■ **SHOULDER AND ELBOW**

Costs, quality of life and cost-effectiveness of arthroscopic and open repair for rotator cuff tears

AN ECONOMIC EVALUATION ALONGSIDE THE UKUFF TRIAL

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Aims
A trial-based comparison of the use of resources, costs and quality of life outcomes of arthroscopic and open surgical management for rotator cuff tears in the United Kingdom NHS was performed using data from the United Kingdom Rotator Cuff Study (UKUFF) randomised controlled trial.

Patients and Methods
Using data from 273 patients, healthcare-related use of resources, costs and quality-adjusted life years (QALYs) were estimated at 12 months and 24 months after surgery on an intention-to-treat basis with adjustment for covariates. Uncertainty about the incremental cost-effectiveness ratio for arthroscopic *versus* open management at 24 months of follow-up was incorporated using bootstrapping. Multiple imputation methods were used to deal with missing data.

Results
There were no significant differences between the arthroscopic and open groups in terms of total mean use and cost of resources or QALYs at any time post-operatively. Open management dominated arthroscopic management in 59.8% of bootstrapped cost and effect differences. The probability that arthroscopic management was cost-effective compared with open management at a willingness-to-pay threshold of £20 000 per QALY gained was 20.9%.

Conclusion
There was no significant overall difference in the use or cost of resources or quality of life between arthroscopic and open management in the trial. There was uncertainty about which strategy was most cost-effective.

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Rotator cuff abnormalities (including degenerative tears and those due to injury) reportedly account for up to 70% of symptoms associated with the shoulder[1] and have significant effects on quality of life and activities of daily living.[2]

Various forms of treatment are available for the symptomatic rotator cuff tear. Conservative management includes combinations of rest, exercise, physiotherapy, and pain relief. Surgery may also be undertaken to repair the tear using either an arthroscopic or open (including "mini-open") technique. Recent studies have shown that the number of rotator cuff procedures is increasing, in part due to a preference for minimally invasive techniques.[3,4] However, little is known about the relative costs and health-related quality of life outcomes of arthroscopic and open procedures to help justify the choice of surgery in the United Kingdom. Existing studies reporting

the costs of rotator cuff repair to the NHS, are non-randomised, based on a small number of patients, and do not incorporate both economic and health-related quality of life outcomes.[5,6]

The United Kingdom Rotator Cuff Study (UKUFF) was a randomised controlled trial, carried out to investigate the clinical and cost outcomes of arthroscopic and open procedures in patients with degenerative full-thickness rotator cuff tears over a period of 24 months after surgery. Full details of the study are described elsewhere (trial registration number ISRCTN 97804283, UK Multi-centre Research Ethics Committee approved, ref: 10/H0402/24).[7,8] On an intention-to-treat (ITT) basis there was no statistical difference between the arthroscopic and open groups; the difference in Oxford Shoulder Score (OSS)[9] at 24 months was 0.76 (95% confidence interval

Table I. The inclusion and exclusion criteria for the United Kingdom Rotator Cuff Study

Inclusion criteria	Exclusion criteria
The patient must satisfy all the following criteria to be eligible for the study:	The patient may not enter the study if ANY of the following apply:
-Aged over 50 years	-Previous surgery on the affected shoulder
-Suffer from a degenerative rotator cuff tear	-Dual shoulder pathology
-Have a full thickness rotator cuff tear	-Significant problems in the other shoulder
-Rotator cuff tear diagnosed using MRI or ultrasound scan	-Rheumatoid arthritis/systemic disease
-Patient able to consent	-Significant osteoarthritis problems
	-Significant neck problems
	-Cognitive impairment or language issues
	-Unable to undergo an MRI scan for any reason

(CI) -1.22 to 2.75; p = 0.452) favouring open management. There was no clinically important difference between the groups at 24 months, based on a predetermined difference in OSS of three points.[7]

The objective of this further study was to compare the use of resources, costs and health-related quality of life outcomes associated with arthroscopic and open surgical management of rotator cuff tears using two-year follow-up data from 273 randomised patients in the UKUFF trial. As far as we are aware, this is the first formal economic comparison of arthroscopic and open rotator cuff repair to be undertaken in the United Kingdom NHS which incorporates both cost and quality of life outcomes, and the first study to estimate NHS costs for rotator cuff repair using data from a randomised controlled trial.

Patients and Methods
We compared health-related quality of life, the use of resources, healthcare costs and cost-effectiveness of arthroscopic management with that of open repair for full thickness rotator cuff tears using data from the UKUFF trial. We used individual data from Stratum A of the study, which consisted of a randomised comparison of arthroscopic and open management.

Between November 2007 and February 2012 a total of 136 patients were allocated (using minimisation according to surgeon, age and size of tear) to arthroscopic and 137 to open surgery in 19 centres in the United Kingdom. After randomisation, the specifics of the procedures were subsequently the choice of the surgeon.[7,8] The inclusion and exclusion criteria for the original study are shown in Table I. There were 81 (60%) men in the arthroscopic group and 88 (64%) in the open group. The mean age was 62.9 years in both groups (standard deviation (SD) 7.1 for arthroscopic and 7.5 for open management).

The primary outcome of the economic analysis was the incremental cost per quality-adjusted life year gained with arthroscopic compared with open repair, using an ITT approach. The online supplementary material includes results using a per-protocol approach (i.e. including only the subset of patients who received their allocated intervention). The perspective was that of the healthcare system (the United Kingdom NHS), and the time horizon was the duration of the UKUFF trial (up to 24 months post-operatively), with longer-term extrapolation if clear evidence was found

of differences in costs or effects. Analyses were conducted using Stata/SE 12 software (StataCorp. LP, College Station, Texas).

Outcomes were compared by ITT, defined as the intended procedure (arthroscopic or open) before surgery commenced. The use of resources relating to the initial procedure, specifically the time in theatre and the number and type of bone anchors, was recorded for each patient by healthcare staff in the operating theatre on a paper-based form. Information on additional equipment used during surgery was obtained via observation, and incorporated as a fixed cost of consumables for each type of procedure. Further details are given in Table II.[10-12] Data for the individual patients were not collected for revision surgery, so the costs of the procedure for these were assumed to be equal to the mean cost of the initial procedure by type. The length of stay in hospital was estimated using the date of surgery and the date of discharge as reported on questionnaires given to the patients two or eight weeks post-operatively.

Data for the use of resources after discharge were collected using questionnaires returned at 12 months and 24 months post-operatively. Items included further surgery, such as revision surgery or the treatment of infected wounds; number of inpatient and outpatient visits, and appointments with a GP, nurse, or physiotherapist. Use of prescribed medications such as painkillers was recorded on the questionnaires at two and eight weeks post-operatively. For the analysis, we assumed that the use reported in the questionnaires was the daily dose throughout the period covered by the questionnaire.

Total costs were calculated by applying unit costs for the 2012 to 2013 cost year obtained from manufacturers and national cost estimates (Table II) to the resource use information obtained from the questionnaires. For surgical equipment, an assumed 30% price discount was applied to list prices obtained from manufacturers (Table II), to represent the estimated price paid by the hospitals.

Health-related quality of life was measured using the responses to the EuroQol (EQ)-5D-3L instrument,[13] obtained from questionnaires returned at baseline and at eight, 12 and 24 months post-operatively. Using Stata command 'eq5d' the EQ-5D-3L responses for each patient at each time point were converted to quality of life valuations, where '1' represents full health and '0' represents death (negative valuations are possible but were none were

Table II. Unit costs

Cost category	Unit cost (£ 2012/13)	Source and description
Surgery costs (all participants)*		
Cost per minute in theatre	16.43	Mean cost per minute in orthopaedic operating theatre. Average over 15 NHS boards in Scotland, year end March 2013. Information Services Division Scotland release 17 December 2013.[10]
Cost per anchor		
Open repair	103.67	Manufacturer's list price with a price discount applied. Costs presented are the mean anchor cost for participants receiving each type of surgery. The list prices (without price discount) for the anchors ranged from £141 to £262. Illustrative average anchor cost here is based on mean total anchor cost divided by mean number of anchors (using imputed data).
Arthroscopic repair	107.43	
Other procedures	98.52	
Additional fixed surgical costs		
Average cost per suture	7.14	Average of manufacturer's list prices (with price discount)[†] for each suture type recorded on theatre forms.
Drapes[‡]	16.41	Manufacturer's list prices (with price discount)[†] for shoulder arthroscopy drape and video camera drape.
Fluid management system one day tubing[‡]	20.30	Manufacturer's list price (with price discount).[†]
90° suction electrode[§]	90.00	Hospital cost obtained (with price discount).[†]
5.5 mm full radius resector[¶]	57.51	Manufacturer's list price (with price discount).[†]
4.0 mm oval burr[¶]	57.51	Manufacturer's list price (with price discount)[†]
Monopolar diathermy electrosurgical single-use pencil[**]	1.93	Manufacturer's list price (with price discount).[†]
Arthroscopic suture needle[††]	157.14	Cost obtained from supplier to the Nuffield Orthopaedic Centre, Oxford (with price discount).[†]
Post-surgery and follow-up costs*		
Cost per inpatient bed day	378.93	Elective inpatient excess bed day from NHS reference costs. Weighted average of all Shoulder and Upper Arm Procedures for Non-Trauma "Trauma & Orthopaedics". From 2012 to 2013 NHS reference cost data file "The main schedule", "EI_XS" tab.[11]
Surgery during follow-up		
Repair (open)	1977.68	All repair costs were calculated using the average cost for each type of procedure within the trial (cost of time in theatre, anchors, and fixed equipment costs). The costs of nights in hospital relating to surgery during follow-up were incorporated separately.
Repair (arthroscopic)	2192.80	
Repair (unknown type)	2085.24	
Reverse shoulder replacement	3722.11	Elective inpatient excess bed day from NHS reference costs. Weighted average inpatient cost for major shoulder and upper arm procedures with/without complications, non-trauma, "Trauma and Orthopaedics". From 2012 to 2013 NHS reference cost data file "The main schedule", "EI" tab.[11]
Washout procedure	337.48	Elective inpatient excess bed day from NHS reference costs. Weighted average of minor and intermediate shoulder and upper arm procedures for non-trauma. From 2012 to 2013 NHS reference cost data file "The main schedule", "EI_XS" tab.[11]
Cost per appointment with GP	37.00	Consultation lasting 11.7 minutes, including direct care staff costs, excluding qualification costs. Personal Social Services Research Unit (PSSRU) costs of health and social care 2013, table 10.8b.[12]
Cost per appointment with nurse	11.34	Based on a 15.5 minute face-to-face consultation. PSSRU costs of health and social care 2013, table 10.6.[12]
Cost per session with physiotherapist	43.69	Weighted average of NHS own costs for hospital and community based appointments. From 2012 to 2013 NHS reference cost data file "The main schedule", "NCL" and "CHSAHP" tabs.[11]
Outpatient visits (shoulder)	162.08	Weighted average outpatient cost for major, intermediate, and minor outpatient procedures (OPROC tab).[11]

* applied to all participants according to resource use for each participant
† an assumed price discount of 30% has been applied to the list prices to produce the cost to the hospital (as shown) for surgical items
‡ all procedures
§ mini-open repair, arthroscopic repair, all sub-acromial decompression (SAD), biceps tenotomy, and capsular release procedures
¶ mini-open repair, arthroscopic repair, and all SAD procedures
** open repair, mini-open repair, and open partial-thickness tear procedures
†† arthroscopic procedures only

observed in this study), using the United Kingdom population tariff.[14,15] Total quality-adjusted life years (QALYs) were calculated for each patient using an area under the curve (AUC) approach after linear interpolation between time points.

Imputation via chained equations (with the 'mi impute chained' command in Stata) was used to impute missing data for initial hospitalisation, use and cost of resources during follow-up, and EQ-5D-3L domains in the original data set.[16] In total, 30 complete data sets were produced (equal to the highest percentage of missing data in any of the variables to be imputed)[17] and subsequently combined using Rubin's rules via the 'mi estimate' command in Stata, to account for variation both within and between data sets.[16]

Cost and quality of life outcomes accrued after 12 months of follow-up were time-discounted at a rate of 3.5% per year, as currently recommended.[18]

A cost-utility analysis was performed using the total costs and QALYs at 24 months of follow-up for those ran-

Table III. Resource use and cost outcomes relating to initial procedure by intention-to-treat using imputed data

Mean resource use	Arthroscopic (n = 136) mean (SEM)	Open (n = 137) mean (SEM)	Arthroscopic vs open mean difference (CI; p-value) (no covariate adjustment)	Arthroscopic vs open mean difference (CI; p-value) (adjusting for age, tear size, centre)	Arthroscopic (n = 136) mean cost, £ (SEM)	Open (n = 137) mean cost, £ (SEM)	Arthroscopic vs open mean cost difference (CI; p-value) (base case, no covariate adjustment)	Arthroscopic vs open mean cost difference, £ (CI; p-value) (adjusting for age, tear size, centre)
Theatre time	71.0 (4.9)	71.1 (3.6)	-0.2 (-12.1 to 11.8; 0.981)	6.8 (-1.3 to 14.9; 0.102)	1166 (80)	1169 (60)	-2 (-199 to 194; 0.981)	111 (-22 to 244; 0.102)
Anchors	1.2 (0.1)	1.4 (0.1)	-0.2 (-0.5 to 0.2; 0.352)	0.0 (-0.3 to 0.3; 0.889)	127 (14)	147 (14)	-20 (-56 to 17; 0.288)	-1 (-29 to 28; 0.959)
Equipment	-	-	-	-	202 (12)	145 (7)	58 (31 to 84; 0.000)	77 (56 to 97; 0.000)
Total cost of surgery	-	-	-	-	1497 (96)	1460 (71)	36 (-200 to 271; 0.766)	187 (35 to 339; 0.016)
Nights in hospital	0.5 (0.1)	0.7 (0.1)	-0.1 (-0.4 to 0.2; 0.399)	-0.1 (-0.4 to 0.2; 0.578)	206 (46)	255 (36)	-49 (-165 to 66; 0.399)	-32 (-147 to 82; 0.578)
Total procedure-related costs	-	-	-	-	1701 (115)	1715 (86)	-14 (-297 to 270; 0.924)	155 (-45 to 354; 0.129)

SEM, standard error of the mean; CI, confidence interval

domised to arthroscopic or open repair. The incremental cost-effectiveness ratio (ICER) was calculated as the incremental cost per QALY gained for arthroscopic compared with open surgery over a 24-month follow-up. Uncertainty about the ICER was characterised using non-parametric bootstrapping[19] by sampling 1000 bootstrap replicates of the mean total cost and mean total effect differences between the two groups. The bootstrapped pairs of cost and effect differences were plotted on the cost-effectiveness plane to illustrate the uncertainty around the point estimate for the ICER, and a cost-effectiveness acceptability curve was produced to illustrate the probability of arthroscopic surgery being cost-effective compared with open surgery at a range of willingness to pay thresholds.

All results are presented on an ITT basis using imputed data, and for the base case mean differences were adjusted for age, centre, and the size of the tear at baseline. Mean differences in quality of life outcomes were also adjusted for EQ-5D levels at baseline.[20] Unadjusted mean differences are also presented.

Results

Of the 273 patients in this study, 136 were randomised to arthroscopic management. In this group, 63 (46%) had an arthroscopic repair for a tear, 28 (21%) had an arthroscopic procedure not including a repair, such as a sub-acromial decompression (SAD), nine (7%) arthroscopic repairs were converted to an open repair during the procedure, and 36 patients (26%) withdrew before surgery. Of the 137 patients randomised to open management, 85 (62%) had an open repair for a tear, 24 (18%) had an arthroscopic procedure not including a repair, such as a SAD, five (4%) had an arthroscopic repair instead, and 23 (17%) withdrew before surgery.[7]

The rate of response to the questionnaires was 100% at baseline, 90% at 12 months and 86% at 24 months follow-up. However, the number of patients with complete data for theatre time, anchors, equipment and length of stay was lower at 85 (63%) at discharge for those randomised to arthroscopic repair and 94 (69%) for those randomised to open repair. At 12 months post-operatively, the number of patients with complete data (for discharge, revision surgery,

use of healthcare resources, out-of-pocket costs, and EQ-5D domains) was 44 (32%) for the arthroscopic group and 60 (44%) for the open group. At 24 months, this was 39 (29%) for the arthroscopic group and 57 (42%) for the open group. The number of deaths during the 24 month period was three: two in the arthroscopic group, and one in the open group. None were related to participation in the study.

The use and costs of resources relating to initial procedures. The use and costs of resources relating to initial procedures are shown in Table III. Both theatre time and the cost of theatre time were slightly higher for arthroscopic than for open management, but this was not statistically significant. The mean time in theatre was 71.0 minutes (standard error of the mean (SEM) 4.9) for those in the arthroscopic group, corresponding to a mean cost of £1166 (SEM 80). For those in the open management group, the mean time in theatre was 71.1 minutes (SEM 3.6) minutes, with a mean cost of £1169 (SEM 60).

Both the number and type (i.e. brand) of anchors were identified from the theatre records and used to incorporate the costs of anchors on an individual patient basis. The mean number of anchors used was 1.2 (SEM 0.1) for the arthroscopic group, with a mean cost of £127 (SEM 14). For the open group the mean number of anchors was 1.4 (SEM 0.1) with a mean cost of £147 (SEM 14). There was no statistically significant difference in either the number of anchors or their cost in each group. However the mean difference in other equipment costs (not including anchors) was statistically significant, at £77 (95% confidence interval (CI) 56 to 97) more for arthroscopic than for open management.

The mean total cost of the initial procedure, incorporating time in theatre, anchors, and other equipment costs but excluding length of stay, was £1497 (SEM 96) for arthroscopic and £1460 (SEM 71) for open management. This cost was significantly greater for arthroscopic management with a mean of £187 (95% CI 35 to 339) more costly than open management.

Overall the total mean procedure-related cost (including the costs of surgery and length of stay) was £1701 (SEM 115) for arthroscopic and £1715 (SEM 86) for open management, however this was not statistically significant.

Table IV. The use and cost of resources and outcomes for follow-up by intention-to-treat using imputed data

Mean resource use	Arthroscopic (n = 136) mean (SEM)	Open (n = 137) mean (SEM)	Arthroscopic vs open mean difference (CI; p-value) (no covariate adjustment)	Arthroscopic vs open mean difference (CI; p-value) (adjusting for age, tear size, centre)	Arthroscopic (n = 136) mean cost, £ (SEM)	Open (n = 137) mean cost, £ (SEM)	Arthroscopic vs open mean cost difference, £ (CI; p-value) (no covariate adjustment)	Arthroscopic vs open mean cost difference, £ (CI; p-value) (adjusting for age, tear size, centre)
Revision procedures between surgery and 12 mths	0 (-)	0.0 (0.0)	-0.01 (-0.02 to 0.01; 0.320)	-0.01 (-0.02 to 0.01; 0.339)	0 (-)	2 (2)	-2 (-7 to 2; 0.320)	-2 (-7 to 3; 0.339)
GP visits between surgery and 12 mths	1.1 (0.2)	1.2 (0.2)	-0.1 (-0.6 to 0.5; 0.831)	0.0 (-0.6 to 0.5; 0.948)	40 (7)	43 (6)	-2 (-22 to 18; 0.831)	-1 (-21 to 19; 0.948)
Nurse visits between surgery and 12 mths	0.3 (0.1)	0.5 (0.1)	-0.2 (-0.5 to 0.1; 0.256)	-0.2 (-0.5 to 0.2; 0.354)	4 (1)	6 (2)	-2 (-6 to 2; 0.256)	-2 (-6 to 2; 0.354)
Physiotherapist visits between surgery and 12 mths	6.1 (0.6)	6.3 (0.5)	-0.2 (-1.7 to 1.4; 0.818)	0.3 (-1.1 to 1.7; 0.685)	267 (24)	275 (24)	-8 (-75 to 59; 0.818)	13 (-49 to 74; 0.685)
Inpatient visits between surgery and 12 mths	0.3 (0.1)	0.4 (0.1)	-0.1 (-0.5 to 0.2; 0.418)	-0.1 (-0.5 to 0.2; 0.485)	119 (37)	170 (51)	-52 (-178 to 74; 0.418)	-45 (-173 to 83; 0.485)
Outpatient visits between surgery and 12 mths	1.6 (0.2)	2.3 (0.3)	-0.7 (-1.5 to 0.0 ; 0.045)	-0.6 (-1.3 to 0.2; 0.134)	259 (31)	380 (52)	-121 (-240 to -2; 0.045)	-92 (-213 to 29; 0.134)
Medication costs between surgery and 12 mths	-	-	-	-	6 (1)	4 (1)	1 (-2 to 5; 0.386)	2 (-2 to 5; 0.336)
Cost after surgery to 12 mth follow-up	-	-	-	-	694 (66)	881 (93)	-187 (-413 to 40; 0.106)	-128 (-350 to 94; 0.256)
Total costs up to 12 mths	-	-	-	-	2395 (149)	2596 (142)	-200 (-607 to 207; 0.333)	26 (-283 to 337; 0.867)
Revision procedures between 12 and 24 mths	0.01 (0.01)	0.02 (0.01)	-0.01 (-0.04 to 0.02; 0.659)	0.00 (-0.04 to 0.03; 0.768)	30 (21)	31 (22)	-1 (-60 to 59; 0.986)	4 (-58 to 66; 0.899)
GP visits between 12 and 24 mths	0.4 (0.1)	0.4 (0.1)	0.1 (-0.2 to 0.4; 0.597)	0.1 (-0.2 to 0.4; 0.600)	17 (5)	13 (4)	3 (-9 to 15; 0.597)	3 (-9 to 16; 0.600)
Nurse visits between 12 and 24 mths	0.1 (0.1)	0.1 (0.0)	0.0 (-0.1 to 0.2; 0.750)	0.0 (-0.1 to 0.1; 0.819)	1 (1)	1 (0)	0 (-1 to 2; 0.750)	0 (-1 to 2; 0.819)
Physiotherapist visits between 12 and 24 mths	1.2 (0.5)	0.5 (0.2)	0.7 (-0.3 to 1.7; 0.196)	0.7 (-0.3 to 1.7; 0.160)	51 (21)	23 (8)	29 (-15 to 72; 0.196)	31 (-12 to 75; 0.160)
Inpatient visits between 12 and 24 mths	0.03 (0.02)	0.00 (0.00)	0.03 (–0.02 to 0.08)	0.03 (–0.02 to 0.08)	12 (9)	0 (-)	11 (-6 to 29; 0.209)	12 (-6 to 30; 0.198)
Outpatient visits between 12 and 24 mths	0.4 (0.1)	0.2 (0.1)	0.2 (-0.1 to 0.5; 0.282)	0.2 (-0.1 to 0.5; 0.212)	67 (23)	39 (12)	27 (-23 to 77; 0.282)	31 (-18 to 80; 0.212)
Total cost from 12 to 24 mths	-	-	-	-	177 (59)	107 (30)	70 (-59 to 200; 0.268)	82 (-49 to212; 0.219)
Total cost over 24 mths	-	-	-	-	2573 (177)	2703 (150)	-130 (-589 to 329; 0.578)	108 (-255 to 471; 0.558)
Total cost over 24 mths (time-discounted)	-	-	-	-	2567 (176)	2699 (149)	-132 (-589 to 324; 0.569)	105 (-255 to 466; 0.565)

SEM, standard error of the mean; CI, confidence interval

The use and costs of resources at 12 months of follow-up. The use and costs of resources at 12 months of follow-up are shown in Table IV.

No patients in the arthroscopic group underwent revision surgery, that is, a repeat repair or a washout, during the first 12 months of follow-up. The mean cost per person of revision surgery for the open group was £2 (SEM 2).

There were no significant differences between the two groups in the number or cost of healthcare appointments, hospital visits and medications during the first 12 months of follow-up.

The mean total cost during the first 12 months of follow-up was £694 (SEM 66) for the arthroscopic group and £881 (SEM 93) for the open group. This difference was not statistically significant.

The use and cost of resources at 24 months of follow-up. The rate of revision surgery between 12 and 24 months of follow-up was low, with a mean cost per patient of £30 (SEM 21) for arthroscopic and £31 (SEM 22) for open management. The mean difference was not statistically significant. Similarly, there were no statistically significant differences between the two groups in the number or cost of healthcare appointments and hospital visits between 12 and 24 months of follow-up. After adjusting for covariates, these differences remained non-significant.

The total mean cost after time-discounting, including initial surgery up to 24 months of follow-up, was £2567 (SEM 176) for arthroscopic and £2699 (SEM 149) for open management, however this difference was not statistically significant.

Quality of life outcomes. Quality of life outcomes using the imputed data are presented in Table V. Substantial improvements were seen in both groups. In the arthroscopic group, the mean EQ-5D improved from 0.55 (SEM 0.03) at baseline to 0.74 (SEM 0.02) 24 months post-operatively. Similarly, in the open management group, the mean EQ-5D improved from 0.52 (SEM 0.02) at baseline to 0.76 (SEM 0.02) at 24 months. The difference in mean EQ-5D between the two groups was not statistically significant at any follow-up point.

The overall mean total QALYs over the 24 month period were 1.34 (SEM 0.04) for arthroscopic, and 1.35 (SEM 0.04) for open management, after time-discounting. The mean difference (95% CI) in total QALYs over the 24 month period of study was not statistically significant after adjusting for covariates.

Incremental cost-effectiveness. The results of the incremental analysis are shown in Table VI. Arthroscopic management was slightly more costly and less effective than open management although the differences were not statistically significant.

Modelling the joint distribution of uncertainty around the cost and effect differences using bootstrapping and adjusting for covariates, there was an estimated 59.8% probability that open management dominates arthroscopic management (that it is less costly and more effective), with a point-estimate in the north-west quadrant of the cost-effectiveness plane. However, there is substantial uncertainty around this ICER (Fig. 1).

At a threshold of £20 000 per QALY gained (in line with the generally accepted lower limit of the threshold in the United Kingdom),[18] there is a 20.9% probability that

Table V. Quality of life outcomes: quality-adjusted life years (QALYs) by intention-to-treat using imputed data

	Arthroscopic (n = 136) mean QALYs (SEM)	Open (n = 137) mean QALYs (SEM)	Arthroscopic *vs* open mean difference in QALYs (CI; p-value) (no covariate adjustment)	Arthroscopic *vs* open mean difference in QALYs (CI; p-value) (adjusting for baseline EQ-5D, age, tear size, centre)
Quality of life				
EQ-5D_index_BL	0.55 (0.03)	0.52 (0.02)	0.03 (-0.04 to 0.10; 0.352)	0.03 (-0.04 to 0.11; 0.336)*
EQ-5D_index_8mo	0.68 (0.03)	0.69 (0.02)	-0.01 (-0.08 to 0.05; 0.691)	-0.03 (-0.09 to 0.04; 0.392)
EQ-5D_index_12mo	0.72 (0.02)	0.71 (0.03)	0.01 (-0.06 to 0.08; 0.852)	-0.01 (-0.08 to 0.06; 0.788)
EQ-5D_index_24mo	0.74 (0.02)	0.76 (0.02)	-0.03 (-0.09 to 0.03; 0.389)	-0.04 (-0.10 to 0.02; 0. 232)
Quality-adjusted life years				
QALYs from baseline to 8 mths	0.41 (0.01)	0.40 (0.01)	0.01 (-0.03 to 0.05; 0.740)	-0.01 (-0.03 to 0.01; 0.392)
QALYs from 8 mths to 12 mths	0.23 (0.01)	0.23 (0.01)	-0.00 (-0.02 to 0.02; 0.911)	-0.01 (-0.03 to 0.01; 0.529)
QALYs from 12 mths to 24 mths	0.73 (0.02)	0.74 (0.02)	-0.01 (-0.07 to 0.05; 0.734)	-0.02 (-0.08 to 0.03; 0.414)
TOTAL QALYs over 24 mths	1.37 (0.04)	1.37 (0.04)	0.00 (-0.11 to 0.10; 0.931)	-0.04 (-0.12 to 0.05; 0.392)
TOTAL QALYs over 24 mths (time-discounted)	1.34 (0.04)	1.35 (0.04)	0.00 (-0.11 to 0.10; 0.935)	-0.04 (-0.12 to 0.05; 0.392)

All outcomes use imputed data
* not adjusted for baseline EQ-5D (EQ-5D_index_BL), only for age, tear size and centre
EQ-5D, EuroQol-5D; SEM, standard error; CI, confidence interval

Table VI. Incremental analysis by intention-to-treat using imputed data

| Adjustment for covariates | Total costs (time-discounted)* | | | Total QALYs over 24 mths (time-discounted)* | | | ICER (quadrant)† Mean incremental cost per QALY gained, £ | Probability (%)§ that arthroscopic repair is: | | | | |
	Arthroscopic mean cost, £ (SEM)	Open mean £ (SEM)	Difference (adjusted for covariates), £ (CI; p-value)	Arthroscopic	Open	Difference (adjusted for covariates), £ (CI; p-value)		More effective	Less costly	Dominant	Dominated	Cost-effective at £20 000 per QALY gained
Adjusted (base case)‡	2567 (176)	2699 (149)	105 (-255 to 466; p = 0.565)	Mean (SEM) 1.34 (0.04)	Mean (SEM) 1.35 (0.04)	-0.04 (-0.12 to 0.05; p = 0.392)	Dominated by open (-£2845 (north-west quadrant of CE plane)	23.0	26.6	9.4	59.8	20.9
Unadjusted	2567 (176)	2699 (149)	-132 (-589 to 324; p = 0.569)	1.34 (0.04)	1.35 (0.04)	0.00 (-0.11 to 0.10; p = 0.935)	£30 001 (south-west quadrant of CE plane)	47.5	74.4	37.5	15.6	53.7

* uncertainty around costs and effects was calculated parametrically
† uncertainty around the ICER was estimated using 1000 bootstrap replicates of final merged data set after multiple imputation
‡ covariates: EuroQol-5D at baseline (for QALY outcomes only), age, tear size, centre
§ out of 1000 replicates
QALY, quality-adjusted life years; ICER, incremental cost per quality-adjusted life year gained; SEM, standard error of the mean; CI, confidence interval; CE, cost-effectiveness
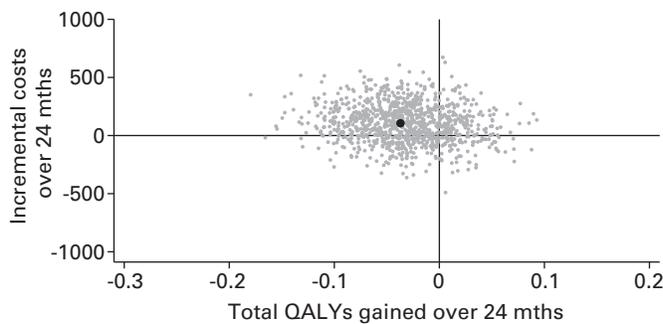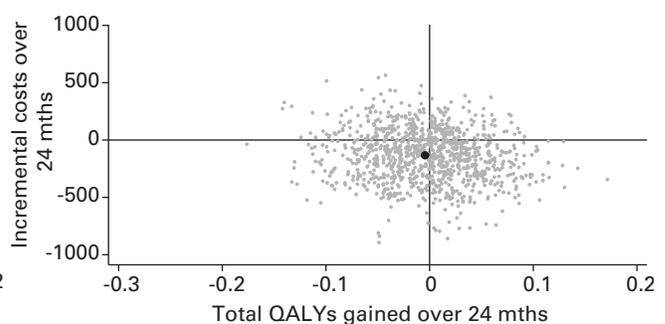

Fig. 1a

Fig. 1b

Cost-effectiveness planes for a) arthroscopic *versus* open management by intention-to-treat, adjusted for covariates and b) arthroscopic *versus* open management by intention-to-treat, no adjustment for covariates.

arthroscopic management was cost-effective (more costly but more effective) compared with open management, and therefore a 79.1% probability that open management was cost-effective at the same threshold (Fig. 2).

Discussion

We found that the mean cost of the procedure was significantly greater (£187, 95% CI 35 to 339) for arthroscopic than for open management, after adjustment for covariates. However, when incorporating the cost of nights in hospital, the overall cost related to the initial procedure was marginally (but not significantly) greater for open management.

We found no significant differences between arthroscopic and open management in the number of healthcare appointments and hospital stays at surgery and at 12 or 24 months follow-up, either before or after adjustment of
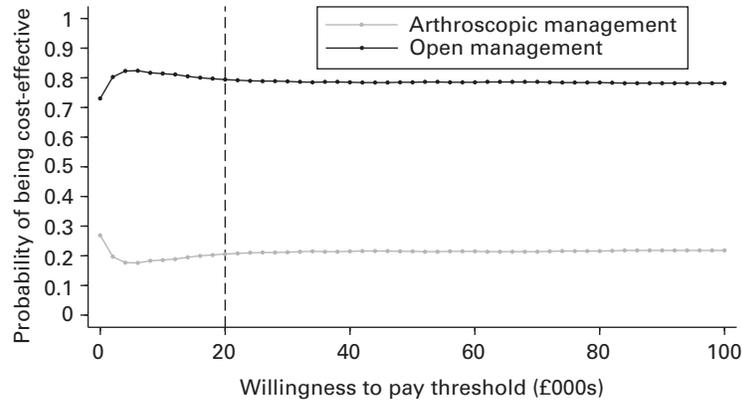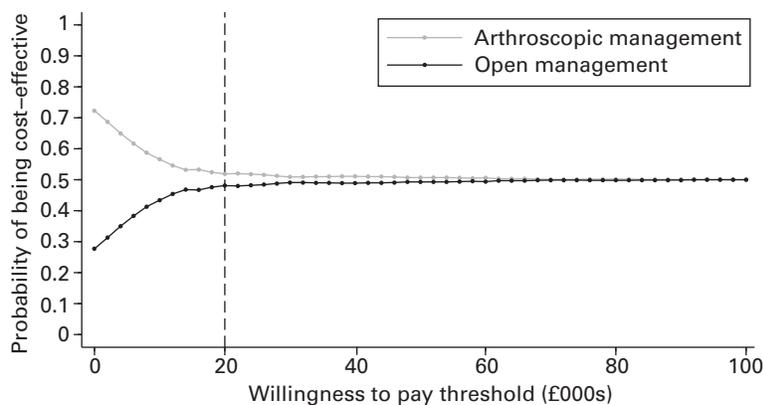
Fig. 2a

Fig. 2b

Cost-effectiveness acceptability curves for a) arthroscopic *versus* open management by intention-to-treat, adjusted for covariates and b) arthroscopic *versus* open management by intention-to-treat, no adjustment for covariates.

covariates. The total mean cost at 12 months was higher (but not significantly so) for open management before adjustment, however after adjustment the cost was marginally (but again, not significantly) higher for arthroscopic management. Similarly, the total overall cost at 24 months was higher (but not significantly so) for open management before adjustment, but after adjustment it was (non-significantly) higher for arthroscopic management.

There was no significant difference between groups, in either the unadjusted or adjusted analyses, in the mean total cost at initial hospitalisation and 12- or 24-month follow-up, despite a significantly higher cost of the procedure in the arthroscopic group. There was also no significant difference in mean total QALYs between the two groups at any time point. Consequently, extrapolating the results beyond the study period would have served no purpose.

The point estimate of the ICER suggested that arthroscopic management was dominated by open management (implying that arthroscopic management is more costly and associated with fewer total QALYs at 24 months). As for the cost and quality of life results, there was considerable uncertainty around this ICER. Arthroscopic management was dominated by open management in 59.8% of the bootstrapped cost and effect differences. Conversely, there was a 20.9% probability that arthroscopic management was cost-effective compared with open management at a threshold of £20 000. Therefore the CIs around the differences in cost and effect between the groups are also reflected in the uncertainty around the ICER, supporting the conclusion that there was no clear difference between the two forms of management in the trial.

Our study was designed prospectively and conducted alongside a national randomised trial involving many centres. It had some limitations. Assumptions had to be made about the price discounts offered to hospitals for anchors and other consumables. Detailed information was not collected on resources used during re-admissions involving surgical procedures, although the procedures themselves were fully documented and were few in number. We believe that the trial fairly reflects the provision of these procedures in the real world, but it should be borne in mind that only 63 (46%) of those randomised to arthroscopic management and 85 (62%) of those randomised to open management actually received the intended procedure; our results should therefore be interpreted as an ITT comparison. The analysis was conducted from the perspective of the healthcare system and did not incorporate societal costs such as time off work.

In a recent paper, Judge et al[3] found that the number of subacromial decompression and rotator cuff repair procedures being performed in England grew rapidly from 1.4 per 100 000 population in 2004/05, to 13.7 per 100 000 in 2009/10, and suggested that one reason for this may be a growing preference for less invasive arthroscopic techniques. A recent study in the United States showed that the volume of rotator cuff repairs increased by 141% over a ten-year period from 1996 to 2006.[4] During this time the number of open repairs increased by 34%, while the number of arthroscopic repairs increased by 600%. Although it is commonly believed that less invasive techniques are associated with shorter periods of recovery and better outcomes, the evidence is conflicting.[21-25] In addition, existing evidence on the comparative costs of the procedures to the NHS is limited to small, non-randomised studies.[5,6]

In this study, we found that the arthroscopic procedure took slightly longer to perform but on an ITT basis this difference was not statistically significant. We found that the cost of the procedure was significantly greater for arthroscopic than for open repair, after adjusting for age, centre and the size of the tear, but that there was no significant difference in overall costs between the two procedures, and we found no discernible difference in overall length of stay in hospital or in the use of resources following the procedures. The point estimate of the ICER suggested that open management dominated arthroscopic management (i.e. arthroscopic management was more costly and less effective). However, due to wide CIs in the differences in cost and effect, there was a high level of uncertainty about which treatment was most cost-effective. This further supports the conclusion that no significant difference between arthroscopic and open management was observed.

Take home message:

The results of this study suggest there is no significant difference between arthroscopic and open management of full-thickness rotator cuff tears in terms of the use and cost of resources and health-related quality of life outcomes in the context of the United Kingdom NHS, based on the findings of the UKUFF trial.

Supplementary material

Tables and figures showing the results using a per-protocol approach can be found alongside the online version of this article at http://www.bjj.boneandjoint.org.uk

Author contributions:
J. Murphy: Carried out cleaning of the data, Conducted the economic analysis, Wrote the paper.
A. Gray: Co-applicant for the UKUFF trial grant, Conceived and oversaw the economic analysis, Contributed to the writing of the paper.
C. Cooper: Trial co-ordinator, Carried out collection and cleaning of the economic data, Reviewed and commented on the results and paper.
D. Cooper: Carried out cleaning of the economic data, Conducted the statistical analysis for the trial, Reviewed and commented on the results and paper.
C. Ramsay: Co-applicant for the UKUFF trial grant, Lead the statistical analysis for the trial, Reviewed and commented on the results and paper.
A. Carr: Principal applicant for the UKUFF trial grant, Advised on clinical aspects of the analysis, Reviewed and commented on the results and paper.

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