International Orthopaedics (SICOT) (2013) 37:2165–2171
DOI 10.1007/s00264-013-1952-z

ORIGINAL PAPER

Microfractures at the rotator cuff footprint: a randomised controlled study

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Received: 11 May 2013 / Accepted: 21 May 2013 / Published online: 13 June 2013

Abstract
Purpose Microfractures at the footprint may be a potential additional source of growth factor and enhance the tendon healing at the bone-tendon junction when repairing rotator cuff tears.
Methods Fifty-seven patients who underwent shoulder arthroscopy for repair of complete rotator cuff tears were randomly divided into two groups, using a block randomisation procedure. Patients underwent microfracture at the footprint in the treatment group. The patients in the control group (n=29) did not receive that treatment. All patients had the same post-operative rehabilitation protocol.
Results The two groups were homogeneous. There was a significant improvement from baseline to the last minimum follow-up of two years. At three months from the index procedure, visual analogue scale (VAS), range of motion (ROM) and University of California at Los Angeles (UCLA) and Constant scores were significantly better in group 1 than in group 2 (P<.05). At the last follow-up (minimum two years), clinical and functional outcomes were further improved in both the groups but inter-group differences were not significant. No technique-related complications were recorded.
Conclusions Microfractures at the footprint are simple, safe, inexpensive and effective at producing less pain in the short term in patients who undergo rotator cuff repair, but at two years they do not result in significantly different outcomes, either clinically or at imaging, compared to traditional rotator cuff repair.

Keywords Rotator cuff · Repair · Cuff footprint · Microfractures · Randomised controlled trial

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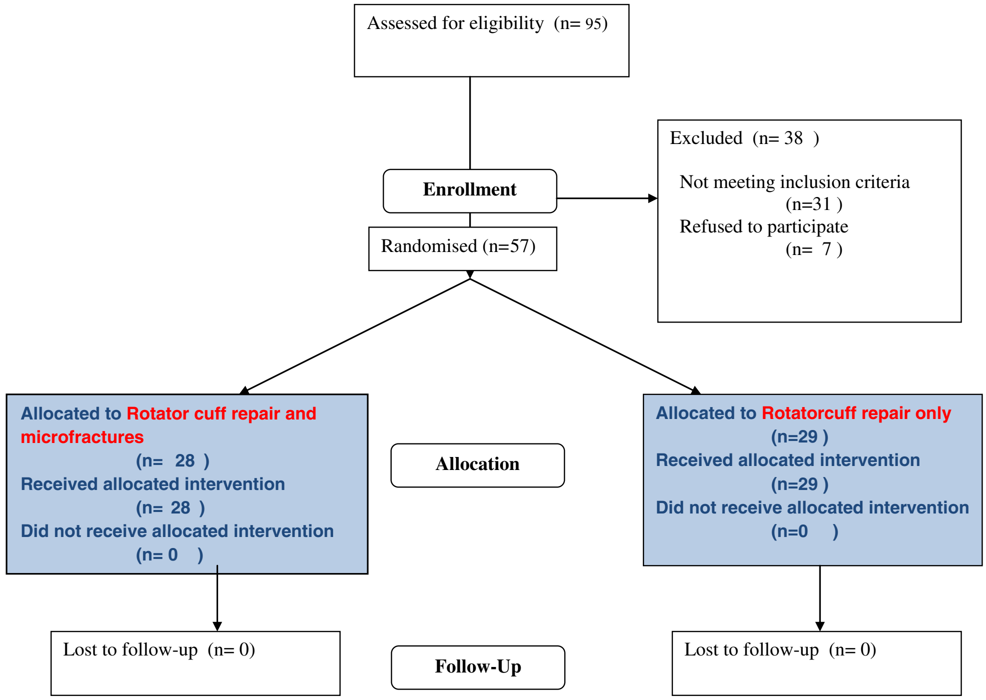
Introduction

Arthroscopic repair of the rotator cuff is well established, with results comparable to mini-open procedures [1]. The aim is to restore the anatomical insertion of the rotator cuff tendon within the anatomical footprint to allow and improve the healing process and encourage the integration of the repaired tendon to the bone [2]. Despite a relatively high rate of clinical success [3–5], healing may be unpredictably inadequate, and re-tearing may occur [6]. A vascularised bed produced at the insertion site of rotator cuff tendons may improve the repair process [7, 8]. Acromioplasty could be a source of growth factors released from the cancellous bone [9], and the role of platelet-rich plasma (PRP) formulations in the management of rotator cuff tears is still controversial [10]. On the other hand, microfracturing of the subchondral bone is supposed to promote the biological repair of cartilage defects to the knee [11] and ankle [12]. Microfractures could be performed in degenerative joint disease of the shoulder, and this procedure could be a simple effective manoeuvre to augment repair of rotator cuff tears. This is a randomised controlled study comparing clinical, functional and imaging outcomes of patients with rotator cuff tears who had undergone tendon repair and microfractures at the footprint (group 1) and only repair (group 2). We hypothesised that microfractures would significantly enhance vascular and healing responses over the rotator cuff insertion site and improve clinical and functional outcomes immediately after the operation, with no significant inter-group differences two years after the index surgery.

Fig. 1 Patient selection process



Materials and methods

This is a randomised controlled trial of 57 patients who underwent arthroscopic repair of full-thickness rotator cuff tears between 2008 and 2009. All procedures were performed after the local Ethics Committee had approved the study. We included patients with the diagnosis of rotator cuff tear unresponsive to conservative management based on clinical assessment and magnetic resonance imaging (MRI). History of shoulder fracture and prior surgery to the affected shoulder, proximal humeral head migration, severe fatty infiltration, severe glenohumeral osteoarthritis, cervical radiculopathy, inflammatory joint disease, osteoporotic changes and subchondral cysts at the footprint were all exclusion criteria. Patients with cardiovascular pathology, psychiatric illness and cerebrovascular disease were also excluded.

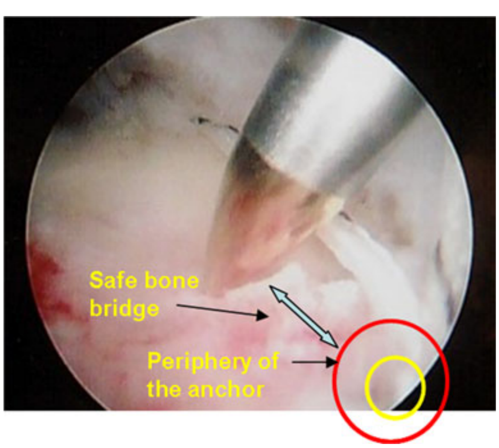


Fig. 2 Bone bridge between microfracture holes and the periphery of the anchor site to avoid compromising the stability of the anchor fixation

Sample size and sample features

The sample size calculation was based on the mean and standard deviation of University of California at Los Angeles (UCLA) scores observed in a pilot study on 14 patients, in which we found a mean difference of 5 points and a standard deviation (SD) of 3.1 points. Power analysis showed that a total sample size of 44 patients (22 patients in each group) would have provided a statistical power of 90 % with a two-sided level of .05 to detect significant differences. The patient selection process is reported in Fig. 1.

Ninety-five patients underwent arthroscopic repair of full-thickness rotator cuff tears during the study period at our institution; 38 patients were excluded as they did not meet the inclusion criteria (31 patients) or declined to participate (seven patients). Fifty-seven patients met the inclusion criteria and were randomly assigned to one of two groups, depending on the procedure. A sealed opaque envelope was used; it contained a card on which the number of the group was printed, 1 (microfracture) or 2 (repair). To obtain a random distribution of the cards, a random number generator was used. An independent investigator used a computer-produced random sequence generator to perform the randomisation and obtain the assignment code of each patient to the specific group.

A total of 28 patients underwent microfractures at the footprint with a standardised method (group 1), and 29 patients underwent rotator cuff repair without bone microfractures (group 2). All patients were assessed at the latest

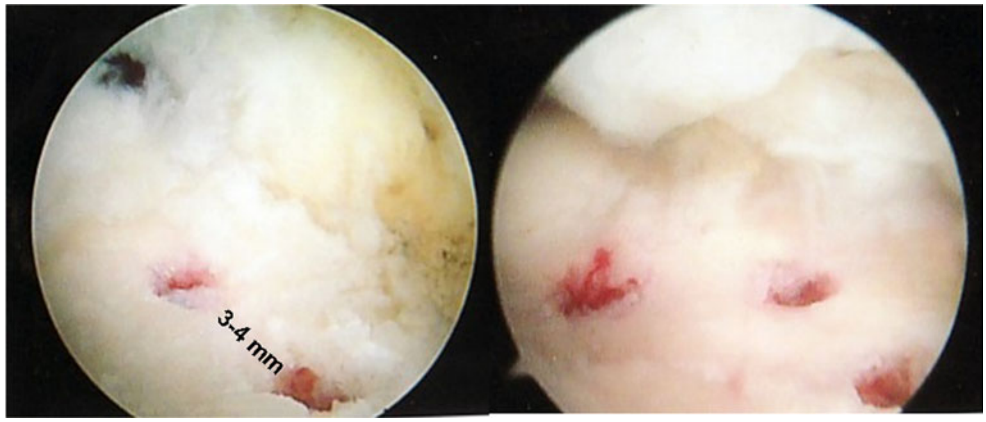


Fig. 3 The holes are made 3–4 mm apart and about 2–4 mm deep to avoid subchondral plate damage between the holes

follow-up. The 28 patients (16 men and 12 women) in group 1 were operated upon at an average age of 61.2 years (range 38–73), after an average of 12.5 months from the onset of symptoms (range seven to 21 months). In group 2, 29 patients (13 men and 15 women) underwent surgery at an average age of 59.8 years (range 34–71), after an average duration of symptoms of 13 months (range six to 20 months).

The first author (LO) made the diagnosis in all patients based on history, clinical examination and MRI findings, and the diagnosis was confirmed at arthroscopy in all instances. At the final assessment, at an average follow-up of 29 months in both groups, an orthopaedic surgeon (NM) who had not been involved in the original management, blinded to the nature of the procedure, examined all the patients and administered all the tests. Preoperatively and at the last follow-up, range of motion (ROM) measurements were recorded in passive maximum forward flexion, abduction, external rotation and internal rotation of the shoulder. Preoperatively, the UCLA and Constant-Murley scores were also determined in each patient.

Surgical technique

An interscalene block was performed in all patients. The beach chair position and a gravity traction of 10 lb were used. Gravity irrigation was provided by 2.5 litre water bags suspended at 8 ft. The tear size was measured from medial to lateral and anterior to posterior. Once the footprint had been identified, it was prepared using a motorised shaver (Arthrex, Naples, FL, USA). A single-row repair was carried out using 5 mm titanium anchors (Corkscrew, Arthrex, Naples, FL, USA). These were inserted through an additional portal and placed at an angle of 45° to the bone surface. The anchors contained double loaded non-absorbable sutures which were passed through the tendon by a suture

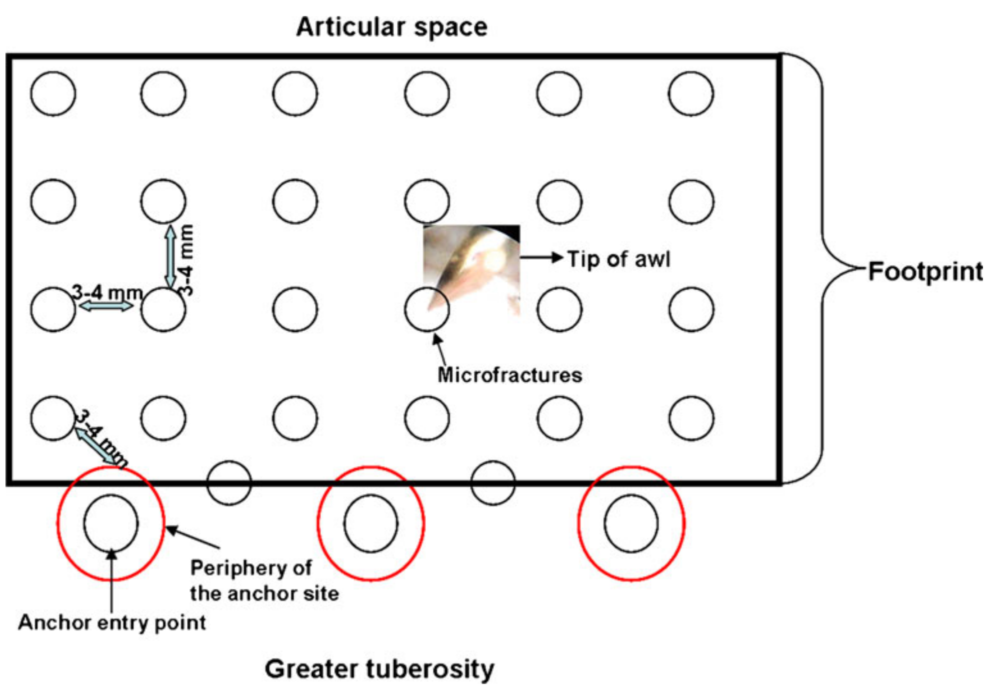


Fig. 4 Schematic representation of the technique

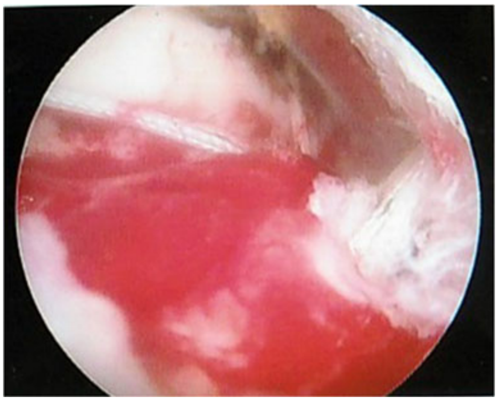


Fig. 5 Fluid irrigation is temporarily stopped to observe marrow fat droplets and blood release from the holes

passer device (Skorpion, Arthrex, Naples, FL, USA); the knots were tied (simple stitches) using a sliding knot. A tenotomy of the long head of the biceps was performed in all instances.

Microfracture technique

An awl (Condropick, Arthrex, Naples, FL, USA) was used with the tip perpendicular to the footprint. When the tissue is not retracted, the anchor position is identified at the lateral side of the footprint. The holes are made 3–4 mm apart and about 2–4 mm deep (Figs. 2 and 3) starting from the juxta-articular space and proceeding into the subacromial space to the tip of the greater tuberosity (Fig. 4). The stability of the bone between the microfractures is assessed in all instances and the irrigation is temporarily stopped to better ascertain that marrow fat droplets and blood come out from the holes (Fig. 5). The repair is then performed in the usual fashion [14] using a single-row technique.

Post-operatively, all patients wore a sling for four weeks; passive ROM exercises were started two weeks after surgery and continued for four weeks. Active exercises were started at six weeks; strengthening exercises were allowed at a minimum of three months.

Follow-up

All patients were assessed three months and at an average of 29 months after the index procedure (range 24–53 months, SD 8.6). Clinical examination was performed in all patients to record ROM measurement; Constant-Murley and UCLA scores were ascertained in all patients. A Constant-Murley final score of 90–100 was considered as excellent, good from 89 to 80, fair from 79 to 70 and poor if less than 70. A score less than 80 was considered failure. At the last follow-up, all patients underwent MRI assessment for rotator cuff tendon integrity and re-tear; a blinded musculoskeletal radiologist not involved in the study evaluated all images. Tendon integrity

Table 1 Clinical and functional comparison

	Group 1			Group 2		
	Baseline	3-month follow-up	Last follow-up	Baseline	3-month follow-up	Last follow-up
External rotation (°)	44. 6±12.0 (25–65)	59.1±9.2 (50–80)	60.8±9.3 (50–80)	46.3±11.7 (20–70)	51.3±13.2 (25–75)	61.0±9.8 (45–85)
Forward flexion (°)	130 .8±12.0 (90–155)	165±11.1 (145–190)	173±12.4 (155–190)	128.2±13.2 (90–160)	150±12.1 (125–180)	171±11.9 (150–190)
UCLA score	15.6±4.1 (9–23)	27.0±6.1 (19–32)	32.6±6.0 (25–35)	15.4±3.9 (10–25)	24.1±6.1 (19–32)	32.1±5.8 (24–35)
Constant-Murley score	46±7.2 (34–70)	67.4±8.1 (65–89)	92.3±7.7 (78–100)	46±8.6 (29–63)	62.4±7.4 (60–81)	91±7.3 (79–100)

Table 2 Inter-group differences (*P* values)

	Inter-group difference		
	Baseline	3-month follow-up	Last follow-up
UCLA	P=0.83	P=0.04	P=0.49
Constant-Murley	P=0.85	P=0.02	P=0.77

was defined as continuity of the repaired tendon and a homogeneous low-intensity or partial high-intensity area on MRI.

Statistical analysis

After assessment of the distribution with the Kolmogorov-Smirnov test, the Mann-Whitney test was used to compare pre- vs post-operative UCLA and Constant-Murley scores and ROM measurements. Independent samples *t* tests were used to compare post-operative UCLA and Constant-Murley scores and ROM measurements between the groups. Mean, SD and 95 % confidence intervals were calculated. The χ^2 test was used to analyse dichotomous variables (imaging findings and return to sports activity). A P value<0.05 was considered to be statistically significant. SPSS version 17.0 (SPSS Inc., Chicago, IL, USA) was used to analyse the data.

Results

At three months, forward elevation and external and internal rotation were significantly improved (P<0.001) compared to preoperatively in both the groups. Visual analogue scale (VAS) assessment, American Shoulder and Elbow Surgeons (ASES) scores and Constant shoulder scores were significantly improved compared to the preoperative status. Comparing the two groups, VAS assessment (P=0.036), UCLA (P=0.04) and Constant (P=0.02) scores were significantly improved in the group of patients undergoing microfracture at the footprint compared to those who had undergone only rotator cuff repair (Table 1). Inter-group and intra-group differences are reported in Tables 2 and 3. UCLA (Figs. 6 and 7) and Constant scores (Figs. 8 and 9) improved over time in both groups.

At the last follow-up, ROM and functional scores were significantly improved compared to preoperatively, with no significant inter-group differences. At the same appointment, when asked about return to activities of daily living, all patients answered that they were able to successfully perform routine activities as before the onset of symptoms. In group 1, 12 of 18 patients (67 %) who practised recreational sports activities had returned to sports at the same level as before the onset of symptoms, without any discomfort. In group 2, nine of 15 (60 %) patients who practised recreational sports activities returned to the same level. No statistically significant inter-group difference was found in terms of return to pre-injury sports activity (P=0.69). In group 1, of six patients who had not returned to the same level of sports they practised before the onset of symptoms, three had changed sports, and three decided spontaneously to give up any sports. In group 2, all six patients who had not returned to the same level of sports activity gave up any sports.

At the last follow-up, the MRI assessment showed evidence of rotator cuff healing in 26 patients of group 1 and 26 patients of group 2 (P=0.67). The five patients with evidence of tendon re-tear were not symptomatic, with UCLA and Constant-Murley scores averaging, respectively, 32 and 89 points.

Discussion

The main finding of this study is that patients undergoing rotator cuff repair and microfractures of the bone at the footprint of the rotator cuff fare better at three months than patients undergoing rotator cuff repair only. At three months, the group of patients undergoing microfractures reported significantly better UCLA and Constant scores, less pain and improved ROM. Nevertheless, the differences were not significant at the last follow-up at a minimum of two years. The rationale of microfracturing the bone is to induce some bleeding, and growth factors from the bone marrow are carried to the tendon-bone interface. The healing process of the tendon at the insertion site may be accelerated and improved, and the integration between tendon and bone is encouraged. The evidence that growth factors improve

Table 3 Intra-group differences (*P* values)

	Intra-group difference					
	Baseline vs 3 months		Baseline vs last follow-up		3 months vs last follow-up	
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
UCLA	P<0.0001	P<0.0001	P<0.0001	P<0.0001	P<0.0001	P<0.0001
Constant-Murley	P<0.0001	P<0.0001	P<0.0001	P<0.0001	P<0.0001	P<0.0001

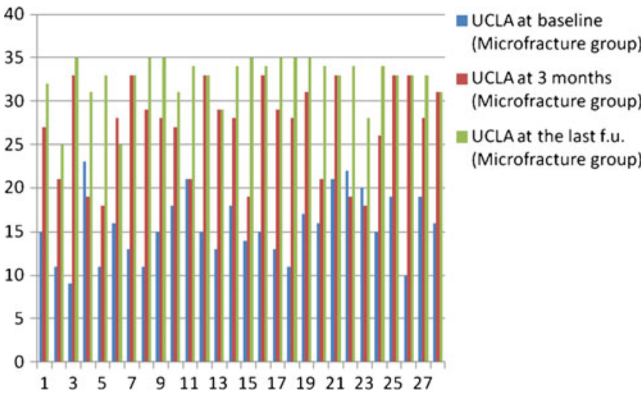


Fig. 6 Assessment of UCLA score in the microfracture group

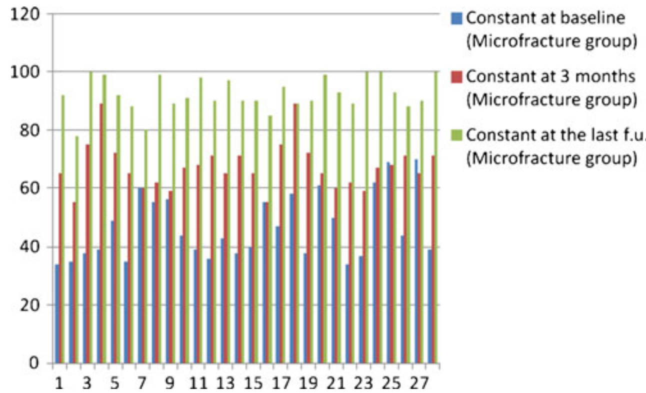


Fig. 8 Assessment of Constant-Murley score in the microfracture group

tendon and ligament healing is strong. In rabbit models of medial collateral ligament (MCL) tear, the administration of platelet-derived growth factor (PDGF)-BB significantly improved the biomechanical properties of the femur–MCL–tibia complex [13].

Growth factors exert different functions and are involved in inflammation, angiogenesis, wound and soft tissue healing [14, 15]. PRP is the novel and emerging approach to management of tendon, ligament and cartilage disorders [15]. The evidence is still scanty and it is uncertain if these products really work. In addition, there is much uncertainty when referring to the concentration of these factors, time of administration and costs. A recent systematic review has shown that PRP does not have an effect on overall re-tear rates or shoulder-specific outcomes after arthroscopic rotator cuff repair [10]. When repairing rotator cuff tears, microfractures of the footprint are supposed to increase the concentrations of growth factors. Acromioplasty increases the concentration of transforming growth factor beta (TGF-β), PDGF-AB and basic fibroblast growth factor (bFGF) in the subacromial space [9], but it is unknown which concentration of growth factors should be reached to enhance the tendon to bone healing process.

Some progenitor cells may reach the interface when the bone is microfractured. Mazzocca et al. reported that connective tissue progenitor cells come from the bone marrow when drilling tunnels for anchor placement [16]. Dopirak et al. [17] performed microfractures in 16 patients with rotator cuff tears, though in a non-standardised fashion. We used a standard technique according to which microfractures are performed once the quality of the bone and the size of the lesion had been assessed, taking care to produce the holes relatively distant from the entry points of the anchors. This is the reason why we performed microfractures only in the lateral aspect of the bone in patients with medium or larger size tears of the rotator cuff. On the other hand, when the lesion is smaller than one centimetre, such a procedure may weaken the bone and compromise the site where the anchors have to be implanted. The strength of the repair depends on the state of the tendon-bone interface [18]. Many factors may compromise the healing process at the tendon-bone interface [19, 20]. Smoking, diabetes and metabolic disorders compromise vascularisation of this area [3]. Microfractures may promote angiogenesis and accelerate the healing process, and histology and imaging should substantiate this. It may be important to concentrate the growth factors delivered through the microfracture holes in the footprint, possibly performing them after the cuff has been repaired. In this way, these factors may be trapped under the tendons. Otherwise, when microfracturing the lateral

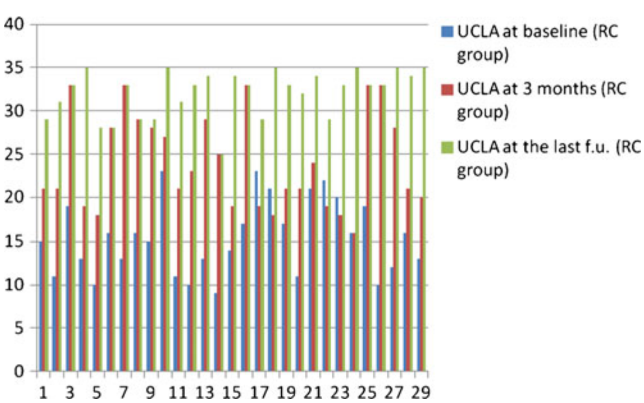


Fig. 7 Assessment of UCLA score in the only rotator cuff repair group

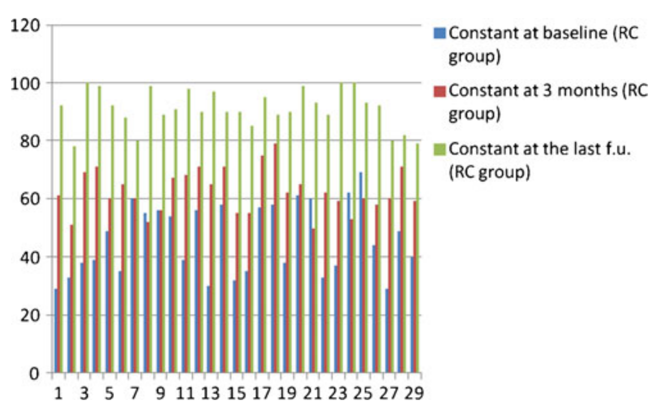


Fig. 9 Assessment of Constant-Murley score in the only rotator cuff repair group

aspect of the footprint, part of these factors may spread into the subacromial space. This randomised controlled study has shown that microfractures accelerate the time of recovery and provide better outcomes in the short term, but there was no difference at two years, with comparable healing rates in the two groups at MRI and comparable clinical results. No complication related to the technique was recorded. According to a recent Level I study, post-operative MRI did not show any significant difference between groups in structural integrity at a mean follow-up of 28 months. However, subgroup analysis showed a significantly greater healing rate in the microfracture group for large tears involving the supraspinatus and infraspinatus [21]. On the other hand, Constant and disabilities of the arm, shoulder and hand (DASH) scores were comparable between the two groups [21].

The main limitation of our study is that we did not assess rotator cuff vascularisation, and patients did not undergo MRI at an intermediate follow-up. This study has several strengths. First, it is a randomised controlled study, and none of the patients was lost to the follow-up. One experienced fellowship trained shoulder surgeon performed all surgical procedures, and an independent investigator not involved in the index surgery examined the patients at follow-up.

In conclusion, this study demonstrates that microfractures at the footprint are simple, safe, inexpensive and effective at producing less pain in the short term in patients who undergo rotator cuff repair, but at two years they do not result in significantly different outcomes, both clinically and at imaging, compared to traditional rotator cuff repair. As the technique is simple, inexpensive and does not markedly increase operating time, it can be left to the preference of the surgeon to use it to provide some greater comfort to the patients in the early post-operative recovery phase.

Conflict of interest The authors declare that they have no conflict of interest

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