

Cuff DJ and Pupello DR. Prospective Randomized Study of Arthroscopic Rotator Cuff Repair using an Early versus Delayed Postoperative Physical Therapy Protocol. Journal of Shoulder and Elbow Surgery 2012; 21:1450-1455.

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Design: Randomized controlled trial

Objective: To evaluate patient outcomes and rotator cuff healing after arthroscopic rotator cuff repair using a postoperative physical therapy protocol with early passive motion compared with a delayed protocol that limited early passive motion.

Population /sample size/setting:

- 68 consenting patients (mean age = 63.2, 38 males, 30 females) undergoing arthroscopic rotator cuff repair were recruited from an orthopaedic surgery institution in Florida.
- Eligibility criteria included the presence of an isolated full-thickness crescent-shaped supraspinatus tear, surgery using a transosseous equivalent suture-bridge technique along with subacromial decompression, consent to be randomized in either group, ultrasound exam to assess healing at 9 months or later post-op, and at least 12 months of clinical follow-up.
- Exclusion criteria included concomitant procedures, partial thickness tears, tears of other patterns or tears that extended into the subscapularis or the infraspinatus, glenohumeral arthritis, Workers' Compensation cases, adhesive capsulitis, or revision rotator cuff repair.

Interventions:

- All participants were randomized to one of two rehabilitation protocols after surgery.
- Early range of motion group (n=33), 18 men, 15 women. On post op day 2 began passive forward elevation and external rotation with a physical therapist (PT) 3 times a week for 3 weeks. From 3-6 weeks progressed to passive forward elevation to tolerance and passive external rotation to 45 degrees. On non-PT days, patients would perform gentle circular pendulum exercises 3 times a day for 5 minutes. Started active PT assisted range of motion (ROM) at 6 weeks, full active ROM by 10 weeks, and strengthening at 12 weeks.
- Delayed range of motion group (n=35), 20 men, 15 women. No formal outpatient PT until 6 weeks post op. Only performed gentle circular pendulum exercises 3 times a day for 5 minutes for the first 6 weeks. No passive forward elevation or external rotation. At 6 weeks began formal PT 3 days a week with passive exercises. Started active PT assisted range of motion (ROM) at 7 weeks, full active ROM by 10 weeks, and strengthening at 12 weeks.
- Patients in both groups were placed in a shoulder immobilizer for 6 weeks after surgery except during PT and daily hygiene.
- Patients were monitored clinically for a minimum of 12 months.

Main outcome measures:

- Outcome measurements included American Shoulder and Elbow (ASES) and Simple Shoulder Test (SST) scores at 12 months post op. Patient-reported satisfaction was also recorded at one year post-op. For shoulder range of motion (ROM), 3 tests were conducted at pre-op, and 6 and 12 months post-op; forward elevation, external rotation, and internal rotation.
- The 3 tests for ROM were recorded on a digital camera and the videos were analyzed 3 times each by the 3 different observers. The 3 observer's measurements for each patient's ROM were averaged and recorded. Interobserver reliability was calculated using a Pearson correlation coefficient with a value > 0.7 indicating a strong agreement between observers. Correlation coefficients for each of the 3 ROMs were 0.92, 0.90, and 0.97 indicating strong interobserver reliability in analyzing these measurements.
- A postoperative ultrasound evaluation was performed at a mean of 12.2 months (range 9-14 months) to assess rotator cuff healing. All ultrasound evaluations were performed by one experienced musculoskeletal radiologist.
- Limited baseline demographic data (gender, age, smoking status, and diabetes) was gathered between the two groups and there were no major differences.
- Both groups showed similar improvement in ASES scores from preoperative levels, but there was no statistical significant difference between the 2 groups at 12 months postoperatively. The early range of motion group went from 43.9 to 91.1 and the delayed range of motion group went from 41.0 to 92.8.
- Similar results were seen for the SST scores with no statistical significant difference between the 2 groups at 12 months postoperatively. The early group improved from 5.5 to 11.1 and the delayed group improved from 5.1 to 11.1.
- Patient reported satisfaction was 94% for the early group and 97% for the delayed group with no statistical difference between the 2 groups.
- Baseline pre op ROMs were nearly the same with no statistical difference between the 2 groups.
- At 6 months, the early group demonstrated a greater average forward elevation of 172° compared to 165° in the delayed group ($P < .0001$). No significant differences were seen for external or internal rotation, but 79% of the early group could fully internally rotate to the lumbar region compared to 60% in the delayed group ($P = .12$).
- At the 12 month follow-up, all 3 ROM tests revealed similarly improved results in both groups with no statistical differences between the 2 groups. Forward elevation was 174° in the early group and 173° in the delayed group. External rotation was 46° in the early group and 45° in the delayed group. 94% of the early group could fully internally rotate to the lumbar region compared to 91% in the delayed group.
- Postoperative ultrasounds at the 12 month follow-up revealed an intact and healed repair in the early group of 85% (15% retear rate) and a slightly higher healing rate in the delayed group of 91% (9% retear rate). The difference in the healing rates between the 2 groups was not statistically significant.
- Ultrasound revealed a total of 8 recurrent rotator cuff tears. Five tears were in the early group and 3 tears were in the delayed group. Of the total 8 tears, 5 were smokers and 6 were diabetic. No other complications were noted in the study.

Authors' conclusions:

- ROM and function all improved after arthroscopic rotator cuff repair at 12 months post op, regardless of early or delayed postoperative rehabilitation protocols.
- Patients who underwent arthroscopic repair of a full-thickness supraspinatus tear and were then prescribed a postoperative rehabilitation protocol of early or delayed initiation of passive range of motion exercises demonstrated very similar clinical outcomes and range of motion at 1-year after surgery.
- There is no significant advantage to beginning early passive ROM after surgery.
- Patients in the delayed range of motion group had a slightly higher rotator cuff healing rate (91% vs. 85%) or a slightly lower retear rate (9% vs. 15%) by ultrasound imaging, indicating there may be a potential benefit to avoiding early passive ROM in an effort to protect the surgical repair.
- The early range of motion group regained range of motion faster with slightly more forward elevation at 6 months post op (172° vs 165°), but no difference was evident at 12 months (174° vs 173°).
- Postoperative early passive motion during rehabilitation could affect structural integrity of the repaired cuff tendon adversely, and delaying formal therapy and avoiding early ROM may be advantageous to the patient by providing a more optimal healing environment for the rotator cuff during the initial 6 weeks after surgery.
- Another potential benefit of delaying formal therapy is the reduced cost and convenience for the patient.

Comments:

- All repairs were performed at one orthopaedic institution using a transosseous equivalent suture-bridge technique to exclude any technical/surgical differences between the 2 groups.
- It is important to note that the delayed ROM group was not subjected to full immobilization during the first 6 weeks after surgery. Patients were instructed to perform “small diameter” circular pendulums in an effort to minimize contraction of the repaired supraspinatus.
- One strength of the study was that it contained a homogenous group of patients who did not undergo any other additional surgical procedures during the time of the repair.
- One weakness of the study is its inability to document patient compliance with the movement restrictions in the postoperative period which might have affected their motion or healing rate. On the other hand, the possible confounders of diabetes and smoking that can also contribute to retears were considered.
- A major weakness of the study was that the sample size was too small and lacked the power needed to detect a statistically significant difference in healing rates or retear rates between the 2 groups. A post hoc power analysis revealed that to achieve 80% power in this study, 138 patients in each group would be required to detect a 10% difference in retear rates that would be statistically significant and also clinically important.
- A typographical error reporting incorrect P values was noted in Table 3.
- The authors did not address whether or not the 3 assessors conducting the outcome measurements were blinded to the rehabilitation protocol of each patient. Lack of blinding could inflate the differences found between the 2 groups away from the null. Since no differences were observed in ROM between the 2 groups, it is unlikely that non-

blinding influenced the direction of the bias substantially, and does not undermine the conclusions of the study.

- They also did not note if the singular radiologist performing the ultrasound evaluations to assess rotator cuff retears was blinded to the rehabilitation protocol of each patient. The non-blinding of the radiologist could have introduced bias that could have potentially inflated the difference in the retear rate between the 2 groups. Since this difference was still small and statistically non-significant, any non-blinding bias was unlikely to undermine the study's conclusions.
- It is unknown if the size of tears was evaluated in this study and if different sized tears were evenly distributed between the 2 groups. Since the healing rate was not adjusted for any possible baseline imbalance in the size of tears in each group, there would remain some uncertainty in the estimate of healing rates.
- Interobserver reliability was calculated for the three ROM evaluators indicating strong interobserver reliability in analyzing the ROM measurements.
- At 6 months postoperatively, there was a statistically significant difference in forward elevation between the 2 groups with the early range of motion group showing better forward elevation (172° vs 165°). The mean difference between the 2 groups was 4% for forward elevation. Even though this 4% mean difference is statistically significant, it only equates to a very small effect size as defined by Cochrane (small < 10%). This difference in forward elevation between the 2 groups does not demonstrate a clinically important difference.

Assessment:

- This study is adequate for some evidence that a postoperative rehabilitation protocol of early or delayed initiation of passive range of motion exercises demonstrate very similar clinical outcomes and range of motion at 1-year after arthroscopic repair of a full-thickness supraspinatus tear indicating no significant advantage to beginning early passive ROM after surgery. Patients in the delayed range of motion group had a slightly higher rotator cuff healing rate by ultrasound imaging (91% vs. 85%), although there was no statistically significant difference, indicating there may be a potential benefit to avoiding early passive ROM in an effort to protect the surgical repair.