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Functional implications of structural “anomalies” in shoulder pain

Kolk, A.

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Does acromioplasty result in favourable clinical and radiologic outcomes in the management of chronic subacromial pain syndrome?

A. Kolk

B. Thomassen

H. Hund

PB. de Witte

HE. Henkus

W.G. Wassenaar

E.R.A. van Arkel

R.G.H.H. Nelissen

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ABSTRACT

Background: The treatment effect of acromioplasty for chronic subacromial pain syndrome (SAPS) on long-term shoulder function and rotator cuff deterioration has still to be determined. This study aims to determine the long-term clinical and radiologic treatment effect of arthroscopic acromioplasty in patients with chronic SAPS.

Methods: In this double-blind, randomised clinical trial, 56 patients with chronic subacromial pain syndrome (median age 47 years; range, 31 – 60 years) were randomly allocated to arthroscopic bursectomy alone or to bursectomy combined with acromioplasty and were followed up for a median of 12 years. The primary outcome was the Constant score. Secondary outcomes included the Simple Shoulder Test, Visual Analogue Scales (VAS) for pain, VAS for shoulder functionality, and rotator cuff integrity assessed with Magnetic Resonance Imaging or ultrasound.

Results: A total of 43 patients (77%) were examined at a median of 12 years' follow-up. Intention-to-treat analysis at 12 years' follow-up did not show a significant additional treatment effect of acromioplasty on bursectomy alone in improvement in Constant score (5 points; 95% confidence interval, -5.1 – 15.6), Simple Shoulder Test score, VAS score for pain, or VAS score for shoulder function. The prevalence of rotator cuff tears was not significantly different between the bursectomy group (17%) and acromioplasty group (10%).

Conclusions: There were no relevant additional effects of arthroscopic acromioplasty on bursectomy alone with respect to clinical outcomes and rotator cuff integrity at 12 years' follow-up. These findings bring the effectiveness of acromioplasty into question and may support the idea of a more conservative approach in the initial treatment of SAPS.

INTRODUCTION

Shoulder complaints have a prevalence of up to 48 per 1000 person-years, and each year up to 20% of the adult population has pain in the shoulder.^{12, 35} Furthermore, shoulder complaints account for a huge part of health care costs and are a common reason for sick leave from work.^{37, 43} The majority of these complaints are primarily attributed to extrinsic compression of the acromion with impingement of the rotator cuff (RC) tendons.^{31, 40} As a result of the ongoing debate over the extrinsic compression theory, the “impingement” entity has recently evolved to a more generic term, “subacromial pain” syndrome (SAPS).^{9, 10, 36, 40, 42}

Acromioplasty has been the standard treatment for patients having subacromial pain, with over 20.000 procedures per year in New York State, as well as in the United Kingdom.^{22, 44} Acromioplasty is considered a successful surgical option in SAPS to reduce mechanical impingement and optimize shoulder function.^{22, 31} Various authors have claimed that acromioplasty may prevent the RC from developing a full-thickness tear.^{1, 11, 32} Existing randomised controlled clinical trials (RCTs) examining the effect of acromioplasty in SAPS have been pragmatic in nature and focused on the difference between surgery and conservative strategies (e.g. supervised exercise therapy).^{4, 5, 13, 14, 24, 25} Thus these study designs have not accounted for the potential impact of bursectomy and placebo effects, resulting in an overestimation of the effect that is attributable to acromioplasty.^{2, 17, 18, 21, 31, 33} One prior RCT has taken those effects into account by randomly allocating SAPS patients to bursectomy alone or to bursectomy combined with acromioplasty. No beneficial effects of acromioplasty were shown 2.5 years after surgery.¹⁵ However, the concept of extrinsic compression leading to RC deterioration implies that clinical shoulder symptoms would increase after many years. Consequently, the value of acromioplasty in the treatment of chronic SAPS and prevention of developing RC tears, while broadly applied, has still to be determined.

The aim of this study was to evaluate the long-term clinical effect of arthroscopic acromioplasty with respect to pain, function, and RC integrity in patients with chronic SAPS. For this purpose, we randomly assigned patients with chronic SAPS either to bursectomy alone or to bursectomy in combination with acromioplasty. Because acromioplasty is expected to reduce extrinsic compression with a consequent effect on shoulder related complaints, we hypothesised that acromioplasty improves long-term shoulder function, reduces pain and prevents the development of RC tears in patients with chronic SAPS.

MATERIALS AND METHODS

Study Design and Eligibility Criteria

The research group recruited patients from a previously described prospective, parallel-group, superiority, double-blinded RCT for long-term evaluation.¹⁵ Patients were invited

for follow-up between February 2015 and April 2016 at the orthopaedic department of a secondary referral centre (Haaglanden Medical Centre, the Hague, the Netherlands).

At the start of the trial, eligible patients obtained the diagnosis of SAPS by a shoulder orthopaedic surgeon (ERAvA) after assessment of medical history, physical examination, radiographs (anteroposterior view with the humerus in external and internal rotation and trans-scapular view), and direct Magnetic Resonance Arthrography (MRA) of the shoulder. Mandatory clinical signs for inclusion were as follows: pain located in the deltoid region for at least 3 months; inability to lie down on the affected shoulder; pain during abduction, backward flexion or internal rotation; positive Neer or Hawkins impingement test; and a positive lidocaine impingement test. In addition, conservative treatment for at least 6 weeks (i.e. subacromial infiltration, nonsteroidal anti-inflammatory drugs, and supervised exercises) had to be unsuccessful. The exclusion criteria were: calcifying tendinitis, biceps tendinitis, partial- or full-thickness RC tear, labral tear, signs of glenohumeral instability, passive restriction of glenohumeral motion, osteoarthritis of the acromioclavicular or glenohumeral joint, rheumatic diseases, cervical radiculopathy, history of shoulder trauma, synovitis, and prior surgery on the affected shoulder.

The study protocol was approved by the medical ethical research committee “Zuidwest Holland”, and registered at the Dutch Trial Register (www.trialregister.nl, Identifier: NTR4723). Each participant gave written informed consent.

Randomisation and Blinding

An independent data manager randomly assigned all eligible patients, just prior to surgery, either to bursectomy alone or to bursectomy plus acromioplasty. Randomisation was performed with 1:1 allocation using a computer-generated random list. Trial participants were blinded for treatment allocation. A blinded independent physician (HEH or AK) clinically assessed each patient. A dedicated musculoskeletal radiologist (WGW), who was uninformed about treatment allocation, performed all radiologic evaluations.

Intervention

Included subjects underwent surgery under general anaesthesia in the lateral decubitus position by an experienced arthroscopic shoulder surgeon (ERAvA).¹⁵ Three standard arthroscopic shoulder portals were created: a posterior portal, a lateral portal, and an anterior portal through the RC interval. Traction was applied to assess the subacromial space. The subacromial space and glenohumeral joint were inspected to rule out alternative diagnoses. All arthroscopic findings were uniformly recorded. First, the subacromial bursa was debrided with a motorized shaver or an electrocautery probe (OPES; Arthrex, Naples, Florida, USA). When the patient was allocated to the acromioplasty group, a motorized burr was used to conduct a partial resection of the anteroinferior surface of the acromion and the distal coracoacromial ligament through the lateral and posterior portals until a flat

surface was created.¹⁵ Postoperatively, patients were allowed to use any painkillers when necessary. All patients started a standardized rehabilitation protocol under supervision of a physiotherapist.

Data collection and Outcome Measures

Patients were evaluated at standardized follow-up visits at baseline and 1.5, 3, 6, 12, 24 months or 4 years after surgery, as previously reported.¹⁵ Of the 80 consecutive patients initially screened for eligibility, 23 patients were excluded because of the exclusion criteria on preoperative MRA or during arthroscopy (Figure 1).¹⁵ In addition, one patient died of lung cancer during follow-up and was excluded from the previous study, leaving 56 participants.¹⁵ These 56 subjects were the source population for the present study. For this study, we invited all initially included patients for a clinical and radiologic follow-up evaluation in 2015 or 2016 (median follow-up 12 years, range 9 – 14 years). Of the 56 patients, 13 patients were lost to follow-up (Figure 1). Long-term clinical data were obtained in 43 patients (77%) and 39 subjects (70%) underwent radiologic evaluation.

The primary outcome measure was shoulder function, expressed with the Constant score (CS).⁸ Secondary outcome measures were the Simple Shoulder Test (SST), a Visual Analogue Scale (VAS) for pain (from 0 to 100mm, with 100mm indicating severe pain), and a VAS for shoulder functionality (from 0 to 100mm, with 100mm indicating severely impaired shoulder function).⁴¹ The SST score was interpreted as a percentage from 0% to 100%, with 100% representing optimal shoulder function. All patients were asked to score their overall satisfaction, amount of pain reduction, improvement of shoulder function, and whether they would recommend this type of surgery to another patient by use of the following 7-point Likert scale: completely agrees, 0; agrees, 1; partly agrees, 2; neutral, 3; partly disagrees, 4; disagrees, 5; and completely disagrees, 6. Subsequently, a score of 0, 1 or 2 on any of these subjective measures (i.e. satisfaction, pain reduction, improvement in shoulder function and recommendations to another patient) was considered a good or excellent outcome.

Baseline acromial morphology was scored by the orthopaedic surgeon with the combination of standard radiographs, MRA and intra-operative findings because variability for the identification of acromial morphology has been reported with radiographs or MRA alone.^{3,29} At follow-up, the RC was evaluated to investigate the presence of long-term deterioration and RC tears using MRA (Aera, Avanto, or Symphony 1.5-T magnetic resonance imaging unit; Siemens, Erlangen, Germany). Standard shoulder MRI protocols were used to create 3- to 4-mm-thick T2 fat saturation and T1 or proton density slices in multiple orthogonal directions. Images were evaluated by a dedicated musculoskeletal radiologist in a standardized manner regarding the presence of tendinosis, a partial-thickness RC tear, a labral tear, acromioclavicular osteoarthritis, and a full-thickness RC tear. In case of a contraindication for MRI or when an intra-articular injection was refused (n=8), ultrasonography by a musculoskeletal radiologist was used.

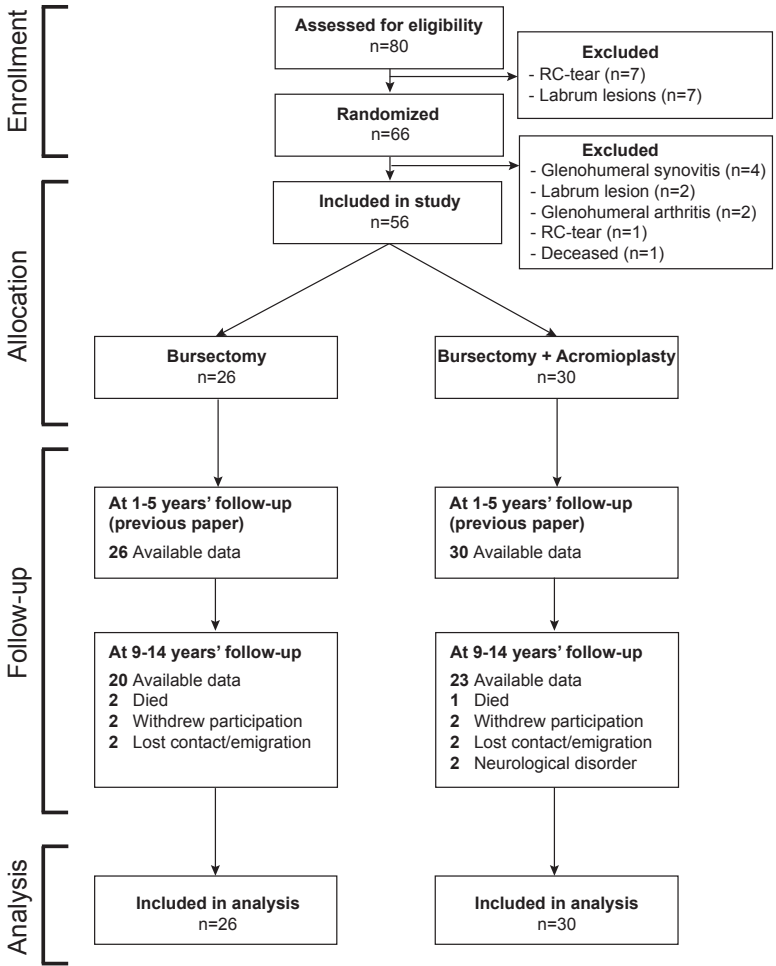


Figure 1. Flow diagram of enrolment, allocation, follow-up and analyses of patients participating in this randomized controlled clinical trial. Abbreviations: RC, rotator cuff.

Statistical analysis

A sample size calculation was performed before the long-term follow-up study was scheduled, with the CS as our primary outcome. We defined a difference of 20 points as clinically important. We assumed a standard deviation of 19 points based on previous work.¹⁵ Therefore, at least 40 participants (20 for each group) were required to detect a statistically significant difference with a power of 90% and a two-sided α of 0.05. The Wilcoxon signed rank test was applied to compare baseline and follow-up continuous outcome data between groups. The prevalence of RC tears in both groups was compared using Fisher’s exact test. Generalized estimating equations (GEE) were applied to compare the effect of treatment in both groups on clinical outcomes using (1) an intention-to-treat (ITT), and (2) an as-

treated approach. GEE make use of all cases (independent from the presence of missing data), deal with the repeated measures design, and account for potential nonparametric distribution in the outcome.

In our primary analysis, we examined the eventual additional effect of acromioplasty on bursectomy alone at 12 years' follow-up. GEE models were constructed with follow-up time (i.e. baseline, 1.5, 3, 6, 12 and 24 months, 4 years and 12 years) as the repeated factor. Covariance was modelled using an autoregressive structure of order 1. Follow-up time, follow-up time \times treatment group (i.e. bursectomy versus bursectomy plus acromioplasty), baseline score, age, sex and shape of acromion (i.e. type I, II, or III according to Bigliani¹) were included as fixed effects. A second analysis was conducted to evaluate the average effect of acromioplasty over the full follow-up period.

The effect of missing data was evaluated using multiple imputation. Fifty datasets with randomly imputed values were created. Analyses were conducted under the assumption that observed values were able to predict missing values (i.e. missing at random [MAR]). Age, sex, group, reoperation, acromial shape, hand dominance, and available outcome data from other evaluations were used to predict missing outcomes. Although this trial was not designed for subgroup analyses, we performed stratified analyses in a group of patients with a type I acromion and in a group with type II or III acromion (type II and III acromion were combined because the number of patients with type III acromion exposed to bursectomy alone was limited) prior to surgery to determine the effect of acromioplasty on the CS. Statistical analyses were conducted using IBM SPSS statistics for Windows (version 20.0, IBM Corp, 2011, Armonk, New York, USA). We considered a two-sided P value of <0.05 statistically significant.

RESULTS

At baseline, participants had a median age of 47 years (interquartile range [IQR] 12 years) with 55% being female (Table 1). Long-term outcomes were evaluated in 43 patients (77%) with a median of 12 years' follow-up (IQR 2 years, range 9 – 14 years). The median follow-up for the complete population (56 patients) was 11 years (IQR 3 years, range 1 – 14 years).

Primary Outcome

At 12 years' follow-up, both treatment groups showed a significant increase in CS (Table 2). Acromioplasty led to a slightly greater improvement in CS (difference of 5 points; 95% confidence interval [CI], -5 – 15.6 points, $P = 0.32$) in the intention-to-treat analysis, but this difference did not reach statistical significance. However, the estimated treatment effect of acromioplasty was not statistically significantly different and its CIs excluded the minimal clinically important difference (MCID) (Table 3). The average effect of acromioplasty

Table 1. Baseline characteristics¹⁵

	Bursectomy	Bursectomy & Acromioplasty
	n= 26	n= 30
Age, median (IQR), yrs.	44 (13)	50 (9)
Follow-up, median (IQR), yrs.	11 (4)	11 (4)
Male sex, n	9 (35%)	16 (53%)
Preoperative symptoms >1yr, n	17 (65%)	26 (87%)
Involved side: right, n	14 (54%)	13 (43%)
Hand dominance: right, n	23 (89%)	26 (87%)
Duration of surgery, median (IQR), min.	33 (21)	39 (10)
Acromion, n		
Type I	11 (42%)	5 (17%)
Type II	13 (50%)	19 (63%)
Type III	2 (8%)	6 (20%)

Abbreviations: IQR, interquartile range; yrs., years; n = number; min, minutes.

including all follow-up evaluations was also not statistically significantly different between both groups. Data obtained from multiple imputation resulted in comparable estimates (Table 3, Figure 2). Subgroup analyses revealed that the effect of acromioplasty on the CS at 12 years' follow-up was 8 points (95% CI, -5.0 – 20.7 points, $P = 0.23$) in subjects with a type II or III acromion and 0 points (95% CI, -19.9 – 19.4 points, $P = 0.98$) in patients with a type I acromion.

Secondary Outcome

We did not demonstrate statistically significant differences in any of the secondary outcome measures at 12 years' follow-up. The average effect of acromioplasty using all follow-up evaluations was not statistically significantly different for the SST and VAS for pain in our analysis using raw data. However, after multiple imputation, we found lower VAS scores for pain scores in the acromioplasty group over the entire follow-up (Table 3). A greater improvement in VAS scores for shoulder functionality of 12 mm (95% CI, -1.6 – 22.6) was found after acromioplasty, with a little effect of data imputation (Table 3).

The prevalence of RC tendinitis, bursal-side RC tears, and full-thickness RC tears was comparable between both treatment groups at 12 years' follow-up (Table 2).

Revision surgery was performed in 11 patients (out of 56 subjects). In the bursectomy group, 6 patients were re-operated, of whom 3 within the first postoperative year: Two underwent an acromioplasty, and one underwent a resection of the distal clavicle, and subsequently an RC repair. Three other patients (at 2, 11 and 12 years postoperatively) were scheduled to undergo RC repair, but in one patient no RC tear was found during surgery. In the acromioplasty group, 5 patients were re-operated, of whom 3 did so within the first post-

Table 2. Clinical and radiologic findings at baseline and follow-up

	Bursectomy			Bursectomy & acromioplasty		
	Baseline	9-14 yrs.	P value	Baseline	9-14 yrs.	P value
Clinical evaluation						
N. of patients	26	20		30	23	
Constant Score ^a , points	59 (26)	81 (24)	<0.001 ^{††}	62 (21)	91 (23)	<0.001 ^{††}
SST ^a , %	42 (52)	67 (46)	0.003 ^{††}	38 (50)	83 (50)	<0.001 ^{††}
VAS for pain ^a , mm	70 (23)	7 (33)	0.004 ^{††}	70 (30)	4 (19)	<0.001 ^{††}
VAS for functionality ^a , mm	70 (33)	10 (55)	0.001 ^{††}	65 (20)	4 (23)	<0.001 ^{††}
Satisfied, n (%)		14 (70%)			18 (78%)	
Improved pain, n (%)		15 (75%)			20 (83%)	
Improved shoulder function, n (%)		15 (75%)			19 (85%)	
Would recommend surgery, n (%)		13 (65%)			19 (83%)	
Radiologic evaluation						
N. of patients		18			21	N.S. [‡]
Acromioclavicular OA, n (%)		8 (44%)			12 (57%)	N.S. [‡]
Articular partial RC tear, n (%)		2 (11%)			1 (5%)	N.S. [‡]
Bursal partial RC tear, n (%)		0 (0%)			1 (5%)	N.S. [‡]
Tendinosis, n (%)		5 (28%)			6 (29%)	N.S. [‡]
Full-thickness RC tear, n (%)		3 (17%)			2 (10%)	N.S. [‡]

Abbreviations: yrs., years; n, number; SST, Simple Shoulder Test; VAS, visual analogue scale; mm, millimetre; N.S., not significant; OA, osteoarthritis; RC, rotator cuff.

^a Median (IQR)

[†] Statistically significant

^{††} Wilcoxon signed rank tests.

[‡] Fishers' exact test.

operative year: One patient underwent a more extensive acromioplasty, and two patients underwent a resection of the distal clavicle. Furthermore, a labral defect was treated after 2 years in one patient, and one patient underwent an RC repair after 11 years.

DISCUSSION

This clinical trial aimed to investigate whether an arthroscopic bursectomy followed by an acromioplasty provides greater long-term improvement in shoulder function or pain relief than does bursectomy alone in patients with chronic SAPS. At 12 years' follow-up, no statistically significant additional effect of acromioplasty on bursectomy alone was found with respect to improved shoulder function or pain reduction. Similarly, the additional effect of acromioplasty on bursectomy alone for the overall follow-up period was not statistically significant for the primary outcome. Moreover, the number of RC tears was comparable

Table 3. Effectiveness of acromioplasty

Raw data [†]		Mean effect	95% CI	P value
Constant Score, points				
At 12 years	ITT	5	-5.1 – 15.6	0.32
	As-treated	2	-7.9 – 12.8	0.65
Average effect over follow-up	ITT	6	-0.7 – 12.5	0.08
	As-treated	5	-1.4 – 11.1	0.13
SST, %				
At 12 years	ITT	11	-5.2 – 27.6	0.18
	As-treated	6	-9.2 – 22.2	0.42
Average effect over follow-up	ITT	11	-0.0 – 22.0	0.05
	As-treated	8	-2.3 – 19.3	0.12
VAS for pain, mm				
At 12 years	ITT	-6	-21.0 – 8.9	0.43
	As-treated	-1	-16.3 – 13.5	0.85
Average effect over follow-up	ITT	-7	-17.4 – 3.2	0.18
	As-treated	-5	-14.7 – 4.6	0.31
VAS for functionality, mm				
At 12 years	ITT	-15	-31.7 – 2.1	0.09
	As-treated	-3	-19.4 – 13.8	0.74
Average effect over follow-up	ITT	-12	-22.6 – -1.6	0.02 [*]
	As-treated	-8	-18.2 – 6.3	0.11
Results after multiple imputation[‡]				
Constant Score, points				
At 12 years	ITT	4	-4.9 – 12.0	0.41
	As-treated	1	-7.2 – 9.5	0.79
Average effect over follow-up	ITT	3	-0.3 – 7.3	0.07
	As-treated	3	-0.6 – 6.7	0.10
SST, %				
At 12 years	ITT	5	-7.9 – 18.3	0.43
	As-treated	2	-10.7 – 14.7	0.76
Average effect over follow-up	ITT	6	-2.0 – 13.2	0.15
	As-treated	5	-2.9 – 12.1	0.23
VAS for pain, mm				
At 12 years	ITT	-6	-16.9 – 5.3	0.31
	As-treated	-2	-13.3 – 9.1	0.71
Average effect over follow-up	ITT	-7	-13.5 – -0.6	0.03 [*]
	As-treated	-6	-12.5 – -0.3	0.04 [*]
VAS for functionality, mm				
At 12 years	ITT	-9	-22.2 – 4.5	0.19
	As-treated	0	-13.1 – 13.2	0.99
Average effect over follow-up	ITT	-7	-14.4 – 0.0	0.05
	As-treated	-6	-12.6 – 1.6	0.13

Abbreviations: CI, confidence interval; ITT, intention to treat; SST, Simple Shoulder Test; VAS, visual analogue scale; mm, millimetre.

^{*} Statistically significant

[†] Generalized estimating equation model with time (i.e. 1.5, 3, 6, 12 and 24 months, 4 years and 12 years), time × group, baseline score, age, sex and shape of acromion were included as fixed effects.

[‡] Generalized estimating equation model with time (i.e. 1.5, 3, 6, 12 and 24 months, 4 years and 12 years), group, baseline score, age, sex and shape of acromion were included as fixed effects.

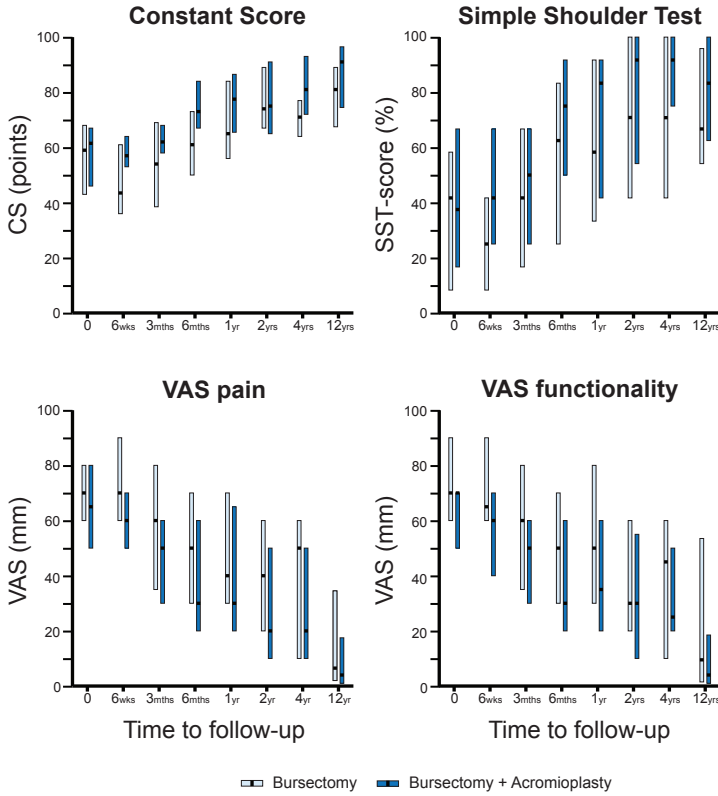


Figure 2. Median and 25th and 75th percentiles of the primary (Constant Score) and secondary outcome measures preoperatively and during follow-up (at 6 weeks, 3 months, 6 months, 1 year, 2 years, 4 years and at a median of 12 years' follow-up). Abbreviations: CS, Constant Score; SST, Simple Shoulder Test; VAS, Visual Analogue Scale.

between both groups, which indicates that acromioplasty does not fully protect RC integrity and RC tears may still develop.

This RCT is the first trial that has investigated the additional long-term effect of acromioplasty on bursectomy alone in the treatment of chronic SAPS. Many previous reports on the effectiveness of acromioplasty in SAPS have been cohort studies.^{2, 17, 18, 21, 31, 33} These studies did not account for the natural course of SAPS and the effect of bursectomy on itself. A solitary bursectomy, as conducted in our control group, is sometimes considered a sham procedure, although debridement of the bursa alone has also been reported to improve clinical outcomes.⁶ Our randomised design enables us to differentiate between the actual effect of acromioplasty and other effects (e.g. placebo effect or effect of bursectomy). We previously found no beneficial effect of acromioplasty at 2.5 years' follow-up.¹⁵ Consistent with the midterm results, we did not find a significant additional treatment effect of acromioplasty over bursectomy alone on the CS at final follow-up.¹⁵ The average effect over

the entire follow-up in our imputed dataset reached statistical significance for VAS scores for pain. However, the CIs of this effect excluded the minimal clinically important difference (MCID) of VAS score for pain (i.e. 14 mm) reported in the literature, which makes its clinical relevance questionable.³⁹

The number of full-thickness RC tears found after acromioplasty in our study is in agreement with the prevalence of RC tears in most SAPS cohorts reported in the literature.^{2, 20} In 4% to 13% of the patients treated with an acromioplasty, a full-thickness RC tear was found at 15 years' follow-up.^{2, 20} On the contrary, Kartus et al reported a percentage of full-thickness RC tears of up to 35% at a mean follow-up of 8.5 years.²³ This high percentage considerably differs from the number of RC tears reported in our study and might be a result of the inclusion of incomplete RC tears (i.e. stage III impingement) at baseline. In the general population, a higher prevalence of RC tears of 35% to 80% has been reported in volunteers aged over 60 years.^{30, 45} The higher prevalence of RC tears in the general population might be surprising when considering that the patient with a history of RC complaints has an assumed a higher baseline risk of the development of an RC tear.

An open or arthroscopic acromioplasty is still a widespread therapeutic option after failed conservative management in clinical orthopaedic practice.^{22, 34} Although inconsistent results have been reported regarding the optimal surgical technique, the arthroscopic technique allowed us to evaluate the glenohumeral joint and to exclude other intra-articular pathology.^{19, 28, 38} Preservation of the deltoid during arthroscopy has been claimed to result in superior function and faster recovery, but consensus on this topic has not been reached yet.^{19, 28, 38} As an alternative to surgery, a number of RCTs showed comparable success rates in SAPS after physiotherapy.^{4, 5, 13, 14, 16, 24, 25} Shoulder exercises might be more cost-effective than surgery especially as our study suggests that the RC is not protected from tearing after an acromioplasty.^{24, 25}

There are some limitations of this study. First, imbalances in the distribution of baseline characteristics existed, although allocation to treatment was random. Therefore, we included several baseline characteristics in our statistical model. Furthermore, the sample size was small. The MCID of the CS was reported after initiation of our study and was shown to be approximately 10 to 11 points.^{7, 26} This study was not designed and lacks power to detect these small differences. However, it is questionable whether a larger study would yield different conclusions, because the MCID of the CS reported in literature (e.g. 10 to 11 points) falls just inside the CI of our estimated treatment effect (intension-to-treat analysis raw data; 95% CI: -0.7 to 12.5 points).²⁶ Similarly, the prevalence of full-thickness tears (10% versus 17%) warrants a larger trial to demonstrate a potential beneficial effect of acromioplasty in preventing the RC from tearing. We do not believe our evaluation of the RC with both ultrasound and MRA has impaired the study because both ultrasound and MRA are accurate modalities for detecting a full-thickness RC tear.²⁷ Moreover, an RCT is usually not designed to perform subgroup analyses (i.e. based on acromial morphology or

coracoacromial morphology) because of limited power. Therefore, our subgroup analyses should be interpreted with care.

Ideally, a future RCT should be performed comparing surgery (i.e. bursectomy with acromioplasty) with a surgical sham procedure in a large sample and subgroup of patients with chronic SAPS to investigate the effectiveness of surgery that could underline or reject our results. Subgroups should involve patients who are more likely to benefit from acromioplasty including patients with a hooked acromion or with fraying of the coracoacromial ligament, because the latter may indicate potential contact of the RC with the coracoacromial arch.

CONCLUSION

Arthroscopic acromioplasty plus a bursectomy does not result in a clinically relevant improvement in shoulder function or relief of pain in patients with SAPS at 12 years' follow-up compared with bursectomy alone. Furthermore, we were unable to prove a statistically significant difference in the prevalence of RC tears between both groups at 12 years' follow-up. These findings bring the effectiveness of acromioplasty for all patients with chronic SAPS into question, and may support the idea of a conservative approach in the initial treatment of SAPS.

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REFERENCES

- 1 Bigliani LU, Ticker JB, Flatow EL, Soslowsky LJ, Mow VC. The relationship of acromial architecture to rotator cuff disease. *Clin Sports Med* 1991;10:823-838.
- 2 Bjornsson H, Norlin R, Knutsson A, Adolfsson L. Fewer rotator cuff tears fifteen years after arthroscopic subacromial decompression. *J Shoulder Elbow Surg* 2010;19:111-115. DOI: 10.1016/j.jse.2009.04.014
- 3 Bright AS, Torpey B, Magid D, Codd T, McFarland EG. Reliability of radiographic evaluation for acromial morphology. *Skeletal Radiol* 1997;26:718-721.
- 4 Brox JI, Gjengedal E, Uppheim G, Bohmer AS, Brevik JI, Ljunggren AE et al. Arthroscopic surgery versus supervised exercises in patients with rotator cuff disease (stage II impingement syndrome): a prospective, randomized, controlled study in 125 patients with a 2 1/2-year follow-up. *J Shoulder Elbow Surg* 1999;8:102-111. DOI: 10.1016/S1058-2746(99)90001-0
- 5 Brox JI, Staff PH, Ljunggren AE, Brevik JI. Arthroscopic surgery compared with supervised exercises in patients with rotator cuff disease (stage II impingement syndrome). *BMJ* 1993;307:899-903. DOI: 10.1136/bmj.307.6909.899
- 6 Budoff JE, Rodin D, Ochiai D, Nirschl RP. Arthroscopic rotator cuff debridement without decompression for the treatment of tendinosis. *Arthroscopy* 2005;21:1081-1089. DOI: 10.1016/j.arthro.2005.05.019
- 7 Christiansen DH, Frost P, Falla D, Haahr JP, Frich LH, Svendsen SW. Responsiveness and Minimal Clinically Important Change: A Comparison Between 2 Shoulder Outcome Measures. *J Orthop Sports Phys Ther* 2015;45:620-625. DOI: 10.2519/jospt.2015.5760
- 8 Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. *Clin Orthop Relat Res* 1987;160-164.
- 9 de Witte PB, de Groot JH, van Zwet EW, Ludewig PM, Nagels J, Nelissen RG et al. Communication breakdown: clinicians disagree on subacromial impingement. *Med Biol Eng Comput* 2013;52:221-231. DOI: 10.1007/s11517-013-1075-0
- 10 Diercks R, Bron C, Dorrestijn O, Meskers C, Naber R, de RT et al. Guideline for diagnosis and treatment of subacromial pain syndrome: a multidisciplinary review by the Dutch Orthopaedic Association. *Acta Orthop* 2014;85:314-322. DOI: 10.3109/17453674.2014.920991
- 11 Epstein RE, Schweitzer ME, Frieman BG, Fenlin JM, Jr., Mitchell DG. Hooked acromion: prevalence on MR images of painful shoulders. *Radiology* 1993;187:479-481. 10.1148/radiology.187.2.8475294 [doi]
- 12 Greving K, Dorrestijn O, Winters JC, Groenhof F, van der Meer K, Stevens M et al. Incidence, prevalence, and consultation rates of shoulder complaints in general practice. *Scand J Rheumatol* 2012;41:150-155. DOI: 10.3109/03009742.2011.605390
- 13 Haahr JP, Andersen JH. Exercises may be as efficient as subacromial decompression in patients with subacromial stage II impingement: 4-8-years' follow-up in a prospective, randomized study. *Scand J Rheumatol* 2006;35:224-228. DOI: 10.1080/03009740600556167
- 14 Haahr JP, Ostergaard S, Dalsgaard J, Norup K, Frost P, Lausen S et al. Exercises versus arthroscopic decompression in patients with subacromial impingement: a randomised, controlled study in 90 cases with a one year follow up. *Ann Rheum Dis* 2005;64:760-764. DOI: 10.1136/ard.2004.021188
- 15 Henkus HE, de Witte PB, Nelissen RG, Brand R, van Arkel ER. Bursectomy compared with acromioplasty in the management of subacromial impingement syndrome: a prospective randomised study. *J Bone Joint Surg Br* 2009;91:504-510. DOI: 10.1302/0301-620X.91B4.21442
- 16 Holmgren T, Bjornsson HH, Oberg B, Adolfsson L, Johansson K. Effect of specific exercise strategy on need for surgery in patients with subacromial impingement syndrome: randomised controlled study. *BMJ* 2012;344:e787. DOI: 10.1136/bmj.e787

- 17 Hultenheim Klintberg I, Karlsson J, Svantesson U. Health-related quality of life, patient satisfaction, and physical activity 8-11 years after arthroscopic subacromial decompression. *J Shoulder Elbow Surg* 2011;20:598-608. DOI: 10.1016/j.jse.2010.08.021
- 18 Hultenheim Klintberg I, Svantesson U, Karlsson J. Long-term patient satisfaction and functional outcome 8-11 years after subacromial decompression. *Knee Surg Sports Traumatol Arthrosc* 2010;18:394-403. DOI: 10.1007/s00167-009-0963-1
- 19 Husby T, Haugstvedt JR, Brandt M, Holm I, Steen H. Open versus arthroscopic subacromial decompression: a prospective, randomized study of 34 patients followed for 8 years. *Acta Orthop Scand* 2003;74:408-414. 10.1080/00016470310017703 [doi]
- 20 Hyvonen P, Lohi S, Jalovaara P. Open acromioplasty does not prevent the progression of an impingement syndrome to a tear. Nine-year follow-up of 96 cases. *J Bone Joint Surg Br* 1998;80:813-816. DOI: 10.1302/0301-620X.80B5.8533
- 21 Jaeger M, Berndt T, Ruhmann O, Lerch S. Patients With Impingement Syndrome With and Without Rotator Cuff Tears Do Well 20 Years After Arthroscopic Subacromial Decompression. *Arthroscopy* 2015. DOI: 10.1016/j.arthro.2015.08.026
- 22 Judge A, Murphy RJ, Maxwell R, Arden NK, Carr AJ. Temporal trends and geographical variation in the use of subacromial decompression and rotator cuff repair of the shoulder in England. *Bone Joint J* 2014;96-B:70-74. DOI: 10.1302/0301-620x.96b1.32556
- 23 Kartus J, Kartus C, Rostgard-Christensen L, Sernert N, Read J, Perko M. Long-term clinical and ultrasound evaluation after arthroscopic acromioplasty in patients with partial rotator cuff tears. *Arthroscopy* 2006;22:44-49. DOI: 10.1016/j.arthro.2005.07.027
- 24 Ketola S, Lehtinen J, Arnala I, Nissinen M, Westenius H, Sintonen H et al. Does arthroscopic acromioplasty provide any additional value in the treatment of shoulder impingement syndrome?: a two-year randomised controlled trial. *J Bone Joint Surg Br* 2009;91:1326-1334. DOI: 10.1302/0301-620X.91B10.22094
- 25 Ketola S, Lehtinen J, Rousi T, Nissinen M, Huhtala H, Kontinen YT et al. No evidence of long-term benefits of arthroscopic acromioplasty in the treatment of shoulder impingement syndrome: Five-year results of a randomised controlled trial. *Bone Joint Res* 2013;2:132-139. DOI: 10.1302/2046-3758.27.2000163
- 26 Kukkonen J, Kauko T, Vahlberg T, Joukainen A, Aarimaa V. Investigating minimal clinically important difference for Constant score in patients undergoing rotator cuff surgery. *J Shoulder Elbow Surg* 2013;22:1650-1655. DOI: 10.1016/j.jse.2013.05.002
- 27 Lenza M, Buchbinder R, Takwoingi Y, Johnston RV, Hanchard NC, Faloppa F. Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered. *Cochrane Database Syst Rev* 2013;9:CD009020. DOI: 10.1002/14651858.CD009020.pub2
- 28 Lindh M, Norlin R. Arthroscopic subacromial decompression versus open acromioplasty. A two-year follow-up study. *Clin Orthop Relat Res* 1993;174-176.
- 29 Mayerhoefer ME, Breitensteiner MJ, Roposch A, Treitl C, Wurnig C. Comparison of MRI and conventional radiography for assessment of acromial shape. *AJR Am J Roentgenol* 2005;184:671-675. 10.2214/ajr.184.2.01840671
- 30 Milgrom C, Schaffler M, Gilbert S, van HM. Rotator-cuff changes in asymptomatic adults. The effect of age, hand dominance and gender. *J Bone Joint Surg Br* 1995;77:296-298.
- 31 Neer CS. Anterior acromioplasty for the chronic impingement syndrome in the shoulder: a preliminary report. *J Bone Joint Surg Am* 1972;54:41-50. DOI: 10.2106/00004623-197254010-00003
- 32 Nordt WE, 3rd, Garretson RB, 3rd, Plotkin E. The measurement of subacromial contact pressure in patients with impingement syndrome. *Arthroscopy* 1999;15:121-125. DOI: 10.1053/ar.1999.v15.015012
- 33 Odenbring S, Wagner P, Atroshi I. Long-term outcomes of arthroscopic acromioplasty for chronic shoulder impingement syndrome: a prospective cohort study with a minimum of 12 years' follow-up. *Arthroscopy* 2008;24:1092-1098. S0749-8063(08)00356-3 [pii];10.1016/j.arthro.2008.04.073 [doi]

CHAPTER 2

- 34 Paloneva J, Lepola V, Karppinen J, Ylinen J, Aarimaa V, Mattila VM. Declining incidence of acromioplasty in Finland. *Acta Orthop* 2015;86:220-224. DOI: 10.3109/17453674.2014.977703
- 35 Picavet HS, Schouten JS. Musculoskeletal pain in the Netherlands: prevalences, consequences and risk groups, the DMC(3)-study. *Pain* 2003;102:167-178. DOI: 10.1016/s0304-3959(02)00372-x
- 36 Reilingh ML, Kuijpers T, Tanja-Harferkamp AM, van der Windt DA. Course and prognosis of shoulder symptoms in general practice. *Rheumatology (Oxford)* 2008;47:724-730. 10.1093/rheumatology/ken044
- 37 Silverstein B, Welp E, Nelson N, Kalat J. Claims incidence of work-related disorders of the upper extremities: Washington state, 1987 through 1995. *Am J Public Health* 1998;88:1827-1833.
- 38 Spangehl MJ, Hawkins RH, McCormack RG, Loomer RL. Arthroscopic versus open acromioplasty: a prospective, randomized, blinded study. *J Shoulder Elbow Surg* 2002;11:101-107. 10.1067/mse.2002.120915 [doi];S1058274602103831 [pii]
- 39 Tashjian RZ, Deloach J, Porucznik CA, Powell AP. Minimal clinically important differences (MCID) and patient acceptable symptomatic state (PASS) for visual analog scales (VAS) measuring pain in patients treated for rotator cuff disease. *J Shoulder Elbow Surg* 2009;18:927-932. DOI: 10.1016/j.jse.2009.03.021
- 40 van der Windt DA, Koes BW, de Jong BA, Bouter LM. Shoulder disorders in general practice: incidence, patient characteristics, and management. *Ann Rheum Dis* 1995;54:959-964. DOI: 10-1136/ard.54.12.959
- 41 van Kampen DA, van Beers LW, Scholtes VA, Terwee CB, Willems WJ. Validation of the Dutch version of the Simple Shoulder Test. *J Shoulder Elbow Surg* 2012;21:808-814. DOI: 10.1016/j.jse.2011.09.026
- 42 Vecchio P, Kavanagh R, Hazleman BL, King RH. Shoulder pain in a community-based rheumatology clinic. *Br J Rheumatol* 1995;34:440-442. DOI: 10.1093/rheumatology/34.5.440
- 43 Virta L, Joranger P, Brox JI, Eriksson R. Costs of shoulder pain and resource use in primary health care: a cost-of-illness study in Sweden. *BMC Musculoskelet Disord* 2012;13:17. DOI: 10.1186/1471-2474-13-17
- 44 Vitale MA, Arons RR, Hurwitz S, Ahmad CS, Levine WN. The rising incidence of acromioplasty. *J Bone Joint Surg Am* 2010;92:1842-1850. DOI: 10.2106/jbjs.i.01003
- 45 Yamaguchi K, Ditsios K, Middleton WD, Hildebolt CF, Galatz LM, Teefey SA. The demographic and morphological features of rotator cuff disease. A comparison of asymptomatic and symptomatic shoulders. *J Bone Joint Surg Am* 2006;88:1699-1704. DOI: 10.2106/JBJS.E.00835

