

Outcome analysis of open versus arthroscopic rotator cuff repair: a retrospective study

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A. Specific aim

The goal of the study is to compare two different surgical methods of rotator cuff repair: open versus arthroscopic.

B. Hypothesis

The null hypothesis (Ho) is that the outcome results of the arthroscopic repair are no different than that of the open repair.

C. Abstract

Rotator cuff tears are a frequent cause of shoulder pain and shoulder surgery in orthopaedics. The use of arthroscopy for the repair of rotator cuff tear has increased significantly in the last 10 years and has begun to replace the traditional open and mini-open repairs. Commonly cited advantages of arthroscopic techniques are glenohumeral joint inspection, treatment of intraarticular joint lesions, smaller incisions, no deltoid detachment, less soft tissue dissection, less pain, and possibly more rapid rehabilitation. Outcomes results of arthroscopic repairs have been reported in the literature (see "Background" below). However, no prospective, controlled trial has been done comparing open versus fully arthroscopic rotator cuff repair. We propose a prospective outcomes analysis study to compare the two procedures. The outcomes analysis will consist of chart reviews, validated questionnaires (eliciting patient satisfaction and lifestyle impact), follow-up physical exams with non-invasive strength testing, and a standardized ultrasonography of both shoulders to evaluate cuff integrity.

D. Background

Arthroscopy in rotator cuff repair is a technological advancement beyond the open procedures first described by Codman in 1911 (Codman, 1934). Authors in the literature have more recently reported successful results using arthroscopic techniques. The first arthroscopic cuff repairs occurred in the late 1980's and were reported by Johnson (1992). A number of authors have reported using the arthroscope for arthroscopically-assisted procedures. For example, in 1990 Levy et al. (1990) reported 80% good and excellent results, Paulos and Kody (1994) reported 88% good and excellent results, and Warner et al. (1997) reported no statistical difference in strength between post-operative shoulder and non-operative shoulder after 25 month follow-up and 93% subjective rating as "excellent."

The first reported completely arthroscopic suture repair was in February 1990 (Wolf, 1998). In terms of outcomes of fully arthroscopic repairs, Baylis and Wolf (1995) found 85% good and excellent results after 27-month average follow-up and reported that their second-look arthroscopy "compared positively" with previous open-repair studies. In 1998, Gartsman et al. (1998) and Tauro (1998) reported results from an all-inside arthroscopic technique with 90% and 92% good to excellent results, respectively. Weber (1999) presented results comparing 151 mini-open repairs versus 29 completely arthroscopic repairs. Twelve of his patients underwent both and all rated arthroscopic as superior.

However, Galatz et al. (2004) recently reported a high recurrence of cuff defects after arthroscopic repair with follow-up of 1 and 2 years, although improved subjective results. In addition,

Wolf (2004) recently reported a large retrospective study with 94% of patients qualified as having good to excellent results. However, this author further acknowledges that a randomized, prospective, matched clinical study is required to advocate superiority.

E. Methods

Subjects will be recruited from patient files at the orthopaedic surgeon's office. Informed consent will be obtained from patients prior to inclusion in the study. Chart review, validated questionnaires, follow-up physical exam, and a standard ultrasound will be performed to evaluate and compare the outcomes of arthroscopic versus open rotator cuff repair. As part of the physical exam, strength testing of external rotation and forward flexion in the scapular plane with a dynamometer (IsoBex 3.0, Medical Device Solutions AG) will be performed. This strength testing will involve having the patient put his/her wrist in soft strap and pull against the device. The strap will be placed at the distal end of the forearm, proximal to the wrist joint. For forward flexion, the patient will be standing, and for external rotation the patient will be seated. The strength-testing device measures the amount of force generated by the patient. The device is non-invasive and puts the patient at no significant risk or injury when using. This strength testing will be part of routine follow-up evaluation and those choosing not to be involved in the study will still undergo this. The device is in common use for routine clinical care and research. In both external rotation and forward flexion testing, the patient will be instructed to exert full force and hold for 5 seconds; a one-minute rest period will be allotted between measurements. The highest value of three trials will be used. A standardized ultrasonography of each post-operative shoulder will be performed to evaluate for rotator cuff integrity. The ultrasound will be a part of our research and is not part of routine clinical care; those choosing not to participate in the study will not undergo the ultrasound. The cost of conducting the ultrasound exam will be covered by the investigators. Rotator cuff repairs will be evaluated with a minimum of one-year follow-up period. We propose to evaluate 110 patients based on power analysis with 0.4 effect size to have a power of 0.90 (two groups of 50 with 5 extra for each group). All patients included in this study will have undergone repair of full-thickness, rotator cuff tears of up to 3cm in the sagittal plane. The size of the tears will be noted from the operative reports. We will match the two study groups as best as possible in terms of age, gender, arm dominance, trauma incidence, activity level, acromial morphology, tear size, duration and type of preoperative symptoms, and preoperative range of motion.

Inclusion criteria:

Patients having undergone surgical repair of a rotator cuff tear up to 3cm measured in the sagittal plane

Exclusion Criteria (patients with):

1. Subscapular tears
2. Glenohumeral instability
3. Superior labral lesions requiring repair
4. Post-traumatic stiff shoulder
5. Previous rotator cuff surgery on joint
6. Massive tears

*No members of vulnerable populations will be included in this study.

Patients will be labeled with numbers (1, 2, 3, etc.) and the only information extracted from the patient chart and interview will be age, gender, hand dominance, details of surgical procedure, radiographic data, results of clinical and ultrasound exam, and results of the questionnaires. Patient names will be linked to the labeled numbers and stored on a password protected computer, to which only the investigators and research assistant will have access.

Outcomes will be evaluated using:

1. Chart review of pre-operative data
2. The validated ASES (American Shoulder and Elbow Society) questionnaire will be used, which is based primarily on the activities of daily living scale, pain score(maximum of 100 points).
3. Follow-up physical exam consisting of range of motion testing and strength testing using a non-invasive dynamometer (IsoBex 3.0, Medical Device Solutions AG) to test both strength of external rotation and strength of flexion in the scapular plane (will be part of routine clinical follow-up)
4. Standardized ultrasonography of post-operative shoulder to evaluate cuff integrity (for research purposes)

F. Significance

Rotator cuff tear is a common orthopaedic clinical problem causing shoulder pain and disability. Prior cohort studies (see above) have reported favorable results of arthroscopic repair of cuff tears. However, no prospective controlled trial has been done comparing open versus fully arthroscopic rotator cuff repair. A prospective study needs to be performed to robustly determine which surgical technique is superior.

G. Statistical Analysis

The Student t test will be used to compare the range of motion, and ASES score. A p value of <0.05 was considered significant.

H. References

1. Baylis RV, Wolf EM. Arthroscopic rotator cuff repair: Clinical and second look assessment. Presented at the annual meeting of the Arthroscopy Association of North America. San Francisco, CA; May, 1995.
2. Codman EA. Rupture of the supraspinatus tendon and other lesions in or about the subacromial bursa. In: The shoulder. Boston: Thomas Todd, 1934.
3. Galatz LM, Ball CM, Teefey SA, Middleton WD, Yamaguchi K. The outcome and repair integrity of completely arthroscopically repaired large and massive rotator cuff tears. *J Bone Joint Surg Am* 2004;86A(2):219-224.
4. Gartsman GM. Arthroscopic rotator cuff repair. *Clinical orthopaedics and related research*. 2001; 390: 95-106.
5. Gartsman GM, Khan M, Hammerman SM. Arthroscopic repair of full-thickness tears of the rotator cuff. *J Bone and Joint Surg Am* 1998;80:832-840.
6. Johnson L. Arthroscopic rotator cuff repair using a staple. Presented at the Maui Sports Medicine Meeting, Kanapali, Maui, April 1992.
7. Kim SH et al. Arthroscopic versus mini-open salvage repair of the rotator cuff tear: Outcome analysis at 2- to 6-years' follow-up. *Arthroscopy* 2003; 19(7): 746-754.
8. Levy HJ, Uribe JW, Delaney LG. Arthroscopic assisted rotator cuff repair: Preliminary results. *Arthroscopy* 1990; 6:55-60.
9. Murray TF et al. Arthroscopic repair of medium to large full-thickness rotator cuff tears: Outcome at 2- to 6-year follow-up. *J Shoulder Elbow Surg* 2002; 11(1):19-24.
10. Paulos LE, Kody MH. Arthroscopically enhanced "mini-approach" to rotator cuff repair. *Am J Sports Med* 1994;22:19-25.
11. Tauro JC. Arthroscopic rotator cuff repair: Analysis of technique and results at a 2- and 3-year follow-up. *Arthroscopy* 1998;14:45-51.

12. Warner JJ, Goitz RJ, Irrgang JJ, Groff YJ. Arthroscopic-assisted rotator cuff repair: patient selection and treatment outcome. *J Shoulder and Elbow Surg* 1997;6:463-672.
13. Weber SC. Arthroscopic versus mini- open rotator cuff repair. Arthroscopy Association of North America Fall Course, San Deigo, CA, 1999.
14. Wolf EM et al. Arthroscopic rotator cuff repair: 4- to 10- year results. *Arthroscopy* 2004; 20(1): 5-12.
15. Wolf EM. Purely arthroscopic rotator cuff repair. In: *Current techniques in arthroscopy*. Ed 3. New York: Thieme, 1998.