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Review Article

Surgical Options for Massive Irreparable Rotator Cuff Tears Management: Systematic Literature Review and Comparison to the Subacromial Spacer

Naggar Leslie*

Private Practice, Lausanne, Switzerland

***Corresponding Author:** Naggar Leslie, Private Practice, Lausanne, Switzerland.

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Abstract

Purpose: Massive and irreparable rotator cuff tears are a very challenging problem for shoulder surgeons. When conservative measures have failed, surgical treatment is considered but there is no gold standard for all the available operative options. The aims of this study are: 1) present a systematic meta-analysis of the surgical treatments outcomes for massive irreparable rotator cuff tear patients without arthropathy; 2) report the results of a prospective series of patients treated with subacromial spacer (balloon or spacer) implantation; and 3) compare the spacer results to the other surgical modalities.

Methods: Articles in peer-reviewed journals, from 1995 to 2016, according to the PRISMA guidelines, were searched for the different techniques: debridement, biceps tenotomy/tenodesis, tuberoplasty, partial repair, tendon transfers, reverse arthroplasty, and other treatments involving grafts.

155 patients were operated with the spacer, in a single-surgeon, prospective and on-going series. The first 54 patients with a minimum 2-year follow-up (over a year after spacer degradation) are reported. Constant and UCLA scores were obtained for the spacer group and compared to the results of the other surgical alternatives in the literature review. Eight patients were lost to follow-up, seven were excluded for medical reasons, and two refused to participate, leaving 36 patients (37 shoulders) available for evaluation.

Results: In the spacer series, the Constant score (preop/postop 39.1 ± 12.5/79.8 ± 7.5) and UCLA score (preop/postop 13.5 ± 4.7/33.1 ± 1.5) have improved significantly, and the enhancement is maintained after spacer degradation. A significant improvement in anterior elevation is observed for the spacer cohort (preop/postop 98.0/175.8), and preoperative pseudoparalysis (< 90° elevation) present in 49% of the cases is reversed in all patients. Compared to the other surgical treatments, the spacer demonstrated superior results.

Conclusions: A risk-benefit evaluation considering cost, operative time, and complications, adjusted to the outcome scores, demonstrates that the spacer group results do better than the different operative options for massive and irreparable rotator cuff tears, and spacer implantation may be considered as a first line of treatment for this indication.

Level of evidence IV.

Keywords: *Rotator Cuff; Rotator Cuff Tear; Massive Rotator Cuff Tear; Irreparable Rotator Cuff Tear; Massive And Irreparable Rotator Cuff Tear; Surgical Treatment; Subacromial Spacer; Balloon*

Introduction

Massive rotator cuff tears (MRCTs) represent 10 - 40% of all tears [7,18,29,42,71,99,128,129,175, 183,229,302,304] and 80% of re-tears [184,197], are usually chronic in the elderly [29,80,152,232,258,304,340], but can also occur acutely, especially in young individuals [21,25,80,101,115,134,230,258,280,309,335]. Symptomatic MRCTs are associated with pain, a significant functional deficit and low

quality of life [18,111,132,170,258]. Pseudoparalysis (PP), often observed in MRCTs, is the inability to actively elevate the arm above 90° [60,75,76,184,240,333,336], while others consider that PP means no active elevation (AE) [26,27,29,308]. MRCTs are usually defined as tears with a size ≥ 5 cm [59] or involving at least two tendons [111].

Good outcome is obtained with complete repair of large and massive tears [16,19,20,23,40-42,45,74,76,103,111,144,152,162,171,186, 205,206,221,234,249,253,274,276,340,349]. However, the results deteriorate with time [103,111,263], and the retear rate is particularly high (20 - 94%) [16,19,45,103,106,111,146,232,253,306,348].

Not all massive tears are irreparable, and irreparable tears are not always massive [73,100,179]. For some, no tear is irreparable [184], while others believe factors indicate that a MRCT is beyond repair: anterosuperior escape, painless PP during anterior elevation, dropping and hornblower signs, acromiohumeral distance < 7 mm, complete tendon retraction, stage >3 fatty infiltration (FI) [7,18,73,98,115, 126,179,184,235,305,344]. MRCTs are also deemed irreparable if structural failure will certainly occur, even if it is possible to repair [115].

The rate of irreparable MRCTs (MIRCTs) ranges between 5-30% of all tears [63,202,256,327] and different classifications have been submitted [29,48,60,67,155,184]. Conservative treatment is advised initially [2,3,57,61,80,170,192,310,341,343,348], but when it fails, and the patient is symptomatic, operative treatment is considered [29,47,87,128,163,207,292].

Surgical management can be divided in palliative treatments: debridement with/out subacromial decompression (SAD) [22,34,36,92, 94,97,104,149,155,178,182,206,217,222,265,273,310,315,350], biceps tenotomy (BTT) or tenodesis (BTD) [26,182,196,204,321], and tuberoplasty or reversed subacromial decompression (RSD) [96,161,189,252,280,317]; and reconstructive measures: partial repair (PR) [11,14,22,39,66,84,97,101,125,155,160,162,180,181,217,221,241,248,251,263,291,310,332,345], tendon transfers (TTs) [12,110,112, 130,135,164,208,230,243,277,283,303,327], and reverse shoulder arthroplasty (RSA), with/out TTs [27,28,31,52,64,65,82,83,85,95, 131, 145,148,224,267,268,287,318,322,323,324,333].

The available TTs are: latissimus dorsi (LD) [6,8,24,49,58,63,68,69,72,81,86,93,108,109,114,116,133,140,154,165-167,174,190,195, 199,213,221,222,226,236,251,256,261,265,311,328,330,346], teres major (TM) [50,51,153,296], combined LD/TM [89,117,195,223], deltoid [79,107,122,124,141,187,200,282,294,313], pectoralis major (PM) [88,102,105,169,172,188,220,229,269,290,312], long head of the triceps [177,202,284], lower trapezius [90]; and rarely pectoralis minor [246], combined PM/LD [4] and combined PM/TM [113]. Anecdotal treatments have also been reported [59,127,176,203].

Biological and biomechanical interposition transplant scaffolds can reconstruct, or bridge, MRCTs [10,53,56,78,123,194,245,266,271, 297] and include: autografts [55,121,138,218,219,270,278,281,320], allografts [30,136,168,183,185,214,217,228,233,248,314,316,339], xenografts [15,120,137,201,232,258, 293,325] and synthetic material [9,157,174,191,246,257,264,275,277,288,319].

Superior capsule reconstruction (SCR) was recently reported, using autologous fascia lata [210], a dermal allograft [1,156,227,254, 255,262,300,347], or an iliotibial ligament with a bone block [209].

The InSpace® (IS) system (OrthoSpace®), a novel treatment for MIRCTs, provides arthroscopic implantation of a subacromial biodegradable spacer, or "balloon" [17,33,77,118,119,159,272,279,285,301]. The balloon serves as a temporary bursa substitute, permitting frictionless gliding between the humeral head (HH) and acromion, and improves biomechanics by lowering the HH. Even though, the implant degrades within 6 to 12 months after implantation [43,193], its effect seems to be maintained over time.

The goals of this paper are: 1) present a systematic meta-analysis of surgical treatment options' outcome of MIRCTs without arthritis (CTA); 2) report the results of a prospective series of subacromial spacer patients, and confirm that results are maintained beyond device degradation; 3) compare the spacer outcome to the other surgical options for MIRCTs.

The hypothesis is that IS implantation provides a less invasive and safer solution, compared to other surgical alternatives, with at least the same clinical outcome.

Materials and Methods

The regional Ethical Committee approved this observational prospective cohort and retrospective literature study (CER-VD 2016-00805).

Radiological evaluation

Included patients had a Hamada stage < 3 on X-rays [142] and an arthro-MRI in a 3.0 Tesla Magnetic Resonance Scanner, Magnetom Skyra, Siemens Medical Solution, Erlangen, Germany, assessing the RC, looking particularly at retraction and fatty infiltration (FI) [98,126], as well as long head of the biceps (LHB) lesions.

All tears were massive [59,111] and were subdivided in posterosuperior (16), anterosuperior (6), and anteroposterior (15) [212,242,330]. The RCT distribution is found in table 1 and the LHB status in table 2.

	Subscapularis	Supraspinatus	Infraspinatus	Teres minor
Complete tear	8	37	27	-
Subtotal tear	12	-	3	1
Partial tear	15	-	7	1

Table 1: *Massive rotator cuff tear (MRCT) pattern of the InSpace cohort.*

Absent	10
Tendinopathy	3
Previous tenotomy	2
Dislocated	7
Partial tear	14
Dislocated and partial tear	3
SLAP IV	1

Table 2: *Long head of the biceps (LHB) lesions in the InSpace cohort.*

Balloon technique

Informed consent was obtained for every patient that accepted to participate in the study.

The patient demographics are outlined in table 3.

Spacer patients operated since 2010	155
Patients having > 2 year follow-up	54
Patients lost to follow-up	8
Excluded patients ‡	7
Patients that refused to participate in the study	2
Final review	36 patients (37 shoulders)
Follow-up average (range)	43.3 months (25 - 66)
Age (range)	68.3 years (49 - 83)
Females/Males	18/19
Right/Left	28/9
Dominant extremity involved	26/37 (70%)
Trauma	21/37 (57%)
Dislocation	4
Preoperative stiffness	10
Previous RC repair	7
Average duration of symptoms prior to surgery	16.5 months (2 days - 10 years)
Pseudoparalysis (active elevation < 90)	18/37 (49%)

Table 3: *Patient demographics.*

‡ Excluded patients: early infection 1; rheumatoid arthritis 1; Parkinson's disease and myocardial infarction precluding rehabilitation 1; breast cancer operation and patient had to interrupt rehabilitation 1; neurological disorder (ataxia) 1; more severe osteoarthritis than seen on preoperative X-rays 1; Worker's compensation 1.

The IS implantation technique has been previously described [279]. The RC was assessed for tendon quality, mobility, retraction, and to confirm the "non-complete" reparability after mobilization. When possible, PR is performed. If present the LHB is addressed by BTT (22) or BTD (3), as it is almost never normal in MRCTs [26,158,225,260,286].

The operative time dedicated to balloon implantation is very short, varying between 5 - 15 minutes.

The rehabilitation is adapted to additional procedures.

Literature search

Peer-review journals were systematically searched, from 1995 to 2016, for all relevant published articles via Medline®/PubMed® (http://www.ncbi.nlm.nih.gov/pubmed), Scopus® and Google Scholar.

The following search terms were used: massive AND/OR irreparable rotator cuff (RC) OR irreparable RC tears (RCTs); pseudoparalysis AND shoulder; balloon OR subacromial spacer; as well as MIRCTs treatment options, associating RC OR RCTs, OR shoulder, with debridement, BTT AND/OR BTD, tuberoplasty. To limit the number of PR results, only massive RC OR massive RCTs were included. Reverse prosthesis AND/OR arthroplasty were associated with RC AND/OR RCT(s) AND/OR massive RCT(s), not including articles exclusively addressing CTA. TTs associated with MRCTs were also examined. Finally, allograft(s) and patch(es) were searched in association with RCT(s) AND/OR MRCTs.

Exclusion criteria for returned papers were:

- The paper was not relevant to the scope of the literature review and did not include long-term results of MIRCTs.
- The Constant-Murley (CS) [62] or UCLA scores [5] were not used.
- No full paper was available.
- The paper had been superseded in a subsequent article by the same author(s).
- Less than 10 patients case reports.
- Articles not separating large from massive RCTs.
- Papers not clearly dissociating the results of two or more treatments.
- Articles that were not in English or French.

A separate literature review database contained: sample size, subjects' demography, follow-up, CS or UCLA score, satisfaction level, and any safety information. The treatment groups were: debridement, tuberoplasty, BTT/BTD, PR, TT, RSA, and other procedures (with only papers related to interposition).

All the articles' bibliographies were subsequently searched to retrieve omitted references.

The PRISMA guidelines were adopted for the meta-analysis [215].

Outcome measurement

The balloon patients were reviewed at 6 weeks, 3 and 6 months, 1 and 2 years, and at the latest follow-up. All patients were evaluated clinically, before and after surgery, using the CS and UCLA scores, and their respective subcategories. The total CS was weighted for age and gender in the normalized CS (NCS) [342]. The CS was valued as excellent (90 - 100%), good (80 - 89%), fair (70 - 79%), (61 - 70%) and poor (< 70%). The UCLA was noted as excellent (34 to 35 points), good (28 to 33 points), fair (21 to 27 points), or poor (0 to 20 points) [91].

The CS subgroups were also analyzed: A: Subjective Pain, B: Activities of Daily Living (ADL), C: Range of Motion (ROM), and D: Power; as well as the Adjusted Total CS (A+B+C).

The strength was measured using a handheld dynamometer (Isobex®) and flexion (degrees) using a manual goniometer.

The patients presenting preoperative PP were compared to the others.

The IS cohort was further subdivided in 4 subgroups: 1) IS implantation only (9); 2) IS and subscapularis repair (12); 3) IS and PR, addressing more than just the subscapularis (10); and 4) IS and subtotal repair (6).

The same outcome measurements were recorded for the meta-analysis articles.

Statistical analysis was performed expressing a mean, standard deviation, minimum, and maximum, with a required significance level of 5%.

The investigation compared the changes from baseline in CS and UCLA scores, with Repeated Measures Analysis (RMA) of covariance model (SAS® MIXED procedure) and including the following fixed effects: time from IS implantation, age, procedure and baseline score. The adjusted means of the yearly assessments are presented along with their respective 95% Confidence Intervals, or Confidence Levels (CL).

The same was provided for the preoperative/postoperative values of the different treatment alternatives and compared to the outcome of the IS cohort. To prove significance, the lower CL of the IS cohort or subgroup should be higher than the upper CL of the tested treatment.

Results

Balloon patients' results

Every patient and section of the CS is improved significantly with respective preoperative/final results for the CS 39.1 ± 12.5/79.8 ± 7.5 and the NCS 45.6 ± 13.9/93.9 ± 7.7 (Figure 1). All the CS subgroups show the same tendency; with preoperative/latest control results increase respectively from 5.1 ± 4.2/13.7 ± 1.6 for pain, 8.4 ± 3.3/19.4 ± 1.4 for ADL, 22.6 ± 8.9/38.5 ± 2.5 for ROM, and 3.0 ± 1.5/8.2 ± 5.3 for power. The change from baseline is shown in table 4. The adjusted CS doubled from 36.1 ± 11.6 to 71.6 ± 3.8 at the final follow-up. The CS results are good/excellent in 94.6% of the patients, fair in 5.4%, and there are no poor results.

	Improvement in Total CS by at least 10 points		Improvement in Total CS by at least 15 points		Improvement in Total CS by at least 20 points		Improvement in Total CS by at least 25 points	
	Number of Subjects with Improvement	%	Number of Subjects with Improvement	%	Number of Subjects with Improvement	%	Number of Subjects with Improvement	%
6 wks	14	41.18	7	20.59	4	11.76	2	5.88
3 mos	31	86.11	27	75.00	23	63.89	16	44.44
6 mos	35	100.0	35	100.0	33	94.29	27	77.14
1 year	33	100.0	32	96.97	31	93.94	28	84.85
2 years	34	100.0	34	100.0	33	97.06	30	88.24
Final FU	37	100.0	37	100.0	36	97.30	33	89.19

Table 4: *Patients' InSpace cohort improvement in Total Constant Score (CS) by at least 10 points, 15 points, 20 points, and 25 points.*

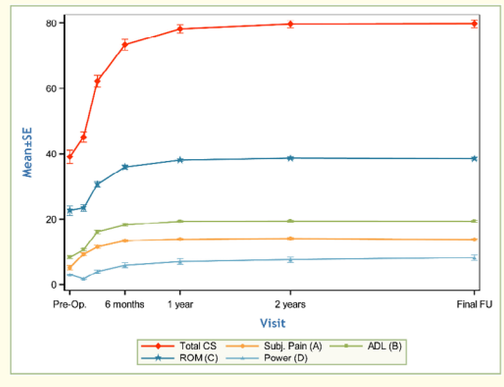

Figure 1: *Total Constant Score (CS) and CS subgroups of the global InSpace cohort.*

The total UCLA score demonstrates the same significant improvement, with preoperative/final results 13.5 ± 4.7/33.1 ± 1.5. Every UCLA subcategory also shows the same trend, with respective increase of preoperative/latest control results from 3.6 ± 2.7/8.9 ± 1.0 for pain, 4.1 ± 2.2/9.2 ± 1.4 for function, 3.4 ± 1.5/4.9 ± 0.4 for active flexion; 2.4 ± 0.8/3.9 ± 1.1 for flexion strength. Every patient was satisfied. The UCLA score are good/excellent in 91.9% of the patients, 8.1% have fair, and no patient has poor results.

All 4 IS subgroups are significantly improved for the CS and NCS (Figure 2), as well as for the UCLA score.

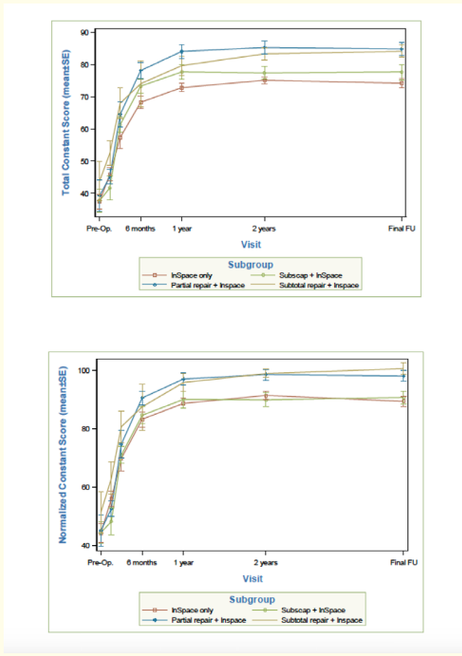

Figure 2: *Total and Normalized Constant Scores of the 4 subgroups of the InSpace cohort.*

A significant anterior elevation improvement is observed for the spacer cohort with preoperative/postoperative 98.0/175.8 degrees ($p < .05$). The PP, present preoperatively in 18 cases (49%), is reversed in all of them (Table 5), though the non-pseudoparalytic ones did significantly better (Figure 3).

Patient Number	Preoperative anterior elevation	Postoperative anterior elevation
1	40	180
2	85	160
3	30	180
4	80	180
5	85	180
6	40	180
7	80	160
8	90	160
9	90	180
10	75	180
11	90	180
12	30	180
13	45	180
14	40	180
15	70	180
16	30	180
17	40	180
18	90	180

Table 5: *Preoperative and postoperative values (degrees) of pseudoparalysis (PP) patients.*

Considering the contributing factors to balloon cohort results, it was observed that trauma had an influence on outcome, but no significant difference was noted when BTT was performed (Figure 3).

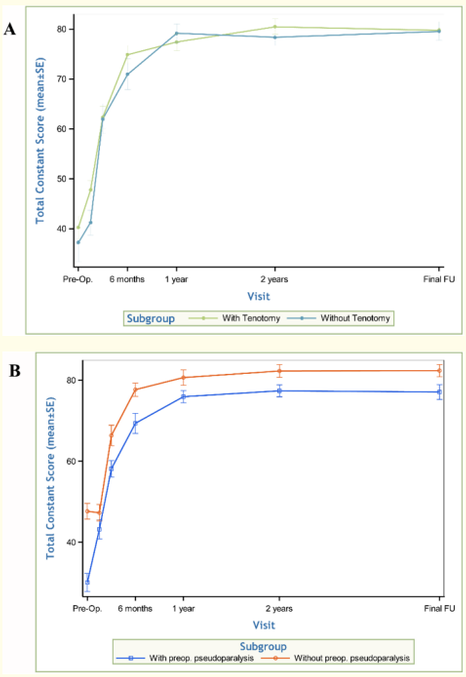

Figure 3: *Evaluation of contributing factors to the results of the balloon cohort: A) Tenotomy; B) Pseudoparalysis.*

As adverse events and complications, there were 2 cases of early posttraumatic partial displacement of the device, but the effect was maintained, 1 case of stiffness which finally resolved with physiotherapy and 1 case of proximal humeral 3-part fracture one year after the spacer implantation which had no influence on the end-result.

Results of the literature search

Using the search terms “massive” AND “irreparable” AND “RC”, 137 studies were identified in PubMed/Medline, and 35 met the inclusion criteria (Figure 4).

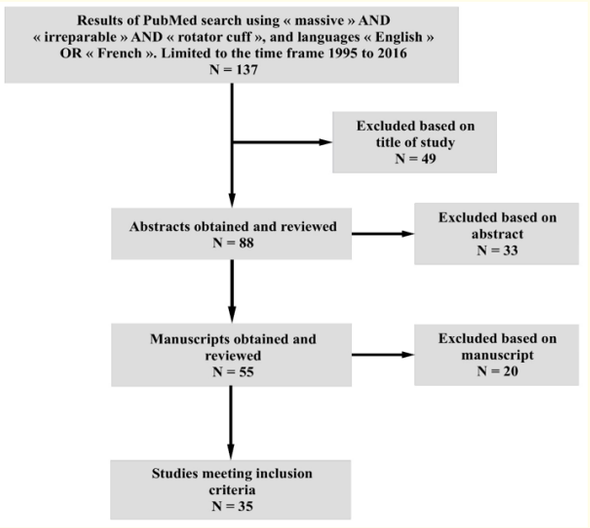

Figure 4: *Flow chart of literature search strategy.*

When completing the literature search (Table 6), only 85 papers met the eligibility criteria (Table 7).

Search strategy 1995-2016	Total	Related to subject	Suitable for meta-analysis
Massive AND/OR irreparable AND rotator cuff	326	199	62
Massive AND irreparable AND rotator cuff	178	126	39
Massive AND irreparable AND rotator cuff tears	170	128	37
Massive AND irreparable AND rotator cuff tear	161	116	37
Pseudoparalysis AND rotator cuff	56	21	2
Pseudoparalysis AND shoulder	56	21	2
Debridement AND rotator cuff	287	49	9
Massive AND rotator cuff AND tenotomy	43	28	5
Massive AND rotator cuff AND tenodesis	33	20	7
Tuberoplasty OR reversed subacromial decompression	23	12	4
Partial repair AND massive rotator cuff	85	40	2
Transfer AND rotator cuff	300	162	44
Latissimus dorsi transfer	737	104	31
Teres major transfer	101	34	5
Deltoid transfer	228	30	11
Pectoralis major transfer	239	28	7
Pectoralis minor transfer	51	6	2
Trapezius transfer	191	27	7
Interposition AND rotator cuff	27	15	4
Patch OR graft AND rotator cuff	233	105	9
Allograft AND rotator cuff	89	39	5
Balloon OR subacromial spacer	32	8	-

Table 6: *Literature search methodology (PubMed/Medline).*

Debridement [104,155,182,265,273,315]	6
Biceps tenotomy/tenodesis [26,182,196,204,321]	5
Tuberoplasty [96,189,251,280]	4
Partial repair [155,162,240,263,332]	5
Tendon transfers ◊	50
RSA with/without Lat dorsi transfer [28,95,267,324,333]	5
Other treatments ◊◊	10

Table 7: *Categories allocation of the meta-analysis papers that met the eligibility criteria.*

◊ Tendon transfer distribution: pectoralis major 6 [88,105,172,188,269,312], pectoralis minor 1 [246], teres major 3 [51,153,296], pectoralis major and latissimus dorsi 1 [4], latissimus dorsi 25 [8,49,63,68,69,72,86,93,114,116,133,140,167,190,195,213,221,222,235,256,261, 311,329,330,346], latissimus dorsi and teres major 3 [117,195,222], deltoid 9, [107,122,124,141,187,200, 282,294,313], long head of triceps 2 [177,202].

◊◊ Other treatments distribution: autografts 3 [55,138,270], allografts 3 [30,217,339], xenografts 2 [15,258], synthetic material 1 [9], and superior capsule reconstruction 1 [210].

Comparison of the balloon results to the other treatments

Regarding the Total CS, Total IS results are significantly superior to debridement, BTT/BTD, tuberoplasty, PR, TTs (including LD, deltoid and PM), RSA, and other treatments (Figure 5A and Table 8). Even when using the IS implant only, with no additional RC treatment,

the results are superior, with significance for BTT/BTD; tuberoplasty; and TTs, including LD and PM (Figure 5A and Table 9). IS implantation outcome is also higher for the UCLA score (Table 8 and Table 9) but IS flexion results undoubtedly dominate all the other techniques (Figure 5B).

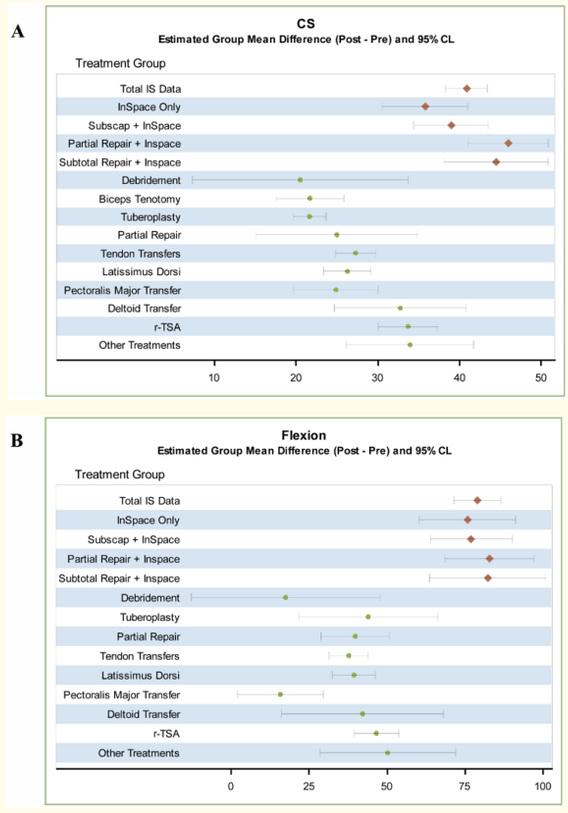

Figure 5: *A: Comparison of the Estimated group mean difference for the Constant Score (CS) between the InSpace cohort (Total IS) and the different InSpace subgroups to the Various Operative Procedures for Massive Irreparable Rotator Cuff Tears. B: Comparison of the Estimated group mean difference for Flexion between the InSpace cohort (Total IS) and the different InSpace subgroups to the Various Operative Procedures for Massive Irreparable Rotator Cuff Tears.*

	CS/Norm CS	CS pain	CS ADL	CS ROM/Flexion	CS strength	UCLA	Flexion
Debridement	+*	+	+*	+*	+*	+	+*
Biceps treatment	+*	+	+*	+*	+*		
Tuberoplasty	+*			+*		+	+*
Partial repair	+*	+*		+*		-	+*
Tendon transfers	+*	+*	+*	+*	+*	+	+*
Lat dorsi	+*	+*	+*	+*	+*	+	+*
Deltoid	+*	+	+	+*	+		+*
Pec major	+*	+	+*	+*	+		+*
Reverse	+*	+	+	+*	+		+*
Other treatments	+*	+	+	+	-	+	+

Table 8: *Estimated group mean difference (EGMD) comparison of the Constant Score (CS) and subgroups, Normative CS (Norm CS), and UCLA score (UCLA) between the Total InSpace cohort and the various operative treatments (VOT).*

ADL: Activities of Daily Living; ROM: Range of Motion.

+: Estimated group mean difference of Total IS results is superior to the measured treatment; -: Estimated group mean difference of Total IS results is inferior to the measured treatment; +: Total IS results are significantly superior to the measured treatment; In the blank cells the data was not provided.*

	CS/Norm CS	CS pain	CS ADL	CS ROM/Flexion	CS strength	UCLA	Flexion
Debridement	+	+	+*	+*	+	+	+*
Biceps treatment	+*	+	+*	+*	+		
Tuberoplasty	+*			+		+	+
Partial repair	+	+		+*		-	+*
Tendon transfers	+*	+	+*	+*	-	+	+*
Lat. dorsi	+*	+	+*	+*	-	+	+*
Deltoid	+	+	+	+	-		+
Pec major	+*	+	+*	+*	-		+*
Reverse	+	+	+	+*	-		+*
Other treatments	+	-	+	+	-	+	+

Table 9: *Estimated group mean difference (EGMD) comparison between the InSpace only group and the various operative treatments (VOT).*

ADL: Activities of Daily Living; ROM: Range of Motion.

+: Estimated group mean difference of IS only results is superior to the measured treatment; -: Estimated group mean difference of IS only results is inferior to the measured treatment; +: IS only results are significantly superior to the measured treatment; In the blank cells the data was not provided.*

Discussion

Balloon (subacromial spacer)

No postoperative physiotherapy is necessary according to some [17,301], but if spacer implantation were a definitive treatment, the device would not have been absorbable.

Chief complaints in MRCTs are pain, functional disability and loss of power. Superior HH migration generates rough subacromial surfaces causing pain, which induces a muscle activation blocking effect. EMG confirms this avoidance mechanism [295]. MRCT patients have muscle reorganization along the upper kinetic chain, with the LD and TM partially compensating [150] and increased deltoid and PM fatigue [151].

Nonetheless, several MIRCTs have satisfactory painless function [18,80,143,259].

How does the balloon work and why is it still efficient after degradation? The balloon diminishes subacromial friction by a soft gliding phenomenon (water bed effect) decreasing pain. The semi-inflated spacer stabilizes the HH like a balanced adjustable ring and, producing HH depression, it allows better biomechanics. This combined effect and the long balloon degradation will give enough time for necessary muscles to resume appropriate activity.

Rehabilitation requires strengthening of the scapular stabilizers, anterior deltoid [2,80,99,192], as well as PM and LD, in addition to the remaining RC [44,237]. Stretching of the upper trapezius and the postero-inferior capsule are mandatory.

Outcomes of published balloon studies are favorable (CS 66.8 to 76.0) [17,77,119,159,272,285], but the very specific postoperative rehabilitation program may explain the higher scores obtained in this study.

Debridement and BTT/BTD

RC debridement and SAD without repair fares satisfactory results in only 50% of large and massive reparable tears [350], with long-term results deteriorating in most patients [152,162,206,216] and secondary superior head migration may transform a painful functional shoulder into a painful nonfunctional one [25,26,206,298,310,331-333,337].

As spontaneous LHB rupture may lead to a pain-free shoulder [46], BTT is considered in MIRCTs [260]. For some, BTD is a cosmetic operation, and BTT is preferred [259].

The reference article on BTT (307 patients) shows good and excellent results in 71.6% of the patients, with 86% subjective satisfaction [321]. Nonetheless, this procedure was also performed in older individuals not willing to participate in the rehabilitation required after RC repair, no patient had PP (mean preoperative AE 153.4°) and acromioplasty was performed in 110 individuals, clouding BTT outcome [80].

Persistent symptoms remain after a minimum two-year follow-up, including muscular cramps, bicipital groove pain, and a Popeye sign, especially present in the BTT group [26].

PP is a contraindication to BTT/BTD [26], with superior HH migration observed during elevation [326], as well as arthritis progression [204,260,321].

Tuberoplasty or reversed subacromial decompression (RSD)

Tuberoplasty may induce significant pain reduction [96,189,252,280], but anterosuperior MRCT patients had less functional improvement [280].

A long-term tuberoplasty outcome study reported satisfactory results in MIRCT patients without PP [252].

Partial repair (PR)

PR may convert a MIRCT in a functional RC tear, improving shoulder biomechanics, and giving near normal function [34-39,239,299].

For some, only slight differences lie between complete and partial MRCT repair [125,162], while others judge PR results inconsistent [22,39,84,221]. Arthroscopic PR might have shorter clinical benefit [345], with clinical and radiographic results deteriorating with time, and only half of the patients are satisfied [291].

Tendon transfers (TTs)

TTs for MIRCTs can improve pain and mobility, but normal shoulder function is not restored [164]. Candidates for TTs are patients younger than 60 years, which should be able to attain 90° elevation preoperatively [42].

Even though LD transfers (LDTs), used in posterosuperior MIRCTs [197,243] heal, and have EMG activity, the gain in strength is absent or very mild [8,69,114,140,330].

LDT induces pain alleviation and functional improvement [165,243] but, with time, pain worsens, and strength loss [86] and arthropathy progression are noted [93].

LDT is usually contraindicated as an isolated procedure in case of PP, a combined irreparable subscapularis tear, deltoid palsy, and associated osteoarthritis [69,132,153,330,334].

Long-term LDT outcome has shown substantial and durable improvements in shoulder function and pain relief, but AE increased only from 118° to 132°, and the results are not as good in patients having subscapularis insufficiency or teres minor FI [116]. Progression of osteoarthritis is also noted [8,114,116,153]. Satisfaction rate ranges from 60 - 80% after LDT [42].

The surgical time was respectively 56 minutes for arthroscopic PR and 65 minutes for LDT [251], with another study showing an average operative time of 54 minutes for the latter [223].

A recent systematic LDT review demonstrated a 9.5% complication rate, including reoperations for a TT tear and revisions to RSA [226], but for others the results can be unpredictable [307].

A sole Teres major transfer (TM) has also been described [50], with acceptable outcome, but the prerequisite is the integrity of the subscapularis [50].

Combined LD/TM transfer has been reported [117,195,223]. Results are quite good after a L'Episcopo procedure, but a clear decline in strength, external rotation, and acromio-humeral distance, with increase in CTA, are observed at 5 years [117]. A comparison of the combined transfer to the isolated LDT showed that the former achieved an increase in abduction strength, while the latter produced a better active abduction and AE, with less risk of CTA progression [195].

PM transfer (PMT) is recommended for elderly patients who have an irreparable subscapularis tendon tear [172,269,338] and a systematic review of PMT has shown improvement in shoulder function, strength and pain relief [290] but the relative CS (70%) is clearly not as good as that observed after direct reconstruction of reparable subscapularis tears [172]. Patients should be informed that full recovery of active mobility, particularly AE and external rotation, should not be expected, with a less favorable outcome in patients with MRCTs.

The recently described results of Pectoralis minor transfer are quite good [247], however, the subscapularis tears were not complete, and corresponded to stage III tears according to the Lafosse classification.

Even though pain relief and satisfaction are high with Deltoid transfer (DT) reconstruction for MRCTs, the long-term survival rates of the flap are very low (12.5%) and superior HH migration is not prevented [124]. Short or medium-term outcomes after DT are satisfactory for work resumption, pain relief and shoulder function, but long-term results are poor, and this treatment is not recommended for MRCTs [200].

Lower trapezius transfer, previously described for brachial plexus lesions [243], seems to have biomechanical advantages on LDT for posterosuperior tears [147,244]. The recently reported results are satisfactory, with a more significant gain in function in patients having less than 60° elevation [90].

A Long Head of the Triceps transfer described for posterosuperior MIRCTs showed good initial UCLA measured outcomes, with few complications [202], but a later study demonstrated residual shoulder abductor and external rotator, as well as elbow extensor strength deficits at 2-year follow-up [177].

Reverse shoulder arthroplasty (RSA) with or without TT

RSA is currently also advocated for MIRCTs without arthritis giving good pain relief, however, the functional results are variable, and the complication rate varies from 4.3% to 68%, with a 10% revision rate [7,54,64,333]. With increasing surgeon experience, a decrease in the RSA complication rate is observed (19% to 10.8%), and revisions are reduced (7.5% to 5%) [326]. Many shoulder surgeons hesitate to recommend RSA in young active patients as there are concerns regarding the longevity, reserving it for older low demand patients [100].

RSA combined with an LD/TM transfer is indicated in case of a deficit of AE and external rotation [31] but, due to a high complication rate, this technique should be limited to patients with major disability and high grades of FI [289].

Even though the overall RSA survival rate was 93% for various indications in a long-term follow-up study, a decline in outcome was observed when comparing with medium-term results, and in the MRCT subgroup, the CS dropped from 63 ± 11 to 55 ± 12 [13].

To my knowledge, there is no available data concerning the operative time for RSA performed for MIRCT, but the mean duration of this procedure for proximal humeral fractures is 123 ± 23.3 minutes [32]. The operative time is longer in obese patients [250]. In case of an additional LDT in combination with RSA, the operative time is lengthened, with a mean of 153 minutes (115 - 280) [267].

Other treatments

Good outcome is reported with Biceps interposition (BI) bridging the gap in MRCTs [55,138,270,278,320]. The advantage of the BI technique is that it uses a very often-sacrificed local autograft, the LHB. However, in a certain number of cases, it is already absent, and this technique cannot be performed.

Significant functional improvement was not shown when comparing the BI group to PR patients, even though complete healing was observed on MRI, respectively in 58% and 26% of the cases [55,194].

A significant function enhancement was noted when comparing Fascia lata (FL) reconstruction to PR in MIRCT patients, and the structural integrity was also superior, respectively 79% versus 58% [218]. FL interposition is not suitable for high-grade MRCTs with infraspinatus grade 3 or 4 FI [219].

Only 53% of the patients had good or excellent UCLA when using tendon allografts to reconstruct MIRCTs, with increased risks of infection and rejection, and more technical difficulties than other less expensive treatment options [217].

Good results are reported for acellular dermal matrix allografts for MIRCTs, though fully intact grafts were found in only 76% of the cases [136,183,214,316,339], and patients complained of lack of improvement in overhead strength [30]. The operative time is quite long ranging from 2 - 3 hours [136,339].

Certain xenograft patches lead to complications and early transplant failure [201,258,293,325].

Dermal tissue xenograft does not lead to tissue rejection or infection, but there is less improvement in patient-reported outcomes and ADLs, than synthetic grafts and allografts [297]. The average surgical time is 2 hours, including the duration for addressing additional intra-articular pathology [15,120,137, 232].

When using a synthetic Mersilene interpositional mesh and SAD for MRCTs, substantial pain relief and functional improvement are observed, with only a 7.3% tear rate [9].

Excellent results were recently reported after SCR, but the presence of a repairable subscapularis tendon and a partial infraspinatus tendon are mandatory [210]. Other restrictions are the difficulty of execution and the fact that it is time-consuming (1.5 hours according to the senior author, and 3 hours for a "beginner") [211]. To avoid the disadvantage of second site surgery, others have used a dermal allograft [1,156,227,254,255,300,347], but the cost is an issue due to the use of a large number of anchors, not counting the eventual dermal allograft.

Comparative study of the various treatments to the balloon

Outcome scores and flexion are superior for the IS cohort in comparison to the different MIRCT treatments (Figure 5A and 5B, Tables 8 and 9).

A cost-effectiveness study is under way for the balloon, but a few thoughts can already be pondered. When comparing cost-effectiveness of different treatments, a few issues have to be considered, such as: the price of the device, the operative time, and the eventual complications. These parameters should then be adjusted to the outcome scores.

If palliative treatments, such as debridement, BTT or tuberoplasty, were effective procedures for MIRCTs, we would not be doing more complex surgeries like TTs, RSA or SCR. Of course, palliative operations can be favored for elderly patients that have poor general health conditions, but this is also the case for the balloon which has higher outcome scores. If the patients' demand is to correct PP, the only option is the subacromial spacer.

The surgical time is 4 to10 times longer for LDT, RSA with/out a combined transfer, the different grafts, and SCR, compared to the spacer [32,223,251,267]. The IS cost is also cheaper than RSA and the dermal allografts used for SCR.

A procedure giving similar or superior scores, requiring a much shorter operating time, with minimal or no complications, as is the case for the balloon, should be viewed as the most cost-effective.

This study has of course certain limitations.

The first is the number of patients lost to follow-up (8). The results of these lost to follow-up patients may be less favorable than the actual balloon cohort. One of these patients immigrated to Thailand, but the 6 months results after balloon implantation were quite good, because she sent a mail saying that her shoulder was subjectively back to 100%.

Another bias is the comparison of a prospective cohort to the results of various operative treatments in the literature. However, as in each treatment group a few articles were eligible, the statistical power is higher and allows us to analyze the eventual advantages of each technique.

The last flaw is that a certain number of papers in the literature were excluded on the basis that they did not consider the same outcome scores as the ones used for the IS patients. However, the CS and UCLA score are widely employed, giving us a reasonable comparison between groups.

Future double blind randomized prospective studies need to support the effectiveness of the balloon in comparison to the other operative treatment alternatives for MIRCTs.

Conclusion

In the MIRCTs setting, the subacromial spacer implantation is a simple and short procedure giving excellent outcomes, which are maintained after balloon degradation, if an adequate rehabilitation is performed, confirming our initial hypothesis. Longer-term follow-up studies need to support that the balloon stands the test of time.

The results of the various operative treatments for MIRCTs are reasonably good. A risk-benefit evaluation considering price, operative time, and complications, adjusted to the outcome scores used in this study, demonstrates that the spacer group gives better results than the other options for MIRCTs, and its choice as a first line of treatment should be considered.

Conflict of Interest

Dr. Naggar is serving on the Scientific Advisory Board of OrthoSpace, the firm manufacturing the subacromial spacer. The manufacturer has funded the statistical data analysis. Dr. Naggar's family and himself have no other conflicts of interest.

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