Sling Versus No Sling After Superior Rotator Cuff Repair: A Propensity Score Matched, Longitudinal, Observational Study at Mid-Term Follow-up

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Background: Patients who underwent arthroscopic rotator cuff repair are often required to wear a sling after surgery despite the known adverse effects of immobilization with the intention to protect the cuff repair. Short-term results have proved to have good clinical outcomes even without a sling.

Purpose: This study aims to compare mid-term clinical and radiological outcomes after arthroscopic rotator cuff repair (RCR) with and without postoperative sling immobilization.

Methods: We retrospectively analyzed a monocentric consecutive cohort of 378 patients scheduled for RCR of small to medium superior cuff tears into sling and no sling groups. A propensity score matching was used to create two groups (n=54) that shared comparable baseline and surgical characteristics. Passive mobilization in elevation and abduction were performed in both groups during the first four weeks after surgery. In the no sling group, active mobilization elbow at the side was allowed. Patients were evaluated both clinically and radiologically with ultrasound at last follow-up.

Results: At six months follow-up, the two groups' return to work and satisfaction were similar. With a minimum follow-up of two years (mean 3.5±1.7 years), both groups exhibited comparable ROM, reported similar PROMs. Most of the patients in each group improved beyond the MCID in ASES score (85% *vs.* 85%, p=1.000). The healing rate was also similar in both groups (p=0.965), with only 4% of the patients who not healed (Sugaya 4 and 5) in each group.

Conclusion: Outcomes between the sling and no-sling groups were similar at six months and three years. Therefore, mobilization early without sling after superior RCRs seems to be a safe and validated rehabilitation regimen.

Level of Evidence: Level 3 (retrospective comparative prognostic trial)

Keywords: Shoulder; Revision; Retear; Outcomes: Complications; Healing; Immobilization.

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Introduction

Considerable variation exists in the patterns and length of postoperative immobilization after rotator cuff repair (RCR) advocated by surgeons with apparent influence from both geographic location and years of clinical experience [1]. Patients are often advised to wear a sling or brace in the first four to six weeks following this type of procedure [2][3][4][5]. Such recommendations remains a matter of surgeon preference rather than being guided by a scientific rationale.

Possible negative effects of immobilization include muscle atrophy, joint adhesions, tendon degradation, [5][6] impaired gait and falls, [7] functional limitations, patient frustration, [6][8] and delayed recovery and return to work [9]. At the other end of the spectrum, early motion gain may compromise tendon healing [10], mainly if aggressive early active and intensive rehabilitation is promoted [11]. To our knowledge, there are no published studies on the mid-term benefits and drawbacks of sling wear *vs.* not wearing.

The aim of this study was to compare mid-term clinical and radiological outcomes after arthroscopic RCR with and without postoperative sling immobilization. The hypothesis was that different regimens of postoperative immobilization would lead to similar clinical and radiological outcomes.

Methods

Study Design and Patient Selection

All patients with RCR repair performed by one author (A.L.) between January 2015 and December 2020 were considered potentially eligible for inclusion in this retrospective comparative study. Data were extracted from a prospective rotator cuff repair database (Follow Health, Rennes, France), the use of which had been approved (Association des médecins du canton de Genève et société médicale #12-26). All patients have been included in various research protocols approved by the local ethical committee (CCER 2015-15 trial registration number NCT02725346, CCER 2016-00818 trial registration number NCT02943005, CCER 2019-02076 trial registration number NCT04321005) [12]. All patients provided written informed consent for their participation and the use of their data and images for research and publishing purposes. The inclusion criteria involved: 1) all patients presenting isolated full-thickness superior tear of small or medium size (<3 cm according Cofield [13]) on magnetic resonance imaging (MRI) +/- arthrography, 2) classified as B1 lesions (avulsion of tendinous attachments) [14], 3) with the potential for complete and "watertight" arthroscopic repair with adequate restoration of the tendons to their footprints [15], and 4) and a minimum of two years follow-up. Only repairable tears of Goutallier grades 0 to 2 were included [16], using a modified 2-grade scale of the Goutallier classification according to Sheean et al.' study [17]. The 2-grade scale is outlined as grade 1 (Goutallier 0, 1 and 2), grade 2 (Goutallier 3 and 4), the standard 5-grade scale having a poor to moderate agreement [18]. These patients were divided into two groups: sling and no-sling groups. Patients were excluded who presented a history of (1) previous shoulder surgery [19][20], (2) anterior or posterior rotator cuff lesions, (3) chronic dislocation, (4) preoperative infection, (5) rotator cuff arthropathy with glenohumeral osteoarthritis and superior migration of the humeral head, (6) psychiatric problems that precluded informed consent or inability to read or write, (7) fatty infiltration of grade 3 or 4 [16], (8) musculotendinous junction lesions [21], (9) partial repairs [17], (10) follow-up time of less than two years, and (11) incomplete documentation.

Study Variables

The primary outcome was the American Shoulder and Elbow Surgeons (ASES) score at last follow-up [22]. Secondary outcomes included rotator cuff tendon healing determined by ultrasound [23] at last follow-up [24][25] as well as Constant score, subjective shoulder value (SSV), and VAS pain at six months and last follow-up. In addition, the following baseline characteristics were assessed: age, sex, shoulder side, limb dominance, multiple comorbidities such as diabetes mellitus, hypertension, hypercholesterolemia, tobacco use, delay between symptom onset and surgical treatment, workers' compensation status, shoulder range of motion (ROM), and the etiology, type, and retraction of RCRs according to Patte [26].

Equity, Diversity and Inclusion Statement

The studied population included women and men from various countries in Southern Africa, North America, Oceania, and Europe, reflecting the usual distribution for this pathology. Additionally, the cohort represented a wide range of ages, backgrounds, and demographics.

Our research team comprised two women and five men at different stages of their careers and clinical disciplines. One author is North American, another is from the Asia, and the remaining authors are from Central Europe. We did not collect or present data on race, socioeconomic status, or other social determinants.

Surgical Technique

A consistent operative technique was used during the study period. Tenodesis or tenotomy of the long head of the biceps was systematically performed. Adjuvant acromioplasty was performed in patients who had radiographic signs of dynamic impingement or to improve visualization [27][28][29], and resection of the distal section of the clavicle was performed when pain was elicited by palpation of the acromioclavicular joint. Demographic and intraoperative data are found in **Table 1**.

Postoperative Rehabilitation

During their hospitalization, all patients received postsurgical recommendations tailored to the type of recommended postoperative immobilization [1]. In the sling group, the arm was

immobilized at the body with a sling for four weeks. During their hospital stay, all patients received identical surgeon recommendations to perform self-mobilization of the shoulder five times a day. Passive mobilization in elevation and elbow at the side was performed by both groups during the first four postoperative weeks, followed by progressive active mobilization. Patients in the no-sling group were prohibited from performing active abduction-elevation (only passive-assisted abduction-elevation was permitted). They were however allowed to perform active mobilization elbow at the side and use their arm in their daily activities, such as driving, typing, exercise and light sports such as nordic walking, oar, paddle, brace. Stroke and training with rowing machine or elliptical trainer [30] were authorized for all repairs after six weeks and two months, respectively. A gentle strengthening program was allowed after three postoperative months.

Table 1. Patient characteristics by postoperative immobilization type (sling vs no sling) before and after propensity score matching (PSM)

	Before PSM			After PSM		
	No Sling (n=144)	Sling (n=234)	p-value	No Sling (n=54)	Sling (n=54)	p-value
Patient demographics						
Age, mean (SD)	52 (10)	56 (9)	<0.001	55 (10)	55 (9)	0.952
BMI, mean (SD)	26 (4)	26 (9)	0.709	27 (5)	29 (15)	0.231
Weight (kg), mean (SD)	77 (16)	78 (15)	0.737	79 (18)	82 (15)	0.185
Height (cm), mean (SD)	172 (9)	172 (12)	0.671	173 (9)	172 (18)	0.308
Symptoms onset* (months), mean (SD)	16 (20)	16 (25)	0.131	15 (20)	15 (20)	0.382
Male sex, n (%)	82 (57)	137 (59)	0.759	32 (59)	36 (67)	0.549
Hypertension, n (%)	22 (15)	26 (11)	0.602	8 (15)	8 (15)	1.000
Hypercholesterolemia, n (%)	11 (8)	25 (11)	0.153	2 (4)	5 (9)	0.437
Diabetes, n (%)	4 (3)	8 (3)	0.568	2 (4)	5 (9)	0.437
Smokers, n (%)	34 (24)	47 (20)	0.900	17 (31)	17 (31)	1.000
Worker compensation, n (%)	48 (33)	51 (22)	0.013	19 (35)	17 (31)	0.683
Lesion(s) characteristics						
Dominant arm, n (%)	100 (69)	158 (68)	0.697	40 (74)	38 (70)	0.667
Traumatic origin, n (%)	67 (47)	112 (48)	0.435	24 (44)	28 (52)	0.441
Tendon retraction grade, n (%)			<0.001			0.683
1	123 (85)	114 (49)		37 (69)	35 (65)	
2	21 (15)	120 (51)		17 (31)	19 (35)	
Lesion type, n (%)			<0.001			1.000
Supraspinatus and infraspinatus tear	32 (22)	128 (55)		24 (44)	25 (46)	
Isolated supraspinatus tear	112 (78)	106 (45)		30 (56)	29 (54)	
Baseline ROM and PROMs						
Foward Flexion (°), mean (SD)	143 (36)	140 (42)	0.901	150 (29)	141 (43)	0.401
External Rotation (°), mean (SD)	44 (20)	41 (20)	0.274	42 (19)	46 (20)	0.165
Internal Rotation score, mean (SD)	8 (4)	8 (4)	0.693	8 (4)	8.0 (4.1)	0.760
Pain on VAS, mean (SD)	58 (19)	56 (18)	0.269	56 (17)	54 (20)	0.626
ASES score, mean (SD)	47 (18)	52 (18)	0.028	53 (18)	52 (19)	0.825
Constant score, mean (SD)	47 (20)	54 (18)	<0.001	51 (19)	53 (19)	0.690
SSV, mean (SD)	44 (22)	48 (22)	0.037	44 (19)	46 (23)	0.597
Surgical characteristics						
Clavicle resection, n (%)	25 (17)	40 (17)	0.947	10 (19)	9 (17)	0.857
Acromioplasty	130 (90)	205 (88)	0.427	54 (100)	54 (100)	1.000
LHB procedure, n (%)			<0.001			0.369
None	18 (13)	10 (4)				
Tenodesis	88 (61)	125 (53)		35 (65)	35 (65)	
Tenotomy	38 (26)	99 (42)		19 (35)	19 (35)	
Suture technique, n (%)			0.508			0.697
Single row	59 (41)	85 (36)		22 (41)	24 (44)	
Double row	85 (59)	130 (56)		32 (59)	30 (56)	
Last follow-up (years)	3.0 (1.6)	4.2 (1.7)	<0.001	3.5 (1.7)	3.5 (1.7)	0.898

PSM, Propensity Score Matching; BMI, Body Mass Index; SD, Standard Deviation; VAS, Visual Analog Scale; ASES, American Shoulder and Elbow Surgeon; SSV, subjective shoulder value; LHB, Long Head of the Biceps; *Time between symptoms onset and surgery. Underlined values indicate statistically significant p-values

Clinical and Radiological Examination

Patient outcomes were recorded preoperatively and at last follow-up with the pain on a visual analog scale (VAS), the ASES(22) and Constant [31] scores, the SSV [32], and ROM. Patients completed the ASES, pain, and SSV scores, along with the subjective components of the

Constant score, using tablets equipped with the Follow Health software (FollowHealth, https://www.follow.fr, 35000 Rennes, France) while waiting in the reception area. ROM and strength measurements were conducted by independent evaluators who were not part of the current study under the supervision of the senior author (A.L.), ensuring the reproducibility of the results. Active anterior elevation and external rotation in 0° of abduction were assessed with a goniometer in the upright position. The internal rotation behind the back was estimated to the nearest spinal level. At last follow-up, tendon repair integrity according to the Sugaya classification was assessed by means of ultrasound by the senior author (A.L.) according to a validated protocol [24][25][33].

Statistical Analysis

A priori sample size calculation to ensure fulfillment of the principal goal of the study indicated that 90 patients (45 in each group) were at minimum needed to detect a minimal clinically important difference in ASES scores of 11.1 points [34] with a standard deviation (SD) of 16 points [35] and a statistical power of 0.90.

Descriptive statistics were used to summarize the data. Continuous variables were reported as mean ± standard deviation and categorical data were reported as proportions. The normality of continuous variable distributions was assessed was determined using a histogram, QQ plot and Shapiro-Wilk test. Comparisons in terms of categorical data were conducted using the Chi-squared or Fisher exact tests. Given the Sling and No-Sling groups significantly differed at baseline in terms of different patient demographics, lesions characteristics, baseline PROMs and ROM as well as surgical characteristics, we used a propensity score matching (PSM) to create two comparable cohorts of 54 patients. We used a nearest neighbor propensity score matching technique (caliper 0.1) and the R package "MatchIt". The variables used for matching were patient age, sex, worker compensation status, hypertension, tendon retraction grade, lesion type, acromioplasty, suture technique and last follow-up. The analyses were performed using R (version 3.6.2, R Foundation for Statistical Computing, Vienna, Austria) and following the intention-to-treat analysis method. P values of <0.05 were considered significant.

Results

A total of 837 shoulders satisfied the inclusion criteria in the time frame selected, of which 378 presented a full-thickness superior rotator cuff tear. Of these patients, 144 (38%) were in the no-sling group and 234 (62%) were in the sling group). Before PSM, the no-sling group (n=144) were significantly younger than the sling group (52±10 *vs.* 56±9, p<0.001) and more often insured by workers' compensation (33% *vs.* 22%, p=0.013). The no-sling group also had a lower grade of tendon retraction (Grade 1: 85% *vs.* 49%, p<0.001), more often isolated supraspinatus tendon tears (78% *vs.* 45%) as well as lower preoperative Constant (47±20 *vs.* 54±18, p<0.001) and SSV (44±22 *vs.* 48±22, p=0.037) scores. The no-sling group also lower rate of tenotomy procedures (26% *vs.* 42%, p<0.001) and were evaluated postoperatively at a lower follow-up (3.0±1.6 *vs.* 4.2±1.7 years, p<0.001). Propensity score matching yielded sling and no-sling groups with 54 patients each (**Figure 1**).

After PSM, both groups shared comparable characteristics regarding patient demographics, lesion characteristics, baseline ROM and PROMs as well as surgical characteristics (**Table 1**). Both groups were also evaluated at a similar follow-up postoperatively (3.5±1.7 years).

At six months follow-up, the two groups satisfaction (78% *vs.* 74%, p=0.653) and return to work rate were comparable (**Table 2**). Also, no statistically significant difference could be observed regarding ROM or PROMs (**Table 3**). At last follow-up, both groups exhibited comparable ROM in FF (161°±25° *vs.* 163°±26°, p=0.403), ER (66°±28° *vs.* 65°±23°, p=0.863) and IR (8.4±3.5 *vs.* 8.8±4.1, p=0.480). Likewise, both groups reported a similar ASES score (85±18 *vs.* 88±16, p=0.225), pain on VAS (16±20 *vs.* 14±17, p=0.509) Constant score (76±17 *vs.* 81±18, p=0.082) and SSV score (86±20 *vs.* 87±18, p=0.628). It is worth noting that the proportion who improved above the minimal clinically important difference in ASES score was similar in each group (85%, p=1.000). The healing rate was similar in both groups (p=0.965), with only 4% of the patients in each group who did not heal (Sugaya 4 and 5).

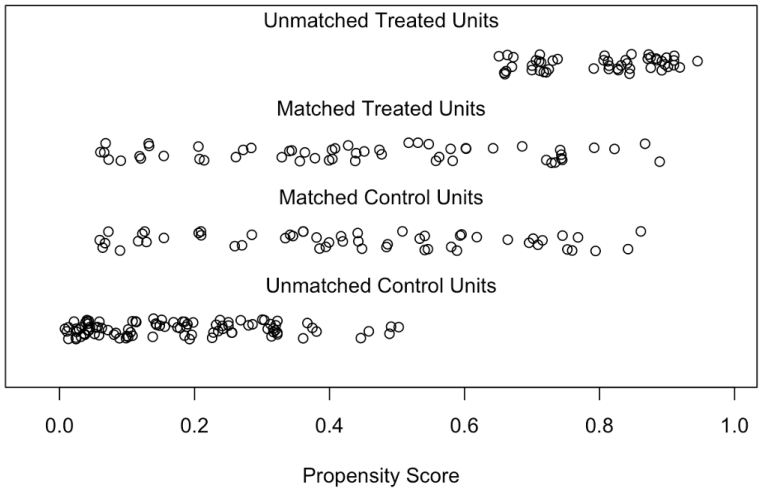


Figure 1. Distribution of propensity scores between the no-sling (treated units) and sling (control units) groups.

Table 2. Postoperative tendon healing at last follow-up, satisfaction and work return at six months

	No Sling (n=54)	Sling (n=54)	p-value
Tendon healing, n(%)			0.965
Type 1	42 (78)	41 (76)	
Type 2	8 (15)	7 (13)	
Type 3	2 (4)	4 (7)	
Type 4	1 (2)	1 (2)	
Type 5	1 (2)	1 (2)	
Satisfaction, n(%)	42 (78)	40 (74)	0.653
Work return, n(%)			0.953
No	6 (11)	5 (9)	
Yes	41 (76)	43 (80)	
Planified	2 (4)	1 (2)	
Retired	5 (9)	5 (9)	

Table 3. Postoperative ROM and PROMs between the Sling and No-Sling groups

	No Sling (n=54)	Sling (n=54)	p-value
ROM, mean (SD)			
Foward Flexion (°)			
6 months	153 (21)	148 (22)	0.104
Last follow-up	161 (25)	163 (26)	0.403
Improvement*	12 (36)	22 (51)	0.153
External rotation (ER, °)			
6 months	39 (17)	40 (18)	0.846
Last follow-up	66 (28)	65 (23)	0.863
Improvement	24 (33)	18 (29)	0.411
Internal rotation (IR, score)			
6 months	8.3 (4.0)	7.7 (4.1)	0.484
Last follow-up	8.4 (3.5)	8.8 (4.1)	0.480
Improvement	0.2 (5.2)	0.8 (5.4)	0.666
PROMs, mean (SD)			
ASES score			
6 months	75 (15)	76 (15)	0.671
Last follow-up	85 (18)	88 (16)	0.225
Improvement	32 (24)	35 (23)	0.405
Pain on VAS			
6 months	22 (19)	18 (15)	0.474
Last follow-up	16 (20)	14 (17)	0.509
Improvement	-40 (24)	-41 (24)	0.724
Constant score			
6 months	73 (14)	74 (15)	0.572
Last follow-up	76 (17)	81 (18)	0.082
Improvement	25 (24)	28 (24)	0.464
SSV			
6 months	78 (14)	77 (16)	0.980
Last follow-up	86 (20)	87 (18)	0.628
Improvement	42 (27)	42 (27)	0.712

SD, Standard Deviation; VAS, Visual Analog Scale; ASES, American Shoulder and Elbow Surgeon; SSV, subjective shoulder value; *Improvement from preoperative status

Discussion

The objective of the present study was to describe the outcomes of patients in the aftermath of arthroscopic repairs for two different postoperative immobilization protocols. The results provided no evidence to support clinical and radiological differences between sling and no-sling groups in ROM, PROMs, and healing rate at a mean follow-up of 3.5 years. Therefore, the posited hypothesis was confirmed.

In a previous high-level study, Lädermann et al. showed in 2019 that, compared with sling immobilization, no immobilization after small to large superior rotator cuff repair was associated with a similar rate on tendon healing at six months. Meanwhile, it does not seem that their results have been yet adopted by the orthopedic community, despite the fact that many studies confirmed that postoperative patient-reported sling or brace adherence is unreliable [36][37]. The present study seems however to confirm the previously mentioned findings.

From a biological standpoint, six postoperative weeks corresponds to the inflammation and proliferation phases of the healing process, at the end of which tendon-to-bone attachment is considered sufficiently robust to withstand applied forces and the gradual increase in load while the tendon continues to remodel [38]. Collin et al. found that lower active range of motion at six weeks postoperative is associated with better healing following ARCR of isolated supraspinatus tears [11]. So, even if strict immobilization in a brace is probably not mandatory for superior repairs, an aggressive early range of motion recovery seems contra-indicated.

A controversy exists in experimental studies regarding the effect of immobilization on restoration of a physiologic structure of enthesis consisting of four zones [38]. On one side, Galatz et al. observed that injection of Botulinum toxin to paralyze the muscle after supraspinatus repair was detrimental to tendon healing, especially when combined with immobilization [39]. Klintberg et al. [40] also found that exercises and motion are essential for adequate healing of tendons and that they should be started soon after surgery, during the proliferative phase of healing. Similarly, Mazuquin et al. [5] reported that mechanical stimuli applied to the collagen fibers at the beginning of their structural arrangement improve the tendons' viscoelastic properties and thereby limit subsequent joint adhesion or stiffness. Künzler et al. furthermore demonstrated that, in normal conditions, the enthesis corresponds postoperatively to simple fibrosis without Sharpey fibers restoration [41]. On the other side, several experimental studies on rats tend to demonstrate the opposite. Gimbel et al. [42] reported that immobilizing rat shoulders improved tendon-to-bone healing and thereby enhanced collagen fiber resistance and organization. Similarly, Peltz et al. [10] found that early motion after surgery had detrimental effects on shoulder biomechanics and tissue healing in rats. The present study seems to demonstrate clinically that no sling for small to large superior rotator cuff tears repaired without tension followed by a very gentle and progressive self-mobilization program might be a reasonable compromise.

Strengths and limitations

The strength of this study is a large, homogeneous cohort with both pre-and postoperative radiological and clinical evaluations. Only shoulders with a low level of fatty infiltration were included to avoid the dilemma of irreparable injuries. One surgeon performed each surgery with similar types of repairs in each group. This study has limitations typical of retrospective designs although all data were collected prospectively in various research protocols. Implementation of associated procedures was not standardized between the two groups; however, the frequency of acromioplasty, tenotomy of the long head of the biceps, and clavicular resection were similar in both groups. The follow-ups of the two groups were different and rotator cuff's retraction was more important in the sling group, factors that could have worsen the results of the non-sling group. This also simply indicates that no-sling is not recommended in the hands of the surgeon in repairs under tension. Lastly, ultrasounds

had been performed by the author. Nevertheless, the same standardized protocol [23] was used and should consequently not influence the results.

Conclusion

Outcomes between the sling and no-sling groups were similar at six months and three years. Therefore, mobilization early without sling after superior rotator cuff repairs seems to be a safe and validated rehabilitation regimen.

Acknowledgements

Not applicable

Conflicts of Interest

Alexandre Lädermann is a paid consultant for Arthrex, Stryker, Medacta, and Enovis. He received royalties from Stryker and Medacta. He is the (co-)founder of FORE, Med4Cast, and BeeMed. He owns stock options in Medacta and Follow Health. He is on the board of the French Arthroscopic Society.

Patrick J. Denard receives royalties from and is a consultant and paid speaker for Arthrex. He is the co-founder of Med4Cast.

Philippe Collin receives royalties from and is a consultant and paid speaker for Stryker and Enovis. He is the co-founder of Med4Cast and Follow. He is on the board of SECEC and IBSES.

The other authors do not have conflict of interest.

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