Rehabilitation following arthroscopic rotator cuff repair: A prospective randomized trial of immobilization compared with early motion

Jay D. Keener
*Washington University School of Medicine in St. Louis*

Leesa M. Galatz
*Washington University School of Medicine in St. Louis*

Georgia Stobbs-Cucchi
*Washington University School of Medicine in St. Louis*

Rebecca Patton
*Washington University School of Medicine in St. Louis*

Ken Yamaguchi
*Washington University School of Medicine in St. Louis*

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Rehabilitation Following Arthroscopic Rotator Cuff Repair

A Prospective Randomized Trial of Immobilization Compared with Early Motion

Jay D. Keener, MD, Leesa M. Galatz, MD, Georgia Stobbs-Cucchi, RN, Rebecca Patton, MA, and Ken Yamaguchi, MD

Investigation performed at the Shoulder and Elbow Service, Department of Orthopaedic Surgery, Washington University, St. Louis, Missouri

Background: The influence of rehabilitation on the outcomes after arthroscopic rotator cuff repair remains unknown. The purpose of this study was to compare clinical results and tendon healing rates following arthroscopic rotator cuff repair utilizing two distinct rehabilitation protocols.

Methods: Over a thirty-month period, 124 patients under the age of sixty-five years underwent arthroscopic repair of a full-thickness rotator cuff tear measuring <30 mm in width. Postoperatively, patients were randomized either to a traditional rehabilitation program with early range of motion or to an immobilization group with delayed range of motion for six weeks. Clinical outcomes assessment included visual analog pain scale score, American Shoulder and Elbow Surgeons (ASES) score, Simple Shoulder Test (SST), relative Constant score, and strength measurements at six, twelve, and twenty-four months. Tendon integrity was assessed with ultrasonography at a minimum of twelve months postoperatively.

Results: There were no significant differences in patient age, tear size, or measures of preoperative function between groups at baseline. Final clinical follow-up was available for 114 subjects (92%). Active elevation and external rotation were better in the traditional rehabilitation group at three months. No significant differences were seen in functional scores, active motion, and shoulder strength between rehabilitation groups at later time points. Functional outcomes plateaued at six or twelve months except for the relative Constant score, which improved up to twenty-four months following surgery. Ninety-two percent of the tears were healed, with no difference between rehabilitation protocols (p = 0.46).

Conclusions: Arthroscopic repair of small and medium full-thickness rotator cuff tears results in reliable improvements in clinical outcomes and a high rate of tendon integrity using a double-row repair technique in patients under the age of sixty-five years. There is no apparent advantage or disadvantage of early passive range of motion compared with immobilization with regard to healing or functional outcome.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Peer Review: This article was reviewed by the Editor-in-Chief and one Deputy Editor, and it underwent blinded review by two or more outside experts. It was also reviewed by an expert in methodology and statistics. The Deputy Editor reviewed each revision of the article, and it underwent a final review by the Editor-in-Chief prior to publication. Final corrections and clarifications occurred during one or more exchanges between the author(s) and copyeditors.

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A commentary by Stephen F. Brockmeier, MD, is linked to the online version of this article at jbjs.org.

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rehabilitation on the healing and clinical results after arthroscopic rotator cuff repair. The timing of shoulder motion and the progression of rehabilitation milestones, in theory, may directly influence tendon healing following surgery, but this remains unanswered.

Traditional rehabilitation following rotator cuff repair has included early passive motion of the shoulder to prevent excessive stiffness\(^4\). As concerns over tendon healing grew, a delayed rehabilitation protocol employing an early period of immobilization gained popularity\(^5,7\). The rationale behind a delayed rehabilitation program stems from concerns that early repair site micromotion and gap formation may negatively affect tendon healing. The timeline for healing after cuff repair surgery in humans is unknown, but large animal models have shown that mature healing takes up to three to four months\(^8,9\). Furthermore, recent research demonstrating that most recurrent tears develop within three to six months following surgery\(^10,11\) further supports an early period of immobilization. Delayed motion may increase the risk of postoperative shoulder stiffness and potentially delays return of shoulder function.

The relative benefits and risks of early, protected shoulder motion compared with immobilization following rotator cuff repair have not been completely defined. The purpose of this study was to compare the clinical results and rates of tendon healing in a cohort of patients prospectively randomized to an early passive motion protocol or to a protocol with a six-week period of immobilization following arthroscopic rotator cuff repair. We hypothesized there would be no difference in the clinical outcomes between groups but that there would be a higher rate of tendon healing in the cohort of patients managed with immobilization following surgery.

**Materials and Methods**

This study was approved by the institutional review board of the Washington University School of Medicine prior to the enrollment of any subjects. This trial is registered at ClinicalTrials.gov (NCT00756015).

**Inclusion and Exclusion Criteria**

For this prospective trial, preoperative inclusion and exclusion criteria were carefully defined prior to the onset of the study and remained unchanged throughout the enrollment period. Patients were recruited from the clinical practice of the three attending surgeons. Patients were eligible for the study if they (1) needed surgery for the management of the persistently painful cuff tear, (2) were sixty-five years of age or less at the time of surgery, (3) had a full-thickness tear of the superior and/or posterior aspect of the cuff of £30 mm in size diagnosed by shoulder ultrasonography, (4) were willing to consent to postoperative rehabilitation randomization, and (5) were willing to commit to the two-year clinical follow-up period.

Exclusion criteria included (1) associated full-thickness subscapularis tears, (2) preoperative shoulder stiffness (defined as passive elevation of £100° and >50% loss of passive external rotation), (3) need for concomitant labral repair, (4) radiographic glenohumeral arthritis, (5) an irreparable tendon defect, and (6) revision cuff repair. Patients who needed concomitant procedures such as distal clavicular excision and biceps tenotomy and/or tenodesis were retained.

**Postoperative Rehabilitation Protocols**

Patients were identified as eligible for the study by the attending surgeon and were then enrolled by a research nurse. Subjects were randomized to one of two

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**TABLE I Postoperative Rehabilitation Protocols**

<table>
<thead>
<tr>
<th>Time</th>
<th>Traditional Rehabilitation Group*</th>
<th>Immobilization Group*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate postop.</td>
<td>Pendulum exercises and elbow, wrist, and hand AROM</td>
<td>Elbow, wrist, and hand AROM</td>
</tr>
<tr>
<td>1-6 wk</td>
<td>Therapist-supervised PROM of shoulder</td>
<td>Shoulder immobilized</td>
</tr>
<tr>
<td>6-12 wk</td>
<td>Initiated AAROM and AROM of shoulder</td>
<td>Therapist-supervised PROM of shoulder</td>
</tr>
<tr>
<td>3-4 mo</td>
<td>Initiated cuff, deltoid, and scapular stabilizer strengthening</td>
<td>Initiate AAROM and AROM of shoulder</td>
</tr>
<tr>
<td>&gt;4 mo</td>
<td>Full activities between 4 and 6 mos on basis of individual progress</td>
<td>Initiate cuff, deltoid, and scapular stabilizer strengthening; full activities between 5 and 6 mo on basis of individual progress</td>
</tr>
</tbody>
</table>

*A-ROM = active range of motion, PROM = passive range of motion, and AAROM = active-assisted range of motion.

---

**TABLE II Functional Outcomes Scores of Rehabilitation Groups Over Time**

<table>
<thead>
<tr>
<th>Time Point</th>
<th>VAS Pain Score*</th>
<th>ASES Score*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TR</td>
<td>IM</td>
</tr>
<tr>
<td>6 mo</td>
<td>1.4 ± 1.6</td>
<td>1.1 ± 1.4</td>
</tr>
<tr>
<td>12 mo</td>
<td>1.1 ± 1.7</td>
<td>0.9 ± 1.2</td>
</tr>
<tr>
<td>Final follow-up</td>
<td>0.9 ± 1.7</td>
<td>0.6 ± 1.1</td>
</tr>
</tbody>
</table>

*Values are given as the mean and the standard deviation. TR = traditional rehabilitation group, IM = immobilization group, VAS = visual analog scale, ASES = American Shoulder and Elbow Surgeons, and SST = Simple Shoulder Test. †Wilcoxon test. ‡T test.
types of postoperative rehabilitation protocols (Table I). A computer program was used to determine a simple randomization sequence using two variables. Each subject was assigned a study number at the time of enrollment in a consecutive sequence. A sealed envelope designating the rehabilitation protocol based on the randomization sequence was assigned for each subject and opened on completion of the surgery. The surgeon was blinded to each subject’s rehabilitation group prior to surgery.

Compliance with sling use, restrictions, and physical therapy were monitored by each attending surgeon at regular follow-up visits (at ten to fourteen days, six weeks, and three months postoperatively) as well as review of physical therapy progress reports. Subjects in both rehabilitation groups were instructed to wear a standard sling (without abduction pillow) at all times for the initial six weeks after surgery except when bathing, dressing, and performing exercises. The sling was also removed periodically to allow elbow motion. We were unable to directly monitor sling use for either group but relied on compliance with postoperative instructions. Physical therapists were given standardized prescriptions outlining the recommended exercises and restrictions pertinent to each phase of rehabilitation. Physical therapy was initiated for the traditional rehabilitation group at the first postoperative visit and at six weeks for the immobilization group. The frequency of therapy visits was recommended to be two times per week; however, flexibility in the frequency of visits was left to the discretion of the therapist on the basis of individual patient progress. Subjects were instructed to perform home exercises independently in accordance with their stage of rehabilitation.

Clinical Evaluations and Outcomes

A trained research nurse familiar with the shoulder examination completed a detailed preoperative physical examination at facilities belonging exclusively to the Barnes-Jewish Hospital system. Questionnaires were completed allowing formulation of a visual analog pain scale (VAS pain) score, the Simple Shoulder Test (SST)\(^1\), the ASES (American Shoulder and Elbow Surgeons) score\(^1\), and the Constant score\(^1\). Constant scores were normalized to the age and sex of the subject\(^1\). Active and passive range of motion was recorded with a goniometer for flexion, external rotation with the arm at the side, and external rotation with the shoulder abducted 90°. Internal rotation was recorded by the maximal height achieved with the thumb when attempting to reach behind the back.

Subjects were followed at six, twelve, and twenty-four months postoperatively, and at each time an independent research nurse performed a complete clinical examination. In addition, active range-of-motion values were reviewed at the three-month examination performed by the attending surgeon to examine potential differences in motion at the time of early follow-up.

Shoulder Ultrasonography

Shoulder ultrasounds were performed preoperatively and after twelve months postoperatively to assess repair integrity. Ultrasounds were performed by one of three experienced radiologists according to a previously published protocol that has validated this modality for accuracy in the postoperative setting\(^16,17\). The radiologists were blinded to the type of postoperative rehabilitation protocol undertaken by each patient.

Full-thickness rotator cuff tears were defined as an echogenic defect within the cuff tendon with fiber discontinuity. Tears were measured in both the sagittal (width or size of the tear) and coronal plane (length or tear retraction). The biceps tendon was assessed for pathological changes. When possible, the location of the anterior edge of the cuff tear to the biceps tendon or lateral aspect of the biceps groove was measured to determine cuff tear location.

Surgical Technique

All surgical procedures were performed with the patient under general anesthesia and in the beach-chair position. All repairs were accomplished with a modified double-row transosseous repair technique. To control for surgical technique, prior to study initiation, all surgeons agreed to a uniform and consistent repair method dependent on tear size. The greater tuberosity was debrided and roughened prior to anchor placement. One or more corkscrew anchors (5.5 mm) were placed in the greater tuberosity just lateral to the articular margin on the basis of tear size. Medial row mattress sutures were passed through the cuff tendon between 10 and 15 mm medial to the tear edge, and the knots were secured. The lateral row fixation was performed in suture-bridge fashion using knotless 4.75-mm interference-type anchors. In all cases, two lateral row anchors were used. Depending on tear size, two, four, or six-strand transosseous-equivalent repair constructs were created. All shoulders underwent subacromial decompression and acromioplasty. A biceps procedure, either tenotomy or tenodesis, was performed on the basis of the presence of pathology noted at the time of surgery and/or the presence of positive biceps signs preoperatively.

Statistical Analysis

Statistical calculations were performed using SAS/Stat software (version 9.3; SAS Institute, Cary, North Carolina). For all comparisons, an alpha level of 0.05 was chosen to represent significance. Comparisons of means between groups were performed with a t test or Wilcoxon test, depending on the data distribution. Proportional comparisons were performed with the chi-square test. Mixed-model analysis of variance was used to investigate the simultaneous effects of time and rehabilitation on specific outcomes. Post hoc tests used the Tukey-Kramer correction to adjust for multiple comparisons.

Prior to the onset of this study, a power analysis was performed on the basis of cuff tendon healing. Previous research from our institution noted a healing rate of approximately two-thirds of rotator cuff tears following repair of similar sized tears with a double-row technique. A theoretical difference in healing of 20% between the two types of postoperative rehabilitation was assumed. Choosing an alpha level of 0.05 and beta level of 0.20, power analysis suggested that we would need seventy subjects per group.

Source of Funding

This study was funded by a research grant from the Barnes-Jewish Hospital Foundation.

<table>
<thead>
<tr>
<th>TABLE II (continued)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Relative Constant Score</strong></td>
</tr>
<tr>
<td>TR</td>
</tr>
<tr>
<td>74.4 ± 13.3</td>
</tr>
<tr>
<td>79.1 ± 10.0</td>
</tr>
<tr>
<td>83.2 ± 11.5</td>
</tr>
</tbody>
</table>
Results

Early Exclusions

Over a thirty-month period (December 2007 to June 2010), 145 subjects were recruited (Fig. 1). A total of twenty-one subjects were later excluded. Sixteen of those subjects were excluded on the basis of intraoperative findings: eight shoulders had tears of >30 mm, five shoulders had partial-thickness tendon defects, one shoulder had a subscapularis tear, one tear was irreparable, and one shoulder had a SLAP (superior labral anterior-posterior) repair. Of the remaining five...
subjects who were later excluded, one died, one developed a deep infection, one was grossly noncompliant with immobilization, one was noncompliant with early follow-up visits, and one moved out of the country in the early period after surgery. The remaining 124 subjects served as our study population.

Baseline Characteristics
Baseline characteristics for the study groups are outlined in the Appendix. Sixty-five subjects composed the traditional rehabilitation group, and fifty-nine subjects made up the immobilization group. No differences with regard to age or sex were noted between groups. There were no differences in the mean tear size between the groups (the traditional rehabilitation group had a mean width of 13.6 mm and length of 14.3 mm, and the immobilization group had a mean width of 13.1 mm and a length of 14.5 mm). Likewise, there were no differences in the baseline VAS pain score, SST score, ASES score, Constant score, active range-of-motion values, or shoulder strength between groups at baseline. Of the fifty-nine subjects in the immobilization group, twenty-two (37.3%) either had a ruptured biceps tendon or underwent a biceps procedure compared with twenty-four (36.9%) of sixty-five subjects in the traditional group.

Functional Outcomes
Outcomes data were available for 103 (83%) of 124 subjects at six months, 105 (85%) of 124 subjects at twelve months, and 103 (83%) of 124 subjects at twenty-four months. A category of final follow-up was created that included the last measured outcomes of a subject at a minimum of twelve months as some patients did not return for either the twelve or twenty-four-month time point. If a subject had both twelve and twenty-four-month data, the latter were used in the final follow-up category. At the time of final follow-up, outcomes data were available for 114 (92%) of 124

<table>
<thead>
<tr>
<th></th>
<th>Abduction Strength* (lb [kg])</th>
<th>External Rotation Strength* (lb [kg])</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TR</td>
<td>IM</td>
</tr>
<tr>
<td></td>
<td>6.2 ± 3.9 (2.8 ± 1.8)</td>
<td>5.2 ± 3.7 (2.3 ± 1.7)</td>
</tr>
<tr>
<td></td>
<td>5.8 ± 4.2 (2.6 ± 1.9)</td>
<td>4.9 ± 2.6 (2.2 ± 1.2)</td>
</tr>
<tr>
<td></td>
<td>6.4 ± 4.3 (2.9 ± 1.9)</td>
<td>6.0 ± 3.5 (2.7 ± 1.6)</td>
</tr>
</tbody>
</table>

Fig. 2
Plots of the American Shoulder and Elbow Surgeons (ASES) score data for both rehabilitation groups over time. Data from the immobilization group (IM) is staggered slightly to the right for illustration purposes. The lines joining the boxes represent the median values for each group (dashed line is the IM group). The boxes demonstrate data distribution between 25% and 75% of the sample, and the whiskers represent between 5% and 95% of the sample. Dots represent data points outside the 5% to 95% sample range. TR = traditional rehabilitation group.
subjects. All measured outcomes with the exception of active external rotation ($p = 0.39$) were significantly improved ($p < 0.05$) compared with baseline measures in both rehabilitation groups.

Functional outcomes comparisons of the rehabilitation groups are summarized in Tables II and III. Initially, comparisons were made between rehabilitation groups. The traditional rehabilitation group compared with the immobilization group had significantly better mean active range of motion into elevation ($136^\circ$ versus $123^\circ$; $p = 0.02$) and external rotation range of motion ($47.0^\circ$ versus $40.1^\circ$; $p = 0.05$) at three months postoperatively. After three months, there were no significant differences in VAS pain score, active range-of-motion values, shoulder strength measures, or any of the functional scales between the groups at the time of the six-month, twelve-month, or final follow-up evaluation. ASES and relative Constant scores improved for both groups compared with baseline over time (Figs. 2 and 3).

The functional outcomes data from both rehabilitation groups were then pooled and compared over various time points to determine when outcomes tended to plateau (Table IV). Both the mean active elevation and external rotation were worse at three months compared with baseline values. At no time point was active external rotation better than the preoperative value;

<table>
<thead>
<tr>
<th>Time Point</th>
<th>VAS Pain Score</th>
<th>ASES Score</th>
<th>Relative Constant Score</th>
<th>SST Score</th>
<th>Elevation (deg)</th>
<th>External Rotation (deg)</th>
<th>External Rotation and Abduction (deg)</th>
<th>Abduction Strength (lb [kg])</th>
<th>External Rotation Strength (lb [kg])</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>5.61</td>
<td>45.0</td>
<td>54.5</td>
<td>5.06</td>
<td>139.6</td>
<td>61.1</td>
<td>76.3</td>
<td>3.94 (1.8)</td>
<td>9.13 (4.1)</td>
</tr>
<tr>
<td>3 mo</td>
<td>1.27†</td>
<td>82.5†</td>
<td>74.5†</td>
<td>9.19†</td>
<td>154.1†</td>
<td>62.6†</td>
<td>80.6</td>
<td>5.74 (2.6)†</td>
<td>14.11 (6.4)†</td>
</tr>
<tr>
<td>6 mo</td>
<td>1.01</td>
<td>88.5†</td>
<td>79.4†</td>
<td>10.17†</td>
<td>160.1</td>
<td>65.5</td>
<td>86.4†</td>
<td>5.41 (2.4)</td>
<td>15.85 (7.1)</td>
</tr>
<tr>
<td>12 mo</td>
<td>0.61</td>
<td>92.4</td>
<td>83.9†</td>
<td>10.80</td>
<td>163.7</td>
<td>64.2</td>
<td>88.5</td>
<td>6.41 (2.9)</td>
<td>16.02 (7.2)</td>
</tr>
<tr>
<td>24 mo</td>
<td></td>
<td></td>
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</tbody>
</table>

*VAS = visual analog scale, ASES = American Shoulder and Elbow Surgeons, and SST = Simple Shoulder Test. †The difference between the designated value and the value at the previous time point was significant ($p < 0.05$) as determined by two-way analysis with Tukey-Kramer adjustment.

![Fig. 3](http://wwwjbjsorg/download/37939288md36800620140101061622) Plots of the relative Constant score data for both rehabilitation groups over time. Data from the immobilization group (IM) is staggered slightly to the right for illustration purposes. The lines joining the boxes represent the median values for each group (dashed line is the IM group). The boxes demonstrate data distribution between 25% and 75% of the sample, and the whiskers represent between 5% and 95% of the sample. Dots represent data points outside the 5% to 95% sample range. TR = traditional rehabilitation group.
A post hoc power analysis was performed using the data regarding repair integrity from the two rehabilitation groups, assuming the healing rates represent the true population. Assuming a desired power of 0.8 to detect a difference at an alpha level of 0.05, 721 subjects per group would be required to reach significance.

**Reoperations**

No subjects required repeat surgery for recalcitrant postoperative stiffness. Two subjects (one from each group) were noted to have an early retear and had revision to a latissimus dorsi transfer and a reverse total shoulder arthroplasty secondary to persistent pain and limited function. No subject with a recurrent tear underwent an attempted revision cuff repair.

**Discussion**

A fundamental question regarding the management of patients undergoing rotator cuff repair surgery relates to defining a safe and effective postoperative rehabilitation protocol. In the present study, we found that initiation of early range of motion after surgery did not alter the outcome or likelihood of tendon healing. There were no differences in final shoulder function between patients treated with either an early or delayed motion protocol. This study also established that, for small and medium cuff repairs, most outcome scores plateau after six to twelve months, with the exception of the Constant score, which improved up to the time of the two-year follow-up. A large body of research has focused on tendon healing and the influence of patient and technique-related factors; however, appropriate postoperative management remains a fundamental and unanswered question. This controlled prospective randomized study provides definitive information, which can guide surgeon recommendations.

Traditionally, repairs have been managed with early passive range of motion followed by delayed active motion and, finally, strengthening exercises. The impetus behind early range of motion has been the concern over stiffness, which is a well-known complication following cuff repair surgery. However, in recent years, a longer period of immobilization has gained popularity as failure of cuff repair healing has been highlighted. Basic-science research in animals has shown some benefit in tendon healing with immobilization following surgery with minimal effect on long-term joint motion.

A prospective study by Cuff and Pupello showed results very similar to those in the present study. In their study, sixty-eight patients were randomized to early passive range of motion or immobilization (although this group was allowed to perform pendulum exercises). The mean age of their subjects was sixty-three years, approximately eight years older than our cohort. The only significant difference between groups was better overhead motion in the early motion group at six months. Otherwise, the clinical results were similar at six and twelve months. Those authors also found no difference in healing between groups, noting that 91% healed in the immobilization group and 85% healed in the early motion group. Although there were slight differences in the subject characteristics between studies, very similar results
were obtained in the present study, including rates of tendon healing. However, no post hoc power analysis was provided in the previous study and the number of subjects was considerably smaller than that in the present study. We believe our findings provide further evidence for the safety of early motion in patients with small and medium tears, with greater power than previous research.

A recent similar study by Arndt et al. demonstrated slightly different findings26. One hundred isolated supraspinatus tears were randomized to early motion or immobilization. They noted improved external rotation and Constant scores and a lower rate of adhesive capsulitis in the early motion group at a mean follow-up period of fifteen months. There was also a trend toward greater elevation at the time of the final follow-up. They found no difference in healing (15% with recurrent tears in the immobilization group versus 23% in the early motion group) by computed tomography (CT) arthrogram. The authors advocated for early motion after cuff repair but commented on the greater potential for retear in this group. One potential concern with that study was the lack of a standardized surgical technique (a combination of single and double-row repairs), which may have influenced functional scores or the rate of tendon healing.

Although early passive range of motion appears to have had no detrimental effect on healing in these studies, aggressive stretching should be avoided. One recent study comparing two types of early stretching after cuff repair showed a higher rate of tendon retears on magnetic resonance imaging (MRI) following aggressive manual stretching and unrestricted self-directed stretching27. The results of our study demonstrate the safety of early passive motion, but these results may not be applicable to all rotator cuff repairs. Tears in the present study were small and medium, repairs were performed with a double-row technique, and the mean age of our patients was fifty-five years. The benefits of immobilization for tendon healing may be more important for older patients or in shoulders with larger cuff tears.

The results of our study can be interpreted in more than one way. Immobilization did not appear to lead to greater risks of shoulder stiffness. Many surgeons choose to protect the repairs during the vulnerable three-month postoperative period. Delaying rehabilitation may reduce the costs of physical therapy visits in the early postoperative period. Conversely, early motion did not appear to impair tendon healing, and passive motion may be safely used earlier, allowing a quicker return of shoulder motion and function. In many instances, patients advocate for early therapy in an effort to feel they are actively participating in their recovery. We did not evaluate patient satisfaction, which may have been enlightening, especially in the early postoperative period.

Despite the prospective randomized nature of this study, there were some limitations. Subject attrition was an issue despite consistent and aggressive attempts to retain subjects. We had complete follow-up for 85% of the subjects at twelve months and 83% at twenty-four months. For this reason, we chose to create a final follow-up classification in which either the twelve or twenty-four-month data were used, which gave us a 92% rate of follow-up. We believe this was valid because we found that many of the functional scales, range-of-motion values, and shoulder strength measures peaked at either six or twelve months following surgery. In addition, after exclusion of several subjects due to surgical findings, we enrolled 124 subjects, which was less than our predetermined power analysis recommended; however, post hoc power analysis demonstrated that we would need over 700 subjects in each treatment group (with the applied healing rates) to find a significant difference between groups. We think that this suggests the present study was sufficiently powered to demonstrate a lack of a clinically significant difference in healing rates between rehabilitation cohorts. Finally, no prestudy power analysis was performed for clinical outcomes. Although none of our comparisons between rehabilitation groups showed a difference in outcome, the study may have been underpowered to draw these conclusions and these statistical comparisons must be considered as exploratory. However, the clinical results were remarkably similar for most outcomes and showed no obvious trends for a clinically meaningful difference in outcomes between groups.

Strengths of our study include the prospective randomization of subjects and strict inclusion and exclusion criteria. In addition, the surgical technique was standardized. An independent, blinded examiner obtained outcome measures and performed follow-up examinations. In addition, independent, blinded radiologists assessed tendon integrity by ultrasound. This study had greater power to detect differences between groups than did previous literature26.

In conclusion, this prospective randomized trial found no differences in clinical outcomes beyond six months between shoulders that had been immobilized for six weeks and those that were allowed early passive motion following arthroscopic repair of small and medium tears in patients under sixty-five years of age. Furthermore, we found no difference in tendon healing between groups. Pain relief and return of function reached a plateau by six to twelve months following surgery. Either early passive motion or a period of early immobilization is equally safe and effective after surgical rotator cuff repair in this cohort.

Appendix
A table showing preoperative patient characteristics by group is available with the online version of this article as a data supplement at jbjs.org.

Jay D. Keener, MD
Leesa M. Galatz, MD
Georgia Stobbs-Cucchi, RN
Rebecca Patton, MA
Ken Yamaguchi, MD
Shoulder and Elbow Service,
Department of Orthopaedic Surgery,
Washington University, CB #8233,
St. Louis, MO 63110.
E-mail address for J.D. Keener: keenerj@wustl.edu
References


