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CLINICAL SCIENCE

Non-surgical and surgical treatments for rotator cuff disease: a pragmatic randomised clinical trial with 2-year follow-up after initial rehabilitation

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ABSTRACT

Background Rotator cuff disease (RCD) causes prolonged shoulder pain and disability in adults. RCD is a continuum ranging from tendinopathy to full-thickness tendon tear. Recent studies have shown that subacromial decompression and non-surgical treatments provide equivalent results in RCD without a full-thickness tendon lesion. However, the importance of surgery for full-thickness tendon tears remains unclear.

Methods In a pragmatic, randomised, controlled trial, 417 patients with subacromial pain underwent 3-month initial rehabilitation and MRI arthrography (MRA) for the diagnosis of RCD. Of these, 190 shoulders remained symptomatic and were randomised to non-surgical or surgical treatments. The primary outcomes were the mean changes in the Visual Analogue Scale for pain and the Constant Murley Score for shoulder function at the 2-year follow-up.

Results At the 2-year follow-up, both non-surgical and surgical treatments for RCD reduced pain and improved shoulder function. The scores differed between groups by 4 (95% CI -3 to 10, $p=0.25$) for pain and 3.4 (95% CI -0.4 to 7.1, $p=0.077$) for function. Among patients with full-thickness ruptures, the reduction in pain (13, 95% CI 5 to 22, $p=0.002$) and improvement in function (7.0, 95% CI 1.8 to 12.2, $p=0.008$) favoured surgery.

Conclusions Non-surgical and surgical treatments for RCD provided equivalent improvements in pain and function. Therefore, we recommend non-surgical treatment as the primary choice for patients with RCD. However, surgery yielded superior improvement in pain and function for full-thickness rotator cuff rupture. Therefore, rotator cuff repair may be suggested after failed non-surgical treatment.

Trial registration details ClinicalTrials.gov, NCT00695981 and NCT00637013.

Key messages

What is already known about this subject?

- Recent studies show that subacromial decompression surgery and non-surgical treatments provide equivalent results in rotator cuff disease without full-thickness tendon lesion. The importance of surgery for full-thickness tendon tears remains unclear.

What does this study add?

- In our pragmatic study setting, we randomised patients with rotator cuff disease (RCD) who were symptomatic after 3-month initial rehabilitation, and measured change of shoulder pain and function after 2 years from randomisation.

How might this impact on clinical practice or future developments?

- Our study shows that the outcome of non-surgical treatment is equivalent to surgical treatment in RCD without full-thickness tendon tear even after unsuccessful initial rehabilitation. However, surgery yields superior improvement in pain and function in patients with full-thickness rotator cuff tear if initial non-surgical treatment is unsuccessful.

range from tendinopathy without frayed tendons to a full-thickness tendon tear.^{8–10}

Non-surgical treatment is recommended for RCD initially. However, RCD is also frequently treated with surgery.^{9 11–13} Subacromial decompression (SAD) surgery is a common procedure for treating a painful shoulder.¹² Recent studies have shown that SAD and non-surgical treatments provide equivalent results in RCD without full-thickness tendon lesions.^{3–5 14–17} Another common procedure is rotator cuff tendon repair. The annual rate for SAD and rotator cuff repair has been up to 130 per 100 000 persons in Finland.^{9 12} Whether surgical or non-surgical treatment is superior for full-thickness rotator cuff tears remains controversial.^{18–22}

In this study, by conducting a pragmatic, randomised, controlled trial we aimed to compare surgical and non-surgical treatments for RCD with or without full-thickness tendon tears after unsuccessful initial rehabilitation. We used the Visual

INTRODUCTION

Among adults, rotator cuff disease (RCD) is the most common cause of prolonged shoulder pain and disability,¹ which represent substantial health-economic burdens for society.² RCD typically manifests as shoulder pain and dysfunction,^{3–5} and has a multifactorial aetiology, including intrinsic (eg, genetics), extrinsic (eg, trauma) and biopsychosocial factors.^{6 7} In RCD, tendon damage occurs in a continuum of acute-to-chronic changes, which



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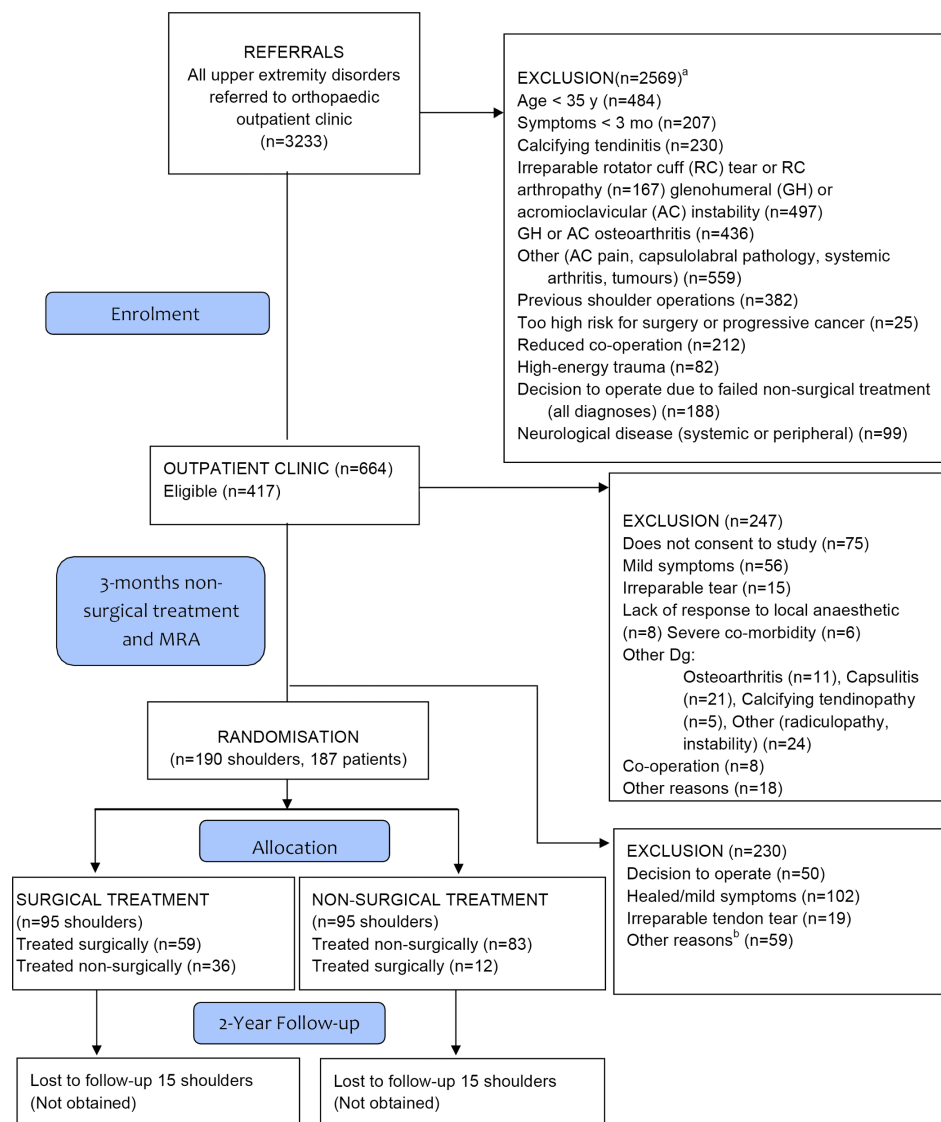


Figure 1 Trial flow chart. MRA of the shoulder. ^aMRA. ^bLack of co-operation or change of diagnosis. mo, months; MRA, MRI arthrography; y, years.

Analogue Scale (VAS) for pain and the Constant Murley score (CMS) for function as primary outcomes.

METHODS

Trial design

This randomised, controlled, pragmatic trial was conducted in Central Finland Hospital in Jyväskylä and Oulu University Hospital.

Patients

We recruited patients with long-term (>3 months) subacromial pain who were referred from primary and occupational healthcare centres and private clinics to the two study hospitals (figure 1). Between June 2008 and December 2014, we screened 3233 referrals concerning an upper extremity disorder, including 664 who presented with symptoms attributable to RCD. The research group physicians (JP, SC, TI, JLi and HL) interviewed the patients (490 in Jyväskylä and 174 in Oulu) and performed structured examinations. Of these, 417 patients met the eligibility criteria (box 1) and provided written informed consent. After inclusion, patients were advised to undergo up

to 15 sessions (protocol provided in the online supplemental appendix).

After the initial 3-month non-surgical treatment, the candidates underwent MRI arthrography (MRA) and were evaluated by a specialist orthopaedic surgeon (TF, KS, KP or TR) for trial eligibility. MRA images were evaluated by clinical radiologist on duty. A full-thickness tendon tear was diagnosed if contrast medium, attributable to a full-thickness tendon tear, was detected in subacromial space in MRA. Subsequently, two study physiotherapists (one in each of the trial hospitals) randomised all suitable symptomatic patients to either non-surgical or surgical treatment (online supplemental table S1). A research assistant not involved in the study prepared a computer-generated, block randomisation list and sequentially numbered, sealed opaque envelopes for patient randomisation. We used a block size of 10 stratified according to gender and type of rotator cuff tendon lesion (RCD with or without a full-thickness tendon tear). The blocks were divided between the trial hospitals. The information regarding the treatment group was open to patients, the treating physicians and the study physiotherapists. Immediately before randomisation (baseline), the physiotherapists evaluated the primary and secondary study outcomes.

Treatment

Box 1 Inclusion and exclusion criteria

Inclusion criteria for all patients

Pain in abduction of the shoulder
 Age over 35 years
 Duration of symptoms at least 3 months
 Written informed consent by the participating subject
 Additional inclusion criteria
 Subacromial impingement without full-thickness tendon lesion
 Pain in two of the three isometric tests (0 or 30 degrees of abduction or external rotation)
 Subacromial injection of lidocaine significantly reduced pain
 Full-thickness tendon rupture
 Full-thickness rotator cuff rupture in one to three tendons documented with MRI arthrography

Exclusion criteria

Previous surgery of the same shoulder
 High-energy trauma before symptoms
 Inflammatory arthritis
 Adhesive capsulitis
 Instability of the affected shoulder
 Severe glenohumeral or acromioclavicular joint osteoarthritis
 Cervical syndrome/radiculopathy
 Progressive cancer
 A too high risk for operation
 Any disease, social problem or other reason reducing the ability to co-operate and jeopardising informed consent
 Irreparable rotator cuff tear on MRI arthrography

Trial procedures

Patients randomised to non-surgical treatment continued the previously initiated rehabilitation programme. Unsuccessful non-surgical treatment was defined as severe pain or poor subjective function in the shoulder during follow-up. These patients were offered a surgical intervention. In surgery, patients without full-thickness tendon tears underwent arthroscopic SAD. Patients with full-thickness tears received rotator cuff repair with single-row technique, with one or more bone anchors, via either an arthroscopic or mini-open approach. When necessary, patients underwent acromioplasty, acromioclavicular joint resection or tenotomy of the long head of the biceps. All patients followed a structured postoperative rehabilitation protocol (see online supplemental appendix).

Outcomes

The primary outcome evaluated 2 years after randomisation was the change in the intensity of pain, during the previous week, on VAS and the change in CMS for rating shoulder function. Outcome measures were recorded at baseline and 3, 6, 12 and 24 months after randomisation. VAS (0 to 100, 100=worst possible pain) was calculated as the mean pain at rest, during arm activity and at night. The study physiotherapists measured shoulder function with CMS (scale: 1 to 100, 100=best).²³ The pain-free (VAS <30) shoulder range of motion was measured by a goniometer.²⁴

With the arm abducted 90 degrees, maximal isometric shoulder abduction strength was measured with a strain-gauge dynamometer (DS Europe, Milan, Italy) at Jyväskylä or a spring scale at Oulu. The sensor was placed at the level of the styloid process of the radius. We used a modified method of measuring the strength by calculating the mean of three efforts instead

of the best out of three as described by Constant.²³ Abduction strength was rated zero when the patient could not achieve the measuring position at 90-degree abduction.

The secondary outcome was the health-related quality of life as measured with the RAND 36-Item Health Survey.²⁵ We also recorded serious adverse events and re-operations.

Statistical analysis

The appropriate sample size was estimated with a simulation-based model. Calculations were based on a 30% difference in pain between treatment groups. When significant, a 30% difference was also likely to be clinically relevant.⁴ We determined that approximately 200 patients (100 per research arm) were required for a two-sided significance level of 0.05 (85% power).

All primary analyses were performed based on the intention-to-treat (ITT) principle. Data are expressed as the mean and SD, the median and IQR or counts and percentages, as appropriate. The non-surgery and surgery groups were compared using the t-test for continuous variables and Pearson's χ^2 test for categorical variables in baseline values. Repeated measures of the changes in primary (ITT and per protocol, PP) and secondary outcomes (ITT) were compared between the non-surgery and surgery groups with mixed-effects models and an unstructured covariance structure (ie, the Kenward-Roger method for calculating the df).²⁶ Fixed effects included group, time and group \times time interactions. We used baseline values as covariates when appropriate. The repeated measurements were taken at different time points, including baseline, 3, 6, 12 and 24 months. Mixed models allowed analysis of unbalanced datasets without imputation; therefore, we analysed all available data with the full analysis set. Normal distributions were evaluated graphically and with the Shapiro-Wilk W test. All analyses were performed in Stata 16.0 (StataCorp LP; College Station, Texas, USA).

Two pre-specified subgroup analyses were performed for subgroups of RCD, with or without full-thickness tendon tears.

RESULTS

Recruitment

After 3 months of pragmatic non-surgical treatment, 247 patients were excluded due to reasons shown in trial flow chart (figure 1) and 187 patients (190 shoulders) randomised (table 1).

Group allocation (full-thickness or non-full-thickness tendon lesion) was based on written statement made by clinical radiologist. Of these, 95 shoulders were randomised to receive surgery (50 shoulders with full-thickness ruptures, of which 44 solely in the supraspinatus tendon) and 95 to non-surgical treatments (48 with full-thickness ruptures, of which 44 were solely in the supraspinatus tendon). In the non-surgery group, 12 (13%) shoulders experienced severe pain and surgery was performed during the 2-year follow-up. In the surgery group, 36 (38%) shoulders experienced pain relief before surgery and did not undergo surgery. Shoulders treated per protocol were 75% (figure 2). Online supplemental table S1 shows the frequency of missing data.

Primary outcomes

At the 2-year follow-up, the mean VAS score decreased by 31 (95% CI 26 to 35) in the non-surgery group and by 34 (95% CI 30 to 39) in the surgery group. The difference between groups was not significant (mean difference: 4, 95% CI -3 to 10; $p=0.25$). The mean Constant score (CS) improved by 17.0 (95% CI 14.4 to 19.7) in the non-surgery group and by 20.4 (95% CI 17.8 to 23.1) in the surgery group. The difference between

Table 1 Baseline characteristics of patients with rotator cuff disease

	Non-surgical group (n=95)*	Surgical group (n=95)*
Patients	93	94
Men, n (%)	50 (53)	52 (55)
Full-thickness ruptures, n (%)	48 (51)	50 (53)
Right shoulder, n (%)	62 (65)	58 (61)
Age, mean (SD)	56 (8)	56 (8)
Duration of pain, months, median (IQR)	12 (8 to 21)	12 (8 to 36)
Traumatic onset	16 (17)	17 (18)
Pain, VAS, mean (SD)		
Rest	37 (26)	36 (25)
Arm activity	60 (23)	55 (26)
Night	51 (29)	50 (28)
Constant score, mean (SD)	55 (16)	57 (17)
Had performed exercises		
PT-guided exercises n (%)	60 (63)	53 (56)
Home exercises, n (%)	52 (55)	44 (46)
Received corticosteroid injections, n (%)	65 (68)	67 (71)

*Shoulders.

PT, physiotherapist; VAS, Visual Analogue Scale.

groups was not significant (mean difference: 3.4, 95% CI -0.4 to 7.1; $p=0.077$; figure 3 and online supplemental table S2).

Among patients without full-thickness rotator cuff ruptures at the 2-year follow-up, the mean VAS decreased by 38 (95% CI 31 to 45) in the non-surgery group and by 31 (95% CI 24 to 38) in the surgery group. The difference between groups was not significant (mean difference: 7, 95% CI -3 to 17; $p=0.19$; figure 3 and online supplemental table S2). The mean CS improved by 21.6 (95% CI 17.8 to 25.3) in the non-surgery group and by 20.9 (95% CI 17.1 to 24.7) in the surgery group. The difference between groups was not significant (mean difference: 0.7, 95% CI -4.6 to 6.1; $p=0.79$).

Among patients with full-thickness ruptures at the 2-year follow-up, the mean VAS score decreased by 24 (95% CI 18 to

30) in the non-surgery group and by 37 (95% CI 31 to 43) in the surgery group. The difference between groups was significant (mean difference: 13, 95% CI 5 to 22; $p=0.002$). The mean CS improved by 13.0 (95% CI 9.4 to 16.7) in the non-surgery group and by 20.0 (95% CI 16.4 to 23.7) in the surgery group. The difference between groups was significant (mean difference: 7.0, 95% CI 1.8 to 12.2; $p=0.008$). The PP results are shown in Supplements (online supplemental figure S1).

Health-related quality of life

At the 2-year follow-up, the changes in mean RAND-36 scores for physical function, general health, vitality, role physical, role emotional, social functioning and bodily pain were not significantly different between the non-surgery and surgery groups. Among patients without full-thickness rotator cuff ruptures, the changes of quality of life were similar in the non-surgery and surgery groups. Among patients with full-thickness rotator cuff ruptures, the bodily pain score improved 13 points (95% CI 3 to 23; $p=0.011$) more in the surgery group than in the non-surgery group (table 2).

Adherence to non-surgical treatment modalities

During the 2-year follow-up, 38% of all patients underwent physiotherapy, 46% performed home-based exercise and 8% received corticosteroid injections. The implementation of home-based exercise was similar between the treatment groups. However, the surgery group had a higher frequency of physiotherapy visits than the non-surgery group ($p<0.001$), and the non-surgery group received more corticosteroid injections ($p=0.015$; online supplemental table S3).

Adverse events

No patients required re-operation, and no serious adverse events were noted.

DISCUSSION

We found equivalent improvements in pain and function at the 2-year follow-up in both treatment groups, and changes in quality of life were not significantly different between the two treatment groups. Similar results were found in the subgroup of patients without full-thickness ruptures. This result is consistent with previous trials of patients with more acute, undefined, initial non-surgical treatment.^{3-5 14 19 21 27}

Among patients with full-thickness rotator cuff ruptures at the 2-year follow-up, pain relief was better with surgery than non-surgical treatment. In this subgroup, the two treatments produced significantly different changes in mean pain, pain at rest and pain during the night. In contrast, both treatments had similar effects on pain related to arm activity. The bodily pain dimension in the RAND-36 quality of life questionnaire improved more with surgery than non-surgical treatments. These findings contrast with recent findings from Kukkonen *et al*, but support earlier findings from Moosmayer *et al*.^{18 20} At the 2-year follow-up, shoulder function improved with both treatments, but the CS improved 7 points more with surgery than non-surgical treatments. The minimum clinically important difference between groups has not been determined unequivocally.^{3 28 29}

Due to the pragmatic approach of the study, exercise compliance was relatively low (online supplemental table S3). Patients had experienced shoulder pain for relatively long periods of time, and many had received physiotherapy before recruitment (table 1). Thus, patients were familiar with the exercise methods, which may explain the relatively low attendance at

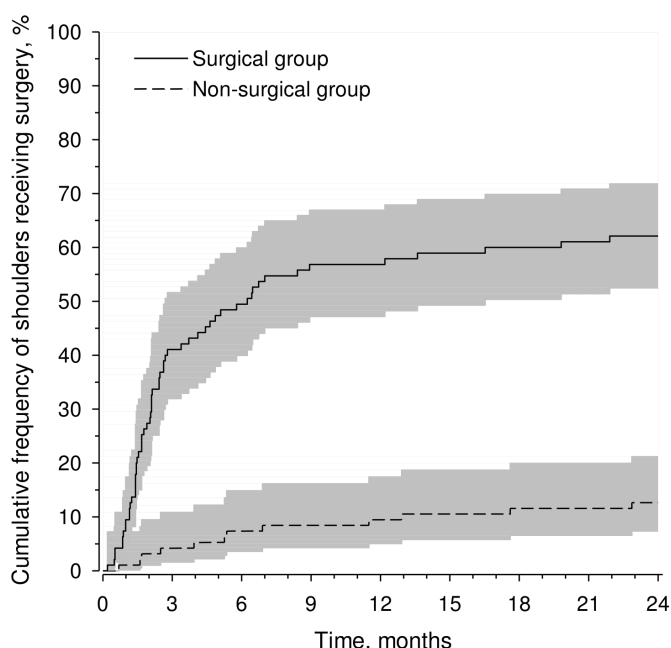


Figure 2 Cumulative frequency of shoulders receiving surgery in surgical and non-surgical randomisation groups with 95% CIs.

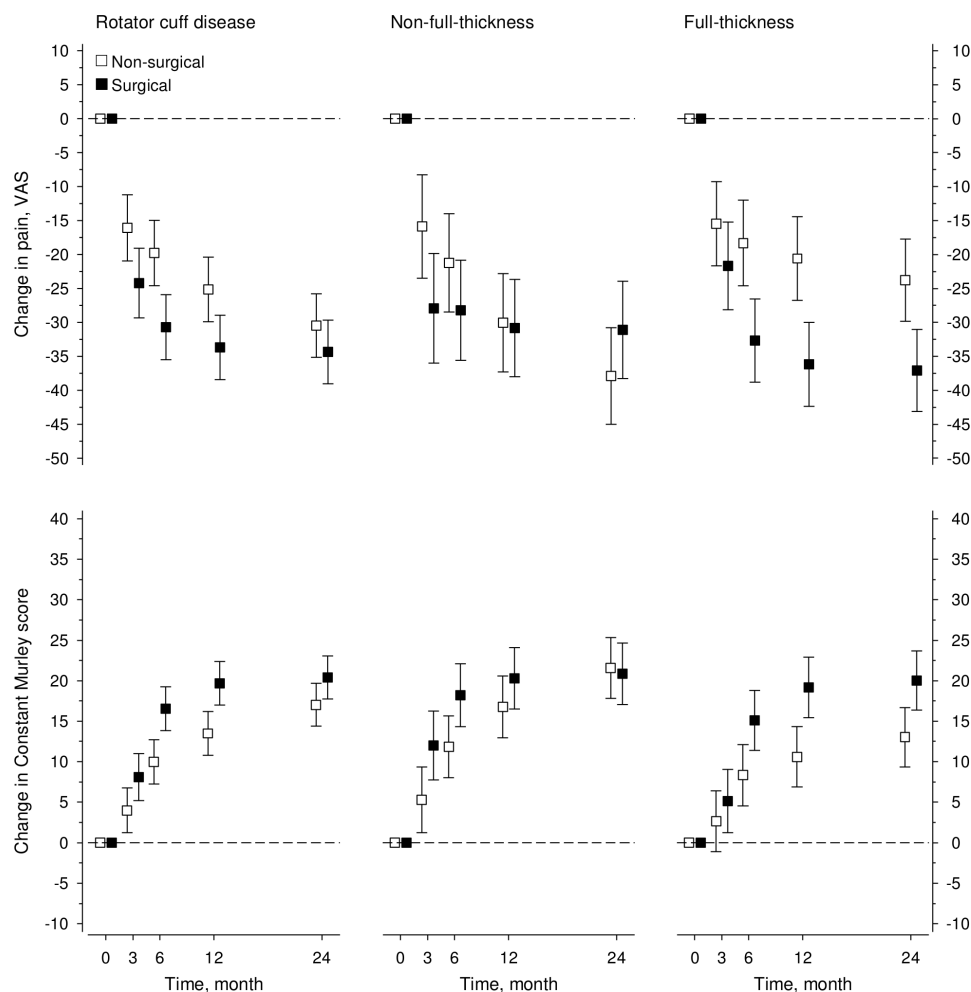


Figure 3 Graphs showing the change in pain in the visual analogue scale (VAS, mm) and the Constant score between baseline and the 2-year follow-up in all patients with rotator cuff disease and without and with full-thickness rotator cuff rupture.

the recommended physiotherapy. In our study design, non-surgical treatment was comparable to ordinary practice. Patients in the surgery group attended physiotherapy significantly more frequently than patients in the non-surgery group. In the non-surgery group, the use of corticosteroid injections was higher compared with the surgery group. Our patients presented with broad RCD aetiology because we initially merely excluded patients with high-energy traumas and irreparable tendon tears. Moreover, we analysed RCD subgroups of patients with and without full-thickness tears.

None of the five previously published trials reported difference in surgical and non-surgical treatments for patients with RCD without full-thickness rotator cuff tears (impingement).^{3–5} In a 2.5-year follow-up study, Brox *et al* found that surgery outcomes were not significantly different from outcomes after 3 to 6 months of intensive, supervised exercise.³ Similarly, in a 4 to 8 year follow-up study, Haahr *et al* found that surgery outcomes were not different from outcomes after intensive supervised physiotherapy.⁴ Ketola *et al* found similar outcomes with supervised exercise treatment versus SAD followed by supervised exercises.⁵ Two recent controlled trials and a meta-analysis of subacromial decompression efficacy in patients with RCD found no difference in VAS pain scores after subacromial decompression, placebo arthroscopy or exercise therapy.^{14–16}

Five randomised controlled trials compared surgical and non-surgical treatments for full-thickness supraspinatus tendon ruptures.^{18–20, 22} Moosmayer *et al* found between-group

differences that slightly favoured surgery based on the VAS for pain, the CS and the American Shoulder and Elbow Surgeons Shoulder Score during a 5-year follow-up.¹⁹ Another study by Kukkonen *et al* found no difference between surgical and non-surgical treatments for non-traumatic supraspinatus tears.²⁷ Lambers Heerspink *et al* detected significant improvements in degenerative rotator cuff tears at a 1-year follow-up that favoured surgery over conservative treatment based on mean scores from the Dutch Simple Shoulder Test and a VAS. However, the CS values were similar between treatment groups.²² Odak *et al* assessed the efficacy of SAD with or without mini-open cuff-repair, yielding no difference between the groups at a 1-year follow-up.³⁰ A study of Ranebo *et al* compared the non-surgical and surgical treatment of small, acute traumatic supraspinatus tears reporting uniform findings between the groups.³¹ Among these randomised, controlled trials, only two included traumatic tears.^{19, 31} In our study, 17% of patients attributed their shoulder problems to low-energy traumas. Generally, traumatic rotator cuff tears are considered an indication for tendon repair, but this lacks solid scientific evidence.³¹ In contrast, non-traumatic rotator cuff tears are often treated conservatively. Tendon degeneration has been demonstrated in a majority of rotator cuff tendon tears.^{10, 32} The different aetiologies of rotator cuff tears may explain the contradictory findings among previous studies.

No previous studies investigated the effectiveness of surgery after adequately performed, but unsuccessful, non-surgical treatment of RCD including both non-full-thickness and full-thickness

Table 2 36-item short form health survey questionnaire (RAND-36) for health-related quality of life

	Baseline		Change from baseline to months 24		P values between groups	
	Non-surgical Mean (SD)	Surgical Mean (SD)	Non-surgical Mean (95% CI)	Surgical Mean (95% CI)	Crude	Adjusted*
Rotator cuff disease (all) n=190						
Physical function	72 (19)	75 (16)	5 (2 to 9)	5 (2 to 8)	0.78	0.65
General health	59 (17)	62 (19)	3 (-1 to 6)	1 (-2 to 4)	0.48	0.42
Vitality	62 (21)	63 (21)	6 (2 to 9)	7 (3 to 10)	0.73	0.89
Mental health	74 (18)	76 (18)	4 (1 to 7)	5 (2 to 7)	0.37	0.61
Role physical	38 (40)	44 (39)	22 (13 to 32)	23 (14 to 32)	0.98	0.99
Emotional role	73 (39)	71 (41)	2 (-7 to 10)	9 (2 to 17)	0.18	0.16
Social function	74 (22)	80 (23)	8 (3 to 12)	5 (1 to 9)	0.41	0.17
Bodily pain	44 (19)	43 (19)	15 (10 to 21)	21 (16 to 26)	0.11	0.15
Non-full-thickness rupture n=92						
Physical function	70 (23)	74 (18)	10 (4 to 16)	3 (-3 to 8)	0.065	0.063
General health	57 (19)	59 (19)	4 (-1 to 9)	1 (-3 to 6)	0.47	0.32
Vitality	59 (22)	58 (21)	8 (2 to 14)	10 (4 to 15)	0.65	0.92
Mental health	73 (18)	75 (18)	4 (-1 to 9)	6 (2 to 10)	0.61	0.58
Role physical	39 (43)	43 (38)	30 (15 to 45)	21 (9 to 34)	0.39	0.43
Emotional role	70 (43)	65 (43)	12 (-1 to 25)	17 (6 to 28)	0.54	0.51
Social function	76 (23)	80 (21)	8 (0 to 15)	6 (0 to 12)	0.75	0.42
Bodily pain	41 (20)	41 (20)	22 (13 to 30)	20 (12 to 27)	0.72	0.46
Full-thickness rupture n=98						
Physical function	74 (16)	76 (14)	2 (-2 to 6)	7 (3 to 11)	0.078	0.096
General health	60 (16)	64 (19)	2 (-2 to 6)	1 (-3 to 5)	0.77	0.91
Vitality	63 (20)	67 (20)	4 (0 to 8)	4 (0 to 8)	0.82	0.73
Mental health	75 (18)	78 (18)	4 (0 to 8)	4 (0 to 8)	0.98	0.82
Role physical	38 (38)	44 (39)	17 (3 to 30)	24 (11 to 37)	0.43	0.44
Emotional role	75 (34)	77 (38)	-6 (-17 to 5)	2 (-9 to 12)	0.30	0.32
Social function	73 (22)	81 (25)	8 (2 to 14)	4 (-2 to 10)	0.39	0.26
Bodily pain	47 (17)	44 (18)	10 (3 to 17)	23 (16 to 30)	0.011	0.006

*Adjusted for baseline values.

tendon lesions. In our trial, all potential participants underwent a structured, 3-month rehabilitation before randomisation; thus, only symptomatic patients were randomised. In addition, the flow of patients referred to specialised care was trackable, and our study approach was pragmatic. We submitted two clinical trial registries (one subgroup for subacromial impingement syndrome stage II and another for full-thickness tendon ruptures) because at the time of registration (2008) it was not generally accepted that rotator cuff disease is an actual continuum that ranges from subacromial impingement syndrome to a full-thickness rotator cuff tendon rupture.

Due to the pragmatic approach, it was reasoned to analyse these two types of tendon lesions together. We minimised the potential influence of technical differences between surgeons for recruitment and surgery; five physicians recruited the patients and five surgeons performed the surgeries. Therefore, our findings can be readily applied to clinical practice.

Our study lacked a placebo surgery group and the study physiotherapists were not blinded. A potential source of bias is that we included three patients twice. The shoulders are not independent when reporting pain and disability. Only 63% of patients who underwent clinical examination were eligible for this study, and 55% of the shoulders preliminarily meeting the inclusion criteria were excluded from randomisation, mostly due to relief of symptoms. Thus, our primary results are only applicable to patients who do not recover after initial non-surgical treatment. Moreover, 26% of patients were not treated PP. The results of the PP analysis supported the results of the ITT analysis. Surgery

yielded superior results in the change of shoulder pain and the function compared with non-surgical management in PP analyses.

CONCLUSIONS

Our results demonstrate that surgery does not provide superior results compared with non-surgical treatment for the majority of patients with RCD. Among patients with symptomatic RCD without a perforating tear, surgery did not provide benefit over non-surgical treatment, even when the initial non-surgical treatment did not provide sufficient pain relief. However, when the RCD included a perforating tear and symptoms continued after initial non-surgical treatment, rotator cuff repair surgery resulted in superior outcomes compared with non-surgical treatment.

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Data availability statement Data sharing not applicable as no data sets generated and/or analysed for this study. Study data cannot be shared publicly because of confidentiality requirements under Finnish law. De-identified patient data is available from the study group and from Central Finland Hospital (contact via www.kssh.fi, juha.paloneva@kssh.fi) for researchers who meet the criteria for access to confidential data.

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Online-only material

Trial protocol

Protocol for active rehabilitation after recruitment before randomization

Protocol for surgical treatment

Post-operative treatment protocol

Supplementary Tables

Supplementary Figure legend

Trial protocol

The trial protocol has been published at ClinicalTrials.gov (accession numbers NCT00695981 and NCT00637013)

Protocol for active rehabilitation after recruitment before randomization

Patients applied a cold pack for 10 to 15 min before exercise, when necessary for pain relief.

The exercise program was designed according to best practices at that time^{1 2}.

Physiotherapists demonstrated and guided the exercises. The load for the first three visits was assessed individually, and each exercise was performed with 20 repetitions maximum (RM), for three sets. After one month, the load was increased, and the number of repetitions was reduced to 15 RM. After two months, the load was increased, and the number of repetitions was reduced to 10 RM. All exercises were to be performed three times per week, and the load was increased by 1 kg, when possible, to achieve the goal RM.

The glenohumeral joint was stretched passively. Hanging exercises were recommended to improve mobility. All patients, except those with hypermobility, hung for 30 s three times per day. When the shoulder range of motion (ROM) was limited, the physiotherapist mobilized the glenohumeral joint with a muscle energy technique, applied in the direction of restricted movement. This treatment included isometric contraction for 5 s and static stretching for 5–10 s, and the sequence was repeated 8 times. In addition, the scapulothoracic joint was mobilized, when the ROM was restricted.

All physiotherapists performed manual therapy according to instructions. After 5 min of cold pack treatment, the supraspinatus was cross-friction massaged (20x3x30 s at 30 s intervals). The same procedure was repeated on the infraspinatus, subscapularis, teres minor, and teres major muscles. Manual treatments were applied to the trapezius, deltoid, long head of the triceps, and the biceps sulcus areas.

Shoulder rehabilitation exercises included: Bent-over row on with dumbbells, biceps curl with dumbbells, dumbbell bench press, cable adduction, internal rotation with dumbbells, lying on the side or standing, with an elastic resistance band, external rotation with dumbbells, lying on the side or standing, with an elastic resistance band and arm flexion with dumbbells.

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Protocol for surgical treatment

All operations were performed by orthopaedic surgeons that regularly practiced arthroscopic shoulder surgery (TF, KS, KP, TR). Patients were placed in a beach-chair position and received general and/or interscalene anaesthesia. Cefuroxime (1.5 g) was administered intravenously, before the operation. Initially, the glenohumeral joint and subacromial space were evaluated arthroscopically. Then, patients without a full-thickness tendon lesion underwent arthroscopic subacromial decompression (subacromial bursectomy and resection of the anterior-inferior surface of the acromion). In patients with full-thickness tears, the tendon(s) was re-attached to the head of humerus, in a single-row fashion. Surgeons used one or more bone anchors and implemented either an arthroscopic or a mini-open approach.

Post-operative rehabilitation treatment protocol

All patients underwent the same early post-surgery rehabilitation protocol and used a sling for three weeks. A physiotherapist demonstrated and guided the patient on how to perform the exercises, starting the first postoperative day. Patients were advised to perform 10 repetitions of each home exercise, three times daily, according to instructions. The exercises included active elbow and finger flexion and extension, shoulder and scapula retraction, pendulum exercises, and passive internal rotation.

Three weeks after surgery, patients visited a physiotherapist at the study hospital outpatient clinic, and the training instructions were repeated. The patients started passive exercises three times per day, including: 10 repetitions of shoulder flexion up to 90°, external rotation up to 20-30°, and internal rotation exercises (lifting the dorsum of the hand behind the lower back). Strength training was commenced with 10 repetitions of light, isometric, 5-s contractions of the shoulder muscles, performed when the shoulder was extended, internally rotated, and externally rotated.

At six weeks, patients visited a physiotherapist at the local primary health care centre or an occupational health clinic. Patients were instructed to start dynamic range of motion exercises daily; these exercises included ten repetitions in flexion, and five repetitions each in external and internal rotations. These exercises were started with yellow resistance bands (Thera-Band®, The Hygenic Corporation Akron, Ohio, USA) and/or light dumbbells. Each exercise was repeated ten times in three sets, three times per week, for at least 24 weeks. The operating surgeon examined patients after three months of rehabilitation.

Supplementary Tables

Table S1. Frequency of missing data at baseline, 3, 6, 12 and 24 months.

	Non-surgery group (N=95) N (%)	Surgery group (N=95) N (%)
Constant score		
Baseline	3 (3)	2 (2)
3 months	25 (26)	34 (36)
6 months	22 (23)	20 (21)
12 months	18 (19)	18 (19)
24 months	14 (15)	15 (16)
Pain VAS		
Baseline	0	0
3 months	25 (26)	34 (36)
6 months	22 (23)	20 (21)
12 months	19 (20)	18 (19)

24 months	15 (16)	15 (16)
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Table S2. Pain measured by visual analogue scale and Constant score at baseline and the change at the 2-year follow-up.

	Baseline		Change from baseline to months 24		P values between groups	
	Non-surgical Mean (SD)	Surgical Mean (SD)	Non-surgical Mean (95% CI)	Surgical Mean (95% CI)	Crude	Adjusted ^a
Rotator cuff disease (All) n=190						
Mean Pain	49.1 (23.3)	47.0 (22.4)	-30.5 (-35.2 to -25.8)	-34.4 (-39.0 to -29.7)	0.25	0.23
Pain at rest	37.0 (26.4)	36.2 (24.8)	-23.7 (-28.5 to -19.0)	-27.8 (-32.5 to -23.0)	0.24	0.21
Pain in arm activity	59.6 (22.7)	55.1 (26.2)	-34.4 (-40.0 to -28.7)	-36.5 (-42.2 to -30.8)	0.60	0.57
Pain at night	50.6 (29.0)	49.6 (28.5)	-33.4 (-38.9 to -27.8)	-38.9 (-44.5 to -33.4)	0.16	0.15
Constant score	59.1 (14.9)	60.7 (14.7)	17.0 (14.4 to 19.7)	20.4 (17.8 to 23.1)	0.077	0.074
Non-full-thickness rupture n=95						
Mean Pain	54.2 (24.9)	46.5 (22.5)	-37.9 (-45.0 to -30.8)	-31.1 (-38.3 to -23.9)	0.19	0.17
Pain at rest	41.0 (28.4)	34.0 (24.7)	-29.3 (-36.7 to -21.9)	-23.2 (-30.7 to -15.7)	0.25	0.27
Pain in arm activity	64.4 (23.7)	57.8 (25.8)	-41.9 (-50.5 to -33.4)	-36.6 (-45.2 to -28.0)	0.39	0.36
Pain at night	57.4 (29.7)	47.8 (30.1)	-42.4	-33.5	0.12	0.098

			(-50.3 to -34.4)	(-41.5 to -25.5)		
Constant score	57.0 (15.2)	59.3 (14.2)	21.6 (17.8 to 25.3)	20.9 (17.1 to 24.7)	0.79	0.75
Full-thickness rupture n=95						
Mean Pain	44.0 (20.8)	47.4 (22.5)	-23.8 (-29.8 to -17.7)	-37.1 (-43.1 to -31.0)	0.002	0.001
Pain at rest	33.1 (24.0)	38.2 (25.0)	-18.8 (-24.8 to -12.7)	-31.7 (-37.7 to -25.7)	0.003	0.002
Pain in arm activity	54.9 (20.8)	52.8 (26.6)	-27.6 (-35.1 to -20.1)	-36.3 (-43.7 to -28.8)	0.061	0.091
Pain at night	44.0 (26.9)	51.2 (27.2)	-25.3 (-32.9 to -17.7)	-43.3 (-50.9 to -35.8)	<0.001	<0.001
Constant score	61.0 (14.6)	61.9 (15.2)	13.0 (9.4 to 16.7)	20.0 (16.4 to 23.7)	0.008	0.008

^aAdjusted for baseline values

Table S3. Implementation of non-surgical treatment modalities during 2-year follow-up.

	Non-surgical treatment, n (%)	Surgery, n (%)	p values between groups
Modalities	48 (51)	58 (61)	0.14
Physiotherapist visits	24 (25)	48 (50)	<0.001
Home-based exercises	39 (41)	49 (52)	0.15
Corticosteroid injections	12 (13)	3 (3)	0.015
None	47 (49)	37 (39)	

Figure S1 legend. Graphs showing per protocol (PP) results of the change in pain in the visual analogue scale (VAS, mm) and the Constant Murley score between baseline and the 2-year follow-up in all patients with rotator cuff disease and without and with full-thickness rotator cuff rupture.

Investigation plan

OPERATIVE VERSUS CONSERVATIVE MANAGEMENT OF ROTATOR CUFF DISEASE (SUBACROMIAL IMPINGEMENT AND ROTATOR CUFF TEAR) A prospective, randomized, controlled trial

Site of research:

Central Finland Hospital, Keskussairaalantie 19, Fin-40620 Jyväskylä, Finland

Oulu University Hospital, Oulu, Finland

Principal investigator:

Professor Juha Paloneva, MD, PhD, Department of Surgery, Central Finland Hospital, Jyväskylä, Finland, and University of Eastern Finland

Research plan: Paloneva, J., *et al.*

1. Background

Painful shoulder is one of the most common musculoskeletal causes of primary care consultation (1). Every 10th individual suffer from pain or disability of the shoulder. Shoulder problems become more common with increasing age. As many as every fifth of those aged 75-80 years is suffering from shoulder problems (2-4). Rotator cuff disease (subacromial impingement syndrome and rotator cuff tears) is the leading cause of prolonged pain and restricted range of motion of the shoulder as well as a significant cause of sick leave.

In the US, approximately 4.5 million physician visits and 40,000 inpatient surgeries are performed for diseases of the rotator cuff every year. The total costs are approximately \$ 600 000 000 (5). Half of the shoulder operations are subacromial decompressions and one fourth rotator cuff repairs (6). Operative treatment is associated with a long sick leave and rehabilitation period. The average duration of sick leave before and after subacromial decompression is 91 and 91 days, respectively. Correspondingly, the duration of sick leave associated with rotator cuff repair is 87 and 112 days (6).

Thus, rotator cuff problems have a significant effect on public health and are associated with high economical impact. Despite the high prevalence and expenses associated with disorders of the rotator cuff, there is little evidence to support or refute the efficacy of common interventions of subacromial impingement syndrome or rotator cuff tears. Therefore, optimal treatment supported by strong clinical evidence (operative vs. conservative, method and timing of surgery) cannot be offered to the patients (7, 8).

1.1.2 Anatomy of the shoulder

Glenohumeral joint is the most mobile human joint. Four muscles (*m. supraspinatus*, *m. infraspinatus*, *m. teres minor* and *m. subscapularis*) arising from the scapula and connecting to the head of the humerus are called rotator cuff muscles of the shoulder joint. The rotator cuff is an important soft tissue structure surrounding the glenohumeral joint. *M. supraspinatus* helps to abduct the upper limb, *m. teres minor* laterally rotates the arm and assists in its adduction, *m. infraspinatus* laterally rotates the arm and *m. subscapularis* medially rotates the arm and adducts it.

1.1.3 Pathophysiology, symptoms and findings

Rotator cuff disease is classically thought to be a continuum that ranges from an acute inflammation of the tendons to a full-thickness rotator cuff tear (9). Impingement has been classified into three stages: Stage I is associated with acute rotator cuff tendinitis. Stage II (also called as subacromial impingement syndrome) involves chronic inflammation and degeneration of the tissues. Full-thickness rotator cuff tear is seen in stage III. Depending on the classification, partial tears are included in either stage II or III (10).

1.1.4 Symptoms and signs of subacromial impingement stages I and II

Impingement stage I is an acute and reversible condition. Stage II involves prolonged symptoms that begin insidiously and may progress. Symptoms may also appear after strain or trauma. Pain is the most prominent manifestation. Pain is typically felt in the deltoid region and it often radiates to the upper arm. Painful arc between 60-120 degrees of abduction and disturbed humeroscapular rhythm

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are typical. Weakness and restricted range of motion of the shoulder may be present. The impingement sign test (passive shoulder flexion while preventing scapular rotation by pressing with a hand on acromion) cause pain. Local anaesthetic injected in the subacromial bursa relieves pain in the impingement sign test (9).

1.1.5 Rotator cuff tear

Rotator cuff tears are most commonly found in the supraspinatus tendon. Tear is usually associated with a degenerative process although the symptoms often become manifested after a minor trauma. Clinical examination reveals pain and weakness as well as restriction of active range of motion. Pain in abduction (painful arc) and external rotation is typical. Patients with a large tear often have difficulties in elevating the upper limb.

1.2 Previous research pertaining to rotator cuff disease and problems

The aim of interventions of rotator cuff disorders is to control pain and restore the function of the shoulder. The treatment of impingement stage I is conservative. The challenges of management of rotator cuff disease are associated with chronic rotator cuff disorders (stages II and III).

The interventions of disorders of the rotator cuff are heterogeneous. There is insufficient evidence to support or disprove the efficacy of common interventions of subacromial impingement stage II and rotator cuff tears. Evidence based knowledge to judge which patients benefit from surgery does not exist.

1.2.1 Impingement syndrome stage II

The first line of management of stage II impingement syndrome is conservative (rest, pain medication, physiotherapy and subacromial corticosteroid injections).

The most common surgical intervention of stage II impingement syndrome is arthroscopic decompression (bursectomy with partial resection of the anterior-inferior part of the acromion). The effectiveness of surgical management of stage II impingement has been questioned in three recent studies. These randomized controlled trials (RCT) compared arthroscopic subacromial decompression to supervised exercises and suggest that there are no statistically significant differences in the results between these two treatment modalities (11-13).

All these RCTs contain a significant methodological defect. According to generally accepted guidelines, conservative treatment with active physiotherapy should be conducted for several months before considering acromioplasty. The treatments before randomization were not defined in any of these trials. According to a study performed by our group, effective conservative treatment (physiotherapy) before referral to orthopaedic surgeon was defectively carried out in majority of cases (16). It is evident that the above-mentioned trials contain individuals that would have recovered during a short period of physiotherapy. The effectiveness of acromioplasty has not been studied after conservative treatment performed according to the common recommendations.

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Arthroscopic decompression is an increasingly common shoulder operation despite the recent evidence questioning the effectiveness of surgery (15). We hypothesize that surgery and rehabilitation would provide equivalent pain and function outcomes.

1.2.2 Rotator cuff tears

The first line of management of rotator cuff tears is non-operative. According to different sources, the symptoms relieve in 33-90 % of the patients. The reported results of rotator cuff repair are good. An acceptable result has been reported in 70-95 % of the patients (4).

However, rotator cuff tears are associated with several controversial issues such as the role of non-operative management, the indications for and timing of surgery and the method of surgical repair (4). Rotator cuff tears do not always cause significant pain or disability; tears have been reported in 34-38 % of asymptomatic individuals and in 30-50 % in cadaver studies (4, 17, 18). Partial or full-thickness tears have been found in more than 50 % of asymptomatic individuals over 60 years of age (19). Half of patients heal spontaneously and even a large tear is not always incompatible with a good over-head function (20). An acute tear after a high-energy trauma of a young (under age 50) individual is considered as an indication for surgery. On the other hand, an aged patient suffering from a chronic tear associated with low demands of activities of daily living as well as poor quality of rotator cuff tendons and muscles are thought to be suitable for conservative treatment (4). The greatest challenges of treatment of rotator cuff tears are encountered with the extensive number of patients between these two extremes.

There is little evidence to support or refute the efficacy of common interventions for rotator cuff tears (7, 22). Only one randomized controlled trial comparing surgical repair of rotator cuff tears to conservative treatment has been reported (23). In this trial pain was 1.7 cm lower (VAS, max 10 cm) and functional index 13 points higher (Constant score, max 100) in favour of surgery after one year follow-up. Although statistically significant, the clinical significance of these data has not been established. The contents of conservative treatment before randomization was not characterised. Therefore, it has to be assumed that the conservative treatment had been carried out ineffectively.

The guidelines for surgical decision making have been insufficiently characterized and level I evidence for any intervention is scarce. The need for randomized controlled trials comparing operative to conservative treatment is obvious (22).

When starting this trial, funded by the Academy of Finland, in 2008, only the trials by Brox and Haahr had been reported. The newly published papers in this field show that there is an increasing interest in defining the effectiveness of rotator cuff surgery. The fundamental issue regarding the superiority of surgery or physiotherapy is unresolved. The present trial aims at responding this need.

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2. Objectives

2.1 Research objectives

The objective is to search out evidence-based data for surgical and non-surgical treatments of rotator cuff disease, including subacromial impingement stage II and full-thickness rotator cuff tear, after initial non-surgical treatment.

This trial included two pre-specified subgroup analyses: The effectiveness of surgical treatment of {1} impingement stage II (including partial tears) and {2} full-thickness rotator cuff tears compared to non-surgical treatment.

We also aim at offering patients the most efficient and effective treatment and reduce the number of operations that do not have sufficient effectiveness. The data obtained facilitate the development of guidelines for management of rotator cuff disease.

2.2 Hypotheses

We test the following specific null hypothesis: there are no differences in outcome of surgical and non-surgical interventions for rotator cuff disease (subacromial impingement syndrome stage II) and full-thickness rotator cuff tear according to age, level of daily living activities, quality of life or the size or the number of tendons involved.

We postulate that there may be subgroups of patients suffering from rotator cuff disease that benefit from surgery whereas other subgroups are best treated conservatively.

3. Research methods and material

This trial is registered with ClinicalTrials.gov, numbers NCT00695981 and NCT00637013.

3.1 Research methods

The research setting is prospective, randomized and controlled. The study is a multicentre trial and will be performed in Central Finland Central Hospital (CFCH, Jyväskylä, Finland) and Oulu University Hospital (OUH, Oulu, Finland).

3.1.1 Clinical examination and patient history

For trial flow chart, see *Figure 1*. Members of the group examines and informs the patients about the trial. The inclusion criteria are; age over 35 years, duration of symptoms at least three months, and the patient accepts both treatment options (operative and conservative). The exclusion criteria are; previous shoulder operations, inability to co-operate, rheumatoid arthritis, severe osteoarthritis of the glenohumeral or acromioclavicular joint, irreparable rotator cuff tear, progressive malign disease, adhesive capsulitis, high-energy trauma before symptoms, cervical syndrome and shoulder instability.

In addition, the patients included in the impingement stage II trial must have pain in abduction of the shoulder and painful arc, pain in two of the three isometric tests (0 and 30 degrees of abduction, or

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external rotation) and a positive result in the impingement test (a subacromial injection of lidocaine reduces pain). Patients with a partial rotator cuff tear are included.

In addition, the patients included in the rotator cuff tear study must have a full-thickness rotator cuff tear in MRI arthrography performed after the 3-4 months period of conservative treatment. The primary cause of the tear must be degenerative.

Patients suitable for the study will subsequently be examined by a physiotherapist. The physiotherapist records the patient history and makes the baseline measurements (Baseline I): basic information of the patients, pain in rest, in exercise, and at night (VAS), objective shoulder function (Constant score), and the quality of life (RAND-36), pain medication used, use of medical services, activities of daily living.

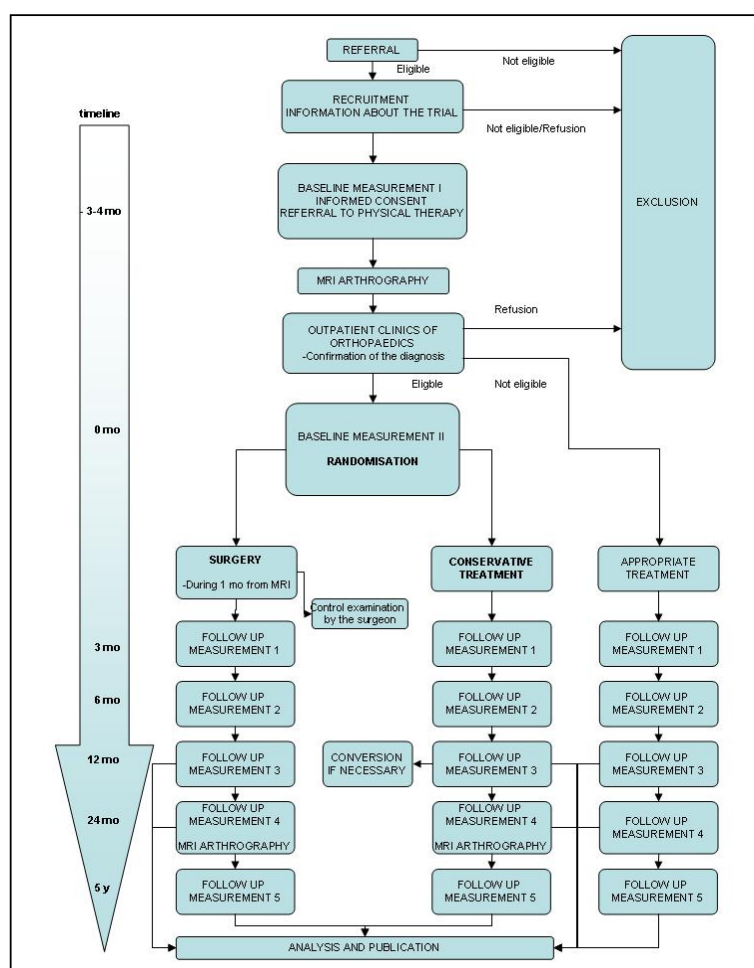


Figure 1. Trial flow chart

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After baseline measurements, the patients are advised to start active physiotherapy. They receive a referral to outpatient physiotherapy. The referral is accompanied by a letter describing a rehabilitation program following generally accepted guidelines. The participation (contents and frequency of training) is recorded during the control visits.

After the 3-4 months period of conservative treatment, an MRI arthrography of the shoulder is performed. Radiographs and MR images will be systematically evaluated by two independent radiologists. A specialist in the outpatient clinics of orthopaedic surgery confirms the diagnosis and assigns the patients still suffering from significant symptoms to the group of impingement stage II or rotator cuff tear. The orthopaedic surgeon is not a member of the group. The baseline measurements will be repeated by the physiotherapist (Baseline II). After baseline measurements, the patients will be randomized to operative or conservative group.

Physiotherapist examines every patient after 3, 6, 12, 24 months, and 5 years. The same data as in the baseline examination will be recorded. In addition, the length of sick leave, complications, treatment drop out as well as the costs associated with the treatment will be recorded. The physiotherapist is not blinded.

Patients excluded from the randomization will undergo the same follow-up protocol than patients included in the study.

3.1.2 Clinical management

The rehabilitation program of patients randomized to non-operative treatment will be guided by physiotherapist. The standardised home-based rehabilitation program consists of exercises that are simple and can be performed at home.

Patients randomized to surgical treatment will be operated according to the generally accepted current practice. The post operative rehabilitation program will be guided by the physiotherapist. All operated patients will be routinely examined six to eight weeks postoperatively by the operating surgeon.

Non-surgical treatment will be considered failed if no improvement in the parameters mentioned above has been observed after six to twelve months and the patient complains significant problems due to pain or disability. These patients will be offered appropriate surgical intervention.

Healing or potential progression of defects in rotator cuff and glenohumeral joint will be evaluated by MRI arthrography 24 months after the randomization.

3.1.3 Outcome variables

The primary outcome variables of both study sections (impingement stage II and tear of the rotator cuff) are the change in pain (VAS) and objective shoulder function (Constant score) after two years from randomization.

3.1.4 Determination of the sample size

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The sample size was evaluated using iterative models ($\beta=0.85$ and $\alpha=0.05$). The calculations are based on a 30 % difference between the groups. When statistically significant, the 30 % difference is likely to be also clinically significant. The number of patients is approximately 200: 100 patients will receive surgical treatment and another 100 will be randomized to non-surgical treatment. Determination of the sample size was based on an article by Haahr, J.P. and colleagues (12).

3.1.5 Randomization

Patients suitable for the trial according to the inclusion and exclusion criteria will be randomized to surgical and non-surgical groups according to a computer generated, blocked randomization list. The block size varies randomly (approximately ten) and is stratified according to gender and type of rotator cuff disease (impingement stage II or full-thickness rotator cuff tear).

3.1.6 Statistical analysis

All analyses will be performed on the intention-to-treat principle. The data will be analyzed by using statistical longitudinal data methods suitable for the measurement scale of the outcome in question. Baseline adjusted models will be used if there are differences between the groups in the outcomes at baseline. Based on patient history, demographic and follow-up data we aim at determining subgroups of patients gaining the most benefit from either operative or conservative intervention.

3.1.7 Cost-effectiveness

The cost-effectiveness of the treatments will be evaluated by determining the quality of life (RAND-36) and pain (VAS) of the patients at baseline before treatment and 3, 6, 12, 24 months and 5 years after the treatment given. The effectiveness will be measured by change in quality of life or pain. The use of health and social services will be measured after 6 and 12 months.

3.2. Research material

Patients. All patients referred to CFCH and OUH suffering from subacromial impingement stage II or rotator cuff tear are potential candidates for the trial. CFCH and OUH are public hospitals offering orthopaedic treatment to the population of 250 000 (CFCH) and 270 000 (OUH) in the surrounding communities. Annually, approximately 1200 patients are referred to these hospitals by general practitioners due to shoulder disorders.

3.3 Materials management plan

4.3.1 Every patient receives a code number that will be used throughout the trial. All data will be recorded in forms designed for the project. 4.3.2 Data will be used for statistical analyses as described in section 4.1. Data will be used for research purposes according to a written permission granted by all individuals included in the trial. 4.3.3 The physical data (forms) will be stored in a Clinical Research File (CRF), established for every individual. Data will be transferred into electronic format and saved in a server located in Central Finland Central Hospital (CFCH). The server is protected by username and password. All physical data containing personal information will be stored in the hospital in a locked room. 4.3.4 Anonymous data will be made available on request after the trial has been finished. 4.3.5 Central Finland Hospital District is the owner of the research material. Only members of the research group will be able to access these data.

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3.4 Ethical issues and research permits

A detailed application for the ethical board of the Hospital District has been presented and approved (Dnro 23/2007, May 23rd, 2007).

Participation in the study is voluntary. Patients will be informed about the study, and the current knowledge as well as the risks associated with both treatment options. The patients will also receive written material about their disease and the trial. The patients will be informed that they can leave the study without any negative consequences. Patients accepting the terms of the study will give a written informed consent. All recognisable personal data will remain confidential.

The clinical management of the patients will be carried out according to generally accepted methods. There are no data showing superiority of any method used in this trial to each other. If non-operative treatment fails to provide relief to the symptoms in six to twelve months, adequate surgical intervention will be offered.

3.5 Risk management

The size of population for recruitment was identified as a critical factor. The number of patients was estimated to be sufficient. To accelerate randomization of the patients, the project was converted into a multicentre trial in 2010. The trial has been actively recruiting patients since 2008.

4. Implementation

4.1 Timetable

Recruitment of the patients began in 2008. The patients will be evaluated 3, 6, 12, 24 months and 5 years after intervention.

5. Researchers and research environment

5.1 Research group and merits

Principal investigator

Juha Paloneva, MD, PhD, specialist in orthopaedics and traumatology, Central Finland Central Hospital (CFCH)

Co-PI

Ilkka Kiviranta, MD, PhD, professor, specialist in surgery, specialist in orthopaedics and traumatology, orthopaedist-in-chief, University of Helsinki, Helsinki University Central Hospital, Finland

Graduate student

Sanna Cederqvist, MD, PhD student, resident surgeon, Central Finland Central Hospital (CFCH), Oulu University Hospital, Oulu, Finland

Experts in shoulder surgery

Tapio Flinkkilä, MD, PhD, associate professor, specialist in orthopaedics and traumatology, Oulu University Hospital, Konsta Pamilo, MD, PhD, Central Finland Hospital, Jyväskylä, Finland; Tero Ridanpää, MD, Central Finland Central Hospital, Jyväskylä, Finland;

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<u>Expert in rehabilitation</u>	Kai Sirniö, MD, PhD, Department of Surgery, Division of Orthopedic and Trauma Surgery, Oulu, Finland;
<u>Recruitment of the patients</u>	Jari Ylinen, MD, PhD, associate professor, head of the dept. of physical and rehabilitation medicine, CFCH
<u>Clinical consultant</u>	Sanna Cederqvist, MD (OUH), Tero Irmola MD, Juho Liukkonen MD, Heidi Lehtokangas MD (CFCH), resident surgeons
<u>Biostatistician</u>	Juhana Leppilahti, MD, Professor, Department of Surgery, Division of Orthopedic and Trauma Surgery, Oulu, Finland; Juho Liukkonen, MD, Department of Emergency Medicine, Central Finland Hospital, Jyväskylä, Finland;
<u>Radiologist</u>	Hannu Kautiainen Primary Health Care Unit, Kuopio University Hospital, Finland and Folkhälsan Research Center, Helsinki
<u>Saara-Maija Hinkkanen</u>	MD, PhD, Department of Radiology, Helsinki University Hospital, Helsinki, Finland
<u>Nina Sevander-Kreus</u>	Physiotherapist, randomization, baseline and follow-up measurements
	Physiotherapist, randomization, baseline and follow-up measurements

5.2 Infrastructure. The trial will be performed in Central Finland Central Hospital and Oulu University Hospital. These hospitals provide the infrastructure (personnel, facilities, and equipment for clinical examination and operations as well as office material and equipment) required by the trial. The examination of the patients including radiographs and MRIs as well as operative treatment and routine postoperative control examination by the operating surgeon belong to the routine clinical practice and do not cause expenses to the project.

Follow-up MRIs 2 years after randomization will be performed at Terveystalo Imaging Services, Jyväskylä, and in Oulu University Hospital, at the Department of Radiology.

5.3.1 National and international collaboration

Oulu University Hospital provides expertise in shoulder surgery, recruitment and examination of patients as well as operative and conservative treatment.

Helsinki University Central Hospital provides collaboration in implementation of national guidelines, produced by our team, for treatment of shoulder disorders in the Hospital District of Helsinki and Uusimaa.

Finnish medical association Duodecim provides expertise in developing national guidelines for management of shoulder disorders.

6. Expected research results and possible risks

6.1 Expected scientific and societal impact. The project provides level I evidence for the treatment of rotator cuff disease. The results help physicians to decide whether the patient should be operated or directed to conservative management. The patients can be offered evidence-based treatments.

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6.2 Potential for scientific breakthroughs. By providing level I evidence on the effectiveness of common surgical shoulder operations there is a potential to more efficiently identify subgroups of patients that recover using conservative treatment or benefit from surgery. It may also be possible to safely reduce the number of operations that do not have sufficient efficacy. This will be a clinical breakthrough and is associated with a significant economical impact.

6.3 Applicability and feasibility. The approach of the trial is pragmatic. The results can be applied to real life clinical practice and recommendations as is.

6.4 Publishment. The project is likely to produce at least 15 publications which will be reported in international and domestic peer-reviewed publication series, and one doctoral thesis. Awareness among potential end-users will also be raised by presenting the results in international and domestic congresses.

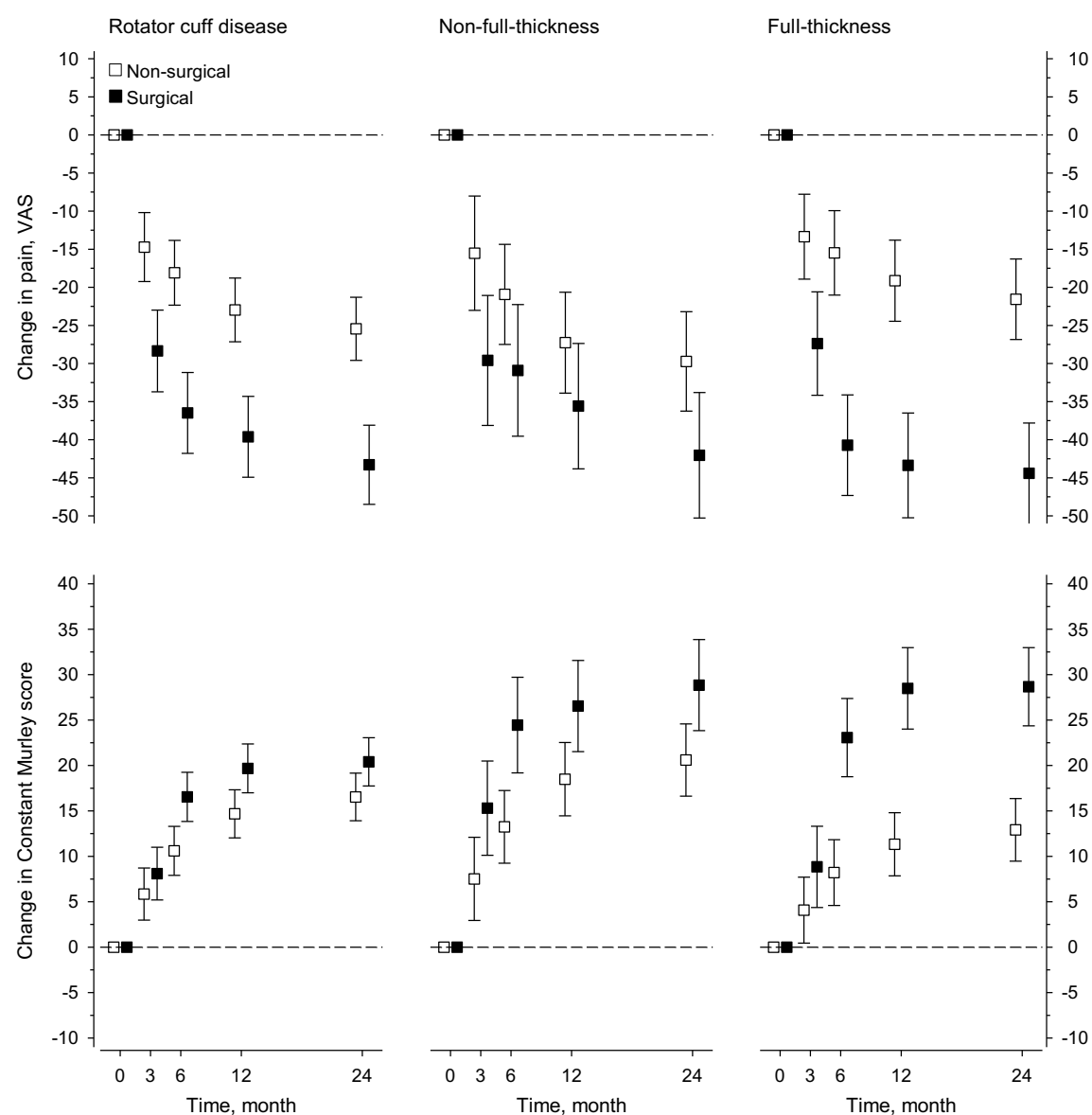
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Figure S3. Graphs showing the per protocol (PP) analysis of change in pain in the visual analogue scale (VAS) and the Constant Murley score (CMS) between baseline and the 2-year follow-up in all patients with rotator cuff disease and without and with full-thickness rotator cuff rupture.



Online-only material

Trial protocol

Protocol for active rehabilitation after recruitment before randomization

Protocol for surgical treatment

Post-operative treatment protocol

Supplementary Tables

Trial protocol

The trial protocol has been published at ClinicalTrials.gov (accession numbers NCT00695981 and NCT00637013)

Protocol for active rehabilitation after recruitment before randomization

Patients applied a cold pack for 10 to 15 min before exercise, when necessary for pain relief.

The exercise program was designed according to best practices at that time^{1,2}.

Physiotherapists demonstrated and guided the exercises. The load for the first three visits was assessed individually, and each exercise was performed with 20 repetitions maximum (RM), for three sets. After one month, the load was increased, and the number of repetitions was reduced to 15 RM. After two months, the load was increased, and the number of repetitions was reduced to 10 RM. All exercises were to be performed three times per week, and the load was increased by 1 kg, when possible, to achieve the goal RM.

The glenohumeral joint was stretched passively. Hanging exercises were recommended to improve mobility. All patients, except those with hypermobility, hung for 30 s three times per

day. When the shoulder range of motion (ROM) was limited, the physiotherapist mobilized the glenohumeral joint with a muscle energy technique, applied in the direction of restricted movement. This treatment included isometric contraction for 5 s and static stretching for 5-10 s, and the sequence was repeated 8 times. In addition, the scapulothoracic joint was mobilized, when the ROM was restricted.

All physiotherapists performed manual therapy according to instructions. After 5 min of cold pack treatment, the supraspinatus was cross-friction massaged (20x3x30 s at 30 s intervals). The same procedure was repeated on the infraspinatus, subscapularis, teres minor, and teres major muscles. Manual treatments were applied to the trapezius, deltoid, long head of the triceps, and the biceps sulcus areas.

Shoulder rehabilitation exercises included: Bent-over row on with dumbbells, biceps curl with dumbbells, dumbbell bench press, cable adduction, internal rotation with dumbbells, lying on the side or standing, with an elastic resistance band, external rotation with dumbbells, lying on the side or standing, with an elastic resistance band and arm flexion with dumbbells.

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Protocol for surgical treatment

All operations were performed by orthopaedic surgeons that regularly practiced arthroscopic shoulder surgery (TF, KS, KP, TR). Patients were placed in a beach-chair position and received

general and/or interscalene anaesthesia. Cefuroxime (1.5 g) was administered intravenously, before the operation. Initially, the glenohumeral joint and subacromial space were evaluated arthroscopically. Then, patients without a full-thickness tendon lesion underwent arthroscopic subacromial decompression (subacromial bursectomy and resection of the anterior-inferior surface of the acromion). In patients with full-thickness tears, the tendon(s) was re-attached to the head of humerus, in a single-row fashion. Surgeons used one or more bone anchors and implemented either an arthroscopic or a mini-open approach.

Post-operative rehabilitation treatment protocol

All patients underwent the same early post-surgery rehabilitation protocol and used a sling for three weeks. A physiotherapist demonstrated and guided the patient on how to perform the exercises, starting the first postoperative day. Patients were advised to perform 10 repetitions of each home exercise, three times daily, according to instructions. The exercises included active elbow and finger flexion and extension, shoulder and scapula retraction, pendulum exercises, and passive internal rotation.

Three weeks after surgery, patients visited a physiotherapist at the study hospital outpatient clinic, and the training instructions were repeated. The patients started passive exercises three times per day, including: 10 repetitions of shoulder flexion up to 90°, external rotation up to 20-30°, and internal rotation exercises (lifting the dorsum of the hand behind the lower back). Strength training was commenced with 10 repetitions of light, isometric, 5-s contractions of the shoulder muscles, performed when the shoulder was extended, internally rotated, and externally rotated.

At six weeks, patients visited a physiotherapist at the local primary health care centre or an occupational health clinic. Patients were instructed to start dynamic range of motion

exercises daily; these exercises included ten repetitions in flexion, and five repetitions each in external and internal rotations. These exercises were started with yellow resistance bands (Thera-Band®, The Hygenic Corporation Akron, Ohio, USA) and/or light dumbbells. Each exercise was repeated ten times in three sets, three times per week, for at least 24 weeks. The operating surgeon examined patients after three months of rehabilitation.

Supplementary Tables

Table S1. Frequency of missing data at baseline, 3, 6, 12 and 24 months.

	Non-surgery group (N=95) N (%)	Surgery group (N=95) N (%)
Constant score		
Baseline	3 (3)	2 (2)
3 months	25 (26)	34 (36)
6 months	22 (23)	20 (21)
12 months	18 (19)	18 (19)
24 months	14 (15)	15 (16)
Pain VAS		
Baseline	0	0
3 months	25 (26)	34 (36)
6 months	22 (23)	20 (21)
12 months	19 (20)	18 (19)
24 months	15 (16)	15 (16)

Table S2. Pain measured by visual analogue scale and Constant score at baseline and the change at the 2-year follow-up.

	Baseline		Change from baseline to months 24		P values between groups	
	Non-surgical Mean (SD)	Surgical Mean (SD)	Non-surgical Mean (95% CI)	Surgical Mean (95% CI)	Crude	Adjusted ^a
Rotator cuff disease (All) n=190						
Mean Pain	49.1 (23.3)	47.0 (22.4)	-30.5 (-35.2 to -25.8)	-34.4 (-39.0 to -29.7)	0.25	0.23
Pain at rest	37.0 (26.4)	36.2 (24.8)	-23.7 (-28.5 to -19.0)	-27.8 (-32.5 to -23.0)	0.24	0.21
Pain in arm activity	59.6 (22.7)	55.1 (26.2)	-34.4 (-40.0 to -28.7)	-36.5 (-42.2 to -30.8)	0.60	0.57
Pain at night	50.6 (29.0)	49.6 (28.5)	-33.4 (-38.9 to -27.8)	-38.9 (-44.5 to -33.4)	0.16	0.15
Constant score	59.1 (14.9)	60.7 (14.7)	17.0 (14.4 to 19.7)	20.4 (17.8 to 23.1)	0.077	0.074
Non-full-thickness rupture n=92						
Mean Pain	54.2 (24.9)	46.5 (22.5)	-37.9 (-45.0 to -30.8)	-31.1 (-38.3 to -23.9)	0.19	0.17
Pain at rest	41.0 (28.4)	34.0 (24.7)	-29.3 (-36.7 to -21.9)	-23.2 (-30.7 to -15.7)	0.25	0.27
Pain in arm activity	64.4 (23.7)	57.8 (25.8)	-41.9 (-50.5 to -33.4)	-36.6 (-45.2 to -28.0)	0.39	0.36
Pain at night	57.4 (29.7)	47.8 (30.1)	-42.4 (-50.3 to -34.4)	-33.5 (-41.5 to -25.5)	0.12	0.098
Constant score	57.0 (15.2)	59.3 (14.2)	21.6	20.9	0.79	0.75

			(17.8 to 25.3)	(17.1 to 24.7)		
Full-thickness rupture n=98						
Mean Pain	44.0 (20.8)	47.4 (22.5)	-23.8 (-29.8 to -17.7)	-37.1 (-43.1 to -31.0)	0.002	0.001
Pain at rest	33.1 (24.0)	38.2 (25.0)	-18.8 (-24.8 to -12.7)	-31.7 (-37.7 to -25.7)	0.003	0.002
Pain in arm activity	54.9 (20.8)	52.8 (26.6)	-27.6 (-35.1 to -20.1)	-36.3 (-43.7 to -28.8)	0.061	0.091
Pain at night	44.0 (26.9)	51.2 (27.2)	-25.3 (-32.9 to -17.7)	-43.3 (-50.9 to -35.8)	<0.001	<0.001
Constant score	61.0 (14.6)	61.9 (15.2)	13.0 (9.4 to 16.7)	20.0 (16.4 to 23.7)	0.008	0.008

^aAdjusted for baseline values

Table S3. Implementation of non-surgical treatment modalities during 2-year follow-up.

	Non-surgical treatment, n (%)	Surgery, n (%)	p values between groups
Physiotherapist visits	24 (25)	48 (50)	<0.001
Home-based exercises	39 (41)	49 (52)	0.15
Corticosteroid injections	12 (13)	3 (3)	0.015

Investigation plan

OPERATIVE VERSUS CONSERVATIVE MANAGEMENT OF ROTATOR CUFF DISEASE (SUBACROMIAL IMPINGEMENT AND ROTATOR CUFF TEAR) A prospective, randomized, controlled trial

Site of research:

Central Finland Hospital, Keskussairaalantie 19, Fin-40620 Jyväskylä, Finland

Oulu University Hospital, Oulu, Finland

Principal investigator:

Professor Juha Paloneva, MD, PhD, Department of Surgery, Central Finland Hospital, Jyväskylä, Finland, and University of Eastern Finland

Research plan: Paloneva, J., *et al.*

1. Background

Painful shoulder is one of the most common musculoskeletal causes of primary care consultation (1). Every 10th individual suffer from pain or disability of the shoulder. Shoulder problems become more common with increasing age. As many as every fifth of those aged 75-80 years is suffering from shoulder problems (2-4). Rotator cuff disease (subacromial impingement syndrome and rotator cuff tears) is the leading cause of prolonged pain and restricted range of motion of the shoulder as well as a significant cause of sick leave.

In the US, approximately 4.5 million physician visits and 40,000 inpatient surgeries are performed for diseases of the rotator cuff every year. The total costs are approximately \$ 600 000 000 (5). Half of the shoulder operations are subacromial decompressions and one fourth rotator cuff repairs (6). Operative treatment is associated with a long sick leave and rehabilitation period. The average duration of sick leave before and after subacromial decompression is 91 and 91 days, respectively. Correspondingly, the duration of sick leave associated with rotator cuff repair is 87 and 112 days (6).

Thus, rotator cuff problems have a significant effect on public health and are associated with high economical impact. Despite the high prevalence and expenses associated with disorders of the rotator cuff, there is little evidence to support or refute the efficacy of common interventions of subacromial impingement syndrome or rotator cuff tears. Therefore, optimal treatment supported by strong clinical evidence (operative vs. conservative, method and timing of surgery) cannot be offered to the patients (7, 8).

1.1.2 Anatomy of the shoulder

Glenohumeral joint is the most mobile human joint. Four muscles (*m. supraspinatus*, *m. infraspinatus*, *m. teres minor* and *m. subscapularis*) arising from the scapula and connecting to the head of the humerus are called rotator cuff muscles of the shoulder joint. The rotator cuff is an important soft tissue structure surrounding the glenohumeral joint. *M. supraspinatus* helps to abduct the upper limb, *m. teres minor* laterally rotates the arm and assists in its adduction, *m. infraspinatus* laterally rotates the arm and *m. subscapularis* medially rotates the arm and adducts it.

1.1.3 Pathophysiology, symptoms and findings

Rotator cuff disease is classically thought to be a continuum that ranges from an acute inflammation of the tendons to a full-thickness rotator cuff tear (9). Impingement has been classified into three stages: Stage I is associated with acute rotator cuff tendinitis. Stage II (also called as subacromial impingement syndrome) involves chronic inflammation and degeneration of the tissues. Full-thickness rotator cuff tear is seen in stage III. Depending on the classification, partial tears are included in either stage II or III (10).

1.1.4 Symptoms and signs of subacromial impingement stages I and II

Impingement stage I is an acute and reversible condition. Stage II involves prolonged symptoms that begin insidiously and may progress. Symptoms may also appear after strain or trauma. Pain is the most prominent manifestation. Pain is typically felt in the deltoid region and it often radiates to the upper arm. Painful arc between 60-120 degrees of abduction and disturbed humeroscapular rhythm

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are typical. Weakness and restricted range of motion of the shoulder may be present. The impingement sign test (passive shoulder flexion while preventing scapular rotation by pressing with a hand on acromion) cause pain. Local anaesthetic injected in the subacromial bursa relieves pain in the impingement sign test (9).

1.1.5 Rotator cuff tear

Rotator cuff tears are most commonly found in the supraspinatus tendon. Tear is usually associated with a degenerative process although the symptoms often become manifested after a minor trauma. Clinical examination reveals pain and weakness as well as restriction of active range of motion. Pain in abduction (painful arc) and external rotation is typical. Patients with a large tear often have difficulties in elevating the upper limb.

1.2 Previous research pertaining to rotator cuff disease and problems

The aim of interventions of rotator cuff disorders is to control pain and restore the function of the shoulder. The treatment of impingement stage I is conservative. The challenges of management of rotator cuff disease are associated with chronic rotator cuff disorders (stages II and III).

The interventions of disorders of the rotator cuff are heterogeneous. There is insufficient evidence to support or disprove the efficacy of common interventions of subacromial impingement stage II and rotator cuff tears. Evidence based knowledge to judge which patients benefit from surgery does not exist.

1.2.1 Impingement syndrome stage II

The first line of management of stage II impingement syndrome is conservative (rest, pain medication, physiotherapy and subacromial corticosteroid injections).

The most common surgical intervention of stage II impingement syndrome is arthroscopic decompression (bursectomy with partial resection of the anterior-inferior part of the acromion). The effectiveness of surgical management of stage II impingement has been questioned in three recent studies. These randomized controlled trials (RCT) compared arthroscopic subacromial decompression to supervised exercises and suggest that there are no statistically significant differences in the results between these two treatment modalities (11-13).

All these RCTs contain a significant methodological defect. According to generally accepted guidelines, conservative treatment with active physiotherapy should be conducted for several months before considering acromioplasty. The treatments before randomization were not defined in any of these trials. According to a study performed by our group, effective conservative treatment (physiotherapy) before referral to orthopaedic surgeon was defectively carried out in majority of cases (16). It is evident that the above-mentioned trials contain individuals that would have recovered during a short period of physiotherapy. The effectiveness of acromioplasty has not been studied after conservative treatment performed according to the common recommendations.

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Arthroscopic decompression is an increasingly common shoulder operation despite the recent evidence questioning the effectiveness of surgery (15). We hypothesize that surgery and rehabilitation would provide equivalent pain and function outcomes.

1.2.2 Rotator cuff tears

The first line of management of rotator cuff tears is non-operative. According to different sources, the symptoms relieve in 33-90 % of the patients. The reported results of rotator cuff repair are good. An acceptable result has been reported in 70-95 % of the patients (4).

However, rotator cuff tears are associated with several controversial issues such as the role of non-operative management, the indications for and timing of surgery and the method of surgical repair (4). Rotator cuff tears do not always cause significant pain or disability; tears have been reported in 34-38 % of asymptomatic individuals and in 30-50 % in cadaver studies (4, 17, 18). Partial or full-thickness tears have been found in more than 50 % of asymptomatic individuals over 60 years of age (19). Half of patients heal spontaneously and even a large tear is not always incompatible with a good over-head function (20). An acute tear after a high-energy trauma of a young (under age 50) individual is considered as an indication for surgery. On the other hand, an aged patient suffering from a chronic tear associated with low demands of activities of daily living as well as poor quality of rotator cuff tendons and muscles are thought to be suitable for conservative treatment (4). The greatest challenges of treatment of rotator cuff tears are encountered with the extensive number of patients between these two extremes.

There is little evidence to support or refute the efficacy of common interventions for rotator cuff tears (7, 22). Only one randomized controlled trial comparing surgical repair of rotator cuff tears to conservative treatment has been reported (23). In this trial pain was 1.7 cm lower (VAS, max 10 cm) and functional index 13 points higher (Constant score, max 100) in favour of surgery after one year follow-up. Although statistically significant, the clinical significance of these data has not been established. The contents of conservative treatment before randomization was not characterised. Therefore, it has to be assumed that the conservative treatment had been carried out ineffectively.

The guidelines for surgical decision making have been insufficiently characterized and level I evidence for any intervention is scarce. The need for randomized controlled trials comparing operative to conservative treatment is obvious (22).

When starting this trial, funded by the Academy of Finland, in 2008, only the trials by Brox and Haahr had been reported. The newly published papers in this field show that there is an increasing interest in defining the effectiveness of rotator cuff surgery. The fundamental issue regarding the superiority of surgery or physiotherapy is unresolved. The present trial aims at responding this need.

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2. Objectives

2.1 Research objectives

The objective is to search out evidence-based data for surgical and non-surgical treatments of rotator cuff disease, including subacromial impingement stage II and full-thickness rotator cuff tear, after initial non-surgical treatment.

This trial included two pre-specified subgroup analyses: The effectiveness of surgical treatment of {1} impingement stage II (including partial tears) and {2} full-thickness rotator cuff tears compared to non-surgical treatment.

We also aim at offering patients the most efficient and effective treatment and reduce the number of operations that do not have sufficient effectiveness. The data obtained facilitate the development of guidelines for management of rotator cuff disease.

2.2 Hypotheses

We test the following specific null hypothesis: there are no differences in outcome of surgical and non-surgical interventions for rotator cuff disease (subacromial impingement syndrome stage II) and full-thickness rotator cuff tear according to age, level of daily living activities, quality of life or the size or the number of tendons involved.

We postulate that there may be subgroups of patients suffering from rotator cuff disease that benefit from surgery whereas other subgroups are best treated conservatively.

3. Research methods and material

This trial is registered with ClinicalTrials.gov, numbers NCT00695981 and NCT00637013.

3.1 Research methods

The research setting is prospective, randomized and controlled. The study is a multicentre trial and will be performed in Central Finland Central Hospital (CFCH, Jyväskylä, Finland) and Oulu University Hospital (OUH, Oulu, Finland).

3.1.1 Clinical examination and patient history

For trial flow chart, see *Figure 1*. Members of the group examines and informs the patients about the trial. The inclusion criteria are; age over 35 years, duration of symptoms at least three months, and the patient accepts both treatment options (operative and conservative). The exclusion criteria are; previous shoulder operations, inability to co-operate, rheumatoid arthritis, severe osteoarthritis of the glenohumeral or acromioclavicular joint, irreparable rotator cuff tear, progressive malign disease, adhesive capsulitis, high-energy trauma before symptoms, cervical syndrome and shoulder instability.

In addition, the patients included in the impingement stage II trial must have pain in abduction of the shoulder and painful arc, pain in two of the three isometric tests (0 and 30 degrees of abduction, or

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external rotation) and a positive result in the impingement test (a subacromial injection of lidocaine reduces pain). Patients with a partial rotator cuff tear are included.

In addition, the patients included in the rotator cuff tear study must have a full-thickness rotator cuff tear in MRI arthrography performed after the 3-4 months period of conservative treatment. The primary cause of the tear must be degenerative.

Patients suitable for the study will subsequently be examined by a physiotherapist. The physiotherapist records the patient history and makes the baseline measurements (Baseline I): basic information of the patients, pain in rest, in exercise, and at night (VAS), objective shoulder function (Constant score), and the quality of life (RAND-36), pain medication used, use of medical services, activities of daily living.

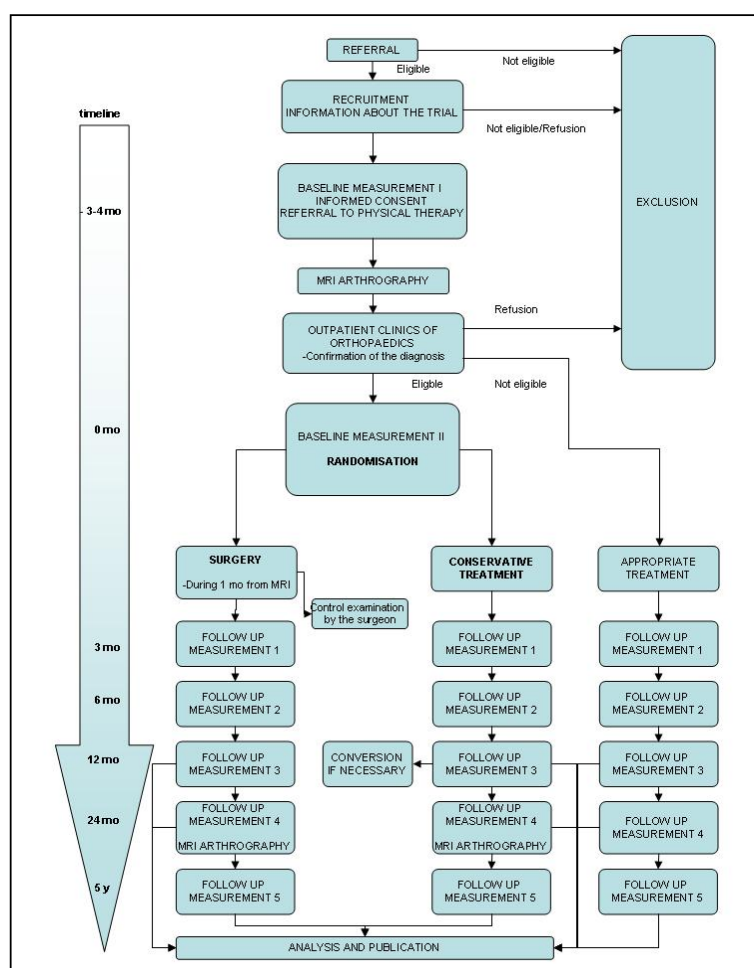


Figure 1. Trial flow chart

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After baseline measurements, the patients are advised to start active physiotherapy. They receive a referral to outpatient physiotherapy. The referral is accompanied by a letter describing a rehabilitation program following generally accepted guidelines. The participation (contents and frequency of training) is recorded during the control visits.

After the 3-4 months period of conservative treatment, an MRI arthrography of the shoulder is performed. Radiographs and MR images will be systematically evaluated by two independent radiologists. A specialist in the outpatient clinics of orthopaedic surgery confirms the diagnosis and assigns the patients still suffering from significant symptoms to the group of impingement stage II or rotator cuff tear. The orthopaedic surgeon is not a member of the group. The baseline measurements will be repeated by the physiotherapist (Baseline II). After baseline measurements, the patients will be randomized to operative or conservative group.

Physiotherapist examines every patient after 3, 6, 12, 24 months, and 5 years. The same data as in the baseline examination will be recorded. In addition, the length of sick leave, complications, treatment drop out as well as the costs associated with the treatment will be recorded. The physiotherapist is not blinded.

Patients excluded from the randomization will undergo the same follow-up protocol than patients included in the study.

3.1.2 Clinical management

The rehabilitation program of patients randomized to non-operative treatment will be guided by physiotherapist. The standardised home-based rehabilitation program consists of exercises that are simple and can be performed at home.

Patients randomized to surgical treatment will be operated according to the generally accepted current practice. The post operative rehabilitation program will be guided by the physiotherapist. All operated patients will be routinely examined six to eight weeks postoperatively by the operating surgeon.

Non-surgical treatment will be considered failed if no improvement in the parameters mentioned above has been observed after six to twelve months and the patient complains significant problems due to pain or disability. These patients will be offered appropriate surgical intervention.

Healing or potential progression of defects in rotator cuff and glenohumeral joint will be evaluated by MRI arthrography 24 months after the randomization.

3.1.3 Outcome variables

The primary outcome variables of both study sections (impingement stage II and tear of the rotator cuff) are the change in pain (VAS) and objective shoulder function (Constant score) after two years from randomization.

3.1.4 Determination of the sample size

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The sample size was evaluated using iterative models ($\beta=0.85$ and $\alpha=0.05$). The calculations are based on a 30 % difference between the groups. When statistically significant, the 30 % difference is likely to be also clinically significant. The number of patients is approximately 200: 100 patients will receive surgical treatment and another 100 will be randomized to non-surgical treatment. Determination of the sample size was based on an article by Haahr, J.P. and colleagues (12).

3.1.5 Randomization

Patients suitable for the trial according to the inclusion and exclusion criteria will be randomized to surgical and non-surgical groups according to a computer generated, blocked randomization list. The block size varies randomly (approximately ten) and is stratified according to gender and type of rotator cuff disease (impingement stage II or full-thickness rotator cuff tear).

3.1.6 Statistical analysis

All analyses will be performed on the intention-to-treat principle. The data will be analyzed by using statistical longitudinal data methods suitable for the measurement scale of the outcome in question. Baseline adjusted models will be used if there are differences between the groups in the outcomes at baseline. Based on patient history, demographic and follow-up data we aim at determining subgroups of patients gaining the most benefit from either operative or conservative intervention.

3.1.7 Cost-effectiveness

The cost-effectiveness of the treatments will be evaluated by determining the quality of life (RAND-36) and pain (VAS) of the patients at baseline before treatment and 3, 6, 12, 24 months and 5 years after the treatment given. The effectiveness will be measured by change in quality of life or pain. The use of health and social services will be measured after 6 and 12 months.

3.2. Research material

Patients. All patients referred to CFCH and OUH suffering from subacromial impingement stage II or rotator cuff tear are potential candidates for the trial. CFCH and OUH are public hospitals offering orthopaedic treatment to the population of 250 000 (CFCH) and 270 000 (OUH) in the surrounding communities. Annually, approximately 1200 patients are referred to these hospitals by general practitioners due to shoulder disorders.

3.3 Materials management plan

4.3.1 Every patient receives a code number that will be used throughout the trial. All data will be recorded in forms designed for the project. 4.3.2 Data will be used for statistical analyses as described in section 4.1. Data will be used for research purposes according to a written permission granted by all individuals included in the trial. 4.3.3 The physical data (forms) will be stored in a Clinical Research File (CRF), established for every individual. Data will be transferred into electronic format and saved in a server located in Central Finland Central Hospital (CFCH). The server is protected by username and password. All physical data containing personal information will be stored in the hospital in a locked room. 4.3.4 Anonymous data will be made available on request after the trial has been finished. 4.3.5 Central Finland Hospital District is the owner of the research material. Only members of the research group will be able to access these data.

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3.4 Ethical issues and research permits

A detailed application for the ethical board of the Hospital District has been presented and approved (Dnro 23/2007, May 23rd, 2007).

Participation in the study is voluntary. Patients will be informed about the study, and the current knowledge as well as the risks associated with both treatment options. The patients will also receive written material about their disease and the trial. The patients will be informed that they can leave the study without any negative consequences. Patients accepting the terms of the study will give a written informed consent. All recognisable personal data will remain confidential.

The clinical management of the patients will be carried out according to generally accepted methods. There are no data showing superiority of any method used in this trial to each other. If non-operative treatment fails to provide relief to the symptoms in six to twelve months, adequate surgical intervention will be offered.

3.5 Risk management

The size of population for recruitment was identified as a critical factor. The number of patients was estimated to be sufficient. To accelerate randomization of the patients, the project was converted into a multicentre trial in 2010. The trial has been actively recruiting patients since 2008.

4. Implementation

4.1 Timetable

Recruitment of the patients began in 2008. The patients will be evaluated 3, 6, 12, 24 months and 5 years after intervention.

5. Researchers and research environment

5.1 Research group and merits

Principal investigator

Juha Paloneva, MD, PhD, specialist in orthopaedics and traumatology, Central Finland Central Hospital (CFCH)

Co-PI

Ilkka Kiviranta, MD, PhD, professor, specialist in surgery, specialist in orthopaedics and traumatology, orthopaedist-in-chief, University of Helsinki, Helsinki University Central Hospital, Finland

Graduate student

Sanna Cederqvist, MD, PhD student, resident surgeon, Central Finland Central Hospital (CFCH), Oulu University Hospital, Oulu, Finland

Experts in shoulder surgery

Tapio Flinkkilä, MD, PhD, associate professor, specialist in orthopaedics and traumatology, Oulu University Hospital, Konsta Pamilo, MD, PhD, Central Finland Hospital, Jyväskylä, Finland; Tero Ridanpää, MD, Central Finland Central Hospital, Jyväskylä, Finland;

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<i><u>Expert in rehabilitation</u></i>	Kai Sirniö, MD, PhD, Department of Surgery, Division of Orthopedic and Trauma Surgery, Oulu, Finland;
<i><u>Recruitment of the patients</u></i>	Jari Ylinen, MD, PhD, associate professor, head of the dept. of physical and rehabilitation medicine, CFCH
<i><u>Clinical consultant</u></i>	Sanna Cederqvist, MD (OUH), Tero Irmola MD, Juho Liukkonen MD, Heidi Lehtokangas MD (CFCH), resident surgeons
<i><u>Biostatistician</u></i>	Juhana Leppilahti, MD, Professor, Department of Surgery, Division of Orthopedic and Trauma Surgery, Oulu, Finland; Juho Liukkonen, MD, Department of Emergency Medicine, Central Finland Hospital, Jyväskylä, Finland;
<i><u>Radiologist</u></i>	Hannu Kautiainen Primary Health Care Unit, Kuopio University Hospital, Finland and Folkhälsan Research Center, Helsinki
<i><u>Saara-Maija Hinkkanen</u></i>	MD, PhD, Department of Radiology, Helsinki University Hospital, Helsinki, Finland
<i><u>Nina Sevander-Kreus</u></i>	Physiotherapist, randomization, baseline and follow-up measurements
	Physiotherapist, randomization, baseline and follow-up measurements

5.2 Infrastructure. The trial will be performed in Central Finland Central Hospital and Oulu University Hospital. These hospitals provide the infrastructure (personnel, facilities, and equipment for clinical examination and operations as well as office material and equipment) required by the trial. The examination of the patients including radiographs and MRIs as well as operative treatment and routine postoperative control examination by the operating surgeon belong to the routine clinical practice and do not cause expenses to the project.

Follow-up MRIs 2 years after randomization will be performed at Terveystalo Imaging Services, Jyväskylä, and in Oulu University Hospital, at the Department of Radiology.

5.3.1 National and international collaboration

Oulu University Hospital provides expertise in shoulder surgery, recruitment and examination of patients as well as operative and conservative treatment.

Helsinki University Central Hospital provides collaboration in implementation of national guidelines, produced by our team, for treatment of shoulder disorders in the Hospital District of Helsinki and Uusimaa.

Finnish medical association Duodecim provides expertise in developing national guidelines for management of shoulder disorders.

6. Expected research results and possible risks

6.1 Expected scientific and societal impact. The project provides level I evidence for the treatment of rotator cuff disease. The results help physicians to decide whether the patient should be operated or directed to conservative management. The patients can be offered evidence-based treatments.

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6.2 Potential for scientific breakthroughs. By providing level I evidence on the effectiveness of common surgical shoulder operations there is a potential to more efficiently identify subgroups of patients that recover using conservative treatment or benefit from surgery. It may also be possible to safely reduce the number of operations that do not have sufficient efficacy. This will be a clinical breakthrough and is associated with a significant economical impact.

6.3 Applicability and feasibility. The approach of the trial is pragmatic. The results can be applied to real life clinical practice and recommendations as is.

6.4 Publishment. The project is likely to produce at least 15 publications which will be reported in international and domestic peer-reviewed publication series, and one doctoral thesis. Awareness among potential end-users will also be raised by presenting the results in international and domestic congresses.

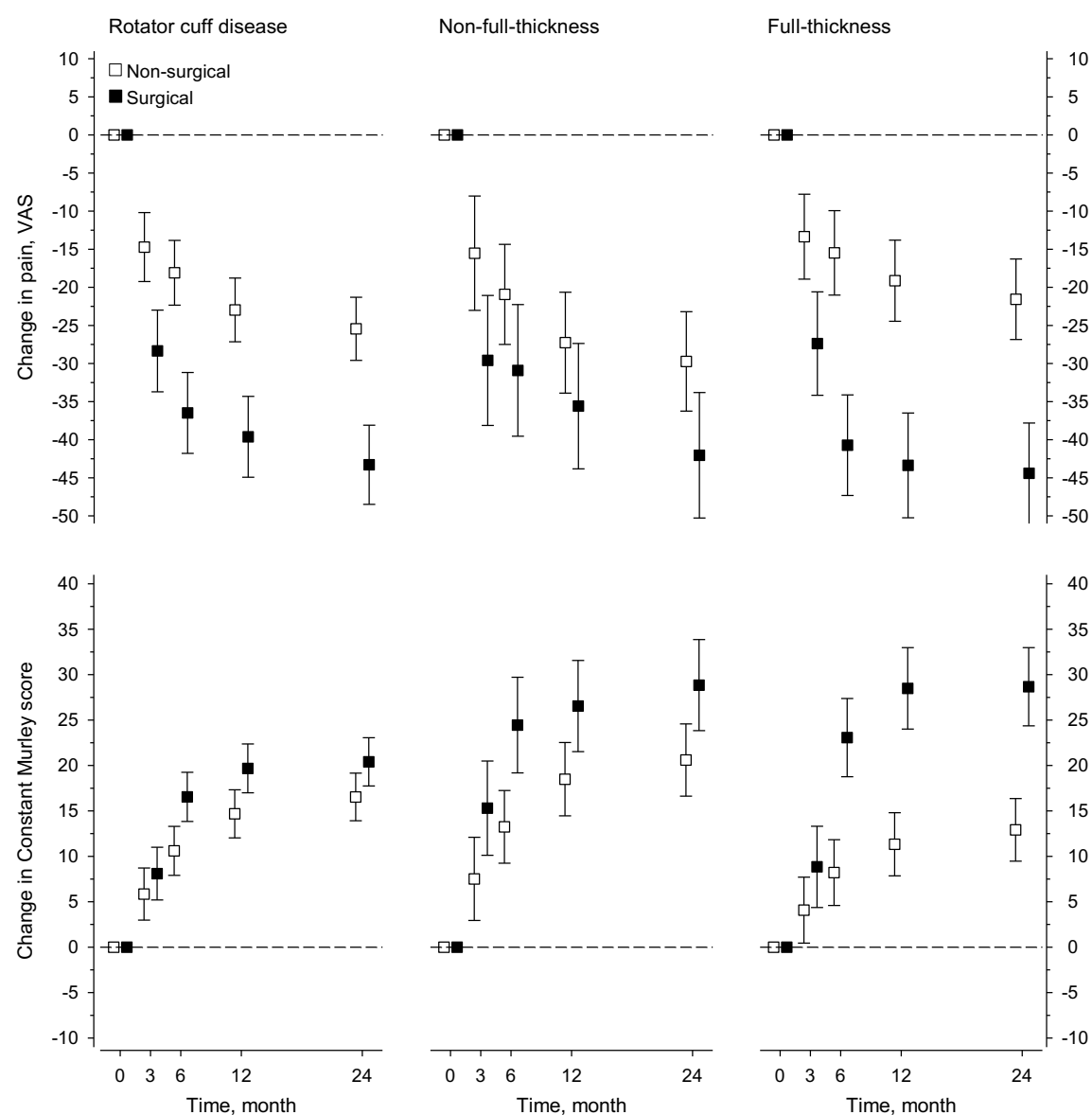
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Figure S3. Graphs showing the per protocol (PP) analysis of change in pain in the visual analogue scale (VAS) and the Constant Murley score (CMS) between baseline and the 2-year follow-up in all patients with rotator cuff disease and without and with full-thickness rotator cuff rupture.



Non-surgical treatment is a good option for people with RCD



Non-surgical treatment is equivalent to surgical treatment even after unsuccessful initial rehabilitation in people with RCD without full-thickness tendon tear.

INTRODUCTION

The rotator cuff is a group of muscles and tendons that surrounds the shoulder joint. Rotator cuff disease (shortened to RCD) is very common and is usually caused by tendon degeneration. RCD may also be associated with an injury. In either case, it causes prolonged shoulder pain and disability in adults. There is a spectrum of RCD, ranging from tendinopathy to full-thickness tendon tear.

Recent studies show that a type of surgery called *subacromial decompression* and non-surgical treatments provide the same results in people with RCD without full-thickness tendon lesion. The importance of surgery for full-thickness tendon tears remains unclear.

WHAT DID THE AUTHORS HOPE TO FIND?

The authors wanted to answer a question frequently asked by GPs, rheumatologists and orthopaedic surgeons: how should I treat a person with RCD?

WHO WAS STUDIED?

The study looked at 417 people with long-term shoulder pain lasting more than 3 months. Everyone was referred from primary and occupational healthcare centres and private clinics to the one of two study hospitals in Finland.

HOW WAS THE STUDY CONDUCTED?

This was a pragmatic, randomised, controlled trial. Everyone with subacromial pain had an MRI image done to confirm the diagnosis of RCD and underwent a 3-month initial rehabilitation. After this time, 190 shoulders still had symptoms, and these people were randomised to non-surgical or surgical treatments. The primary outcome was the mean change in shoulder pain and function after 2 years.

WHAT WERE THE MAIN FINDINGS OF THE STUDY?

The main finding was that non-surgical and surgical treatments for RCD provided equivalent improvements in pain and function.

ARE THESE FINDINGS NEW?

Yes. There have been previous studies, but none have looked at the same thing. This study focused on surgery after adequately performed – but unsuccessful – non-surgical treatment of RCD including both non-full-thickness and full-thickness tendon lesions. In this trial, all potential participants underwent a structured, 3-month rehabilitation before randomisation to ensure that only symptomatic patients were included.

WHAT ARE THE LIMITATIONS OF THE STUDY?

The two main limitations are that this study did not have a placebo surgery group, and the study physiotherapists were not blinded – meaning they knew which treatment people had received. Also, 26% of people were not treated as planned. This is because some people were randomised then decided not to undergo surgery, and some were randomised to non-surgical treatment but later wanted surgery due to severe pain.

WHAT DO THE AUTHORS PLAN ON DOING WITH THIS INFORMATION?

The authors plan to do a longer follow-up to clarify whether non-surgical or surgical treatment is the best option for RCD. Their 5-year follow-up results will be reported later.

WHAT DOES THIS MEAN FOR ME?

If you have RCD, the best choice will be made in discussion with your doctor. The authors of this paper recommend non-surgical treatment as the primary choice. However, surgery can give superior improvement in pain and function for people with a full-thickness rotator cuff rupture. Therefore, rotator cuff tendon repair may be suggested if non-surgical treatment does not work for you.

If you have any concerns about your disease or its treatment, you should talk to your doctor.

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