



Functional and radiologic results of the crimson duvet procedure in rotator cuff treatment: a randomized controlled clinical trial

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Background: Rotator cuff tears are one of the more frequent pathologies of the shoulder. Arthroscopic techniques and biologic augmentation have been developed to improve the rate and quality of healing. The crimson duvet procedure (CDP) theoretically provides mesenchymal stem cells through microfracture treatment of the footprint. The aim of this research was to evaluate the effect of CDP in patients who had undergone arthroscopic surgery for complete rotator cuff repair.

Methods: A prospective randomized clinical trial was performed in a total of 123 patients, consisting of 59 women and 64 men, with a mean age of 58 years. We included patients with a clinical and radiologic diagnosis of a complete rotator cuff tear. All patients were treated with arthroscopic rotator cuff repair. In group 1, the surface of the footprint was débrided; in group 2, the footprint underwent microfracture. The primary outcome was the nonhealing rate, which was detected by magnetic resonance imaging (MRI) or ultrasonography, and the secondary outcome was the functional result. A Sugaya classification of I to III was considered to indicate healing. For clinical evaluation, the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) and Constant scores were evaluated, along with the range of motion. The functional evaluation was performed preoperatively and at 6 months and 1 year postoperatively. The radiologic (MRI or ultrasonography) evaluation was performed at 6 months. Neither the patients nor the radiologists and physical therapists who performed the postoperative evaluations were informed of the random selection.

Results: We observed a healing rate of 85.11% in the control group and 93.7% in the CDP group, which was not significant ($P = .19$). However, a significant improvement in function was observed in all patients. The ASES score improved from 68.9 (SD 13.8) preoperatively to 92.2 at 6 months and to 96.4 (SD 6.2) at 12 months ($P < .05$), but no difference was observed between the groups. A similar level of improvement was observed in the Constant score.

Conclusion: The arthroscopic repair of complete rotator cuff tears presents good and excellent clinical results in most patients. Nevertheless, nonhealing occurs at a rate that depends mainly on the age of the patient and the size of the tear. The addition of CDP did not improve the functional results or the healing rate.

Level of evidence: Level II; Randomized Controlled Trial

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Keywords: Rotator cuff tear; crimson duvet procedure; microfracture; footprint; arthroscopic repair; healing rate

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Rotator cuff tears are one of the more frequent pathologies of the shoulder. It has been established that 30% of patients older than 60 years present a tear (partial or full thickness); many of these patients are symptomatic and experience pain and limitations in terms of functional activity and sports.²⁶ Treatment through arthroscopic repair

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has shown excellent functional results,³¹ but the rate of rerupture is high, reaching up to 50%-94% in massive ruptures, with progressive deterioration of the functional results.^{14,23} The arthroscopic technique has evolved in different aspects, from the single- and double-row techniques to the transosseous equivalent method, with better anchor designs and materials, and with the inclusion of 2 or even 3 sutures or tapes. Stronger configurations, such as those including rip stops or mechanical augmentation, can now be used.^{1,16,22}

Biologic augmentation is also a strategy that has been developed and is considered relevant for improving the rate and quality of healing.^{9-11,18,19,32} The use of platelet-rich plasma, growth factor, patches, and bone marrow stimulation are procedures that promote biologic processes in the healing response.^{4,7,9,13} The crimson duvet procedure (CDP) was proposed to be applied in shoulder rotator cuff repair by Snyder in 2009, with the objective of providing mesenchymal stem cells through microfracture of the footprint.²⁷ Some authors have shown a significant improvement in the healing rate or clinical results,^{25,29} but other research revealed no difference with the addition of this procedure.²¹

The objective of this research was to evaluate the clinical and radiologic effects of CDP in patients who underwent arthroscopic surgery for complete rotator cuff repair. The hypothesis was that CDP improved the functional outcome and healing rate in patients who underwent arthroscopic rotator cuff repair compared with controls.

Materials and methods

This single-center, prospective, randomized clinical trial performed at our institute was conducted from January 2015 to December 2019. A total of 123 patients, consisting of 59 women and 64 men, with a mean age of 58 years (range 27-79) and a diagnosis of a complete rotator cuff tear were included (Fig. 1). A statistical power analysis was performed to calculate the sample size. With a power of 80%, a 95% confidence level, and alpha value of 0.05, the sample size was estimated to be 58 patients in each group. The inclusion criteria were a clinical and radiologic diagnosis of a superior or posterosuperior complete rotator cuff tear through magnetic resonance imaging (MRI) or ultrasonography and failure of conservative treatment for at least 6 months. The exclusion criteria were a history of shoulder surgery, osteoarthritis, Goutallier grade III or IV fatty infiltration, shoulder inflammatory disease, an intraosseous cyst larger than 5 mm on the larger tuberosity, a psychiatric disorder, or a history of brain stroke.

All patients were treated with arthroscopic rotator cuff repair. Two groups were randomly established. In group 1, repair was performed with a standard arthroscopic technique. In group 2, the same standard technique was performed, but the footprint was prepared by microfracture.

The primary outcome was the nonhealing rate,²⁰ which was detected by MRI or ultrasonography, and the secondary outcome was the functional result (Fig. 2). Neither the patients nor the

radiologists and physical therapists who performed the postoperative functional evaluations were informed of the random selection. For the clinical evaluation, the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) score, Constant score, and range of motion were determined. The functional evaluation was performed preoperatively and 6 months and 1 year postoperatively. The radiologic (MRI or ultrasonography) evaluation was performed at 6 months.

Surgical technique

All surgeries were performed with the patient in the beach chair position under general anesthesia using a regional interscalene block for postoperative pain control. The skin was marked preoperatively, and a posterior portal was used for intra-articular visualization. The subscapular and biceps tendons were evaluated, and direct visualization of the supraspinatus and infraspinatus was performed for rupture confirmation and size evaluation.

Once the intra-articular step was completed, a 30° scope was inserted in the subacromial space. After débridement and acromioplasty, the scope was moved to the lateral portal. The edge of the tendon was débrided, and mobilization for proper tuberosity attachment was then performed. The footprint was prepared by motorized débridement (Great White 4.2 shaver; ConMed, Tampa, FL, USA). In the CDP group, holes (microfractures) were prepared with a mechanical awl (Condropick; Arthrex, Naples, FL, USA) (Fig. 3, A). The holes were made at a distance of 3 mm and a depth of 3-5 mm, so the number of microfractures was determined in relation to the surface of the exposed footprint (Fig. 3, B). Once the tuberosity was prepared (Fig. 3, C), we inserted the anchors (Fig. 3, D). The selection of a single- or double-row technique was determined according to the size of the tear.²⁸ In the case of tears smaller than 1 cm, a single-row technique was applied, and for tears larger than 1 cm, a double-row technique was preferred (Fig. 4, B).

Statistical analysis

The Stata 15 program (StataCorp, College Station, TX, USA) was used for data management and analysis, as well as determination of the sample size and randomization.

Fisher exact test was used to study the association between dichotomous variables, and the Mann-Whitney *U* test was used for the remaining statistical studies. A *P* value <.05 was considered to indicate statistical significance.

A code of 1 or 0 (CDP or Control) was prepared for random selection. This code was hidden from the patients and the coauthors who performed the clinical and radiologic evaluations.

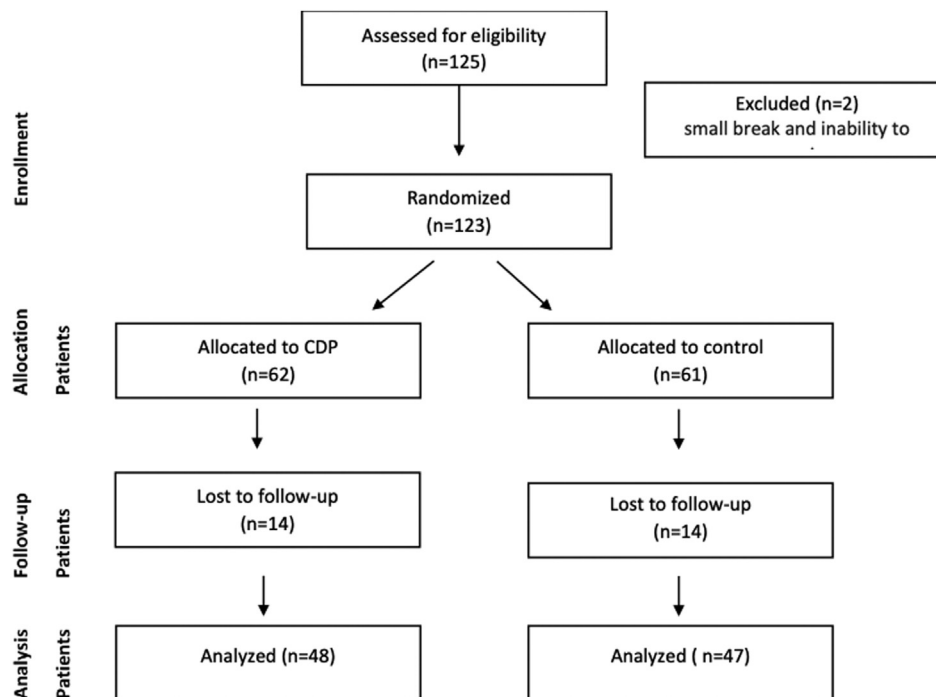


Figure 1 Selection process. From the initial sample of 125 patients who met the criteria of eligibility, 123 were randomized, with 62 in the CDP group and 61 in the control group. Among them, 14 patients from each group were lost to follow-up, with 48 remaining for analysis in the CDP group and 47 in the control group. *CDP*, crimson duvet procedure.

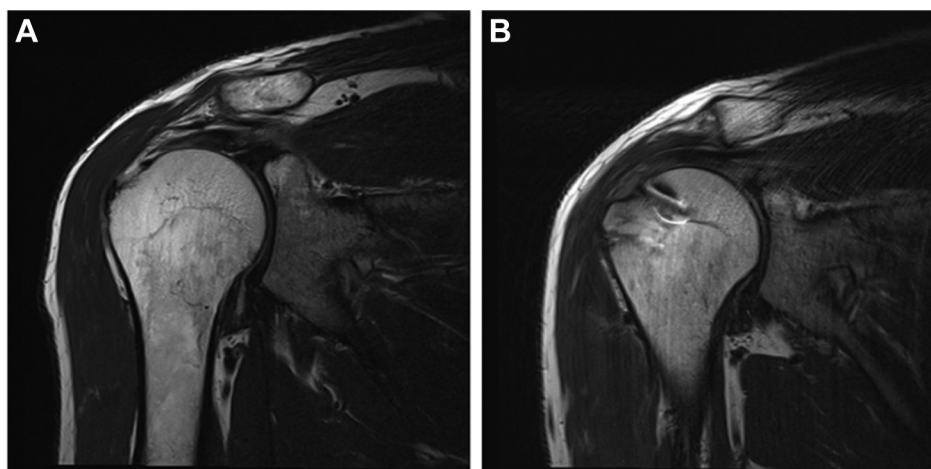


Figure 2 T2-weighted coronal view of the total rotator cuff tear. (A) Preoperative T2-weighted coronal view shows a supraspinatus total tear. (B) Postoperative T2-weighted coronal view shows complete healing of the greater tuberosity after a double-row repair.

Results

A total of 123 patients were included in the study. Sixty-two patients (50.4%) were included in the CDP group, and 61 patients (49.6%) in the control group (Fig. 1). The mean age of the patients was 58.9 years in the CDP group and 57.8 years in the control group. There was no difference between the groups in age, sex distribution, history of trauma, or preoperative Constant or ASES score. There was also no difference in the time of symptom onset

or surgery (Table I). In 77% of cases, a complete (preoperative and at 6 months of follow-up) radiologic evaluation was performed. The healing rate was 85.1% in the control group and 93.7% in the CDP group ($P = .19$) (Table II). We found an OR of 0.38 for nonhealing in the CDP group ($P = .09$), showing a trend of a lower rate but no statistical significance (95% CI -1.57).

Among all patients, the ASES score improved from 68.9 (SD 13.8) preoperatively to 92.2 at 6 months and 96.4 (SD 6.2) at 12 months ($P < .05$). A significant

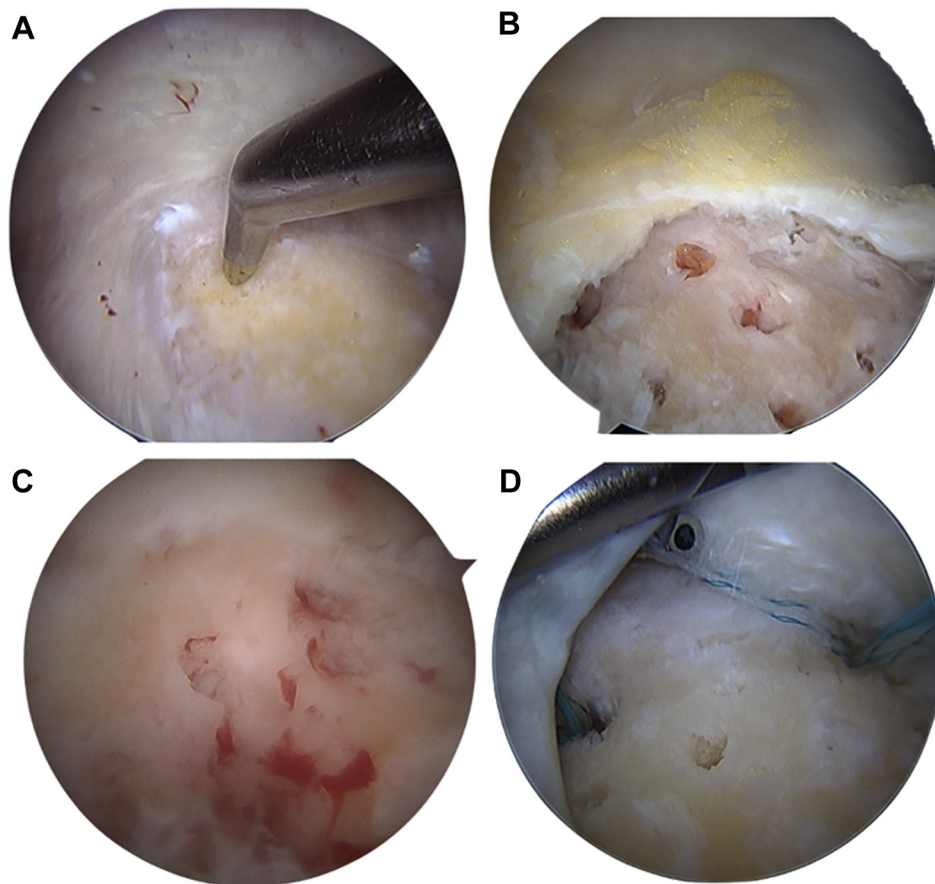


Figure 3 Arthroscopic view from the lateral portal at the right shoulder with the patient in beach chair position. **(A)** Posterior superior cuff tears, showing the footprint after the débridement. Insertion of the arthroscopic awl through an accessory superolateral portal. **(B)** Microfractures were done every 3-5 mm of distance on the exposure footprint. **(C)** Bleeding from the subchondral bone through the microfracture, visualization with the saline pump off. **(D)** Insertion of 2 suture anchors in the medial aspect of the footprint, for the linked double-row repair.

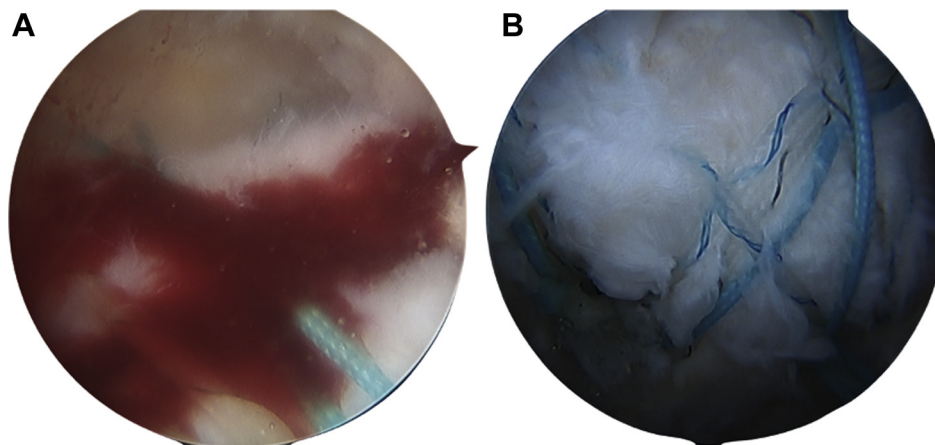


Figure 4 Arthroscopic view from the lateral portal at the right shoulder with the patient in beach chair position. **(A)** The crimson duvet effect (clot) is seen with the pump off, before the lateral row is finished. **(B)** Final view of the linked double-row repair, where the microfractures are covered with the tendon.

difference was observed in the pre- and postoperative functional scores at 6 and 12 months in both groups, but no difference was observed between the groups. In the control group, the ASES score improved from 67.8 (SD 13.6)

preoperatively to 91.4 (SD 11.3) at 6 months and 95.7 (SD 7.6) at 12 months. In the CDP group, the ASES score improved from 70.1 (SD 13.9) preoperatively to 92.9 (SD 7.9) at 6 months and 96.9 (SD 4.0) at 12 months.

Table I Sociodemographic and intraoperative variables

Variables	Total population	CDP group	Control group	P value
Demographic variable				
Age, yr, mean (SD)	58.8 (8.5)	58.9 (7.7)	57.8 (9.2)	.67
Male	64 (52)	29 (56.6)	25 (67.4)	.28
Diabetes	13 (10.6)	5 (8.1)	8 (13.1)	.39
Time to surgery, mean (SD)	9.4 (11.5)	7.7 (7.1)	11.1 (14.5)	.59
Traumatic onset	45 (36)	21 (33.9)	24 (39.3)	.57
Intraoperative variable				
Length, mm, mean (SD)	14.1 (5.4)	13.7 (5.8)	14.5 (4.9)	.42
Width, mm, mean (SD)	15.5 (6.8)	16.5 (7.8)	14.6 (5.5)	.11
Area, mm ² , mean (SD)	233.8 (171.9)	247.2 (204.2)	219.8 (129.9)	.38
Total tear	101 (82.1)	50 (80.6)	51 (83.6)	.81
Acromioplasty	106 (86.2)	56 (90.3)	50 (81.9)	.20
Biceps procedure	70 (56.9)	32 (51.6)	38 (62.3)	.27
Double row	44 (35.7)	24 (38.7)	20 (32.8)	.57

SD, standard deviation; CDP, crimson duvet procedure.

Table II Functional evaluation, preoperative, at 6 and 12 months

Variables	Total	CDP group	Control group	P value
Nonhealing, n (%)	10 (10.5)	3 (6.2)	7 (14.9)	.19
ASES				
Preoperative	68.9 (13.8)	70.1 (14)	67.8 (13.7)	.36
6 mo	92.2 (9.6)	92.9 (8)	91.4 (11.1)	.43
12 mo	96.4 (6.2)	96.9 (4.4)	95.8 (7.6)	.34
Constant score				
Preoperative	52.7 (20.4)	53.4 (19.6)	52 (21.3)	.70
6 mo	85.1 (14.3)	85.5 (12.4)	84.7 (16.1)	.78
12 mo	91.9 (8.9)	92.9 (6)	90.9 (11.2)	.24
Anterior flexion				
Preoperative	139.6 (39.5)	138.1 (42.4)	141.1 (36.6)	.67
6 mo	160.4 (20.7)	164 (16.1)	156.7 (24.3)	.03
12 mo	168.7 (9.1)	170 (6.6)	167.4 (10.9)	.07
External rotation				
Preoperative	51.6 (15.8)	51.3 (17.3)	51.9 (14.3)	.83
6 mo	58.1 (14.1)	58.7 (13.4)	57.4 (14.9)	.64
12 mo	64.4 (10.2)	65.1 (9.2)	63.6 (11.3)	.46

Values are mean (standard deviation) unless otherwise noted.

In the control group, the Constant score improved from 52 (SD 21.3) preoperatively to 84.7 (SD 16.1) at 6 months and 90.8 (SD 11.23) at 12 months. In the CDP group, the Constant score improved from 53.43 (SD 19.63) preoperatively to 85.5 (SD 12.4) at 6 months and 92.9 (SD 5.9) at 12 months (Table II).

There was no difference in the functional result of the pre- or postoperative evaluation between the CDP and control groups (Table II). Nevertheless, we did find a difference in the range of motion; the active anterior elevation in the CDP group was 164° (SD 16.1), whereas that in the control group was 156° (SD 24.3) ($P < .03$).

Regarding nonhealing, we found a significant difference according to the age of the patient and the size of the tear. The average age was 64.2 years (SD 7.5) among patients with nonhealing vs. 59 years (SD 8.6) among those with healing ($P = .03$), and the area of tendon rupture was, respectively, 296.8 mm² (SD 170.6) and 213.2 mm² (SD 150.5) ($P = .04$; Table III). Finally, we looked for an association between function and healing, comparing nonhealing with healing patients, and we found a significant difference in the ASES score (86.8 [SD 17.1] vs. 92.6 [SD 8.7], $P = .04$) and the Constant score (72.5 [SD 21.9] vs. 86.1 [SD 13.2], $P = .003$) at 6 months.

Table III Variable between healed and nonhealed patients

Variables	Healed, mean (SD)	Nonhealed, mean (SD)	<i>P</i> value
Age, yr	59 (8.6)	64.2 (7.5)	.0359
Size, mm ²	213.2 (150.5)	298 (170.6)	.0498
ASES			
6 mo	92.6 (8.7)	86.8 (17.1)	.0463
12 mo	97.3 (4.9)	88.2 (11.5)	.0014
Constant			
6 mo	86.1 (13.2)	72.5 (21.9)	.0039
12 mo	93 (7.5)	82.5 (17)	.0005

ASES, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; SD, standard deviation.

At 12 months as well, the ASES score (88.2 [SD 11.5] vs. 97.3 [SD 4.9], $P < .001$) and Constant score (82.5 [SD 17] vs. 93 [SD 7.5], $P < .005$) were significantly different (Table III).

Discussion

A variety of techniques are currently used to improve the results of rotator cuff repair. Unfortunately, many of them have not resulted in predictable clinical or radiologic improvement, and some of them are complex and expensive procedures.¹ Ideal healing should reproduce the normal transition of the tendon, cartilage, and bone zones.³² Improvements in surgical materials should not change the fibroblastic scar tissue that is observed in rotator cuff tears postoperatively. Improvements by biologic augmentation may be a solution not only to diminish nonhealing but also to obtain higher-quality healing.^{23,24}

The use of patches, which improve the mechanical and biologic conditions for healing, has yielded improved results. But there are some issues with this approach, such as the cost, the possibility of disease transmission, and the technical difficulties in arthroscopic surgery. Hence, this approach is not routinely used.⁸

The addition of stem cells has also been studied by many authors, and both mesenchymal stem cells and adipose-derived stem cells have been used.¹⁵ According to some authors,³ the application of stem cells during rotator cuff surgery has shown no significant efficacy. Nevertheless, Hernigou et al¹² injected concentrated bone marrow stem cells (BMSCs) into the tendon-bone interface, and after 24 months of follow-up, they found that the healing rate in the experimental group was significantly higher than that in the control group (100% vs. 67%), with a significant reduction in the retear rate (13% vs. 56%). Nevertheless, the clinical application of BMSCs has been limited because of the high cost and time required for BMSC extraction, culture, and differentiation; the possible complications of severe pain and infection caused by bone

marrow aspiration before surgery; and the gradual decrease in BMSC quantity with aging.¹⁵

The application of bone marrow stimulation technology to subchondral bone has been confirmed by many scholars and is supposed to promote the biologic repair of cartilage defects of the knee or ankle joint.¹⁵ The CDP, described by Snyder²⁷ in 2009, involves the drilling of holes or creation of microfractures on the surface of the footprint to allow BMSCs to flow and growth factors from the bone marrow cavity to reach the interface between the tendon and bone attachment (Fig. 4, A).

The main advantage of CDP has been the simplicity of the procedure, and the presence of stem cells at the interface of tendon footprint and the tuberosity has been confirmed, as reported in the literature.⁵ Kida et al¹³ drilled at the tuberosity and observed that BMSCs could adhere to the tendon-bone interface via the holes in the footprint and better promote healing of the rotator cuff to improve the strength of fixation.

In our study, the addition of CDP did not represent an extra cost or require extra time during the surgery. Any complications in our patients were secondary to CDP.

Li et al¹⁵ described in a systematic review that bone marrow stimulation has no significant influence on clinical results but can promote healing of the rotator cuff and decrease the retear rate. Pulatkan et al²⁵ reported a significant improvement in terms of the rerupture rate in a group of patients treated with a single-row technique with the addition of microfracture compared with patients treated with a single- or double-row technique without microfracture. Because it was a retrospective study, the authors concluded that a prospective randomized study was needed for a better understanding of the microfracture effect. In a prospective randomized study of 80 patients treated using double-loaded single row (SR) repair for large cuff tears, Milano et al¹⁷ found a healing rate of 60% in those who underwent microfracture compared with 12.5% in controls, as determined on MRI. Dierckman et al⁶ reported a high rate of repair and excellent clinical results in a series of patients with medium to large tears treated with a medial anchor and CDP.

In our study, the difference in the nonhealing rate between the 2 groups did not reach statistical significance, but the number of patients who presented a nonhealing was higher in the control group (7 patients) than in the CDP group (3 patients). This represents a very interesting trend. The number of participants, 58 patients in each group, was determined considering a higher rate of rerupture than we found in the study. Additionally, 22% of patients did not undergo a final radiologic evaluation, and this could have an effect on the conclusion.

Regarding the functional evaluation, we did not find any significant difference between the groups, which is different from the findings of other studies.²¹ We only found a significant difference in active anterior flexion at 6 months

in patients who underwent CDP, but the results have no clinical relevance because the difference was only 7° and the difference was not observed at the 12th month postoperatively.²¹ Osti et al²¹ reported a significant improvement in clinical results at the 3-month follow-up, but these differences were not evident after 1 year of follow-up.

The average age of patients who developed a retear was higher than that of patients with a healed cuff. It is well known that in older patients, the chance of rerupture is higher.³⁰ We also found an association between nonhealing and the functional results, which has also been previously described.¹⁴

One of the strengths of our study is that it was designed as a randomized clinical trial, and the patients and clinical and radiologic evaluators were blinded to the randomization. This may be confirmed considering the lack of an association between the groups (Table I).

Nevertheless, this study also has some weaknesses. Two different imaging modalities were applied for the evaluation of healing (ultrasonography and MRI), although both have shown good results in the evaluation of rotator cuff tears.² Additionally, 22% of patients were missing radiologic data. Finally, the estimation of the number for each group was performed considering a higher rate of rerupture than that found in our study.

Conclusions

The arthroscopic repair of complete rotator cuff tears presents good and excellent clinical results in most patients. Nevertheless, nonhealing occurs at a rate that depends on several factors. According to our results, the hypothesis that CDP improved functional results and/or the healing process was rejected.

Disclaimer

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