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SHOULDER

Critical period and risk factors for retear following arthroscopic repair of the rotator cuff

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Abstract
Purpose The incidence of retear following rotator cuff repair remains a major concern, and the cause and timing of retear remain unclear. The aim of this study was to prospectively investigate the timing of retears following rotator cuff repair at multiple time intervals. The hypothesis was that the 'critical period' for retears extends beyond the first three post-operative months.
Methods The authors prospectively studied 206 shoulders that underwent arthroscopic double-row (without suture bridge) suture anchor repair for rotator cuff tears. Patients were recalled to three follow-up visits at the following post-operative time intervals: 3, 6, and 12 months or longer. Ultrasonography was performed at each visit, and Constant score was collected during the last visit.
Results A total of 176 shoulders attended all required follow-up visits with mean age 56.0 years. Ultrasonography revealed retears in 16 shoulders (9.1 %) at 3 months, in 6 shoulders (3.4 %) at 6 months, and in 5 others (2.8 %) at the last follow-up, while it confirmed intact rotator cuffs in 149 shoulders (84.7 %) at the last follow-up (median 35.5; range 12–61). The incidence of retears was significantly associated with tear size ($p = 0.001$) and tendon degeneration ($p = 0.003$).
Conclusion The 'critical period' for healing following rotator cuff repair, during which risks of retears are high, extends to the first 6 months. The risk of retear is greatest for massive 3-tendon tears, which may require longer periods of protection. The clinical relevance of this study is the identification of patients at risk of retear and the adjustment of their rehabilitation strategy and time for return to work.
Level of evidence III.

Keywords Shoulder · Rotator cuff tear · Double-row repair · Arthroscopic rotator cuff repair · Retear

Introduction

The integrity of the rotator cuff following surgical repair is influenced by various factors, including patient age, pre-operative tear size, muscle atrophy, fatty infiltration, and rehabilitation methods [2, 20, 33, 37, 41]. The incidence of retear following rotator cuff repair remains a major concern, particularly for chronic massive tears [17], as retorn tendons have considerably inferior outcomes compared to intact tendons [15, 24, 25, 30, 42]. Estimates published over the last decade suggest that retear rates are in the range of 11–57 % [2, 10, 26, 42, 43, 46]. Recent review articles reported that retear rates are significantly lower after double-row than single-row repairs [5, 16, 32, 45], but that the specific suture technique had no influence on repair integrity [3]. Numerous studies also investigated the efficacy of platelet concentrates and found they do not significantly improve clinical outcomes or tendon healing [27, 44].

Despite numerous studies on the incidence and risk factors for retears following rotator cuff repair [2, 10, 26, 42,

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43, 46], the cause and timing of retears remain unclear [19, 22]. It is generally accepted that biological healing of repaired rotator cuff tendons takes 8–12 weeks [21]. Some authors investigated the timing of retear using serial imaging and suggested that retears occur most commonly during the first three post-operative months [1, 21, 23, 28, 31]. Recently, Kim et al. [22] observed partial healing without retear (Sugaya type III) in 39.3 % of shoulders within the first 3 months and confirmed retears in 6.6 % of shoulders during the nine following months. In the authors' experience, the 'critical period' of retear extends beyond the first 3 months, particularly in patients with risk factors [19].

Most studies on the timing of retear have relatively short follow-up periods or limited number of serial images, thus limiting our understanding of the causes and onset of retear. The aim of the present study was to prospectively investigate the timing of tendon retear following arthroscopic double-row rotator cuff repair in more detail, using a sizeable cohort, and at multiple time intervals. The hypothesis was that the 'critical period' for healing and recovery following rotator cuff repair extends to the first six post-operative months, during which the incidence of retear is significantly higher than in the forthcoming months. Accurate knowledge of this 'critical period' would enable clinicians to prescribe appropriate rest and rehabilitation strategies, particularly for patients that would return to manual work.

Materials and methods

The authors enrolled a consecutive series of 257 shoulders in 243 patients (14 bilateral) that underwent arthroscopic double-row suture anchor repair by a surgeon experienced in the procedure and technique (JB), between January 2007 and June 2010, as a treatment for rotator cuff tear. The operative technique was consistent throughout this 3-year period; there was no new equipment or approaches introduced. Each patient enrolled gave written consent for his or her participation in this prospective study. The overall outcomes for this series were recently published in a study [2] that correlated clinical scores with radiographic findings as per the classification of Sugaya [42] (Fig. 1).

The authors sought to form a homogenous cohort for which post-operative outcomes would not be affected by concomitant pathologies or previous surgery that could jeopardize functional or anatomic outcomes. Therefore, the inclusion criteria were: availability of plain X-rays of the affected shoulder, availability of a pre-operative MRI scan or computed tomography (CT) arthrogram, diagnosis of full-thickness rotator cuff tear confirmed intra-operatively. Furthermore, the exclusion criteria were (Fig. 2): partial-thickness tears ($n = 4$), revision operations ($n = 9$), shoulder joint stiffness ($n = 4$), Hamada stage 2 or more (acromiohumeral distance <6 mm) on plain X-rays ($n = 9$), arthritis and rheumatologic disorders ($n = 6$), severe musculoskeletal pathologies ($n = 8$), gleno-humeral joint instability ($n = 4$), or acromioclavicular joint dislocation ($n = 7$). Therefore, a total of 206 shoulders were included for prospective outcome evaluation.

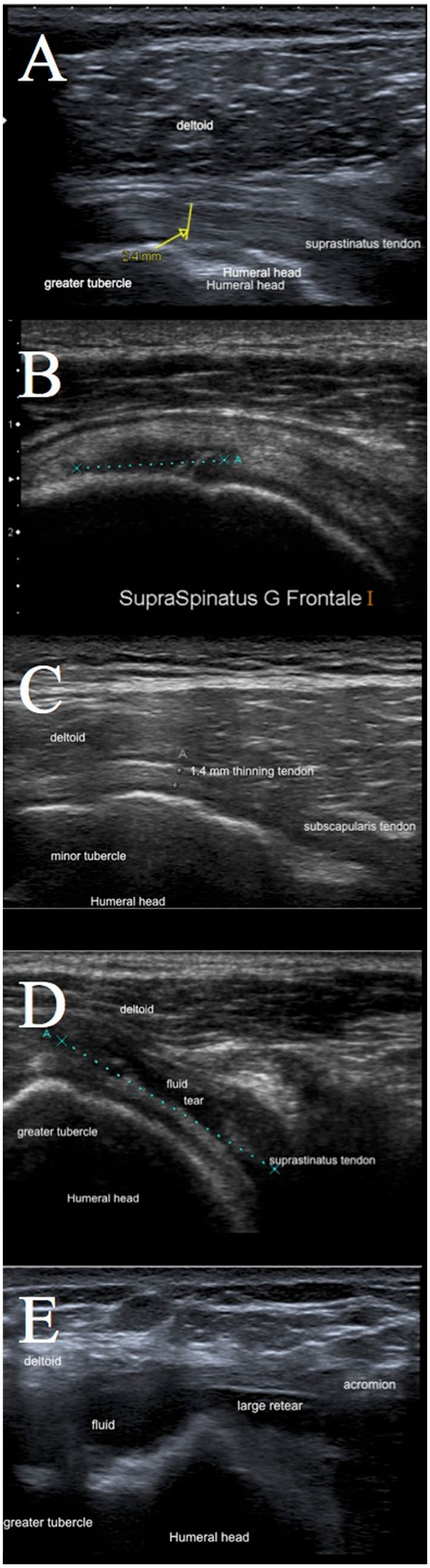
Pre-operative assessment

All patients were examined pre-operatively, and their rotator cuff muscle quality was assessed on CT or MRI images for fatty infiltration using the modified Goutallier classification [11, 14]. The use of two different imaging modalities for pre-operative assessment could introduce bias, but recent articles indicate that equivalent assessment of fatty infiltration could be achieved using either CT or MRI [4, 29, 35]. Fatty infiltration of the infraspinatus muscle, which has been shown to be the most rapidly and extensively affected rotator cuff portion [6], was of stages 0 and 1 in 67 patients (26 %), stage 2 in 156 patients (61 %), stage 3 in 33 patients (13 %), and stage 4 in 1 patient (0.4 %). Tendon tear size and retraction were assessed following the classification of Patte [38], and stages 1 and 2 (distal and intermediate retraction) were regrouped as non-retracted and stage 3 (over the glenoid retraction) as retracted.

Surgical technique

All patients were operated in the beach-chair position under general anaesthesia. An interscalene block was typically performed before surgery with 3 kg side arm traction. Four to six arthroscopic portals (on demand) were used: posterolateral portal and posterior soft point for viewing (scope), and anterior (rotator interval), lateral, posterior, and posterolateral for work. BioCorkscrew FT double-loaded anchors (Arthrex Inc., Naples, FL) were used with four 5.5 mm × 15 mm NeedlePunch needles and two #2 FiberWires to perform double-row repair. A NeedlePunch suture passer (Arthrex Inc., Naples, FL) was used to pass the sutures through the tendon.

If needed, biceps tenodesis ($n = 73$) was performed high in the bicipital groove with a lasso-loop technique using the suture anchor. Subscapularis repair was performed if required ($n = 57$) before repairing the posterior rotator cuff. The scope was then moved to the subacromial space, which was cleared of reactive synovitis, bursal tissue, and adhesions. Subacromial decompression was performed with acromioplasty ($n = 32$) if the acromion had a prominent anterodistal edge and a sharp spur at the lower aspect of the acromioclavicular joint [36]. The torn tendon was denoted 'healthy' ($n = 109$) if its appearance was normal or 'degenerated' ($n = 67$) if thinned, delaminated, or cleaved.



◂**Fig. 1** Integrity of the repaired rotator cuff classified into five types using ultrasonography; **a** type I indicates a repaired rotator cuff with sufficient thickness (>2 mm) with echostructure as normal tendon hyperechoic and fibrillar on each image; **b** type II indicates a repaired rotator cuff that had sufficient thickness (>2 mm) associated with a partial hypo-echogenicity or heterogenicity; **c** type III indicates a repaired rotator cuff that had insufficient thickness (<2 mm) without discontinuity; **d** type IV indicates the presence of a minor full-thickness discontinuity of which border is well visible, suggesting to a small tear; **e** type V indicates the presence of a major discontinuity of which the medial border is not visible under the acromial arch, suggesting a medium or large tear

After visualization, assessment of the type and mobility of the lesion, preparation, and release of the tendon, the superior surface of the greater tuberosity was carefully abraded using a burr, removing soft tissue and some of the cortical bone, to create a bed of bleeding cancellous bone. Side-to-side sutures were used prior to tendon-to-bone sutures in order to convert L-shaped or U-shaped tears to C-shaped tears [9, 40]. The remaining sutures from the biceps tenodesis were passed through the supraspinatus tendon using a NeedlePunch suture passer device (Arthrex Inc., Naples, FL). An additional medial double-loaded anchor was used in case of large tear extending posteriorly just lateral to the cartilage margin. All the sutures from the medial row were passed, but tightened at the end of the procedure. One or two suture anchors were introduced laterally on the greater tuberosity for the lateral row was first tightened to reduce the rotator cuff (without suture bridge) and finally the medial row to increase the footprint coverage. All repairs were 'watertight' except for large subscapularis tears, which required release including rotator interval debridement.

Post-operative rehabilitation

The arm was supported in a sling at 20° of abduction for the first 6 weeks following surgery. Passive motion exercises were initiated on the first post-operative day, and, when possible, hydrotherapy was initiated after skin healing. Active shoulder motion was allowed after 6 weeks, whereas active–passive motion was started earlier according to the pre-operative tear size. Patients were not allowed to perform any strengthening or strenuous work for 6 months after the surgery. Light sports and demanding activities were allowed after 6 months.

Post-operative assessment

All patients were recalled for three post-operative US examinations at 3, 6, and 12 months or longer (last

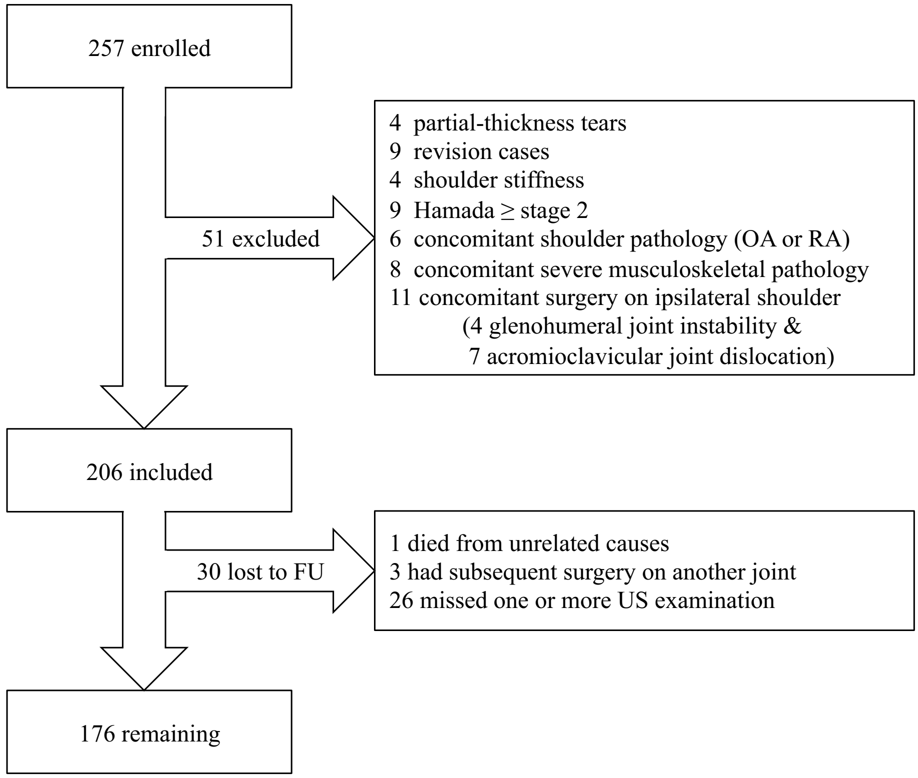


Fig. 2 Flowchart indicating numbers of patients included, excluded, and lost to follow-up

follow-up). Patients were exempt from attending their next scheduled US examination if a retear was diagnosed radiographically (Sugaya [42] type IV or V). Functional assessment using the Constant score was only performed during the last visit at a minimum follow-up of 12 months. Physical examination and collection of the Constant score at the last follow-up visit were done by a different blinded clinician (EF) than the one who performed the surgery. Radiographic evaluation was performed using ultrasound by a blinded radiologist (RB) using a linear transducer set at either 7–11 MHz for heavier morphotypes (deep penetration but lower spatial resolution) or 14–18 MHz for lighter morphotypes (shallow penetration but higher spatial resolution) and a Xario SSA 660A and SSA probe with precision 660 LG (Toshiba Medical Systems, Otawara, Japan). During the ultrasound assessment, the patients were seated with the affected arm maintained free at the side of the trunk. The rotator cuff repair was examined in the three planes (axial, sagittal, and coronal).

A prospective evaluation protocol was established and approved in April 2007 by the institutional review board (IRB) of the Centre Ostéoarticulaire des Cèdres (COAC IRB #2007-03).

Statistical analysis

Statistical analyses were performed using R version 3.2.2 (R Foundation for Statistical Computing, Vienna, Austria). Descriptive statistics were used to summarize the data. Data were not normally distributed. Between-group differences were evaluated using Wilcoxon rank-sum tests (Mann–Whitney *U* test). When three or more groups were compared, Kruskall–Wallis tests were used followed by Wilcoxon rank-sum tests for pairwise comparisons (with Holm's correction for multiplicity). Categorical data were analysed using Pearson's Chi-square tests or Fisher's exact tests. Interval censored survival analyses were performed, and survival estimates were compared using log-rank tests. Survival estimates are presented as percentage 'retear free survival' with their 95 % confidence intervals (95 % CIs). Assumptions for individual tests were checked before the analyses were performed. As the study was explorative, a priori sample size calculation was not performed, since there was no established control group. p values <0.05 were considered statistically significant.

Results

Of the initial 206 patients included, 1 died (0.5 %) before the end of the follow-up period from unrelated causes, 3 patients (1.5 %) had subsequent surgery on another joint (2 total knee replacements and 1 spine fusion) that prevented them from attending the latest follow-up visit, and 26 patients (12.6 %) missed one or more of the scheduled US examinations (Fig. 2). Therefore, a total of 176 shoulders

(85.4 %) from 165 patients (84 men and 81 women) were available for analysis (Table 1).

The final ultrasound examination confirmed intact rotator cuffs (Sugaya [42] type I–III) in 149 shoulders (84.7 %)

Table 1 Patient demographics and intra-operative assessment

	Shoulders ($n = 176$)
Patient demographics	
[a]Age (years)	56.0 ± 9.0 (21–83)
Men:women	84:81
Dominant side	126 (72 %)
Smokers	34 (19 %)
Diabetics	4 (2 %)
Cardiovascular disease	19 (11 %)
Hypertension	32 (18 %)
Onset—traumatic	61 (35 %)
Retracted tendon	42 (24 %)
Tear size confirmed arthroscopically	
Isolated SSP	80 (45 %)
Isolated SSC	8 (5 %)
[b]Anterosuperior (SSP + SSC)[a]	29 (16 %)
[b]Posterosuperior (SSP + ISP)[a]	40 (23 %)
Three tendons	19 (11 %)
Pre-operative evaluation	
[a]Passive elevation	172 ± 12.7 (120–180)
[a]Active elevation	167 ± 26.9 (45–180)
[a]External rotation	53.0 ± 13.2 (20–80)
[a]Strength (/25)	11.0 ± 7.3 (0–25)
[a]Pain (VAS)	8.0 ± 1.8 (1–8)
Post-operative evaluation	
[a]Strength (kg)	13.0 ± 5.5 (4–25)
[a]Pain (VAS)	2.0 ± 2.1 (0–8)
[a]SSV	81.0 ± 20.9 (0–100)

[a] Values given as mean ± SD (range)

[b] Classification of Patte [38]: *SSP* supraspinatus, *ISP* infraspinatus, *SSC* subscapularis, *VAS* visual analogue scale, *SSV* subjective shoulder value

at the last follow-up (mean 36.6 months; median 35.5; range 12–61). A total of 27 retears (15.3 %) were observed, of which three required revision surgery (two reversed shoulder arthroplasty and one suture anchor removal), and the 24 others were asymptomatic or managed with medication if necessary. The Constant score for those 24 retorn rotator cuffs was good (>85 points) in 3 patients, fair (70–85 points) in 14 patients, and poor (<70 points) in 7 patients. Only 3 of the 27 retears were caused by traumatic incidents (two observed at 6 months and one observed at 12 months).

The incidence of retears was significantly related to pre-operative tear size, tendon degeneration (thinning, delamination, or cleavage, observed intra-operatively), fatty infiltration, patient age, tendon retraction, and Constant score at the last follow-up (Tables 2, 3). The incidence of retears was not related to other pre-operative tear characteristics (dominant side, bilateral procedures, or cause of pathology) or to concomitant patient conditions (smoking, diabetes, or hypertension). Retears were observed in 15 % (9 of 61, all within 6 months) of the traumatic tears and in 16 % (18 of 97; 13 within 6 months) of the progressive tears (n.s).

Considering retear as the end-point, the 6-month survival for the complete series was 87.5 % (95 % CI 82.7–92.5 %). By contrast, the 6-month survival was only 57.9 % (95 % CI 39.5–85.0 %) for three-tendon tears, compared to 88.4 % (95 % CI 81.2–96.3 %) for two-tendon tears and 93.2 % (95 % CI 88.1–98.6 %) for one-tendon tears (Fig. 3). In parallel, the 6-month survival was merely 77.6 % (95 % CI 68.2–88.3 %) for degenerated tendons, compared to 93.6 % (95 % CI 89.1–98.3 %) for healthy tendons (Fig. 4).

Discussion

The most important finding of this study was that the 'critical period' for healing and recovery following rotator cuff repair is not limited to the first 3 months, as nearly a quarter

Table 2 Incidence of retear in relation to quantitative variables

	Retorn < 3 m $n = 16$ (9.1 %)		Retorn at 3–6 m $n = 6$ (3.4 %)		Retorn at the last FU[a] $n = 5$ (2.8 %)		Intact at the last FU[a] $n = 149$ (84.7 %)
	Median (range)	*p* value[b]	Median (range)	*p* value[b]	Median (range)	*p* value[b]	Median (range)
Age at index operation	62 (44 to 83)	0.0038	62 (49 to 67)	n.s.	57 (55 to 77)	n.s.	55 (21 to 80)
Constant score pre-op	56 (12 to 73)	n.s.	37 (12 to 58)	0.0556	58 (41 to 71)	n.s.	58 (10 to 92)
Constant score at the last FU	72 (48 to 91)	0.0002	71 (47 to 78)	0.0032	79 (64 to 93)	n.s.	85 (42 to 100)
Constant score improvement	26 (−12 to 54)	n.s.	23 (10 to 58)	n.s.	22 (8 to 34)	n.s.	24 (−12 to 79)

n.s. not significant

[a] The last follow-up (FU) was at a mean of 36.6 months (SD 11.8; median 35.5; range 12–61)

[b] All *p* values compare groups of retorn cuffs versus the group that remained intact at the last follow-up

Table 3 Incidence of retear in relation to qualitative variables

	Retorn before 3 months $n = 16$ n (%)	Retorn at 3–6 months $n = 6$ n (%)	Retorn after 6 months[a] $n = 5$ n (%)	Intact at the last FU[a] $n = 149$ n (%)
Pre-operative tear size $p = 0.001)$[b]				
1-Tendon tear ($n = 88$)				
Isolated SSP ($n = 80$)	4 (5.0)	2 (2.5)	1 (1.3)	73 (91.3)
Isolated SSC ($n = 8$)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
2-Tendon tear[c] ($n = 69$)				
Anterosuperior (SSP + SSC) ($n = 29$)	3 (10.3)	0 (0.0)	2 (6.9)	24 (82.8)
Posterosuperior (SSP + ISP) ($n = 40$)	3 (7.5)	2 (5.0)	2 (5.0)	33 (82.5)
3-Tendon tear ($n = 19$)	6 (31.6)	2 (10.5)	0 (0.0)	11 (57.9)
Tendon retraction ($p = 0.038$)[b]				
Non-retracted ($n = 134$)	9 (6.7)	5 (3.7)	2 (1.5)	118 (88.1)
Retracted ($n = 42$)	7 (16.7)	1 (2.4)	3 (7.1)	31 (73.8)
Fatty infiltration ($p = 0.002$)[b]				
Stage I ($n = 43$)	0 (0.0)	0 (0.0)	0 (0.0)	43 (100.0)
Stage II ($n = 113$)	13 (11.5)	4 (3.5)	5 (4.4)	91 (80.5)
Stage III ($n = 19$)	2 (10.5)	2 (10.5)	0 (0.0)	15 (78.9)
Stage IV ($n = 1$)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)

SSP supraspinatus, *ISP* infraspinatus, *SSC* subscapularis

[a] The last follow-up (FU) was at a mean of 36.6 months (SD 11.8; median 35.5; range 12–61).

[b] Fisher's exact test indicating statistically significant differences in retear rate among the subgroups

[c] Classification of Patte [38]

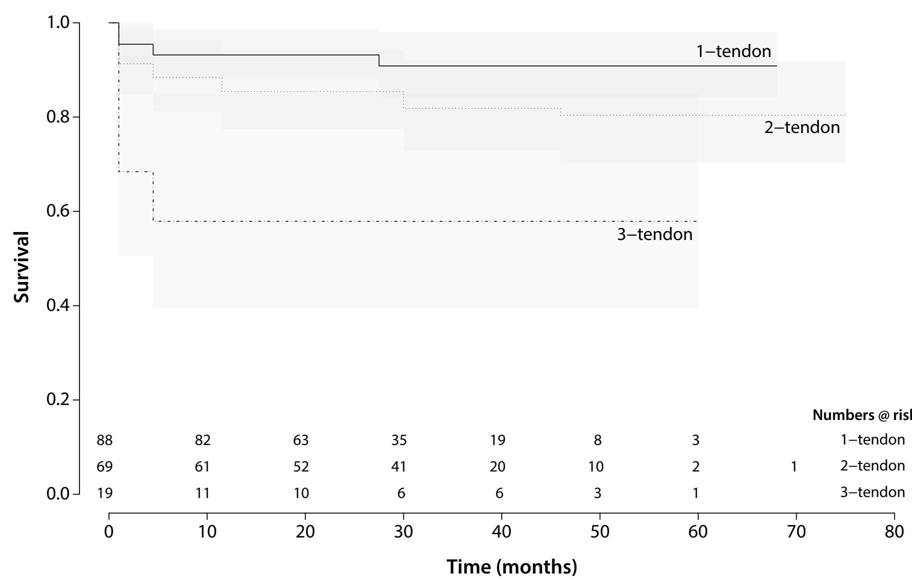


Fig. 3 Survival curves indicating the incidence and timing of retears for different tear sizes

of retears occur in the following 3 months. The findings corroborate the recent literature, which indicates that retears occur mostly during the first three post-operative months (9.1 %) [1, 21–23, 28, 31], but also suggest that the so-called critical period may extend until six post-operative months, particularly for patients with risk factors as large tear size, degenerated tendons, tendon retraction, and fatty infiltration [2, 20, 33, 37, 41]. The incidence of retear following rotator cuff repair remains a major concern, particularly for chronic massive tears [17], as retorn tendons have considerably inferior outcomes compared to intact tendons [15, 24, 25, 30, 42]. The overall incidence of retear was 15.3 % ($n = 27$) at

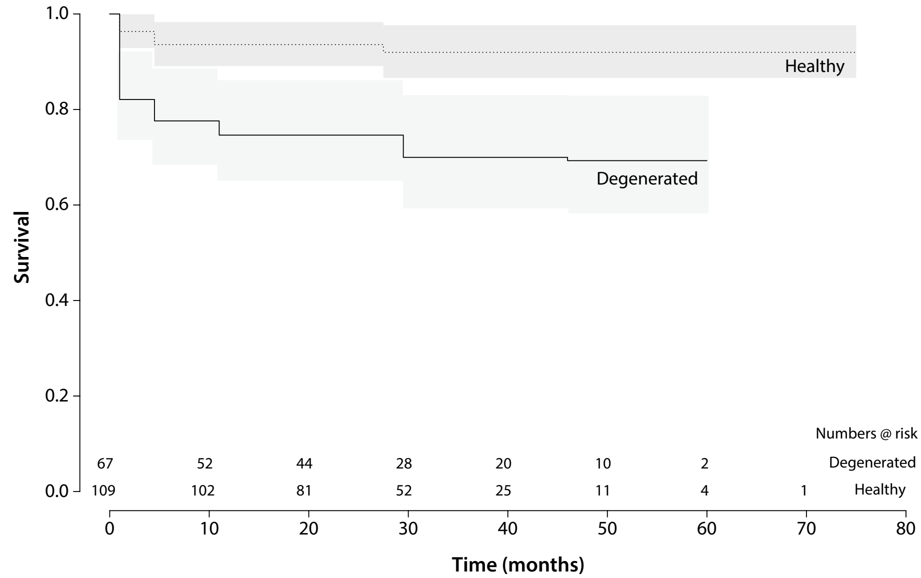


Fig. 4 Survival curves indicating the incidence and timing of retears for rotator cuffs which were intra-operatively assessed as degenerated versus healthy rotator cuffs

a mean follow-up of 32.9 months, which is close to the lowest values in clinical studies published over the past decade [2, 10, 18, 26, 42, 43, 46].

The aim of the present study was to prospectively investigate the timing of tendon retears following arthroscopic double-row rotator cuff repair (without suture bridge) using a sizeable cohort ($n = 176$) and at multiple time intervals (3, 6, and 12 months or longer). Of 27 retears, 16 (59 %) occurred during the first three post-operative months, but 6 (22 %) occurred between three and six post-operative months, and 5 (19 %) occurred after 6 months. Our results suggest that the two factors most associated with early retears are pre-operative tear size and tendon degeneration, in agreement with the recent systematic review of Henry et al. [17] who reported a 'pooled retear rate' of 79 % following repairs of chronic massive rotator cuff tears, and with the prospective study of Collin et al. [7] who reported that 20 % of patients were unable to resume normal activity at 6 months.

Of the rotator cuffs with retears ($n = 27$), a very small number required revision surgery ($n = 3$), and the remaining majority ($n = 24$) was managed conservatively, yielding good functional scores in a few (12.5 %), fair scores in most (58.3 %) and poor scores in some (29.2 %). The post-operative functional scores were significantly lower for retorn rotator cuffs with retears than for those intact, but most retorn rotator cuffs still had considerable improvement in post-operative scores compared to pre-operative scores (median improvement, 21 points, range −2 to 58 points). Recent systematic reviews [5] noted that retears do not necessarily cause inferior functional outcomes [5, 32], possibly because retears are initially asymptomatic and may require more than 1 or 2 years to become detectable by scoring systems [32].

The main strengths of this study are its relatively large sample size (176 patients) and the acquisition of multiple serial images, made possible using ultrasound imaging, which was recently proved adequate for the evaluation rotator cuff integrity [2, 8, 12], thereby avoiding exposure of patients to radiation and/or excessive costs associated with standard modalities as computed tomography (CT) or magnetic resonance imaging (MRI) [13, 34, 39]. The study has several limitations, typical of non-randomized studies, notably (1) the wide variability of follow-up (12–75 months) which could alter clinical and functional observations, (2) the inclusion of patients with various sizes of subscapularis tears which may have impact on the prognosis of repair integrity, (3) the use of two different imaging modalities pre-operatively (CT and MRI) to assess muscle quality and fatty infiltration, (4) the inability to analyse the inter- and intra-observer accuracy because US is a dynamic imaging modality and its interpretation must be done in the presence of the patient [13], and (5) the portion of patients lost to follow-up (14.6 %) which the authors consider successful considering the difficulty of recalling patients for 3 post-operative ultrasound examinations. The clinical relevance of this study is the identification of patients at risk of retear and the adjustment of their rehabilitation strategy and time for return to work.

Conclusions

The present study revealed that incidence of retears following rotator cuff repair was highest during the first 3 months (9.1 %) but that it was non-negligible between three and 6 months (3.4 %). The risk of retear is greatest for massive 3-tendon tears, which may require longer periods of protection and/or high-strength augmentation techniques like load-sharing rip-stop repairs.

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