

The rotator cuff tear repair with a new arthroscopic transosseous system: the Sharc-FT[®]

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Abstract

Purpose Today, in rotator cuff tear repair, the transosseous sutures are considered superior from a biological and biomechanical point of view. Our purpose is to present the early clinical and biomechanical data of a new arthroscopic rotator cuff tear transosseous repair system: the Sharc-FT[®].

Materials and methods A total of 34 patients with rotator cuff tear affecting supraspinatus and infraspinatus, 1 to 3 cm wide, were treated and evaluated from 2010 to 2013. The average age was 63.2 years. Mean follow-up was 18.6 months. All patients were assessed through Constant score in the preoperative step and at 3-, 6-, and 12-month follow-up, performing an MRI 6 months after surgery.

Results The patients have shown a mean preoperative Constant score of 24.5 pt that constantly increases after surgery, until a mean value of 86.9 at 12 months. Regarding complications two cases of adhesive capsulitis were recorded.

Conclusions This device permits to obtain transosseous sutures with cortical fixation; to greatly reduce the problems of lack of bone resistance; to decrease motion at tendon–footprint interface improving fatigue resistance; to make the stress–load distribution homogeneous at the footprint, thus optimizing biological healing. A later evaluation will be necessary, especially for the incidence of retears.

Keywords Cuff tear · Arthroscopic · Transosseous · Sharc-FT · Suture bridge

Introduction

Over the past 40 years, rotator cuff tear repair techniques have undergone a remarkable evolution, permitting a gradually improved tendon to bone fixation. In 1944, McLaughlin [1] was the first to describe a transosseous rotator cuff tear repair that has represented the gold standard of the types of repair of these lesions, open or mini-open.

The advent of the arthroscopy technique has revolutionized the approach to this kind of surgery; in the last years, we have attended to the appearance of many devices of fixation: screwed or beaten anchors, made of materials like titanium, peek or reabsorbable ones. The repair techniques also evolved from single row to double row [2–5], until the development of transosseous-equivalent configurations like the suture bridge technique, to obtain a better tendon compression to the footprint interface optimizing contact area and pressure, as well as pullout strength and less interface motion [6, 7].

These surgical repair techniques have become of common use in arthroscopic approach, but the rate of pull out with poor bone stock is still high [8], as well as the rate of failure at tendon level, so the problem of rotator cuff retears is still not completely solved [9]. To improve outcomes after repair, healing biology at the footprint interface must be advanced.

The transosseous repair fixation system represents today the most reliable surgical technique from the biological and mechanical point of view, even if it still needs to be improved.

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The purpose of our analysis is to present the early clinical and biomechanical data of a new arthroscopic rotator cuff tear transosseous repair system: the Sharc-FT®.

Methods

From September 2010 to January 2013, 67 patients (31 male–36 female) were treated with an average age of 63.2 years (range 41–75) and a rotator cuff tear that affected supraspinatus and infraspinatus tendons, 1 to 3 cm wide, by MRI evaluation.

All patients were assessed with the constant score (0–100 points) in the preoperative phase and at 3-, 6-, 12-months follow-up. Six months after surgery, patients underwent a MRI for healing evaluation. We have completely evaluated 34 patients with a mean follow-up of 18.6 months (range 12.4–22.3).

The operative technique consisted of one Sharc-FT® device with its relative three sutures. A couple of the adopted configurations are sketched in the picture below reported (Fig. 1).

To minimize variability, all patients were treated by the same two surgeon (P. B., E. R. D.).

After surgery, the upper limb was immobilized in a 20° abduction sling for 30 days, passive physiotherapy was started after 10 days, while active physiotherapy after 3 weeks.

Surgical technique

The Sharc-FT® was developed in collaboration with NCS-LAB of Carpi (Modena, Italy) (Fig. 2).

This device is characterized by its placement, in a region with a good bone quality, located about 15–20 mm distally to the great tuberosity; management of two to four inner sutures to achieve a medial row in the footprint that can be developed also within lateral sutures in traction or compression configuration, so the possibility to perform a wide and personalized range of repairs with internal and external

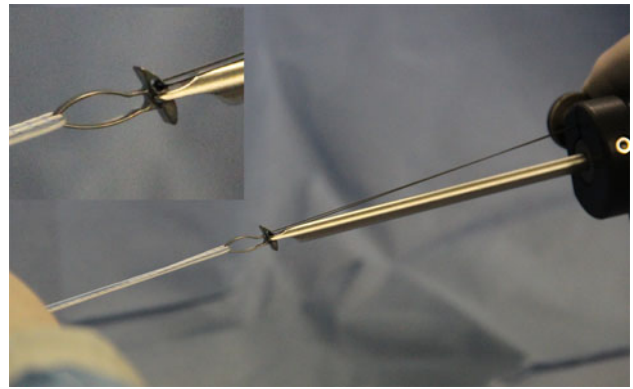


Fig. 2 The Sharc-FT® with the suture wires connected to the front part and a shuttle wire to the *back surface*

sutures; and its shape, created to maximize the resistance to pull out effect and to prevent suture–bone interaction. Its *in vivo* use was preceded by laboratory biomechanical tests in repaired rotator cuff tear created on young fresh frozen bovine humeri. To simulate the tears an artificial 35 × 10 mm defect of thickness was performed at the supraspinatus tendon insertion after removing other tendons. This tendon lesion was repaired to its physiological footprint using four simple half stitched polyethylene sutures tied with the same force and the Sharc-FT® suture platform.

Two tests were developed: the loading cyclic test and failure test by a multi-actuator Italsigma IT08-074. In both, the device has shown good results in comparison with the data measured with other repair techniques using anchors with different suture configurations.

The Sharc-FT® application needs specific surgical instrumentations that allow guided and repeatable procedure saving operative time: the special compass (Fig. 3) permits easy passage of the shuttle transosseous sutures and the implant carrier assures a beating insertion of the Sharc-FT®, overcoming the traditional difficulties related to the transosseous arthroscopic suture repair procedures.

Patients were positioned in lateral decubitus with the operated upper limb in traction, under general anesthesia.

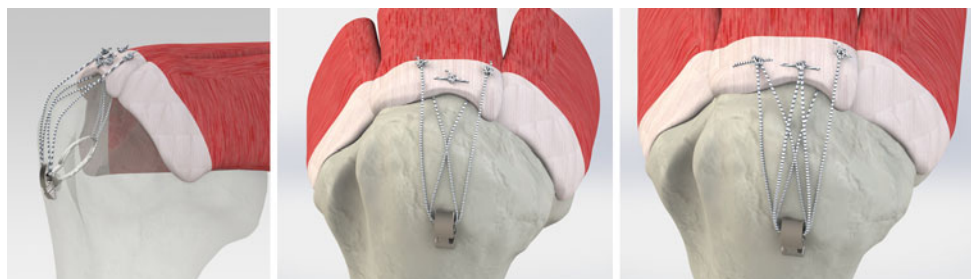


Fig. 1 Example of device positioning (*left*); one transosseous Mattress stitch and 2 simple stitches from the external hole (*middle*); two transosseous Mattress stitches and *closed loops* in the external hole and one simple stitch (*right*)



Fig. 3 The compass

After tendon preparation for suture, the surgeon proceeded with the footprint preparation creating a heavy surface decortication with an extension of several millimeters with a bonecutter. Then the Sharc-FT[®] system instrumentations could be applied: first, the proximal 3 mm \varnothing hole on the footprint was made; and second, the guide compass could be assembled and set to perform the distal lateral 3 mm \varnothing hole 3 cm from the greater tuberosity edge. The shuttle wire could then be passed through the transosseous tunnel with the compass, so it could drag the suture wires connected to the front part of the Sharc-FT[®] up to obtain the back surface of the device in contact with the cortical bone (Fig. 4).

To conclude the rotator cuff tear was sutured.

Results

The 34 operated and completely evaluated patients with a mean follow-up of 18.6 months (range 12.4–22.3) showed a mean constant score before surgery of 24.5 pt (min 16.4–max 68.1). Three months after surgery, the mean value was

Table 1 Constant score results summary

Constant score	Mean	Min	Max
Presurgery	24.5	16.4	68.1
3 months	63.1	43.6	82.0
6 months	83.2	47.0	89.5
12 months	86.9	47.5	90.4

63.1 pt (min 43.6–max 82.0); at 6 months 83.2 pt (min 47.0–max 89.5); finally, at 12 months 86.9 pt (min 47.5–max 90.4) (Table 1).

At 6 months, all patients had undergone an MRI for rotator cuff and surgical repair evaluation: there was no device mobilization nor rotator cuff re-tear.

There were no other outstanding complications, except for two cases of adhesive capsulitis treated with prolonged rehabilitation.

Discussion

The rotator cuff tear represents one of the most frequent musculoskeletal lesions. In spite of numerous technological innovations, re-tears are still complications with extremely variable rate (Galatz et al. JBJS 2004) [10].

The first transosseous repair technique was developed by McLaughlin in 1944 [1]; since then, technological improvements, in particular with the coming of arthroscopy, have produced a very high possibility of repairing these lesions [11–13].

In rotator cuff tear repair procedures, anchors are the most commonly used devices, which can be screwed or beaten, of various kinds of materials, with 2 or 3 sutures, and permit several repair configurations (single row, double rows, suture bridge having multiple sutures configurations).

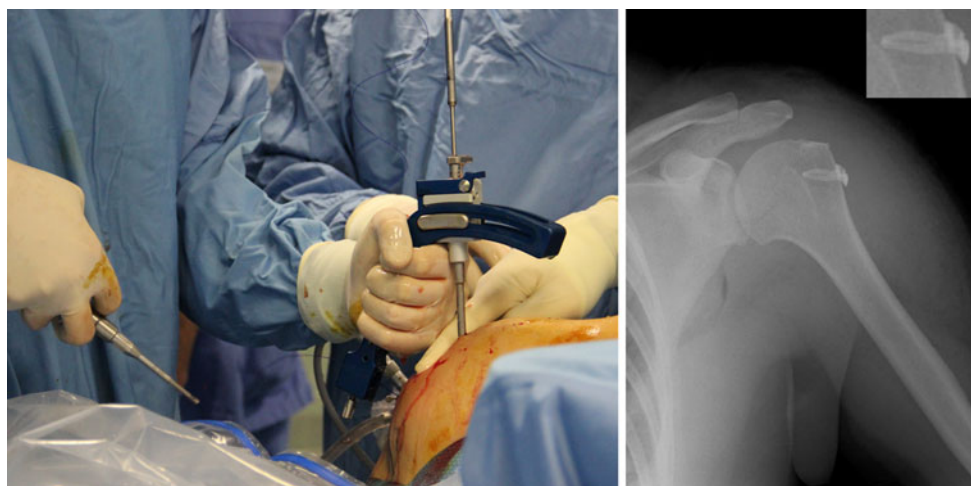


Fig. 4 The shuttle wire passage in the transosseous tunnel (left); X-ray of the Sharc-FT[®] implant (right)

However, possible failure induced the development of other types of sutures over the years, until the production of anchors that can allow a transosseous-equivalent repair technique [14]. The problems related to the migration and pullout of these devices, especially in patients with a poor bone stock, still represent the principle complications nowadays.

Today, the transosseous suture is considered superior in rotator cuff tear repair from a biological and biomechanical point of view [12, 13, 15]. In fact, it allows reduction of the tendon–bone gap formation, taking into consideration that a displacement of 3 mm is considered a repair failure [16]; it increases blood contribution through the tunnel, maximizing the healing potential; it enhances the contact area between footprint and the repaired tendon; it reduces stress at the repaired tendon–bone interface; and it avoids the presence of hardware on the footprint.

A recognized concern is represented by the cortical cut that can occasionally, when poor bone stock is present, modify the tunnel geometry leading to an unwanted early gap formation between tendon and footprint.

The development of an arthroscopic transosseous suture system has undergone some basic biomechanical evaluations. In the estimation of maximum load to failure, no differences between repair with anchors or with the transosseous system can be shown [17, 18]. Tocci et al's study [19] on fatigue resistance demonstrated, in high stress load, a bigger gap between tendon and bone in the repair with anchors, while in low stress load, no differences between the two systems were shown.

In anchor repair, the failure occurs at tendon level, whereas in the transosseous one in the tunnel [20, 21]. The footprint coverage has appeared greater in the transosseous technique [22–24], such as the bone–tendon interface stability [22]. The stress load is distributed much more in the bone tunnel of the transosseous repair, whereas in anchor repair, the stress load is charged to tendon and device insertion points, increasing the retear rate [25]. In addition, the pressure is homogeneously delivered in transosseous sutures unlike the anchor repair, where elevated values recorded in tendon–bone interface have increased the risk of ischemic damage to tendon tissue [24].

From these biomechanical assumptions, a transosseous suture system was developed which allows conjugation of the validity of this type of repair technique with the advantages of arthroscopy: the Sharc-FT[®]. This device permits to obtain arthroscopic transosseous sutures with cortical fixation; to create a traction-compression lateral suture inside the footprint prepared purposely; to greatly reduce the problems of poor bone resistance; to decrease motion at tendon–footprint interface improving fatigue resistance; finally, to make the stress–load distribution at the footprint homogeneous, optimizing biological healing.

Our initial clinical experience has obtained encouraging results. In our study, we have taken into consideration the same type of rotator cuff tear affecting supraspinatus and infraspinatus, 1 to 3 cm wide: 6 months after the surgical operation, MRI examination highlighted a very good biological tendon healing without retears. Constant score values were satisfactory, except in one case, probably due to an error of surgical indication.

We did not have complications in short and long term, except for two cases of adhesive capsulitis; we noted an initial increase in surgical time compared with the anchor technique due to the learning curve in the compass use.

Nevertheless, this study shows some limitations: it is retrospective, the follow-up is still very short and the system needs to be tested in much wider rotator cuff tears.

A later evaluation will be necessary, especially for the incidence of retears.

Conclusions

The improvement of suture technique in rotator cuff tears has permitted a considerable increase in the possibility of a successful treatment of this pathology; nevertheless, the complication of relapses remains. From the point of view of technological evolution, a new system of arthroscopic transosseous suture has been created. This first clinical experience confirms the efficacy of this system which could have a very interesting evolutionary application.

These early clinical results are consistent with the relevant cyclic and static (ultimate tensile load) results measured in a biomechanical test set up [26] confirming that the measured mechanical primary stability could be, as reported in several previous papers, at the basis of the good clinical outcome.

Conflict of interest We certify that there is no actual or potential conflict of interest in relation to this article.

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