■ SHOULDER AND ELBOW

Arthroscopic decompression not recommended in the treatment of rotator cuff tendinopathy

A FINAL REVIEW OF A RANDOMISED CONTROLLED TRIAL AT A MINIMUM FOLLOW-UP OF TEN YEARS

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Aims

Rotator cuff tendinopathy has a multifactorial origin. Rejecting the mechanistic theory has also led to abandoning operative treatment at initial presentation in the first line. Physiotherapy exercise programmes are the accepted first line treatment. The aim of this study was to assess the long-term additional benefits of subacromial decompression in the treatment of rotator cuff tendinopathy.

Patients and Methods

This randomised controlled trial of 140 patients (52 men, 88 women, mean age 47.1 years; 18 to 60) with rotator cuff tendinopathy extended previous work up to a maximum of 13 years. The patients were randomised into two treatment groups: arthroscopic acromioplasty and a supervised exercise treatment and a similar supervised exercise treatment alone. Self-reported pain on a visual analogue scale (VAS) was the primary outcome measure. Secondary measures were disability, working ability, pain at night, Shoulder Disability Questionnaire score and the number of painful days during the three months preceding the final assessment.

Results

A total of 90 patients (64%) returned questionnaires at a mean 12 years after randomisation. On an intention-to-treat basis, both treatment groups reached statistically significant improvement compared with the initial VAS for pain, but there was no significant difference between groups. The same was true in the secondary outcome measures. Due to group changes, the results were also analysed per protocol: operated or not. No significant differences between the groups were found.

Conclusion

The natural history of rotator cuff tendinopathy probably plays a significant role in the results in the long-term. Even though the patients who underwent operative treatment had a stronger belief in recovery, which is likely to be surgical and the effect of placebo, the exercise group obtained similar results. In the future, an optimum exercise regime should be searched for, as the most clinically and cost-effective conservative treatment for rotator cuff tendinopathy.

Cite this article: *Bone Joint J* 2017;99-B:799–805.

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doi:10.1302/0301-620X.99B6.BJJ-2016-0569.R1 $2.00

Bone Joint J 2017;99-B:799–805.
Received 14 June 2016; Accepted after revision 16 January 2017

Rotator cuff tendinopathy (RCT) is considered to be the most common cause of shoulder pain in primary health care clinical practice.[1-4] Approximately 1% to 2% of adults seek medical attention for shoulder pain every year.[1,5] The concept of this syndrome was introduced by Neer[6,7] who defined it into three stages. Recent advances in understanding of the natural history and aetiology of RCT have led to rejecting the mechanistic theory and point to a multifactorial origin of the condition, with contributions from external compression, age-related degeneration, inflammation, and vascular compromise.[8,9] Furthermore, the results of several studies suggest that operative treatment of RCT has no role in first line treatment.[10-15]

There are also problems in defining the diagnosis and cause. When a 'dynamic' aetiology is dominant, the patient might be treated with physiotherapy. If, however, it is anatomical, this might lead to surgical treatment. The previously commonly used term 'shoulder impingement syndrome' should be avoided as it might limit consideration of the cause. A proper diagnosis is a base for delivering the

most appropriate treatment.[16-18] It is suggested that the symptoms of this syndrome should be called 'anterolateral shoulder pain', and that the spectrum of rotator cuff abnormalities should be called 'rotator cuff disease' or 'RCT'.[18]

After diagnosis, the initial treatment of RCT is symptomatic, comprising rest, subacromial corticosteroid injections,[19] and oral non-steroidal anti-inflammatory drugs.[20] Evidence-based physiotherapy exercises yield the best results compared with controls or placebo in the treatment of RCT in the mid-term,[21-22] and it is the accepted first-line treatment after acute pain management. However, failing to understand the intrinsic pathology of the condition may cause misjudgment when deciding on the appropriate treatment, which may then be aimed at extrinsic factors with decompression.[23,24]

We initiated this randomised controlled trial over ten years ago to assess the additional benefit of decompression. The cost-effectiveness, and the two- and five-year results, as well as the subgroup analyses, have been published elsewhere.[12-14] The combined (arthroscopic acromioplasty) was not cost-effective compared with exercise alone. There was no statistically significant difference in the clinical results between groups at two and five years. In this study we report the 11- to 13-year results in order to assess the long-term benefit of arthroscopic acromioplasty in the treatment of RCT.

Patients and Methods

The study design was a prospective, randomised controlled trial. A total of 140 patients with unilateral RCT were included (52 men and 88 women) with a mean age of 47.1 years (18 to 60). MR imaging was performed at the initial presentation. Patients with rotator cuff tears were excluded.

For inclusion in the study the symptoms had to be resistant to conservative treatment during the preceding three months. None of the patients had undergone previous shoulder surgery. Precise inclusion and exclusion criteria and the study protocol have been published previously.[12-14]

The two treatment groups were a devised combined treatment group, and a supervised exercise treatment group. In the combined treatment group, arthroscopic acromioplasty was performed and followed by a supervised and structured exercise programme. In the second group, the patients were treated only with supervised exercises. The exercise programme was similar in both groups. Physiotherapists informed the patients about the training and an individually planned, structured, and progressive exercise regime was provided for each patient. At follow-up visits this programme was consolidated and modified, and systematically evaluated. Along with the controlled exercises, the training also included those that were intended to be continued independently at home.

The patients were reviewed two and five years after randomisation. One physiotherapist (AML) performed all the assessments, blinded to the groups (patients wore t-shirts to conceal the presence of any scars). A further review was undertaken at least ten years from randomisation. This was carried out via questionnaires. The information collected included working status and conditions including changes at work due to shoulder disabilities, retirement, sick leave, medication and painful days. In addition, information concerning pain in the contralateral shoulder was requested. The questionnaires were first distributed in mid-November 2014, and by mid-January 2015 a reminder letter was sent to non-responders. The patients were asked to fill out the questionnaire and return it using an enclosed envelope. The letters were sent only to participants who had attended the five-year visit. Completed and returned questionnaires were coded and used in analysis.

Self-reported pain on a 0 to 10 visual analogue scale (VAS) was used as the primary health outcome measure. Secondary outcome measures were disability, working ability and pain at night (VAS), as well as Shoulder Disability Questionnaire score[25,26] and reported painful days during the three months preceding the review.

The health-related quality of life was measured at five and ten years using the 15D tool[27] and compared with the age-adjusted population values. The 15D quality of life consists of questions concerning breathing, mental function, speech, vision, mobility, usual activity, vitality, hearing, eating, excretion, sleeping, distress, discomfort and symptoms, depression and sexual activity. All the questions have five possible answers ranging from none to severe problems. The utility score ranges from 0 to 1, with 1 being equivalent to full health and 0 to death.[27]

The study was approved by the Ethics Committee of the Hospital District.

Statistical analysis. Power calculations were performed before using VAS as the outcome measure. Using 1.5 points (standard deviation (SD) 2.5) as a clinically important change, the sample size was estimated to be 45 patients per group, if 5% type I (alpha) and 20% type II (beta) errors were allowed. As the SD of the outcome measure was only a rough estimate, 70 patients were originally included in both groups.

Descriptive statistics are presented as percentages, frequencies, and means. The independent samples Student's *t*-test was used for group comparisons, paired samples *t*-test for comparisons within groups over time and the chi-squared test to compare the proportion of pain-free patients between groups. A p-value < 0.05 was considered statistically significant. Statistical analyses were performed using IBM SPSS Statistics for Windows v19.0 (IBM Corp., Armonk, New York).

Results

The mean time to final review was at 12.3 years (11.0 to 13.8). We received 90 responses from the original 140 participants (64%). The replies were analysed on an intention-to-treat basis and also according to the actual treatment given, whether operated or not.

Table I. Demographic data: all and treatment group comparison as intention-to-treat

Results after 10 yrs (intention-to-treat)		All, n (%) (n = 90)	Combined treatment group, n (%) (n = 44)	Exercise group, n (%) (n = 46)	p-value*
Working status	Currently working	33 (*37*)	19 (*43*)	14 (*30*)	0.40
	Entrepreneur	6 (*7*)	2 (*5*)	4 (*9*)	
	Student	2 (*2*)	0	2 (*4*)	
	Unemployed	3 (*3*)	2 (*5*)	1 (*2*)	
	At home	0	0	0	
	Retired	46 (*51*)	21 (*48*)	25 (*54*)	
Modified job description to accommodate shoulder symptoms	Yes	14 (*16*)	4 (*9*)	10 (*22*)	0.14
Sick leave due to shoulder reasons (/1 yr) categories	None	87 (*97*)	43 (*98*)	44 (*96*)	0.37
	1 to 7 days	1 (*1*)	1 (*2*)	0	
	8 to 14 days	1 (*1*)	0	1 (*2*)	
	> 14 days	0	0	0	
Retired due to shoulder reasons		5 (*6*)	1 (*2*)	4 (*9*)	0.34
Contralateral shoulder symptomatic	No	57 (*63*)	30 (*70*)	27 (*60*)	0.23
	Yes	31 (*34*)	13 (*30*)	18 (*40*)	
Overall state of health compared with before treatment	A lot better	47 (*54*)	23 (*56*)	24 (*52*)	0.96
	Slightly better	16 (*18*)	8 (*20*)	8 (*17*)	
	The same	8 (*9*)	3 (*7*)	5 (*11*)	
	Slightly worse	10 (*12*)	4 (*10*)	6 (*13*)	
	A lot worse	6 (*7*)	3 (*7*)	3 (*7*)	

*chi-squared or Fisher's exact test

Table II. Primary and secondary outcome measures: all and treatment group comparison as intention-to-treat

Results after 10 yrs as intention-to-treat	All (n = 90)	Combined treatment group (n = 44)	Exercise group (n = 46)	p-value*
Age, mean (range) (yrs)	59.2 (40 to 73)	58.4 (40 to 73)	59.9 (40 to 71)	0.35
Time from randomisation, mean (range) (yrs)	12.3 (11.0 to 13.8)	12.3 (11.0 to 13.8)	12.3 (11.2 to 13.3)	0.77
Self-reported VAS for pain, mean (range)	2.3 (0 to 10)	2.8 (0 to 10)	1.8 (0 to 7)	0.12
Change in VAS for pain at 5 to 10 yrs, mean (range)	0.2 (-8 to 9)	0.8 (-8 to 9)	-0.3 (-7 to 5)	0.14
p-value within group	p = 0.52	p = 0.20	p = 0.45	
Change in VAS for pain at 0 to 10 yrs, mean (range)	-4.1 (-10 to 5)	-3.6 (-10 to 5)	-4.5 (-10 to 3)	0.18
p-value within group	p < 0.001	p < 0.001	p < 0.001	
VAS for pain at night, mean (range)	2.1 (0 to 10)	2.5 (0 to 10)	1.7 (0 to 8)	0.19
VAS for disability, mean (range)	2.2 (0 to 9)	2.5 (0 to 9)	2.0 (0 to 8)	0.41
VAS for working ability, mean (range)	7.3 (0 to 10)	7.5 (0 to 10)	7.2 (0 to 10)	0.57
SDQ score, mean (range)	25 (0 to 100)	23(0 to 100)	27 (0 to 100)	0.61
Painful days per previous 3 mths, mean (range)	14 (0 to 90)	18 (0 to 90)	12 (0 to 90)	0.32
Total days on which NSAIDs were consumed per previous 3 mths due to shoulder pain, mean (range)	8.5 (0 to 90)	10 (0 to 90)	7 (0 to 85)	0.47

*independent samples student's *t*-test (group comparisons) or paired samples *t*-test (comparisons within groups over time)
VAS, visual analogue score; SDQ, Shoulder Disability Score; NSAIDs, non-steroidal anti-inflammatory drugs

When the patients found out their treatment group at recruitment, 65% (42/65) in the combined treatment group and only 28% (16/58) in the exercise group answered that they believed a full recovery would be possible with this randomised treatment branch.

At randomisation, the two groups did not differ. The demographic data after ten years are presented in Table I.

After ten years, the mean self-reported pain score according to intention-to-treat was 2.8 in the combined treatment group and 1.8 in the exercise group (p = 0.12) (range 0 to 10 in both, independent samples Student's *t*-test). The findings are presented with the previously published results[12,13] (Fig. 1). There was no clinically or statistically significant difference between groups at two, five and over ten years. The VAS in the combined treatment group did not decline further after five years than the exercise treatment alone, but again there was no statistically significant difference (Table II, Fig. 1).

At two and five years, both groups had significantly improved compared with the initial presentation, but there were no differences between the groups when using an intention-to-treat principle. The results continued to improve between two to five years of follow-up (Table II). Self-reported VAS pain values at 0, two and five years were 6.5, 2.9, and 2.2 in the exercise group and 6.4, 2.5, and 1.9 in the combined treatment group, respectively. The p-values

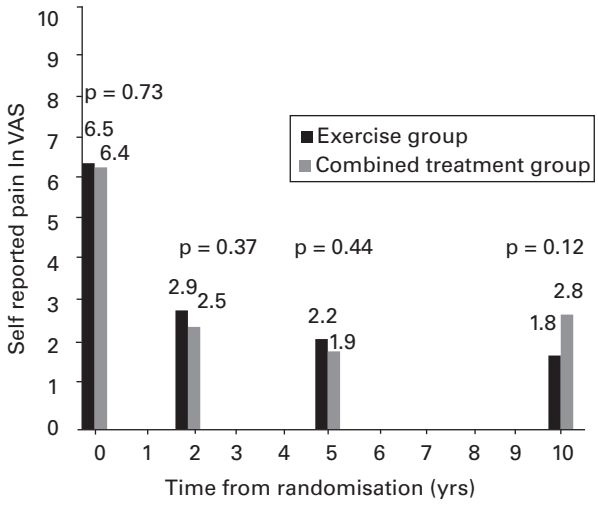

Fig. 1

Self-reported pain in visual analogue scale (VAS) in an intention to treat. Baseline values and values at two, five, and after ten years after randomisation.

Table III. Primary and secondary outcome measures: all and treatment group comparison as per protocol

Results after 10 yrs as per protocol	All (n = 90)	Combined treatment group (n = 44)	Exercise group (n = 46)	p-value*
Age, mean (range) (yrs)	59.2 (40 to 73)	57.8 (40 to 68)	60.6 (40 to 73)	0.07
Time from randomisation, mean (range) (yrs)	12.3 (11.0 to 13.8)	12.3 (11.0 to 13.4)	12.4 (11.2 to 13.8)	0.25
Self-reported VAS for pain, mean (range)	2.3 (0 to 10)	2.8 (0 to 10)	1.8 (0 to 8)	0.09
Change in VAS for pain at 5 to 10 yrs, mean (range)	0.2 (-8 to 9)	0.9 (-5 to 9)	-0.4 (-8 to 8)	0.06
Change in VAS for pain at 0 to 10 yrs, mean (range)	-4.1 (-10 to 5)	-3.7 (-9 to 5)	-4.6 (-10 to 3)	0.18
VAS for pain at night, mean (range)	2.1 (0 to 10)	2.5 (0 to 10)	1.7 (0 to 9)	0.19
VAS for disability, mean (range)	2.2 (0 to 9)	2.6 (0 to 9)	1.8 (0 to 8)	0.19
VAS for working ability, mean (range)	7.3 (0 to 10)	7.3 (0 to 10)	7.4 (0 to 10)	0.88
SDQ score, mean (range)	25 (0 to 100)	25 (0 to 100)	25 (0 to 100)	0.99
Painful days per previous 3 mths, mean (range)	14 (0 to 90)	16 (0 to 90)	13 (0 to 90)	0.65
Total days on which NSAIDs were consumed per previous 3 mths due to shoulder pain, mean (range)	8.5 (0 to 90)	8 (0 to 90)	9 (0 to 90)	0.85

*independent samples (group comparisons) and Student's *t*-test
VAS, visual analogue score; SDQ, Shoulder Disability Score; NSAIDs, non-steroidal anti-inflammatory drugs

between groups were 0.73, 0.37 and 0.44 respectively. The changes within groups were highly significant in both groups ($p < 0.001$).

Between five and over ten years, the changes in mean self-reported pain in VAS within treatment groups were 0.8 (-8 to 9) in the combined treatment group and -0.3 (-7 to 5) in the exercise group. Within groups the changes were not statistically significant (*t*-test, $p = 0.20$ and $p = 0.45$ respectively). The change from baseline to over ten years was highly significant (*t*-test, $p < 0.001$) in both groups (Table II). Between groups there were no significant differences in change from five to over ten years ($p = 0.18$). A per protocol analysis revealed the five- to ten-year changes in the mean VAS for the operated was 0.9 and for the non-operated was -0.4 (*t*-test, $p = 0.06$). In the operated patients the VAS for pain deteriorated in this interval, but continued to decline in the non-operated group, though with no statistically significant difference (Table III).

Working ability both on an intention-to-treat basis and per protocol was not significantly different between the groups. There were no differences in the other secondary outcome measures (Tables II and III).

The distribution of retirement was identical with 24 patients in each group. In both groups, 14 had retired because of old age, one for prolonged unemployment and nine for health reasons. In the operated group, one patient stated the shoulder was the primary reason for retirement and in the non-operated group, four patients attributed their retirement to their shoulder. Pain on the contralateral side was reported in 13 of the combined treatment group (30%) and 18 patients (40%) in the exercise group (Table I).

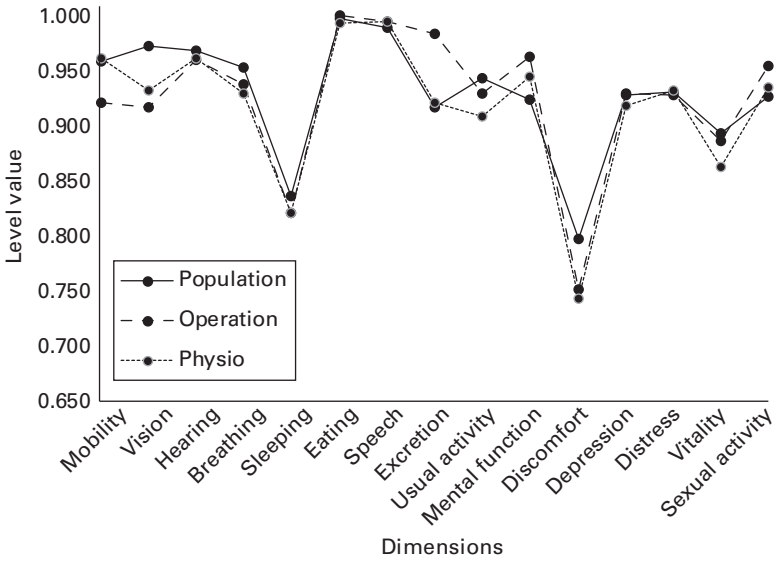

Fig. 2

15D quality of life index in both groups (Operation and Physio), and in comparison to age- and gender-adjusted standard population (Population) over ten years after randomisation.

At five years, only five patients had received corticosteroid injections during the previous year. This figure remained the same at ten years. Four of the five patients having injections were from the operated group, both at five and ten years.

At two years, 41% (48/117) of patients said, that they had continued doing exercises even after the supervised period. This had increased to 64% (48/75) at five years.

The 15D quality of life index was analysed on an intention-to-treat setting. There were no statistically significant differences between treatment groups (Fig. 2). The total score of 15D at ten years was 0.906 in the combined treatment group and 0.886 in the exercise group ($p = 0.38$).

Both values were then compared with the age- and gender-adjusted general population. All patients had lower mean values in mobility, breathing, sleeping, usual activities, discomfort, depression, and vitality parameters ($p = 0.031$, $p < 0.001$, $p < 0.001$, $p < 0.001$, $p < 0.001$, $p < 0.001$, $p < 0.001$, respectively; Mann-Whitney U test). Also shoulder patients had lower 15D results than the population (total score of patients 0.896 and general population 0.922; $p < 0.001$) (Fig. 2).

Discussion

In this study we specifically analysed the eventual additional value provided by arthroscopic acromioplasty over and beyond the effect obtained using a structured and supervised exercise programme alone. Both treatment groups reached a statistically significant change compared with baseline, but there were no differences between the groups. Even though the patients who were operated on had a stronger belief in their recovery, the exercise group reached similar results. Our findings underline the impact of the natural history of RCT, though somewhat unknown, on the long-term effects of arthroscopic acromioplasty. The trend to slightly but non-significantly poorer outcomes (Fig. 1, Table III) in the surgical arm may be related to follow-up bias as this has only appeared since the five-year follow-up. However, it may be a direct effect of surgery and merits further study. There are no previous randomised controlled studies with long-term results comparing operative and non-operative treatments, and only a few studies on RCT have published long-term follow-up.[28-31] Haahr et al[11,28] reported results between four and eight years in the treatment of RCT (out of 90 patients, 78 responded); similar improvements in self-reported outcomes were found in the operative and conservative treatment groups. Björnsson et al[29] analysed 70 patients who had had an arthroscopic subacromial decompression 15 years previously. They had no control group and their main aim was to evaluate the development of cuff ruptures with ultrasound. Odenbring et al[30] report that good short-term results of arthroscopic acromioplasty were maintained after 12 years in a prospective cohort study.

Long-term studies have a problem of patients lost to follow-up. For example, in a retrospective study at eight years Ertan et al[31] investigated the natural history of subacromial impingement syndrome in 253 patents. They could not

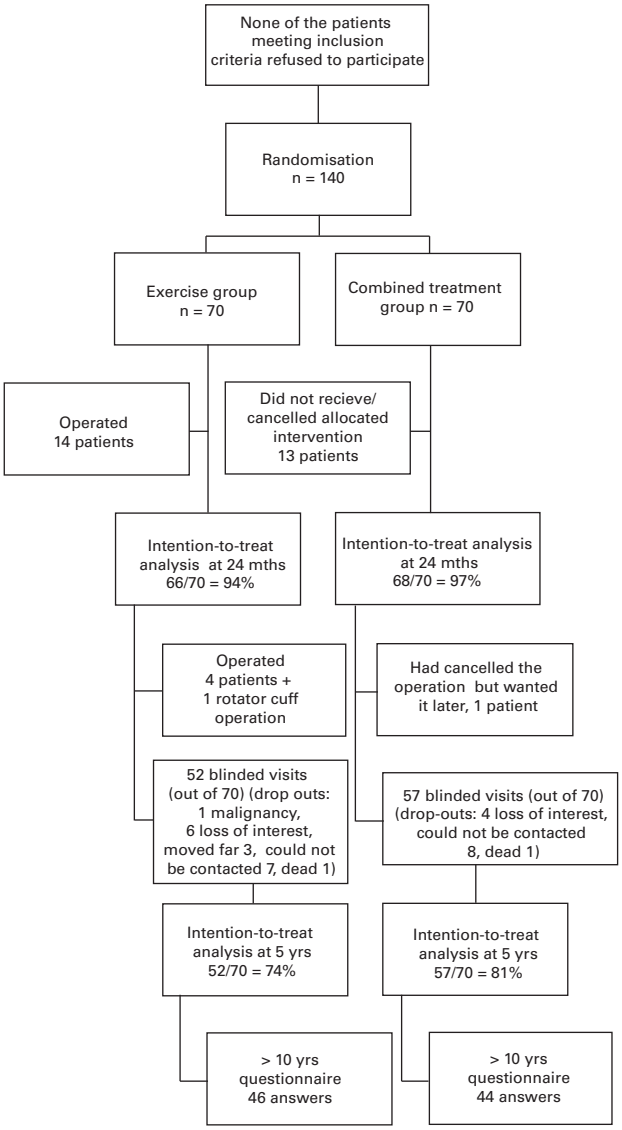

Fig. 3

Flowchart showing the number of patients at each follow-up point.

reach 95 of the patients, a further six were deceased and 21 had incomplete data. Of the remaining 131 patients, an additional 68, more than half, were unwilling to participate or were excluded, leaving only 63 patients to be analysed. In our study, the bias due to loss to follow-up was small; it was possible to analyse 134/140 randomised patients at two years and 109/140 at five years.[12,13] Even at ten years, 90 patients responded. Only 19 patients, of those who attended the five-year control, could not be contacted. There is, of course, a certain loss compared with baseline amount (Fig. 3).

Our patients' belief in the healing capability of an operation was higher compared with those randomised in the exercise group. Only one out of four patients thought they would be completely healed with the exercise programme. Even though the combined treatment group had stronger belief and there was a potential placebo benefit from surgery, the exercise group reached similar, or even marginally better results.

This long-term follow-up verifies the findings from other prospective studies.[10,11,28] The indications for arthroscopic acromioplasty in the treatment of RCT should be redefined; structured exercise treatment should be the basis. This will mean a reduction in the cost of treatment and absence resulting from sick leave, and will minimise financial implications, as well as possibly operative complications. Our study has challenged the possible placebo value of ineffective surgical treatment.[32]

Overall, it seems that patients suffering from anterolateral shoulder pain have a wide variety of symptoms decreasing the quality of life compared with the normal population. Whether this is specific to RCT patients or affects all people with shoulder symptoms is a subject for further study. However, further basic science and translational research is vital in order to understand the pathogenesis better.[33]

Take home message:

- This randomised controlled trial shows the long-term results after arthroscopic acromioplasty.
- There is no additional benefit from arthroscopic acromioplasty in the treatment of rotator cuff tendinopathy.
- The study had good compliance.
- There is no clear knowledge of the natural course of the treatment.

Author contributions:
S. Ketola: Participated in the conception and conduct of the study, Contributed to the final manuscript, Planning of the study, Recruitment of the patients, Organisation of the study, Collection and organisation of the data and statistics, Clinical analysis of the data, Literature review, Writing the draft, Critical commenting and improvement of the manuscript.
J. Lehtinen: Participated in the conception and conduct of the study, Contributed to the final manuscript, Recruitment of the patients, Clinical analysis of the data, Critical commenting and improvement of the manuscript.
I. Arnala: Participated in the conception and conduct of the study, Contributed to the final manuscript, Planning of the study, Organisation of the study, Clinical analysis of the data, Critical commenting and improvement of the manuscript.

The authors would like to thank A. M. Lampela (AML), physiotherapist, for assistance and examinations in this study, MSci H. Huhtala for her statistical expertise, and Prof. Sintonen for providing the 15D age-adjusted general population data for comparison.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

This article was primary edited by G. Scott.

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