

Garofalo R, Conti M, Notarnicola A, et. al. Effects of one-month continuous passive motion after arthroscopic rotator cuff repair: results at 1-year follow-up of a prospective randomized study. *Musculoskeletal Surgery* 2010; 94:S79-S83.

Critique author: Linda Metzger 2-7-14

Design: Prospective randomized clinical trial

Objective: To determine if the addition of continuous passive motion exercise to a standard physiotherapy rehabilitation program of passive self-assisted range of motion exercises after arthroscopic rotator cuff repair yields a better functional recovery for the shoulder than the standard physiotherapy alone.

Population /sample size/setting:

- 100 volunteer patients (mean age = 60, 47 males, 53 females) undergoing arthroscopic repair of a rotator cuff tear were recruited from the Shoulder Unit of Humanitas Institute in Rozzano, Italy.
- Eligibility criteria included the presence of a grade C2-C3 tear of the upper rotator cuff, and a good educational level.
- Exclusion criteria included previous surgery at the same site, or other comorbidities.
- All rotator cuff repairs were performed by the same surgeon and all physiotherapy was supervised by the same physician.

Interventions:

- All participants were randomized to one of two interventions after surgery and were matched for age and gender; 1) passive self-assisted mobilization range of motion exercises (n=46) supervised by the physiotherapist consisting of 3 series of 10 repetitions each, of pendulum movements and progressive active abduction, forward flexions and external rotation (control group) or, 2) the same physiotherapy regimen as the control group AND an additional assisted passive mobilization protocol using the mechanized continuous motion Arthromot S3 device (CPM group) (n=54). This protocol consisted of a total of 2 hours/day in 4 sessions lasting 30 minutes each.
- Interventions for both groups lasted 4 weeks immediately post-surgery.
- Both groups underwent the same physical therapy protocol during weeks 5 through 28. Passive therapy progressed from weeks 5 to 28, and at 13 weeks active-assisted range of motions exercises began and continued through 28 weeks.

Main outcome measures:

- Outcome measurements included pain intensity using the visual analog scale (VAS scale 0-10), and range of motion for abduction (ABD), forward flexion (FF), and external rotation in abduction (ER2). Measurements were taken at 2.5, 6, and 12 months post-surgery. An independent examiner assessed all the patients.
- All participants completed all 3 assessments. No participants were lost to follow-up.
- At the first follow-up assessment at 2.5 months, participants in the continuous passive motion (CPM) group showed statistically significant better scores for all the outcome

measurements than the control group: VAS scores 7.5 vs. 9.1, FF 133.2 vs. 120.7, ABD 66.7 vs. 60.1, and ER2 63.5 vs. 56.

- At the second follow-up assessment at 6 months, participants in the continuous passive motion (CPM) group still showed statistically significant better scores for all the range of motion outcome measurements than the control group: FF 158.1 vs. 151.7, ABD 86.9 vs. 82.3, and ER2 83 vs. 79.1. There was no longer any significant difference in the VAS scores between the 2 groups (0.5 vs. 0.6).
- At the 12 month follow-up assessment, there were no statistically significant differences between the scores for all outcome measurements for the 2 groups

Authors' conclusions:

- The use of CPM is able to accelerate functional recovery, yielding better short-term results, whereas there were no statistically significant differences between the 2 intervention groups at long-term follow-up (12 months). The long-term results of the 2 interventions are the same.
- Subjects treated with CPM demonstrate that at 2.5 and 6 months after rotator cuff repair, the continuous passive mobilization for 2 hours a day yields significantly better pain control and joint ROM recovery than passive manual mobilization alone.
- CPM should be used in combination with traditional physiotherapy rehabilitation for patients needing a shorter recovery time for occupational reasons, such as sooner return to work.

Comments:

- The participants and the physical therapists treating the participants could not be blinded to the intervention received by each participant. However, the examiner conducting the outcome assessments should be blinded to the participants' intervention groups. The study did not address if the independent examiner assessing the patients was uninvolved with the interventions of the trial and unaware of the treatment group to which each of the subjects had been allocated.
- General baseline characteristics were not evaluated for the 2 groups, except that they were stratified and matched for age and gender, and so it is unknown if there were any underlying differences between the 2 groups. Baseline outcome measurements were also not assessed, either before surgery or immediately following surgery, and so it is unknown if there were any differences in pain or range of motion between the 2 groups before the physiotherapy interventions were even started. Specific unknown baseline characteristics or baseline outcome measurements may not have been evenly distributed among the 2 interventions during randomization causing an imbalance which could be a source of uncertainty of the effects. No interpretations can be made without baseline data.
- It would have been useful for the authors to include standard deviations for all results.
- At the first follow-up assessment at 2.5 months, the mean difference in VAS scores between the 2 groups was 1.6 points or a 16% difference. To determine clinical relevance of results and define effect sizes, the Cochrane Review Group defines a medium effect size as a mean difference that is between 10% and 20% of the scale. Thus a medium effect size is seen for pain reduction between the 2 groups at 2.5 months of follow-up.

- At the first follow-up assessment at 2.5 months, the mean difference in ROM scores between the 2 groups was 3.7% for ABD, 6.9% for FF, and 8% for ER2. These mean differences (all statistically significant) are all less than 10% of the scale and would be considered by Cochrane to equate to a small effect size. The effect sizes are even smaller at the 6 month follow-up (all statistically significant). A statistically significant difference in ROM improvement does not necessarily imply a clinically significant difference, and is not the sole reason for judging one intervention superior to another. These mean differences are so small that they would only change a Constant-Murley score used to assess shoulder function by no more than 2 points. I believe the authors overestimated the clinical importance of the small differences detected and that these differences do not demonstrate a significant clinical improvement.
- The improvement in VAS scores in both groups between the 2.5 and 6 month assessments is unfathomable. The CPM group VAS score improved from 7.5 to 0.5 and the control group improved from 9.1 to 0.6. The authors failed to address this huge improvement in any way and left us wondering why severe pain at 2.5 months all but disappeared at 6 months. It is possible that this is a gross typographical error that the editors missed.
- The CPM intervention used in this study is a safe and effective rehab approach for patients after rotator cuff surgery that may garnish greater patient compliance than traditional passive self-assisted mobilization.
- The cost of the CPM device may prohibit its widespread use.
- The CPM intervention group received an additional 2 hours of passive therapy a day for 4 weeks using the CPM device compared to the control group. It is unclear from the results of this study, that if the control group received an additional 2 hours per day of passive non-CPM therapy or even another type of physiotherapy, equalizing the amount of therapy time between the 2 groups, whether the CPM intervention group would have still realized better outcomes in the short-term.
- One limitation of the study was that no assessment was performed at 4 weeks post-surgery when the CPM intervention ended. An assessment at this time may have impacted the ability of the study to reveal the limited, short-term therapeutic benefit for patients in the CPM intervention.
- At least one mistake was noted between the outcome measurement numbers in the text and those listed on the figures.
- The absence of a no treatment group in this study limits its ability to assess whether the changes are due to the natural history of shoulder pain or the passage of time. However, the absence of a no treatment group does not undermine the study, and I agree that this is ethically justified.

Assessment:

This study is inadequate as evidence for or against the addition of continuous passive motion exercise to a standard physiotherapy rehabilitation program of passive self-assisted range of motion exercises after arthroscopic rotator cuff repair due to the absence of any baseline data.