Patient-reported outcome and risk of revision after shoulder replacement for osteoarthritis

1,209 cases from the Danish Shoulder Arthroplasty Registry, 2006–2010

Jeppe V Rasmussen, Anne Polk, Stig Brorson, Anne Kathrine Sørensen, and Bo S Olsen

Department of Orthopedic Surgery, Herlev University Hospital, Denmark.
Correspondence: jevera01@heh.regionh.dk
Submitted 13-07-03. Accepted 14-01-06

Purpose — We used patient-reported outcome and risk of revision to compare hemiarthroplasty (HA) with total shoulder arthroplasty (TSA) and stemmed hemiarthroplasty (SHA) with resurfacing hemiarthroplasty (RHA) in patients with glenohumeral osteoarthritis.

Patients and methods — We included all patients reported to the Danish Shoulder Arthroplasty Registry (DSR) between January 2006 and December 2010. 1,209 arthroplasties in 1,109 patients were eligible. Western Ontario Osteoarthritis of the Shoulder index (WOOS) was used to evaluate patient-reported outcome 1 year postoperatively. For simplicity of presentation, the raw scores were converted to a percentage of the maximum score. Revision rates were calculated by checking reported revisions to the DSR until December 2011. WOOS and risk of revision were adjusted for age, sex, previous surgery, and type of osteoarthritis.

Results — There were 113 TSAs and 1096 HAs (837 RHAs and 259 SHAs). Patients treated with TSA generally had a better WOOS, exceeding the predefined minimal clinically important difference, at 1 year (mean difference 10, $p < 0.001$). RHA had a better WOOS than SHA (mean difference 5, $p = 0.02$), but the difference did not exceed the minimal clinically important difference. There were no statistically significant differences in revision rate or in adjusted risk of revision between any of the groups.

Interpretation — Our results are in accordance with the results from other national shoulder registries and the results published in systematic reviews favoring TSA in the treatment of glenohumeral osteoarthritis. Nonetheless, this registry study had certain limitations and the results should be interpreted carefully.

Stemmed hemiarthroplasty (SHA), which evolved from the early monoblock design of Charles Neer (1917–2011), is still used in the treatment of glenohumeral osteoarthritis. The original design has been modified to a modular prosthesis with the head connected to the stem by a taper locking system. The results have been reported in numerous studies, showing substantial pain relief and improved function (Gartsman et al. 2000, Norris and Iannotti 2002, Edwards et al. 2003, Lo et al. 2005, Haines et al. 2006, Radnay et al. 2007). Nonetheless, some patients fail to benefit from the operation, which may be due to glenoid wear (Parsons et al. 2004). Total shoulder arthroplasty (TSA) may be the preferred treatment due to a superior functional outcome, but the risk of glenoid loosening has been worrying (Bishop and Flatow 2005, Bryant et al. 2005, Radnay et al. 2007, Singh et al. 2011).

The first resurfacing hemiarthroplasty (RHA) to be used in a greater numbers was the SCAN (Scandinavian) Cup, which was introduced in 1981 for the treatment of rheumatoid arthritis (Jonsson et al. 1986). A few years later, the concept was applied to other diagnoses including osteoarthritis (Levy and Copeland 2001). The modern hydroxyapatite-coated resurfacing arthroplasty, which is still used today, was introduced in 1993 (Levy and Copeland 2004). Even so, despite the long-term use of RHA the functional outcome and risk of revision have only been reported in small case series (Levy and Copeland 2004, Bailie et al. 2008, Al-Hadithy et al. 2012, Mansat et al. 2013).

In this study, we used patient-reported outcome and risk of revision to compare hemiarthroplasty (HA) and TSA in patients diagnosed with glenohumeral osteoarthritis, and also to compare SHA and RHA.

Patients and methods

Reporting to the Danish Shoulder Arthroplasty Registry (DSR) is mandatory for all Danish hospitals and private clinics

DOI 10.3109/17453674.2014.893497

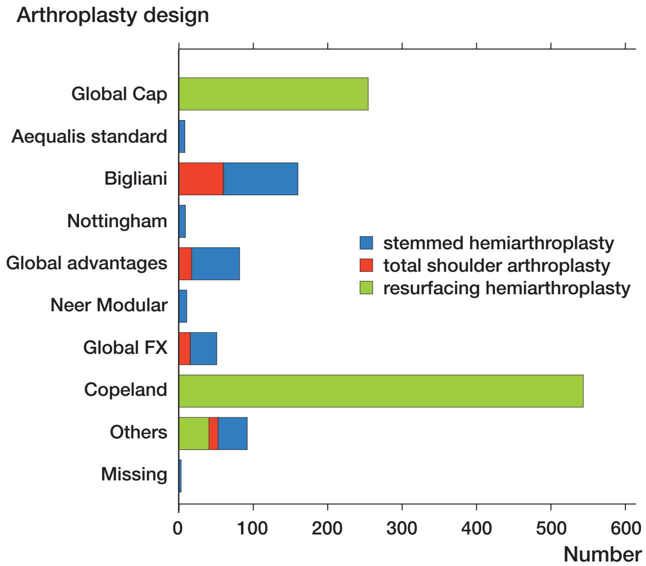

Figure 1. Implants used from January 2006 through December 2010.

performing shoulder arthroplasty surgery. Data are reported by the surgeon at the time of surgery using an internet-based system (Rasmussen et al. 2012a). From comparison with data from the National Patient Registry, the Statistical Department of the Danish National Board of Health, 90% of all shoulder arthroplasty operations were reported to the registry between January 2006 and December 2010.

We included all patients diagnosed with primary or secondary osteoarthritis reported to the DSR between January 2006 and December 2010. Only primary operations were included. 1,209 arthroplasties in 1,109 patients were eligible (100 patients were replaced bilaterally) (Figure 1).

Patient-reported outcome was assessed with a mail survey 12 months after the operation using the Western Ontario Osteoarthritis of the Shoulder index (WOOS) (Lo et al. 2001). WOOS is a disease-specific tool for measurement of the quality of life of patients diagnosed with osteoarthritis. We used a cross-cultural and validated Danish version of WOOS (Rasmussen et al. 2013). There are 19 questions to be answered on a visual analog scale ranging from 0 to 100; thus, the total score ranges from 0 to 1,900, with 1,900 being the worst score. For simplicity of presentation, we converted the raw scores to a percentage of the maximum score, with 100 as the best score. The minimal clinically important difference for WOOS has been suggested to be 10% (Polk et al. 2013), which we also used in this study.

Revision rates were calculated by checking revisions reported to the DSR until December 2011 and by checking deaths with the Danish National Register of Persons. We defined a revision as the removal or exchange of any component or the addition of a glenoid component. In cases of revision within 1 year postoperatively, WOOS was registered as missing due to revision. In cases of revision later than 1 year postoperatively, WOOS was registered as usual and was included in the analyses of patient-reported outcome. If more than 1 revision was recorded, only the first one was counted. In the analysis of patient-reported outcome, we included only patients with a complete questionnaire. Responders were defined as patients who returned a completed questionnaire 1 year postoperatively or after a postal reminder, whereas non-responders were defined as patients who did not complete or return the questionnaire after the postal reminder.

Statistics

We compared demographic data by age, sex, type of osteoarthritis (primary or secondary), previous surgery in the same shoulder (yes or no), and response rate using student t-test (continuous variables) or chi-square test (categorical variables). WOOS was adjusted for potential confounders including age, sex, previous surgery in the same shoulder (yes or no), and type of osteoarthritis (primary or secondary) with use of general linear models when arthroplasty designs were compared.

We used the Kaplan-Meier method to calculate and illustrate the unadjusted revision rates and a Cox proportional hazard regression model was used to calculate hazard ratios as a measure of relative risk of revision with 95% confidence intervals (CIs) when adjusting for confounders. Age, sex, previous surgery in the same shoulder (yes or no), and type of osteoarthritis (primary or secondary) were included in the analysis. The number of patients that were revised within the first year is described for each arthroplasty design; differences were analyzed using chi-square test.

Previous studies have found that the consequences of including bilaterally operated patients are negligible in the analysis of implant survival (Schwarzer et al. 2001, Robertsson and Ranstam 2003, Lie et al. 2004, Ranstam et al. 2011). We do not know the consequences of including bilaterally operated patients in the analysis of WOOS. We therefore analyzed the differences in WOOS between arthroplasty designs with or without inclusion of bilaterally operated patients.

The analysis was performed using SPSS version 19.0. The level of statistical significance was set at 0.05.

Ethics

The study was approved by the Danish Data Protection Agency (J. no. 2007-58-0015).

Results

975 patients (81%) returned a completed questionnaire (Table 1). There were 113 TSAs and 1,096 HAs. Demographic data were similar (Table 2). Mean WOOS scores for TSA and HA were 78 (SD 25) and 66 (SD 26). TSA had a better score, exceeding the minimal clinically important difference, when WOOS was adjusted for potential confounders (mean difference 10, CI: 5–15; $p < 0.001$). The analysis without bilaterally

Table 1. The reasons for not responding, with number and percentage of all arthroplasties included

	No.	Percentage of all arthroplasties
Continuing non-responders	131	11
Incomplete questionnaires	40	3.3
Revision within 1 year	41	3.4
Dead within 1 year	19	1.6
Unknown civil registration number	3	0.2
Responders	975	81
Total	1,209	100

Table 2. The differences in demographics between TSA and HA

	Total shoulder arthroplasty	Hemiarthroplasty	p-value
Total no. of patients	113	1,096	
Women	72 (64%)	637 (58%)	0.5 [a]
Previous surgery	13 (12%)	226 (21%)	0.2 [a]
Non-responders	20 (18%)	214 (20%)	0.6 [a]
Primary osteoarthritis	100 (89%)	923 (84%)	0.2 [a]
Mean age (SD)	69 (9)	67 (11)	0.06 [b]

[a] Chi-square test.
[b] Student's t-test.

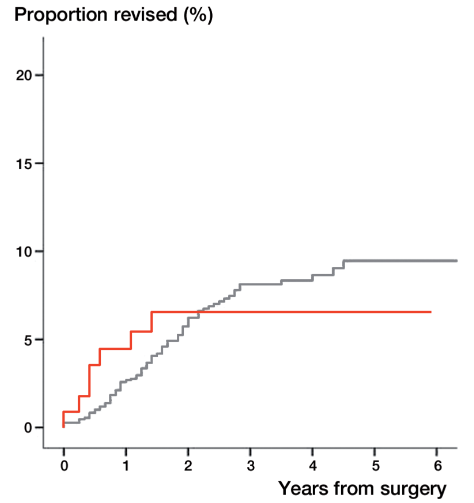

Figure 2. The unadjusted cumulative revision rate for hemiarthroplasty (grey) and total shoulder arthroplasty (red) showing no significant difference between arthroplasty designs (p = 1.0, Kaplan-Meier method).

operated patients showed similar results (mean difference 12, CI: 6–18; p < 0.001).

7 TSAs (6%) and 79 HAs (7%) had been revised by the end of 2011. The unadjusted cumulative revision rates were similar (Figure 2). When we compared TSA with HA as reference, there were no significant differences in risk of revision adjusted for age, sex, previous surgery in the same shoulder, and type of osteoarthritis (RR = 1.1, CI: 0.5–2.4; p = 0.8). 5 TSAs (5%) and 36 HAs (3%) were revised within the first year.

There were 837 RHAs and 259 SHAs. The patients treated with RHA were more often male and more often younger, and there were fewer non-responders than with SHA (Table 3). Mean WOOS scores for RHA and SHA were 67 (SD 26) and 64 (SD 26). RHA had a statistically significantly better score when WOOS was adjusted for potential confounders (mean difference 5, CI: 1–9 CI; p = 0.02). However, the difference did not exceed the minimal clinically important difference. The analysis without bilaterally operated patients showed identical results (mean difference 5, CI: 1–10; p < 0.001).

16 SHAs (6%) and 63 RHAs (8%) had been revised by the end of 2011. The unadjusted cumulative failure rates were similar (Figure 3). When we compared RHA with SHA as reference, risk of revision was similar when we adjusted for age, sex, previous surgery in the same shoulder, and type of osteoarthritis (RR = 0.9, CI: 0.5–1.6; p = 0.8). 12 SHAs (5%) and 24 RHAs (3%) were revised within the first year.

Table 3. The differences in demographics between SHA and RHA

	Stemmed hemiarthroplasty	Resurfacing hemiarthroplasty	p-value
Total no. of patients	259	837	
Women	170 (66%)	467 (56%)	0.02 [a]
Previous surgery	55 (21%)	171 (20%)	0.8 [a]
Non-responders	65 (25%)	149 (18%)	0.01 [a]
Primary osteoarthritis	208 (80%)	715 (85%)	0.1 [a]
Mean age (SD)	71 (11)	65 (11)	< 0.01 [b]

[a] Chi-square test.
[b] Student's t-test.

Discussion

3 randomized clinical trials have compared SHA and TSA (Gartsman et al. 2000, Lo et al. 2005, Sandow et al. 2013). One trial (Lo et al. 2005) reported WOOS scores of 91 and 82 after TSA and HA at 2 years. Also, Constant-Murley score and UCLA shoulder rating scale were similar. Another trial found a slightly better outcome (UCLA rating scale) after TSA than after SHA without the difference being statistical significant (Gartsman et al. 2000). The third trial (Sandow et al. 2013) found that pain relief was initially better with TSA but the difference did not persist at the final follow-up examination at 10 years, and Constant-Murley score and UCLA shoulder rating scale were similar. These randomized clinical trials were small, with 33–51 arthroplasties; however, the results (UCLA shoulder rating scale) have been summarized in a systematic review and meta-analysis (Bryant et al. 2005) showing a statistically significant superior outcome after TSA. The outcome after TSA and SHA has also been reported in numerous studies, including larger prospective studies (Edwards et

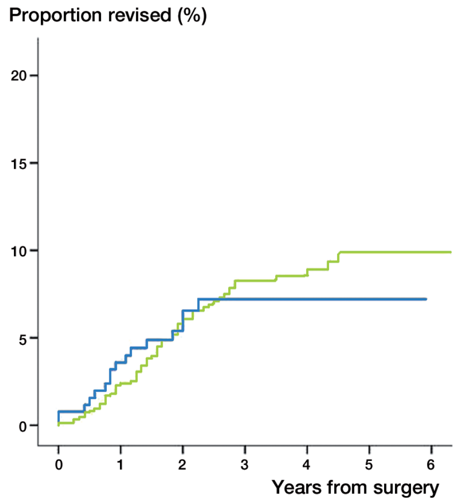

Figure 3. The unadjusted cumulative revision rate of stemmed hemiarthroplasty (blue) and resurfacing hemiarthroplasty (green) showing no difference between arthroplasty designs (p = 0.9, Kaplan-Meier method).

al. 2003, Singh et al. 2012), and the results have been summarized in a systematic review favoring TSA (Radnay et al. 2007). A cadaver study found that RHA more closely restores the mechanics of the shoulder than SHA (Hammond et al. 2012); however, there have been no previous clinical studies comparing RHA with other arthroplasty designs.

Revision following stemmed SHA and TSA has been reported in numerous case series and few prospective studies. The results of 23 studies have been summarized in a systematic review (Radnay et al. 2007) reporting that 7% of TSAs and 10% of SHAs were revised without the follow-up times being specified. Revision was only required in 2% of the TSAs using an all-polyethylene glenoid component. Revision rates following SHA and TSA have also been described in a clinical multicenter study involving 690 arthroplasties (601 TSAa and 89 SHAs) with a mean follow-up time of 3.5 years. There were 68 revisions (10%). A high revision rate following TSA related to the use of a metal-backed glenoid component, later abandoned, has been reported (Edwards et al. 2003). However, differences in revision rate between TSA, SHA, and especially RHA should be interpreted carefully. RHA in particular facilitates revision to other arthroplasty designs, and some surgeons may choose to revise an RHA in cases with only slightly inferior outcome. These patients might not have been revised if they had had a similar inferior outcome following SHA or especially TSA.

It has been suggested that a coated glenoid component should be added to RHA in patients with non-concentric erosion of the glenoid (Levy and Copeland 2004). However, it can be difficult to expose the glenoid without removing the humeral head, making it a technically demanding operation. Information about the functional outcome and risk of revision is inconclusive (Levy and Copeland 2004, Pritchett 2011). No total resurfacing arthroplasties have been reported to the DSR, and the Danish orthopaedic surgeons appear to prefer conventional TSA when replacement of the glenoid is required.

There have been few publications from national shoulder arthroplasty registries (Rasmussen et al. 2012b). A report from a Norwegian study (Fevang et al. 2013) gave the pre- and postoperative patient-reported outcome in 336 patients diagnosed with osteoarthritis, using the Oxford shoulder score. Patients treated with TSA had a mean improvement of 20 units whereas patients treated with HA had a mean improvement of 13 units. The difference of 7 units exceeded the minimal clinically important difference, and was statistically significant. Another study from the Norwegian registry showed a cumulative 5- and 10-year revision rate for patients diagnosed with osteoarthritis and treated with HA of 6% and 9%, respectively. There was no comparison of arthroplasty designs for patients with glenohumeral osteoarthritis (Fevang et al. 2009). The annual report from the National Joint Replacement Registry in Australia (Australian Joint Replacement Registry 2013) described a 4-year cumulative revision rate of 6%, 8%, and 10% following TSA, SHA, and RHA, respectively. Only the difference between TSA and RHA was statistically significant. The registry in Australia does not collect data on functional outcome (Rasmussen et al. 2012b). The New Zealand National Joint Registry (2013) reported a 4-year cumulative survival rate of 97%, 95%, and less than 90% following TSA, SHA, and RHA. The patient-reported outcome (Oxford shoulder score) showed a poorer outcome for both SHA and RHA than for TSA, and a poorer outcome for SHA than for RHA. To our knowledge, the results reported in the annual reports from both Australia and New Zealand are not adjusted for diagnosis and should be interpreted with caution. Nonetheless, as in Denmark, there is a trend of superior patient-reported outcome and a lower risk of revision after TSA than after HA (RHA and SHA) in other national shoulder registries. There are no annual reports or peer-review articles available from the national shoulder registries in Sweden and Finland.

Many factors influence the outcome and revision rate after shoulder arthroplasty in patients with osteoarthritis: disease-related factors such as type of osteoarthritis, size of osteophytes, previous surgery, rotator cuff pathology, previous trauma with the possibility of instability etc; patient related factors such as quality of bone stock, comorbidity, and the ability to follow rehabilitation; surgeon- and hospital-related factors such as surgical skills including the possibility of exposing the glenoid when using TSA. There is little information about all these factors, and as the patients are not randomly allocated, there may be different distributions in the groups compared.

In this registry study, there are no data on the indication for the type of implant to be used. The relatively rare use of TSA in Denmark may indicate that TSA is used in selected patients only. Thus, the types of implants used in this study may have been selected according to specific patient characteristics, which add considerable limitations to the interpretation of the results.

Another limitation is that there was no preoperative measurement of patient-reported outcome. Thus, differences in preoperative shoulder function may have influenced the differences in WOOS score between groups, making the patient-reported outcome less reliable than the results from prospective comparative studies and randomized clinical trials with a preoperative measurement.

Inclusion of bilaterally operated patients violates the assumption that arthroplasties are independent. Even so, bilaterally operated patients were included in the analysis of WOOS in order to obtain greater statistical power. The consequences of this have not been described, but exclusion of bilaterally operated patients did not statistically significantly change the results and the conclusion.

There was no information about WOOS in the early failures that were revised within the first year. Thus, since early failures were not included in the analysis of WOOS, an uneven distribution may have skewed the outcome (mean WOOS score would be falsely high if the percentage of early revision in one group is higher than in others). Nonetheless, we compared the percentage of early failures and found similar outcome in different arthroplasty designs.

It is most likely that not all revisions are captured in the DSR, leading to underestimation of revision rates. Furthermore, incorrect reporting may reduce the accuracy and reliability of the data. Finally, there was only a short-term follow-up of the patient-reported outcome and the difference between TSA and HA may not persist in a long-term follow-up evaluation.

This registry study also had several advantages. Randomized clinical trials and prospective studies use inclusion and exclusion criteria in an attempt to make patients as homogeneous as possible. Furthermore, the surgeons are often more experienced and interested in the specific type of operation than general shoulder surgeons. Thus, such studies provide information that cannot always be generalized (McCulloch et al. 2009). The results of this nationwide study can be generalized more easily, not only to the average shoulder surgeon but also to the average patient from the outpatient clinic regardless of comorbidity, age, and severity of osteoarthritis. Another advantage was the large sample size with high statistical power.

In summery, we found that the patient-reported outcome following TSA was superior to that of HA (SHA and RHA) with a statistically significant difference exceeding the minimal clinically important difference. Furthermore, the risk of revision tended to be lowest following TSA. Our results are in accordance with the results from other national shoulder registries and the results published in systematic reviews favoring TSA in the treatment of glenohumeral osteoarthritis. This registry study does have certain limitations, however, and the results should be interpreted with caution.

JR: conception and design of the study, data processing, statistics, writing of the paper, and incorporation of input from the other authors; AP: collection of data, data processing, and review of the manuscript; SB and AKS: writing of the paper and interpretation; BO: conception and design of the study, interpretation, and review of the manuscript.

We thank Tobias Wirenfeldt Klausen for statistical advice and the Danish orthopedic surgeons for data reporting.

No competing interests declared.

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