

Two rotator cuff tear repair techniques for sovraspinatus tendon tear: transosseous sharc-ft vs single row repair

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Summary. *Background:* Despite rotator cuff repair techniques have developed significantly in last decade, pushed by the progress in technology and materials, the treatment of rotator cuff tears and re-tears is still a big challenge for shoulder surgeons. The aim of this study is to perform clinical and radiological evaluation (ultrasound and MRI) of patients treated with transosseous sharc-ft, and single row techniques for sovraspinatus rotator cuff tear at 6, 12 and 24 months follow up. *Methods:* Twenty-eight consecutive patients who underwent arthroscopic repair for rotator cuff tear were enrolled in the study and divided in two different groups: group A (14 patients) underwent a single row technique repair; group B (14 patients) underwent a transosseous sharc-ft technique repair. All participants had MRI or ultrasound examination confirmed full-thickness tears of sovraspinatus tendon before surgery. All the patients underwent clinical evaluation at 45 days, 3 months, 6 months, 12 and 24 months post-operatively with VAS, Dash, Constant and ASES score. Diagnostic ultrasound examination was performed at 6 months follow up while the MRI examination at 1 and 2 year follow up. *Results:* The whole primary variables didn't show any significant difference and the groups were homogenous (age, Goutallier fatty infiltration, VAS, DASH, Constant, ASES). Some statistically significant differences are visible at discrete variables in a specific time: Dash at 12 months and Constant at 24 months show a significant improvement versus single-row technique. *Conclusion:* The arthroscopic transosseous repair technique with sharc-ft showed excellent results with little significant statically difference between this technique and the single row for this kind of lesion after 1 year of follow-up. Clinical data from this study confirmed, with the help of ultrasound examination and MRI, the excellent clinical outcome obtained by the patients. Further studies are needed to find differences between these techniques in the repair of large and massive rotator cuff lesions. (www.actabiomedica.it)

Key words: rotator cuff repair, sovraspinatus, transosseous, arthroscopic repair

Introduction

Despite rotator cuff repair techniques have developed significantly in last decade, pushed by the progress in technology and materials, the treatment of rotator cuff tears and re-tears is still a big challenge for shoulder surgeons. Many authors have already ana-

lyzed the percentage of re-tear in rotator cuff repair comparing different type of suture techniques: single row (SR), double row (DR), transosseous equivalent (TE), showing a lower percentage in re-tear for TE or DR technique (1).

Recently Park et al have confirmed the better outcome of suture bridge (transosseous equivalent)

technique in rotator cuff repair reporting a lower percentage of re-tears at 6 months and a better clinical follow up in comparison to what reported by Miller in a previous study (2).

Transosseous repair technique of rotator cuff tear, in particular with the use of sharc-ft device, has already been studied from a biomechanical stand point showing better biomechanical performance in the extension of foot print coverage and contact pressure (3).

The aim of this study is to perform a clinical and radiological evaluation (ultrasound and MRI) of patients treated with transosseous sharc-ft and single row techniques for supraspinatus rotator cuff tear at 45 days, 3 months, 6 months, 12 and 24 months follow up.

Materials & Methods

Patients

From March 2014 to January 2016 twenty-eight consecutive patients who underwent arthroscopic repair for rotator cuff tear in the Orthopaedic and Traumatologic Department (Polyclinic University Hospital in Modena) were enrolled in the study and randomly divided in two different groups: group A (14 patients) underwent a single row technique repair (Table 1); group B (14 patients) underwent a transosseous sharc-ft technique repair (Table 2). All participants had MRI or ultrasound examination confirmed full-thickness tears of supraspinatus tendon before surgery. The indication for surgery was, in all cases, after failure of a non-operative management. All the patients signed informed consent before participating in the study. Tear size satisfying our inclusion criteria (3 cm in greatest dimension) was confirmed at the time of surgery in all patients under arthroscopic visualization. The tear size was the same among the two groups (in compliance with the inclusion criteria). Exclusion criteria were: tears of two or more tendons; massive tear more than 3 cm of dimension; subscapularis tendon tear; Goutallier classification more than 3; gleno-hu-

Table 1: preoperative data Group A

GROUP A																			
Preoperative data										Rotator cuff tear				Preoperative clinic					
History										Surgery									
N°	Patient	Age	Sex	Sport	Affected side	Dominant side	Treatment	Type	Deviat. protoc.	CLBB tenotomy	Acromionplasty	Form	Position	Patte Goutallier	VAS	DASH	Constant	ASES	
1	C.G.	58	F	no	sx	dx	02/04/14	Single-row	\	Yes	No	L	Superior	2	1	4	62,07	52	43,3
2	G.M.R.	68	F	no	dx	dx	04/06/14	Single-row	\	Yes	Yes	L	Superior	2	2	7	49,11	44	36,67
3	B.M	53	F	no	sx	dx	06/05/15	Single-row	\	No	Yes	L	Superior	1	1	6	10	72	72
4	C.D.	53	M	no	dx	dx	07/05/15	Single-row	\	No	Yes	L	Superior	1	1	9	25	63,5	43,3
5	N.A.	61	F	no	dx	dx	13/05/15	Single-row	\	Yes	Yes	U	Superior	1	1	6	71	23	20
6	M.C.	58	M	no	dx	dx	27/05/15	Single-row	\	Yes	Yes	U	Superior	1	1	5	72	6,5	70
7	M.A.	39	M	thay	dx	sx	22/07/15	Single-row	\	Yes	Yes	U	Superior	2	1	7	73	36	41,6
8	Z.M	54	F	no	dx	sx	09/09/15	Single-row	\	Yes	Yes	L	Anterior	1	1	4	31,25	66	56
9	B.R.	61	F	no	dx	dx	09/09/15	Single-row	\	Yes	No	U	Superior	1	1	3	43,33	61	58
10	Z.A.	59	M	no	dx	dx	24/09/15	Single-row	\	Yes	Yes	L	Anterior	2	2	4	47,5	47	46,9
11	A.R.	45	M	no	dx	dx	01/10/15	Single-row	\	No	Yes	U	Superior	2	2	0	23,33	65	61,3
12	G.C.	61	F	no	dx	dx	08/10/15	Single-row	\	No	Yes	U	Superior	1	1	5	37,17	58	62,3
13	C.G.	38	M	no	dx	dx	11/12/15	Single-row	\	No	Yes	L	Anterior	1	1	2	47,5	46	50
14	S.C.	50	F	no	dx	dx	08/01/16	Single-row	\	Yes	Yes	L	Superior	1	1	6	24,2	57	55
	AVERAGE	54												1,4	1,2	5	44	49,8	51,8

Table 2. preoperative data Group B

GROUP B																			
Preoperative data										Preoperative clinic									
History										Rotator cuff tear									
Surgery										Position									
N° Patient	Age	Sex	Sport	Affected side	Dominant side	Treatment	Type	Deviat. protoc.	CLBB	Acromioplasty	Form	Position	Patte	Goutallier	VAS	DASH	Constant	ASES	
1	D.M.	55	M	no	dx	05/03/14	Sharc-FT	\	Yes	Yes	L	Anterior	1	1	6	45	63	58,33	
2	B.R.	61	F	no	sx	07/05/14	Sharc-FT	\	Yes	Yes	L	Anterior	2	1	6	29,31	47	48,33	
3	B.M.	60	F	no	dx	18/06/14	Sharc-FT	\	Yes	No	L	Superior	2	2	5	57,41	42	40,01	
4	M.T.	62	M	no	dx	29/10/14	Sharc-FT	\	Yes	Yes	L	Superior	1	1	8	53,5	28	23,35	
5	P.A.A	48	F	no	dx	03/12/14	Sharc-FT	\	No	Yes	L	Superior	2	1	7	34,2	37	35	
6	T.L.	60	F	no	dx	23/04/15	Sharc-FT	\	Yes	Yes	L	Superior	1	2	6	51	45	42	
7	R.B.	64	F	no	dx	23/04/15	Sharc-FT	\	Yes	Yes	L	Superior	1	2	7	57,8	33	27	
8	B.F.	57	M	no	sx	19/05/15	Sharc-FT	\	Yes	Yes	L	Superior	1	1	2	3	84	85	
9	M.L.L.	54	F	no	dx	04/06/15	Sharc-FT	\	No	No	U	Superior	1	1	4	62	26	43,3	
10	V.G.	58	M	tennis	dx	12/08/15	Sharc-FT	\	No	Yes	L	Anterior	1	1	0	17,5	75,5	81,6	
11	M.M.	44	M	no	dx	16/09/15	Sharc-FT	\	Yes	Yes	L	Anterior	1	1	4	40	58	56	
12	O.M.	59	M	no	dx	24/09/15	Sharc-FT	\	Yes	No	U	Superior	1	1	0	0	90	89	
13	F.E.	60	F	no	dx	02/12/15	Sharc-FT	\	No	yes	L	Anterior	2	1	3	57,69	61	58,3	
AVERAGE													57	1,3	1,2	4	39,1	53	52,9

meral arthritis; neurologic lesion; acromion-clavicular disease; metabolic disease; smoke habit more than 20 cigarettes per day.

Surgery

The same experienced shoulder surgeon performed all rotator cuff repairs. All procedures were performed with the patient under general anesthesia and supplemented with a preoperative interscalene block placed under ultrasound guidance.

Sovraspinatus tendon repair was performed using the single row (group A) or the transosseous technique (group B) previously described by Pellegrini et al (Fig. 1) (4).

All patients were immobilized after surgery using an abduction sling for 3 weeks (Donjoy Ultrasling III AB 45°, DJ Orthopedics, LLC, Vista, California) and after this initial phase a standardized supervised physical therapy protocol was initiated (Fig. 2). Patients were instructed to remove the abduction sling only for daily bathing and dressing needs during the first 3 weeks after surgery, and passive range of motion, excluding pendulums, was not permitted during this period. The rehabilitation protocol included pas-

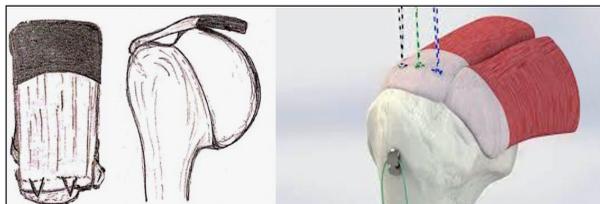


Figure 1. comparison between single-row technique vs. Sharc-ft technique

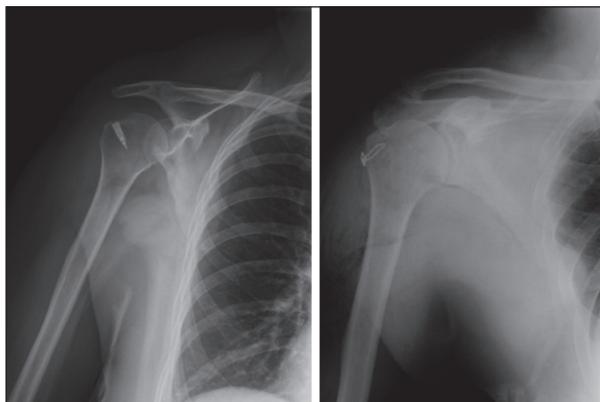


Figure 2. post-operative X-Ray: anchor vs. Sharc-ft

sive range of motion from weeks 2 to 6, with active and active-assisted range of motion thereafter. A focused strengthening program was initiated at week 10.

Clinical evaluation, Ultrasound and MRI

All the patients underwent clinical evaluation at 45 days, 3 months, 6 months, 12 months and 2 year post-operatively with VAS, Dash, Constant and ASES score (5-7).

Diagnostic ultrasound examination was performed at 6 months follow up while the MRI examination at 1 and 2 year follow up.

Ultrasound examination was performed using ultrasound scanner (Model iU22 Philips) with linear high-frequency probe (L12-5 MHz). A tendon was considered not torn if at ultrasonography continuous and stretched fibers over the humeral head and no alteration of ultrasound signal was visualized (8;9).

At the time of 12 months and 24 months follow up, all the patients underwent an MRI evaluation with a 1,5 Tesla MRI in order to evaluate the footprint coverage and the integrity of the tendon repaired. The tendon evaluation was performed according to Sugaya et al classification (10).

In addition, X-ray examination of the shoulder was performed in true AP and axillary projection. Authors look for osteolytic lesion around suture device, suggestive for device mobilization.

Statistical analysis

MATLAB software (MathWorks, Natick, MA, USA) was used to perform statistical analysis of data. The normal distribution of the data was checked and one-way repeated ANOVA or the nonparametric Friedman test was used to evaluate the effect of the repair. Sample size was calculated with the aim to achieve a minimum beta value higher than 0.8 statistical power ($\alpha = 0.05$) for scores data analysis; 13 cases were calculated as an adequate number (1 standard deviation was set to consider the difference as statistically significant). Because of the possibility of drop-out, a higher number of patients were included in the study (i.e. 14 patients). A multiple-comparison test was used for pairwise post hoc analyses. Data analysis was applied to evaluate homogeneity between groups involved in the study and single scores have been com-

pared at different timing.

A two-tailed p value < 0.05 was considered significant.

Results

One patient of group B was excluded from the study for personal reason. The T-Student test used for statistical analysis showed no differences ($P > 0,05$) in the two groups of patients enrolled in terms of pre study evaluation (Age, Goutallier fatty infiltration, tendon retraction, VAS, DASH, ASES and Constant score collected before the study). The whole primary variables didn't show any significant difference and the groups were homogenous.

Group A

This patient group underwent single row technique repair; the mean age was 54 years (min 38 – max 68). The 14 patients were 8 women and 6 men; for 10 patients the shoulder was the dominant side. Nine patients underwent biceps tenotomy and 12 patients acromioplasty. The supraspinatus tear was L-shape tear for 8 patients and U-shape in the other 6.

At the time of 45 days after surgery the clinical follow up showed a VAS value of 5.3, a Dash score of 43.2 a Constant score of 39.5 and an ASES score of 41.

At 90 days of follow up the Group A patients had a VAS value of 3.6, a Dash score of 26.7 a Constant score of 60.8 and an ASES score of 65.5.

At 6 months the clinical data collected were: VAS value of 2.1, a Dash score of 21.3 a Constant score of 62.7 and an ASES score of 71.5. In ultrasound examinations authors found no case of re-tear at 6 months of follow up confirmed by the good to excellent clinical outcome emerged with the scores collected (table 1). Moreover, at X-ray examination authors find no osteolytic lesion.

At 1 year follow-up the patients had a VAS value of 1.7, Dash score of 13.2, Constant score of 75 and an ASES score of 80.3. Authors find a re-tear with the MRI evaluation. (Fig. 3).

At 2 years clinical examination showed a VAS value of 1.5, Dash score of 9.1, Constant score of 78.6

and an ASES score of 83. The patients enrolled in the study underwent the MRI control showing same results already collected in the previous MRI control. The patient with re-tear confirmed by poor clinical outcome asked for a new surgical approach (Table 3).

Group B

This patients group underwent transosseous shark-ft technique repair; the mean age was 57 years (min 44 – max 64). The 13 patients were 7 women and 6 men; for 11 patients the shoulder affected was the dominant side. Nine patients underwent biceps tenotomy and 10 patients acromionplasty. The sovraspinatus tear was L-shape tear for 11 patients and U-shape in the other 2.

At the time of 45 days after surgery the clinical follow up showed a VAS value of 4.7, a Dash score of

42.8 a Constant score of 37.7 and an ASES score of 37.82.

At 90 days of follow up the Group B patients had a VAS value of 2.8, a Dash score of 22.6 a Constant score of 64.5 and an ASES score of 71.4.

At 6 months the clinical data collected were: VAS value of 1.2, a Dash score of 12.8 a Constant score of 73.5 and an ASES score of 78.6. In ultrasound examinations authors find no case of re-tear at 6 months of follow up confirmed by the good to excellent clinical outcome emerged with the scores collected (table 2). Moreover at X-ray examination authors found no osteolytic lesion (Fig. 4).

At 1 year follow-up the patients had a VAS value of 0.9, Dash score of 3.5, Constant score of 82.5 and an ASES score of 85; none of the Group B cohort had re-tear at radiological examination with MRI.

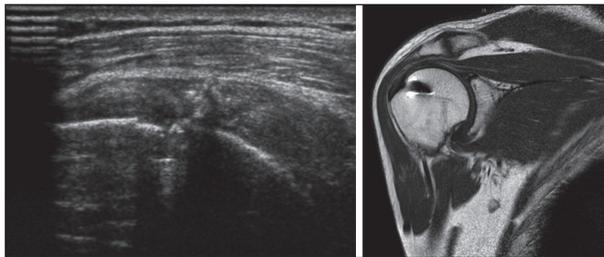


Figure 3. Ultrasound evaluation at 6 months and MRI evaluation at 24 months for patient treated with screw fixation (group A)

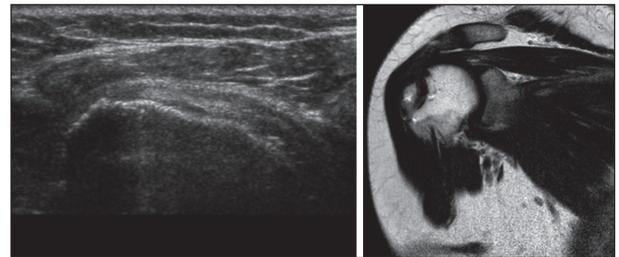


Figure 4. Ultrasound evaluation at 6 months and MRI evaluation at 24 months group B.

Table 3. clinic evaluation Group A at 24 months

GROUP A											
N°	Patient	Clinic evaluation 24 months				MRI					
		VAS	DASH	Constant	ASES	Healing	Re-tear	Sugaya	Goutallier	Complications	Other
1	C.G.	5	61,2	49,5	43,3	NO	YES	5	3	Pain	\
2	G.M.R.	0	0	88	90	YES	NO	1	0	NO	\
3	B.M	0	1	92	98	YES	NO	1	0	NO	\
4	C.D.	2	1,7	84	90	YES	NO	1	1	NO	\
5	N.A.	1	12,4	68	70,3	YES	NO	3	1	NO	\
6	M.C.	2	5,8	74	81,6	YES	NO	2	0	NO	\
7	M.A.	0	4,2	82	96,6	YES	NO	1	0	NO	\
8	Z.M	1	5,8	76	88,3	YES	NO	1	0	NO	\
9	B.R.	1	2,9	85	93,3			NOT PERFORMED			
10	Z.A.	6	20,6	55	60	YES	NO	1	0	NO	AC arthritis
11	A.R.	1	0,8	93	90			NOT PERFORMED			
12	G.C.	0	0	85	86,3	YES	NO	1	0	NO	\
13	C.G.	2	2,5	91	78,9	YES	NO	1	0	NO	\
14	S.C.	0	8,6	78	94,9			NOT PERFORMED			
								11 MRI, 91% healing			
								1 AC arthritis, 9%			
AVERAGE		1,5	9,1	78,6	83,0			1,6	0,5		

At 2 years clinical examination showed a VAS value of 0.9, Dash score of 2.9, Constant score of 87.1 and an ASES score of 89.4. The patients enrolled in the study underwent the MRI control showing same results already collected in the previous MRI control (Table 4).

To summarize the data comprehension we evaluate from a statistical standpoint the various variables as a function of time. We used a two-sample t-test procedure and the null hypothesis, intended as the difference between two population means is equal to zero ($H_0: m_1 - m_2 = 0$) and tests it against an alternative hypothesis two-tailed ($m_1 - m_2 \neq 0$). If the test's p-value is less than the chosen significance level 0,05, we reject the null hypothesis. (tab 5). Some statistically significant differences are visible at discrete variables in a specific time: Dash at 12 months and Constant at 24 months show a significant improvement versus single-row technique.

Discussion

Rotator cuff tears are usually associated with pain, weakness and loss of function. In particular this kind

of lesions occur both in heavy worker population as well as sedentary people leading to poor autonomy in daily activities and frequently to an important social cost. Moreover, repair technique for these lesions are usually difficult and associated with a re-tear rate.

One report published in 2007 involved a prospective series of 106 patients with rotator cuff tears repaired using a double-row technique (11); Although the overall re-tear rate was 17%, the re-tear rate in large to massive rotator cuff tears was 40% on MRI. In the same year, the re-tear rate of large to massive tears was reported to be 17% using the double-row technique (11). Huijsmans et al reported a failure rate in double-row repairs of large to massive cuff tears of 36% on ultrasonography (12).

Table 5. statistical analysis of various variables as a function of time

Timing	45 days	3 months	6 months	12 months	24 months
	p-value	p-value	p-value	p-value	p-value
VAS	0,577	0,580	0,268	0,280	0,346
DASH	0,962	0,602	0,147	0,036	0,176
Constant	0,776	0,529	0,133	0,079	0,050
ASES	0,608	0,354	0,218	0,159	0,188

Table 4. clinic evaluation Group B at 24 months

GROUP B											
Clinic evaluation 24 months						MRI					
N°	Patient	VAS	DASH	Constant	ASES	Healing	Re-tear	Sugaya	Goutallier	Complications	Other
1	D.M.	1	5,4	86,5	88	YES	NO	1	0	NO	\
2	B.R.	0	1,7	73,5	79,6	YES	NO	1	0	NO	\
3	B.M.	0	1,8	88	93	YES	NO	1	1	NO	AC arthritis
4	M.T.	0	1,7	85	86,6	YES	NO	1	0	NO	AC arthritis
5	P.A.A	1	1,7	89	93,3	YES	NO	1	0	NO	\
6	T.L.	3	5,8	88	76,6	YES	NO	1	0	NO	AC arthritis
7	R.B.	0	0,8	95	100	YES	NO	1	1	NO	AC arthritis
8	B.F.	0	0,8	96,6	100	YES	NO	1	0	NO	\
9	M.L.	3	1,7	90	85,6	YES	NO	1	0	NO	AC arthritis
10	V.G.	0	0,8	89	100	YES	NO	1	0	NO	\
11	M.M.	0	1,2	97	92,6	YES	NO	1	0	NO	\
12	O.M.	2	2,5	77	86,6	YES	NO	1	0	NO	\
13	F.E.	2	7,5	78	80	YES	NO	1	0	NO	AC arthritis
						13 MRI, 100% healing					
						6 AC arthritis, 45%					
AVERAGE		0,9	2,9	87,1	89,4			1,0	0,2		

The above cited studies were performed using arthroscopic double-row repair. On the other hand, several studies have employed arthroscopic suture bridge repair. One study in 2008, 25 patients who had undergone arthroscopic suture bridge repair at a mean follow-up of 14.61 months and MRI resulted in 88% of repairs healed; however, massive tears cases in that study were only 3 (13).

This study is the first in literature evaluating re-tear after transosseous repair technique with the use of *sharc-ft* for rotator cuff repair; authors opted for using ultrasound examination at 6 months follow-up as previously reported in many papers (1,2) supported by Codsi (14). In the community setting, ultrasound may be used to evaluate the integrity of a repaired rotator cuff tendon and represents a comparable alternative to MRI when evaluating the integrity of a rotator cuff repair (14).

Both diagnostic ultrasound and magnetic resonance imaging (MRI) are used for investigation of the presence and severity of rotator cuff lesions. There is no consensus as to which is the more accurate and cost-effective study. Shoulder ultrasound has the advantage of being relatively inexpensive and widely available and permits dynamic imaging. However, several papers have reported wide variability in the ability of ultrasound to accurately differentiate between partial thickness and full-thickness rotator cuff tears, particularly between observers (15-17). For this reason the authors choose to follow the patients at 1 and 2 year after surgery with the MRI evaluation.

Rutten MJ et al. (2010) refuted the hypothesis that ultrasound of the shoulder is operator-dependent and related to experience. In this study, there was excellent agreement for the detection of rotator cuff tears, which only slightly improved with the increasing experience of the general radiologist. Accuracy of rotator cuff tear detection was high and in accordance with the results in the literature (18).

In our study the whole primary variables didn't show any significant difference and the groups were homogenous (age, Goutallier fatty infiltration, VAS, DASH, Constant, ASES). Some statistically significant differences are visible at discrete variables in a specific time: Dash at 12 months and Constant at 24 months show a significant improvement versus single-row technique. The MRI evaluation at 1 year follow up

shows, moreover, how the transosseous techniques can help the evaluation of tendon repair avoiding the screw interference and bone edema around the screws.

The transosseous approach has been known as a valid repair strategy. Over time, various criticisms were made about this technique mainly ascribable to two main categories: technical difficulties mainly related to the reproducibility in an arthroscopic environment and stability of the construct (in the suture-bone contact area).

The authors believe that the problems above described can be solve in a transosseous approach by interposing a device isolating sutures from bone (*Sharc-Ft*®). With this new approach, a direct impingement is avoided and, in the closed ring configuration, the contact pressure is mitigated and the risk of local bone damage reduced. This also prevents the user to know the value of bone density (3). As reported by Baudi et al, transosseous repair with *sharc-ft* had good to excellent clinical outcome at one year follow-up but the rate re-tear was not investigated in that study (19).

The transosseous techniques can also help in the re-tear patients treatment avoiding the step of screw removal or the use of new screws.

Conclusion

Results from this study confirmed with the help of ultrasound examination and MRI the excellent clinical outcome obtained by our patients. Despite of the limited number of subjects, all patients involved in the study were affected by rotator cuff with a *sovraspinatus* tear less than 3 cm, therefore creating a homogeneous group of patients confirmed with statistical analysis. Furthermore, few studies in literature have the support of an MRI evaluation to confirm the re-tear percentage of the previous tendon repairs.

The arthroscopic transosseous repair technique with *sharc-ft* shown excellent results with little significant statically difference between this technique and the single row for this kind of lesion starting from 1 year follow up.

Further studies are needed to find differences between these techniques in the repair of large and massive rotator cuff lesions.

Compliance with Ethical Standards: No founding for this study. Conflict of Interest: Authors have no conflict of interest. Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent: Informed consent was obtained from all individual participants included in the study.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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