Lee BG, Cho NS, Rhee YG. Effect of Two Rehabilitation Protocols on Range of Motion and Healing Rates after Arthroscopic Rotator Cuff Repair: Aggressive vs. Limited Early Passive Exercises. Arthroscopy: The Journal of Arthroscopic and Related Surgery 2012; 28:34-42.

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Design: Randomized controlled trial

Objective: To determine which rehabilitation protocol, aggressive or limited early passive rehabilitation, yields better range of motion (clinical outcome) and healing rates (structural outcome) for the shoulder after arthroscopic single-row repair for a full-thickness rotator cuff tear.

Population /sample size/setting:

- 64 consenting patients (mean age = 55, 41 males, 23 females) undergoing arthroscopic repair of a rotator cuff tear were recruited in Seoul, South Korea. Initially 85 enrollees, but 6 were lost to follow-up, and 15 refused postoperative MRI evaluation.
- Eligibility criteria included the presence of a full-thickness rotator cuff tear, medium-sized (1-3 cm) or large-sized (3-5 cm) tears only, and surgery using a single-row repair technique.
- Exclusion criteria included previous surgery at the same site, partial rotator cuff tears, small sized tears, massive tears, suture bridge repairs, modified Mason-Allen single row repair, SLAP lesions, acromioclavicular or advanced glenohumeral arthritis, Workers' Compensation claim, or those who needed tenotomy or tenodesis of the long head of the biceps, and those undergoing revision procedures.
- All rotator cuff repairs were performed by the same surgeon (senior author) who was blinded to the randomization of the rehabilitation protocol before surgery.

Interventions:

- All participants were randomized to one of two rehabilitation protocols after surgery.
- Group A (n=30) - aggressive early passive rehab aims to get to preoperative ROM at an early stage. One day post-op to hospital discharge, passive ROM exercises 2 times a day with a physical therapist (PT), supplemented with unlimited self-passive stretching exercises (pendulum and forward flexion) in a tolerable range, and passive ROM exercises 3 times a day, 10 repetitions each time, in a tolerable range. For 3 weeks after discharge, continue the protocol, only the PT sessions are eliminated. For 3-6 weeks after discharge, continue with the passive ROM exercises 3 times a day.
- Group B (n=34) – minimum passive exercises to prevent joint stiffness until the rotator cuff was healed. Rehab protocol used a continuous motion machine for gentle stretching 2 times a day for 3 weeks and gradually increased the range to the tolerable level without PT support until 6 weeks post op.
- Active assisted exercises started at 6 weeks post-op or when full passive ROM was regained for both groups. Once active exercises were started, groups A and B followed the same rehabilitation protocol.
- The mean follow-up period was 23.8 months for Group A and 26.4 months for Group B.

Main outcome measures:

- Outcome measurements included pain intensity (pre and postoperative) using the visual analog scale (VAS scale 0-10). Quantitative muscle strength, elevation strength, and external and internal rotation was tested. For shoulder range of motion (ROM), 5 tests were performed. The preoperative exam was performed one day before surgery and postoperative evaluations were conducted at 3, 6, 9, and 12 months. One orthopaedic surgeon performed all the preoperative and postoperative evaluations.
- A postoperative MRI evaluation was performed at a mean of 7.6 months (range – 6-12 months) to assess tendon healing. All MRI's were reviewed by one experienced radiologist.
- There were no significant differences in the demographic data between the two groups.
- In Group A, the VAS score for pain at rest decreased from a preoperative mean of 1.77 to 0.23 at one year post op, and during motion from 6.36 to 1.47. In Group B, the VAS score for pain at rest decreased from a preoperative mean of 1.56 to 0.15 at one year post op, and during motion from 5.79 to 1.53.
- Both groups showed significant improvement in pain scores from preoperative levels, but there was no statistically significant difference between the 2 groups at 3, 6, and 12 months postoperatively.
- At 3 months postoperatively, Group A showed decreases in 2 ROM tests compared to preoperative levels, whereas Group B showed decreases in all 5 ROM tests.
- At 3 months postoperatively, Group B presented slower recovery and showed a statistically significant decrease in all 5 ROM tests compared to Group A. At 12 months postoperatively, there were no statistically significant differences in the 5 ROM tests between the 2 groups.
- Group A showed improvement from preoperative levels in all 5 ROM tests at 12 months, but Group B showed improvement from preoperative levels in only 2 ROM tests at 12 months.
- Both groups recorded significant postoperative improvement in muscle strength and at one year there was no statistical difference in muscle strength between the 2 groups.
- There were no significant differences in fatty degeneration and muscle atrophy between the two groups.
- Both groups reported statistically significant improvement in clinical assessment at 12 months follow-up, but there was no statistical difference between the 2 groups.
- Postoperative MRI scans revealed a retear rate in Group A of 23.3% and in Group B of 8.8%. Even though the retear rate was higher in Group A, the difference was not statistically significant.

Authors' conclusions:

- Pain, ROM, muscle strength, and function all significantly improved after arthroscopic rotator cuff repair, regardless of early postoperative rehabilitation protocols.
- The group undergoing aggressive early passive rehabilitation showed better recovery of ROM until 3 months postoperatively than the group with limited early passive rehabilitation, but after 6 months postoperatively, no difference was found between the 2 groups except for internal rotation at 90° of abduction.

- The retear rate of the aggressive early passive rehabilitation group was more than twice the rate of the limited early passive rehabilitation group, although there was no statistically significant difference in the final retear rate.
- The aggressive early passive rehabilitation protocol puts more stress on the repaired rotator cuff than the limited early passive rehabilitation protocol and may increase the possibility of anatomic failure at the repaired cuff.
- Postoperative early motion during rehabilitation could affect structural integrity of the repaired cuff tendon adversely and limited early passive rehabilitation would be better than aggressive early passive rehabilitation after arthroscopic rotator cuff repair.
- A gentle rehabilitation with limits in ROM and exercise times after arthroscopic rotator cuff repair would be better for tendon healing without taking any substantial risks.

Comments:

- All repairs were performed by one surgeon using only a single-row repair technique to exclude any technical/surgical differences between the 2 groups.
- The participants and the physical therapists treating the participants could not be blinded to the intervention received by each participant. However, the examiner, a senior author and orthopedic surgeon, conducting the outcome assessments should be blinded to the participants' intervention groups. The study did not address if the sole examiner assessing the patients both before and after surgery at 3, 6, 9, and 12 months was blinded to the rehabilitation protocols of the trial and unaware of the rehabilitation group to which each of the subjects had been allocated.
- General baseline characteristics were evaluated for the 2 groups, and there were not any underlying significant differences between the 2 groups, except that there was a slight imbalance in the number of large-sized tears in each group.
- Group B had 1/3 more "large-sized" rotator cuff tears than Group A (14 vs. 9), but group B still had a lower retear rate (8.8% vs. 23.3%) than Group A. This difference was not statistically significant (P = .106) and may be underestimated. If larger tears are more likely to retear, then the retear rate in Group B may be slightly artificially inflated, since more large-sized tears were present in this group. If the sample size of the study had been larger to increase the study's power to see a difference, and the large-sized tears had been more evenly distributed between the 2 groups, a statistically significant difference between the tear rates in the 2 groups may have resulted. Since the retear rate was not adjusted for the baseline imbalance in the number of large-sized tears in each group, there remains some uncertainty in the estimate of retear rates.
- This was a homogeneous study that excluded selection bias that could have impacted results by including only medium-sized or large-sized tears without undue tension.
- One limitation of the study was that the sample size was too small to determine any statistical significance by parametric analysis, so only nonparametric analyses were carried out.
- Another limitation of the study was that possible confounding factors that could have contributed to retears were not considered including compliance with post op rehabilitation, immobilization, bracing, diabetes, and smoking. Baseline data on diabetes and smoking was not collected.

- Interobserver and intraobserver reliability were not evaluated on MRI interpretation, even though only one experienced radiologist reviewed all the scans.
- The authors have not reported the length of the hospitalization period, and as a result it is unknown how long the first segment of the rehabilitation protocol is for both groups. If the hospitalization period varies by individual, then the authors have not addressed any possible differences in the mean length of the hospitalization period between the 2 groups and how this might affect the rehabilitation protocols.
- The authors failed to designate a primary outcome. They also did not address the 21 dropouts of which 6 patients were lost to follow-up and 15 refused postoperative MRI evaluation.
- Even though Group A has slightly lower preoperative ROM in 4 of the 5 tests, Group A has slightly better ROM in 4 of 5 tests at 12 months of follow-up.
- At 3 months postoperatively, there were statistically significant differences in all 5 ROM tests between the 2 groups with Group A consistently displaying better ROM than Group B. The mean difference in ROM scores between the 2 groups ranged from 8.8% to 22.8% for the 5 tests. These mean differences (all statistically significant) equate to medium to large effect sizes as defined by Cochrane. These statistically significant differences in ROM between the 2 groups do seem to demonstrate a clinically important difference, and suggest that the aggressive early rehab protocol is superior to the limited early rehab protocol.
- The aggressive early passive rehabilitation protocol may be more suitable for patients needing a shorter recovery time for occupational reasons, such as sooner return to work.

Assessment*:*

- This study is adequate for some evidence that aggressive early passive rehabilitation yields faster recovery of range of motion (clinical outcome) at 3 months after arthroscopic single-row rotator cuff repair than limited early passive rehabilitation, but after 12 months postoperatively no differences in range of motion were found between the 2 groups. The retear rate of the aggressive early passive rehabilitation group was more than twice the rate of the limited early passive rehabilitation group (without adjustment for the imbalance in the pre-op status between groups), although there was no statistically significant difference in the final retear rate. This evidence must be qualified, since the consequences of a retear are greater than a later recovery. Under these circumstances, clinical importance vs. statistical significance supersedes the clinical outcome of gaining a few degrees of ROM earlier in rehabilitation, and thus limited early passive rehabilitation is recommended.