Short-term survival and patient-reported outcome of total stemless shoulder arthroplasty for osteoarthritis are similar to that of stemmed total shoulder arthroplasty: a study from the Danish Shoulder Arthroplasty Registry

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Background: The use of stemless total shoulder arthroplasty (TSA) for osteoarthritis increases, but there is a paucity on its safety and efficacy and how it performs in comparison with stemmed TSA. The aim was to compare the 5-year cumulative survival rate and patient-reported outcome after stemless and stemmed TSA for osteoarthritis.

Methods: We included all stemmed (n = 1197) and stemless (n = 253) TSA for osteoarthritis reported to the Danish shoulder arthroplasty registry from January 1, 2014, to December 31, 2018.

Results: Six (2.4%) stemless and 24 (2%) stemmed TSA were revised. The 5-year cumulative implant survival rates were 0.96 for stemless TSA and 0.97 for stemmed TSA. In the multivariate Cox regression model, the hazard ratio for revision was 1.1 (95% confidence interval, 0.5-2.6) for stemless TSA compared with stemmed TSA. The mean Western Ontario Osteoarthritis of the Shoulder (WOOS) index was 82 (standard deviation = 21) for stemmed and 86 (standard deviation = 19) for stemless TSA. The stemless TSA had a statistically significant better WOOS compared with stemmed TSA, but the difference of 6.2 (95% confidence interval, 1.4-10.4) was not regarded as clinically relevant. There was no difference in WOOS between the Nano and the Eclipse systems.

Discussion: We found a good 5-year cumulative implant survival rate of stemless TSA, which was comparable with stemmed TSA. Although the stemless TSA had a statistically significant better patient-reported outcome compared with stemmed TSA, the difference was not clinically relevant. Sparing the humeral shaft canal for later revision could be an argument for using stemless TSA instead of stemmed TSA.

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The primary aim was to compare the 5-year cumulative survival rates for stemless and stemmed TSA. The secondary aims were to compare the patient-reported outcome of stemless and stemmed TSA and to compare the outcome of the 2 most frequently used stemless arthroplasty systems.

We hypothesized that the survival rate and patient-reported outcome for stemless TSA would be comparable with stemmed TSA and that different stemless arthroplasty systems would have comparable outcomes.

Materials and methods

Sources of data

The study was based on prospectively collected data from the Danish Shoulder Arthroplasty Registry (DSR). The DSR is a national database established in 2004.17 The Danish public health care service finances the registry. Reporting is mandatory for all Danish public hospitals and private clinics. The surgeon reports patient-related data (registration number, date of birth, sex, diagnosis, and previous surgery) and data related to the procedure (date of surgery, arthroplasty type, and brand) at the time of surgery. In case of revision, the surgeon reports the date of revision, the reason for revision, implant removal, and the new arthroplasty type and brand.

The completeness of reporting is calculated by comparing the number of procedures captured by the registry with the number of procedures reported to the Danish National Patient Registry. The Danish National Patient Registry is an administrative database used to reimburse expenses for any hospital treatment, including shoulder arthroplasty. The completeness was above 90% each year from 2014 to 2018. Data have high accuracy when information from medical journals is used as a gold standard.10

The revision arthroplasty procedure is linked to the primary arthroplasty using the Central Personal Registration (CPR) number. The CPR number is a unique number given to all Danish citizens at birth. The CPR number was also used to track the patients in case of emigration or death. The end of follow-up was defined as the date of revision, date of death, or December 31, 2018.

Study population

A total of 2417 arthroplasties for osteoarthritis were reported to the DSR during the study period. We excluded 241 arthroplasties that were used for fracture sequelae and 722 arthroplasties that were not a stemmed or a stemless TSA (ie, reverse shoulder arthroplasty, hemiarthroplasty, or resurfacing arthroplasty) or because the arthroplasty type was recorded as missing. Thus, 1197 stemmed TSA and 253 stemless TSA were included in the study. The demographics of the 2 arthroplasty types were comparable (Table 1). The median follow-up time was 36 months (range 1–70 months).

Outcome measures

Revision for any reason was used as the primary outcome. A revision was defined as the exchange or removal of any component. In the case of more than one reason for revision, only the reason with the highest rank was included. The hierarchy was infection, periprosthetic fracture, luxation and instability, loosening of any component, rotator cuff problem, and others.

The Western Ontario Osteoarthritis of the Shoulder (WOOS) index at 1 year is used as a patient-reported outcome. The WOOS index is a patient-administered, disease-specific questionnaire for the measurement of the quality of life of patients with shoulder osteoarthritis. It provides scores for 4 domains: (1) physical symptoms; (2) sport, recreation, and work; (3) lifestyle; and (4) emotions. Patients answer each question using a visual analog scale. Each question counts 0–100 points, with a total score of 1900, where 1900 is worst and 0 is best. The raw scores are reversed and converted to percentages of the maximum score for simplicity of presentation. The questionnaire has been translated into Danish and validated for patients with glenohumeral osteoarthritis.14 The questionnaire was sent to the patients by a secretary from the DSR without the surgeons being involved. In case of revision within a year, death, or emigration within 1 year after surgery, the WOOS index could not be obtained. In case of revision later than 1 year after surgery, the WOOS index is recorded as usual.

Patients who returned an incomplete questionnaire with 1 question missing were included in the statistical analysis using the multiple imputation method.11 The minimal clinically relevant difference for the WOOS index in patients with shoulder arthroplasty for osteoarthritis has been reported to be 12 of a maximum score.13 We adopted this value and used it to define a clinically relevant difference.

Statistical analysis

Descriptive statistics were used to report demographics, follow-up time, time to revision, and reason for revision. Based on the distribution of data, the results were reported as mean and standard deviation (SD) or median and range.

The Kaplan-Meier method was used to illustrate the unadjusted cumulative survival rates, and the log-rank test was used for comparisons.10 Hazard ratio with 95% confidence intervals (CIs) were calculated using the Cox regression model. Age (≤55 years or >55 years), gender, and previous surgery (yes or no) were included in the multivariate model.

General linear models were used to compare the WOOS index for stemless and stemmed TSA and to compare stemless arthroplasty systems. Age (≤55 years or >55 years), sex, and previous surgery (yes or no) were included in the multivariate model.

Patients with bilateral shoulder arthroplasty were included in the survival analyses as if they were independent. Estimates were given with 95% CI, P value <.05 was considered significant, and all P values were 2-tailed. All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) version 25.0 (IBM Corp, Armonk, NY, USA).

Results

The number of stemmed TSA remained stable, whereas the number of stemless TSA increased during the study period (Fig 1). In the stemmed TSA group, there was 794 Global Advantage (DePuy Orthopaedics, Inc., Warsaw, IN), 105 Global Unit (DePuy Orthopaedics, Inc.), 192 Comprehensive (Zimmer Biomet, Warsaw, IN, USA), 76 Anatomical shoulders (Zimmer, Warsaw, IN, USA), 25 Bigliani-Flatow (Zimmer, Warsaw, IN, USA), 3 Arthrex Universe

| Table 1 | Demographic data and proportions of stemmed and stemless TSA, age, and follow-up time are presented in mean and range. |
|---------|-------------------------------------------------------------------------------------------------------------------|
| Factor  | Stemmed TSA (n = 1179)                                                                 | Stemless TSA (n = 253) |
|---------|-------------------------------------------------------------------------------------------------------------|-------------------------|
| Mean age (yr) | 70 (46-95)                                                                                     | 68 (43-84)                 |
| ≤55 yr | 79 (76%)                                                                                          | 36 (14%)                 |
| >55 yr | 1118 (93%)                                                                                         | 217 (86%)                |
| Sex    | Male 421 (35%)                                                                                      | 114 (45%)                |
| Female | 776 (65%)                                                                                          | 139 (55%)                |
| Previous surgery | 92 (11.3%)                                                                                                | 22 (11.8%)               |
| Mean follow-up time (mo) | 38 (6-71)                                                                                       | 32 (12-68)               |

TSA, total shoulder arthroplasty.
(Arthrex, Inc., Naples, FL, USA), and 2 Aqualis (Tornier, Edina, MN, USA) arthroplasties. In the stemless TSA group, there were 148 Nano arthroplasties (Zimmer Biomet) and 87 Eclipse arthroplasties (Arthrex, Inc.). The number of Simplicity arthroplasties (Tornier, Edina, MN, USA) was \( n = 16 \) and Sidus arthroplasties (Zimmer Biomet, IN, USA) was \( n = 2 \).

### Survival rates

Six (2.4%) stemless TSA and 24 (2%) stemmed TSA were revised. The median time to revision was 22 months (range 1-41 months) for stemless TSA and 14 months (range 5-23 months) for stemmed TSA. Only 4 (0.5%) stemless TSA and two (0.4%) stemless TSA were revised because of aseptic loosening of either the glenoid or the humeral component (Table II). The 5-year cumulative implant survival rate was 0.96 (95% CI, 0.93-0.99) for stemless TSA and 0.97 (95% CI, 0.95-0.98) for stemmed TSA (Fig 2). The difference was not statistically significant, \( P = .82 \). The hazard ratio for revision of stemless TSA was 1.1 (95% CI, 0.5-2.6, \( P = .823 \)) in the univariate model and 1.0 (95% CI, 0.41-2.4, \( P = .99 \)) in the multivariate model with the stemmed TSA as reference.

### Patient-reported outcome

A total of 13 patients died, and 18 patients were revised within 1 year, so the WOOS index questionnaire was sent to 1419 patients, of whom 1011 (71%) returned a complete questionnaire, 39 (3%) returned an incomplete questionnaire with 1 question missing, 13 (1%) patients returned an incomplete questionnaire with more than 1 question missing, and 356 (25%) patients did not respond. A total of 1050 (74%) arthroplasties were included in the analyses.

The mean WOOS index was 82 (SD = 21) for stemmed TSA and 86 (SD = 19) for stemless TSA. In the univariate linear regression model, the stemless TSA had a better score than the stemmed TSA (difference 5.9, 95% CI 1.4-10.4, \( P = .011 \)) but was not regarded as clinically relevant.

The number \( n = 16 \) of Simplicity arthroplasties and \( n = 2 \) Sidus arthroplasties was considered too low for meaningful analysis and were not included in the analysis of stemless arthroplasty systems. The demographic data for the Nano and the Eclipse systems were comparable (Table III). In the univariate linear regression model, the Nano system had a statistically better score than the Eclipse system (mean difference 6.2, CI 0.3-12.2, \( P = .040 \)), but the difference was not regarded as clinically relevant, and it did not remain statistically significant in the multivariable model (mean difference 3.4, CI: −3.1 to 8.9, \( P = .34 \)). One Nano and one Eclipse stemless TSA were revised. The time to revision was 21 months and 23 months, respectively.

### Discussion

The number of stemless TSA increased during the study period. The 5-year cumulative survival rates of stemmed and stemless TSA were comparable. There were no clinically relevant differences in WOOS index between stemmed and stemless TSA or between Nano and Eclipse stemless systems.

#### Stemless and stemmed TSA

The 5-year accumulative implant survival rate of stemless TSA was high and comparable with that of stemmed TSA. Our results

![Figure 1](https://via.placeholder.com/150)  
**Figure 1** Number of stemmed total shoulder arthroplasty (in blue) and stemless shoulder arthroplasty (in orange) during the study period.

### Table II

| TSA type   | Indication         | Frequency | Percentage of total revisions |
|------------|--------------------|-----------|-------------------------------|
| Stemmed TSA | Aseptic loosening | 6         | 0.5% (25%)                    |
|            | Cuff arthropathy  | 5         | 0.4% (20%)                    |
|            | Missing data      | 5         | 0.4% (20%)                    |
|            | Infection         | 3         | 0.3% (12.5%)                  |
|            | Glenoid erosion   | 3         | 0.2% (8.3%)                   |
|            | Dislocation       | 2         | 0.2% (8.3%)                   |
|            | Total             | 24        | 2% (100%)                     |
| Stemless TSA | Dislocation      | 2         | 0.8% (33.3%)                  |
|            | Instability       | 2         | 0.8% (33.3%)                  |
|            | Glenoid erosion   | 1         | 0.4% (16.7%)                  |
|            | Aseptic loosening | 1         | 0.4% (16.7%)                  |
|            | Total             | 6         | 2.4% (100%)                   |

TSA, total shoulder arthroplasty.
confirm the findings of previous studies comparing the arthroplasty survival rate of stemmed and stemless TSA. Rasmussen et al included 761 stemless TSA in a multinational register study and found a 6-year cumulative survival rate of 0.95. Batten et al included 143 stemless TSA and reported a 5-year implant survival rate of 0.96. Loosening was a rare indication for revision, and the cementless metaphyseal fixation does not seem to have a negative effect on the short-term arthroplasty survival.

Few studies have compared the functional results of stemless and stemmed TSA, and they have not been able to demonstrate any differences between the 2 arthroplasty types. Razmjou et al included 761 stemless TSA in a multinational register study and found a 6-year cumulative survival rate of 0.95. Batten et al included 143 stemless TSA and reported a 5-year implant survival rate of 0.96. Loosening was a rare indication for revision, and the cementless metaphyseal fixation does not seem to have a negative effect on the short-term arthroplasty survival.

Berth and Pap compared 41 TESS stemless TSA to 41 Affinis (Mathys, Bettlach, Switzerland) stemmed TSA in a prospective study using quasirandom allocation depending on medical record numbers. At 2 years, the Constant scores were 65 for the stemless TSA and 73 for the stemmed TSA. The difference between the groups was not statistically significant. Uschok et al included 20 Universe II stemmed TSA (Arthrex, Freiham, Germany) with 20 Eclipse stemless TSA in a prospective randomized trial. Twenty-nine patients fulfilled the 5-year follow-up. The Constant scores at 5 years were 70 for stemmed TSA and 73 for stemless TSA. This study had limitations. There was no sample size calculation before the study initiation, no information about the randomization and concealment of allocation, no blinding of patients, and a difference in the preoperative score (eg, Eclipse 54 and Universe II 26) may indicate a baseline imbalance. The authors concluded that both implants showed good functional outcomes at 5 years.

Differences in functional outcomes between stemless and stemmed TSA might be related to different resection guide systems and, subsequently, the ability to restore anatomy and stability. We hypothesize that the stemmed TSA with an intramedullary resection system will lead to an accurate resection with inclination and retroversion as defined by the guide system. The extramedullary resection guide system of the stemless TSA can be more technically demanding, especially in case of severe destruction of the humeral head, but it also offers an individual resection that fits the individual anatomy. There is no postoperative radiographic evaluation in the DSR, so we could not examine the correlation between arthroplasty position and functional outcome. We found a statistically significant better outcome of stemless TSA compared with stemmed TSA, but the difference was small and not clinically relevant. Which arthroplasty design to use can be based on personal preference, availability, or economy. However, sparing the humeral shaft canal for later revision could be an argument for using stemless TSA instead of stemmed TSA.

### Table III

| Factor                        | Nano (n = 148) | Eclipse (n = 87) |
|-------------------------------|----------------|-----------------|
| Median age (yr)               | 70 (33-87)     | 63 (41-82)      |
| ≤ 55 yr                       | 9 (6%)         | 17 (20%)        |
| > 55 yr                       | 139 (94%)      | 70 (81%)        |
| Sex                           |                |                 |
| Male                          | 55 (37, 2%)    | 44 (51%)        |
| Female                        | 93 (63%)       | 43 (49%)        |
| Previous surgery              | 11 (7, 4%)     | 17 (19, 5%)     |
| Follow-up time (mo)           | 32 (5-69)      | 26 (6-51)       |

TSA, total shoulder arthroplasty.
Stemless systems

Arthrex introduced the Eclipse system in Europe in 2005 as a first-generation stemless shoulder arthroplasty system. It was approved by the Food and Drug Administration in the United States in 2019. The system includes a humeral head that is connected to a threaded central cage unit; the cage is fixed by screwing it into the metaphyseal bone. The Nano system is a second-generation stemless TSA introduced by Zimmer Biomet in Europe in 2013 as a modified version of the TESS shoulder arthroplasty system. The Nano does not have Food and Drug Administration approval for use in the United States. It has a collarless impact design; the 6-armed metaphyseal component has impaction implantation. The different methods of fixation (eg, the screw and ingrowth fixation vs. impact fixation) may lead to different arthroplasty survival rates. The number of stemless arthroplasties in this study was too low to make any safe conclusion about the implant survival rate, but both systems appear to be safe.

There are other differences between the 2 arthroplasty systems. This includes differences in height and diameter of the humeral head component and whether an eccentric humeral head component is available. Different guide systems may also influence the resection and subsequently the ability to restore the anatomy and stability. Although we found a statistically significant better outcome for the Nano system compared with the Eclipse system in the univariate model, the difference was not regarded as clinically relevant, and it did not remain statistically significant in the multivariable model.

A systematic review identified 11 case series reporting the results of the TESS, the Eclipse, and the Simplicity systems. All studies reported significant improvement in shoulder function, and the authors concluded that all 3 systems had promising outcomes with short- to mid-term follow-up. A study from the Nordic Arthroplasty Registry Association reported a 6 times higher risk of revision compared with stemmed TSA, the difference was regarded as clinically relevant, and it did not remain statistically significant in the multivariable model.

Methodological considerations

The strength of this study was the high number of patients, which makes it possible to compare not only the patient-reported outcome but also arthroplasty survival rates for stemmed and stemless TSA. Data were retrieved from a comprehensive national database, which adds high external validity to the study.

This observational study is not optimal to compare or detect differences in effect size of different arthroplasty designs or systems. Osteoarthritis was the indication for all arthroplasties, but we do not know the indication or reason for choosing a stemmed or a stemless TSA. It may be related to surgical tradition, personal preference, or economy. This risk of selection bias is important to keep in mind. Furthermore, any systematic differences in the distributions of bone cysts, glenoid wear, rotator cuff status, metabolic diseases, or other unknown factors may also have influenced the results. Owing to the lack of preoperative score, we had no information about the improvement in the WOSI index (eg, the effect of the operation).

Conclusion

We found high 5-year cumulative implant survival rates for stemless TSA, which was comparable with stemmed TSA. Although the stemless TSA had a statistically significant better patient-reported outcome compared with stemmed TSA, the difference was not clinically relevant. Sparing the humeral shaft canal for later revision could be an argument for using stemless TSA instead of stemmed TSA. Longer follow-up is needed to confirm the low risk of revision, and randomized clinical trials are needed to confirm whether stemless and stemmed TSA perform equally.

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