Gartsman GM, O'Connor DP. Arthroscopic rotator cuff repair with and without arthroscopic subacromial decompression: A prospective, randomized study of one-year outcomes. J Shoulder Elbow Surg 2004;13:424-6.

Design: Randomized clinical trial

Population/sample size/setting:

- 93 patients (mean age 59.7, 51 men, 42 women) treated for rotator cuff tear in a university orthopedic department
- Included if they had an isolated, repairable full-thickness supraspinatus tear and type 2 (curved) acromion
- Excluded if they had type 1 or 3 acromion, two-tendon tears, partial or irreparable tears, prior or concomitant shoulder surgery, or workers' compensation claims

Main outcome measures:

- Randomized with allocation concealment to cuff repair with subacromial decompression (n=47) or cuff repair alone (n=46)
- Postoperative treatment in both groups included continuous passive motion for 2 weeks, with increasing levels of exercise and examinations at 3 months, 6 months, and 12 months after surgery
- American Shoulder and Elbow Surgeons (ASES) shoulder score questionnaire mailed to participants 12 months after surgery
- ASES scores improved equally in both groups from 31 to approximately 91 after adjusting for tear length (20.1 mm in decompression group and 22.5 mm in non-decompression group)

Authors' conclusions:

- For full-thickness supraspinatus tear and type 2 acromion, subacromial decompression has no significant effect on outcome at 1 year

Comments:

- Details of subacromial decompression are not stated, but this would probably consist of acromioplasty, coracoid ligament resection, and subacromial bursectomy (control group may or may not have had bursectomy)
- Exclusion of workers' comp from sample is noteworthy; this study may represent an optimistic scenario for outcome of surgery
- Table 1 notes that groups differed at outset with respect to length of tear, but since longer tears were observed in non-decompression group, this difference would be expected to strengthen, rather than weaken, the authors' conclusions
- The number of participants who dropped out is not reported; it is not likely that all patients completed all of the followup visits, but there is insufficient accounting for the flow of patients through the study
- The power calculation is clearly stated, with an assumed clinical difference of 7 points on the ASES, a standard deviation of 10 points, and a Type I error of

0.05, with 99.5% power, yielding the sample sizes of 45 patients in each group
    - Using a standard formula for sample sizes in a study which assumes a normal distribution of outcome data, a study with 99.5% power would require 85 patients in each group
    - However, the actual power of the study, with 45 patients in each group, is not greatly diminished due to the mathematical properties of the cumulative normal distribution; the power is closer to 91%, which is still sufficient to test the null hypothesis of no group difference
- Although the ASES scores are reported to be the primary outcome, it is apparent that only the patient-reported part of the ASES was used to make the comparisons; the full ASES includes sections which are done by an examiner, and these were deleted to prevent examiner bias
    - The original study protocol is not available, and it cannot be ascertained that the patient-reported section of the ASES was the primary outcome designated at the start of the study; selective outcome reporting cannot be excluded as a source of bias

Assessment: Adequate for some evidence that in patients with reparable full-thickness rotator cuff tears and a Type II acromion, there are no appreciable differences in pain and shoulder function between rotator cuff repairs done with and without subacromial decompression