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Effects of one-month continuous passive motion after arthroscopic rotator cuff repair: results at 1-year follow-up of a prospective randomized study

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Abstract The study included 100 patients who underwent an arthroscopic rotator cuff repair. All patients suffered about a rotator cuff tear that was repaired arthroscopically with a suture anchor technique. Immediately postoperatively, patients were randomly allocated to one of two different postoperative physiotherapy regimens: passive self-assisted range of motion exercise (controls: 46 patients) versus passive self-assisted range of motion exercise associated with use of continuous passive motion (CPM) for a total of 2 h per day (experimental group: 54 patients), for 4 weeks. After this time, all the patients of both groups underwent the same physical therapy protocol. An independent examiner assessed the patients at 2.5, 6 and 12 months particularly about pain with the VAS scale (0–10) and the range of motion (ROM). Our findings show that postoperative treatment of an arthroscopic rotator cuff repair with passive self-assisted exercises associated with 2-h CPM a day provides a significant advantage in terms of ROM improvement and pain relief when compared to passive self-assisted exercise alone, at the short-term follow-up. No significant differences between the two groups were observed at 1 year postoperatively.

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Introduction

Postsurgical physiotherapy is essential after arthroscopic repair of rotator cuff tears. The rehabilitation program aims to re-establish full symmetrical active and passive movement, to balance the muscle force on the coronal and axial planes and to restore painless, free, functional movement [1, 2].

The size and location of the lesion, the presence of any comorbidity and the surgical technique adopted are all factors that may affect the success of the rehabilitation protocol. Clinicians are particularly concerned with maximizing the effectiveness of the physiotherapy program, since any reduction in the time spent on this could have a negative effect on the final outcome and extent of recovery of the physiological joint function [3].

Postoperative protocols after a rotator cuff tendon repair are debated. Peltz et al. [4] hypothesized that if shoulder mobilization is started too early, a loss of range of motion (ROM) may ensue due to the formation of fibrotic scar adhesions. For this reason, cautious active- and passive-assisted postoperative mobilization is advised in the literature, if necessary supported by aquatic therapy [5] and neuromuscular electrostimulation [6].

Aim of the present work was to assess the efficacy of continuous passive mobilization (CPM) using a mechanized device.

CPM relies on a motorized external tool that allows passive mobilization of a joint along a pre-set movement axis. Salter introduced the biological concept of CPM in the early 1980s [7], demonstrating that in the rabbit knee

CPM could speed healing and cartilage regeneration when compared with prolonged joint rest. Coutts et al. [8] were the first to apply CPM in a clinical setting immediately after total knee arthroplasty: the study by Salter had supplied the rationale, and the researchers hypothesized that CPM increases collagen tissue healing, achieving a good, cross-linking-free fiber orientation and thus restoring good functional motion. In the last 20 years, CPM has been widely applied as an adjunct to physiotherapy after total knee replacement, but the correct method of application is still controversial. In fact, although many Authors recommend CPM [9, 10], others consider that it adds little value to the standard rehabilitation protocol [11, 12]. There is currently a strong interest in assessing the true efficacy of these machines, also for rehabilitation of the arm and shoulder [13, 14].

The present study hypothesis was that the addition of CPM to a standard rehabilitation program after arthroscopic rotator cuff repair might yield a better functional recovery than the standard rehabilitation technique alone.

Materials and methods

From January 2004 to March 2007, 100 patients (47 men, 53 women; mean age 60 years, range 38–80) undergoing arthroscopic repair of a rotator cuff tear were enrolled in this prospective randomized trial. Approval was obtained from the local Ethics Committee, and all patients gave written informed consent to take part. Inclusion criteria were the presence of a grade C2–C3 tear of the upper rotator cuff, according to the criteria of Snyder [15], no previous surgery at the same site, no comorbidities and a good educational level. All the surgical procedures were performed by the same surgeon at the Shoulder Unit of Humanitas Institute in Rozzano (Milan, Italy), using a double-loaded titanium suture anchor, associated, sometimes, with a latero-lateral reinforcement suture. All patients were operated on in lateral decubitus and under locoregional anesthesia.

Postoperatively, the shoulder was immobilized in an Ultra Sling II brace for 4 weeks. After surgery, the patients were immediately randomly allocated into two groups, named A and B, matched for age and sex. Group A, consisting of 46 patients, underwent a protocol of passive self-assisted mobilization supervised by the physiotherapist consisting in 3 series of 10 repetitions each, of pendulum movements and progressive passive abduction, forward flexions and external rotation; while group B, consisting of 54 patients, underwent an additional assisted passive mobilization protocol using the Arthromot S3 device (Ormed, Germany) for a total of 2 h/day in 4 sessions lasting 30 min each. Then, from the 5th to the 28th week the same rehabilitation therapy was administered in both groups, namely from the 5th to the 12th week, continuation of the passive mobilization with the physiotherapist consisting in exercise of passive progressive forward flexion, external rotations and abduction, plus initial proprioception exercises. From the 13th to the 28th week, we continue the passive program to resume complete ROM, and we start active-assisted ROM exercises depending on the degree of pain tolerance; furthermore, we start progressive isometric reinforcement exercises for internal and external rotators, and for scapular stabilizers muscles [2].

An independent examiner assessed the patients at 2.5, 6 and 12 months, about pain evaluated on the basis of the VAS scale (0-10) and the range of motion (ROM) for Abduction (ABD), Forward Flexion (FF) and External rotation in abduction (ER2). Student's t test for paired data and the Wilcoxon test, with 95% confidence intervals, were used for comparison. Statistical significance was set at $P < 0.05$.

Results

No intra- or postoperative complication was observed in patients included in this study.

All patients completed 1-year follow-up (FU) evaluation.

At the first FU, scheduled at 2.5 months, subjects in group B had statistically significantly better values for the VAS (7.5 ± 0.1) ($P < 0.01$), FF (133 ± 21.1) ($P < 0.01$), ABD (66.7 ± 14.5) ($P < 0.05$) and ER2 (63.5 ± 15.4) ($P < 0.05$) than group A subjects: VAS (9.1 ± 0.2), FF (120.7 ± 20.6), ABD (60.1 ± 14) and ER2 (56 ± 14).

At 6 months of FU, group B patients still showed significant differences for FF (158.1 ± 9.4) ($P < 0.01$), ABD (86.9 ± 5.3) ($P < 0{,}01$) and ER2 (83 ± 7.7) ($P < 0.05$) when compared to the group A values: FF (151.7 ± 12.5), ABD (82.3 ± 7.6) and ER2 (79.1 ± 7.4). There was no longer any significant difference in the VAS values between group B (0.5 ± 0.1) and group A (0.6 ± 0.1) ($P > 0.05$).

At the third FU at 1 year, there were no statistically significant differences between the values for all the parameters: group B VAS (0.2 ± 0.1) ($P > 0.05$), FF (165.2 ± 8) ($P > 0.05$), ABD (90 ± 2.5) ($P > 0.05$) and ER2 (86 ± 4) ($P > 0.05$) versus group A VAS (0.2 ± 0.2), FF (158 ± 10.1), ABD (88 ± 1.8) and ER2 (85 ± 4.2).

The Figs. 1, 2 and 3 summarize the results of the ROM in the two different groups of patients.

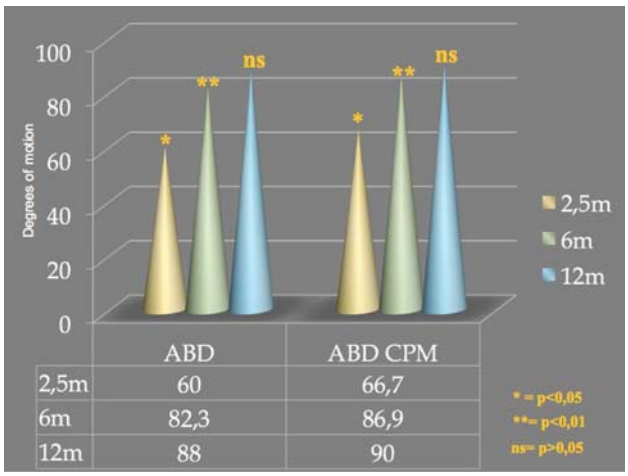

Fig. 1 Results of degrees of abduction in group A (ABD) and group B (ABD CPM) at 2.5 months (2.5m), 6 months (6m) and 12 months (12m)

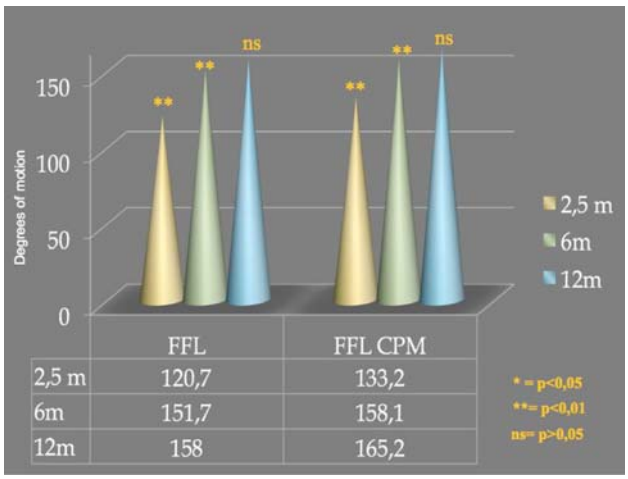

Fig. 2 Results of degrees of front flexion in group A (FFL) and group B (FFL CPM) at 2.5 months (2.5m), 6 months (6m) and 12 months (12m)

Discussion

Our findings demonstrate that the use of CPM is able to accelerate functional recovery, yielding better short-term results, whereas there were no statistically significant differences between the two rehabilitation protocols at long-term follow-up. Some authors believe that immobilization after rotator cuff repair avoids the formation of further scar tissue in the subacromial space, preventing the onset of joint stiffness [4]. Furthermore, it has been demonstrated that mechanical stress activates MAP-kinases, triggering a cascade of pro-inflammatory cytokines such as TNF-alpha and IL-6, that cause fibroblast proliferation and the formation of an adhesive capsulitis [16].

Instead, other authors are convinced that passive mobilization is preferable to immobilization. Ferretti et al. [17]

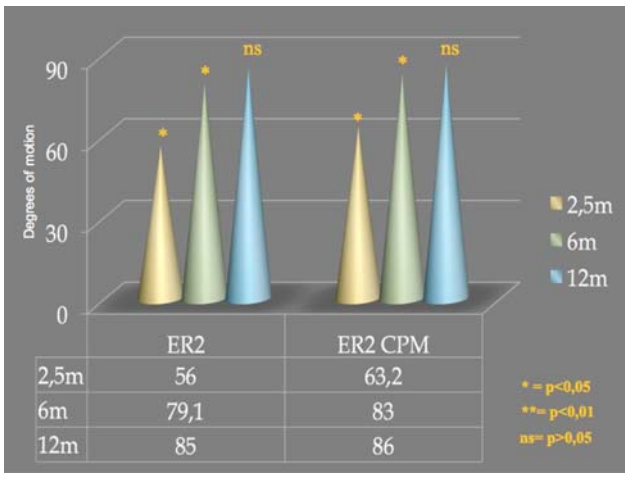

Fig. 3 Results of degrees of extra-rotation in abduction in group A (ER2) and group B (ER2 CPM) at 2.5 months (2.5m), 6 months (6m) and 12 months (12m)

demonstrated that the application of continuous passive mobilization in a rabbit joint arthrosis model has powerful anti-inflammatory effects, mediated by IL-10 production and the suppression of GAGs degradation. This results in an efficient qualitative and quantitative reorganization of the collagen tissue [18], as well as increased tendon vascularization [19] and metabolic activity of the tenocytes [20, 21].

In a meta-analysis, Milne et al. [22] concluded that the combined use of CPM and segmental rehabilitation provides better short-term results when compared to the classic rehab program after knee replacement surgery. However, there is still no consensus as to the best period of application of CPM and how long each session should last. In some reviews, the application of CPM is advised in the early phase of postsurgical rehabilitation [22, 23].

In any case, only few studies have assessed the results of application of these devices (the "Arthromot-System") for the rehabilitation of shoulder injuries [13, 14]. In 1996, Raab et al. [24] reported better results, following subacromial decompression, with the association of CPM with standard postoperative rehabilitation in 14 patients when compared to 12 control cases. At 3 months of follow-up, the ROM was significantly better in the experimental group and, in women aged >60 years, pain control was more efficacious.

In 1998, Lastayo et al. [25] applied CPM for 55 min/day over the first 4 weeks postoperatively in 17 patients who underwent cuff repair; after 32 weeks, no statistically significant differences in terms of VAS, force and ROM were observed when compared to the control group.

In 2005, Michael et al. [26] randomized 55 subjects undergoing surgical cuff repair to two groups, one treated with rehabilitation alone and the other with adjunctive

CPM. They found that the recovery of 90° abduction occurred 12 days earlier in the CPM group, that also suffered significantly less pain. When compared to the 3 previous papers [22, 25, 26], our experience is based on a larger patients sample and longer follow-up. Our data on 54 patients treated with CPM demonstrate that at 2.5 and 6 months FU, the continuous passive mobilization for 2 h/day yields significantly better pain control and joint ROM recovery than passive manual mobilization alone, done by the experienced physiotherapist. However, the final long-term results of the two protocols are the same.

Our trial has some limitations. First of all, an ideal study design would require comparison of the same surgical procedure simultaneously or in sequence in the same patient, to eliminate bias due to individual variability. Secondly, different rehabilitation protocols after rotator cuff repair are available, and that used in our study may differ from what was used in other investigations.

However, this study had also some strengths related to the large sample size; all the surgical procedures were performed by the same surgeon, the physiotherapy was supervised by the same physician and performed by experienced shoulder physiotherapists associated with the physician itself. Furthermore, no patient was lost to follow-up.

The main reasons why CPM is not supported in the literature may have to do with the cost of the device and the finding that the long-term functional results seem to be the same as after a traditional rehab program [25]. Since our results demonstrate that clinical application of CPM brings about an earlier recovery of the joint ROM and better pain control, we suggest that CPM should be used in association with classic rehab in patient categories needing a shorter recovery time for occupational reasons, such as sportsmen. The method induces a faster recovery of the ROM and muscle force after rotator cuff repair surgery [27].

In literature, various Authors have advised the application of CPM in the first 4 postoperative weeks. This is the best time, in our opinion, since it is in this phase that healing and remodeling of the tendon-bone contact area occur [28]. Further clinical studies are needed to verify the best daily duration of the application of CPM, ranging between 55 min [25] and 3 h [14], as reported in previous clinical protocols.

Conflict of interest None.

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