Advantages of arthroscopic rotator cuff repair with a transosseous suture technique. A prospective randomized controlled trial.

ABSTRACT

Background: Rotator cuff tear is a common finding in patients with painful, poorly functional shoulder. The surgical management of this disorder has improved greatly and can now be fully arthroscopic.

Purpose: The aim of this study was to evaluate clinical and radiological results of arthroscopic rotator cuff repair using two different techniques: single-row anchor fixation versus transosseous hardware-free suture repair.

Study design: Prospective randomized controlled clinical trial.

Methods: Sixty-nine patients with rotator cuff tears were enrolled: 35 patients were operated with metal anchors and 34 with standardised transosseous repair. The patients were clinically evaluated before surgery, during the 28 days following surgery and at least 1 year after the operation using validated rating scores (Constant score, QuickDASH, numerical rating scale). Final follow-up was obtained at more than 3 years by a QuickDASH evaluation in order to detect any difference from previous follow-up. During the follow-up, rotator cuff integrity was determined through magnetic resonance imaging and classified into the five Sugaya's categories.

Results: Patients operated with the transosseous technique had significantly less pain, especially from the 15th postoperative day: in the third week the mean value of NRS for anchor group was 3.00 while for tunnel group was 2.46 (p-value = 0.02), in the fourth week the same values were 2.44 and 1.76 respectivly (p-value < 0.01). There were no differences in functional outcome between the two groups at the final evaluation. In the evaluation of rotator cuff repair integrity, based on Sugaya magnetic resonance imaging classification, no significant difference between the two techniques in terms of re-tear rate were found (p-value = 0.81).

Conclusions: There were no significant differences between the two arthroscopic repair techniques in terms of functional and radiological results. However, postoperative pain decreased more quickly after the transosseous procedure, which, therefore, emerges as a possible improvement in the surgical repair of the rotator cuff.

Clinical relevance: Since there is a significant postoperative pain reduction with transosseous technique, it can be considered a valid alternative to anchor repair.

Key terms: rotator cuff, transosseous arthroscopic repair, anchor repair, re-tear rate, MRI evaluation.

What is known about the subject: Arthroscopic single-row suture anchor repair represents the gold standard in arthroscopic rotator cuff surgery. Transosseous hardware-free repair has been the gold standard open procedure for a long time.

What this study adds to existing knowledge: This first randomized controlled trial of arthroscopic transosseous versus anchor techniques for rotator cuff repair shows equivalent functional and imaging results, but reduced postoperative pain after the former.

INTRODUCTION

Rotator cuff injury is a common cause of pain and shoulder disability.[36] Studies in symptomatic and asymptomatic populations have revealed that this injury is very common: the prevalence in cadaveric studies ranges from 5% to 40% of the population,[49] with a significant increase in subjects over the age of 60.[50]

Various risk factors have been evaluated: age seems to play a pivotal role in the development of this disorder, and smoking, resulting in a reduced supply of oxygen in the footprint area, increases the risk of rupture. Indeed, dose- and time-dependent relationships between smoking and rotator cuff disease have been identified.[3] High cholesterol levels, diabetes and some familiar predisposition are all additional factors that can lead to a possible increased risk of developing degenerative rotator cuff disease.[49]

Despite the high prevalence of rotator cuff tears, there is not a consensus on the optimal treatment. Numerous studies have compared different surgical approaches trying to identify the technique that can provide the best tendon repair and can reduce the re-tear rates. Over the years, there has been a remarkable evolution in surgical techniques, moving from open procedures, to mini-open and, finally to arthroscopic techniques.

Arthroscopic repair surgery is a valid therapeutic approach, which can provide good clinical results and a low level of complications.[46] Different arthroscopic repair techniques have been developed in the last 20 years. Single-row, double-row, and transosseous equivalent are arthroscopic techniques, based on implantable devices, which provide good clinical outcomes.[12,19,23,31,32,55]

The open transosseous technique was considered the gold standard for repair of rotator cuff lesions until the end of the last century. This technique provided the best clinical and biomechanical results but, for a long time, was feasible only with the open approach.

In 2006, Cicak *et al*.[15] and Matis *et al*.[33] proposed two different methods to realize the transosseous suture with an arthroscopic approach. These techniques have been developed in the last few years with the introduction of specific devices able to create a standardized transosseous tunnel.[22,27]

The aim of the present work was to evaluate the results of the latest arthroscopic transosseous cuff repair procedure, and compare them with those of the longer-established single-row suture anchor repair technique in patients followed from the preoperative period until more than 3 year postoperative.

Therefore we wished to test the null hypothesis that there were not statistically significant differences in post-operative values of VAS score between metal anchor and transosseous repair groups.

MATERIALS AND METHODS

Study design

This was a prospective, randomized, controlled, double-blind clinical trial. The CONSORT (Consolidated Standards of Reporting Trials) statement guidelines were followed to perform this randomized controlled study and present the results. A flow diagram according to CONSORT guidelines illustrates the grouping and flow of patients in our clinical study (*Figure 1*).

The randomization list was prepared preoperatively. Block randomization was performed to allocate patients to one of the two treatment groups. An independent investigator, not involved in the surgical treatment, prepared and sealed opaque envelopes bearing the type of operation to perform. After the phase of diagnostic arthroscopy to confirm the lesion and eligibility for the study, patients were randomized into one of the two treatment groups. Patients were not informed about which technique was used on the day of the surgery or at the follow-up visits. The examiners who evaluated the patients' shoulder also did not know the type of surgery performed.

The study protocol was approved by the Regional Ethical Committee (authorization number 2769; January 29, 2013) and registered at ClinicalTrials.gov (ClinicalTrials.gov ID: NCT01815177; March 3, 2013).

Population

Postoperative pain was considered as the primary variable for calculating the sample size. To observe a difference in pain of 2 points on the numerical rating scale (NRS) between the two groups with a standard deviation of 2 points, power of 80% and alpha value of 5%, the minimum number of patients to be enrolled per group was 17, allowing for a possible drop-out of 10-15% of the patients.

The study was concluded with the enrolment of 69 patients randomized into the two groups: repair with the use of metal anchors (35 patients) and transosseous repair (34 patients). Three patients (4%) dropped out of the study: one because of rotator cuff revision surgery and two postoperative voluntary drop-outs. The revision surgery has been considered as a drop out because a different surgeon evaluated the patient and gave the indication to a revision, without any possibility for the surgeon of this study to evaluate the clinical condition and the radiological exams and to asses the real necessity for a revision surgery. One other patient was unable to undergo the radiological control after the development of an absolute contraindication to this procedure (metallic splinter). This patient was still able to undergo the clinical evaluation at more than 3 years (*Figure 1*).

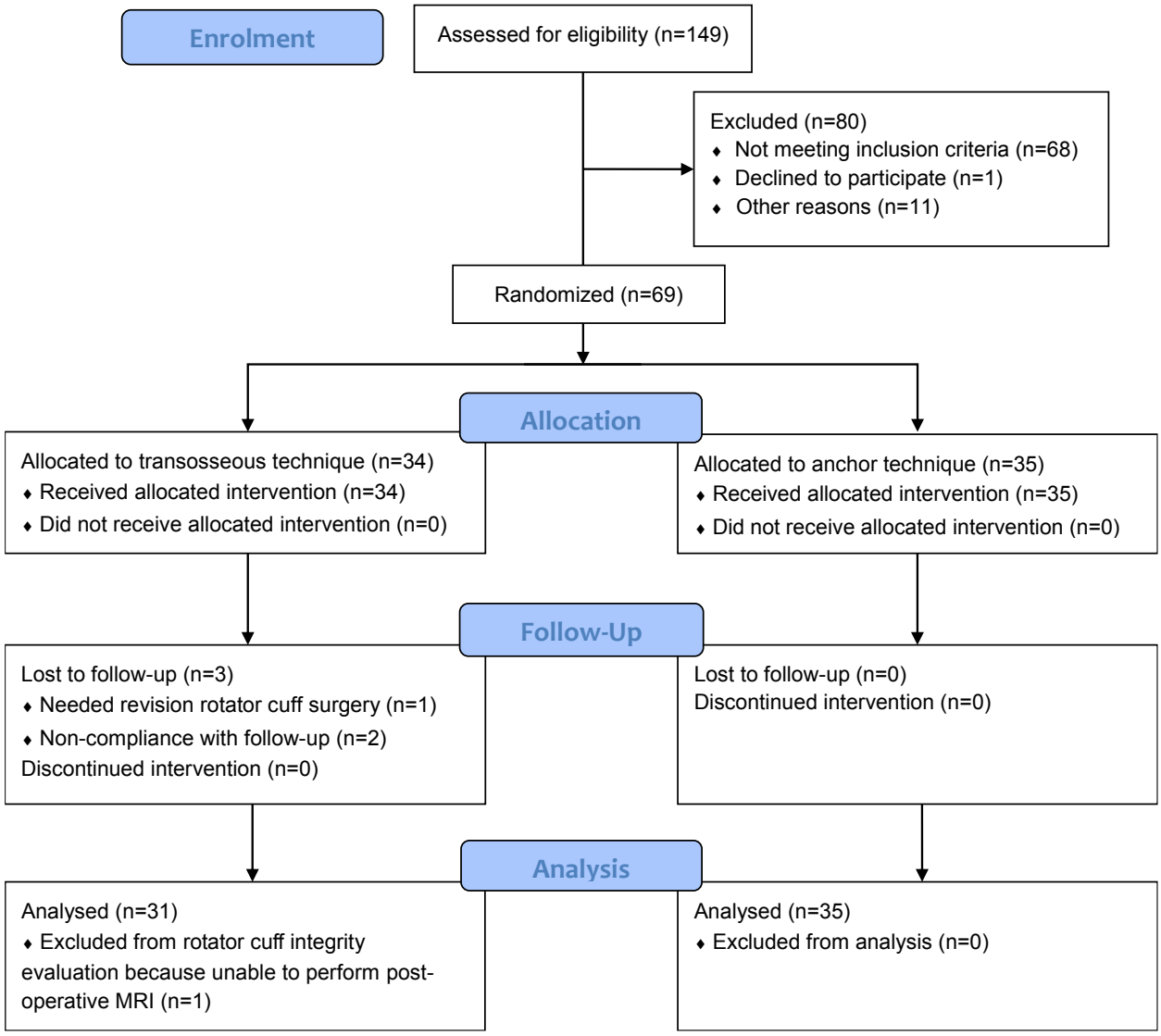

Figure 1. Flow diagram of the study.

Statistical analysis

Continuous variables are expressed as means and standard deviations (SD) or medians, and first and third quartiles [Q1 - Q3] as appropriate, while the dichotomous variables are expressed in numbers of cases and frequencies.

The Kolmogorov-Smirnov test was used to evaluate the normal distribution of the sample and, if the null hypothesis of this test could not be rejected, the non-parametric Mann-Whitney test (U test) and Wilcoxon's test were applied for the analysis of the samples. Variables with a Gaussian distribution were analysed with Student's *t*-test. Dichotomous variables were analysed using the chi square test. Associations with p values <0.05 are considered statistically significant.

Eligibility criteria

From January 2013 to February 2014, 69 patients with lesions of the rotator cuff, confirmed by arthroscopic evaluation, were enrolled, according to inclusion and exclusion criteria listed in *Table 1.*

Table 1. Eligibility criteria.

Inclusion criteria:

- Age between 18 and 65 years
- Full thickness rotator cuff lesion
- Informed consent to participation in the study
- Body mass index ≤33

Exclusion criteria:

- Injuries of the subscapularis tendon
- Need for tenodesis of the long head of the biceps
- Massive retracted rotator cuff lesions
- Disorders of the shoulder such as osteonecrosis, fractures and osteoarthritis (glenohumeral and acromioclavicular)
- Osteomyelitis, active infections or sepsis
- Muscular atrophy and peripheral neurovascular impairment
- Body mass index >33
- Patients with metabolic disorders, and serious comorbid conditions that could limit the follow-up (e.g. neoplastic diseases, immune deficiencies, hepatitis)

Preoperative evaluations

Preoperatively, an investigator took a careful medical history and performed a specific clinical examination of the shoulder. All patients then underwent standard imaging studies for evaluation of the rotator cuff lesion: X-ray (in true anteroposterior, A/P, and outlet views) and magnetic resonance imaging (MRI) without contrast.

In addition, patients were evaluated using validated clinical scores: the NRS[8], Constant score[16] and QuickDASH (Disabilities of the Arm, Shoulder and Hand) Outcome Measure[17]. The numerical pain rating scale assigns a numerical value to pain from 0 to 10: patients rate their pain considering 0 as the absence of pain and 10 as the worst imaginable pain. The Constant score is calculated using a system that combines tests of shoulder function (range of motion and strength, for a total of 65 points) with a subjective assessment of disability determined by the shoulder pathology (pain and limitation in common daily activities, for a total of 35 points). The QuickDASH Outcome Measure is based on a self-assessed questionnaire: 11 questions evaluate the patient's disability and symptoms on a scale of responses ranging from 1 to 5 where 1 means "no difficulty / symptoms" and 5 means "extreme difficulty".

Intraoperative evaluations

The primary diagnostic arthroscopy allowed an assessment of the tendon tear using the following criteria: type (articular, bursal or full thickness); form (crescent, U, V, L or L reverse); lesion size (anteroposterior and mediolateral diameters and Snyder's classification[45]); and tendon injury percentage (primarily supraspinatus and, possibly, of the other cuff tendons). Snyder classification describes the extent, the location and the size of the tear. The location is classified as articular (Type A), bursal (Type B), and complete (Type C). The dimension for the full thickness tears is defined as: 1-small tear; 2-moderate tear < 2 cm of only one tendon without retraction; 3-large complete tear,

146 usually 3-4-cm, with minimal retraction; 4-massive rotator cuff tear involving 2 or more rotator cuff
147 tendon with retraction associated.[45]
148 Acromial type was also assessed according to the Bigliani-Morrison classification.
149
150 Postoperative evaluations
151 Patients were asked to fill out a form indicating their perceived pain each day until the 28th day after
152 surgery (corresponding to the time the arm-sling was removed) and the onset of any adverse clinical
153 events. Pain was assessed using the NRS.
154 At 2 months after surgery, stiffness was evaluated using the criteria described by Chung *et al*.[13]
155 Passive range of motion in three directions (forward elevation, external rotation at the side and
156 internal rotation at the back) was measured with a goniometer by a single blinded examiner. Shoulder
157 stiffness was defined as: passive forward elevation less than 120°, passive external rotation with the
158 arm at the side less than 30°, and passive internal rotation at the back lower than L-3. Patients who
159 met any one of these criteria were considered to have a stiff shoulder.
160 After at least 1 year, the patients were evaluated by MRI and, again, with the NRS, Constant score
161 and QuickDASH Outcome Measure. In order to evaluate any other modification, a new QuickDASH
162 analysis was run at more than 3 years after surgery.
163
164 Radiological assessment
165 The radiological control at 1 year consisted of MRI at 1.5 Tesla (Magnetom Sonata Maestro Class,
166 Siemens Medical Solutions, Erlangen, Germany). The study protocol required T1-Spin Echo oriented
167 transverse, coronal, and sagittal views. T1-TIRM (Turbo Inversion Recovery Magnitude) coronal and
168 sagittal projections were also obtained. Images had a 256 x 256 matrix.
169 In order to reduce the duration of these controls, imaging was performed only for rotator cuff tendons
170 and muscles. Rotator cuff integrity was evaluated according to Sugaya's classification[47,48] *(Figure 2,*
171 *Table 2).*

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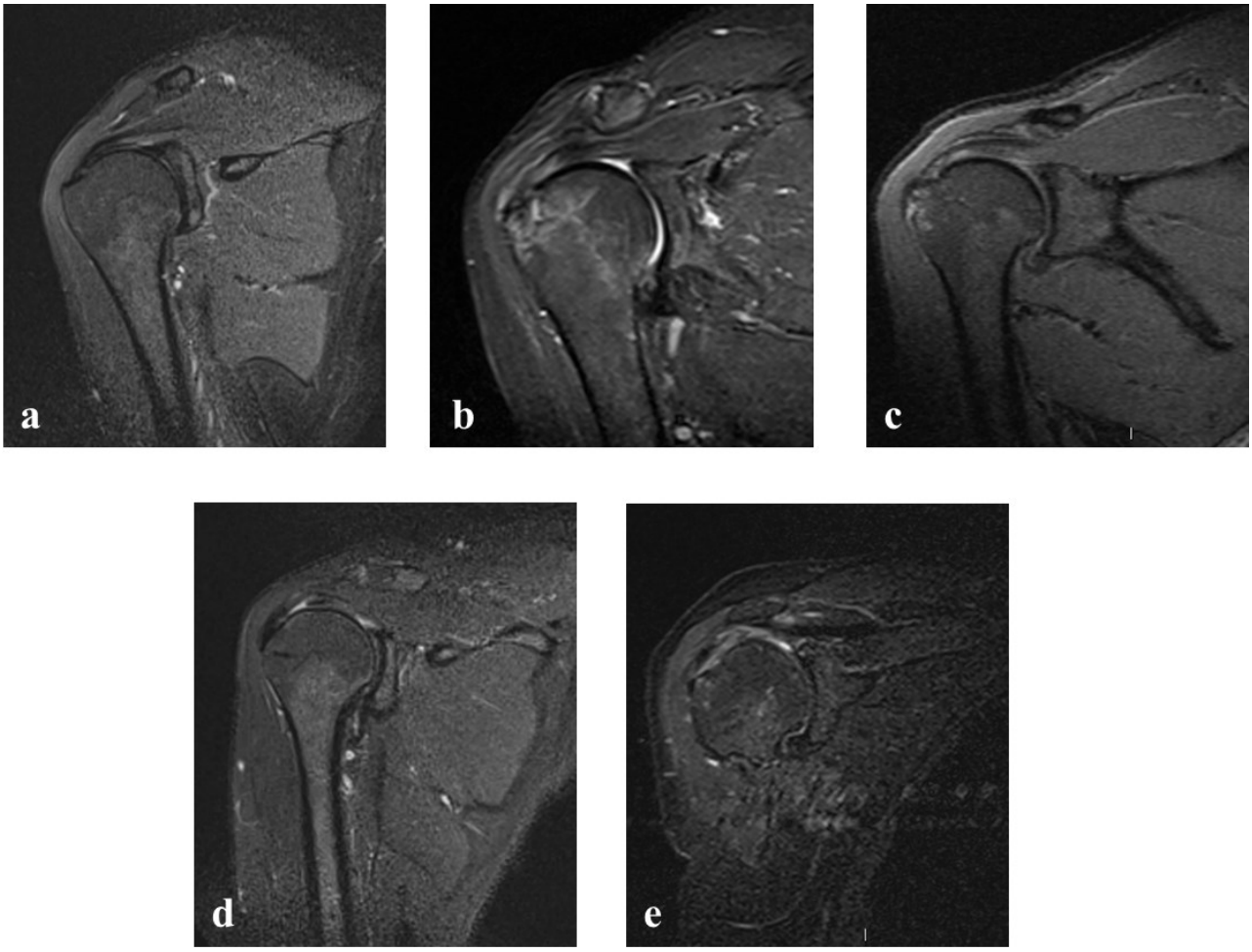

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Figure 2. Classification according to Sugaya et al[46]: a, type I; b, type II; c, type III; d, type IV; e, type V. See descriptions in Table 2.

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Table 2. Sugaya's classification criteria.

- Rotator cuff with sufficient thickness in comparison to normal rotator cuff and with homogeneous hypointense signal (type I)
- Rotator cuff with sufficient thickness in comparison to normal rotator cuff associated with partial areas of hyperintensity (type II)
- Insufficient thickness of rotator cuff, reduced to <50% compared to a healthy shoulder but without discontinuity. This picture suggests lesions with partial delamination (type III)
- Presence of minor discontinuities in one or two images, indicative of a small full-thickness lesion (type IV)
- Presence of major discontinuities observable in more than two images, suggestive of a medium or large full-thickness lesion (type V)

The same radiologist evaluated all images with no information on the patients' clinical evaluation.

Surgical technique

A single surgeon (P. R.), who was not involved in the clinical follow-up, performed all the operations. These were carried out with the patients in the lateral decubitus position with brachial plexus block and associated sedation (blended). The upper limb was kept at about 30° of abduction and 30° of flexion. The diagnostic arthroscopy was performed using an optic at 30° introduced by the posterior portal. Front and side portals were conducted using the outside-in technique.

Once the patient's tendon injury and eligibility had been confirmed, the subject was randomized into one of the two groups. The degree and type of tendon injury were then recorded.

In one of the two groups, the tendon was repaired using metal suture anchors REVO® and ThRevo® (Conmed, Utica, New York) with two and three suture wires, respectively. A standard single-row suture anchor repair has been used for this group. A *Tennessee Slider* knot was commonly utilized to fix the tendon *(Figure 3)*.

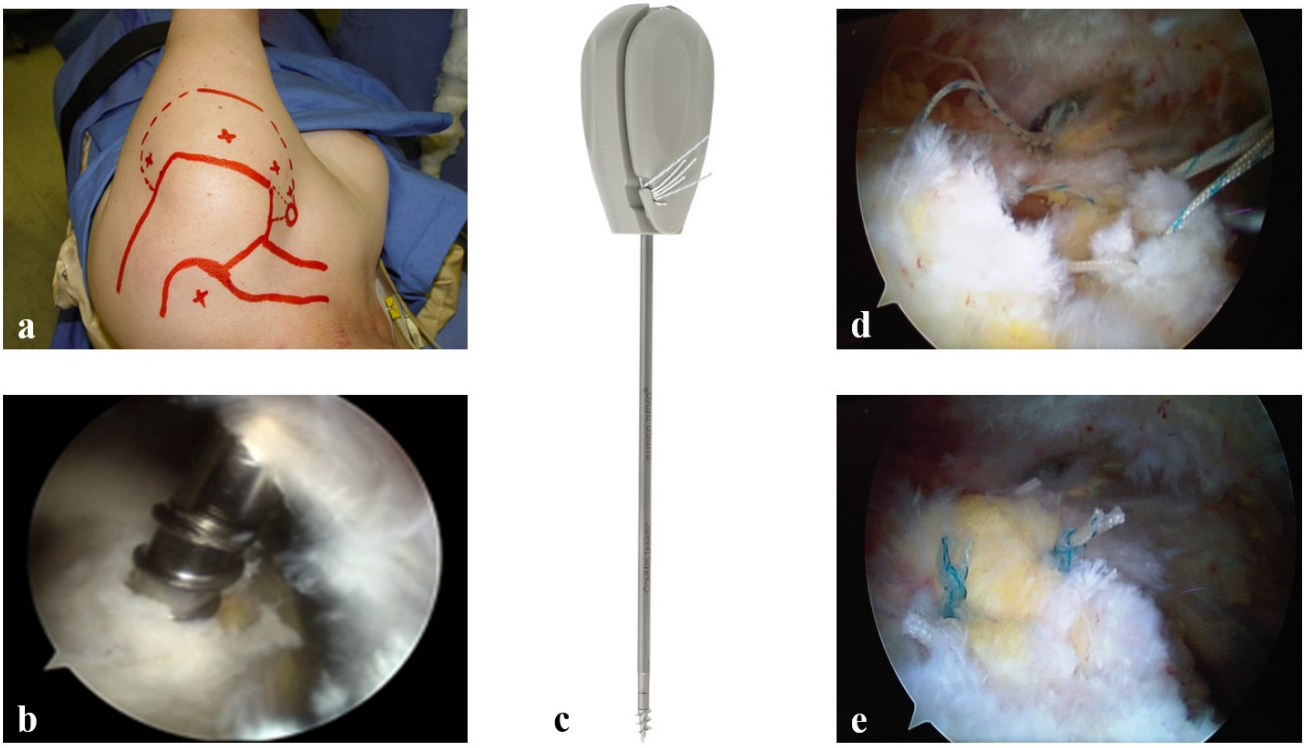

Figure 3. Arthroscopic anchor repair. a: portal placement for arthroscopic rotator cuff repair; b: insertion of the metal anchor in the humeral head; c: metal suture anchor ThRevo® (Conmed, Utica, New York); d: passage of the sutures into the tendon; e: final repair view.

In the other group, the rotator cuff was repaired using a transosseous technique, tunnelling the bone with the ArthroTunneler® arthroscopic transosseous tunnelling device (Tornier Inc., Edina, Minnesota). As a first step of this approach, a specific drill guide is inserted through an accessory lateral superior portal to create a 2.9-mm medial tunnel close to the articular margin. The hooked device (ArthroTunneler, Tornier, Edina, MN, USA) is introduced into the vertical drill tunnel. This device allows to obtain a 2.5 mm lateral tunnel, positioned 1.5 cm from the lateral edge of the greater tuberosity. Then, a shuttle suture is introduced by the ArthtroTunneler device into the lateral tunnel and retrieved from the medial tunnel. This suture shuttle will load the FiberWire® (Arthrex, Naples, FL, USA) sutures through the tunnel. The sutures, then, are loaded through the cuff using a suture passer. The suture configurations and the number of tunnels are finally determined depending on the shape of the tear *(Figure 4, 5)*.

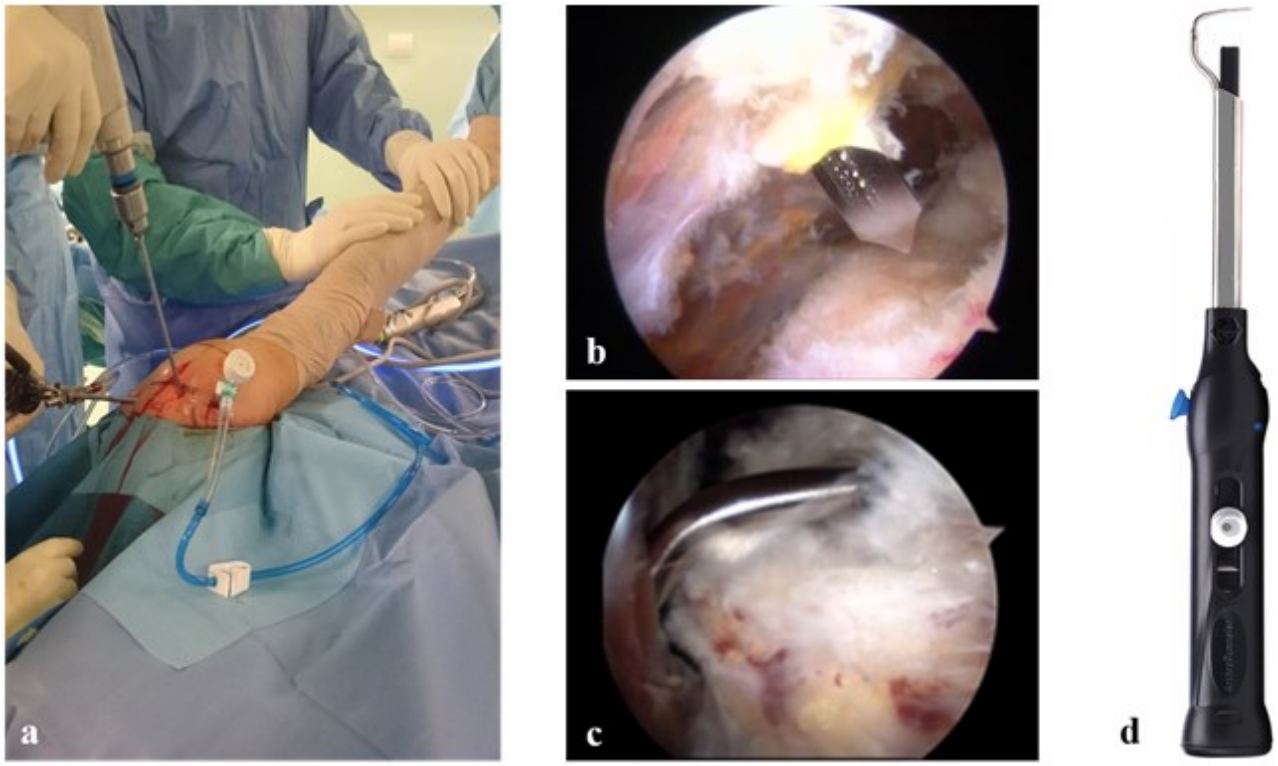

Figure 4. Arthroscopic transosseous repair. a, b: creation of the medial/vertical tunnel; c: insertion of the device in the medial tunnel and creation of an orizontal lateral tunnel; d: ArthroTunneler® arthroscopic transosseous tunnelling device (Tornier Inc., Edina, Minnesota, USA).

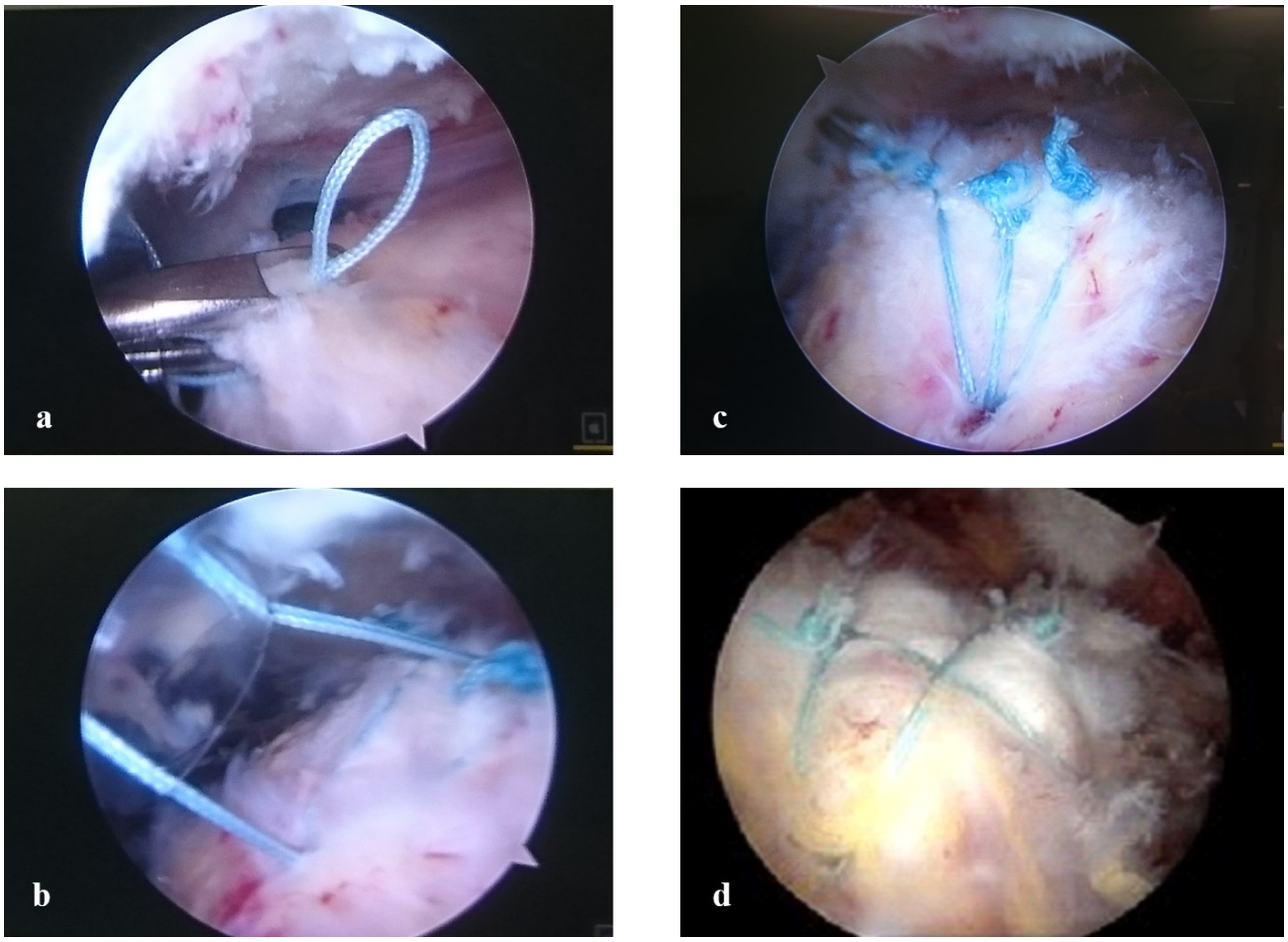

Figure 5. Arthroscopic transosseous repair. a: passage of wire through the tendon; b: repair with simple sutures; c, d: different possible final results: one tunnel with three suture knots and two tunnels with an X-box crossed configuration.

Acromioplasty with Sampson's technique was carried out in patients with type 2 or 3 acromial morphology according to Bigliani's classification. In cases of tendinopathy of the long head of the biceps, a tenotomy was performed.

Finally, surgical times for each surgery were collected.

Rehabilitation protocol

All patients enrolled wore an arm-sling day and night for 4 weeks after surgery, during that period the sling was removed only to eat and perform personal hygiene and light exercises of mobilization of the elbow and scapulo-thoracic joint. From the 29th day, unless otherwise indicated, patients began

passive physical therapy to recover the full range of motion of the shoulder joint. From the end of the 2nd month, patients started active physical therapy, lasting 4 weeks, to regain muscle strength.

RESULTS

The study population consisted of 39 (59%) women and 27 (41%) men with a mean age of 54.5 years (range, 38-65 years) and standard deviation of 6.75. The mean body mass index of the studied population was 25.7 (range, 17.6-33) with a standard deviation of 3.91. The shoulder repaired was on the dominant side in 46 (70%) cases and on the non-dominant side in the other 20 (30%) cases.
The mean preoperative dimensions of the lesions were 20.59 mm (range, 5-50 mm) for the anterior to posterior axis and 20.22 mm (range, 5-60 mm) for the medial to lateral side with standard deviations of 10.3 and 13.9, respectively. The mean surgery times were: 61.5 ± 16.2 min for the transosseous group and 53.7 ± 10.7 min for anchor technique. The difference, evaluated with t-test, was not significant (p-value 0.17). The follow-up period lasted, on average, 40 months (range, 31 – 46 months).
Table 3 shows the distribution of lesions according to the surgical technique and degree of tendon damage classified as proposed by Snyder.

Table 3. Distribution of types of lesion according to Snyder's classification and divided by surgical technique.

	C1	C2	C3	C4	Total
Anchor	11	12	5	7	**35**
Tunnel	3	11	7	10	**31**
Total	14	23	12	17	**66**

The Constant and QuickDASH scores at 15 months showed significant improvements in comparison with preoperative scores (*Table 4*). The median improvements in Constant values were 7.2 points in

the anchor repair group and 5.6 points in the group where the transosseous technique was adopted. The disability level decreased by 43.1 points in the anchor group and by 51.1 points in the transosseous group.

Table 4. Constant and QuickDASH results in each group.

	Preoperative	15 months follow-up	p-value
Constant			
Anchor	65.1 [54.9 - 72]	72.3 [67.1 – 79.6]	<0.001
Tunnel	64.3 [53.8 – 73.5]	69.9 [65.9 – 80.7]	0.0033
QuickDASH			
Anchor	45.4 [25 – 56.8]	2.3 [0 - 18.9]	<0.001
Tunnel	55.6 [47.2 – 72.2]	4.5 [0 – 15.9]	<0.001

Data are reported as median [Q1 - Q3].

At the 15 months follow-up pain scores had decreased from pre-operative values by 3.8 points and 4.5 points in the anchor and transosseous groups, respectively, which were both statistically significant reductions (p-values < 0.01) (*Table 5*).

Table 5. NRS results divided by surgical technique.

	Preoperative	15 months follow-up	p-value
Anchor	5.1 ± 2.6	1.3 ± 2.1	<0.001
Tunnel	5.7 ± 2.5	1.2 ± 1.8	<0.001

Data are reported as mean ± SD

At the final follow-up (40 months), the value of QuickDASH remained substantially stable, in comparison with the 15 months follow-up, for both the technique and the differences are not statistically significant (*Table 6*).

Table 6. QuickDASH results at final follow-up in each group

	15 months follow-up	Final 40 months follow-up	p-value
QuickDASH			
Anchor	2.3 [0 - 18.9]	2.3 [0 – 9.1]	0.29
Tunnel	4.5 [0 – 15.9]	2.3 [0 – 9.1]	0.39

Data are reported as median [Q1 - Q3].

There were no statistically significant differences between the two groups in terms of Constant (p-value = 0.25), QuickDASH (p-value = 0.52) and NRS (p-value = 0.91) values determined at the 15 months follow-up (*Table 7*). The some result for the QuickDASH at the final follow-up (p-value = 0.78).

Table 7. Mean values of the scores at 15 months follow-up.

	Anchor	Tunnel	p-value
Constant	72.3 [67.1 – 79.6]	69.9 [65.9 – 80.7]	0.25
QuickDASH	2.3 [0 - 18.9]	4.5 [0 – 15.9]	0.52
NRS	1.3 (± 2.1)	1.2 (± 1.9)	0.91

Data are reported as mean (± SD) or median [Q1 - Q3]

The analysis of postoperative pain, measured daily for 28 days after surgery, did not show a significant difference between the two techniques. Although mean NRS values were almost always lower after surgery with the transosseous technique than with the anchor technique, the differences in daily means between the two groups were not statistically significant (p-value min. 0.19 - 0.96 max).
However, the weekly mean value of NRS showed a significant difference in pain levels in favour of the transosseous technique in the third and fourth weeks after surgery (p-value = 0.02 and < 0.01, respectively) (*Table 8*).

Table 8. Weekly NRS values for the first 4 weeks after rotator cuff repair.

	Week I	Week II	Week III	Week IV
Anchor	5.45 ± 2.81	3.70 ± 2.77	3.00 ± 2.44	2.44 ± 2.41
Tunnel	5.45 ± 2.89	3.50 ± 2.68	2.46 ± 2.56	1.76 ± 2.31
p-value	0.99	0.43	0.02	<0.01

Data are reported as mean (± SD)

The evaluation at 2 months showed that 17 patients in the anchor group and 12 patients in the transosseous group had a stiff shoulder; this difference in frequency was not statistically significant (p-value = 0.42) (*Table 9*).

Table 9. Normal and stiff shoulders at 2 months after surgery.

	Stiff	Normal	Total
Anchor	17	18	**35**
Tunnel	12	19	**31**
Total	29	37	**66**

The mean NRS scores 2 month after surgery were not statistically different between the two groups, being 2.3 points in the anchor group and 1.4 points in the transosseous group (p-value = 0.11).

The distribution of degrees of rotator cuff integrity, evaluated by MRI at least 1 year after surgery, was substantially similar in the two groups (*Table 10*).

Table 10. Postoperative cuff integrity defined by Sugaya's classification.

Surgical technique	Sugaya's classification					Total
	I	II	III	IV	V	
Anchor	7 (20%)	17 (49%)	7 (20%)	3 (9%)	1 (3%)	**35**
Tunnel	5 (17%)	17 (57%)	4 (13%)	4 (13%)	0 (0%)	**30**
Total	**12 (18%)**	**34 (52%)**	**11 (17%)**	**7 (11%)**	**1 (2%)**	**65**

According to Sugaya's classification[47,48] at the assessment at least 1 year after anchor or transosseous repair, 69% vs 74%, respectively, of the rotator cuffs had sufficient thickness; 20% vs 13% of the rotator cuffs were intact with insufficient thickness and 12% vs 13% rotator cuffs had discontinuities and, therefore, different degrees of re-rupture.

Dichotomising the MRI results in terms of integrity/rupture[43] (Sugaya's classes I, II, III = intact; Sugaya's classes IV, V = re-ruptured), 88% of the anchor group and 87% of the transosseous group were intact. The difference in terms of re-rupture between the two groups was not statistically significant (p-value = 0.81). Furthermore, the difference in functional outcome between the intact and re-ruptured group (*Table 11*), expressed by the Constant and QuickDASH scores, revealed no differences (p-values = 0.57 and 0.56, respectively).

Table 11. Comparison between postoperative functional outcomes of patients with intact or re-ruptured rotator cuffs.

	Intact	Re-ruptured	p-value
Constant	70.1 [66.2 – 79.6]	69.4 [62.7 – 77.9]	0.57
QuickDASH	4.5 [0 – 13.6]	6.8 [0 – 27.3]	0.56
Power (Kg)	7.02 (± 3.33)	5.73 (± 3.19)	0.31
NRS	1.11 (± 1.85)	2.75 (± 2.49)	0.03

Data are reported as mean (± SD) or median [Q1 - Q3]

The difference in strength between patients with an intact rotator cuff and those with a re-ruptured rotator cuff (7.02 kg vs 5.73 kg, respectively) was not statistically significant (p-value = 0.31). However, the difference in pain between these two groups turned out to be statistically significant (p-value = 0.03) with a mean NRS score of 1.11 in the group of patients with intact rotator cuffs and 2.75 in the group with re-ruptured rotator cuffs.

No postoperative complications, except for re-tears, occurred during the study period.

DISCUSSION

The main finding of this first randomized controlled trial comparing the arthroscopic transosseous technique with the single-row suture anchor technique for rotator cuff repair is that the two techniques provide similar results with regards to MRI-assessed tendon healing and shoulder function. However, patients operated with the transosseous approach tended to have less postoperative pain in the third and fourth weeks after surgery. This trend appeared statistically significant. Overall, re-tear rates with both techniques were very low and scarcely associated with clinical performance.

Rotator cuff repair is based on the creation of a fibrovascular interface between tendons and bone, which is necessary for complete healing and tendon insertion reconstruction.[10] The two surgical techniques analysed in this study have different capacities to create ideal conditions for tendon healing. Compared with transosseous suturing, the use of anchors in a "single-row" configuration determines a stronger concentration of force vectors in suture passage areas and, consequently, greater circumferential tension forces on the tendon.[39,44] Furthermore, the transosseous technique allows the creation of a larger suture tendon contact area than that created during the anchor procedure, increasing the adhesion pressure at the footprint surface.[38] These two factors, combined with the stability of the tendon-to-bone interface, play key roles in obtaining a long-lasting repair.[29] These considerations regard "open" surgery, where transosseous tunnel repair is still considered the "gold standard".[41] Since arthroscopic transosseous repair has only recently been introduced, there are few

315 studies related to the biomechanical characteristics of this type of repair. Based on the results of a
316 controlled laboratory study, Kummer *et al*.[26] suggested that arthroscopic transosseous rotator cuff
317 repair with an X-box crossed suture configuration provides similar strength and stability to an
318 arthroscopic transosseous equivalent suture-bridge repair.
319 As reported by Spennacchio *et al*.[46], arthroscopic rotator cuff repair ensures good long-term results,
320 with clinical outcomes often being better than radiological results. This study confirms that surgical
321 rotator cuff repair leads to performance enhancement, evidenced by pain reduction and improvements
322 in Constant and QuickDASH scores.[1,13] Nevertheless, no significant differences in postoperative
323 clinical results were observed. These findings suggest that the biomechanical differences between
324 anchor and transosseous repair do not cause relevant disparities in healing capacity.
325 According to the daily assessments of pain for 4 weeks following surgery, postoperative pain was not
326 significantly different in the groups treated with the two techniques, although pain appeared to
327 decrease more rapidly following transosseous repair. However, when pain data were grouped by
328 week, patients treated with the transosseous procedure had significantly less pain in the third and
329 fourth weeks after surgery than did patients treated with anchors, while there was almost total
330 equivalence in the first 14 days. One possible explanation for these findings could be the similar
331 invasiveness of the surgical procedure for both techniques: in the early postoperative days,
332 inflammation/oedema and repair processes for the surgical wounds are almost equivalent, whereas
333 from the third week, it is possible that there is less pain with the transosseous technique because of
334 the absence of metal anchors in the bone. Another reason for the faster pain reduction could be the
335 improvement in the vascular pattern that may contribute to a better biological healing.[52]
336 The limitations of both techniques are well described in the literature. The main limitations of the
337 anchor procedure are: 1) difficulty of re-operation due to the presence of anchors in the greater
338 tuberosity; 2) possible mobilization of the anchors; 3) anchor impingement in abduction movements;
339 and 4) implant costs.[27] On the other hand, the limitations of transosseous repair are: 1) longer surgery
340 time; 2) need for surgeons who are very experienced in shoulder arthroscopic techniques; and 3) risk

341 of rupture of the cortical component of the tunnel's lateral margin, especially in elderly osteoporotic
342 patients[4,9]. Black *et al*.[6] evidenced this limitation in two patients, out of a group of 31, who had
343 intraoperative rupture of the lateral margin of the tunnel. The longer surgery time could be a
344 consequence of the learning curve in guide use[2] and, so, it could decrease in the future.
345 In our study, we did not find any clinical evidence of the limitations described above, further
346 supporting a substantial similarity between the two techniques.
347 Recently, a review paper regarding arthroscopic rotator cuff repair complications[40] evidenced that the
348 adverse events most frequently reported in literature are tendon re-rupture and non-healing. The
349 ranges of prevalence for these complications appeared to be very wide, also as a consequence of
350 preoperative differences in lesion size[7,34,54]: Galantz *et al*.[21] reported a 94% re-rupture rate at 2 years,
351 while Sugaya *et al*.[47] described 10% of negative cases following a "double-row" technique.
352 A review published in 2010, based on data from 1252 patients divided by surgical technique and
353 lesion size, quantified re-rupture frequencies at 1 year of follow-up after surgery for lesions less than
354 1 cm, between 1 and 3 cm, and greater than 4 cm as 18%, 31%, and 44%, respectively, following
355 "single row" anchor repair and 17%, 20% and 44%, respectively, after "open" transosseous repair.[19]
356 Regarding the transosseous arthroscopic technique, Kuroda *et al*.[27] reported a re-rupture rate of 6%
357 at 24 months and Flanagin *et al*.[20] a 3.7% failure rate at 38 months: while the former study used MRI
358 to assess the re-tear occurrence, the latter was based on clinical evaluation.
359 In our study, the overall re-rupture rate at a mean follow-up of 15 months was 13%, with 11% being
360 minor discontinuities and only 2% being medium-large, full-thickness lesions.
361 The values obtained are at the lower extreme of the previously defined broad range and in line with
362 the best case studies of healing. The difference in re-rupture frequency between the two procedures
363 is not statistically significant. This finding, which apparently does not match with the theoretically
364 better healing capacity offered by the transosseous technique,[51] is consistent with the findings of
365 empirical studies comparing the "open" transosseous technique with arthroscopic suture anchor
366 repair.[5,19]

Thus the causes of rotator cuff repair failure do not depend predominantly on different surgical technique but, rather, on reduced bone density, patient's age, size of the lesion, degree of fatty muscle belly infiltration, level of myotendinous retraction, and smoking.[7,11,13,14,35,37]

Although re-tears occur infrequently more than 3 months after rotator cuff repair[25], a possible limitation of this study is the lack of a radiological evaluation at 40 months follow-up. A difference in re-tear rates could become clearer over a longer time than that covered by the follow-up of this study[53], and the superiority of one technique over the other in term of healing capacity could therefore appear in the future with longer radiological evaluation. Nevertheless, the stability of QuickDASH score between the 15 months follow-up and the 40 months follow-up suggests that no more complications occurred in this period. A second limitation to our study may be that the assessment of lesion dimension was performed after the randomization process. This process resulted in a difference in lesion dimension distribution for the C1 type lesion, which are more represented in the anchor group. Another limitation is that massive retracted lesions and lesions that involved the subscapularis tendon were excluded from this study.

Confirming previous published data[30,42], this study underlines the poor link between rotator cuff repair failure and patients' functional impairment: there were no significant differences in Constant and QuickDASH scores between patients with intact rotator cuffs and patients with different levels of re-rupture.[24,28,48] However, according to Malavolta *et al*.[30], there is a significant difference in postoperative pain between patients with intact rotator cuffs and patients with full-thickness rotator cuff lesions.

Shoulder function can be preserved even in the presence of a tendon lesion, when this is not excessively extended, as proven by the fact that in the United States each year only 6% of patients with a full-thickness rotator cuff tear seek help from surgery.[18] The reduction of pain after surgical repair can, therefore, in itself provide a fundamental contribution to improving patients' quality of life.[5]

CONCLUSION

In this study we evaluated the results of arthroscopic transosseous repair compared to the single-row suture anchor repair.

In line with the assumptions of the study, the two procedures provided substantially equivalent results in terms of functional and radiological results. Given the similarity of outcomes of the two described techniques, it appears advisable to choose a treatment depending on other factors such as bone tissue quality, surgical experience, and operative costs. However, transosseous repair was found to be associated with faster pain reduction in the first postoperative month, with a more quick decrease in pain from the third week. Overall, the transosseous technique appears to offer similar results as single-row anchor repair in arthroscopic rotator cuff repair.

Conflict of Interest:

The authors declare that they have no conflicts of interest regarding this study.

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