



## Comparative Study of the Functional and Clinical Outcomes of Two Different Rotator Cuff Repair Techniques: Suture Anchor versus Transosseous Sharc-FT

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### ABSTRACT

**Aim:** The aim of the present study was to compare the functional and clinical outcomes of suture anchor and transosseous Sharc-FT fixation options in mini-open repair of rotator cuff tears.

**Material and Methods:** Between January 2010 and July 2016, 60 patients were operated on in the Orthopedics and Traumatology Clinics of Duzce University Hospital and Duzce State Hospital. Thirty patients in whom repair was performed with suture anchor (Group 1) and 30 patients in whom repair was performed with Transosseous Sharc-FT® (Group 2) were compared. Preoperative and postoperative shoulder ranges of motion, the visual analog scale scores, constant shoulder scores, Oxford shoulder scores, and Q-DASH shoulder scores were evaluated in Group 1 and Group 2 patients.

**Results:** A total of 62% of the participants were male and 38% were female. Gender distribution was homogeneous in both groups (P=0.426). The mean age of the subjects was 57.35 ± 8.69 (41-78) years. No significant difference was noted between the groups in terms of mean age (P=0.232). On the basis of the post-hoc test results, the postoperative constant score was significantly higher in Group 2 compared with that in Group 1 (P<0.001).

**Conclusion:** Rotator cuff repair using transosseous Sharc-FT fixation material provides tighter stability compared with suture anchor and has superior functional, radiological, and pain scores. Furthermore, early rehabilitation is another advantage of using Transosseous Sharc-FT in patients who prefer undergoing rotator cuff repair over other fixation options.

**Keywords:** Rotator cuff tears; transosseous suture; single-row suture.

## Rotator Manşet Onarımında İki Farklı Tekniğin Fonksiyonel ve Klinik Sonuçlarının Karşılaştırmalı Olarak İncelenmesi: Sütür Ankor ve Transosseöz Sharc-FT

### ÖZ

**Amaç:** Bu çalışmada, rotator manşet yırtıklarında sütür ankor ve transosseöz sharc-FT fiksasyon seçeneklerinin mini-açık onarımının fonksiyonel ve klinik sonuçlarını karşılaştırmayı amaçladık.

**Gereç ve Yöntemler:** Ocak 2010 - Temmuz 2016 arasında Düzce Üniversitesi Hastanesi Ortopedi ve Travmatoloji Kliniğinde ve Düzce Devlet Hastanesi Ortopedi ve Travmatoloji Kliniğinde Ocak 2010 - Temmuz 2016 tarihleri arasında 60 hasta ameliyat edildi. 30 hasta sütür ankor (grup 1) ile tamir edilen ve 30 Transosseöz Sharc -FT® (grup 2) ile ameliyat edilen hastalar karşılaştırıldı. Preoperatif ve postoperatif omuz hareket açıklığı, VAS skoru, Constant omuz skoru, Oxford omuz skoru ve Q-DASH omuz skoru grup 1 ve 2 hastada değerlendirildi.

**Bulgular:** Katılımcıların %62'si erkek, %38'si kadındı. Gruplara göre cinsiyet dağılımı homojendi (P=0,426). Deneklerin yaş ortalaması 57,35 ± 8,69 (41-78) idi. Gruplar arasında yaş ortalaması açısından anlamlı fark yoktu (P=0,232). Post-hoc testine göre, ameliyat sonrası Constant skoru Grup 2'de Grup 1'den anlamlı olarak yüksek bulundu (P<0,001).

**Sonuç:** Transosseöz Sharc-FT fiksasyon malzemesi ile rotator manşet onarımının, sütür ankor'a göre sıkı stabilite sağladığı ve üstün fonksiyonel, radyolojik ve ağrı skorlarına sahip olduğu sonucuna vardık.

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Ayrıca, erken rehabilitasyonun Transosseöz Sharc-FT kullanılarak diğer tespit seçeneklerine göre rotator manşet onarımı geçiren hastalar için bir avantaj olduğu sonucuna vardık.

**Anahtar Kelimeler:** Rotator manşet yırtığı; transosesöz dikiş; tek sıra dikiş.

## INTRODUCTION

Arthroscopic, open, or mini-open rotator cuff repair is a common orthopedic procedure with a high success rate in terms of patient satisfaction and functional recovery. According to Gerber et al., an ideal repair has high fixing strength, minimal gap formation, and sufficient mechanical balance for tendon-bone healing (1). Initially, all rotator cuff repairs were performed openly, and single-row fixation was used after transosseous bone tunnels were discovered (2-4). With the advances in arthroscopic repair procedures, old fixation suture anchor repair techniques have been replaced with transosseous repair techniques. Arthroscopic rotator cuff repair has become more popular in recent years and satisfactory results have been reported by several authors (5,6). Potential advantages include less postoperative pain, very low deltoid morbidity, and faster rehabilitation. Despite these advantages, this procedure is technically difficult and requires a lot of practice for a surgeon to become competent (7,8). Furthermore, despite the advances in instrumentation and surgical techniques, there remains a 20%–60% risk of rupture (7-9). Although arthroscopic rotator cuff repair techniques continue to evolve, no single-best arthroscopic method has been identified so far, and open transosseous rotator cuff repair techniques remain the gold standard for tendon healing (10). Although many treatment methods are used in rotator cuff repair, independent of the surgical approach (e.g., open repair, mini-open repair [deltoid split separation], and arthroscopic repair), transosseous techniques have provided better functional reconstruction and lower pain compared with other methods (11-13). There are a variety of device options for applying a transosseous technique, such as bone needle or ArthroTunneler™ (14, 15). Sharc-FT® (NCS Lab Srl, Modena, Italy), a novel implantable transosseous device, was designed for rotator cuff surgery using a special instrument, Taylor Stitcher. Recently, we have published satisfactory clinical and functional outcomes of our patients undergoing deltoid-splitting rotator cuff repair using this new transosseous device (16). The aim of the present study was to compare the clinical and functional outcomes of transosseous repair and single-row suture anchor repair in mini-open rotator cuff repairs.

## MATERIAL AND METHODS

The study was approved by the Duzce University Clinical Research Ethics Committee (Duzce, Turkey) (No. 2016/62, 27 June 2016). The study was conducted in accordance with the principles of the Helsinki Declaration. Informed consent was obtained from the parents/guardians of the patients included in the study. This is a retrospective, non-randomized, comparative study of a series of consecutive patients who underwent rotator cuff repair between January 2010 and July 2016 in two hospitals (Duzce State Hospital and Duzce

University Faculty of Medicine Hospital). All data were prospectively recorded and retrospectively analyzed.

The following patients were included: Patients with full-thickness rotator cuff tear (RCT), no previous shoulder surgery, and no previous shoulder infection.

The following patients were excluded: Patients with glenohumeral instability, arthritis, and stiffness were excluded from the study.

It was decided to recruit a total of sixty patients to obtain clinically and statistically significant difference in accordance with the study with a 5% significance level, 80% power and an effect size of 0.32. After exclusion criteria were applied, the shoulders included in the study were divided into suture anchor repair group (n=30 patients) and transosseous Sharc-FT repair group (n=30 patients). All patients were evaluated for range of motion and follow-up scores preoperatively, at 3 and 6 months postoperatively, and at the final follow-up. The visual analog scale (VAS) score, constant score, Oxford shoulder score, and Q-DASH shoulder score were used for pain and function.

### Surgical Procedure

All patients were prepared for surgery in the chaise-longue position. A mini-open skin incision was performed using a longitudinal incision from the lateral side of the acromion (Figure 1). The trans-deltoid approach was used to access the rotator cuff. The rotator cuff adhesion site was prepared by removing the cortical bone. The flexibility of the rotator cuff was checked and then was mobilized. The fixation of tendon on the bone was performed with transosseous repair or single-row suture anchor repair.



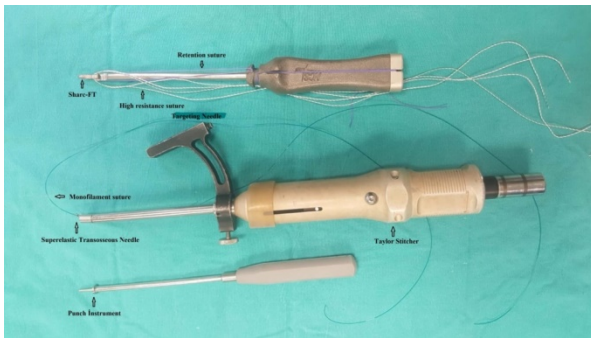
**Figure 1.** The skin marked for deltoid-splitting incision approximately 3 cm.

Transosseous repair: The repair was performed with a transosseous needle (Taylor Stitcher elastic needle) and the rotator cuff was fixed to the adhesion site. The fixation implant (Sharc-FT) was applied 2-cm distal to the tubercle majus to repair the rotator cuff footprint. Distal and proximal sutures were tied to each other and double-row transosseous repair was performed (Figure 2A). The transosseous needle (Taylor Stitcher elastic

needle) and fixation implant (Sharc-FT) used for rapid transosseous repair are shown in Figure 2B.



**Figure 2A.** Full-thickness rotator cuff was repaired with novel transosseous device (Sharc-FT).



**Figure 2B.** The implantable device (Sharc-FT) applied with punch, Taylor Stitcher with superelastic transosseous needle.

Single-row suture anchor repair: The size, location, and severity of the torn tendon were evaluated and the torn margin gap and larger tuberosity was carefully smoothed. Since the torn tendon was labeled with traction sutures after removing the hypertrophic bursal tissue around the separated area to improve visualization, we confirmed the involvement and configuration of the torn tendon by rotating the arm and tried anatomical reduction on the footprint of the larger tuberosity. After the footprint was prepared using a ring curette or file, the torn tendon was repaired with single-row suture anchor technique. X-rays were obtained in both groups postoperatively (Figures 3A, B).

#### Statistical Analysis

The data were statistically analyzed using SPSS 22. Descriptive statistics (mean, standard deviation, median, minimum, maximum, and interquartile range-IQR) were calculated for all the data obtained. The normality of quantitative variables was examined using the Shapiro-Wilk test. Independent samples t test and Mann-Whitney U test were used for comparisons between groups. When comparing measurements at different time periods between the groups for score variables that were not

normally distributed, parameter estimations were obtained by applying the Generalized Estimating Equations method (Gamma with log link; post hoc: LSD). Pearson Chi-Square test was used for investigating the relationships between categorical variables.  $P < 0.05$  was considered statistically significant in all analyses.



**Figure 3A.** Postoperative transosseous Sharc-FT radiography.



**Figure 3B.** Postoperative Suture anchor radiography.

#### RESULTS

Of all participants, 62% were male and 38% were female. Gender distribution was homogeneous between groups ( $P=0.426$ ). The mean age of the subjects was  $57.35 \pm 8.69$  (41-78) years. No significant differences were noted between the groups in terms of mean age ( $P=0.232$ ). Mean follow-up period was significantly higher in Group 1 compared with that in Group 2 ( $P=0.008$ ). Other clinical characteristics of the patients are provided in Table 1 in detail.

**Table 1.** Demographic data of patients

		Group									p
		1			2			Total			
		n	R %	C %	n	R %	C %	n	R %	C %	
Gender	Male	13	56.5	43.3	10	43.5	33.3	23	100	38.3	0.426
	Female	17	45.9	56.7	20	54.1	66.7	37	100	61.7	
Side	Right	26	56.5	86.7	20	43.5	66.7	46	100	76.7	0.067
	Left	4	28.6	13.3	10	71.4	33.3	14	100	23.3	
Follow-up Period *		30.87±18.28 (2-60)			18.37±5.40 (2-60)			24.62±14.78 (2-60)			0.008
Age *		58.70±8.46 (41-78)			56.00±8.84 (43-76)			57.35±8.69 (41-78)			0.232

\* Mean ± Standard Deviation (min-max), R %: Row %, C %: Column %

**Table 2.** Comparison of changes in preoperative and postoperative Constant, Oxford, and VAS values of patients

	Group	Period	Mean	SD	Median	Min-Max	IQR	p	OR for Group*Period (95% Wald CI)
Constant	1	Preop	37.1	7.0	38.5	20-60	8	<0.001	1.207 (1.089-1.337)
		Postop	52.6	8.5	55.0	30-67	13.3		
	2	Preop	38.3	10.8	36.0	18-65	15.5		
		Postop	65.6	10.2	67.0	50-90	16.5		
Oxford	1	Preop	47.6	4.4	48.0	31-55	4	<0.001	1.590 (1.395-1.783)
		Postop	39.5	5.7	40.0	24-46	4.5		
	2	Preop	49.0	6.8	50.0	35-58	10		
		Postop	25.6	6.9	26.0	16-38	10.8		
VAS	1	Preop	7.2	1.1	7.0	5-10	2	<0.001	2.137 (1.812-2.519)
		Postop	4.6	1.3	5.0	2-8	1		
	2	Preop	7.3	1.1	7.0	6-10	2		
		Postop	2.2	1.0	2.0	1-4	2		

SD: Standard Deviation, Min: Minimum, Max: Maximum, IQR: Interquartile Range, OR: Odds Ratio, CI: Confidence Interval

**Table 3.** Comparison of changes in Quickdash, Flexion, Extension, Abduction, and Adduction values between groups

	Group									p
	1			2			Total			
	Mean±SD	Median	Min-Max	Mean±SD	Median	Min-Max	Mean±SD	Median	Min-Max	
Quickdash	38.8±3.8	40	28-44	28.0±2.8	27	24-36	33.4±6.4	32	24-44	<0.001
Flexion	77.2±10.5	75	60-110	112.3±33.9	100	70-180	94.8±30.6	90	60-180	<0.001
Extension	22.5±8.0	20	5-40	22.7±7.7	20	10-35	22.6±7.8	20	5-40	0.778
Abduction	68.8±12.6	70	30-90	105.2±27.7	90	80-180	87.0±28.2	85	30-180	<0.001
Adduction	25.8±19.0	20	15-120	20.3±10.8	20	10-45	23.1±15.6	20	10-120	0.087

SD: Standard Deviation, Min: Minimum, Max: Maximum

Descriptive values and comparison results of the constant score, Oxford shoulder score, and VAS score are provided in Table 2. The difference between preoperative and postoperative constant measurement values was significant in both groups, and the difference between the groups changed in each period (P<0.001). On the basis of the post-hoc test results, the postoperative constant score was significantly higher in Group 2 compared with that in Group 1 (P<0.001). In both groups, the preoperative constant score value was significantly lower than the postoperative value (P<0.001). In addition, the change in the constant score value measured in Group 2 was approximately 21% higher than that in Group 1 (P<0.001).

The difference between preoperative and postoperative Oxford shoulder scores was found to be significant in both groups and the difference between the groups changed in each period (P<0.001). Post-hoc test results showed that the postoperative Oxford shoulder score was significantly lower in Group 2 compared with that in Group 1 (P<0.001). In both groups, the preoperative Oxford shoulder score was significantly higher than the postoperative value (P<0.001). In addition, the change in the Oxford shoulder score measured in Group 2 was approximately 59% higher than that in Group 1 (P<0.001). On the basis of the post-hoc test results, the postoperative VAS score was significantly lower in Group 2 compared with that in Group 1 (P<0.001).

In both groups, the preoperative VAS score was significantly higher than the postoperative score ( $P < 0.001$ ). In addition, the change in the VAS score value measured in Group 2 was approximately 114% higher than that in Group 1 ( $P < 0.001$ ). Descriptive values of Quickdash, shoulder flexion, extension, abduction, and adduction, and comparisons between groups are provided in Table 3. The median Quickdash value was significantly higher in Group 1 than in Group 2 ( $P < 0.001$ ). The median shoulder flexion and abduction values were significantly higher in Group 2 than in Group 1 ( $P < 0.001$  for each). No significant difference was noted between the groups in terms of extension and adduction values ( $P > 0.05$ ).

## DISCUSSION

In our study, transosseous repair was clinically superior to suture anchor repair. Both transosseous repair and single row seam anchor rotator cuff repair can be applied successfully. Until recently, open transosseous repair had been considered the gold standard for rotator cuff repairs (17). The disadvantages of open repair include long healing period, postoperative pain, deltoid muscle trauma, poor cosmetic appearance with larger incisions, and the inability to evaluate intra-articular abnormalities; however, the outcomes of open, mini-open, and arthroscopic rotator cuff repair are similar (18). Recently, arthroscopic repair of the rotator cuff with suture anchor has become popular. Both transosseous repair and suture anchor repair have provided successful results in rotator cuff fixation (18). In recent years, the focus of studies has shifted to the development of new implants and surgical instruments to increase fixation stability especially in osteoporotic patients and shorten the surgical time. In the present study, we aimed to compare elastic needle and Sharc-FT-assisted rapid transosseous repair with single-row suture anchor repair. Transosseous suture techniques have been described as repeatable fixation methods that can be applied with open, mini-open, and arthroscopic repair procedures for the treatment of RCTs. Owing to the superior biomechanical properties of the transosseous technique, excellent clinical results have been achieved in long-term follow-up (19,20). Pellegrini et al. (21) first described the arthroscopic technique of the transosseous Sharc-FT. Later, Baudi et al. (13) reported successful results in the early period for RCTs repaired with arthroscopic transosseous Sharc-FT. In a cadaver study conducted by Kilcoyne et al. in 2017, transosseous repair was noted to be superior to other techniques in the mini-open treatment method (22). Recently, arthroscopic studies have shown that transosseous repair provides good functional results (23-25). In 2016, Flanagan et al. published the successful mid-term results of transosseous repair in 109 patients (24). In our present study and another recent study, we achieved good functional and clinical results using the new transosseous device Sharc-FT in mini-open rotator cuff repair (16). In 2018, Dyrna et al. (26) compared this new device (Sharc-FT) biomechanically with suture anchor as a revision option following failed rotator cuff surgeries. They found that even in revision surgeries, Sharc-FT was a viable option for commonly used suture anchors that provide

equivalent fixation properties. Unlike other transosseous methods, this transosseous device has a perforated body that is intended to handle one to four (or more) internal sutures, and it is specially shaped to maximize resistance to tensile strain and to prevent suture-bone interaction (16). Transosseous cortical fixation sutures form a lateral suture with tensile compression within the footprint, greatly increasing weak bone resistance problems, reducing movement at the tendon-footprint interface, increasing fatigue resistance, and homogenizing the load distribution on the footprint, thus optimizing biological recovery (26). Rotator cuff surgical techniques continue to evolve, but the complications of repair are not completely resolved. Despite the success of suture anchor repair, there are some risks. Chief among these is the risk of recurrent tears (20%–60%), reported at different rates in the literature (27). On the contrary, Kuroda et al. determined the risk of recurrent tears with transosseous repair to be 6% (14). In a prospective study, the rates of recurrent tear were similar between arthroscopic transosseous suture and double-row suture anchor (28). In the present study, patients were clinically evaluated for recurrent tears, and no recurrence was observed in either group. Suture anchor fixation is frequently used despite causing complications such as arthritis, retraction, and osteolysis (29, 30). There are other issues with the use of anchors in rotator cuff repair. For example, revision surgery may become difficult in case of recurrent tears, because the previous anchors are difficult to remove, thus leaving limited space for new anchor placement (14). Here, one of the primary devices (Sharc-FT) is approximately 15/20 mm away from the distal side of the large tubercle. This feature provides a significant reduction in suture weakening by the bone (13,21). In addition, the cost of multiple anchors is high, and displacement of the anchors may cause osteolysis of the large tubercle and lead to the anchors hitting the shoulder joint (31). On the other hand, the restrictive aspect of conventional transosseous repair is the risk of tearing the cortical portion of the lateral edge of the tunnel (32,33). There are limited studies comparing transosseous repair with suture anchors clinically. In the present study, we clinically compared the mini-open transosseous repair and suture anchor repair in RCTs.

In the present study, we found that the recurrence rate did not differ significantly according to the repair technique (4.88% for suture anchor and 8.94% for Sharc-FT;  $P = 0.105$ ). This result may be due to the relatively low incidence of recurrent tears (6.74%) in our population. In addition, subgroup analysis revealed differences for large tears: Transosseous application facilitated postoperative re-work after repair of larger tears, which suggests that it may be a better approach. A similar difference for small tears could be observed if we had a larger sample size. Since the final follow-up period of the transosseous group is shorter, a longer follow-up period may be required to be more confident about the results. However, patients had a better mean value for all measured variables. The constant score, Oxford shoulder score, Functional VAS score, Quickdash score, and range of motion were significantly better in the transosseous group. Despite the

high complication rates reported with open repair, we did not encounter any serious complications.

### Limitations of the Study

There are certain limitations of this study. The study was designed as a retrospective study and short-term results after surgery were examined. In addition, the number of patients was relatively limited. Furthermore, despite the relatively low complication rates for rotator cuff repair in our study, a longer follow-up may lead to higher complication rates.

### CONCLUSION

In rotator cuff repair, transosseous repair with Sharc-FT yielded better functional and clinical outcomes compared to suture anchor. Transosseous repair with this new device (Sharc-FT) provides an advantage in terms of early rehabilitation.

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