



Risk and risk factors for revision after primary reverse shoulder arthroplasty for cuff tear arthropathy and osteoarthritis: a Nordic Arthroplasty Register Association study



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Background: Reverse shoulder arthroplasty (RSA) has gained increasing popularity in the treatment of rotator cuff tear arthropathy (CTA). The purpose of this study was to evaluate the survival of RSA and the risk factors for revision following RSA.

Methods: RSA patients with CTA or osteoarthritis were identified from the Nordic Arthroplasty Register Association registry data (2004-2013). Kaplan-Meier survival analysis was used to calculate survival probabilities. Cox multiple regression analysis was used to calculate revision rates adjusted for sex, arthroplasty brand, age (<70 years), and year of surgery.

Results: The study included 1904 patients with RSA (1904 RSAs) (69% women; mean age, 74 years; age range, 35-97 years). Revision was performed in 95 patients (5%), with a 10-year cumulative revision rate of 0.91. The most common reason for revision was infection (n = 42), followed by loosening (n = 16) and instability (n = 12). Most revisions occurred less than 6 months after the primary operation. Men had a significantly increased risk of revision compared with women (risk ratio, 3.8; 95% confidence interval, 2.4-6.1). The most common implants were the Delta Xtend (n = 1366) and Delta Mark III (n = 246). The risk of revision of the Delta Mark III was 2.1 (95% confidence interval, 1.1-4.3) compared with the Delta Xtend. Age and year of surgery were not statistically significantly associated with risk of revision.

Conclusion: The overall midterm risk of revision after RSA for CTA was low (5%). The most common reason for early revision was infection. Male sex was associated with a significantly increased risk of revision.

Level of evidence: Level III; Retrospective Cohort Design Using Large Database; Treatment Study

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No institutional review board approval was required for this study.

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Keywords: Reverse shoulder arthroplasty; cuff tear arthropathy; osteoarthritis of shoulder; revision; register study; infection; male sex

Reverse shoulder arthroplasty (RSA) was designed to treat pseudoparalytic and painful shoulder in cuff tear arthropathy (CTA).¹¹ Promising early reports on improved functional outcomes and pain relief in this disabling condition have been followed by a significant increase in primary RSA operations.^{5,13,18} The incidence of RSA has been reported to be up to 3.4/100,000 person-years in California.⁶

Despite favorable clinical results, RSA—as with all shoulder replacement surgical procedures—is associated with various complications such as instability, periprosthetic fracture, infection, and component loosening.^{3,4} These complications may lead to revision of the prosthesis. Previous studies with small cohorts and heterogeneous indications have suggested the complication and revision rate of RSA to be as high as 40%.²¹ RSA revision is often a disastrous event in terms of the clinical outcome.⁸ Therefore, it is essential to acknowledge and prevent the risk of revision prior to the primary operation. In previous reports, demographic factors such as young age and male sex have been associated with revisions of shoulder arthroplasties in general.^{17,19} However, the evidence is sparse and not directly applicable to elective primary RSA for CTA.

The purpose of this study was to evaluate the risk factors for and risk of revision in patients with primary RSA for CTA in Scandinavia based on registry data.

Materials and methods

Anonymous data collected by the national shoulder arthroplasty registries in Denmark, Norway, and Sweden from 2004–2013 were merged into a combined dataset under the umbrella of the Nordic Arthroplasty Register Association (NARA). The dataset includes information on patient demographic characteristics (age, sex, and diagnosis); information on the primary operation (operation date, arthroplasty type, and implant model); and in the case of revision, the date of and reason for revision. If more than 1 diagnosis or reason for revision had been reported, a hierarchy was used so that only the single most important diagnosis or reason for revision was registered in the common dataset.¹⁶ We had certain challenges defining patients with CTA. First, no clear definition of CTA exists. Furthermore, the Norwegian dataset is based on a common joint form without the possibility to report CTA as the primary diagnosis. Therefore, to capture all patients treated with RSA for a rotator cuff–insufficient shoulder, we included patients with either CTA or osteoarthritis (OA) as the primary diagnosis.

Statistical analysis

Descriptive statistics were used to report demographic data. The Kaplan-Meier method was used to illustrate the unadjusted cumulative survival rate, and the log-rank test was used for comparison. Cox multiple regression analysis was used to calculate the ad-

justed revision rate for sex, arthroplasty brand, age (<70 years or ≥70 years), and year of surgery. The statistical analysis was performed using SPSS software (version 19.0; IBM, Armonk, NY, USA). The level of statistical significance was set as $P < .05$, and all P values were 2-tailed.

Results

A total of 19,857 shoulder arthroplasties were reported from 2004–2013 and included in the common dataset. There were 3828 RSAs (19.2%), and of these, 1904 had either CTA ($n = 1312$, 69%) or OA ($n = 592$, 31%) as a diagnosis (Fig. 1). There were 1284 women (67.4%). The mean age was 74 years (standard deviation, 8 years; range, 35–97 years), and 505 patients (27%) were younger than 70 years. The mean follow-up time was 32 months (range, 0–119 months). The yearly number of different arthroplasty brands used is presented in Figure 2. The most commonly used arthroplasty brands were the Delta Xtend (DePuy Synthes, Warsaw, IN, USA) ($n = 1366$, 72%) and Delta Mark III (DePuy Synthes) ($n = 246$, 13%).

Altogether, 95 RSAs (5%) were revised. The overall 10-year survival rate was 91% (Fig. 3). The most common reasons for revision were infection ($n = 42$), loosening ($n = 16$), and instability ($n = 12$) (Table I). The mean time from primary operation to revision was 14 months (standard deviation, 18 months; range, 0–79 months). Of the revisions, 48 (51%) occurred less than 6 months after the primary operation. Men had a significantly increased risk of revision compared with women (risk ratio, 3.8; 95% confidence interval, 2.4–6.1). The 10-year survival rates for men and women were 0.95 and 0.81,

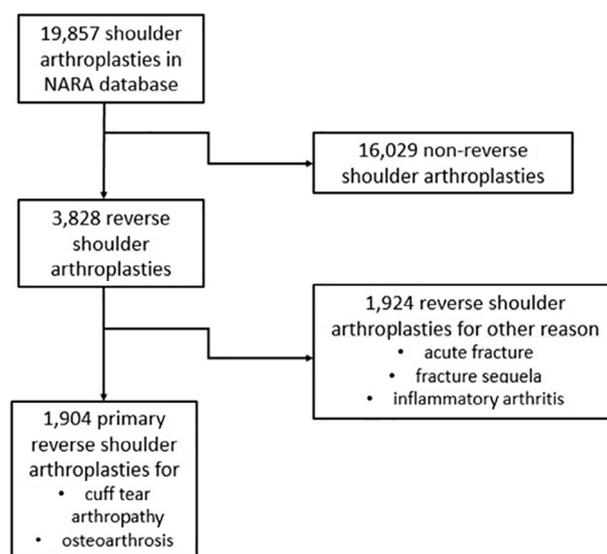


Figure 1 Flowchart of patient selection. NARA, Nordic Arthroplasty Register Association.

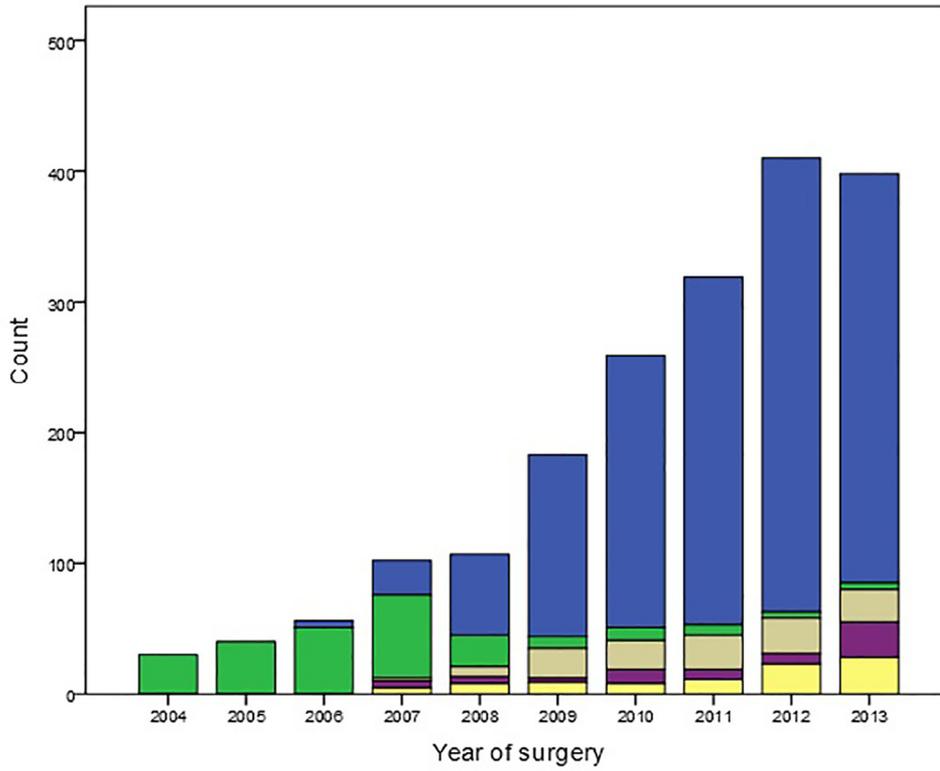


Figure 2 Arthroplasty brand, number of operations, and year of operation. DePuy Delta Xtend is shown in *blue*; Mark III, *green*; TESS (Biomet, Warsaw, IN, USA), *light brown*; Aequalis (Wright Medical, Memphis, TN, USA), *purple*; and other brands, *yellow*. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

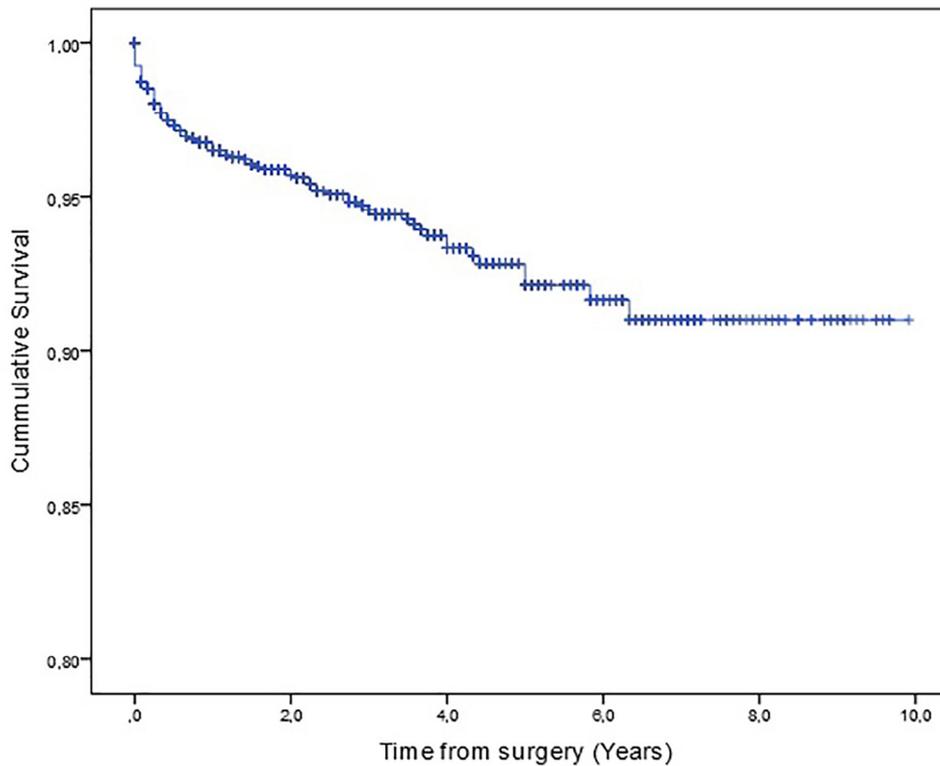


Figure 3 Survival curve of all primary reverse shoulder arthroplasties for cuff tear arthropathy.

Table I Reasons for revision and prevalence

Reason for revision	Frequency (cumulative %)	Overall risk	Female/male, n (%)	Median age (range), yr	Mean time to revision (range), mo
Infection	42 (44%)	2.2%	11 (0.9)/31 (5)	73 (54-86)	7 (0-60)
Loosening	16 (17%)	0.8%	9 (0.7)/7 (1.1)	72 (60-87)	16 (0-60)
Instability	12 (13%)	0.6%	5 (0.4)/7 (1.1)	76 (59-88)	7 (0-70)
Other	12 (13%)	0.6%	6 (0.5)/6 (1)	73 (63-85)	3 (0-76)
Missing	10 (11%)	0.5%	4 (0.3)/6 (1)	74 (54-88)	9 (0-53)
Periprosthetic fracture	3 (3%)	0.1%	2 (0.2)/1 (0.2)	82 (72-89)	4 (1-5)

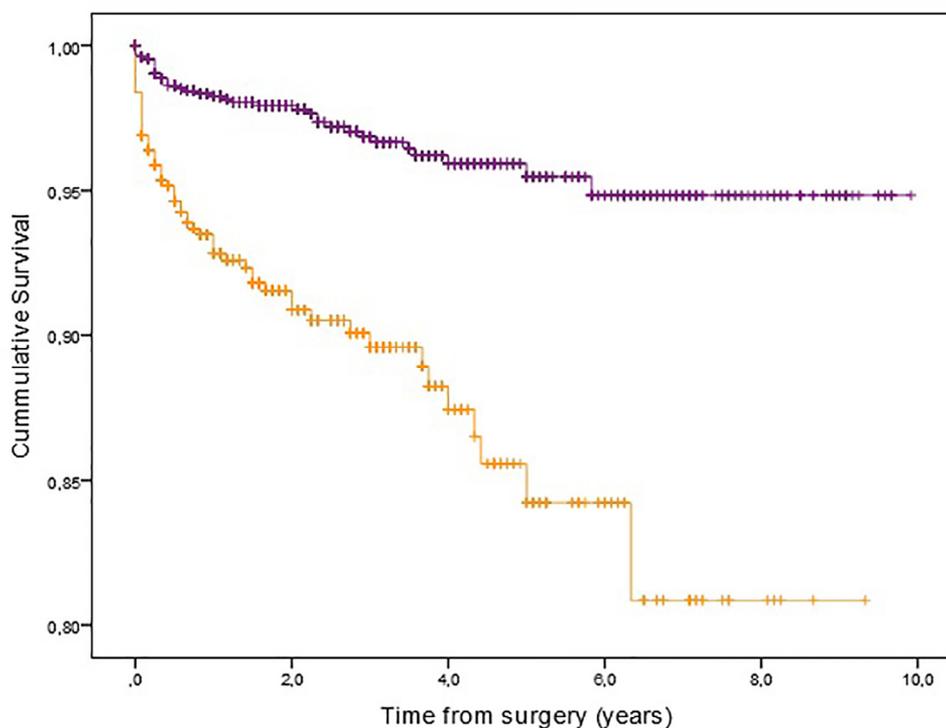


Figure 4 Survival rate for men (orange) and women (purple). (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

respectively, with $P < .001$ (Fig. 4). Patient age and year of surgery were not significantly associated with risk of revision. Overall, 50 Delta Xtend implants (4%) and 29 Delta Mark III implants (12%) were revised. The 10-year survival rates for these implants were 0.95 and 0.86, respectively. This difference was statistically significant, with $P = .004$ (Fig. 5). The risk of revision of the Delta Mark III was 2.1 (95% confidence interval, 1.1-4.3) compared with the Delta Xtend.

Discussion

The main finding of this study was a relatively low proportion of revisions (5%) after RSA for CTA in the combined NARA data. Contrary to previous reports, this proportion is clearly lower than expected.²² Male sex was associated with an increased risk of revision in our registry cohort. This finding is in accordance with previous reports.^{10,20}

In general, the Western population is aging and the need for arthroplasty is increasing. Promising early functional results have led to increased use of RSA worldwide.^{2,13} This can be seen in our data as well, and we found that the number of RSAs has increased by 10-fold in Scandinavia during our 10-year study period. Overall, our revision rate was lower than rates in previously published reports.^{4,23} Possible explanations might be improvements increasing patient selection and implant development, together with increasing surgeon understanding of the nuances of surgical techniques.

In our study, the most common reason for revision was infection, and a higher infection prevalence seems to be one factor explaining higher revision rates for men compared with women. In previous studies, men had a reportedly increased risk of infection after open shoulder surgery compared with women.^{17,22} This difference is potentially due to abundant colonization by *Cutibacterium acnes* (formerly *Propionibacterium acnes*) in male skin.¹⁴ Because of difficulties related to

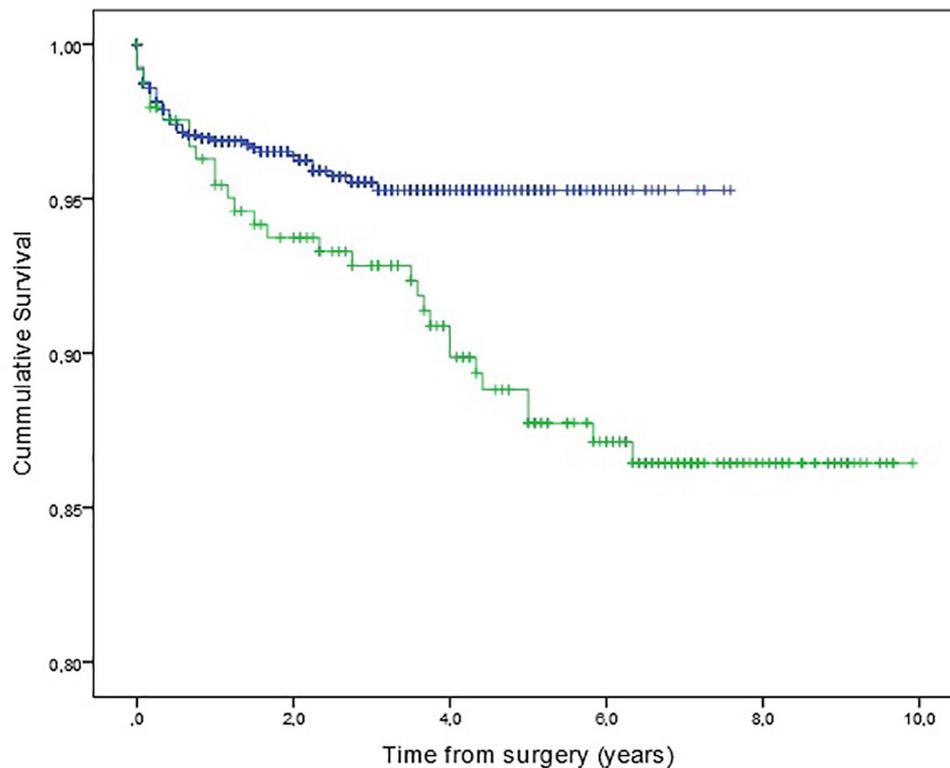


Figure 5 Survival curves of the 2 most commonly used arthroplasty brands: Delta Xtend (*blue*) and Delta Mark III (*green*). (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

detection of this low-virulent pathogen, the true incidence of revisions for infections may be underestimated by registry data.¹² Therefore, it is possible that the missing data on the reason for revision in our cohort may also include some undetected infections.

Young age has been previously associated with a high risk of revision after RSA.¹⁵ However, in our study, age did not correlate with the revision risk. The relatively low total number of revisions especially among younger patients and high mean age in our cohort, together with the hierarchy used in the reasons for revision, may partly explain this difference compared with previous studies in the literature.¹ In previous RSA cohorts with heterogeneous operative indications, instability has been reported to be the most common reason for revision and has been associated with young age, post-traumatic conditions, and revision surgery.³ In contrast to previous reports, we included primary RSA for CTA and OA only, and there were few revisions because of instability. In the Australian registry, instability has been reported to be the most common reason for RSA revision in CTA patients. There may be other factors contributing to instability, such as soft-tissue coverage and surgical approach⁷; however, our data did not allow us to analyze these factors.

The Delta Mark III arthroplasty brand was associated with a significantly higher risk of revision than the Delta Xtend. The very early survival curves for these 2 brands were similar, but after 1 year, survival differed markedly. This finding is in accordance with a previous report on the poorer modular

mechanical properties and design of the Delta Mark III implant.²¹ This may also represent the early learning curve in both patient selection and the technical procedure for RSA in Scandinavia. However, the year of surgery did not have an effect on the revision rate. The later-introduced Delta Xtend prosthesis has shown a similar—and good—survival rate when compared with data from the Australian registry.² The Delta Mark III is no longer available in Scandinavia.

We acknowledge that there are a number of limitations in our study. First, our mean follow-up time was relatively short. According to Favard et al,⁹ the clinical results of RSA when using Grammont-style prostheses deteriorate after 10 years, and therefore, a longer follow-up is needed. Second, the incomplete coverage of national registry data is a limitation of this study. However, the Swedish, Norwegian, and Danish registries have been estimated to cover 80%–90% of the shoulder prostheses, which is still high; therefore, we do not think this has biased our results.¹⁶ Because of heterogeneous national data, the common dataset is very condensed, and we had no further patient-related data (medical, radiographic, surgical, and so on) available or data on patient-reported outcomes, which may have confounded our findings. Finally, as with all registry studies, the only outcome we were able to evaluate was revision operation. There might have been other complications that did not lead to revision surgery but compromised the end result. The main strength of the study is the comprehensive inclusion of consecutive primary RSAs for CTA in Scandinavia. The high number of RSAs

represents the evolution of clinical practice in Scandinavia. Further development of these large registry data is of paramount importance. A systematic registry study clearly outperforms sporadic small-sized studies in terms of power, for example, when investigating the factors related to a relatively low revision risk. The NARA collaborative network enables us to further follow up the patients, expand the collaboration, and generate a common and more comprehensive national registry dataset.

Conclusion

The number of RSAs for CTA and osteoarthritis has so far been rapidly increasing in Scandinavia. The risk of revision after RSA is low according to our current data. However, with longer follow-up, the number of revisions may increase. It is noteworthy that male sex was a clear risk factor for RSA revision, and male patients should be informed of this risk. Further studies are needed to understand all factors related to risk of RSA revision.

Disclaimer

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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