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The short-term survival of total stemless shoulder arthroplasty for osteoarthritis is comparable to that of total stemmed shoulder arthroplasty: a Nordic Arthroplasty Register Association study

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Background: The purpose of this study was to compare the short-term survival rate of total stemless, metaphyseal fixated, shoulder arthroplasty with that of total stemmed shoulder arthroplasty in the treatment of osteoarthritis.

Methods: Data were collected by the national arthroplasty registries in Denmark, Finland, Norway, and Sweden and merged into 1 dataset under the umbrella of the Nordic Arthroplasty Register Association. For the present study, we included all patients with osteoarthritis treated with either stemless (n = 761) or stemmed (n = 4398) shoulder arthroplasty from 2011 to 2016.

Results: A total of 21 (2.8%) stemless and 116 (2.6%) stemmed shoulder arthroplasties were revised. The 6-year unadjusted cumulative survival rates were 0.953 for stemless shoulder arthroplasty and 0.958 for stemmed shoulder arthroplasty, $P = .77$. The most common indication for revision of both arthroplasty types was infection. Five (0.7%) stemless and 16 (0.4%) stemmed shoulder arthroplasties were revised because of loosening of either the glenoid or the humeral component. In the multivariate

No institutional review board approval was required for this retrospective study.

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cox regression model, which included age, category, gender, year of surgery, previous surgery, and arthroplasty type, the hazard ratio (HR) for revision of the stemless shoulder arthroplasty was 1.00 (95% confidence interval [CI], 0.63-1.61), $P = .99$, with the stemmed shoulder arthroplasty as reference. Male gender (HR = 1.50 [95% CI, 1.06-2.13], $P = .02$) and previous surgery (HR = 2.70 [95% CI, 1.82-4.01], $P < .001$) were associated with increased risk of revision.

Conclusion: The short-term survival of total stemless shoulder arthroplasty appears comparable with total stemmed shoulder arthroplasty, but longer observation time is needed to confirm whether they continue to perform equally.

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

Keywords: Stemless; stemmed; shoulder; arthroplasty; revision; survival; registry; collaboration

Shoulder arthroplasty has evolved from monoblock designs to modular shoulder arthroplasty systems with stems attached to different head size and neck shaft offsets and angles. This enables reliable restoration of the patient's original shoulder joint geometry,[2] and total stemmed shoulder arthroplasty is recommended by the American Academy of Orthopedic Surgeons as a treatment for end-stage osteoarthritis (OA) with an intact rotator cuff.[8] Coherently, the number of shoulder arthroplasties is rapidly increasing worldwide.[14]

Nevertheless, there are concerns related to the stemmed humeral component that can be fixated with or without cement. In case of nonconvertible systems, removal of the humeral component can be challenging with high risk of intraoperative complications such as periprosthetic fractures.[10,16,21,24] In theory, the bone-preserving design of the stemless design facilitates revision should the need of a revision arthroplasty arise. Furthermore, it has been hypothesized that the stemless design is even more adaptive to the patient's anatomy, so that anatomical considerations could be further improved by using modern stemless humeral components.[11,12,20]

Despite potential benefits, there are also concerns related to stemless shoulder arthroplasty systems. The metaphyseal fixation relies on adequate bone quality, and the risk of component loosening, especially in elderly patients, could in theory be higher than with stemmed humeral components. Moreover, a tight press-fit metaphyseal central anchor or screw fixation may predispose to intraoperative fractures of the greater tuberosity.[7]

The purpose of this study was to compare the survival rates of total stemless, metaphyseal fixated, shoulder arthroplasty with that of total stemmed shoulder arthroplasty in the treatment of OA and to report the indications for revision. Our hypothesis was that there would be no statistically significant differences in arthroplasty survival between the stemless and the stemmed total shoulder arthroplasty or between the stemless shoulder arthroplasty systems.

Materials and methods

Sources of data

The Finnish arthroplasty registry was established in 1980 and has included shoulder arthroplasties from the beginning, which makes it the oldest national registry collecting data on shoulder arthroplasties. The arthroplasty registry in Norway was established in 1994 and has included shoulder arthroplasties since 1997. The Swedish and the Danish shoulder arthroplasty registries were established in 1999 and in 2004, respectively.[18]

All private and public hospitals in the 4 countries report to the national registries. The surgeons report patient-related data (gender, age, previous surgery, diagnosis) and operative data (date, arthroplasty type, and brand) at the time of surgery. Each registry has documented high completeness of reporting.[5,15,22] Data from the Danish, Norwegian, and Swedish registries were merged into a common dataset under the umbrella of the Nordic Arthroplasty Register Association (NARA) in 2014.[17] The Finnish registry data were merged in 2017.

Inclusion criteria

In the NARA dataset, the indication is based on a hierarchy with the following diagnoses: acute fracture, fracture sequelae, inflammatory arthritis, rotator cuff problem, and OA. If more than 1 diagnosis is reported, only the one that has the highest rank in the hierarchy is recorded. Thus, for the present study, all patients with OA reported together with any other diagnosis were excluded, and the included patients were considered as having primary OA.

The database contains data on 35,253 shoulder arthroplasties inserted between January 2004 and December 2016. A total of 9739 arthroplasties were used for an acute fracture, 3326 for fracture sequelae, 2748 for inflammatory arthritis, 3587 for rotator cuff problem, and 14,677 for OA. In 1176 arthroplasties, the diagnosis was recorded as ''other'' or was missing.

Of the 14,677 arthroplasties for OA, there were 857 total stemless shoulder arthroplasties, 5637 total stemmed shoulder arthroplasties, 3492 resurfacing hemiarthroplasties, 272 stemless hemiarthroplasties, 2370 stemmed hemiarthroplasties, and 1884 reverse shoulder arthroplasties. A total of 75 arthroplasties were categorized as others, and for 90 arthroplasties, the arthroplasty

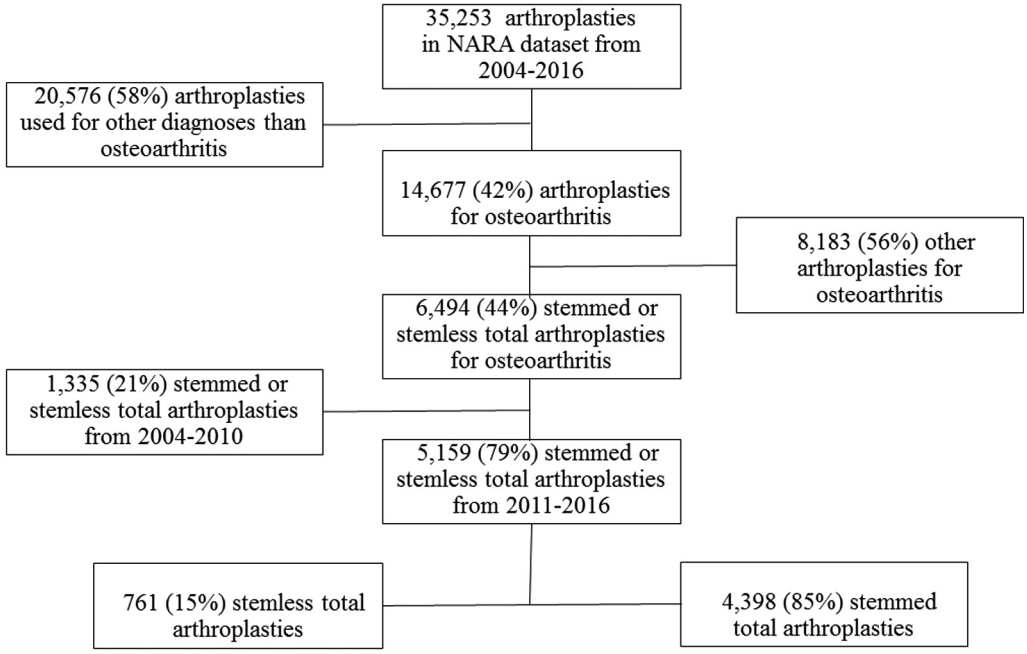

Figure 1 Flowchart of patient selection. *NARA*, Nordic Arthroplasty Register Association.

type was missing. For the present study, we included all total stemless, metaphyseal fixed, shoulder arthroplasties (n = 761) and all total stemmed shoulder arthroplasties (n = 4398) used for OA from January 2011 to December 2016. Data from 2004 to 2010 were not included in the present study because of few stemless total shoulder arthroplasties (Figs. 1 and 2).

Study outcome

We used revision for any reason as study outcome. A revision was defined as removal or exchange of any component. As for primary arthroplasties, the surgeon reports patient-related data, operative data, and revision data (date, reason for revision, new arthroplasty type, and brand) at the time of surgery. The recorded reasons for revision were infection, periprosthetic fracture, luxation and instability, loosening of any component, rotator cuff problem, and "other." The reason for revision is based on a hierarchy in cases where more than 1 reason has been recorded, so that only the reason with the highest rank was included in the analysis.

The revision arthroplasty is accurately linked to the primary arthroplasty using a unique civil registration number given to all citizens at birth. The civil registration number is also used to track patients who died. For patients who underwent revision arthroplasty, the date of the revision procedure was regarded as the end of follow-up. For patient who died, the date of their death was regarded as the end of follow-up. For all other patients, the end of follow-up was set to December 31, 2016.

Statistics

Descriptive statistics were used to report demographic data, follow-up time, time to revision, and reason for revision. The Kaplan-Meier method was used to illustrate the unadjusted cumulative survival rates, and the log-rank test was used for comparison. The cox regression model was used to calculate hazard ratios (HR) with 95% confidence intervals (CI). Age (categorical variable), gender, period of surgery (binary variable), and previous surgery (binary variable) were included in the multivariate model when we compared the total stemless shoulder arthroplasty with the total stemmed shoulder arthroplasty (binary variable) and when we compared total stemless shoulder arthroplasty brands (categorical variable). Patients with bilateral shoulder arthroplasty were included in the survival analyses as if they were independent. The level of statistical significance was set at $P < .05$, and all P values were 2-tailed. The analyses were performed using SPSS version 22.0 (IBM Corp., Armonk, NY, USA), and Figures 3 and 4 were made using R version 3.4.1 (The R Foundation, Vienna, Austria).

Results

Study population

The number of stemmed and stemless total shoulder arthroplasties for OA increased toward the end of the study period (Fig. 1). The mean age was 64 years (range, 31-89 years) for the total stemless shoulder arthroplasty and 68 years (range, 20-96 years) for the total stemmed shoulder arthroplasty. The proportion of women was 49% for the total stemless shoulder arthroplasty and 59% for the total stemmed shoulder arthroplasty. Previous surgery was recorded in 87 patients (11%) treated with a total stemless shoulder arthroplasty and in 485 patients (10%) treated

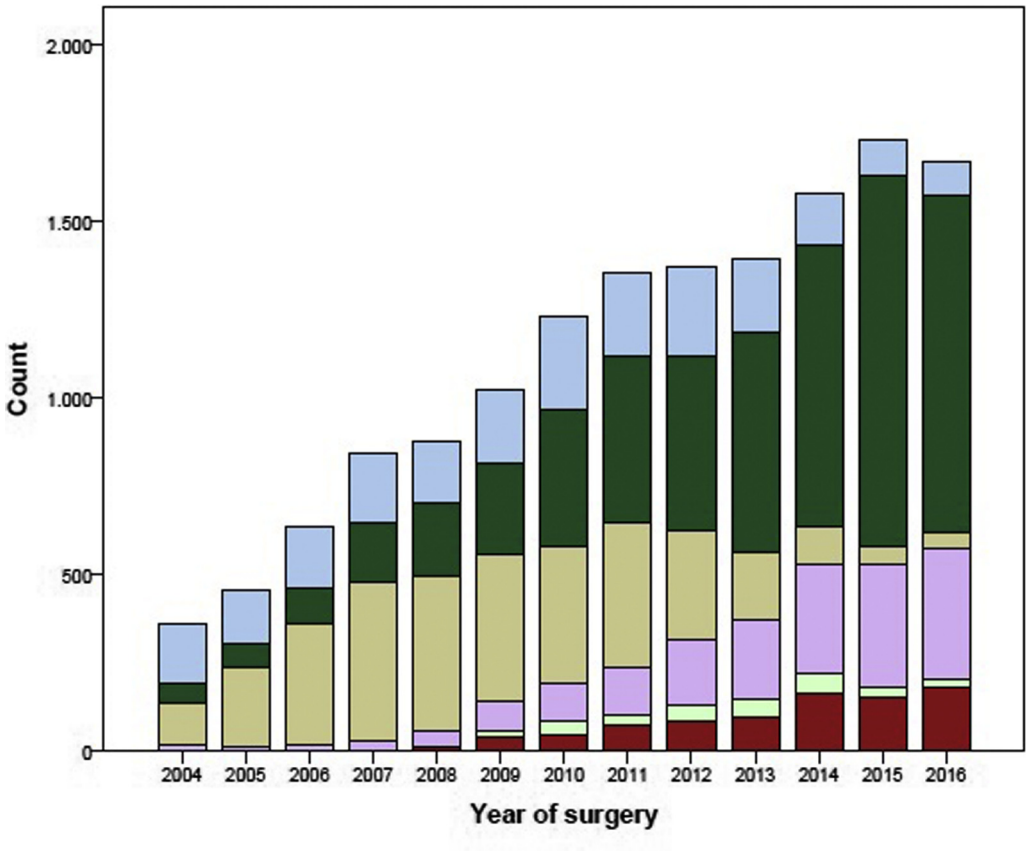

Figure 2 Number of total stemless shoulder arthroplasties (dark red) and total stemmed shoulder arthroplasties (dark green) for osteoarthritis from 2004 to 2016. Other arthroplasty types include stemmed hemiarthroplasty (light blue), resurfacing hemiarthroplasty (gray), reverse shoulder arthroplasty (purple), and stemless hemiarthroplasty (light green).

with a total stemmed shoulder arthroplasty. The mean follow-up time of total stemless shoulder arthroplasty and total stemmed shoulder arthroplasty was 28 months(range, 0-71 months) and 29 months (range, 0-71 months), respectively.

Survival rates of total stemless shoulder arthroplasty and total stemmed shoulder arthroplasty

A total of 21 (2.8%) total stemless shoulder arthroplasties and 116 (2.6%) total stemmed shoulder arthroplasties were revised. The mean time to revision was 15 months (range,

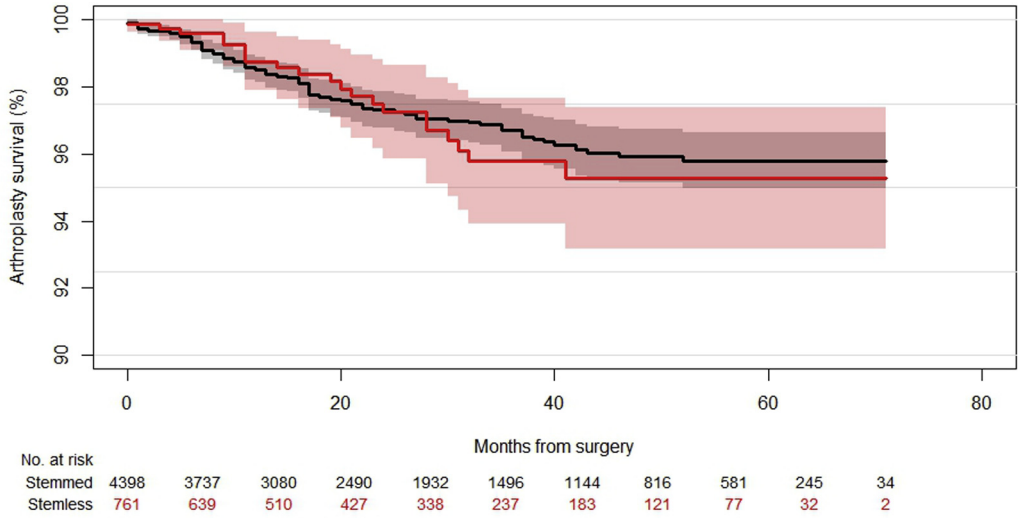

Figure 3 The unadjusted cumulative survival rate of total stemless shoulder arthroplasty (red) and total stemmed shoulder arthroplasty (black), $P = .77$.

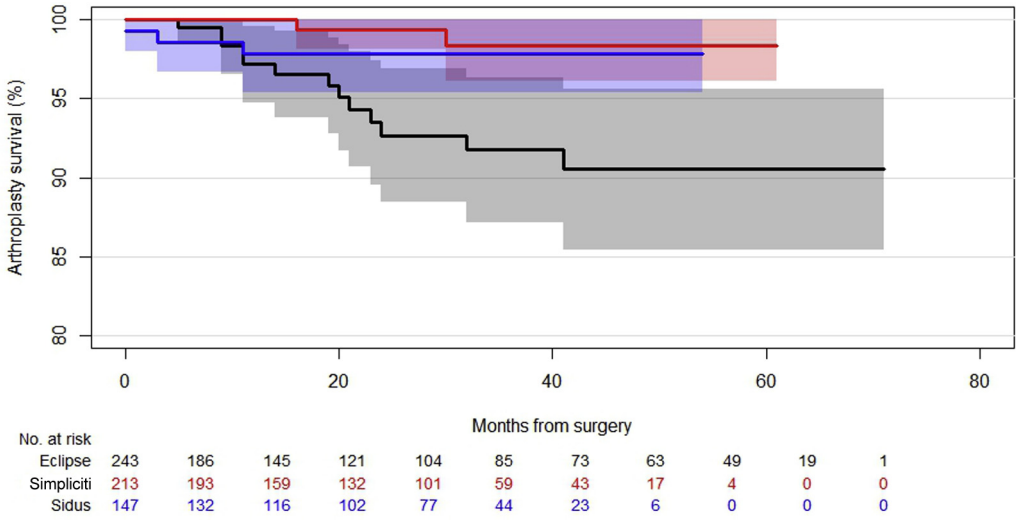

Figure 4 The unadjusted cumulative implant survival rate of the Eclipse (black), the Simpliciti (red), and the Sidus arthroplasty (blue), $P < .01$.

0-52 months) and 18 months (range, 0-41 months), respectively. The 1- and 6-year unadjusted cumulative survival rates were 0.987 (95% CI, 0.979-0.995) and 0.953 (95% CI, 0.931-0.975) for total stemless shoulder arthroplasty and 0.985 (95% CI, 0.981-0.989) and 0.958 (95% CI, 0.950-0.966) for stemmed total shoulder arthroplasty (Fig. 3). The differences were not statistically significant, $P = .77$. The HR for revision of the total stemless shoulder arthroplasty was 1.00 (95% CI, 0.63-1.61), $P = .99$, with the total stemmed shoulder arthroplasty as the reference (Table I). Male gender (HR = 1.50 [95% CI, 1.06-2.13], $P = .02$) and previous surgery (HR = 2.70 [95% CI, 1.82-4.01], $P < .001$) were associated with increased risk of revision.

The most common indication for revision of both arthroplasty types was infection. Only 5 (0.7%) total stemless arthroplasties and 16 (0.4%) total stemmed arthroplasties were revised because of loosening of either the glenoid or the humeral component (Tables II and III).

Total stemless shoulder arthroplasty brands

There were 243 Eclipse arthroplasties (Arthrex, Inc., Naples, FL, USA), 213 Simpliciti arthroplasties (Wright Medical, Memphis, TN, USA), 147 Sidus arthroplasties (Zimmer Biomet, Warsaw, IN, USA), 96 Nano arthroplasties (Zimmer Biomet), and 62 TESS arthroplasties (Zimmer Biomet). The Eclipse had a low unadjusted 6-year cumulative survival rate compared with the Simpliciti and the Sidus (Fig. 4). The HR for revision of the Eclipse was

Table I Cox regression model with hazard ratio, 95% confidence interval (CI), and *P* value

Factor	Univariate model (95% CI)	*P* value	Multivariate model (95% CI)	*P* value
Sex				
Female	1.0 (reference)		1.0 (reference)	
Male	**1.63 (1.16-2.28)**	**.004**	**1.50 (1.06-2.13)**	**.023**
Age (yr)				
≥75	1.0 (reference)		1.0 (reference)	
55-75	2.01 (1.13-3.59)	.02	1.28 (0.69-2.39)	.43
≤55	1.31 (0.84-2.04)	.23	1.10 (0.70-1.73)	.68
Previous surgery				
No	1.0 (reference)		1.0 (reference)	
Yes	**2.90 (1.98-4.26)**	**<.001**	**2.70 (1.82-4.01)**	**<.001**
Arthroplasty type				
Stemmed	1.0 (reference)		1.0 (reference)	
Stemless	0.93 (0.57-1.49)	.77	1.00 (0.63-1.61)	.99
Year of surgery				
2011-2013	1.0 (reference)		1.0 (reference)	
2014-2016	0.93 (0.64-1.34)	.69	0.96 (0.66-1.38)	.81

Table II Indications for revision of stemless and stemmed shoulder arthroplasty systems

Indications for revision	Stemless		Stemmed	
	N	Percentage	N	Percentage
Infection	8	1.1	27	0.6
Periprosthetic fracture	0	0.0	1	0.0
Luxation and instability	3	0.4	28	0.6
Loosening of any component	5	0.7	16	0.4
Rotator cuff problem	2	0.3	22	0.5
Others	3	0.4	12	0.3
Missing	0	0.0	10	0.2
Total	21	2.8	116	2.6

6.37 (95% CI, 1.42-28.66), $P = .02$, with the Simpliciti as the reference (Table IV). The Nano and the TESS were not included in the survival analysis because of few cases ($n < 100$).

Discussion

The number of both total stemless shoulder arthroplasties and total stemmed arthroplasties is increasing. With a mean follow-up of approximately 30 months, the survival of the total stemless shoulder arthroplasty was comparable with that of the total stemmed shoulder arthroplasty. Loosening of either the humeral or glenoid component was a rare indication for revision for both arthroplasty types. The Eclipse system had a high risk of revision compared with the Simpliciti system.

Comparison of total stemless shoulder arthroplasty and total stemmed shoulder arthroplasty

The functional outcome of total stemless shoulder arthroplasty and total stemmed shoulder arthroplasty has only been compared in a small randomized trial and in few small prospective studies. Uschok et al[23] included 20 total stemless shoulder arthroplasties (Eclipse) and 20 total stemmed shoulder arthroplasties (Universe II) in their study, but only 29 arthroplasties had a complete 5-year follow-up. The Constant scores were comparable (eg, Eclipse 73 and Universe II 70). The study had limitations besides the low number of arthroplasties and a high proportion of dropouts. Especially, the difference in preoperative Constant score is noteworthy (eg, Eclipse 54 and Universe II 26).

Berth and Pap[1] included 39 TESS arthroplasties and 39 Affinis stemmed arthroplasties (Mathys, Bettlach, Switzerland). The patients were assigned to one of the 2 groups based on odd or even medical record numbers. Demographic data, follow-up time, and baseline scores were identical. There were no significant differences in Constant score between the 2 groups at 2 years (eg, TESS 54 and Affinis 49) or in the Disabilities of the Arm, Shoulder and Hand (DASH) score (eg, TESS 47 and Affinis 47). The authors concluded that the mid-term results of stemless shoulder arthroplasty for OA could be considered as good, and similar to standard anatomical arthroplasty.

Razmjou et al[19] included 73 total shoulder arthroplasties for OA in their prospective study. There were 17 TESS arthroplasties, 17 NEER II arthroplasties, and 39 Bigliani-Flatow arthroplasties. Demographic data and baseline WOOS score were identical. The Western Ontario Osteoarthritis of the Shoulder index scores at 2 years were 85, 86, and 84, respectively. The authors concluded that there was a significant improvement regardless of implant type.

To our knowledge, this is the first study to compare the survival rates of total stemless shoulder arthroplasty and total stemmed shoulder arthroplasty. The proportion of

Table III Demographic data and proportion of revisions for the stemless shoulder arthroplasty brands

	Eclipse	Simpliciti	Sidus	Nano	TESS	All
Number	243	213	147	96	62	761
Sex (% female)	37	49	55	67	57	49
Age (yr)	61 (31-84)	64 (37-85)	66 (39-88)	68 (33-87)	67 (44-89)	64 (31-89)
Previous surgery	16%	13%	5%	10%	7%	11.4%
Revision	5.3%	0.9%	2.0%	0%	4.8%	2.8
Revision (loosening)	1.2%	0%	0.7%	0%	1.6%	0.7
Follow-up (mo)	28 (0-71)	27 (0-61)	28 (0-54)	13 (0-33)	48 (1-71)	28 (0-71)

Age and follow-up time are presented as mean and range.

Table IV Cox regression model with hazard ratio, 95% confidence interval (CI), and *P* value

Factor	Univariate model (95% CI)	*P* value	Multivariate model (95% CI)	*P* value
Sex				
Female	1.0 (reference)		1.0 (reference)	
Male	2.16 (0.77-6.07)	.14	1.76 (0.61-5.06)	.29
Age (yr)				
≥75	1.0 (reference)		1.0 (reference)	
55-75	2.88 (0.32-23.75)	.35	0.93 (0.09-9.33)	.95
≤55	3.06 (0.40-23.39)	.28	1.71 (0.21-13.66)	.61
Previous surgery				
No	1.0 (reference)		1.0 (reference)	
Yes	**3.83 (1.43-10.23)**	**<.007**	**4.29 (1.51-12.17)**	**.006**
Arthroplasty brand				
Simpliciti	1.0 (reference)		1.0 (reference)	
Sidus	2.06 (0.34-12.31)	.43	2.42 (0.40-14.65)	.34
Eclipse	**6.58 (1.48-29.19)**	**.013**	**6.37 (1.42-28.66)**	**.016**

Only the Simpliciti, the Sidus, and the Eclipse systems were included in the model. The Nano and the TESS were not included because of few cases ($n < 100$).

revisions and the 6-year cumulative survival rates in this multinational study were similar. In the Cox regression model, which included age, gender, and previous surgery, the risk of revision of stemless and stemmed shoulder arthroplasty was comparable. Nevertheless, the results should be interpreted carefully. There is no information in the NARA dataset about humeral and glenoid component combinations or detailed information about the design and fixation technique of the glenoid components. Thus, the comparison of total stemless shoulder arthroplasty and total stemmed shoulder arthroplasty was based on the assumption that there are no systematic differences in the use of glenoid components.

The stemless shoulder arthroplasty system relies extensively on adequate metaphyseal bone quality, and therefore, the risk of loosening may be higher than for the stemmed shoulder arthroplasty, especially if the stemless is inappropriately used in cases with poor bone quality. However, in this study, aseptic loosening was a rare indication for revision surgery. The results of the present study and previous studies indicate that the functional outcome and survival of stemmed and stemless total shoulder arthroplasty is similar in the treatment of OA.

Stemless shoulder systems

The TESS was released into the European market in 2004 by Biomet. It was the first system to use a stemless, metaphyseal fixed, humeral component, combined with either the metal-backed or cemented glenoid component. The results of 63 arthroplasties with a minimum of 3 years of follow-up were published in 2010.[7] There were significant improvements in Constant score, Oxford Shoulder score, and range of motion. Five intraoperative complications with fracture of the lateral cortex were reported. There was no radiographic sign of loosening, osteolysis, or stress shielding. The TESS has been redesigned with a second-generation system, the Nano.

The Eclipse was introduced in 2005 by Arthrex. Habermeyer et al[6] reported the intermediate results of the Eclipse stemless shoulder system. A total of 39 total arthroplasties and 39 hemiarthroplasties for primary OA or post-traumatic OA were included with a mean follow-up time of 6 years. There was significant improvement in Constant score. In contrast to other previous studies, the complication rate (13%) and reoperation rate (9%) were high. The reasons for revision were mostly rotator cuff problem and loosening of the glenoid component. None of the revisions were related to the humeral component, although the authors reported findings of decreased bone density around the humeral screw in 46% of the patients. In a study by Johansson et al,[9] it was found that the Eclipse system had an unexpectedly high rate of deep infections with *Cutibacterium acnes*. The HR was 4.3 times higher after adjustments for age and gender compared with stemmed shoulder arthroplasty systems or reverse shoulder arthroplasties.

The Simpliciti stemless shoulder system was introduced in 2010 by Tornier and has, as the only stemless shoulder arthroplasty system, been approved by the Food and Drug Administration in the United States in 2015. A multicenter study included 157 arthroplasties and found significant improvements in Constant score, DASH score, and range of motion. There were no radiographic signs of loosening. Three complications were recorded. None of them were related to the humeral component.[4]

The Sidus was introduced in 2012 by Zimmer. Krukenberg et al[13] reported 2-year results of 73 patients with Sidus total shoulder arthroplasty and 32 with hemiarthroplasty. There was significant improvement in Constant, American Shoulder and Elbow Surgeons

shoulder index, and subjective shoulder value scores together with clinical findings related to range of motion. One patient was noted with an intraoperative fracture at greater tuberosity with no further treatment required. There were no signs of radiologic loosening or migration around the humeral component, nor revisions in this series.

Currently, worldwide there are 8 stemless shoulder arthroplasty systems in the market, 3 of which are included in our survival analysis.[3] We found low survival rates of the Eclipse shoulder system that had the longest follow-up, and the lower survival rates may represent a learning curve or evolution in the arthroplasty system. The more recent stemless humeral components rely on a metaphyseal press fit anchor fixation that is different from that of Eclipse and may contribute to the reliable short-term results.

One advantage of nationwide registry data is that the results can be generalized to all shoulder surgeons and not just to surgeons who were either highly specialized or had participated in the evolution of the stemless design. However, even in this multinational registry study, the number of each stemless shoulder arthroplasty system was low, and it can be hypothesized that the results of stemless arthroplasty systems reflect the results of a few surgeons.

Previous surgery

We found that previous surgery was associated with a high risk of revision. There is, however, no detailed information about the type of previous surgery in the NARA dataset, so the reason for this finding is speculative. Periprosthetic infection was the most common indication for revision for both arthroplasty types, and the higher risk of revision in patients with any type of previous surgery could possibly be explained by a higher risk of periprosthetic infection. Accordingly, Werthel et al[25] identified 68 periprosthetic infections in 4577 arthroplasties and found that patients with a history of previous nonarthroplasty surgery had an increased risk of revision due to periprosthetic infection of 1.8. However, there were, various diagnoses and arthroplasty types, and consequently the risk of revision because of periprosthetic infection might not be the same in our cohort of patients with total anatomical shoulder arthroplasty for OA only. A more in-depth analysis is needed to fully understand the role that previous surgery plays in the risk of revision after anatomical total shoulder arthroplasty for OA.

Strength and limitations

The major strength of the study is the collaboration of 4 national shoulder arthroplasty registries to create a multinational dataset with case level data, high completeness, and a high number of patients. However, there were still few revisions in the stemless group and, therefore, uncertainties about the estimate survival. The major limitation of the study is that the minimal dataset only includes basic variables. Thus, there is no information about comorbidity, preoperative functional status, and radiographic findings including bone cysts and poor bone quality of the proximal humerus. This may influence the choice of arthroplasty type and, thereby, introduce bias by indication. There are also uncertainties regarding the indication for revision. If an infection is not proven at the time of revision, it might not be reported to the registries as the indication for revision even though the infection is later identified with the longer incubation time needed for especially the *C. acnes*. Furthermore, the follow-up time is relatively short, and although the implant survival is promising, loosening may first occur in the long term. Finally, implant survival is not the only relevant outcome after shoulder replacement. Some failures may never be revised for several possible reasons that are not reported to the registries. Also, some revisions may lead to good outcome and cannot be regarded as permanent failures.

Conclusion

The short-term survival of the total stemless shoulder arthroplasty appears comparable with that of the total stemmed shoulder arthroplasty, but longer observation time is needed to confirm if they continue to perform equally. Loosening was a rare indication for revision for both arthroplasty types.

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Disclaimer

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