
Design: Randomized clinical trial

Research question: In the setting of arthroscopic repair of full-thickness rotator cuff repairs, are outcomes improved when acromioplasty is added to the cuff repair?

Population/sample size/setting:

- 95 patients (64 men, 31 women, mean age 59) treated for full-thickness rotator cuff tears at Rush University in Chicago
- Eligible if they were over 18 and had a full-thickness superior cuff tear
  - If the patient reported a traumatic episode within 6 weeks of presenting for treatment, the tear was classified as traumatic; all others were classified as degenerative
  - Plain x-rays taken in the sagittal and coronal planes were assessed by independent radiologists and classified as type I, II, or III with very good interrater reliability
- Exclusion criteria were isolated subscapularis tear, partial tear, irreparable tears, revision surgery, and partial repairs (which could not be repaired to the footprint after appropriate releases)

Main outcome measures:

- All patients had repair by one of four fellowship-trained sports medicine surgeons using their preferred technique
- Randomization was to either acromioplasty (n=52) or no acromioplasty (n=43)
  - The acromioplasty group had release of the coracoacromial ligament and flattening of the anterior-inferior surface of the acromion
  - 114 were originally randomized; these 95 had complete 2 year followup data
  - 65 were randomized to acromioplasty; 13 did not have 2 year followup data
  - 49 were randomized to no acromioplasty; 6 did not have 2 year followup data
- All patients were discharged the day of surgery, and both groups had the same rehabilitation program: passive motion begun 1 to 2 weeks after surgery, with active motion begun at 6 weeks and strengthening exercises at 12 weeks
- Followup visits were scheduled for outcome assessment at 6 months, 12 months, and 2 years
Outcomes were the American Shoulder and Elbow Surgeons score (ASES), the Simple Shoulder Test (SST), the UCLA score, the Constant score, and pain VAS.

In addition to these measures, range of motion and strength were assessed by sports medicine fellows preoperatively and at each followup visit.

Both groups had significant improvements in the SST, UCLA, ASES, Constant, and pain VAS scores between baseline and all followup points.

For example, the Constant score for the acromioplasty group improved from 48.3 at baseline to 75.0 at 24 months; for the non-acromioplasty group, the score went from 51.9 to 78.7.

The outcome scores for each group were the same at one year and at two years.

At each followup point, the outcome improvements were equal between acromioplasty and non-acromioplasty groups.

Similarly, the physician-measured range of motion scores were equal between groups at all followup points.

However, only 8 acromioplasty patients and 9 non-acromioplasty patients had physical examinations at two years.

In the acromioplasty group, there was one reoperation; for the non-acromioplasty group, there were four reoperations during the two years of the study (p=0.11).

Authors’ conclusions:

- No difference was shown in clinical outcomes of arthroscopic repair of full thickness rotator cuff tears between patients who did and did not have acromioplasty.
- However, there were insufficient numbers of patients with a Type III acromion to be certain that a difference was not present.
- There were limitations in the data; some outcomes were collected by mail or phone interview.
  - At one year, the data included 46% of available UCLA scores and 32% of available Constant scores.
- These results do not mean that there are no circumstances in which acromioplasty could have merit; primary impingement may be a real phenomenon in some cases.

Comments:

- Randomization and blinding are probably satisfactory, but there are major limitations due to incomplete followup.
- That is, there were only 17 patients who had a physical exam at the 2 year followup evaluation, 8 in the acromioplasty group and 9 in the non-acromioplasty group.
  - Because the Constant, UCLA, and ASES scores include a physician evaluation component, the study is not adequate for its comparison of these outcomes at two years.
- The SST and VAS scores, which are all patient-reported outcomes, could be adequately compared at the two year followup.

- The numbers of participants at the 6 month and 12 month followup times are simply not reported and there is insufficient information to infer them.

- The discussion section includes a rather obscure passage in which it is said that the numbers of patients in the two groups was unequal “due to unintentional randomization bias”.
  - Of the 114 patients randomized, 65 were allocated to acromioplasty and 49 were in the control group.
  - This is not a large imbalance; the binomial distribution can be calculated for this allocation frequency and the p value is 0.08, which is greater than 0.05.

- The reoperation rate was not statistically significant between the two groups (p=.011).

- Similarly, the authors refer to MacDonald 2011, who also reported a statistically non-significant reoperation rate between the acromioplasty and control groups, which was also in favor of acromioplasty.

- It is likely that the reoperation numbers are complete or nearly complete at the two year mark; MacDonald 2011 also had a two year followup period.

- The reoperation rates from the two studies can be pooled, and a statistically significant relative risk can be obtained, using the number originally randomized as the denominator and the number of reoperations as the numerator:

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Acromioplasty</th>
<th>Control</th>
<th>Weight</th>
<th>Risk Ratio M.H. Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abrams 2014</td>
<td>1</td>
<td>4</td>
<td>49</td>
<td>0.19 [0.02, 1.23]</td>
</tr>
<tr>
<td>MacDonald 2011</td>
<td>0</td>
<td>4</td>
<td>37</td>
<td>0.09 [0.01, 1.65]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>110</td>
<td>86</td>
<td>100.0%</td>
<td>0.14 [0.02, 0.77]</td>
</tr>
</tbody>
</table>

Heterogeneity: Chisq = 0.18, df = 1 (P = 0.68); $I^2 = 0%$.
Test for overall effect: Z = 2.25 (P = 0.02).
- The outcomes of these reoperations are not available, and there is no data to suggest that they were successful, but about 9% of the non-acromioplasty patients had a repeat operation during two years of followup; the risk for the acromioplasty patients was about 14% that of the comparison group.

- A major consideration is that there is still not enough information to assess the appropriateness of acromioplasty in patients with rotator cuff tears; as the authors point out, some patients may have an element of true impingement to explain their symptoms, and the shape of the acromion may enter into the equation for this to happen.

Assessment: adequate for some evidence that patient-reported pain and function does not differ greatly when acromioplasty is either done or not done in the setting of full thickness rotator cuff.
tears repaired arthroscopically. There is inadequate evidence that physician-measured outcomes are equivalent for the two operations. There is adequate evidence, with data pooled from Abrams 2014 and MacDonald 2011, that reoperations are done less often in the two years following surgery when an acromioplasty is included as part of the arthroscopic rotator cuff repair operation.

Reference: