■ SHOULDER AND ELBOW

Effectiveness of open and arthroscopic rotator cuff repair (UKUFF)

A RANDOMISED CONTROLLED TRIAL

A. Carr,
C. Cooper,
M. K. Campbell,
J. Rees,
J. Moser,
D. J. Beard,
R. Fitzpatrick,
A. Gray,
J. Dawson,
J. Murphy,
H. Bruhn,
D. Cooper,
C. Ramsay

From NDORMS, University of Oxford, Oxford, United Kingdom

■ A. Carr, DSc FMedSci , Nuffield Professor of Orthopaedic Surgery
■ C. Cooper, MSc, Senior Trial Manager
■ J. Rees, MD, Professor of Orthopaedic Surgery and Musculoskeletal Science, NDORMS
■ D. J. Beard, DPhil, Professor of Musculoskeletal Sciences; Co-Director, Royal College of Surgeons Surgical Trials Unit (SITU-Oxford) University of Oxford, Botnar Research Centre, Windmill Road, Headington, Oxford OX3 7LD, UK.

■ M. K. Campbell, PhD, Professor of Health Services Research
■ H. Bruhn, PhD, Trial Manager
■ D. Cooper, PhD, Statistician
■ C. Ramsay, BSc, PGDip, PhD, Professor, Unit Director University of Aberdeen, Health Services Research Unit, Foresterhill, Aberdeen, AB25 2ZD, UK.

■ J. Moser, MSc, Consultant Physiotherapist
Nuffield Orthopaedic Centre, Oxford University Hospitals Trust, Windmill Road, Headington, Oxford, OX3 7HE, UK.

■ R. Fitzpatrick, DPhil, Professor of Public Health and Primary Care, Nuffield Department of Population Health
■ A. Gray, PhD, Professor of Health Economics and Director HERC, Nuffield Department of Population Health
University of Oxford, Richard Doll Building, Old Road Campus, Oxford, OX3 7LF, UK.

■ J. Dawson, MA, MSc, DPhil, Professor, Nuffield Department of Population Sciences
■ J. Murphy, DPhil, Health Economist, Nuffield Department of Population Sciences
University of Oxford, Old Road Campus, OX3 7LF, UK.

Correspondence should be sent to A. Carr; email: andrew.carr@ndorms.ox.ac.uk

doi:10.1302/0301-620X.99B1.BJJ-2016-0424.R1 $2.00

Bone Joint J 2017;99-B:107–15.
Received 12 May 2016; Accepted after revision 23 September 2016

Aims

The appropriate management for patients with a degenerative tear of the rotator cuff remains controversial, but operative treatment, particularly arthroscopic surgery, is increasingly being used. Our aim in this paper was to compare the effectiveness of arthroscopic with open repair of the rotator cuff.

Patients and Methods

A total of 273 patients were recruited to a randomised comparison trial (136 to arthroscopic surgery and 137 to open surgery) from 19 teaching and general hospitals in the United Kingdom. The surgeons used their usual preferred method of repair. The Oxford Shoulder Score (OSS), two years post-operatively, was the primary outcome measure. Imaging of the shoulder was performed at one year after surgery. The trial is registered with Current Controlled Trials, ISRCTN97804283.

Results

The mean OSS improved from 26.3 (standard deviation (SD) 8.2) at baseline, to 41.7 (SD 7.9) two years post-operatively for arthroscopic surgery and from 25.0 (SD 8.0) to 41.5 (SD 7.9) for open surgery. Intention-to-treat (ITT) analysis showed no statistical difference between the groups at two years (difference in OSS score -0.76; 95% confidence interval (CI) -2.75 to 1.22; p = 0.452). The confidence interval excluded the pre-determined clinically important difference in the OSS of three points. The rate of re-tear was not significantly different between the two groups (46.4% for arthroscopic and 38.6% for open surgery; 95% CI -6.9 to 25.8; p = 0.256). Healed repairs had the most improved OSS. These findings were the same when analysed per-protocol.

Conclusion

There is no evidence of difference in effectiveness between open and arthroscopic repair of rotator cuff tears. The rate of re-tear is high in both groups, for all sizes of tear and ages and this adversely affects the outcome.

Cite this article: *Bone Joint J* 2017;99-B:107–15.

Symptoms from the shoulder are common, occurring in approximately 14% of the population. In the United Kingdom, between 1% and 2% of adults seek advice annually from their general practitioner (GP) for symptoms from the shoulder[1] and constitute 2.4% of all GP consultations made per annum.[2] About 70% of patients with these symptoms have rotator cuff pathology,[3] which can impair the ability to work and affect activities of daily living.[4] The risk of a rotator cuff tear increases significantly with age.[5] In the United States, more than of 300 000 rotator cuff repairs are performed annually at a cost of about $3 billion.[6]

Despite the conservative management of rotator cuff tears, surgery is often required for patients with persistent pain and functional impairment.[3] However, recurrent tears may follow surgery. Recurrences are more commonly found in larger tears and surgery is less successful in older patients and in those with radiological evidence of fatty degeneration of the rotator cuff muscles.[7,8] Rates of re-rupture range from 13% to 68%[9-11] and may be associated with a poor outcome.[12] There was a marked increase in the number of rotator cuff repairs which were undertaken in New York between 1996 and 2006, from 30.0 to 101.9 per 100 000 people per year.[13] In the United Kingdom there was a fivefold increase of between 2001 and 2010.[14] This involved a sixfold increase in arthroscopic repairs compared with a 34% increase in open repairs.[15] It has been argued that arthroscopic repair allows for

a more effective repair through better visualisation of the tissues and causes less damage locally, allowing faster post-operative recovery. However, which technique gives better clinical results remains unclear.[16-23]

We have conducted a randomised controlled trial (RCT) to compare the effectiveness of these two forms of repair.

Patients and Methods

The design was a pragmatic multicentre, parallel group, comparative effectiveness RCT of open *versus* arthroscopic rotator cuff repair (UKUFF REC Reference Number 10/H0402/24). The study involved 19 centres in the United Kingdom and was conducted between November 2007 and December 2012. It was modified in 2009 with the removal of a non-operative arm due to high rates of early crossover to surgery. Patients were included if they were aged > 50 years with symptoms from a degenerative full thickness tear of the rotator cuff and had failed to respond to conservative treatment including physiotherapy and cortisone injection. Full inclusion and exclusion criteria were published in the protocol.[24]

Surgery was either arthroscopic (fixation of tendon to bone using only arthroscopic techniques) or open (fixation to bone under direct vision through a surgically created opening in the deltoid muscle). The precise technique and method of fixation was not prescribed and surgeons used their preferred method. Details of the technique including the method of repair and theatre equipment were recorded, as well as the size of the tear and the ease and completeness of the repair. An alternative procedure was recorded if the allocated technique could not be carried out. Surgeons had to perform a minimum of five rotator cuff repairs per year to be eligible to take part in the trial. The participating surgeons represented a cross-section of high, medium and low volume practitioners from both general and teaching hospitals.

Randomisation and masking. Recruitment of patients occurred in two steps. Their eligibility was assessed by the local Consultant Orthopaedic Surgeon who introduced the trial to the patient using a prompt sheet and an assessment form. If patients agreed to take part, they were randomised using an automated service provided by the Centre for Healthcare Randomised Trials (CHaRT) at the Health Services Research Unit, University of Aberdeen.[25] Allocation was minimised using surgeon, age (< and > 65 years) and size of tear (small, medium, large and massive). After randomisation the patient was considered irrevocably part of the trial, irrespective of what occurred subsequently. In view of the nature of the interventions, patients were aware of treatment allocation.

Outcomes. The primary outcome measure was the Oxford Shoulder Score (OSS),[26] completed at two years after randomisation. Secondary outcome measures included the assessment of function and health related quality of life using the Shoulder Pain and Disability Index (SPADI),[27] the Mental Health Inventory (MHI-5)[28] and the EuroQol-5D scale (EQ-5D).[29,30] The outcomes assessed pain, weakness and loss of function. The patients rated satisfaction at 12 and 24 months and the overall state of their shoulder at eight, 12 and 24 months after randomisation. Surgical complications intra-operatively and at two and eight weeks post-operatively were recorded, and also at one and two years after randomisation. All patients who underwent a rotator cuff repair were assessed with MRI or high definition ultrasound imaging 12 months after surgery by a clinician blinded to the form of treatment.

Sample size. The sample size was constructed to detect a difference in the OSS[26] 24 months post-operatively of 0.38 of a standard deviation (SD) for the comparison of arthroscopic *versus* open surgery at 80% power. This difference was based on our experience of developing the OSS and using it in a variety of settings, where a three-point score difference was deemed a clinically important difference.[31]

The detectable difference of 0.38 was originally constructed by combining evidence from a direct randomised comparison with indirect (non-randomised) comparison data from the original non-operative arm. However, when that arm was dropped the sample size was reassessed with the aim of detecting the difference of 0.38 of an SD by direct randomised comparison data only. Attrition was expected to be low (10%) as were the effects of clustering of outcomes within surgeon (intracluster correlation (ICC) < 0.03).[32-34] Both of these factors required the sample size to be increased; however, the primary analysis was to be adjusted for a baseline OSS, which conversely allowed the sample size to be decreased by a factor of "1-correlation squared". Our previous studies showed that the correlation in the OSS between the pre-operative value and that at six months post-operatively in patients similar to the potential participants in this trial was 0.57. Assuming a conservative correlation of 0.5 implied that the sample size could be reduced by 25%, and still maintain the same power. Therefore, a study with a total of 267 patients was considered sufficiently powered to detect a clinically important change in each comparison, assuming that attrition and clustering accounted for approximately 25% of variation in the data. The target level of power was 80% and clustering was by centre. An independent Data Monitoring Committee met on four occasions and did not recommend any fundamental changes to the protocol.

The primary statistical analyses were based on the intention-to-treat (ITT) principle, and thus all patients who were randomised, irrespective of subsequent compliance, were analysed with the randomised intervention. The outcomes were compared using repeated measures mixed models with centre as a random effect, and with adjustment for minimisation variables (size of tear and age) and the baseline values for each patient, where available, as fixed effects. Reflecting the level of noncompliance, the effect on the primary outcome of those patients who actually received an arthroscopic or open repair was estimated (a "per-protocol analysis") by the instrumental variable approach as described by Nagelkerke et al[35] As with the ITT analysis, the model also adjusted for centre, minimisa-

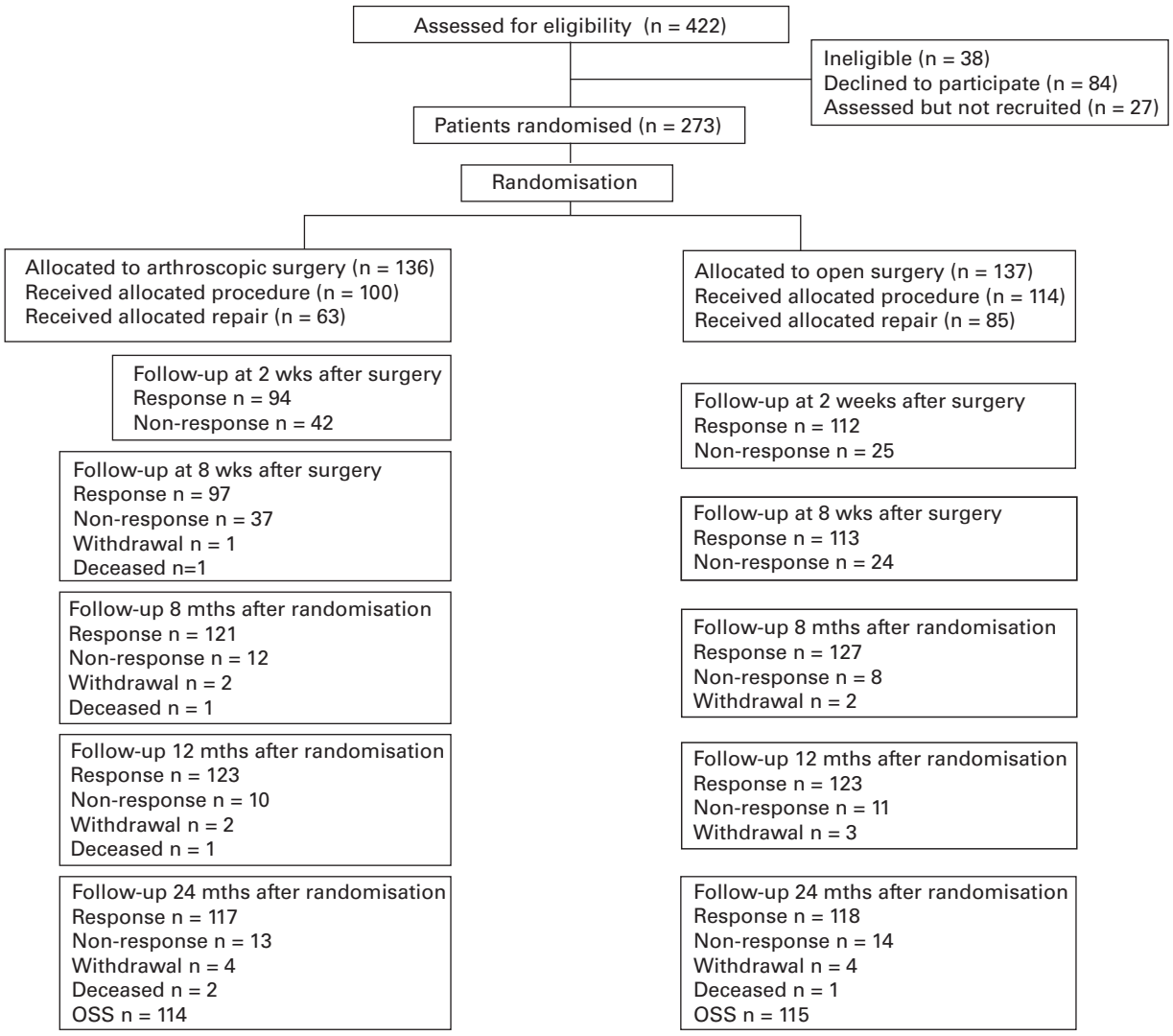

Fig. 1

Trial profile.

tion variables (age; size of tear) and baseline OSS score. The learning effects of the performance of the surgeon improving during the trial were tested for by developing a covariate for each surgeon that indicates increasing experience in the trial (e.g. first patient randomised = 1; second = 2 etc). This covariate was used in subsequent analyses to measure the size of trend in effects over time.

Subgroup analyses were also undertaken by the size of the tear (small *versus* medium/large) and age (≤ 65 *versus* > 65) using tests of interaction. Subgroup analyses were two-sided tests at 1% significance. If a patient was followed up at eight, 12 or 24 months but was missing at baseline the missing baseline data was replaced by the mean for the centre. Conservative levels of statistical significance ($p < 0.01$) were sought reflecting the exploratory nature of these analyses.

Results

A total of 273 from 422 eligible patients in 19 centres were recruited during the period of the study. The trial flowchart is shown in Figure 1. Baseline characteristics were balanced between the two randomised groups (Table I). Table II shows the type of procedure undertaken in each group. For the 136 patients randomised to the arthroscopic group, nearly half (63; 46.3%) underwent a full arthroscopic repair. A few began as an arthroscopic procedure and were converted to open, others underwent an arthroscopic procedure and 36 (26.5%) did not undergo any surgery. Of the arthroscopic procedures not involving a repair, a subacromial decompression was the most common. A total of 100 patients (73.5%) underwent the intended randomised arthroscopic procedure, though only 63 (46.3%) had an arthroscopic repair. Of the 137 who were randomised to

Table I. Baseline characteristics of patients for the intention-to-treat (ITT) and per protocol analyses

Results for all patients (ITT)		**Arthroscopic surgery group (n = 136)**	**Open surgery group (n = 137)**
Age (yrs) (mean, SD)		62.9 (7.1)	62.9 (7.5)
Duration of shoulder problem (yrs) (mean, SD)		2.6 (5.3)	2.5 (4.1)
Gender (n, %)	Male	81 (*59.6*)	88 (*64.2*)
	Female	55 (*40.4*)	49 (*35.8*)
Handedness (n, %)	Right-handed	125 (*91.9*)	115 (*83.9*)
	Left-handed	7 (*5.1*)	17 (*12.4*)
	Both	4 (*2.9*)	5 (*3.6*)
Highest qualification (n, %)	None	63 (*46.3*)	59 (*43.1*)
	Secondary	41 (*30.1*)	49 (*35.8*)
	Higher	32 (*23.5*)	27 (*19.7*)
	Missing	0	2 (*1.5*)
Employment status (n, %)	Full-time	47 (*34.6*)	58 (*42.3*)
	Part-time	18 (*13.2*)	15 (*10.9*)
	Homemaker	4 (*2.9*)	5 (*10.9*)
	Retired	59 (*43.4*)	54 (*39.4*)
	Unemployed	7 (*5.1*)	4 (*2.9*)
	Missing	1 (*0.7*)	1 (*0.7*)
Off-sick (n, %)		7 (*10.8*)	6 (*8.2*)
Working reduced hours (n, %)		10 (*15.4*)	7 (*9.6*)
Not off sick or working reduced (n, %)	Hours	45 (*62.9*)	76 (*55.9*)
	Missing	3 (*4.6*)	2 (*2.8*)
OSS (mean, SD)		26.2 (8.1)	25 (7.9)
SPADI (mean, SD)		60.9 (22.0)	61.6 (22.0)
SPADI pain (mean, SD)		70.0 (19.5)	70.1 (20.5)
SPADI disability (n; mean, SD)		136; 55.1 (25.0)	135; 56.4 (24.7)
MHI-5 (n; mean, SD)		136; 22.5 (4.9)	137; 22.9 (4.5)
EQ-5D (n; mean, SD)		135; 0.548 (0.299)	136; 0.519 (0.291)
Size of tear (n, %)	Small/medium	103 (*75.7*)	103 (*75.2*)
	Large/massive	33 (*24.3*)	34 (*24.8*)
Method of diagnosing tear (n, %)	MRI	41 (*30.1*)	36 (*26.3*)
	Ultrasound	87 (*64.0*)	93 (*67.9*)
	Missing	8 (*5.9*)	8 (*5.8*)
Received no treatment on the shoulder in the last 5 yrs (n, %)		15 (*11.0*)	10 (*7.3*)
Received physiotherapy on the Shoulder in last 5 yrs (n, %)	Yes	77 (*56.6*)	83 (*60.6*)
	No	41 (*30.1*)	38 (*27.7*)
	Missing	18 (*13.2*)	16 (*11.7*)
Received cortisone injection in shoulder in last 5 yrs (n, %)	Yes	79 (*58.1*)	83 (*60.6*)
	No	40 (*29.4*)	35 (*25.5*)
	Missing	17 (*12.5*)	19 (*13.9*)
Received other treatment on the shoulder in the last 5 yrs (n, %)	Yes	18 (*13.2*)	28 (*20.4*)
	No	72 (*52.9*)	61 (*44.5*)
	Missing	46 (*33.8*)	48 (*35.0*)

SD, standard deviation; OSS, Oxford Shoulder Score; SPADI, Shoulder Pain and Disability Index; MHI-5, Mental Health Inventory; EQ-5D,EuroQol-5D scale

open surgical management, 85 (61.6%) had an open repair and five (3.6%) had an arthroscopic repair. A total of 24 had another concomitant arthroscopic procedure, the most common also being a subacromial decompression. A total of 23 did not undergo any surgery, the main reasons being related to either medical comorbidities or that they were asymptomatic and therefore did not require either procedure.

The size of tear was similar in the two groups. The mean operating time was statistically significantly shorter in the open group (open, 57.2 minutes; arthroscopic, 69.4 minutes; effect size -12.2; 95% confidence interval (CI) -21.4 to -3.0, p = 0.010) as was the mean total time in the operating theatre (open, 87.6 minutes; arthroscopic, 100.3 minutes; effect size -12.7; 95% CI -23.5 to -1.9, p = 0.021).

A total of three patients in each group required re-admission after surgery and two in each group required revision surgery. One in each group had a post-operative complication; one being a deep infection requiring debridement and the other patient required a longer stay in hospital for pain relief. All complications and revision operations were managed within 17 months of randomisation. A total of three patients died of unrelated causes during follow-up, two in the arthroscopic group and one in the open group.

The data at two weeks after surgery are shown in Table III, when few patients reported being pain-free and approximately two thirds were taking painkillers. Of those who were employed, about 80% were still off work, but there were no clinically important differences between the groups. The data at eight weeks after surgery were similar

Table II. Adherence to the form of surgical management in each group

	Surgery group	
	Arthroscopic (n = 136) (n, %)	**Open (n = 137) (n, %)**
Received any surgery	100 (*73.5*)	114 (*83.2*)
Received an arthroscopic repair	63 (*46.3*)	5 (*3.6*)
Received an open repair after attempted arthroscopic repair	9 (*6.6*)	0
Received an open repair	0	85 (*62.0*)
Received another operative procedure	28 (*20.6*)	24 (*17.5*)
ASAD	20 (*14.7*)	16 (*11.7*)
ASAD and excision distal clavicle	1 (*0.7*)	3 (*2.2*)
Biceps tenotomy	2 (*1.5*)	0
Capsular release	1 (*0.7*)	2 (*1.5*)
Partial thickness repair	0	2 (*1.4*)
Not documented	4 (*3.0*)	1 (*0.7*)
Did not receive intervention	36 (*26.5*)	23 (*16.8*)
Still awaiting surgery when study ended	2 (*1.5*)	2 (*1.5*)
Cancelled due to other medical problem	11 (*8.1*)	3 (*2.2*)
Complete withdrawal from study	2 (*1.5*)	0
Due to family commitments	2 (*1.5*)	1 (*0.7*)
No longer symptomatic	7 (*5.1*)	7 (*5.1*)
Patient deceased	1 (*0.7*)	0
Patient withdrew from waiting list for unspecified reasons	7 (*5.1*)	7 (*5.1*)
Work commitments	3 (*2.2*)	2 (*1.5*)
Unknown	1 (*0.7*)	1 (*0.7*)

ASAD, arthroscopic subacromial decompression

to those at two weeks with the exception that those with no or mild pain improved from 35% to 50%, with the concomitant effect of reducing the use of painkillers from 66% to 55%, and the number who had returned to work increased from 28% to 55%. There were no clinically important differences between the groups at this time.

The OSSs two years post-operatively are shown in Table IV and Figure 2. Using ITT analysis, there was no evidence of a difference between the two groups (difference = -0.76; 95% CI -2.75 to 1.22; p = 0.452). The CIs were small enough to exclude the pre-specified clinically important difference of three points. The per-protocol sensitivity analysis of the primary outcome measure produced a similar result to the ITT analysis though the CIs were wider (difference = -0.46; 95% CI -5.30 to 4.39; p = 0.854). There was no evidence of any differences between the groups in any of the measures of general health at all follow-up times. The mean OSS increased markedly from baseline (25.7) to eight months post-operatively (36.5) and continued to increase although at a slower rate to 24 months (41.5).

The rate of re-tear was similar in both groups, 46.4% for arthroscopic *versus* 38.6% for open surgery (relative effect: odds ratio 1.52; 95% CI 0.84 to 2.75; absolute risk difference 9.5%; 95% CI -6.9 to 25.8; p = 0.256) (Table V).

The OSS showed a consistent pattern within each group, whereby in those patients in whom repair of the rotator cuff was not possible, the OSS was worse. Those with a re-tear had a slightly better OSS and finally those with no tears had the most improved OSS. The OSS improved in both the arthroscopic and open groups. The next best results were for the repaired tears that re-tore. The worst results were in those with an irreparable tear (Table VI).

There was no evidence that any of the subgroups were statistically significantly different at the 1% level (p = 0.843 for the size of the tear and p = 0.024 for age). The statistical model to investigate any trend in OSS at two years as the experience of the surgeon increased during the trial did not show any significant learning effect (trend in OSS + 0.04 per procedure; 95%CI -0.21 to 0.29; p = 0.744).

Discussion

This multicentre trial, conducted in 19 centres in the United Kingdom is the largest trial of rotator cuff repair ever undertaken globally. The results have shown no significant differences in effectiveness between arthroscopic and open surgery. A significant improvement in the primary outcome, the change in the OSS between baseline and two years post-operatively, and in all the secondary outcome measures which included the SPADI, EQ-5D and MHI5 was found with both surgical techniques. The rate of significant complications was very low and less than that described by Moosmayer et al,[36] but similar to that of Kukkonen et al.[37] The overall rate of infection was 0.7% and the rate of revision surgery was 1.5%.

Healed repairs have the best clinical outcome, repaired tears that re-tore had the next best outcome and the worst results were seen in patients with irreparable tears. The mean difference in the OSS at two years between healed tears, re-tears and irreparable tears was approximately three OSS points for each. The clinical improvement seen in the patients with re-tears may be explained by one or more of the following factors. First, the repair may have healed partially, resulting in a smaller tear with improved function and less pain. Secondly, the interpretation of post-operative

Table III. Data at two weeks after surgery

Results for all patients	Arthroscopic surgery group (n = 136) (n, %)	Open surgery group (n = 137) (n, %)
Completed follow-up	94 (*69.1*)	112 (*81.8*)
Within the last 24 hrs have you worn a sling?		
Yes	60 (*63.8*)	78 (*69.6*)
No	32 (*34.0*)	31 (*27.7*)
Missing	2 (*2.1*)	3 (*2.7*)
Within the last 24 hrs how would you regard the worst pain from your shoulder?		
None	6 (*6.4*)	6 (*5.4*)
Mild	30 (*31.9*)	34 (*30.4*)
Moderate	36 (*38.3*)	50 (*44.6*)
Severe	17 (*18.1*)	19 (*17.0*)
Unbearable	3 (*3.2*)	1 (*0.9*)
Missing	2 (*2.1*)	2 (*1.8*)
Were you troubled by pain from your shoulder in bed last night?		
No, not at all	25 (*26.6*)	25 (*22.3*)
Yes, just at first	8 (*8.5*)	6 (*5.4*)
Yes, some of the night	38 (*40.4*)	44 (*39.3*)
Yes, through the night	21 (*22.3*)	35 (*31.3*)
Missing	2 (*2.1*)	2 (*1.8*)
Within the last 24 hrs have you taken any painkillers because of your shoulder?		
Yes	62 (*66.0*)	76 (*67.9*)
No	29 (*30.9*)	34 (*30.4*)
Missing	3 (*3.2*)	2 (*1.8*)
Are you currently employed?		
Yes	46 (*48.9*)	57 (*50.9*)
No	46 (*48.9*)	53 (*47.3*)
Missing	2 (*2.1*)	2 (*1.8*)
If employed are you:		
Off sick	38 (*82.6*)	44 (*77.2*)
On reduced duties	3 (*6.5*)	5 (*8.8*)
Working usual hours and duties	5 (*10.9*)	8 (*14.0*)

Table IV. Health status at 8, 12 and 24 months post-operatively

Results for all patients (ITT)	Arthroscopic surgery group (n = 136) (n; mean, SD)	Open surgery group (n = 137) (n; mean, SD)	p-value
OSS at baseline	129; 26.3 (8.2)	131; 25.0 (8.0)	
OSS at 8 mths	121; 36.1 (9.2)	127; 37.0 (8.6)	0.200
OSS at 12 mths	122; 38.3 (9.5)	122; 39.6 (8.5)	0.108
OSS at 24 mths	114; 41.7 (7.9)	115; 41.5 (7.9)	0.452
MHI5 at baseline	128; 22.4 (4.9)	130; 22.9 (4.5)	
MHI5 at 8 mths	118; 23.8 (4.9)	124; 23.8 (4.4)	0.500
MHI5 at 12 mths	118; 23.5 (5.0)	119; 23.6 (4.6)	0.783
MHI5 at 24 mths	116; 24.4 (4.0)	118; 24.3 (4.5)	0.648
EQ5D at baseline	129; 0.551 (0.297)	131; 0.518 (0.293)	
EQ5D at 8 mths	120; 0.680 (0.300)	124; 0.700 (0.257)	0.296
EQ5D at 12 mths	119; 0.727(0.278)	118; 0.711(0.300)	0.724
EQ5D at 24 mths	116; 0.76(0.235)	118; 0.778(0.219)	0.163

ITT, intention-to-treat; SD, standard deviation; OSS, Oxford Shoulder Score; MHI-5, Mental Health Inventory; EQ-5D, EuroQol-5D scale

scans is prone to error due to anatomical changes created by the surgery, and determining the size of a further tear is difficult. Thirdly, the subacromial decompression and debridement that was invariably performed in these patients may also result in an improvement in symptoms and function. Fourthly, there may be a treatment effect due to the period of rest and physiotherapy after surgery. Fifthly there may be a placebo component to the treatment effect. A total of 22 patients (27.2%) withdrew from the trial whilst on the waiting list for surgery due to resolution of symptoms. Previous studies have reported that a re-tear is more likely after repair of large and massive tears due partly to the increased difficulty in fixing tendon to bone securely without tension at the suture/tendon interface and partly to the reduced healing potential in the tendons with larger tears.[7-12] In this study, re-tears were found in all sizes of tear and we found no difference in the rate of re-tear between small/medium and large/massive tears. These earlier studies[7-12] also link the development of a further tear to advancing age. We, however, found no difference in the rates of re-tear between those aged < 65 years and > 65 years. This may be because the number of large and massive tears and patients aged > 65 was relatively small.

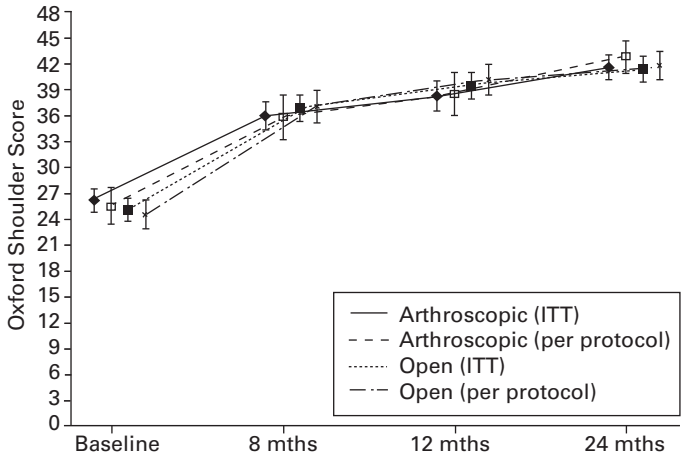

Fig. 2

Mean and 95% confidence intervals of Oxford Shoulder Scores for arthroscopic and open surgery for the intention-to-treat (ITT) and per protocol analyses.

Table V. Imaging at baseline and one year post-operatively

	Arthroscopic surgery group (n = 136) (n, %)	Open surgery group (n = 137) (n, %)	p-value
Size of tear			
Small/medium	103 (*75.7*)	103 (*75.2*)	
Large/massive	33 (*24.3*)	34 (*24.8*)	
Received any surgery	100 (*73.5*)	114 (*83.2*)	
Rotator cuff repairs performed	72 (63 arthroscopic, 9 arthroscopic converted to open)	90 (85 open, 5 arthroscopic)	
Scans performed at 12 mths	69	83	
Scan results (all tears)			
Re-tear	32 (*46.4*)	32 (*38.6*)	0.256
Healed repair	32 (*46.4*)	47 (*56.6*)	
Inconclusive	1 (*1.4*)	1 (*1.2*)	
Missing	4 (*5.8*)	3 (*3.6*)	
Size of re-tear (all tears)			
Small/medium	16 (*50.0*)	20 (*62.5*)	
Large/massive	13 (*40.6*)	10 (*31.3*)	
Not clear	3 (*9.4*)	2 (*6.3*)	

Table VI. Oxford Shoulder Score at two years

	Arthroscopic surgery group (n; mean, SD)	Open surgery group (n; mean, SD)
OSS at 2 yrs (all tears)		
Healed repair	30; 44.5 (4.1)	47; 43.6 (5.8)
Re-tear	30; 41.8 (8.8)	29; 40.8 (7.6)
Impossible to repair	7; 37.3 (6.1)	8; 35.1 (9.7)

SD, standard deviation; OSS, Oxford Shoulder Score

Despite a significant increase in the rate of surgery to repair the rotator cuff during the past ten years, evidence for the real effectiveness of this procedure is poor.[38-41] The UKUFF trial was carried out in 19 centres representing the real world in which rotator cuff repair is performed making the results highly applicable. Previous studies and trials have been small and have involved either only one or a small number of centres, and have therefore not had the same generalisability as this trial.

The study has limitations. The rate of withdrawal from the planned surgery was high. We believe that this reflects the usual rates of withdrawal from waiting lists that are seen for this procedure in the United Kingdom. The reasons for withdrawal included resolution of symptoms and the development of other medical conditions that prevented surgery taking place. The levels of withdrawal were equal in both groups. The reasons why patients did not undergo a repair were either that no tear was found at the time of surgery or that it was irreparable, because it was too large, too retracted or the quality of the tissue did not allow secure fixation. Although caution must be used in interpreting these results, it is important to note that the lack of

a significant difference between the arthroscopic and open ITT groups was also observed in the per protocol data.

In conclusion, the best outcome was seen in patients in whom the repair had healed. The rates of re-tear were high and re-tears were found in all sizes of tear and all ages of patients. New strategies to improve tendon healing are needed to improve the outcomes.

Take home message:

- There is no evidence of benefit of arthroscopic rotator cuff repair when compared with open repair.
- The rate of re-tear is high (40%) with no difference between the two surgical methods of repair.
- Healed repairs have the best clinical outcome.

Author contributions:

A. Carr: Contributed to the design and development of the study protocol, Data analysis and interpretation, Writing manuscript, Read, commented on and approved the final manuscript.
C. Cooper: Contributed to the design and development of the study protocol, Data analysis and interpretation, Writing manuscript, Read, commented on and approved the final manuscript.
M. K. Campbell: Contributed to the design and development of the study protocol, Data analysis and interpretation, Statistical input, Read, commented on and approved the final manuscript.
J. Rees: Contributed to the design and development of the study protocol, Data analysis and interpretation, Read, commented on and approved the final manuscript.
J. Moser: Contributed to the design and development of the study protocol, Data analysis and interpretation, Read, commented on and approved the final manuscript.
D. J. Beard: Contributed to the design and development of the study protocol, Data analysis and interpretation, Read, commented on and approved the final manuscript.
R. Fitzpatrick: Contributed to the design and development of the study protocol, Data analysis and interpretation, Read, commented on and approved the final manuscript.
A. Gray: Contributed to the design and development of the study protocol, Data analysis and interpretation, Read, commented on and approved the final manuscript.
J. Dawson: Contributed to the design and development of the study protocol, Data analysis and interpretation, Read, commented on and approved the final manuscript.
J. Murphy: Contributed to the design and development of the study protocol, Data analysis and interpretation, Read, commented on and approved the final manuscript.
H. Bruhn: Contributed to the design and development of the study protocol, Data analysis and interpretation, Read, commented on and approved the final manuscript.
D. Cooper: Contributed to the design and development of the study protocol, Data analysis and interpretation, Statistical input, Read, commented on and approved the final manuscript.
C. Ramsay: Contributed to the design and development of the study protocol, Data analysis and interpretation, Statistical input, Read, commented on and approved the final manuscript.

The UKUFF study is funded by National Institute for Health Research (NIHR) Health Technology Assessment programme (grant reference number 05/47/02). This study was supported by Oxford Surgical Intervention Trials Unit (SITU) and the Royal College of Surgeons Surgical Trials Initiative. UKUFF was also supported by the Oxford NIHR Biomedical Research Centre and Biomedical Research Units. The authors would like to thank all participants for their involvement in the study and all the principal investigators and their teams at each of the UKUFF sites and to the British Elbow and Surgery Society (BESS). Independent members of the Trial Steering Committee were as follows: Professor Jane Blazeby (Chair), Ms Jo Gibson, Mr David Stanley, Dr Andrew Cook, Major General Dair Farrar-Hockley (patient and public representative) and Professor Jeremy Fairbank. Members of the independent Data Monitoring Committee were as follows: Professor Roger Emery (Chair), Dr Jeremy Lewis and Dr Richard Morris.The funding source had no role in the design and conduct of the study, in the collection, analysis and interpretation of the data, or in the preparation, review, or approval of the manuscript.

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

This article was primary edited by S. P. F. Hughes and first proof edited by J. Scott.

References

1. **Urwin M, Symmons D, Allison T, et al.** Estimating the burden of musculoskeletal disorders in the community: the comparative prevalence of symptoms at different anatomical sites, and the relation to social deprivation. *Ann Rheum Dis* 1998;57:649–655.
2. **Linsell L, Dawson J, Zondervan K, et al.** Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. *Rheumatology (Oxford)* 2006;45:215–221.
3. **Mitchell C, Adebajo A, Hay E, Carr A.** Shoulder pain: diagnosis and management in primary care. *BMJ* 2005;331:1124–1128.
4. **van der Windt DA, Thomas E, Pope DP, et al.** Occupational risk factors for shoulder pain: a systematic review. *Occup Environ Med* 2000;57:433–442.
5. **Sher JS, Uribe JW, Posada A, Murphy BJ, Zlatkin MB.** Abnormal findings on magnetic resonance images of asymptomatic shoulders. *J Bone Joint Surg [Am]* 1995;77-A:10–15.
6. **Oh LS, Wolf BR, Hall MP, Levy BA, Marx RG.** Indications for rotator cuff repair: a systematic review. *Clin Orthop Relat Res* 2007;455:52–63.
7. **Goutallier D, Postel JM, Gleyze P, Leguilloux P, Van Driessche S.** Influence of cuff muscle fatty degeneration on anatomic and functional outcomes after simple suture of full-thickness tears. *J Shoulder Elbow Surg* 2003;12:550–554.
8. **Matthews TJ, Hand GC, Rees JL, Athanasou NA, Carr AJ.** Pathology of the torn rotator cuff tendon. Reduction in potential for repair as tear size increases. *J Bone Joint Surg [Br]* 2006;88-B:489–495.
9. **Harryman DT II, Mack LA, Wang KY, et al.** Repairs of the rotator cuff. Correlation of functional results with integrity of the cuff. *J Bone Joint Surg [Am]* 1991;73-A:982–989.
10. **Bishop J, Klepps S, Lo IK, et al.** Cuff integrity after arthroscopic versus open rotator cuff repair: a prospective study. *J Shoulder Elbow Surg* 2006;15:290–299.
11. **Boileau P, Brassart N, Watkinson DJ, et al.** Arthroscopic repair of full-thickness tears of the supraspinatus: does the tendon really heal? *J Bone Joint Surg [Am]* 2005;87-A:1229–1240.
12. **Fehringer EV, Sun J, VanOeveren LS, Keller BK, Matsen FA III.** Full-thickness rotator cuff tear prevalence and correlation with function and co-morbidities in patients sixty-five years and older. *J Shoulder Elbow Surg* 2008;17:881–885.
13. **Vitale MA, Arons RR, Hurwitz S, Ahmad CS, Levine WN.** The rising incidence of acromioplasty. *J Bone Joint Surg [Am]* 2010;92-A:1842–1850.
14. **Judge A, Murphy RJ, Maxwell R, Arden NK, Carr AJ.** Temporal trends and geographical variation in the use of subacromial decompression and rotator cuff repair of the shoulder in England. *Bone Joint J* 2014;96-B:70–74.
15. **Colvin AC, Egorova N, Harrison AK, Moskowitz A, Flatow EL.** National trends in rotator cuff repair. *J Bone Joint Surg [Am]* 2012;94-A:227–233.
16. **Chaudhury S, Gwilym SE, Moser J, Carr AJ.** Surgical options for patients with shoulder pain. *Nat Rev Rheumatol* 2010;6:217–226.
17. **Weber SC.** Arthroscopic debridement and acromioplasty versus mini-open repair in the treatment of significant partial-thickness rotator cuff tears. *Arthroscopy* 1999;15:126–131.
18. **Youm T, Murray DH, Kubiak EN, Rokito AS, Zuckerman JD.** Arthroscopic versus mini-open rotator cuff repair: a comparison of clinical outcomes and patient satisfaction. *J Shoulder Elbow Surg* 2005;14:455–459.
19. **Abrams GD, Gupta AK, Hussey KE, et al.** Arthroscopic Repair of Full-Thickness Rotator Cuff Tears With and Without Acromioplasty: Randomized Prospective Trial With 2-Year Follow-up. *Am J Sports Med* 2014;42:1296–1303.
20. **van der Zwaal P, Thomassen BJ, Nieuwenhuijse MJ, et al.** Clinical outcome in all-arthroscopic versus mini-open rotator cuff repair in small to medium-sized tears: a randomized controlled trial in 100 patients with 1-year follow-up. *Arthroscopy* 2013;29:266–273.
21. **MacDonald P, McRae S, Leiter J, Mascarenhas R, Lapner P.** Arthroscopic rotator cuff repair with and without acromioplasty in the treatment of full-thickness rotator cuff tears: a multicenter, randomized controlled trial. *J Bone Joint Surg [Am]* 2011;93-A:1953–1960.
22. **Mohtadi NG, Hollinshead RM, Sasyniuk TM, et al.** A randomized clinical trial comparing open to arthroscopic acromioplasty with mini-open rotator cuff repair for full-thickness rotator cuff tears: disease-specific quality of life outcome at an average 2-year follow-up. *Am J Sports Med* 2008;36:1043–1051.
23. **Gartsman GM, O'Connor DP.** Arthroscopic rotator cuff repair with and without arthroscopic subacromial decompression: a prospective, randomized study of one-year outcomes. *J Shoulder Elbow Surg* 2004;13:424–426.
24. **Carr AJ, Rees JL, Ramsay CR, et al.** Protocol for the United Kingdom Rotator Cuff Study (UKUFF): a randomised controlled trial of open and arthroscopic rotator cuff repair. *Bone Joint Res* 2014;3:155–160.
25. **No authors listed.** The Centre for Healthcare Randomised Trials Randomisation Service. http://w3.abdn.ac.uk/hsru/CHaRT/public/content/ShowPage.aspx?page=randomisation-service (date last accessed 16 November 2016).

26. Dawson J, Fitzpatrick R, Carr A. Questionnaire on the perceptions of patients about shoulder surgery. *J Bone Joint Surg [Br]* 1996;78:593–600.

27. Breckenridge JD, McAuley JH. Shoulder Pain and Disability Index (SPADI). *J Physiother* 2011;57:197.

28. Cuijpers P, Smits N, Donker T, ten Have M, de Graaf R. Screening for mood and anxiety disorders with the five-item, the three-item, and the two-item Mental Health Inventory. *Psychiatry Res* 2009;168:250–255.

29. The EuroQol Group. EuroQol-a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16:199–208.

30. Brooks R. EuroQol: the current state of play. *Health Policy* 1996;37:53–72.

31. Dawson J, Rogers K, Fitzpatrick R, Carr A. The Oxford shoulder score revisited. *Arch Orthop Trauma Surg* 2009;129:119–123.

32. Campbell M, Grimshaw J, Steen N. Sample size calculations for cluster randomised trials. Changing Professional Practice in Europe Group (EU BIOMED II Concerted Action). *J Health Serv Res Policy* 2000;5:12–16.

33. Hoyle RA. *Statistical strategies for small sample research.* London: Sage Publications Ltd, 1999.

34. Goldstein H. *Multilevel statistical models.* Second ed. London: Edward Arnold, 1995.

35. Nagelkerke N, Fidler V, Bernsen R, Borgdorff M. Estimating treatment effects in randomized clinical trials in the presence of non-compliance. *Stat Med* 2000;19:1849–1864.

36. Moosmayer S, Lund G, Seljom U, et al. Comparison between surgery and physiotherapy in the treatment of small and medium-sized tears of the rotator cuff: A randomised controlled study of 103 patients with one-year follow-up. *J Bone Joint Surg [Br]* 2010;92-B:83–91.

37. Kukkonen J, Joukainen A, Lehtinen J, et al. Treatment of non-traumatic rotator cuff tears: A randomised controlled trial with one-year clinical results. *Bone Joint J* 2014;96-B:75–81.

38. Coghlan JA, Buchbinder R, Green S, Johnston RV, Bell SN. Surgery for rotator cuff disease. *Cochrane Database Syst Rev* 2008;1:CD005619.

39. MacDermid JC, Holtby R, Razmjou H, Bryant D, JOINTS Canada. All-arthroscopic versus mini-open repair of small or moderate-sized rotator cuff tears: a protocol for a randomized trial [NCT00128076]. [NCT00128076]. *BMC Musculoskelet Disord* 2006;7:25.

40. Cho CH, Song KS, Jung GH, Lee YK, Shin HK. Early postoperative outcomes between arthroscopic and mini-open repair for rotator cuff tears. *Orthopedics* 2012;35:1347–1352.

41. Kasten P, Keil C, Grieser T, et al. Prospective randomised comparison of arthroscopic versus mini-open rotator cuff repair of the supraspinatus tendon. *Int Orthop* 2011;35:1663–1670.