-tendon healing.[54] The use of periosteum to enhance graft augmentation has also been proposed, with promising histological outcomes.[55] However, there is currently limited evidence to support its use in rotator cuff repair.[56]

Older polyester grafts aim to reinforce rather than affect the healing of the underlying tendon. More recently, this has been attempted using novel materials, biological enhancement, and the development of nano-scaffolds, with encouraging short-term outcomes.[3,39,57-59] However, in a recent case series, Muench et al. trialed a biologically enhanced collagen scaffold and experienced poor healing outcomes.[31] These materials are still in their infancy and have yet to progress to large-scale clinical trials. Implantation techniques have also been shown to affect healing, with some centers trialing a combination of bone marrow stimulation and patch augmentation to biologically encourage this with good outcomes.[53,60]

As well as being potentially ineffective, adverse tissue reactions must be considered for all graft types. These are generally rare but have been reported in the literature.[50,61-63] Walton et al. reported severe inflammatory reactions to porcine SIS.[50] Rashid et al. also found that the more promising human allografts and porcine dermal grafts could cause significant disruption of the ECM of the underlying native tendon, with increased friability and worse alignment of collagen fibers.[61] Barad et al. reported an instance of severe subacromial inflammation with the formation of rice bodies secondary to a bio-inductive collagen scaffold.[63] It is important to mention that although several studies have shown adverse reactions to animal patches, most of these have investigated the earlier models. As mentioned before, newer animal ECM patches undergo more modern and complete DNA extraction procedures than the earlier patches. Although the subsequent inflammatory response appears to be less, in most patients it seems not to affect clinical outcomes.[27]

Clinical & Radiological Outcomes

Drawing conclusions about the clinical outcomes of cuff repair with patch augmentation is very challenging. There are a variety of implantation approaches, surgical techniques and patches, which themselves result in highly variable outcomes. Moreover, there are generally only a small number of comparative studies or research investigating each patch type, often with a short follow-up period. Yoon et al. found an overall retear rate ranging from 8.3% to 73.4%, depending on graft type, indication, and technique.[60] It does seem that in the right environment, patch augmentation can provide good functional outcomes, as has been illustrated by several studies. There are three existing types of patch augment, within which there are many subsets. These include animal grafts (xenograft), human grafts (autograft/allograft) and synthetic grafts.

Xenograft

So far, a great deal of focus has been given to grafts from animal donors, with mixed results [Table 1]. Iannotti et al. conducted a randomized-controlled trial (RCT) investigating porcine SIS for use in chronic two-tendon cuff tears. They found no significant improvement in terms of healing on MRI in the group treated with the augment. They reported that successful healing was a strong indicator of better functional outcomes and patient satisfaction. The augmentation group had worse healing rates, with 4/15 (27%) patients healing successfully, compared to 9/15 (60%) cases in the control group.[17] Likewise, a larger RCT by Bryant et al. in 2016 examined porcine small intestine grafts and similarly found that they conferred no benefit, with the study group performing worse in terms of risk of failure at 1 year.[64] Sclamberg et al. have also found poor radiological outcomes, in addition to unsatisfactory clinical outcomes, with recurrent tears in 10 of their 11 patients on MRI at 6 months.[65]

However, the porcine dermal grafts have shown more promising results.[66,67] A prospective RCT in 2019 by Avanzi et al. examined the healing outcomes of using porcine dermal patches based on MRI and clinical assessment. They found a healing rate of 97.6% in the patch group, compared with only 59.5% in the control. They also demonstrated improved tendon thickness, strength restoration, and functionality in the patch group.[68] A retrospective study by Castagna et al. in 2018 recognized similar outcomes in patients who had large or massive cuff tears (with fatty infiltration of the cuff on MRI). Although the patch group showed no healing improvement, they had a significant improvement in their functional outcomes in comparison with the control group. Moreover, the patch was reported to result in improved outcomes even in instances of recurrent tear.[4] In addition, a prospective, multicenter study by Lederman et al. followed 61 cuff repairs that had been augmented with porcine dermal graft and concluded that this mode of repair significantly improved functional outcomes relative to preoperative scoring.[66]

In 2016, a prospective single-surgeon series by Consigliere et al. demonstrated significantly improved functional outcomes and pain scores at both 3 and 6 months when using denatured porcine ECM to repair large and massive rotator cuff tears.[27] An additional study by the same group in 2021 examined 44 consecutive patients to further evaluate this type of graft. They again found improved clinical outcomes at 3 months, 6 months, and 1 year, with no adverse reactions reported.

Table 1. Summary of clinical trials investigating the use of xenografts for patch augmentation

Study	Study design	Level of evidence	Application	Study group	Control (n)	Study outcomes	Duration of followup	Results
Bryant et al. (2016) (64)	RCT	I	Moderate/large cuff tears	Porcine SIS (38)	No augment (28)	Cuff integrity (MRI), Clinical/ functional outcomes	24 months	Lower risk of failure in study group at 1 year (*P=0.33*). No significant improvement in clinical/functional outcomes.
Avanzi et al. (2019) (68)	RCT	I	Small/medium cuff tears	Porcine dermal graft (46)	No augment (46)	Healing rate (MRI), Clinical/functional outcomes	24 months	Healing rate 97.6% in study group vs. 59.5% in control (*P<0.05*). Improved clinical/functional outcomes.
Iannotti et al. (2006) (17)	RCT	II	Chronic 2-tendon cuff tears	Porcine SIS (15)	No augment (15)	Healing rate (MRI), Clinical/functional outcomes	14 months	Healing rate 27% in study group vs. 60% in control (*P=0.11*).
Castagna et al. (2018) (4)	Retrospective comparative study	III	Large/massive cuff tears	Porcine dermal graft (35)	Matched cohort No augment (35)	Healing rate (MRI), Functional outcomes	24 months	No significant difference in re-tear rate at 2 years. Significant improvement in functional outcomes in study group vs. control.
Lederman et al. (2016) (66)	Prospective cohort study	III	Large cuff tears	Porcine dermal graft (61)	N/A	Healing rate (MRI), Functional outcomes	24 months	33.9% re-tear rate at 1 year. Significantly improved functional outcomes vs. pre-op at 12 and 24 months
Flury et al. (2017) (69)	Retrospective comparative study	III	Cuff tear (complete SS tear)	Porcine dermal graft (20)	Matched cohort No augment (20)	Re-tear rate (MRI), Clinical/functional outcomes	24 months	Re-tear rate 20% in study group vs. 47.4% in control at 2 years (P=0.096) No significant difference in clinical/functional outcomes
Ciampi et al. (2014) (70)	Retrospective cohort Study	III	Massive cuff tears	Bovine pericardium–derived collagen patch (49)	No augment (51)	Re-tear rate (MRI), Clinical/functional outcomes	36 months	Re-tear rate 51% in study group vs. 41% in control at 1 year. No improvement to clinical outcomes or re-tear rate vs. control.
Leuzinger et al. (2016) (77)	Comparative study	III	Cuff tear (primary + re-rupture)	Porcine SIS (29)	N/A	Re-tear rate (MRI), Clinical outcomes	6 months, 3 years	Significantly improved outcome scores vs. pre-op at 6 months and 3 years. Success rate 64.7%.
Consigliere et al. (2017) (27)	Prospective case series	IV	Cuff tear	Porcine dermal ECM (10)	N/A	Clinical/functional outcomes	7 months	Improvement in pain and functional outcome scores vs. pre-op.
Consigliere et al. (2021) (28)	Prospective case series	IV	Cuff tear	Porcine dermal ECM (44)	N/A	Re-tear rate (MRI), Clinical/functional outcomes, Complications	12 months	Re-tear rate 15.9%. Improved clinical and functional outcome scores vs. pre-op.
Sclamberg et al. (2004) (65)	Retrospective case series	IV	Cuff tear	Porcine SIS (11)	N/A	Re-tear rate (MRI), Clinical outcomes.	6 months	Re-tear rate 91%. No clinical improvement, 45% had worse outcomes scores vs. pre-op.
Gupta et al. (2013) (67)	Retrospective case series	IV	Massive or full thickness 2-tendon cuff tears (irreparable)	Porcine dermal ECM (27)	N/A	Re-tear rate (USS), Clinical/functional outcomes	32 months (average)	73% of repairs intact. Improved clinical/functional outcomes vs. pre-op.
Bokor et al. (2015) (71)	Prospective case series	IV	Cuff tear (SS tear requiring repair)	Bovine tendon patch (9)	N/A	Re-tear rate, tendon footprint and thickness (MRI)	24 months	100% of repairs intact in study group at 1 year. Successfully induced tissue formation.

These patients were also evaluated with MRI at 1 year and found to have lower structural failure rates (15.9%) when compared to similar cohorts in other studies examining conventional rotator cuff repair. The size of the tear preoperatively was an independent predictor for the risk of retear.[28]

Despite showing considerable promise, dermal grafts are not flawless, and results may vary. Flury et al. explicitly investigated patients aged >60 years with supraspinatus tears. They found that augmenting a repair with a patch took 22 minutes on average and did not lead to improved functional scores nor a reduced rate of recurrent tear.[69] Adverse radiological tissue reactions are rare for most grafts but are well documented. These tend to occur more commonly with older patches that have not been subjected to modern processing and "denaturing" of their DNA.[25,50,61,63] Ciampi et al. also examined the use of collagen xenografts derived from bovine pericardium but found that these did not improve clinical outcomes or the rate of recurrent tear.[70] However, Bokor et al. evaluated processed porous collagen scaffolds derived from bovine tendons and found that they successfully induce tissue formation and help to restore the normal anatomy of the footprint area.[71]

Autograft & Allograft

Grafts from human donors have also been widely investigated [Table 2]. A prospective multicenter RCT by Barber et al. investigated the efficacy and safety of using acellular human dermal grafts (GraftJacket) to repair large and two-tendon rotator cuff tears. At a 2-year follow-up, 85% of patients in the augmented group had an intact cuff on MRI, compared to only 40% in the control group. The graft patients also had improved functional outcome scores, and there were no complications related to the presence of the graft.[16] A prospective study by Gilot et al. in 2015 compared arthroscopic cuff repair with/without human dermal patch augmentation in 35 patients and found that the patch improved both the clinical outcomes and rate of retear.[72] Petri et al. also investigated the use of dermal allografts to augment open revision cuff repairs. They found these types of allografts to be safe and effective in terms of patient satisfaction and functional outcomes.[73] In addition, Hall et al. reported significantly improved clinical and functional outcomes, with no retears identified at a 2-year follow-up.[74] A similar series by Hohn et al. and Burkhead et al. again reported positive clinical outcomes but experienced retear rates of 31% and 27% respectively.[75,76] Out of all graft types, allografts seem to have shown the most promising results so far. A study by Leuzinger et al. in 2016 compared the clinical outcomes of a commercially available xenograft, allograft, and synthetic graft. The best outcome scores were obtained for a human dermal allograft (GraftJacket), followed by the synthetic graft (Artelon), and finally the porcine SIS xenograft (Restore).[77]

Autografts are less frequently used but have also had good outcomes. It is worth noting that these may be more suitable if cultural or religious reasons make other graft types unsuitable. In 2013, Mori et al. evaluated the use of fascia lata autografts to augment otherwise irreparable large or massive cuff tears, compared to partial repair. They reported no complications secondary to graft use and found the graft group to have significantly better outcomes in terms of pain, muscle strength, and function. On MRI at final follow-up, 79.2% of patients in the graft group had both an intact graft and tendon, compared to only 58.3% in the control group.[78] Rosales-Varo et al. have recently demonstrated a much faster improvement in postoperation pain scores using a fascia lata autograft. However, they found no significant improvements in function, pain, or retear rates at 1-year follow-up.[79] Autologous quadriceps tendon has also been tested by Tempelaere et al., with improved functional outcomes for rotator cuff repair but a high postoperative complication rate at the donor site.[80]

In a study, Scheibel et al. investigated autograft repair using a periosteal flap taken from the humerus just distal to the greater tuberosity. The mentioned study reported promising results when first published in 2006. However, a further study by Holwein et al. in 2019 showed no improvement in healing response on MRI and ultrasound scan, as well as unsatisfactory clinical outcomes and retear rates. As a result, the researchers no longer recommend this approach.[56,81] It is also clear that tendon quality affects the histological outcomes of cuff repair, with Mori et al. demonstrating significantly worse functional outcomes for autograft repair in tendons with a higher degree of fatty infiltration.[82]

Synthetic and Biological Grafts

Advanced manufacturing techniques (e.g. 3D printing and electrospinning) have enabled the reproduction of desirable tissue qualities through the creation of intricate nano-scaffolds and biologically enhanced grafts. Furthermore, these methods make synthetic augmentation an exciting field for future research. However, so far, outcomes with synthetic grafts have been mixed [Table 3]. Shepherd et al. described long-term outcomes (almost 10 years) for patients treated with synthetic patch augmentation between 1996 and 2005. They observed an improvement in pain, function, and range of motion.[83] In 2018, Ranebo et al. published a study addressing the long-term clinical outcomes of a synthetic polyester graft (Dacron) used for interposition with screw fixation. The outcomes at almost 20-year follow-up were poor; therefore, it was concluded that such grafts were unable to prevent further cuff tear arthropathy or maintain cuff integrity in the long term.[84] However, this was a retrospective single-center case series of small size, and it is worth noting that techniques and materials have come a long way in the last 20 years. Accordingly, more recent studies suggest that synthetic polyester patches may have the potential to improve patient outcomes.[85-87]

In the last few years, several new materials have been tested. Ciampi et al. evaluated a polypropylene patch (Repol Angimesh) and demonstrated significantly improved function and retear rates, compared to both standard rotator cuff repair and repair with the absorbable bovine patch described above.[70] An RCT by Cai et al. in 2018 investigated the use of 3D collagen scaffolds in 104 patients with large and massive cuff tears. Their scaffolds were composed of multiple, aligned

Table 2: Summary of clinical trials investigating the use of autografts and allografts for patch augmentation

Study	Study design	Level of evidence	Application	Study group	Control (n)	Study outcomes	Duration of followup	Results
Barber et al. (2012) (16)	RCT	II	Large two-tendon cuff tears	Acellular dermal allograft (22)	No augment (20)	Healing and re-tear rate (MRI), Clinical/ functional outcomes, Complications.	24 months	85% of repairs intact in study group vs. 40% in control. Clinical/functional outcomes improved in study group, no complications related to augment.
Gilot et al. (2015) (72)	Prospective comparative study	III	Large/massive cuff tears (>3cm)	Acellular dermal allograft (20)	No augment (15)	Re-tear rate (USS), Clinical outcomes	24.9 months (mean)	Significantly improved clinical outcomes and rate of re-tear in augmented group vs. control.
Leuzinger et al. (2016) (77)	Comparative study	III	Cuff tear (primary + re-rupture)	Acellular dermal allograft (28)	N/A	Re-tear rate (MRI), Clinical outcomes	3 years	Significantly improved outcome scores vs. pre-op at 6 months and 3 years. Success rate 87.5%.
Mori et al. (2013) (78)	Retrospective comparative study	III	Large or massive cuff tears (irreparable)	Fascia lata autograft (24)	Partial repair (24)	Healing and re-tear rate (MRI), Clinical/ functional outcomes, Complications	24 months	79.2% of repairs intact in study group vs. 58.3% in control. Significantly improved clinical/functional outcomes in study group.
Rosales-Varo et al. (2017) (79)	Case-control study	III	Complete cuff tears	Fascia lata autograft (10)	No augment (10)	Re-tear rate (MRI), Clinical/ functional outcomes, Complications	12 months	Re-tear rate 10% in study group vs. 20% in control. Faster improvement in post-op pain. No significant difference in clinical/functional outcomes or re-tear rate.
Tempelaere et al. (2016) (80)	Retrospective comparative study	III	Massive cuff tears	Quads tendon autograft (23)	No augment (27)	Functional outcomes	Mean: 59 months (study), 55 months (control).	Improved functional outcomes in study group but high rates of donor site complications.
Mori et al. (2015) (82)	Cohort study	III	Large/massive cuff tears with fatty degeneration of SS (high-grade) and infraspinatus (high-grade vs. low grade)	Fascia lata autograft (45)	N/A	Re-tear rate (MRI) Clinical/functional outcomes, Complications	24 months	*With low-grade infraspinatus degeneration:* 73.1% of repairs intact vs. 10.6% in control. Significantly improved clinical/ functional outcomes.
Muench et al. (2020) (31)	Case series	IV	Revision massive cuff tear	Human dermal allograft with with PRP and BMA (22)	N/A	Clinical outcomes	12 months	Substantial clinical benefit in 41%. 32% reached or exceeded the patient-acceptable symptomatic state criteria.
Holwein et al. (2019) (56)	Prospective case series	IV	Small degenerative full thickness tears (<6mm)	Humeral periosteal flap autograft (23)	N/A	Healing and re-tear rate (MRI/US), Clinical outcomes	Pre-op, post-op, 1 year, 11 years	No improvement in healing, unsatisfactory clinical outcomes and re-tear rates.
Petri et al. (2016) (73)	Case series	IV	Open revision massive posterosuperior cuff tears	Acellular dermal allograft (13)	N/A	Clinical/functional outcomes, Complications	30 months (mean)	Significantly improved functional outcome scores, no improvement in pain scores. No complications.
Hall et al. (2020) (74)	Retrospective case series	IV	Revision cuff repair	Acellular dermal allograft (9)	N/A	Re-tear rate (USS), Clinical outcome scores	2 years	Improved clinical/functional outcomes vs. pre-op. All cuffs intact on USS at 2 years.
Hohn et al. (2018) (75)	Retrospective case series	IV	Revision repair, full thickness (>2cm) tears	Acellular dermal allograft (23)	N/A	Clinical outcomes	2 years (minimum)	Significant improvement in post-op outcome scores. Only 6 patients with pre-op scores.
Burkhead et al. (2007) (76)	Case series	IV	Massive cuff tear (>5cm, primary + re-rupture)	Acellular dermal allograft (17)	N/A	Re-tear rate (MRI), Clinical/functional outcomes	1.2 years (mean)	Re-tear rate 27%. Significantly improved clinical/ functional outcomes.
Scheibel et al. (2006) (81)	Prospective case series	IV	Full thickness cuff tears	Humeral periosteal flap autograft (23)	N/A	Re-tear rate (MRI), Functional outcomes, Complications	14.4 months (mean)	Re-tear rate 20%. Significantly improved clinical outcome scores vs. pre-op.

Table 3. Summary of clinical trials investigating the use of synthetic grafts for patch augmentation

Study	Study design	Level of evidence	Application	Study group	Control (n)	Study outcomes	Duration of followup	Results
Cai et al. (2018) (57)	RCT	II	Large/ massive cuff tears	3D collagen scaffold (54)	No augment (58)	Healing and re-tear rate (MRI), Clinical/functional outcomes	28.2 months (mean)	Re-tear rate 13.7% in study group vs. 34% in control (*P=0.02*). Significantly improved clinical/ functional outcomes at 12 months, but no difference at final follow-up.
Ciampi et al. (2014) (70)	Retrospective cohort Study	III	Massive cuff tear	Polypropylene patch (52)	No augment (51)	Re-tear rate (MRI), Clinical/functional outcomes	36 months	Re-tear rate 17% in study group at 1 year vs. 41% in control (*P=0.001*). Significantly improved clinical/functional outcomes vs. control.
Leuzinger et al. (2016) (77)	Comparative study	III	Cuff tear (primary + re-rupture)	Artelon® polyurethane urea patch (32)	N/A	Re-tear rate (MRI), Clinical outcomes	6 months, 3 years	Significantly improved outcome scores vs. pre-op at 6 months and 3 years. Success rate 73.7%.
Cowling et al. (2020) (86)	Comparative feasibility study	III	Massive cuff tear	Polyester patch (29)	No augment (39)	Clinical outcomes and "fat fraction" on MRI	6 months	Improved clinical outcomes. A definitive clinical trial is feasible.
Shepherd et al. (2013) (83)	Case series	IV	Massive cuff tear (irreparable)	PTFE patch (6)	N/A	Re-tear rate (USS), Clinical/functional outcomes	10 years	80% of repairs intact at 10 years. Improved clinical/functional outcomes vs. pre-op.
Ranebo et al. (2018) (84)	Case series	IV	Cuff tear (irreparable)	Polyester graft (13)	N/A	Re-tear rate (USS), Functional outcomes, Complications	20 years	75% developed cuff tear arthropathy at 20 years. Graft no longer intact in 70%.
Nada et al. (2010) (85)	Retrospective case series	IV	Chronic massive tears	Polyester graft (21)	N/A	Appearance on MRI, Clinical/functional outcomes	36 months	Patient satisfaction 90%. Intact tendon in 88%. Improved clinical/ functional outcomes vs. pre-op.
Smolen et al. (2019) (87)	Case series	IV	Massive cuff tear	Polyester patch (50)	N/A	Healing and re-tear rate (MRI/CT), Clinical outcomes	52 months	Re-tear rate 14%. Significantly improved clinical outcomes.
Thon et al. (2019) (90)	Case series	IV	Large/massive cuff tear	Bio-inductive collagen patch (23)	N/A	Healing rate (USS & MRI)	2 years	96% healing rate at 2 years.
Encalata-Diaz et al. (2011) (91)	Case series	IV	Full thickness 2-tendon cuff tears	Polycarbonate polyurethane patch (10)	N/A	Re-tear rate (MRI), Clinical/functional outcomes	1 year	Re-tear rate 10% on MRI. Significantly improved clinical/ functional outcomes vs. pre-op.
Petrie & Ismaiel (2013) (92)	Prospective case series	IV	Full-thickness massive cuff tears (irreparable)	Polyester (LARS) patch (31)	N/A	Clinical/functional outcomes, Acromiohumeral (AH) interval (XR)	3.3 years (mean)	Significantly improved clinical/ functional outcomes and AH interval vs. pre-op.
Burkhard et al. (2020) (93)	Prospective case series	IV	Full thickness posterosuperior cuff tears	Bioabsorbable poly-4-hydroxybutyrate patch (16)	N/A	Re-tear rate (MRI), Clinical/functional outcomes	1 year	100% of repairs intact. Significantly improved clinical/functional outcomes vs. pre-op

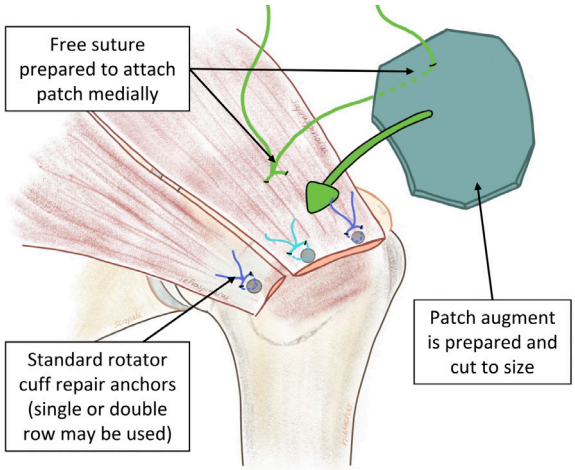
layers that imitate the rotator cuff's ECM and appear to promote early cellular infiltration and desirable mechanical properties.[88,89] They found that patients in the graft population had significantly improved retear rates, superior tendon-bone integration, and better functional outcomes in the short term.[57] However, at the final follow-up, there was no statistically significant improvement in functional outcomes. Accordingly, the researchers concluded that larger, long-term trials were needed to assess the true potential of the scaffolds. Thon et al. have recently tested a bio-inductive collagen patch and reported it to be safe with excellent healing outcomes on MRI and ultrasound scan at 2 years.[90] Similarly, Encalata-Diaz et al. trialled the use of polycarbonate polyurethane patches and reported excellent results.[91]

The polyester Ligament Augmentation & Reconstruction System patch has also gained popularity as a synthetic augmentation graft for massive rotator cuff repairs and shown excellent results when used for the management of otherwise irreparable tears.[92] Burkhard et al. even tested a bioabsorbable poly-4-hydroxybutyrate patch, with 100% of repairs intact at 1-year follow-up.[93]

It is possible that the issue with many of these synthetic patches is that they do not possess the same mechanical properties as native tissue. With a synthetic patch-augmented rotator cuff construct, a significant proportion of the force may be transmitted through the synthetic patch rather than the native rotator cuff tissue, creating more "stress shielding" and less "load sharing". This may negatively influence healing.

The more 'novel' nano-scaffolds have been around for over 10 years but have recently garnered more interest, with several studies establishing their excellent tissue compatibility and biomechanics.[19,21,88,94] These are able to more closely replicate the characteristics of the ECM, and, in theory, this helps promote cell differentiation and subsequent tissue regeneration. In 2020, Kim et al. found that these nano-scaffolds led to superior tendon healing in both acute and chronic rotator cuff tears, though they conceded that the mechanism behind this process is poorly understood.[21] Electrospinning and its variations allow the manufacture of fibers that closely mimic ECM in terms of size and arrangement and can imitate ECM by acting as a vector for growth factors.[33,95] Grafts made by means of this technique have shown positive results in animal trials and in vitro but clinical trials are still lacking.[19,39,88,96]

Another exciting avenue of research has been the biological enhancement of a graft with existing favorable mechanical characteristics, thus allowing the best of both worlds. These have had encouraging but variable results so far, and much more work is needed. Jiang et al. recently developed a multi-layered polylactic-co-glycolic acid scaffold enhanced with mesenchymal stem cells from human adipose, manufactured more precisely with the aid of 3D printing. These were again shown to have excellent tissue compatibility and favorable mechanical properties.[20] On the other hand, Muench et al. attempted to enhance a human dermal allograft with PRP and BMA with poor functional results.[31] Novel techniques like this illustrate exciting new possibilities in this field. However, despite the availability of encouraging pre-clinical research, we are still awaiting well-designed, prospective clinical trials to investigate the potential of these implants in vivo.[97]

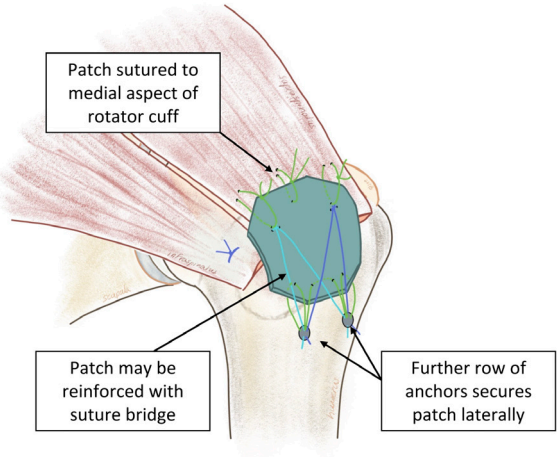


An initial standard cuff repair is performed using either a single or double row of suture anchors (single row shown here). The patch is prepared and passed into the joint using the medial free suture as shown.

Figure 1. Example of technique used for patch augmentation (Step 1).

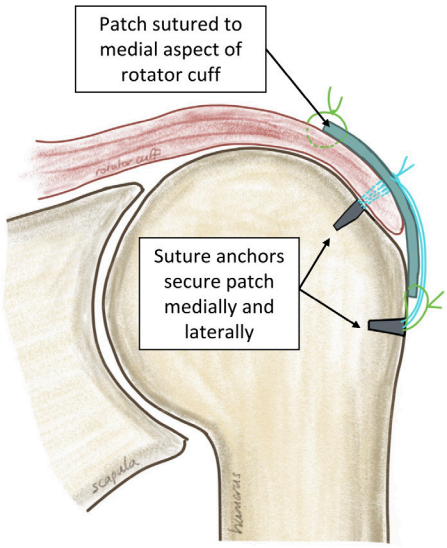
Techniques for Patch Augmentation

Several arthroscopic surgical techniques have been described in detail and these have certainly evolved over the years.[53,98-101] Initially, many surgeons utilized open techniques, but with advancements in arthroscopic technology and skills, arthroscopic techniques for patch augmentation have gained popularity in recent years [Figures 1-3]. Earlier arthroscopic techniques involved essentially "overlaying" the repaired rotator



The patch is laid over the cuff repair and secured with free sutures medially, suture anchors laterally and may be augmented with a suture bridge.

Figure 2. Example of technique used for patch augmentation (Step 2).



A cross section of a rotator cuff repair (single row) with patch augmentation.

Figure 3. Example of technique used for patch augmentation (Step 3).

cuff while incorporating the patch into a transosseous or transosseous-equivalent double-row repair construct.[102] Most of such constructs involve no medial stabilization of the patch, only using lateral stabilization. This may be an important factor as if load sharing with the repaired tendon contributes to improved rotator cuff healing, it would be reasonable to suggest that medial stabilization of the patch to the cuff is crucial.

Therefore, we modified our technique to incorporate the medial stabilization of the patch.[6] Other more modern techniques involve patch insertion using special deployment devices and then fixing the patch medially, anteriorly, and posteriorly with polylactic and polyetheretherketone staples.[103] It is fair to say that there is no consensus on any single method that should be used to perform patch augmentation.

Discussion

Rotator cuff surgery has been the subject of significant advances in the last 20 years and is associated with extremely good clinical outcomes. However, it is reasonable to suggest that radiological outcomes (e.g. tendon healing rates as assessed by soft tissue imaging) do not match the clinical outcomes, particularly with larger tears in the more senior population. It is well documented that many patients with radiological failures (tendon healing failure or re-tears) still do well clinically.[25] However, there is also plenty of evidence that those with well-healed tendons do have superior clinical outcomes.[1]

As a result, over the next 10 years, our aim should be to not only have good clinical outcomes but also improve the tendon healing rate. The key question is whether patch augmentation can achieve improved healing without compromising good clinical outcomes. If we look at the history of rotator cuff repair, anchorless transosseous repairs were initially used and were then followed by single-row repairs secured using anchors. Double-row repairs were then devised and became the popular choice. Could patch augmentation be our next step?

Patch technology and patch augmentation techniques are continuing to advance rapidly. In our opinion, these advances should be based on three pillars:

1) Development of patches that resemble native tissue in all aspects, as much as possible
2) Biological enhancement of patches using various products, including stem cells
3) Improved instrumentation for arthroscopically delivering and stabilizing the patches consistently and reliably, without adding significantly to surgical time

The perfect patch would be one that continues to provide desirable biomechanical reinforcement while also managing to biologically promote healing and cellular infiltration without an adverse tissue reaction. It would also be easy to deliver this patch surgically and stabilize it arthroscopically.

It does seem that patch augmentation has the capacity to significantly improve outcomes for patients with rotator cuff tears, in particular those with large or massive tears. It is clear that with careful patient and graft selection, beneficial effects can be seen in terms of healing, biomechanics, and radiological/clinical outcomes. There is still debate over the superiority of patch augmentation over standard repairs in terms of healing improvement. However, what is certain is that there exists a need for sufficiently powered, randomized, prospective trials directly comparing standard arthroscopic rotator cuff repair with repair using different types of patch augmentation. There is no doubt that patch augmentation is an exciting topic and will be the subject of many scientific discussions in various conferences and research papers in the next decade.

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