

Lower age increases the risk of revision for stemmed and resurfacing shoulder hemi arthroplasty

A study from the Swedish shoulder arthroplasty register

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Background and purpose — The number of patients where shoulder hemiarthroplasty (SHA) is an option is still substantial. Descriptive analyses performed by the Swedish Shoulder Arthroplasty Registry (SSAR) showed that while patients receiving SHA designs, i.e. resurfacing hemi (RH) and stemmed hemi (SH), reported similar shoulder functionality and quality of life, the revision rate for RH (12 %) was larger than for SH (6.7 %); this difference was studied.

Patients and methods — All primary SHA (n = 1,140) for OA reported to SSAR between 1999 and 2009 were analyzed regarding risk factors for revision and PROM outcome, 950 shoulders with primary OA (POA), and 190 secondary OA (SOA). Mean age was 67.4 years (SD 10.8). PROM including WOOS and EQ-5D were collected at 5 years, until December 31, 2014.

Results — 76/950 prostheses because of POA and 16/190 prosthesis because of SOA were revised. Age at primary surgery was the main factor that influenced the risk of revision, lower age increased the risk of revision, and was also the explanation for the difference between SH and RH. We also found that SH and RH had similar outcomes measured by PROM, but the POA group had higher scores than the SOA group with a clinically relevant difference of 10% in WOOS.

Interpretation — The risk of revision for SH and RH is similar when adjusted for age and does not depend on primary diagnosis or sex. A lower age increases the risk of revision. Patients suffering from POA experience better shoulder functionality than SOA patients irrespective of implant type.

cal shoulder hemiarthroplasty (SHA) where only the humeral head is replaced, another is the anatomical total shoulder arthroplasty (TSA), where both sides (humeral head and glenoid) of the joint are replaced with artificial components. The third is the reversed total shoulder arthroplasty (RSA), where the humeral head and glenoid joint are “reversed” to a sphere on the glenoid side and a socket on the humerus. The TSA has been considered to result in better pain relief than SHA, and has a growing share of the total number of performed arthroplasties. The Swedish Shoulder Arthroplasty Registry (SSAR) shows that SHAs have good effect on osteoarthritic pain relief and improved function, but the improvement seems to develop slower than after TSA, and at 5 years the Patient Reported Outcome Measures (PROM) remain inferior to those after TSA (Swedish Shoulder Arthroplasty Registry. Annual Report 2016, pp. 13–14). Other studies with long follow-up time has shown similar results between SHA and TSA (Lo et al. 2005).

Stemmed shoulder hemiarthroplasty

The stemmed shoulder hemiarthroplasty (SH) is the original anatomical shoulder arthroplasty concept developed by Charles Neer for SHA treatment of proximal shoulder fractures (Neer et al. 1982). The Neer prosthesis has been successful both as SHA and TSA with addition of a polyethylene glenoid surface, but some authors have showed less predictable results for SHA (Mansat et al. 2002). There have been no major problems reported regarding cemented and uncemented stem fixation in the humerus (Raiss et al. 2014), and more recently short stems or stemless designs have also been developed. The short-stemmed shoulder arthroplasty will not be further discussed in this study since it was not in use in Sweden during this study period.

There has been a rapid development of implants available on the market regarding prosthetic designs. One is the anatomi-

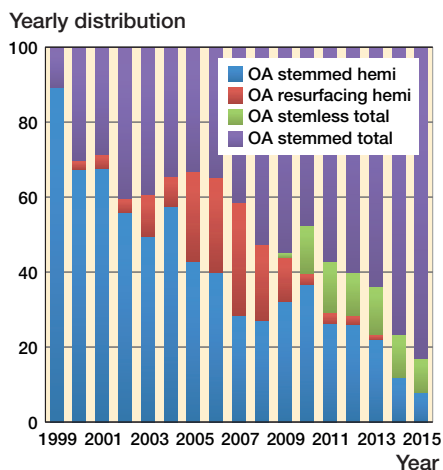


Figure 1. Proportion of different implant types for treatment of OA reported to the Swedish Shoulder Arthroplasty Register during the period 1999–2015. “OA stemmed total” includes only anatomical implants. OA = osteoarthritis.

Resurfacing shoulder hemiarthroplasty

The resurfacing shoulder hemiarthroplasty (RH) was introduced in Sweden in the 1980s (Jónsson et al. 1986) and later commonly performed in Sweden between 2003 and 2009 (Figure 1). The RH is a procedure designed to minimize bone removal in the proximal humerus and to restore the normal anatomy of the humeral head (Burgess et al. 2009). Instead of cutting the humeral head, only the cartilage of the humeral side is removed, and replaced by a new metal joint surface. One potential benefit of this design is that it facilitates arthroplasty in patients with an altered anatomy (e.g. malunion after fracture) or uncertainty of the rotator cuff function. It also reduces the occurrence of “kissing implants” in patients with elbow implants, and a primary resurfacing procedure might facilitate the treatment of a late periprosthetic fracture (Levy and Copeland 2004).

The TSA currently might be considered the gold standard for treatment of osteoarthritis of the shoulder. However, the steadily increasing total number of shoulder replacements indicates that an SHA could still be considered in some circumstances: patient request, expectations, age, and pre-existing medical conditions. Furthermore, there has been a growing interest regarding possible new materials for SHA designs (Carpenter et al. 2016, Garret et al. 2017). Thus, the SHA and knowledge concerning its past and current performance and outcome would also be valuable for future comparisons.

Descriptive analyses performed by SSAR indicate that patients receiving RH and SH have similar PROM results. However, the revision rate for RH (12%) is larger than for SH (6.7%). In this study, we identify risk factors for revision and compare results obtained using different PROM instruments for revision of elective primary RH and SH for osteoarthritis (OA), within SSAR. The secondary aim of this study is to

investigate the performance of SHA in terms of revision risk and patient satisfaction for patients suffering from POA and SOA.

Patients and methods

This was a registry study from the SSAR. The Swedish Shoulder and Elbow Society started the register in 1999 (Rahme et al. 2001). It collects data from primary shoulder arthroplasties and revisions performed in Swedish hospitals. Currently all units that perform shoulder arthroplasties report to the SSAR, and over 80% of the shoulder arthroplasties in Sweden are registered. During 2015, a total of 1,624 primary shoulder arthroplasties were reported in Sweden, of which 650 were primary arthroplasties for osteoarthritis (Swedish Shoulder Arthroplasty Registry. Annual Report 2015, pp. 14–15). The Swedish Shoulder Arthroplasty Registry collects the disease-specific PROM, Western Ontario Osteoarthritis of the Shoulder index (WOOS), and the generic PROM EuroQol 5 dimension 3L (EQ-5D). In Sweden in 1999, 90% of the arthroplasties for osteoarthritis were performed as SHA and only 10% as TSA. Now, more than 15 years later, this ratio has reversed (Figure 1).

We analyzed all elective primary SHA, both cemented and uncemented, reported within SSAR from January 1, 1999 to December 31, 2009 for the diagnoses primary osteoarthritis (POA) and secondary osteoarthritis (SOA). In the SSAR, SOA is defined as sequelae after trauma, dislocations, or other injuries to the joint, as well as late sequelae after infection in the joint. 950 shoulders were diagnosed with POA and 190 with SOA. Previous surgery to the shoulder was in many cases reported parallel to the diagnosis of POA, depending on the type of procedure. Patients with non-union after fracture or cuff deficiencies were excluded from the analysis. Implants not considered to be stemmed, nor of the resurfacing type, were also excluded from the study, e.g. short-stemmed implants or implants with bipolar heads. Finally, 198 surgeries with incomplete information were excluded from the study (Figure 2).

In our dataset, there were 998 patients receiving one shoulder implant and 71 patients were operated on both shoulders. The total number of implants is 1,140 (142 bilateral). Of those 1,140 implants, 92 were revised (8.1%) (Table 4). In unilaterally operated patients, 69 prostheses were revised (6.9%). In bilaterally operated patients, 7 implants were revised (4.9%); of those, 3 patients were revised only on 1 side (2.1%), and 2 patients were revised on both sides (2.8%).

The primary outcome was revision of an implant. Revision was defined as either removal, exchange, or addition of an implant component. Causes for revision were categorized by a hierarchy where the last group “other” includes glenoid erosion, overstuffing of the joint, and malposition of the implant. This definition is in accordance with the Nordic Arthroplasty Register Association (NARA), and its shoulder group definitions (Rasmussen et al. 2016).

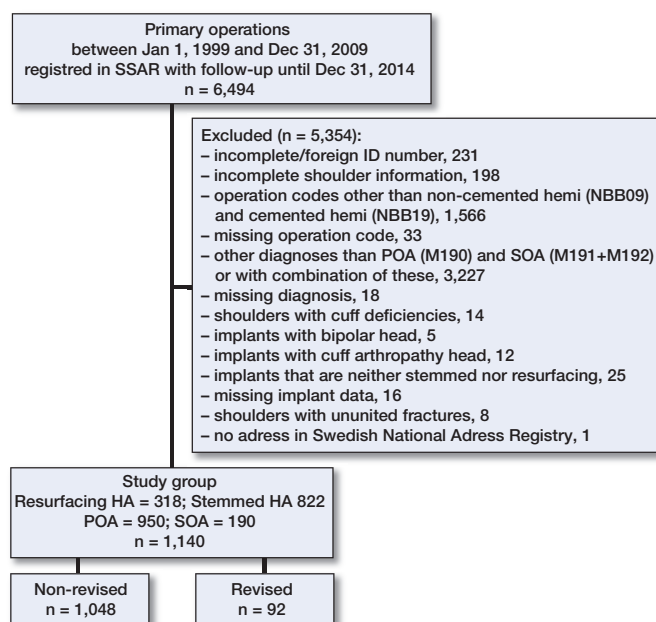


Figure 2. Data included in the study. POA = primary osteoarthritis, SOA = secondary osteoarthritis, HA = hemiarthroplasty.

The Western Ontario Osteoarthritis of the Shoulder index

The WOOS is a patient-reported, disease-specific questionnaire for the measurement of quality of life in patients with osteoarthritis. The WOOS results can be combined to a single score representing the percentage of a healthy shoulder from 0% to 100%. The 5-year follow-up WOOS was a secondary outcome measure in this study.

EuroQol 5 dimension 3L

The EQ-5D version used in SSAR is an instrument widely used to measure the generic quality of life (EuroQol Group 1990). Combined to a single index ranking from -0.54 (worse than death when below zero) to 1 (best imaginable health state).

Satisfaction level

The SSAR also sends out a question on patient satisfaction level (SL). SL is collected as an ordinal Likert scale. “How satisfied are you with the shoulder after the operation?” offers 5 possible alternatives: very disappointed, slightly disappointed, neither disappointed nor satisfied, slightly satisfied, and very satisfied. We analyzed the rate “satisfied/neutral” vs. not “satisfied”.

In order to obtain information within the registry about the PROM after the operation, the SSAR send out a package including the three mentioned evaluation forms by mail, to all patients still alive at 5 years after the surgery. The overall response rate is above 60% with only a single request to the recorded patients within the Swedish National Address Registry.

Statistics

The survival times for the implant were analyzed using a Cox regression model. Since there are some patients who were operated bilaterally (142 bilateral implants, 7 revised) the correlation of the data is incorporated in the model by modifying the variance–covariance matrix and the standard errors using a cluster term to allow for intragroup correlation. Earlier studies performed on revision risk of knee prostheses show that there are negligible consequences of analyzing bilateral observations as independent in the survival model, as long as the revision rate for bilateral patients is low (Ranstam 2012). In the shoulders we observed a low bilateral revision rate and the correlation in implant survival for bilateral patients may be lower than in the knee case, thus we believe that the cluster correction in the variance–covariance matrix is sufficient to handle the intragroup correlation in the model. Furthermore, 277 patients (26%) died during the follow-up period and 5 patients (0.5%) were lost to follow-up. These patients were censored in the analysis. We assumed that the censoring is independent, meaning that, after adjusting for covariates, the risk for revision for the censored patients is similar to the risk for revision for patients who remain in follow-up with the same covariates.

The objective of the analysis is to investigate whether the risk of revision depends on the implant type by using a simple model. We controlled for potential confounding factors recorded in the SSAR: sex, diagnosis (POA or SOA), and age at the primary operation, and operation year. The operation year is used as proxy for the learning effect. We also tested for interaction effects between age and implant, implant and diagnosis, and diagnosis and age. We retained only the statistically significant terms in the model in order to obtain smaller standard errors for the remaining estimates. The proportional hazard assumption was tested using the Schoenfeld residuals. The overall fit of the model was assessed visually using the Cox–Snell residuals.

Differences in PROM values between implant type and diagnosis were assessed using the Kruskal–Wallis test and chi-square test. In this case, only 1 operation was considered for the bilateral cases.

The analysis was performed using the software Stata version IC/13.1 for Windows, (StataCorp LP, College Station, TX USA). A p-value of 0.05 or less was considered statistically significant for all the analyses presented in this work.

Ethics, funding, and potential conflicts of interest

The study was approved by the local ethics committee in Stockholm on the June 8, 2016, study number 2016/1016-31/4. Funds were received from Greta and Johan Kocks Stiftelser to conduct the study. 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. The authors report no potential conflicts of interest regarding this study.

Table 1. Implants by brand, number, and percentage of the total number of implants

Implant type	n	%
Resurfacing implants (RH):		
Copeland	205	65
Durom	9	3
Epoca RH	8	2.5
Global Cap	96	30
Total resurfacing	318	100
Stemmed implants (SH):		
3M-modular	120	15
Aequalis	149	18
Anatomical Shoulder	21	2.5
Bigliani Flatow	188	23
Bio-modular	24	3
Comprehensive	15	2
Global	74	9
Neer 2	54	6.5
Neer 3 modular	64	8
Nottingham	100	12
Others	13	1.5
Total stemmed	822	100

Number of revisions

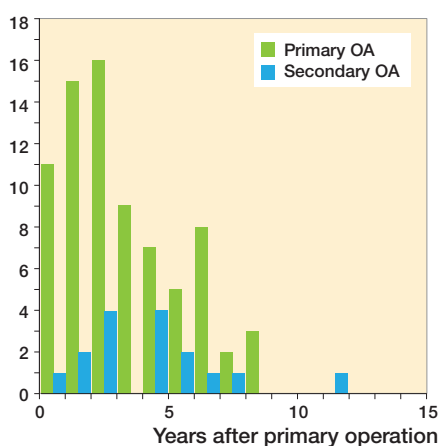


Figure 3. Time to revision for shoulder hemiarthroplasty for primary and secondary osteoarthritis 1999–2009.

Revision-free survival (%)

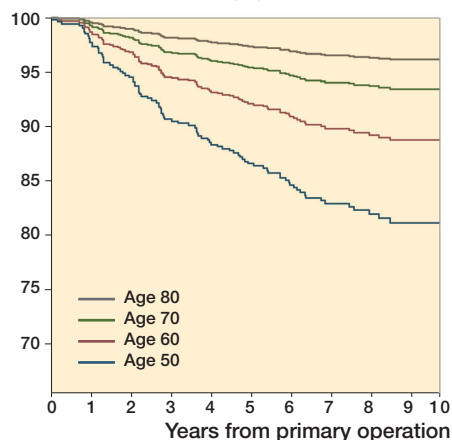


Figure 4. Survival curves for different median ages and results from the Cox model. Only age has a significant effect for revision (no statistically significant effect from diagnoses, implant and sex). Age at primary operation: Hazard ratio = 0.94 (CI 0.93–0.96) $p < 0.001$.

Table 2. Primary procedures and revisions by diagnosis, type of implant, age distribution, and sex

Diagnosis Implant	Primary operation		Revision	
	women	men	women	men
Primary OA				
RH, n	141	139	14	15
median age	71	62	65	63
SH, n	362	308	23	24
median age	74	65	72	63
Total, n	503	447	37	39
median age	73	64	68	63
Secondary OA				
RH, n	14	24	3	5
median age	59	62	52	56
SH, n	80	72	4	4
median age	71	61	52	55
Total, n	94	96	7	9
median age	68	60	52	55

RH = resurfacing hemiarthroplasty; SH = stemmed hemiarthroplasty; OA = osteoarthritis.

Table 3. Reasons for revision, divided by diagnosis and type of implant

Reason for revision	Primary OA		Secondary OA	
	RH	SH	RH	SH
Periprosthetic fracture	1	1	0	0
Dislocation	2	4	0	0
Loose implant	3	2	0	0
Rotator cuff problem	0	2	0	0
Pain and other	23	37	8	8
Total	29	47	8	8

For abbreviations, see Table 2

Results

1,140 primary procedures were included. 318 (28%) were resurfacing implants and 822 (72%) were stemmed implants (Table 1).

For patient, implant, and revision characteristics see Table 2. The frequency of previous surgical treatment of the shoulder was similar between the RH ($n = 32$, or 10%) and SH ($n = 75$, or 9%) groups. A stabilizing procedure was the most common finding among previous surgery in the SOA group but there were no differences between the 2 types of implants, and a previous operation did not increase the risk for revision.

Revisions

92 implants were revised during the study period. The reasons for revision were similar between RH and SH, and in both groups the most common cause of revision was “Pain and other” which includes glenoid erosion, overstuffing of the joint, and malposition of the implant (Table 3).

The frequency of revisions was highest for RH in the SOA population ($n = 8$, 21%), and this group also had the lowest median age at primary surgery (56 years) (Table 4).

The median time to revision for all SHAs was 2.8 years (0.9–11.4) years. For POA it was 2.8 (0–8.7) years, and for SOA 4.1 (0.8–11.4) years (Figure 3).

The hazard ratio (HR) for revision was not statistically different either for which year the surgery was performed, or for the sex of the patient (Figure 4). As expected, the age of the patient affected the probability of receiving a revision, i.e. older patients have a lower probability of revision. As an example, if a patient is 1 year older, he or she has an approximately 6% lower risk of revision surgery than the younger

Table 4. Percentage of revisions divided by diagnosis and type of implant

Diagnosis Implant	Primary operations ^a		Revisions ^a	
	n	Mean age	n	%
Primary OA				
RH	280	66	29	10
SH	670	70	47	7
Total	950	68	76	8
Bilateral	138	69	7	5
Secondary OA				
RH	38	56	8	21
SH	152	65	8	5
Total	190	63	16	8
Bilateral	4	72	0	–

^a Shoulders
For abbreviations, see Table 2

patient. The hazard ratio for revision was not statistically significant comparing the 2 different implant types (HR = 0.70, 95% CI 0.45–1.07), which means we could not show a difference in survival time for SH or RH in patients of the same age.

PROM

At 5 years after surgery 115 patients were deceased. Of the remaining 1,025 shoulders we could collect a complete WOOS at 5 years for n = 712 (70%), a completed EQ-5D was found for 722 (70%), and for patient satisfaction level n = 764 (74%) (Table 5). The PROM collected at 5-year follow-up was similar for RH and SH for all 3 PROMs: WOOS, EQ-5D, and SL. However, there was a statistically and clinically significant difference in outcome between patients with SOA (68%) and POA (78%) for WOOS% (p = 0.03).

Age was the only significant factor also for shoulder-specific PROM instruments, with the PROM 5-year WOOS% of a healthy shoulder and satisfaction level. WOOS% increased 2.3% when age increased 10 years (0.04–0.43), and for SL the odds to be satisfied increased by 1.22 (1.03–1.46) for 10 years' increase in age at primary surgery.

Discussion

Age at primary surgery was the main factor influencing the risk of revision: we found that a lower age increased the risk of revision. The revision rates in our study are in accordance with earlier publications (Fevang et al. 2009, Dillon et al. 2013, Rasmussen et al. 2014). We also found that SH and RH had similar outcomes measured by PROM. There was a clinically relevant difference between POA and SOA regarding shoulder functionality (difference 10% in WOOS). The group with POA had higher scores than the SOA group.

Table 5. Outcome by PROM as WOOS, EQ-5D, and Satisfaction level at the 5-year follow-up including all patients, also those patients revised before 5 years

Diagnosis/ implant type	WOOS ^a		EQ-5D ^b		SL ^c satisfied or neutral (%)	
	n	median (%)	n	median	n	
Primary OA	589	78	598	0.7	634	76
Secondary OA	123	68	124	0.7	130	68
p-value ^d		0.03		1.0		0.06
RH	204	76	209	0.7	220	74
SH	508	78	513	0.7	544	74
p-value ^d		0.1		0.4		0.1
Total	712	77	722	0.7	764	75

^a WOOS = Western Ontario Osteoarthritis of the Shoulder index.
^b EQ-5D = EuroQol 5 dimension 3L.
^c SL = Satisfaction level (% patients reporting satisfied or neutral vs. not satisfied).
^d The Kruskal–Wallis test for WOOS and EQ-5D and the chi-square test for SL.

Revision

The most commonly given reason for revision in all groups was “Pain and other”. This may include a number of different reasons, such as unidentified low-grade infection (Levy et al. 2013), and unspecified pain due to overstuffing or glenoid erosion. Similar to our results, a revision rate of 25% in SHA has been reported at long-term follow-up of mean 17 years, with a mean age of 51 years at index surgery for the revised shoulders, and with deterioration of the result over time (Levine et al. 2012). In another smaller study with 78 shoulders the revision rate was found to be higher for RH (10%) than SH (0%), but with similar functional scores (Lebon et al. 2014). As opposed to dislocations, periprosthetic fractures, and rotator cuff ruptures, “pain” has to be considered a more relative indication for revision surgery. To be noted also is that one-third of the patients in a recent study developed glenoid erosion 2.5 years after SHA, with a threefold risk for females with OA (Herschel et al. 2017).

Similar to our study, a higher risk for a revision and for an unsatisfactory result in the younger population has also been demonstrated (Sperling et al. 1998) and in addition a less good result in secondary osteoarthritis has been reported (Sperling et al. 2002). In a report from the Danish Shoulder Arthroplasty Registry on 1,209 shoulder arthroplasties, there were no differences in failure rates between SH and RH, or between types of osteoarthritis (POA or SOA), a finding that is contrary to our study (Rasmussen et al. 2014). This Danish study had a shorter follow up compared with our minimum 5 years, which might be a possible reason for differences between the results. But also in the study by Rasmussen et al., the RH group was also significantly younger than the SH group (mean 65 and 71 years respectively). Since revision surgery after RH is considerably less demanding than revision after SH, it has

been argued that resurfacing is a good option in young and active patients where the risk for a future revision might be higher (Levy et al. 2015). The RH procedure, however, has proven to be more technically demanding than expected, and incorrect sizing of the humeral head is one potential problem (Mechlenburg et al. 2013, Lebon et al. 2014). The RH replacement sometimes tends to be of a larger size than the original anatomical head, which may cause “overstuffing” of the joint. This overstuffing might be a cause of pain and decreased range of motion (ROM) (Mechlenburg et al. 2013, Smith et al. 2013).

Earlier studies have found younger age also to be a risk factor in TSA. In a study by Singh and colleagues, younger age gave a significantly higher risk for revision after primary TSA (Singh et al. 2011). This age-related risk might influence the choice of primary type of implant, if a revision is expected to be a likely outcome in the future (Chillemi and Franceschini 2013). The prosthetic design may also affect the threshold for revision surgery, or influence the indication, if a revision is later considered.

PROM

We found a clinically relevant difference in median WOOS with 78% of a healthy shoulder for patients diagnosed with POA, and 68% for patients with SOA, while the type of implant did not affect the outcome. Younger patients might have higher expectations of surgical results and greater demands, but whether this is an argument for the choice of the primary implant, or causing a lower threshold for revision, is not possible to assess within this study. A functional outcome that would have been acceptable for an older patient could for a younger and more active patient be less than satisfactory. Studies with long-term follow-up have shown that SHA (SH and RH) of the shoulder yields good clinical results (Pritchett 2011, Levine et al. 2012). The clinical outcome after shoulder arthroplasty for SOA has previously been shown to be inferior compared with the results for POA, although the SOA group also showed improvement (Matsoukis et al. 2003, Fevang et al. 2012). As a comparison, the mean 5-year WOOS% in the SSAR for TSA is 86% for POA, and 76% for SOA (Swedish Shoulder Arthroplasty Registry. Annual Report 2015, p. 17), and the difference of 8% in the result for SHA in our study is not fully the 10% that has been suggested as the minimal clinically important difference for WOOS% (Polk et al. 2013). This obvious difference in outcome, however, has probably influenced the shift towards TSA at the expense of SHA. A growing number of shoulder arthroplasties and subsequently more experienced shoulder surgeons, in combination with improved implant instruments, are probably also reflected in the increasing proportion of TSAs, as the technical challenges of a TSA might be considered less of an obstacle than has previously been the case. Young age is considered a risk factor for TSA as well, but few studies have analyzed age in detail,

comparing different age groups. This is evident from other national shoulder arthroplasty registers, such as Australia (Australian Orthopaedic Association National Joint Replacement Registry. Annual Report, 2016). There have been some results reported for young patients indicating higher revision rates in patients aged 50 or younger (Schoch et al. 2015). There was no statistically significant difference in EQ-5D-score and SL. This might indicate that these instruments are not sensitive enough to detect differences in shoulder function, and therefore it is important to use shoulder-specific instruments. We could not find any comparable studies regarding age-related outcome of PROM for shoulder arthroplasties.

The strengths of our study are the high number of patients and a minimum of 5-year follow-up time. Also, the possibilities to draw generalized conclusions are an important effect of a nationwide registry data analysis. We made analyses with separation of the two OA diagnoses into POA and SOA; this separation is to our knowledge not possible in many national registries, but should be possible within the Nordic countries (Rasmussen et al. 2016). A limitation is our 70% response rate on PROM at 5 years. We do not have information additional to the data within the registry, or on the non-responders to the PROM questionnaires. These are weaknesses that comes with a registry-based study, as described by Polk et al. (2013). However, they found that the non-responders did not seem to bias the overall result (in WOOS) after shoulder replacement. Also, a limitation of this study is that we do not report a comparison of SHA with TSA, but this was not within the aim of our study.

From our results, we consider it would be of special interest to further study the impact of age on PROM and revision rate for all types of shoulder implants.

In summary, we found that the observed difference in risk of revision between RH (12%) and SH (6.7%) was due to age, and a lower age increased the risk of revision. Quality of life and satisfaction level were similar for implant type and diagnosis. However, there was a clinically relevant difference in WOOS between the diagnoses, whereby the patients with POA had a better outcome than the SOA group. We found no difference in WOOS between implant types.

MÖ, KH, BS: Design of the study, primary draft of the manuscript, review of the analyses, and finalizing the manuscript. HR: Registry contact, providing data, review of the analyses and manuscript. AR: Design of the study, draft of the manuscript, preparing data, analyses, review of the manuscript.

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