SYSTEMATIC REVIEW

Non-acute Rotator Cuff Tear: Repair Augmented with Reconstituted Absorbable Collagen Scaffold (RACS)- Systematic Review

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Abstract

Background: There have been studies indicating that the non acute rotator cuff repair can be augmented with reconstituted absorbable collagen scaffold (RACS) which results in better structural integrity and functional outcome. Hence, this review aims to systematically analyse the available evidence based on its methodological quality, technique and functional outcome.

Methods: Systematic review was carried on PubMed for articles related to non acute rotator cuff repair reconstituted absorbable collagen scaffold . Also, Colemans method of scoring was used to assess the methodological quality of the studies.

Results: Among the studies included, the minimum follow up duration was 12 months. All the studies reported statistically significant improved outcomes following repair with reconstituted absorbable collagen scaffold for partial thickness tears, full thickness tears and in massive tears.

Conclusion: Repair reconstituted absorbable collagen scaffold seems to be a viable option to improve the structural integrity following non acute rotator cuff repair.

Level of evidence: I

Keywords: Biological augmentation, Collagen scaffold outcome analysis, Rotator cuff repair

Introduction

Rotator cuff tear is one of the common degenerative disorder of the shoulder affecting the aging population (1). Although rotator cuff tear is a prevalent disorder there has been no consensus on a set protocol for the treatment of rotator cuff injuries. Partial thickness rotator cuff injuries (involving <50% of tendon thickness) are commonly managed conservatively with activity modification and physical therapy (2). Debridement with or without subacromial decompression is another common treatment modality for partial thickness tears. Most partial thickness tears invariably progress to full thickness tears despite various modalities of management (3). Complete tear of the rotator cuff tendon is managed surgically but is often associated with re-tears which is thought to be due to a number of factors including age, degenerative changes, dimensions of the tear and quality of the tendon tissue (4). There are studies which suggest that recreating the normal tendon footprint and decreasing the stress on the tendon changes the biomechanical environment of the healing tendon. This change in the biomechanical environment can lead to better prognosis following

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rotator cuff tendon repair and also reduce the incidence of re-tears (5).

It is speculated that by the year 2030, 20% of the total population of the United Sates will be of age 65 or older (6). This changing population dynamics increases the need for alternative treatment modalities which address the limitations of the currently prevalent treatment options. In the recent years, several studies that use an absorbable collagen scaffold of high porosity which allows for rapid growth, maturation and alignment of tendon like tissue have surfaced (7-11). We conducted a systematic review of the literature to analyse various studies which used reconstituted absorbable collagen scaffold for the repair of non acute rotator cuff tears. The aim of this systematic review is to estimate the efficiency of repair with reconstituted absorbable collagen scaffold of non acute rotator cuff tear in terms of functional outcome, radiological outcome and incidence of complications.

Materials and Methods

The phrases "rotator cuff bio inductive" "rotator cuff bioabsorbable collagen" and "rotator cuff bioabsorbable patch" were searched on PubMed and Google scholar to identify articles evaluating the use of reconstituted absorbable collagen scaffold for the treatment of non acute rotator cuff tears. No language filter was used for the search. The search for the systematic review was done with accordance to the PRISMA guidelines. A total of 40 were retrieved. After reviewing the summary of the texts, three articles written in English were marked for abstract review. Single case reports, review articles, and letters to editors were excluded. The abstracts of the remaining articles were read, and only those that focused on the functional outcome, radiological outcome and complications of repair with reconstituted absorbable collagen scaffold were included in the review. Two additional studies that used bioabsorbable collagen were included through hand searching cited references. The research was performed partly in IASRM, New Delhi, India and Dallas, USA. The PRISMA algorithm was followed and a total of 5 articles were included in this systematic review [Figure 1].

Quality Assessment

Two investigators independently performed the quality assessment using the Coleman Methodology criteria, which has a maximum score of 100 [Table 1] (12).

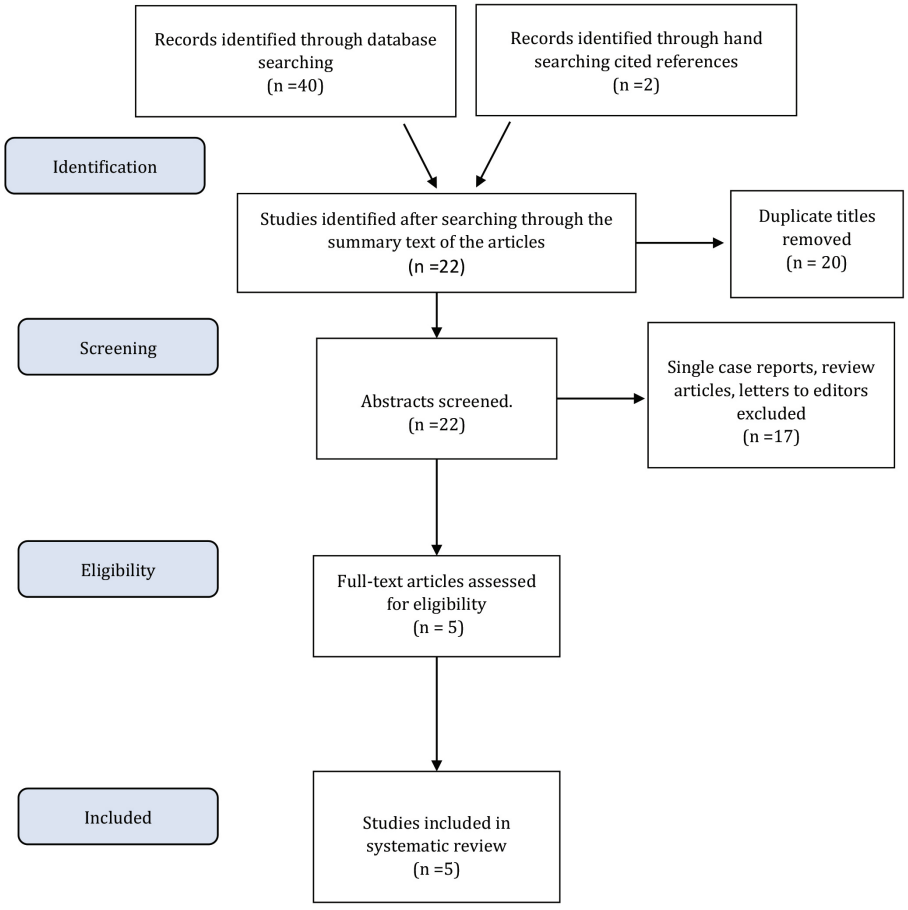

Figure 1. PRISMA Flowchart.

Results

Patient demographics

251 patients from 5 different studies underwent repair of non acute rotator cuff tears with reconstituted absorbable collagen scaffold . All five studies included details of the number of male and female patients. The male to female ratio is 1.3 with 146 men and 105 women enrolled in the studies.

The mean age of the patients varied from 53.8 to 57.9. The mean follow-up period was from 12 months to 24 months.

Study characteristics

In this review we analysed four prospective case studies and one retrospective case series, which were published between 2015 to 2020. Three of the studies originate from USA and two other studies originate from Australia [Table 1] (7-11).

Inclusion Criteria

Three of the five studies included patients who had chronic shoulder pain for more than 3 months despite treatment with activity modification, analgesics, anti-inflammatory and physical therapy (7-9). Thon et al included patients who underwent a minimum of 6 weeks of intensive treatment with various modalities (10). McIntyre et al study included patients who were symptomatic despite treatment with physical therapy and corticosteroid injections (11).

Regarding the type of tear, the studies had included isolated partial thickness tears as well as both partial and full thickness tears (7-9, 11). While the study conducted by Thon et al included patient undergoing both primary and revision surgeries.

Patients with previous rotator cuff surgeries and acute rotator cuff injuries were excluded from the study. This differentiation was not mentioned in the studies conducted by Thon et al and Bokor et al (7-10).

Surgical procedure and Implant characteristics

The patients were treated under general anaesthesia in all the 5 studies (7-11), patients received additional supraclavicular block prior to the general anaesthesia (10). Initial diagnostic arthroscopy followed by foot preparation for the rotator cuff repair.

All the studies used Reconstituted collagen scaffolds which were made from highly-purified, type I collagen from bovine tendons, these collagen scaffolds were highly porous (85-90%) were used and these were attached using PLA staples to the tendon and PEEK staples to the bony surfaces. The implant was available in 2 standard sizes 20*25mm or 25*30mm. The implants were designed to be completely absorbed by 6 months and the staples used were designed to be absorbed in 12 months.

Postoperative care

The post-operative rehabilitation protocol consisted of up to 6 weeks immobilisation in arm sling or in case weaning of arm sling as early as possible. Passive and active assisted exercised were initiated from 6 weeks onwards. However, all the studies uniformly advised against resistances exercises for a minimum for of 6 weeks.

Clinical outcome analysis

Among the studies included, the clinical outcome was analysed using the American shoulder and elbow society

Table 1. Study characteristics and patient demographics

STUDY	TYPE OF STUDY	NO.OF SUBJECTS. (Male/Female)	MEAN AGE	Clinical Scoring Used	Coleman score for methodological quality of the study
Bokor et al, 2015 (7)	Prospective clinical trial	9 (6/3)	56.4 (50-66)	ASES Constant & Murley score	75
Bokor et al, 2016 (8)	Prospective study	13 (8/5)	53.8 (42-67)	ASES Constant & Murley score	78
Schlegel et al, 2018 (9)	Prospective, multicentre open label trial	33 (19/14)	54.6 (34-75)	ASES Constant & Murley score	82
Thon et al, 2019 (10)	Case Series	23 (15/8)	57.9 (32-71)	ASES	82
McIntyre et al, 2019 (11)	Multicentre retrospective case series	173 (98/75)	54.2 (24-74)	ASES, SANE, VR-12, & WORC	53

(ASES), American shoulder and elbow society scale.), single-assessment numeric evaluation (SANE), Veterans RAND 12-Item (VR-12), and Western Ontario Rotator Cuff (WORC)

scale, Constant and Murley score, single-assessment numeric evaluation (SANE), Veterans RAND 12-Item (VR-12), and Western Ontario Rotator Cuff (WORC). These methods were employed both pre operatively and post operatively. The studies pertaining to single tendon repair augmented with bio inductive scaffolds had reported clinically and statistically significant results (*P<0.001*) (7-9, 11). In patients with large and massive tears, satisfactory clinical outcome was observed (10).

Radiological outcome analysis

The studies had used post-operative MRI and Ultrasonography for evaluation of repair healing. The studies which used MRI post operatively indicates that the tendon healing was significant and there was no incidence of tear progression (7-9, 11). Both ultrasound and MRI were used in the study by Thon et al and had demonstrated similar and significant increase in tendon thickness (10). The outcome analysis is tabulated in [Table 2].

Complications

Although at negligible at rates, the reported post-operative complications among the 251 shoulders were superficial skin infection (n=2), capsulitis (n=3), biceps tendinitis (n=1), bursitis (n=1),scapular dyskinesia (n=8), progressive pain and disability leading to total shoulder arthroplasty (n=1), joint stiffness (n=1).

Table 2. Pre and Post-Operative Clinical Scoring with mean duration of follow up

STUDY	ASES		CONSTANT-MURLEY		TENDON THICKNESS		MEAN FOLLOW UP (MONTHS)
	PRE-OP	POST-OP	PRE-OP	POST-OP	PRE- OP	POST-OP	
Bokor et al, 2015 (7)	OVERALL: 44.6 PAIN:4.9	OVERALL: 87.8 PAIN:0.7	OVERALL: 50.7 PAIN:7.1	OVERALL: 78.0 PAIN:1.1	NR	3Mo M- 8.3 ±0.38 F-7.2 ±0.08 6Mo M-7.6 ±0.33 F-7.0 ±0.53 12Mo M-7.3 ±0.31 F-6.9 ±0.37 24Mo M-6.8 ±0.49 F-6.2 ±0.25	25.8 (24.5-30.4)
	Significant improvement with *P < 0.001*						
Bokor et al, 2016 (8)	OVERALL: NR PAIN: NR	OVERALL: NR PAIN: NR	OVERALL: NR PAIN: NR	OVERALL: NR PAIN: NR	NR	NR	27.0 (23.3-32.0)
	Significant improvement with *P<0.001*		Significant improvement in pain score with *P<0.001* and overall *P<0.01*				
Schlegel et al, 2018 (9)	OVERALL: 57.0 ± 3.2 PAIN: 4.2 ± 0.4	OVERALL: 89.1 ± 2.8 PAIN: 0.6 ± 0.2	OVERALL: 57.1 ± 2.8 PAIN: NR	OVERALL: 81.4 ± 2.2 PAIN: NR	3.1 ± 0.3 mm	3Mo- 5.4 ± 0.3 mm	12.4 (10.8-13.5)
	Significantly improved with *P<0.0001*		Significantly improved with *P<0.0001*				
Thon et al, 2019 (10)	OVERALL: NR PAIN: NR	OVERALL: 82.87 6 16.68 PAIN:	OVERALL: NR PAIN:NR	OVERALL: NR PAIN:NR	NR	3 Mo 6.29 (3.5-9) 6 Mo 6.75 12 Mo 7.72 24 Mo 7.28 (6.3-9)	24
McIntyre et al, 2019 (11)	OVERALL: 47 PAIN: NR	OVERALL: 85.6 PAIN:NR	OVERALL:NR PAIN:NR	OVERALL: NR PAIN:NR	NR	NR	12.7 (12-17.2 m)
	Significant with *P < 0.001* in patients with Partial thickness tears.						

Table 3. Reported incidence of Post-operative complications among the studies

S.No	Study	Post-operative Complications
1.	Bokor et al (7)	Capsulitis 0.003% (1/251)
2.	Bokor et al (8)	Biceps tendinitis 0.003% (1/251) , adhesive capsulitis 0.003% (1/251), bursitis 0.003% (1/251)
3.	Schelgel et al (9)	Superficial skin infection 0.007% (2/251)
4.	Thon et al (10)	Scapula dyskinesia 0.03% (8/251), progressive pain and disability 0.003% (1/251)
5.	McIntyre et al (11)	Infection 0.003% (1/251), Joint stiffness due to loose body 0.003% (1/251)

Revision arthroscopy for debridement was needed in two cases (n=2). The complications reported in each study are highlighted in Table 3.

Discussion

Rotator cuff tear is a common ailment affecting the aging population. Despite an increase in the number of literatures published on rotator cuff repair there is a lack of significant improvement post-surgery. Partial thickness tears tend to progress to full thickness tears at an alarming rate of 35% over a period of 5 years (13). Although a number of studies have suggested conversion of partial thickness tears to full thickness tears followed by surgical repair. The re-tear rate of repaired full thickness tendon tears at an average of 23.7 months post-surgery is 26.6% (14). Factors contributing to re-tear includes advanced age, large tears, fatty infiltration etc. A number of studies suggest that recreating the normal tendon footprint could decrease the stress on the tendon aiding in better functional outcome post-surgery.

To address the growing need for an alternate solution Von Kampen et al conducted a study on sheep using highly porous collagen scaffolds derived from purified type 1 collagen of bovine tendons (15). This highly porous low tensile collagen scaffold was thought to cause proliferation and growth of host tissue thereby increasing the tendon thickness at the affected site. This increase in tendon thickness is thought to create a biologically conducive environment with low tendon stress which promotes further healing of the tendon.

The sheep were monitored postoperatively and evaluated at weeks 6, 12, 26 and 52. At 6 weeks there was a new layer of tissue overlaying the defect in the tendon. This tissue was fibrovascular in nature. At 12 weeks there was a layer of tissue overlying the entire tendon and was adherent to the underlying tendon. By 26 weeks this tissue was more mature and was oriented regularly and by 52 weeks it histologically resembled a tendon.

This is in consensus with our review where patients who underwent collagen implant for partial and full thickness tears had a visible area of new tissue growth which happened rapidly post-surgery. This new tissue further matured and was found to be indistinguishable from the underlying tendon.

This phenomenon was observed on second look arthroscopy and by post-operative MR images (8, 9). Satisfactory outcomes were reported for isolated tendon tears as well as multiple tendon repairs (10). In addition to these clinical studies, histological studies have demonstrated the progress of integration of these bio inductive scaffolds into human tissue and becomes almost indistinguishable at the end of 6 months (16).

With regards to revision procedures for rotator cuff repair, the success rate was 60-80%, but with bio inductive scaffolds the success rate for revision rate was nearing 90% (10).

Patient satisfaction post-surgery with a bio inductive collagen implant is significantly greater than that following standard treatment option. This was assessed using the ASES function and pain scale and the Constant-Murley scale.

The limitations include the lack of large sample size and non-randomisation. Furthermore, comparative studies with existing treatment options are the way forward to determine the potential beneficial effects of this treatment strategy. Although, at its nascent stage bio inductive scaffolds can be deemed to be both safe and efficacious in the treatment of non acute rotator cuff tears.

Re-tears following rotator cuff repairs are common. And every effort to mitigate this complication needs to be taken to prevent the disability and morbidity associated with it. With the available existing literature, repair of non-acute rotator cuff tears augmented with reconstituted absorbable collagen scaffold seems to restore its integrity by blending into the native tendon and thereby improving the outcomes both clinically and radiologically.

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References

1. Milgrom C, Schaffler M, Gilbert S, van Holsbeeck M. Rotator-cuff changes in asymptomatic adults. The effect of age, hand dominance and gender. The Journal of bone and joint surgery. British volume. 1995; 77(2):296-8.
2. Matthewson G, Beach CJ, Nelson AA, Woodmass JM, Ono Y, Boorman RS, et al. Partial thickness rotator cuff tears: current concepts. Advances in orthopedics. 2015; 2015.
3. Mall NA, Kim HM, Keener JD, Steger-May K, Teefey SA, Middleton WD, et al. Symptomatic progression of asymptomatic rotator cuff tears: a prospective study of clinical and sonographic variables. The Journal of Bone and Joint Surgery. American volume. 2010; 92(16):2623.
4. Le BT, Wu XL, Lam PH, Murrell GA. Factors predicting rotator cuff retears: an analysis of 1000 consecutive rotator cuff repairs. The American journal of sports medicine. 2014; 42(5):1134-42.
5. Lee TQ. Current biomechanical concepts for rotator cuff repair. Clinics in orthopedic surgery. 2013; 5(2):89-97.
6. Colvin AC, Egorova N, Harrison AK, Moskowitz A, Flatow EL. National trends in rotator cuff repair. The Journal of Bone and Joint Surgery. American volume. 2012; 94(3):227.
7. Bokor DJ, Sonnabend D, Deady L, Cass B, Young A, Van Kampen C, et al. Preliminary investigation of a biological augmentation of rotator cuff repairs using a collagen implant: a 2-year MRI follow-up. Muscles, ligaments and tendons journal. 2015; 5(3):144.
8. Bokor DJ, Sonnabend D, Deady L, Cass B, Young A, Van Kampen C, et al. Evidence of healing of partial-thickness rotator cuff tears following arthroscopic augmentation with a collagen implant: a 2-year MRI follow-up. Muscles, ligaments and tendons journal. 2016; 6(1):16.
9. Schlegel TF, Abrams JS, Bushnell BD, Brock JL, Ho CP. Radiologic and clinical evaluation of a bioabsorbable collagen implant to treat partial-thickness tears: a prospective multicenter study. Journal of shoulder and elbow surgery. 2018; 27(2):242-51.
10. Thon SG, O'Malley L, O'Brien MJ, Savoie III FH. Evaluation of healing rates and safety with a bioinductive collagen patch for large and massive rotator cuff tears: 2-year safety and clinical outcomes. The American Journal of Sports Medicine. 2019; 47(8):1901-8.
11. McIntyre LF, Bishai SK, Brown III PB, Bushnell BD, Trenhaile SW. Patient-reported outcomes after use of a bioabsorbable collagen implant to treat partial and full-thickness rotator cuff tears. Arthroscopy: The Journal of Arthroscopic & Related Surgery. 2019; 35(8):2262-71.
12. Coleman BD, Khan KM, Maffulli N, Cook JL, Wark JD. Studies of surgical outcome after patellar tendinopathy: clinical significance of methodological deficiencies and guidelines for future studies. Scandinavian Journal of Medicine & Science in Sports: Review article. 2000; 10(1):2-11.
13. Kartus J, Kartus C, Rostgård-Christensen L, Sernert N, Read J, Perko M. Long-term clinical and ultrasound evaluation after arthroscopic acromioplasty in patients with partial rotator cuff tears. Arthroscopy: The Journal of Arthroscopic & Related Surgery. 2006; 22(1):44-9.
14. McElvany MD, McGoldrick E, Gee AO, Neradilek MB, Matsen III FA. Rotator cuff repair: published evidence on factors associated with repair integrity and clinical outcome. The American journal of sports medicine. 2015; 43(2):491-500.
15. Van Kampen C, Arnoczky S, Parks P, Hackett E, Ruehlman D, Turner A, et al. Tissue-engineered augmentation of a rotator cuff tendon using a reconstituted collagen scaffold: a histological evaluation in sheep. Muscles, ligaments and tendons journal. 2013; 3(3):229.
16. Arnoczky SP, Bishai SK, Schofield B, Sigman S, Bushnell BD, Hommen JP, et al. Histologic evaluation of biopsy specimens obtained after rotator cuff repair augmented with a highly porous collagen implant. Arthroscopy: The Journal of Arthroscopic & Related Surgery. 2017; 33(2):278-83.