

PB-PG-0110-21121 – NIHR Research for Patient Benefit Programme – Final report

Project title: A randomised controlled trial of total resurfacing versus hemi resurfacing in the treatment of primary osteoarthritis of the shoulder.

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Plain language summary

We performed a pilot randomised trial to compare the benefits and costs of two treatments for shoulder arthritis: Total resurfacing, where the surgeon covers the ball of the shoulder with metal and the socket with plastic; and hemi-resurfacing, where the surgeons covers the ball with metal but leaves the socket alone. We recruited 30 patients in two specialist hospitals over two years and followed them up for a year.

We did not find any significant difference in outcome in this small pilot study, and we had considerable problems with recruitment. We found that there were rather few patients for whom shoulder resurfacing might be suitable. Also, since we planned the study, the introduction of new types of shoulder replacement, and the increasing recognition that total shoulder resurfacing is very technically difficult, means that fewer and fewer surgeons now offer total shoulder resurfacing.

In conclusion, we recommend that a full trial of total and hemi-resurfacing is not feasible because of difficulty in recruiting sufficient patients, and should not be performed. Total resurfacing has been found to be technically difficult, and is rapidly being replaced by newer, simpler techniques and devices. Investigation of these will offer greater patient benefit.

Keywords

Shoulder

Arthritis

Replacement

Arthroplasty

Resurfacing

Randomised Controlled Trial

Summary of research findings

BACKGROUND

For significant primary osteoarthritis of the shoulder, patients traditionally receive a shoulder replacement (SR). SRs have been shown to have excellent results in terms of function and are as cost effective as a total hip replacement and a coronary heart bypass for improving quality of life.

Shoulder resurfacing is a newer form of replacement where the anatomy is maintained as the head is not removed. This has the advantage of easier restoration of the inclination, version, curvature of radius and offset of the humeral head in comparison to SR. It also preserves more of the patient's own bone, making any revision surgery potentially easier. In comparison to SR, resurfacing has a decreased mean operative time; blood loss and hospital stay. Mid-term survival of shoulder resurfacing has been comparable to SR in two national joint registries (New Zealand and Australia). These advantages of resurfacing over SR have ensured that the proportion of shoulder resurfacings have increased year on year.

As for SR, there are two types of shoulder resurfacing surgery: In total resurfacing, both the humeral head and the glenoid bone are resurfaced, providing reconstruction of both sides of the joint and a metal on plastic articulation; in hemi resurfacing, just the humeral head is resurfaced, providing a metal on cartilage or metal on bone articulation. As for hemi-arthroplasty in SR, hemi-resurfacing has the advantage that it is quicker, cheaper and less technically demanding, but it is not clear whether it provides pain relief and function that is as good as total resurfacing. The evidence as to which form of SR (total or hemi-arthroplasty) performed better is inconclusive. To date, no randomised trials have been performed comparing total resurfacing with hemi resurfacing.

The aim of this pilot study was to test the feasibility of a multi-centre RCT of the clinical and cost effectiveness of total resurfacing versus hemi-resurfacing of the shoulder.

OBJECTIVES

The primary objective of the study was:

- To quantify differences in functional and quality of life measures between total resurfacing and hemi resurfacing at one year post-operatively
- The secondary objectives were:
- To estimate the distribution of outcome measures within a trial and compare with published observational studies.
- To determine the feasibility of the randomisation and trial processes.
- To evaluate the optimal sample size for a full trial.
- To determine the complication rate of total resurfacing versus hemi resurfacing at one year post-surgery.
- To estimate the likely cost difference and distribution of costs between total resurfacing and hemi resurfacing in order to inform a full trial.

METHODS

All potential participants for this study were identified by Consultants in shoulder clinics at the University Hospitals Coventry and Warwickshire (UHCW) and West Hertfordshire Hospital (WHH) NHS Trusts. Eligible patients were medically fit for an operation, and had arthritis of the shoulder that was deemed suitable for a total resurfacing by the consultant surgeon. The patients were informed verbally and in writing about the trial and informed consent was obtained.

Participants were randomised in a 1:1 allocation to a total resurfacing (TR) or hemi resurfacing (HR). The randomisation sequence was computer generated and administered by an independent randomisation service. Patients, research associates, data clerks and the statistician were blind to the allocation of participants.

Prior to surgery, patients completed: the Oxford Shoulder Score (OSS), the Constant-Murley (CM) shoulder score and the EQ-5D. Patient demographics and medication was also recorded using both hospital patient records and patient questionnaire.

Each patient then underwent the assigned surgery according to the preferred technique of the operating surgeon. This ensured that the results of the trial could be generalised to as wide a group of patients and surgeons as possible. For TR, the glenoid was prepared and a cemented high-density polyethylene implant inserted. The humeral head was resurfaced with a cobalt-chrome implant. The approach to the joint was the same for both procedures, as was the post-operative rehabilitation. For HR, the humeral head was resurfaced with a cobalt-chrome implant; the glenoid had no surgical intervention.

After the operation, patients were reviewed using the OSS, and EQ-5D at 6 weeks, and the OSS, CM shoulder score and EQ-5D at 3 months, 6 months and 12 months post-operatively. Records were kept of any complications associated with the treatment. Primary, community and social care service usage were collected using a patient questionnaire, at 3, 6 and 12 months.

The main analysis investigated differences in the OSS, CM Score and EQ-5D, between the two treatment groups on an intention-to-treat basis, at 12 months post-operation. As this was a pilot study, the main analysis was exploratory – to assess the size and direction of observed differences between the two groups, and the variability and distribution of the outcome measures at each assessment. Differences in outcomes between treatment groups were assessed using t-tests; based on an assumed approximate normal distribution for the outcome measures. The moderating effects of patient age and gender on the treatment effect were also explored using analysis of covariance, that included these two variables in addition to the main treatment factor. Fisher's exact test was used to assess differences in a range of complications after surgery. The results of these analyses were used to recommend an optimal sample size, based on a formal power analysis, and design for the full RCT.

The aim of the health economics analysis was to estimate the likely cost difference and distribution of costs between TR and HR and to compare the cost-effectiveness of TR versus HR. If appropriate, the primary objective was to evaluate the incremental cost effectiveness of TR versus HR. Initially descriptive statistics of costs and EQ-5D scores were performed and parametric tests conducted to evaluate any important differences in the end points within the time frame of the trial. Then an analysis comparing the outcomes as measured in QALYs and costs up to 12 months follow-up using the trial data was carried out.

Similar analyses were used for costs from the societal perspective; this perspective included the costs of lost productivity and private expenses in addition to the NHS costs. Finally, an adjusted analysis was carried out, adjusting for baseline gender, age, and EQ-5D score.

RESULTS

Recruitment

Patients were recruited between February 2012 and February 2014 at UHCW and UHH trusts, at a rate of 1.25 patients per month. This was less than half of that anticipated.

Baseline Characteristics

Randomisation ensured a generally good balance of patient characteristics between groups. By chance, participants in the TR group had marginally better function (OSS and CMS) and quality of life (EQ-5D) than the HR group; therefore baseline scores for these outcome measures were used as covariates in the definitive analysis.

Outcomes for full population

There were statistically significant (p -values <0.001) improvements in function (as measured by OSS and CMS) from baseline to 12 months. There was no evidence for improvement in health-related quality of life (as measured by EQ-5D) at 12 months ($p=0.468$), but there was evidence of a statistically significant improvement at 6 months ($p<0.001$).

Outcomes by treatment group

There was some evidence that function was significantly better in the TR group than the HR group (p -values for OSS and CMS were 0.056 and 0.075). However, adjusting for baseline OSS gave a p -value of 0.232, with adjusted treatment group difference 6.0 (95% CI; -4.1 to 16.2); baseline OSS was by chance lower in the TR group than the HR group. Similarly, adjusting for baseline CMS gave a p -value of 0.179, with adjusted treatment group difference -8.5 (95% CI; -21.4 to 4.4). Including age and gender as covariates, in addition to baseline OSS data, did not improve model fit for 12 month OSS, the primary outcome measure.

Complications

There was no evidence for group differences in any of the reported complications.

Cost effectiveness analysis

Resource use and QALY data were available for 13 patients with TR and 10 with HR.

The mean total NHS resource use costs were respectively £6,137 for total resurfacing and £7,892 hemi resurfacing and were significantly higher for hemi resurfacing (+£1,755). Lost earnings and productivity losses to employers through sickness absences and informal care are similar in both arms and represent between £75 and £91. There were significant differences in NHS resource use costs and societal costs between the treatment arms according to the t -tests.

After adjustment for baseline differences, there was a QALY difference 0.008 in favour of TR.

DISCUSSION

There was no evidence for statistically significant differences in the primary or secondary outcome measures between groups in this small pilot study. However the reported treatment difference for OSS (primary outcome), after appropriate adjustment for baseline scores, of 6.0 (95% CI; -4.1 to 16.2) was equal to the minimum clinically important difference (MCID) for OSS of approximately 6 points (van Kampen et al. 2013). Therefore, if the true treatment difference for the OSS is 6, with standard deviation of 13, we would need to recruit 100 participants to each of the TR and HR groups to be able to reject the null hypothesis that the population means of the groups are equal with probability (power) 0.9. The type I error probability (false positive rate) associated with this test of this null hypothesis is 0.05 (5%). Allowing for 20% loss to follow-up, which is consistent with the numbers reported here, a sample size of 240 would be required for a full trial.

Patient and public involvement

In line with good practice guidelines published by INVOLVE, initial consultation was achieved through informal interviews with patients and their family, friends and carers. These consultations took place in the outpatient dept with patients who had been referred for intervention with osteoarthritis of the shoulder and were conducted by research physiotherapists involved in upper limb trials. The NHS PALS were consulted and agreed that the outpatient department was the most appropriate place to consult the public.

These initial consultations allowed us to identify aspects of shoulder arthroplasty that were considered priorities by patients and the public. Improved shoulder function was a high priority for all patients, and the longevity of the implants was also a consideration. One of the patients involved in the initial consultation volunteered to review the full proposal and gave advice regarding the lay section of this grant application. We invited this patient to participate in the selection of the research staff who had direct contact with trial participants and also to join the Trial Steering Committee.

Throughout the research project, patients and public members were kept informed of progress and developments through newsletters which were displayed in waiting areas for shoulder clinics in the participating hospitals.

Data sharing statement

See link

[\[https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253\]](https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253) for the NIHR position of the sharing of research data. The NIHR strongly supports the sharing of data in the most appropriate way, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic

growth in the UK. All requests for data should be directed to the award holder and managed by the award holder.

References

van Kampen, D.A., Willems, W.J., van Beers, L.W.A.H. et al. Determination and comparison of the smallest detectable change (SDC) and the minimal important change (MIC) of four-shoulder patient-reported outcome measures (PROMs). J Orthop Surg Res 8, 40 (2013).

Disclaimer

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This project was carried out between January 2012 and January 2015. This final report has not been peer-reviewed. The report was examined by the Programme Director at the time of submission to assess completeness against the stated aims.