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## **On rotator cuff tears : studies on evaluation, clinical outcome and surgical treatment**

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# CHAPTER 6

## **Clinical Outcome in All-Arthroscopic Versus Mini-Open Rotator Cuff Repair in Small- to Medium-sized Tears: A Randomised Controlled Trial in 100 Patients with One Year Follow-Up**

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### ABSTRACT

#### Purpose

The purpose of this study was to compare clinical outcome of All-Arthroscopic (AA) versus Mini-Open (MO) rotator cuff repair in patients with a full-thickness small to medium-sized tear in the first postoperative year.

#### Methods

One hundred patients were randomised to either AA or MO rotator cuff repair at the time of surgery on an intention-to-treat basis. Patients were evaluated preoperatively, and at 6, 12, 26, 52 weeks postoperatively using the DASH as a primary outcome score, and the Constant, VAS-pain/-impairment, and measuring active forward flexion/external rotation as secondary outcome scores. Ultrasound evaluation was used to assess structural integrity of the repair 1 year postoperatively.

#### Results

Forty-seven patients were analysed in the AA-group and 48 in the MO-group. 5 patients were lost to follow-up. Mean age was 57.2 (SD 8.0) years in the AA-group and 57.8 (SD 7.9) years in the MO-group. Primary and secondary outcome scores showed significant improvement in both groups postoperatively. The difference in the overall mean primary and secondary postoperative outcome scores was not statistically significant between the treatment groups (DASH between group mean difference -3.4, 95%CI: -10.2 to 3.4,  $p = 0.317$ ). However, at the 6 weeks follow-up moment, DASH-score, VAS-pain and -impairment, and active forward flexion were significantly more improved in the AA-group compared to the MO-group. A retear was seen in 8 patients (17%) in the AA-group and in 6 patients (13%) in the MO-group. Adhesive capsulitis developed in 5 patients in the AA-group (11%) and in 6 patients (13%) in the MO-group.

#### Conclusion

There are no significant differences between All-Arthroscopic or Mini-Open repair technique in the first year when comparing functional outcome, pain, range of motion and complications. Patients do attain the benefits of treatment somewhat sooner with the arthroscopic procedure after 6 weeks.

## INTRODUCTION

The mini-open repair has historically been considered to be the gold standard for small- to medium-sized rotator cuff tears. It is a fast and straightforward procedure and it has been proven to be an effective treatment modality with good to excellent results in 90% of cases.<sup>1-6</sup> Over the past decade there has been a shift from a mini-open to an all-arthroscopic technique in rotator cuff repair surgery as a result of advances in surgical instrumentation, operative technique and surgeon experience. The most effective method of repair, however, is controversial given that both techniques have good clinical outcome.<sup>1-11</sup> The arthroscopic procedure is believed to have favourable early outcome due to reduced morbidity, less postoperative stiffness and faster rehabilitation when compared to the mini-open procedure as a result of smaller skin incisions, less soft-tissue dissection, and avoidance of deltoid muscle detachment.<sup>12-17</sup> Several studies have been published comparing the results of the mini-open to the all-arthroscopic repair procedure. Unfortunately these studies were conducted in a retrospective and non-randomised fashion with relatively small numbers.<sup>12-17</sup> Systematic review of these studies did not show significant differences in postoperative range of motion, pain, stiffness, rehabilitation, and complication rate.<sup>18-20</sup> High-quality randomised controlled trials for comparison of these techniques are currently unavailable.

The purpose of the study was to evaluate the early clinical outcome of all-arthroscopic versus mini-open rotator cuff repair technique in patients with a full-thickness small- to medium-sized tear in a randomised controlled trial. The hypothesis is that the functional results will be similar between the treatment groups in the first postoperative year, with respect to outcome scores, retear rate and postoperative stiffness.

## METHODS

**Study design.** A prospective randomised clinical trial in patients undergoing rotator cuff repair using All-Arthroscopic (AA) or Mini-Open (MO) technique was conducted in a large community teaching hospital. Patients with shoulder pain were referred to our out-patient clinic by primary health care physicians. The patients were

evaluated for the presence of a full-thickness rotator cuff tear based on history, clinical examination, standard AP and scapular Y-view radiographs of the shoulder and gadolinium-enhanced magnetic resonance arthrography in a 1.5 Tesla scanner. Eligible patients were I) younger than 70 years of age and II) had a small- to medium-sized full-thickness supraspinatus and/or infraspinatus tendon tear with < stage 3 fatty muscle infiltration based on MR arthrography findings.<sup>21,22</sup> Patients were excluded when there were signs of I) glenohumeral instability, restricted glenohumeral movement as a result of II) adhesive capsulitis, III) glenohumeral arthritis or IV) rheumatoid arthritis, V) if there was involvement of the subscapularis tendon, VI) a SLAP-lesion or VII) if patients had had prior shoulder surgery, VIII) diabetes or IX) a high risk of non-compliance, e.g. patients without a permanent home or substance abuse.

From March 2008 to December 2010 all patients meeting the inclusion criteria were enrolled in the study on an intention-to-treat basis. Randomisation for either an AA or MO repair procedure was performed by use of a computer-generated randomisation sequence just before surgery in the operating room after the patient was brought under general anaesthesia by contacting an independent biostatistician who ensured that the block sizes were confidential to protect the integrity of the randomisation scheme. Patients were randomised using variable permuted block sizes on a 1:1 ratio. This study was approved by the Medical Ethics Committee of our hospital and all patients signed an informed consent form for participation in the study.

**Surgical technique.** The surgeries were performed by two senior shoulder surgeons experienced in both the AA and MO repair techniques. All patients were operated under general anaesthesia in lateral decubitus position with the arm held in a 3-point shoulder distraction device. The shoulder was prepped and draped in the usual sterile fashion. In the AA procedure a standard arthroscopic pump was used, maintaining fluid pressure at 40 mmHg. The arthroscope was placed in the subacromial space through a standard posterior portal, subsequently lateral and posterolateral working portals were established. Bursectomy was performed using a shaver and an electrocautery device to obtain a clear view of the cuff tear and the undersurface of the acromion. The MO approach is through a 5 cm lateral incision starting at the anterior border of the acromion. The fibers of the deltoid muscle are

split by blunt dissection and maximal visualisation is established using a soft tissue retractor. Care is taken not to damage the axillary nerve running closely to the distal edge of the incision and to minimise detachment of deltoid muscle fibers from the lateral part of the acromion. Partial bursectomy is performed using dissection scissors. The rest of the procedure is basically the same for both techniques, albeit in the AA-group through the arthroscopic portals and in the MO-group through a direct lateral approach. The dimensions and geometry of the cuff tear are determined using a probe with 5 mm markings. The torn tendons are probed and manipulated with a soft tissue gasper to assess lateral, anterior and posterior mobility and elasticity. Anterior and posterior adhesions between tendons, bursa and deltoid muscle are removed to increase mobility. No specific releases between the tendons and the glenoid were performed. The edges of the tear are debrided and the insertion site for the suture anchors on the major tubercle is prepared using a shaver. A Suture Bridge repair construct<sup>23</sup> is applied, using 2 to 4 anchors depending on the size of the tear, to secure the tendons in both groups using a 5.5 mm CorkScrew (Arthrex, Naples, Florida) in the medial row and a knotless 3.5 mm Bio-PushLock anchor (Arthrex, Naples, Florida) in the lateral row. In case of a longitudinal extension of the tear, the margin convergence technique was applied first. In case of degeneration or (sub-)luxation of the long head of the biceps, biceps tenotomy was performed; when there was a large type 3 subacromial spur, acromioplasty was performed. After wound closure a standard dressing is applied and the arm is placed in a sling for 6 weeks. A postoperative radiograph of the operated shoulder is made to evaluate the position of the bone anchors.

**Postoperative rehabilitation.** Both groups received identical postoperative rehabilitation protocols under supervision of a physical therapist at our institution. Active exercises of the elbow, wrist and hand were encouraged immediately. The rehabilitation protocol consisted of active abduction in the scapular plane limited to 70 degrees and 0 degrees of external rotation in the first 4 to 6 weeks as tolerated. After this active range of motion exercises were started. When the patient was free of pain, scapula and rotator cuff isotonic strengthening exercises were initiated. When patients preferred a physical therapist near their home our physical therapist contacted the designated therapist and sent a copy of the rehabilitation protocol.

**Patient evaluation.** Preoperatively (< 2 months prior to surgery) and postoperatively at 6 weeks, 12 weeks, 26 weeks and 52 weeks several outcome measures were collected by the research coordinator. The primary outcome measure of the study was the Disabilities of the Arm, Shoulder and Hand score (DASH).<sup>24</sup> As secondary outcome measures the Constant-Murley score<sup>25</sup>, active forward flexion and external rotation and the Visual Analogue Score (VAS-pain and VAS-impairment) were used.<sup>26</sup> 12 months postoperatively a standardised ultrasonogram of the operated shoulder was performed by an independent, experienced musculoskeletal ultrasonographer to evaluate the integrity of the repaired tendons. Since there is no ultrasound based classification system for rotator cuff repairs available, the repairs were scored as intact or retear. Patients filled out the DASH-scores and VAS-pain/-impairment scores on their own without the presence of the examiner. As a result of the obvious incision pattern the patient and the examiner could not be blinded postoperatively.

**Sample size and statistical analysis.** The sample size calculation was based on a previous study comparing AA and MO rotator cuff repair looking at early postoperative outcome after 3 and 6 months with the DASH score as the primary outcome measure.<sup>17</sup> A difference of 10 points on the DASH-score could be detected at individual follow-up points and thus was considered a relevant difference in the primary outcome measure. With a power of 0.8 ( $1-\beta$ ) and a significance level ( $\alpha$ ) of 0.05, each treatment arm needed 45 patients. Given the anticipated drop-out rate of 10%, 100 patients were included in the study.

Measured values are reported as mean with standard deviation (SD), estimates are presented as mean with 95%-confidence interval (CI). The postoperative outcome measures were analysed according to the intention-to-treat principle. In order to account for the repeated measures design and the correlation of measurements within patients, analysis was performed using a linear mixed-model (heterogeneous first-order autoregressive covariance structure, incorporation of a random intercept and time as a categorical variable). The baseline values of the variables were used as covariates in the main analysis to adjust for possible differences between the groups and to increase to power of the analyses. Differences between both groups were assessed by estimating either the main effect of the treatment or the interaction between treatment and time, first as an overall effect over the entire follow-up period



to safeguard against multiple testing. Assessment of the interaction between treatment and time allows investigation of a possible changing of the magnitude of the treatment effect over time (i.e. whether or not the estimated mean difference between both treatments is constant over time). At 6 weeks and 52 weeks of follow-up, mean differences were estimated as specified in the study protocol. No adjustment for multiple comparisons was considered necessary. Chi-square test was performed for the comparison of retear rate and other complications.

In all analyses, the model assumptions were satisfied. A  $p$ -value of  $<0.05$  was considered to be significant (SPSS statistical software 18.0, SPSS Inc, Chicago, IL).

## RESULTS

**Patients.** One-hundred-forty-four patients were assessed for eligibility in the study, forty-four patients were excluded: 16 patients declined to participate because they insisted on an arthroscopic treatment and 28 patients did not meet the inclusion criteria: 13 patients were too old, 10 patients had a massive cuff tear, 3 patients had prior shoulder surgery and 2 patients were expected to be non-compliant (Figure 1). Finally, 100 patients were enrolled and randomised to the two treatment arms, 50 patients each. Figure 1 shows a flow diagram of the enrollment, allocation and follow-up of the patients. Biceps tenotomy was performed in 17 patients: 8 in the AA-group and 9 in the MO-group. Acromioplasty was performed in 7 patients: 4 in the AA-group and 3 in the MO-group. Mean operative time was 73.5 (SD 17.6) minutes in the AA-group and 53.8 (SD 12.7) minutes in the MO-group. Patient characteristics were comparable between the two groups and are depicted in Table 1.

**Treatment effects.** In both treatment groups, a significant improvement after the first postoperative year was found in the primary outcome measure, the DASH score (Figure 2A and Table 2). The mean postoperative DASH-score was 65.6 (95%CI: 60.8 to 70.5) in the AA-group and 69.1 (95%CI: 64.3 to 73.9) in the MO-group. This difference was not statistically significant (between group mean difference -3.4, 95%CI: -10.2 to 3.4,  $p = 0.317$ ). There was some evidence for an overall interaction between treatment and time ( $p = 0.06$ ) and this occurred only at the first follow-up moment of 6 weeks postoperatively ( $p = 0.028$ ). At the other follow-up moments,

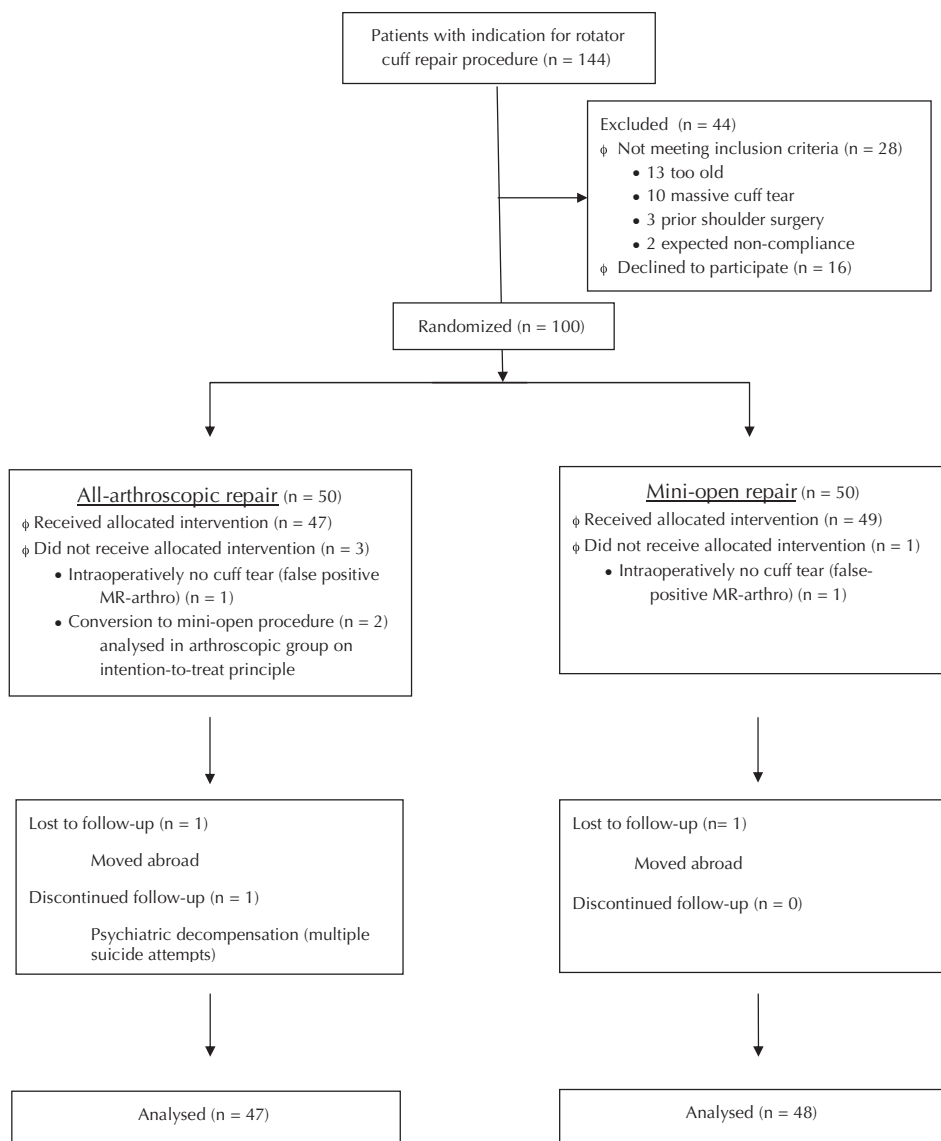
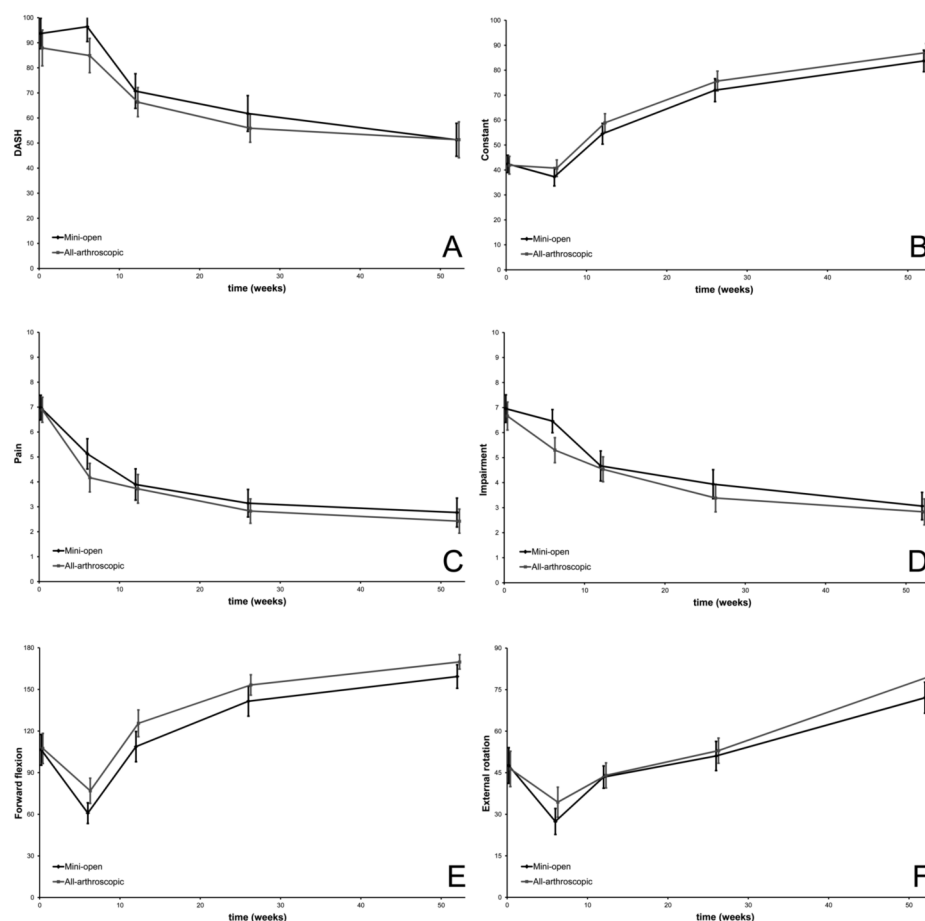


Figure 1. Flow diagram showing enrollment, allocation and follow-up of patients.

**Table 1.** Patient characteristics.

	All-Arthroscopic (n = 47)	Mini-Open (n = 48)
Mean age (years $\pm$ SD)	57.2 ( $\pm$ 8.0)	57.8 ( $\pm$ 7.9)
Sex (n)	18 female 29 male	20 female 28 male
Etiology (n)	Fall: 29 Unknown: 18	Fall: 30 Unknown: 18
Dominant side affected [n (%)]	34 (72%)	38 (79%)
Smoker [n (%)]	12 (25%)	7 (15%)
Mean tear size (mm $\pm$ SD)	Sagittal (20 $\pm$ 9) Frontal (23 $\pm$ 8)	Sagittal 19 ( $\pm$ 8) Frontal (22 $\pm$ 8)
Fatty muscle infiltration (n)		
Stage 0	17	21
Stage 1	21	21
Stage 2	9	6
Stage 3	0	0
Stage 4	0	0
Baseline variables (mean $\pm$ SD)		
DASH (0 - 100 points)	88 ( $\pm$ 25)	93 ( $\pm$ 22)
Constant (0 - 100 points)	42 ( $\pm$ 12)	42 ( $\pm$ 12)
VAS-pain (1 - 10 points)	6.9 ( $\pm$ 1.8)	7.0 ( $\pm$ 1.8)
VAS-disability (1 - 10 points)	6.7 ( $\pm$ 2.0)	7.0 ( $\pm$ 1.9)
Active forward flexion (degrees)	107 ( $\pm$ 38)	106 ( $\pm$ 39)
Active external rotation (degrees)	46 ( $\pm$ 22)	47 ( $\pm$ 23)

Abbreviations: DASH, disabilities of the arm, shoulder and hand; VAS, visual analogue scale.



**Figure 2.** Graphic representation of mean outcome scores (± SD) of the All-Arthroscopic (black line) and Mini-Open (grey line) procedures over time (weeks). DASH score (A), Constant score (B), VAS-pain (C), VAS-impairment (D), active forward flexion in degrees (E), and active external rotation in degrees (F).

no significant interaction was present ( $p > 0.05$ ). This was also reflected in testing of the mean difference at the prespecified follow-up moments of 6 and 52 weeks postoperatively. At 6 weeks postoperatively, the mean difference was -11.5 (95%CI: -20.6 to -2.3,  $p = 0.014$ ) points in favour of the AA-group. At 52 weeks, no significant difference was present (-0.1 points, 95%CI: -9.8 to 9.8,  $p = 0.998$ ).

## All-Arthroscopic Versus Mini-Open Rotator Cuff Repair

**Table 2.** Results of primary and secondary outcome measures.

	All Arthroscopic A	Mini open A		Main effect B	Treatment x Time interaction C	Pre- specified time point
Outcome	Mean (SE)	Mean (SE)	Between group mean difference (95%CI)	p-value	p-value	p-value
DASH						
Wk 6-52	66 (2.4)	69 (2.4)	-3.4 (-10.2 to 3.4)	0.317	0.06	0.014
Wk 6	85 (3.5)	96 (3.0)	-11.5 (-20.6 to -2.3)			
Wk 12	66 (3.0)	71 (3.5)	-4.4 (-13.6 to 4.7)			
Wk 26	56 (2.8)	62 (3.6)	-5.9 (-15.1 to 3.3)			
Wk 52	51 (3.7)	51 (3.4)	-0.1 (-9.8 to 9.8)			
Constant Score						
Wk 6-52	66 (1.6)	62 (1.6)	3.6 (0.7 to 7.9)	0.100	0.976	0.174
Wk 6	41 (1.7)	37 (1.9)	3.4 (1.5 to 8.5)			
Wk 12	59 (1.9)	55 (2.1)	4.4 (-1.2 to 10.0)			
Wk 26	76 (2.0)	72 (2.3)	3.7 (-2.5 to 9.8)			
Wk 52	87 (1.8)	84 (2.2)	3.4 (-2.4 to 9.1)			
VAS pain						
Wk 6-52	3.3 (0.2)	3.7 (0.2)	-0.4 (-1.0 to 0.2)	0.177	0.268	0.028
Wk 6	4.2 (0.3)	5.1 (0.3)	-0.9 (-1.8 to -0.1)			
Wk 12	3.7 (0.3)	3.9 (0.3)	-0.2 (-1.0 to 0.7)			
Wk 26	2.8 (0.3)	3.2 (0.3)	-0.3 (-1.1 to 0.4)			
Wk 52	2.4 (0.2)	2.8 (0.3)	-0.4 (-1.1 to 0.4)			
VAS impairment						
Wk 6-52	4.1 (0.2)	4.5 (0.2)	-0.4 (-0.1 to 1.0)	0.142	0.054	0.001
Wk 6	5.3 (0.3)	6.5 (0.2)	-1.2 (-1.8 to -0.5)			
Wk 12	4.5 (0.3)	4.7 (0.3)	-0.2 (-0.9 to 0.7)			
Wk 26	3.4 (0.3)	3.9 (0.3)	-0.6 (-1.4 to 0.3)			
Wk 52	2.8 (0.3)	3.1 (0.3)	-0.4 (-1.0 to 0.5)			
Forward flexion						
Wk 6-52	130 (3.4)	118 (3.4)	12.0 (2.9 to 21.0)	0.010	0.801	0.009
Wk 6	77 (4.6)	61 (3.8)	16.1 (4.2 to 28.0)			
Wk 12	126 (4.9)	109 (5.5)	17.8 (2.0 to 31.5)			
Wk 26	153 (3.7)	141 (5.5)	11.7 (-1.5 to 24.9)			
Wk 52	170 (2.6)	159 (4.3)	10.5 (0.4 to 20.6)			
External rotation						
Wk 6-52	53 (1.6)	49 (1.6)	4.2 (-0.2 to 8.7)	0.062	0.246	0.059
Wk 6	34 (2.8)	27 (2.4)	7.0 (-0.3 to 14.2)			
Wk 12	44 (2.3)	43 (2.1)	0.6 (-5.5 to 6.7)			
Wk 26	53 (2.3)	51 (2.7)	1.9 (-5.1 to 9.0)			
Wk 52	80 (2.0)	72 (2.9)	7.4 (0.4 to 14.4)			

<sup>A</sup> Values adjusted for baseline measurements.

<sup>B</sup> Assumes no interaction with time and indicates testing for overall between group mean difference over the entire postoperative follow-up period

<sup>C</sup> Indicates testing for overall changing treatment effects with time over the entire postoperative follow-up period

Similar results were found for the secondary outcome measures (Figure 2B-F and Table 2). However, with regard to the postoperative active function, there was some evidence towards an overall better result in the AA-group. This was most pronounced for active forward flexion, which was significantly higher over the entire follow-up period (between group mean difference 12.0°, 95%CI: 2.9 to 21.0,  $p = 0.010$ ). Postoperative active external rotation was slightly better (between group mean difference 4.2°, 95%CI: -0.2 to 8.7,  $p = 0.062$ ). Notably, these difference were constant over time and appeared to result from a difference in the postoperative *decrease* in active function. Consequently, these differences are not compensated but existed throughout the remaining postoperative follow-up period.

**Structural integrity of the repair.** Ultrasonographic assessment of the integrity of the repair after 12 months revealed intact repairs in 39 patients (83%) in the AA group and 41 (87%) patients in the MO group ( $p = 0.74$ ). Of the 8 patients (17%) with a retear in the AA group 3 patients were symptomatic, and 3 of these patients were smokers. Out of the 6 patients (13%) with a retear in the MO group 2 patients were symptomatic, and 2 patients were smokers. Two patients with a symptomatic retear had revision cuff repair, 1 in the AA-group and 1 in the MO-group. The observed complications are listed in Table 3.

**Table 3.** Complications.

	All-Arthroscopic n = 47	Mini-Open n = 48	p-value
Retear [n (%)]	8 (17%)	6 (13%)	0.740
(smoker)	(3)	(2)	
Adhesive capsulitis [n (%)]	5 (11%)	6 (13%)	0.776
(smoker)	(0)	(0)	
Biceps tendinopathy (n)	1	1	0.988
Anchor pullout (n)	1	0	0.991
Superficial infection (n)	0	1	0.991
Miscellaneous (n)	1 PE after 4 weeks	1 CVA after 2 months	0.988

Abbreviations: PE, pulmonary embolism; CVA, cerebrovascular accident

## DISCUSSION

Our results show no significant difference between the all-arthroscopic and mini-open repair technique with regard to the primary (DASH-score) and secondary (Constant, VAS-pain, VAS-disability) outcome scores, retear rate and postoperative stiffness. There was a significant improvement in postoperative range of motion in the AA-treatment group: both postoperative forward flexion and postoperative external rotation were higher in this group. Average postoperative forward flexion was 12 degrees better and external rotation 4 degrees. Clinical relevance of the magnitude of the estimated difference is unclear.

Although no overall significant interaction between the treatment and time was identified, and as such the overall mean difference between both groups did not change over time during the first postoperative year, several outcome measures, including the DASH-score, were significantly more improved in the AA-group compared to the MO-group at the 6 weeks follow-up moment. Consequently, benefit of the treatment may be obtained slightly sooner in the AA-group, but is not higher in the remaining follow-up period and the treatment effect does not become larger over time compared to the treatment effect in the MO-group. However, the improved postoperative range of movement in the AA-group versus the MO-group was maintained at all follow-up intervals.

Earlier reports published on all-arthroscopic versus mini-open rotator cuff repair did not find significant differences between the treatment groups.<sup>12-17</sup> These studies had major limitations, because they were non-randomised, retrospective comparative studies with a relatively high rate of patients lost to follow-up. Although systematic review of these studies did generate an adequate sample size, the quality of the reviews is limited to the best level of evidence available, which was level III.<sup>18-20</sup> Our prospective randomised controlled trial is the first high quality study with structured surgical, rehabilitation and follow-up protocols comparing the two surgical techniques. Our results show no significant differences between the AA and MO groups in the first year when looking at functional outcome and complications. However the all-arthroscopic procedure does achieve its treatment effect faster, e.g. after 6 weeks, than the mini-open procedure with regard to improvement in DASH score, VAS-pain/-impairment scores and range-of-motion. This could be attributed

to greater compromise of deltoid muscle tissue in the MO-group resulting from increased swelling and detachment of the muscle fibers from the acromion.<sup>27</sup> Although the arthroscopic technique is technically more demanding than the mini-open surgery, a strong asset of the arthroscopic procedure is the ability to evaluate and treat lesions in the entire shoulder joint in the same session. We did not look at this aspect in our study because patients with simultaneous lesions were excluded. An advantage of the mini-open repair procedure is that it consumes less operative time. Since both procedures have similar satisfactory results, and given that the arthroscopic technique is surgically more challenging and taking into account that the arthroscopic procedure has a somewhat faster rehabilitation, the decision regarding the technique used should be based on the surgeon's preference and experience.

Our study has some limitations. We do not have long-term data comparing the two treatment groups. The main focus of the study was on the short-term results, because the arthroscopic procedure is believed to have less morbidity and faster functional rehabilitation as a result of its minimal invasive character. This is why we were interested in the results in the first postoperative year and performed multiple evaluations in this early time period. Patients will remain under follow-up to assess long-term results. Our study might have been slightly under-powered since we did not detect any major differences. When looking at the study by Kang<sup>17</sup> the SD of the DASH was about 17 points at six months follow-up and we may have needed 130 patients instead of 100 to detect more significant differences. Another limitation is that we did not measure the use of postoperative analgesics and time to return to work or sports activities for the assessment of early recovery. On the other hand the outcome measures used are reliable and validated measurement instruments for the evaluation of clinical results in rotator cuff repair surgery.<sup>28</sup>

## CONCLUSION

There are no significant differences between All-Arthroscopic or Mini-Open repair technique in the first year when comparing functional outcome, pain, range of motion and complications. Patients do attain the benefits of treatment somewhat sooner with the arthroscopic procedure after 6 weeks.



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