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Analysis of revision shoulder arthroplasty in the German nationwide registry from 2014 to 2018



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Keywords: Reverse shoulder arthroplasty Revision Outcome Complication Imaging Total shoulder arthroplasty Fracture

Level of evidence: Level III; Retrospective Cohort comparison using large database; treatment study **Background:** The purpose of this study is to identify and analyze primary revision arthroplasties of the shoulder in the Germany Shoulder Arthroplasty Registry. The objective is to provide demographic and clinical data of the included cases and information about the revision surgery itself and to compare the findings to other registry studies and clinical studies.

Methods: All documented cases of primary revision arthroplasties of the Germany Shoulder Arthroplasty Registry in the time period 2014-2018 (n = 975) were included in the initial data analysis. Exclusion criteria were multiple revisions and data sets with a missing link of the revision arthroplasty to the data set of the primary implantation leaving n = 433 cases that were included. SPSS software (IBM SPSS Statistics for Windows, version 24.0; IBM Corp., Armonk, NY, USA) was used for statistical analyses. Results: The age of patients with revised anatomic implants (66.3 years) was significantly lower than that of patients with reverse implants (77.1 years) (P = .001). Female patients with anatomic and fracture implants were significantly older than their male counterparts (70.1 vs. 60.5 years, P = .001; 74.3 vs. 62 years, P = .019) and showed a significantly higher rate of revision than their male counterparts (P = .001). The reason for revision was significantly different for anatomic and reverse implant systems (P = .001). Aseptic loosening of either the humeral or glenoid component was the most common reason for revision for anatomic implants, whereas unspecified reasons, dislocation, and loosening of the glenosphere were the most common reasons for reverse implants. The most common type of revision procedure for anatomic implants was conversion to a reverse system in about one third of the cases. Most of the revisions of reverse implants were not specified and almost equally distributed for revision at the humeral or the glenoid side. Anatomic implants showed significantly better Constant-Murley scores (26.1 points) than reverse implants (19.6 points) (P = .001) and significantly better function before revision for passive flexion (P = .002), passive abduction (P = .015), active external rotation (P = .002), and passive external rotation (P = .002).

Conclusion: This study provides a well-documented basis to compare revision arthroplasties of the shoulder performed in Germany over the last decade as documented in the nationwide registry with other nationwide registries and with clinical studies. Especially, the detailed analysis of intraoperative and postoperative complications and the shoulder function at the time of revision offers new information in addition to the results of other registries.

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The German Shoulder Arthroplasty Registry was initiated in 2006 under the patronage of the German Workgroup for Osteosynthesis International, the German Society for Orthopaedics and Orthopaedic Surgery, the German Society for Trauma Surgery and the German Society of Shoulder and Elbow Surgery. Since 2012, it has been continuously run by the German Society of Shoulder and

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Elbow Surgery. It is completely voluntary and has undergone several modifications of the entry data sheets since the establishment 14 years ago and is now completely Web based.¹⁵

The registry was intended to be an instrument of quality control and for early identification of risks and complications associated to shoulder arthroplasty surgery for shoulder surgeons. In recent years, adaptions and amendments were made to include clinical and functional data of the documented cases and exact documentation of implants to allow a more specific analysis for the future.

The increasing number of performed shoulder arthroplasties in the last decade in Germany (Fig. 1) goes along with a growing number of documented cases in the registry (Fig. 2). Inseparable from an increasing number of primary arthroplasties is the number of revisions which amounted to about 4000 cases in 2018 in Germany¹⁶ (Fig. 1). These effects can similarly be observed in other developed countries regardless of different healthcare systems. ^{2,4,12,13}

The purpose of this study is to identify and analyze primary revision arthroplasties of the shoulder in the Germany Shoulder Arthroplasty Registry. The objective is to provide demographic and clinical data of the included cases and information about the revision surgery itself and to compare the findings to other registry studies and clinical studies.

Methods

All documented cases of primary revision arthroplasties of the Shoulder Arthroplasty Registry in the time period 2014 to 2018 (n = 975) were included in the initial data analysis. Exclusion criteria were multiple revisions and data sets with a missing link of the revision arthroplasty to the data set of the primary implantation, leaving n = 433 cases that were included (Fig. 3).

In about one third of the cases, inconsistent data were recognized. In most cases, it could be solved without further actions,

for example, the tick box for type of implant was chosen as being RSA (reverse shoulder arthroplasty), but the documented endoprosthesis parts were all for total shoulder arthroplasty (or anatomic shoulder arthroplasty) as well as the primary diagnosis. If inconsistency could not be solved, the documenting institution was contacted and provided with the key code of the database, and the database entry could be clarified by the operating surgeon using the patient file.

SPSS software (IBM SPSS Statistics for Windows, version 24.0; IBM Corp., Armonk, NY, USA) was used for statistical analyses. The statistical significance level was set at 5% (*P* values < .05). Continuous variables were reported as means \pm standard deviations, median, value range, and 95% confidence intervals. The normality of data was tested by visual inspection using boxplots and scatterplots and statistically using the Kolmogorov-Smirnov and Shapiro-Wilk tests. As the normality assumption was uncertain in great portions of the data, group comparison was performed using the U-test of Mann-Whitney and the Chi-square test for multiple response analysis.

Results

The age of patients with revised anatomic implants of 66.3 years was significantly lower than that of patients with reverse implants with 77.1 years (P = .001). Female patients with anatomic implants were significantly older than their male counterparts (70.1 years vs. 60.5 years, P = .001); the same effect applies for female patients with a fracture compared with male patients (74.3 years vs. 62 years, P = .019) (Table 1).

Female patients showed a significantly higher rate of revision (60%, n = 261) than their male counterparts (40%, n = 172) (P = .001) (Table I).

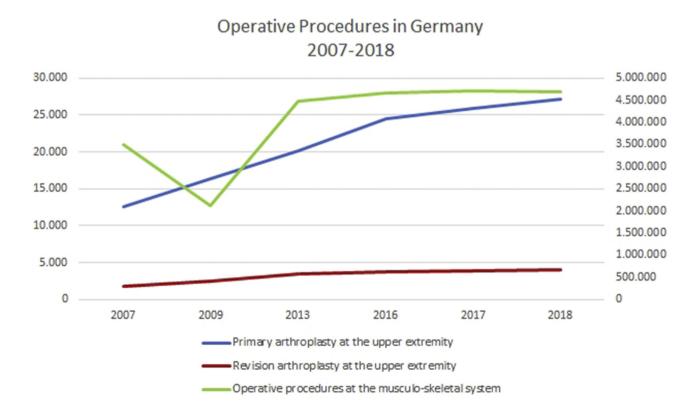


Figure 1 Annual number of primary arthroplasty cases (blue) at the upper extremity, revision arthroplasty at the upper extremity (red) (Y-axis at the left) and all operative procedures at the musculoskeletal system (green) (y-axis at the right with different scaling) in the time period 2007-2018. (Note that there is no differentiation for shoulder and elbow arthroplasties in the official report. It is assumed, that less than 1000 primary elbow arthroplasties are performed per year with a 10% revision rate).

Number of registered cases

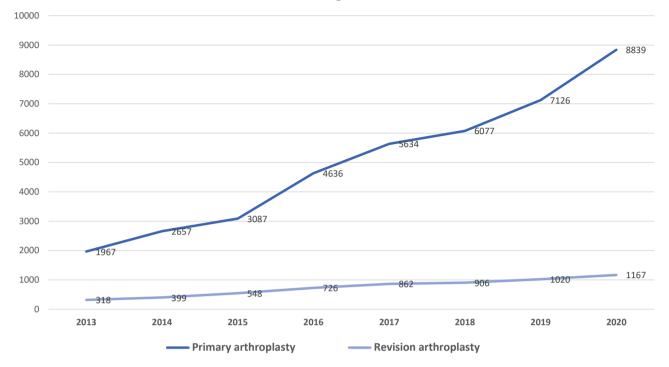


Figure 2 Number of documented cases for primary and revision arthroplasty in the German Shoulder Endoprosthesis Registry (SPR) from 2013-2020. SPR, Shoulder Arthroplasty Registry.

The sex distribution in regard to age at implantation for anatomic arthroplasties was not significantly different for reverse arthroplasties or for reverse fracture arthroplasties (Table I).

The surgeons considered standard radiographs to be sufficient for preoperative imaging in 59% of the cases, and only 29% of the cases received additional imaging such as computed tomography or magnetic resonance imaging.

Only 7% (n = 31) of the registered cases were revisions of implants that were related to fracture treatment for the primary procedure. Revised hemiarthroplasties accounted for 21% of the

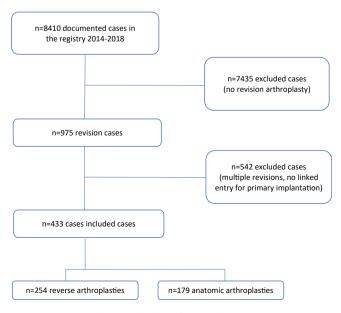


Figure 3 Flowchart of patient selection

cases, n = 16 of them (18%) were fracture endoprostheses. Forty-one percent (n = 179) of the revision cases were reverse implants at the primary procedure.

The reason for revision was significantly different for anatomic and reverse implant systems (P = .001) (Fig. 4, A-C). Aseptic loosening of either the humeral or glenoid component was the most common reason for revision for anatomic implants, whereas unspecified reasons, dislocation, and loosening of the glenosphere were the most common reasons for reverse implants (Fig. 4, A-C).

Revision within the first year showed a significantly different pattern of reasons for the revision with more dislocations and infections compared with revisions with a survival of more than 12 months with more rotator cuff deficiencies, glenoid loosening, and glenoid protrusion (P = .001) (Fig. 5). Revision of anatomic implants within the first year was noted in n = 104 cases compared with n = 107 cases of reverse implants which is in contrast to the period after 1 year (n = 150 vs. n = 72; P = .001).

The most common type of revision procedure for anatomic implants was conversion to a reverse system in about one third of the cases. Most of the revisions of reverse implants were not specified and almost equally distributed for revision at the humeral or the glenoid side (Fig. 6).

Ninety-eight percent of the cases with stemless revised implants did not have intraoperative complications compared with 92% of standard stems and 91% of short stems. 96% of the cases with stemless revised implants did not have postoperative complications compared with 91% standard stems and 92% of short stems (Figs. 7 and 8).

Intraoperative and postoperative complications did not significantly differ based on the revised stem (stemless, short stem, standard stem) or the implant system (anatomic vs. reverse) (Fig. 8-10).

The mean survival until revision of the revised implants of 42.8 months for anatomic systems was significantly lower than

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Mean age at the time of revision surgery in months. Comparison of groups using Mann-Whitney test.

Type of implant	Mean	Min	Max	SD		Mean	Min	Max	SD	Р
Anatomic (n = 254)	66.31	28	89	11.624	Reverse ($n = 179$)	77.11	45	89	9.439	.001
Anatomic female ($n = 153$)	70.14	28	89	10.121	Anatomic male $(n = 101)$	60.5	31	82	11.387	.001
Reverse female $(n = 108)$	71.76	48	89	8.758	Reverse male $(n = 71)$	70.13	45	89	10.377	.278
Fracture anatomic (n = 19)	71.05	55	88	10.469	Fracture reverse $(n = 12)$	73.58	54	88	9.737	.509
Fracture anatomic female $(n = 14)$	74.29	58	88	9.817	Fracture anatomic male $(n = 5)$	62	55	71	6.403	.019
Fracture reverse female $(n = 7)$	73	63	80	6.272	Fracture reverse male $(n = 5)$	74.4	54	88	14.153	.755

that of reverse implants with 27.7 months (P = .001) and for patients who were initially operated for a fracture compared with nonfracture cases (19.9 months vs. 31.5 months, P = .049). Survival did not differ in terms of sex distribution among these categories (Table II).

Age was not a risk factor for reduced survival in general or for the subgroups of anatomic and reverse arthroplasty, hemiarthroplasty or arthroplasty for fractures. Anatomic implants showed significantly better Constant-Murley scores (26.1 points) before revision surgery compared with reverse implants (19.6 points) (P = .001) and also for all subcategories of the Constant-Murley score (Table III). In terms of range of motion patients with anatomic implants had significantly better function before revision for passive flexion (P = .002), passive abduction (P = .015), active external rotation (P = .002), and passive external rotation (P = .002).

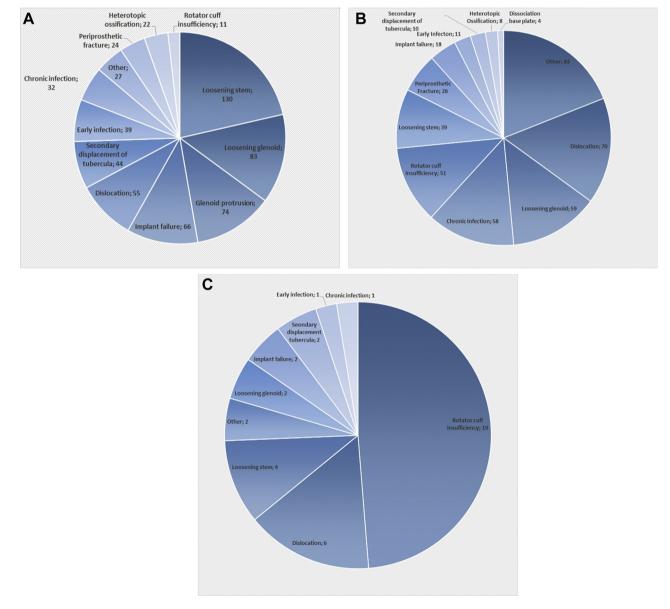


Figure 4 Reason for revision for anatomic (A) and reverse (B) and fracture (C) arthroplasties. Multiple answers were possible.

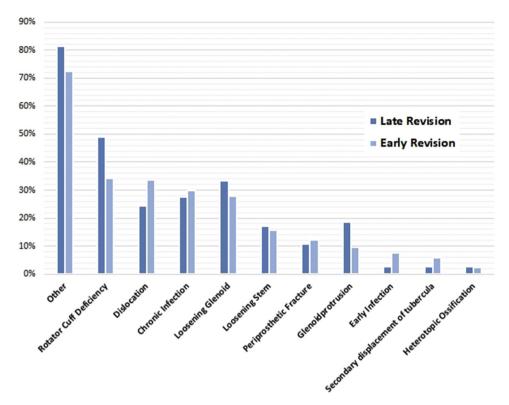


Figure 5 Reason for revision for early revision (≤ 12 months after primary procedure) and late revision (> 12 months after primary procedure) (P = .001).

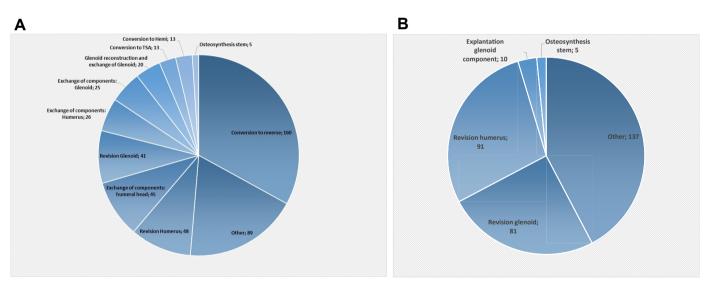


Figure 6 Type of Revision procedure for anatomic (A) and reverse (B) implants. Multiple answers were possible.

Discussion

The most striking result of the study is the fact that a number of patients needed revision surgery very early after primary implantation with a mean of 36 months overall, 43 months for total shoulder arthroplasty, 28 months for RSA and only 20 months for fracture prostheses. This relatively short period is confirmed by many other studies and registries and is in sharp contrast to the overall survival rate, which is comparable with that after hip and knee replacements. ^{2,9,13}

Knowles et al compared European and North American studies in a meta-analysis and observed a mean interval until revision of 42 months in North America and 51 months in Europe without separating total (anatomic) from reverse arthroplasties.

In our study, women were much more likely to undergo revision surgery (P = .001) than male patients and age per se was not a risk factor for revision surgery, which confirms the results of many other studies and registries. ^{2,9,13,19}

On the other hand, there are several publications that observed an increased risk for revision with lower age.^{14,18,23} Wagner et al²³ found a clear negative correlation of age and revision risk and described for every increase in 1 year of age a 3% decreased risk of revision surgery and a 13% decreased risk of revision surgery for mechanical implant failure based on the analysis of prospectively

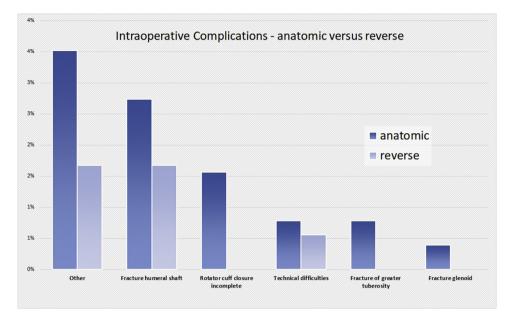


Figure 7 Intraoperative complications in anatomic and reverse revision arthroplasties in percent of the documented cases.

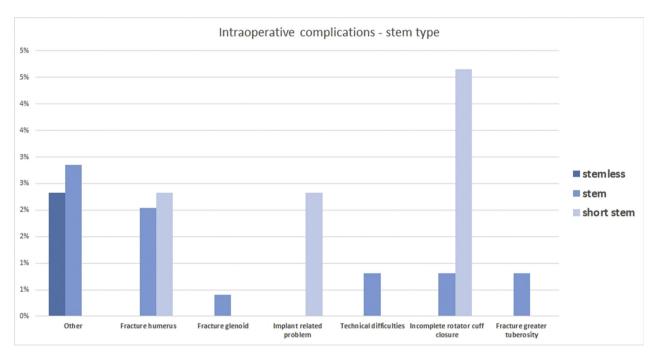


Figure 8 Intraoperative complications for all revision arthroplasties based on stem type (stemless, standard stem, short stem) in percent of the documented cases.

collected data of 5494 consecutive shoulder arthroplasties performed from 1970 to 2012.

Our study confirms the data from the Australian registry, that reverse implants are less likely to undergo revisions compared with anatomic implants after a given time period of 3 months (12 months in our study).² Similar effects are seen in the National Joint Registry (National Joint Registry of England, Wales, Northern Ireland, and the Isle of Man) with lower revision rates of reverse implants at 6 years after primary implantation compared to anatomic implants.¹²

Another noticeable result is the fact that the number of intraoperative complications (overall 7%, anatomic 10%, reverse 4%) and the number of postoperative complications (overall 26%,

anatomic 31%, reverse 17%) were lower for revised reverse arthroplasties which is in contrast compared with other clinical studies. $^9\,$

Knowles et al⁹ described the most common indication for revision surgery to be rotator cuff tear, deficiency, or arthropathy (26%) of the cases in North America and Europe combined which is comparable with the results in the Australian registry (25%).² In our study we found aseptic loosening of the implant to be the most common reason for revision for total shoulder arthroplasty (35%) and only 4.3% of the cases were specifically labeled with rotator cuff insufficiency, whereas the number of 28% is comparable for RSA. Forty-nine percent of the fracture prostheses in our study were revised because of rotator cuff failure.



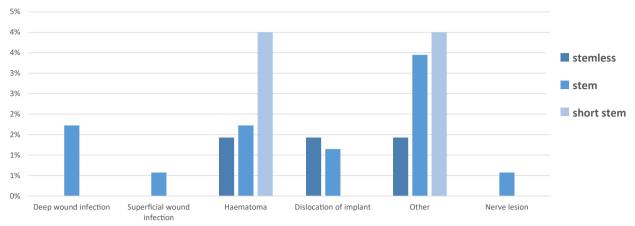
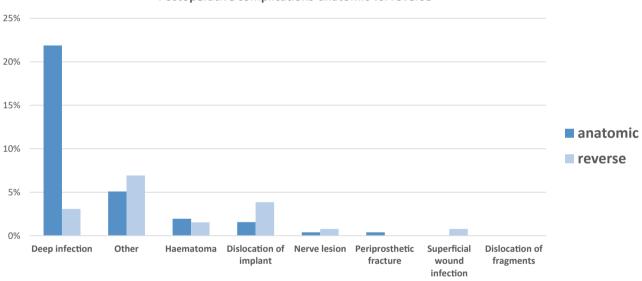


Figure 9 Postoperative complications based on stem type (stemless, standard stem, short stem) as percent of the documented cases.



Postoperative complications-anatomic vs. reverse

Figure 10 Postoperative complications for anatomic or reverse implant systems as percent of the documented cases.

The New Zealand Joint registry reports about 19% of the cases without distinction between anatomic and reverse arthroplasties with implant loosening as the main reason, whereas pain was the leading cause for revision, a category that most other registries and studies do not specifically list. ^{2,13} Adding the numbers for loosening, implant breakage of the glenoid insert, or the glenoid component in the Australian registry, the result of 27.5% of the cases is comparable with the results from our registry, which does not as much subclassify the reasons for revision. ²

This is an example for the limited possibilities to compare results from registries and large clinical series based on a variation in study and registry design and the way of reporting the data.

The numbers of dislocations (35%) and infection (20%) as the reason for revision of reverse implants in the Australian registry are comparable with our results (39% and 32% respectively) but different for implant loosening (18% vs. 54%).² Our results are confirmed by the study of Boileau⁵ with prosthesis instability (38%) and infection (22%) as the leading reasons for revision of RSAs.

Moeini et al¹¹ report about a 10-year cumulative revision rate for reverse arthroplasties of 8% as a result of the analysis of n = 17730arthroplasties in the Nordic Arthroplasty Register Association from Denmark, Norway, and Sweden. Based on the same registry, Lehtimäki et al¹⁰ report about a moderate midterm risk of revision of RSAs of 5% with infection being the most common reason for revision. Although we cannot calculate a cumulative risk based on the limitations of our registry as explained in the following text, the number of 38% of reverse implants in our data is revised for infections.

We cannot confirm an increased revision rate of reverse implants in male patients within the first 6 months after primary implantation as observed in the Australian registry. ²

The National Joint Registry report about rotator cuff insufficiency as the reason for revision in 56% of the anatomic cases, followed by instability (18%) and loosening of the glenoid (16%).¹² The main reason for reverse implants is infection (28%), followed by instability (26%) and loosening of the glenoid (13%).¹²

Table II

Mean survival of implants from primary implantation to index revision in months.

Type of implant	Mean	Min	Max	SD		Mean	Min	Max	SD	Р
Anatomic all	42.8	0	240	50.45	Reverse all	27.7	0	361	49.88	.001
Anatomic female	38.9	0	216	48.16	Anatomic male	48.5	0	240	37.10	.117
Reverse female	32.9	0	361	56.38	Reverse male	20.3	0	193	37.11	.104
Fracture primary diagnosis	20.0	0	182	32.25	No fracture primary diagnosis	31.5	0	182	32.25	.049

The most common revised implants in our study were reverse (41%), followed by total shoulders (38%) and hemiarthroplasties (21%). This is in contrast to that reported by Knowles et al who described the majority of revisions in Europe and North America combined to be 47% being hemiarthroplasties. ⁹ One possible explanation for that is the fact that the less favorable clinical results of many clinical studies and registry data and a high rate of secondary conversion from hemishoulder arthroplasties to total shoulder arthroplasties was highlighted very early in the German shoulder community resulting in a limitation of hemiarthroplasties for cases with surface replacement (cups) by many users. Open reduction and internal fixation remain the standard procedure for proximal humerus fractures. In addition, favorable results of reverse arthroplasties for this patient group lead to a quick adoption in the community; 39% of the fracture cases are RSAs in this study.

The New Zealand registry report quantifies the risk for revision to be 0.17% for patients with 82% of the maximum Oxford Shoulder Score compared with an increased risk of 2.24% if the score falls less than 66% of the maximum.¹³ With a mean overall Constant-Murley score of 26 points for revised anatomic and 20 points for reverse implants, we can confirm this observation but were not able to calculate the risk for revision owing to insufficient clinical data regarding function from the primary operation.

Despite the fact, that the importance of preoperative planning is highlighted in many publications in terms of correct definition of the pathology and classification in the axial plane (retroversion, Walch classification of glenoid erosion, classifications of glenoid bone loss, and so on)^{3,6,17,20,21,24,25} and the coronal plane (inclination, classification of Habermeyer, Sperling, Sirveaux, and others)^{1,7,8,22,26} and a trend to perform a 3-dimensional analysis and additional use of specialized software in recent publications, only one third of the cases documented in our registry had three-

Table III

Constant-Murley score at the time of revision.

CS	Anaton	nic			Revers	Р			
	Mean	Min	Max	SD	Mean	Min	Max	SD	
CS total	26.17	0	65	14.13	19.59	0	49	11.31	.001
CS ADL	7.22	0	16	3.25	5.72	0	14	3.47	.003
CS pain	4.91	0	13	3.50	4	0	15	3.63	.024
CS ROM	10	0	30	6.67	7.79	0	26	6.47	.013
CS force	4.05	0	20	5.87	2.08	0	10	3.52	.018

Table IV

Range of Motion at the time of revision in degree.

ROM	Anato	nic			Reverse				Р
	Mean	Min	Max	SD	Mean	Min	Max	SD	
Active flexion	65.76	0	160	33.66	57.31	0	150	37.21	.119
Passive flexion	94	0	170	37.18	74.41	0	170	41.31	.002
Active abduction	58.09	0	160	28.52	52.9	0	140	32.91	.101
Passive abduction	83.16	0	180	35.92	71.28	0	160	37.21	.015
Active ARO	17.59	-30	70	18.39	8.92	-10	40	11.06	.003
Passive ARO	27.27	-30	80	19.27	17.77	0	50	15.8	.002

dimensional preoperative imaging. A similar number for revisions (33%) is reported in the Australian National Registry where a higher number of computed tomography scans (64%) are undertaken for primary arthroplasties. 2

This highlights the importance of anonymously collecting such data in a registry and gives the surgeons feedback and training to improve the management of revision arthroplasties. The transfer of latest developments and standards of the specialized surgeons to the general surgical community apparently needs improvement and the establishment of a number of training courses and a qualification system for post-training education of our national society (German Society of Shoulder and Elbow Surgery) already reflects on this issue. A general trend and economic pressure to reduce the costs per case with fixed reimbursement schemes (DRG system) may have a negative effect as well and should be carefully observed.

It needs to be noted that the majority of the revisions of anatomic implants in our study (63%) resulted in a reverse arthroplasty for the patient, which is in concordance with many other publications and that the average age of these patients with 66 years was fairly young. ²

Assuming a favorable mean survival of the revision reverse arthroplasties of about 10 to 15 years and an increasing life expectancy, the affected patients have a high likelihood of at least another or even two more revision arthroplasties. Further compromise of clinical function under these circumstances with that previous medical history must be assumed and puts a burden not only on the expectations for the patient but also on the healthcare system that has to provide the resources for these demanding and expensive interventions in the future.

The fact that patients with anatomic implants presented with better range of motion and Constant-Murley scores compared with patients with reverse implants before revision surgery probably is attributable to the better status of the rotator cuff in general in patients with anatomic implants (Table IV). Another factor could be the prospect for a successful conversion of a painful and/or failed total shoulder arthroplasty to a reverse implant, whereas the failed reverse implant will be much more difficult to revise in clinical practice, thus increasing the threshold for revisions of the latter.

Limitations

There are several strengths of the study. Based on its character as a registry study, we were able to include a rather high number of revision cases in contrast to most of the clinical studies, even if they are from high-volume specialized centers. Another positive effect from being a registry study is the homogeneity of the data in contrast to multicenter studies, where different categorization schemes and scoring systems are often used which limit the information of the pooled data, which will always depend on the smallest denominator.

The biggest weakness of the study and the biggest disappointment performing the analysis of the data is the fact that we cannot provide a meaningful survival analysis for the implants in contrast to other registries, such as the Australian Joint Registry is doing for many years. The data in our study represent only about 10% of all revisions performed in Germany during the study period. Therefore, we cannot guarantee that our study population statistically represents the entire population. In fact, there are numerous suspicious factors, that the study data indeed are not representative for the German population. Eighty percent of the data comes from 17 clinics which indicate that most of the revision surgeries are performed in high-volume centers and/or that those centers apparently have a much higher commitment to perform correct entries into the national database compared with peripheral hospitals.

A number of efforts have been made in the past to increase the percentage of documented cases, but the reality shows only moderate improvement over time. Economic pressure and lack of time and personnel to keep the registry entries up-to-date seem to be the biggest problems. We expect a substantial change of the situation, once the planned centralization of all registries and the legislative obligation to document all types of medical implants in Germany (not only orthopedic implants) will be in place in the next few years.

Conclusion

This study provides a well-documented basis to compare revision arthroplasties of the shoulder performed in Germany over the last decade as documented in the nationwide registry with other nationwide registries and with clinical studies. Especially, the detailed analysis of intraoperative and postoperative complications and the shoulder function at the time of revision offer new information in addition to the results of other registries.

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