No Functional Difference Between Three and Six Weeks of Immobilization After Arthroscopic Rotator Cuff Repair: A Prospective Randomized Controlled Non-Inferiority Trial.

Kjersti Kaul Jenssen, M.D., Kirsten Lundgreen, M.D., Ph.D., Jan Erik Madsen, M.D., Ph.D., Rune Kvakestad, M.D., Are Hugo Pripp , M.Sc., Ph.D., and Sigbjørn Dimmen, M.D., Ph.D.

Purpose: The aim of this study was to compare clinical and radiologic results among patients with 3 versus 6 weeks of immobilization after arthroscopic rotator cuff (RC) repair in a prospective randomized controlled non-inferiority trial. **Methods:** One hundred twenty patients were included after RC surgery for a small- to medium-sized tear of supraspinatus and upper infraspinatus tendons. Group A was immobilized in a simple sling for 3 weeks, and group B had a brace with a small abduction pillow with the arm in neutral position for 6 weeks. All patients started active range of motion when they removed the sling/brace. One hundred eighteen (98%) patients were assessed at 1-year follow-up. They underwent magnetic resonance imaging (MRI) of the shoulder, filled out the Western Ontario Rotator Cuff (WORC) index, and were evaluated with a Constant Murley (CM) score. **Results:** Statistical non-inferiority was demonstrated for the 2 groups on the basis of the WORC index, the primary endpoint at 1 year. The objective for the non-inferiority test was to determine whether the expected mean WORC index for group A was at most 13% worse than standard treatment (Group B). The WORC index at 1 year was similar in both groups, with mean percent scores of 83% in group A and 87% in group B (mean difference = −4; 95% one-sided CI −9, −4). Age-adjusted CM scores were also similar, with means of 86 in group A and 90 in group B (mean difference = −4; 95% CI −13, 5; $P = .37$). MRI after 1 year showed 50 (89%) patients in each group with healed RC repair. Four patients in group A had complications: 1 acute postoperative infection, 2 cases of postoperative capsulitis treated with corticosteroid injections, and 1 repeat operation because of a loose anchor and subacromial pain. No patients in group B had complications. **Conclusion:** RC repair resulted in improved postoperative shoulder function, regardless of whether the shoulder was immobilized for 3 or 6 weeks. Three weeks of postoperative immobilization with sling use was non-inferior to the commonly used regimen involving 6 weeks of immobilization in a brace with regard to the WORC index at 12 months' follow-up. MRI indicated similar degrees of healing between the groups. Based on these findings, it is safe to immobilize patients in a simple sling for 3 to 6 weeks after repair of small to medium RC tears. **Level of evidence:** Level I.

Rotator cuff (RC) repair is one of the most common surgical procedures for shoulder disorders, and the functional results are generally good. Most RC tears are now repaired arthroscopically, and the surgical techniques for repair are widely discussed. The literature on rehabilitation after surgery is scarcer, although rehabilitation protocols exist to protect the repair and restore shoulder function and might be equally important to the healing process and to the recovery of joint function.

Postoperative shoulder stiffness with reduced range of motion (ROM), persistent functional impairment and increased morbidity is a common complication after rotator cuff repair.[1-3] The cause is unknown but may be related to prolonged immobilization and conservative rehabilitation programs.[4] There is poor consensus on the postoperative rehabilitation regimen and its relevance.[5] Early postoperative passive ROM is advocated to minimize stiffness and adhesions and might result in earlier return to work.[5-7] Critics have raised concerns

From the Lovisenberg Diaconal Hospital (K.K.J., K.L., R.K., S.D.); and Oslo University Hospital (J.E.M., A.H.P.), Oslo, Norway.

The authors report that they have no conflicts of interest in the authorship and publication of this article. Full ICMJE author disclosure forms are available for this article online, as supplementary material.

Received December 5, 2017; accepted May 15, 2018.

Address correspondence to Kjersti Kaul Jenssen, M.D., Lovisenberg Diaconal Hospital, Lovisenberggt. 17, 0847 Oslo, Norway. E-mail: kjersti.kaul.jenssen@me.com

0749-8063/171460/$36.00

https://doi.org/10.1016/j.arthro.2018.05.036

that this approach may cause excessive motion and strain on the repair and increase the risk of insufficient healing of the tendon to bone.[1,8,9] The time for mature tendon to bone healing after RC repair in humans is unknown. Advocates for prolonged immobilization find support in animal studies where the tendon to bone healing process takes 3 to 4 months.[10-12] Experimental studies have also shown that low levels of controlled load through immobilization improves tendon-to-bone healing, contrary to unprotected repairs.[13-16]

In the last decade, a few randomized controlled trials (RCT) have concluded that early range of motion after RC repair is not harmful to the healing process or to functional results at final follow-up.[4,6,7,9,17-21] However, the optimal time of immobilization is still unknown. Only 1 RCT was found that addressed the postoperative immobilization time after arthroscopic RC repair.[22] They concluded that 4 weeks of immobilization was as good as 8 weeks when it comes to healing of medium-sized RC repairs. Most shoulder surgeons recommend use of a sling for 6 weeks after surgery to protect the repair, even when they start a passive range-of-motion protocol early. Often, patients are reluctant to use a sling for 6 weeks and will choose to take it off earlier than recommended, and thus compliance regarding immobilization is uncertain. It would therefore be of interest to shoulder surgeons to know whether it is safe to shorten the immobilization time and what that would mean for the prognosis in terms of tendon healing and shoulder function, both in the short term and in the long run.

The purpose of this study was to compare clinical and radiologic results among patients with 3 versus 6 weeks of immobilization after arthroscopic RC repair in a prospective randomized controlled non-inferiority trial. The main hypothesis was that 3 weeks of postoperative immobilization with sling use is non-inferior to the commonly used regimen involving 6 weeks of immobilization in a brace with regard to functional results at 12 months' follow-up. A secondary hypothesis was that 3 weeks of immobilization with sling use is not harmful to the healing process compared with 6 weeks of immobilization in a brace.

Material and Methods

Study Design

The study was designed as a prospective randomized non-inferiority trial with 12 months' follow-up. One hundred twenty patients were included and randomized from 2013 to 2015. The treating surgeon was blinded to the randomization before and during surgery, and the radiologist was blinded throughout the analysis of the study. It was not possible to blind the patients.

Inclusion and Exclusion Criteria. Patients from a single orthopedic practice of 5 shoulder surgeons were enrolled in this prospective randomized controlled trial. Inclusion and exclusion criteria were predefined and kept unchanged throughout the study period. Eligible patients had repairable full-thickness RC tears $\leq$3 cm affecting the supraspinatus or upper infraspinatus tendon. The patients had dysfunctional and painful shoulders due to a chronic RC tear nonresponsive to exercise therapy for a minimum of 3 months or an acute on chronic RC tear.

Exclusion criteria were (1) irreparable cuff tears, (2) tears >3 cm, (3) full-thickness subscapularis tendon tear, (4) adhesive capsulitis, (5) concomitant labral repair, (6) revision repair, (7) fatty muscle infiltration of the RC >50%, (8) shoulder joint osteoarthritis, (9) diabetes mellitus, and (10) systemic inflammatory disorders.

Surgical Technique. Specialized shoulder surgeons performed all RC repairs. The surgical setup, equipment, and anesthesiology procedures were identical in both groups and remained unchanged throughout the study period. All patients were operated on under general anaesthesia with a suprascapular nerve block and local infiltration anesthesia in the lateral decubitus position. RC repair was performed with an arthroscopic, single-row, repair technique using 1 or 2 triple-loaded Healicoil PK (Smith & Nephew Endoscopy) suture anchors after debridement and micro fracture of the tendon footprint. Subacromial decompression was performed in all patients. Pathology of the long biceps tendon was treated with tenodesis or tenotomy, depending on patient and surgeon preferences.

Randomization. A computer calculated the block randomization, and all patients were given a study number, which they kept throughout the trial. Randomization into groups took place in the operation theater at the end of each surgical procedure. The treatment allocation was organized by an independent nurse who distributed sealed and numbered opaque envelopes to the nurse manager in the operation theater. The envelope was not opened until the surgical repair was complete, and thus the treating surgeon was blinded to the randomization assignment before and during surgery.

Postoperative Protocol. Eligible patients were randomized into 2 groups: group A had early active range of motion (ROM) starting at 3 weeks and group B had delayed active ROM starting 6 weeks after surgery. Group A had a simple sling for 3 weeks while group B had a brace with a small abduction pillow with the arm in neutral position for 6 weeks after surgery. The patients were told to keep the sling/brace on day and night and to take it off 3 times a day to perform pendulum exercises. Some of the patients asked to remove the brace when they sat still because they