High Failure Rates of Polyethylene Glenoid Components in Stemless Anatomic Total Shoulder Arthroplasty for Primary and Secondary OA

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Background: Glenoid component loosening remains a challenge in anatomic total shoulder arthroplasty (aTSA). The aims of this study were to evaluate complications, implant survival, and revision rates in patients with primary and secondary osteoarthritis (OA) undergoing stemless aTSA using the Arthrex Eclipse humeral implant with a cemented pegged all-polyethylene glenoid component and to identify risk factors leading to revision.

Methods: Of 211 patients who underwent primary stemless aTSA (using the Eclipse humeral component with a cemented pegged all-polyethylene glenoid) with prospectively documented data in a local registry, 197 were evaluated, grouped by OA pathology (primary OA, 153 patients; secondary OA, 44 patients). Demographic and functional data (e.g., age, sex, shoulder function) and the cause of OA were documented preoperatively in both groups. Comparative analyses were conducted to assess complications and implant revisions between the study groups. In addition, various radiographic parameters (e.g., glenoid morphology, critical shoulder angle, lateral acromion index, implant sizing [humeral component overhang], radial matching of the humeral and glenoid components, glenohumeral distance, and medial glenoid cement penetration) were evaluated to explore their potential association with revision. A subset of these parameters was subsequently included in the multivariable Cox model on the basis of clinical relevance.

Results: After a median postoperative period of 72 months, the overall revision rate was 51%. The reasons for revision were glenoid component loosening (85%), periprosthetic humeral fracture (9%), early rotator cuff failure (3%), and low-grade infection (3%). The median implant survival in patients with primary OA (95 months; 95% confidence interval [CI]: 84 to 108) was significantly longer than that in patients with secondary OA (71 months; 95% CI: 60 to 88; p = 0.027). Female patients had a significantly shorter time to revision than male patients (p = 0.016). There were no significant differences in complications or revision rates by OA pathology. Secondary OA, the presence of medial glenoid cement penetration, and an anterior overhang of the humeral component were associated with an increased risk of revision.

Conclusions: Our findings indicate a high rate of glenoid component loosening as the primary cause of revision in patients with primary and secondary OA undergoing stemless aTSA with the Eclipse and a cemented pegged all-polyethylene glenoid component. This outcome emphasizes the need for careful consideration of implant design, patient selection criteria, and implant positioning and cementation in order to optimize implant survival.

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

Anatomic total shoulder arthroplasty (aTSA) is a well-established surgical procedure for patients with end-stage shoulder joint degeneration resulting from osteoarthritis (OA) or posttraumatic conditions[1]. Research has shown that aTSA in patients with primary OA enhances functional outcomes and maintains an acceptable 5-year implant survival rate of 98%[1]. However, this rate drops to 63% after 10 years[1]. Failure of the glenoid component has been recognized as the primary indication for aTSA revision[2].

The use of a stemless aTSA implant combined with a cemented all-polyethylene glenoid, such as the Eclipse shoulder arthroplasty system (Arthrex), potentially facilitates natural

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joint motion and enhances bone preservation[3-5]. Currently, the only available comparative data on the combination of the Eclipse implant and a cemented pegged all-polyethylene glenoid are limited to a cohort of 20 patients with a mean follow-up period (and standard deviation) of 60.0 ± 18.5 months[6]. In that study, Magosch et al. found concerning rates of radiolucent lines and osteolysis in patients who received a cemented pegged all-polyethylene glenoid compared with a keeled component[6]. To date, there is also a lack of evidence comparing the outcomes following aTSA using stemless humeral and cemented pegged all-polyethylene glenoid components in patients with primary versus secondary OA[7,8].

The aims of this study were to evaluate complications, implant survival, and revision rates and to identify factors influencing the risk of revision surgery in patients with primary and secondary OA who received the Eclipse stemless aTSA implant with a cemented pegged all-polyethylene glenoid component.

Materials and Methods

All stemless aTSA cases with a pegged glenoid component that were prospectively recorded in a local REDCap (Research Electronic Data Capture)-based[9] arthroplasty registry between January 2011 and December 2016 were analyzed retrospectively[10]. Seven attending surgeons performed all operations at the same institution. The implant system that was used consisted of the Eclipse humeral component paired with a cemented pegged all-polyethylene glenoid component (Arthrex). The cohort was stratified into 2 groups: those with primary OA and those with secondary OA.

Patients were eligible for inclusion if they had a diagnosis of either primary or secondary OA and were undergoing primary aTSA with a stemless humeral component and a cemented pegged all-polyethylene glenoid. Any patients with a history of prior surgery for osseous reconstruction of the humerus or glenoid, such as osteosynthesis or osseous stabilization, including a subscapularis tenotomy and repair, were excluded. Evidence of rotator cuff insufficiency and/or severe retroversion of the glenoid were contraindications for aTSA. The study was approved by the institutional review board (KEK-ZH-Nr. 2014-0483).

Preoperative Assessments

Patient demographic characteristics, functional scores, and the underlying cause of OA were documented preoperatively. These included the patient's age; sex; Constant score[11]; Shoulder Pain and Disability Index (SPADI) score[12]; abbreviated Disabilities of the Arm, Shoulder and Hand (QuickDASH) score[27]; and specific diagnosis.

Standard true anteroposterior and axial radiographs, along with magnetic resonance imaging (MRI) and/or computed tomography (CT), were performed to evaluate degenerative changes of the glenohumeral joint. Glenoid morphology, distinguishing between centered (Walch A) and decentered (Walch B or C), was assessed for primary OA[13] and secondary OA[14]. Additionally, the anatomy of the shoulder joint was analyzed, including measurements of the critical shoulder angle (CSA)[15] and lateral acromion index (LAI)[16].

Documented operative details included operative time, blood loss (in mL), implant material, and radial matching of the humeral and glenoid components, as recorded in the surgical report. The relationship between humeral head size and glenoid component size was evaluated in order to detect an incorrect size matching of the humeral and glenoid components according to the manufacturer's recommendations. A standard deltopectoral approach was performed in all patients. The subscapularis tendon was tenotomized from 0.5 to 1 cm medial to the lesser tuberosity and repaired end-to-end using 4 to 5 nonabsorbable sutures. The long head of the biceps tendon was addressed with either a tenotomy or a tenodesis. In cases of concentric bone loss (Walch type A), minimal concentric reaming was performed to achieve optimal implant seating. In cases of Walch type-B glenoids, asymmetric reaming was performed to correct retroversion and to achieve optimal implant seating. A standardized cementation technique was used, including lavage, pressurized cementation, and final implant positioning using manual pressure until cement hardening.

Postoperative Radiographic Assessments

To assess the structural and positional integrity of the implant and surrounding anatomical structures, we evaluated several parameters on postoperative true anteroposterior and axial radiographs. These evaluations were conducted using standardized rotations of the shoulder and scapula. The extent of medial glenoid cement penetration, as an indicator of medial vault violation, was assessed using the qualitative method described by Pace et al.[17]. Additionally, we measured the inclination angle between the humeral shaft and humeral component; the humeral screw position on axial radiographs (graded as centered or decentered); the humeral component overhang in relation to the humeral cut surface (classified as superior or inferior overhang on anteroposterior radiographs, anterior or posterior overhang on axial radiographs, or no overhang); and the distance between the humeral component and the native glenoid, representing the glenohumeral distance (GHD) (Figs. 1-A and 1-B).

Follow-up Assessments

Complications and radiographic assessments were routinely evaluated at 2 and 5 years, with additional evaluations between 6 and 12 years after aTSA, depending on patient follow-up report findings at the 5-year mark (Fig. 2). All complications were assessed and categorized by etiology. A complication was defined as any adverse event or postoperative condition requiring surgical intervention, including loosening, periprosthetic fracture, rotator cuff failure or instability, and infection. Glenoid and humeral component loosening were identified as revision reasons on the basis of radiolucencies being visible in ≥2 zones of the glenoid component-bone or humeral component-bone interface, as previously described[6,18]. However, radiographic findings were not always associated with pain or dysfunction. The indication for revision was based on clinical symptoms and/or progression of

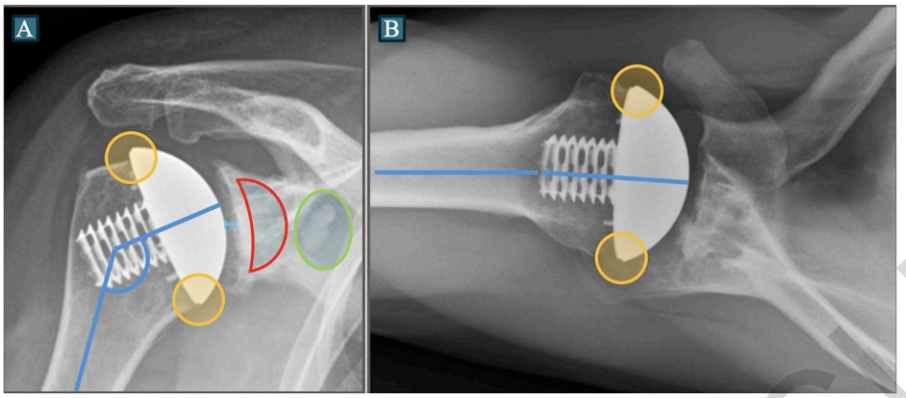

Fig. 1

Figs. 1-A and 1-B Postoperative radiographic assessment parameters. This figure highlights the key parameters that were evaluated in radiographic registry data. Anteroposterior (**Fig. 1-A**) and axial (**Fig. 1-B**) radiographs of 2 right shoulders are shown. The inclination angle between the humeral shaft and humeral component is shown as a blue angle. The glenohumeral distance (GHD) is indicated as "H" in light blue. Medial glenoid cement penetration is highlighted by a green circle. The regions with radiolucent lines are marked in red. Superior humeral component overhang is highlighted by an orange circle (**Fig. 1-A**, superior). The areas of interest for inferior (**Fig. 1-A**, inferior), anterior (**Fig. 1-B**), and posterior (**Fig. 1-B**) humeral component overhang are also marked by orange circles. The centered alignment of the humeral component is marked by blue lines **(Fig. 1-B).**

radiography-proven glenoid component loosening. Signs of radiographic loosening without progression and without clinical impairments were not considered to be complications.

Statistical Analysis

Data were extracted from the arthroplasty registry using a Stata (StataCorp) script and analyzed in RStudio (version 4.3.0; Posit). Descriptive and comparative analyses were performed with the threshold of significance set at 0.05. Shapiro-Wilk and Levene tests were used to confirm a normal distribution and equal variance of the data, respectively. Based on the characteristics of the variables, various statistical tests for continuous variables (i.e., t test, Mann-Whitney U test, or Welch test) and categorical variables (i.e., Z test or Fisher exact test) were utilized. Comparative analyses were conducted to evaluate the revision rate and time to revision across different study groups (primary versus secondary OA, male versus female, Walch A versus B or C, and correct versus incorrect radial matching of the glenoid and humeral components). Kaplan-Meier survival curves and the log-rank test were utilized for the statistical comparison of the time until an implant needed revision.

To identify potential factors influencing the need for subsequent revision surgery at any point in time, we employed a multivariable Cox proportional hazards (PH) regression model. The dependent variable was defined as the duration from the initial surgery to the revision intervention. To account for potential clustering effects due to variability among surgeons, we included the surgeon as a random effect in the model. We followed the recommendations of Peduzzi et al., who suggested that the number of variables in a Cox regression model should

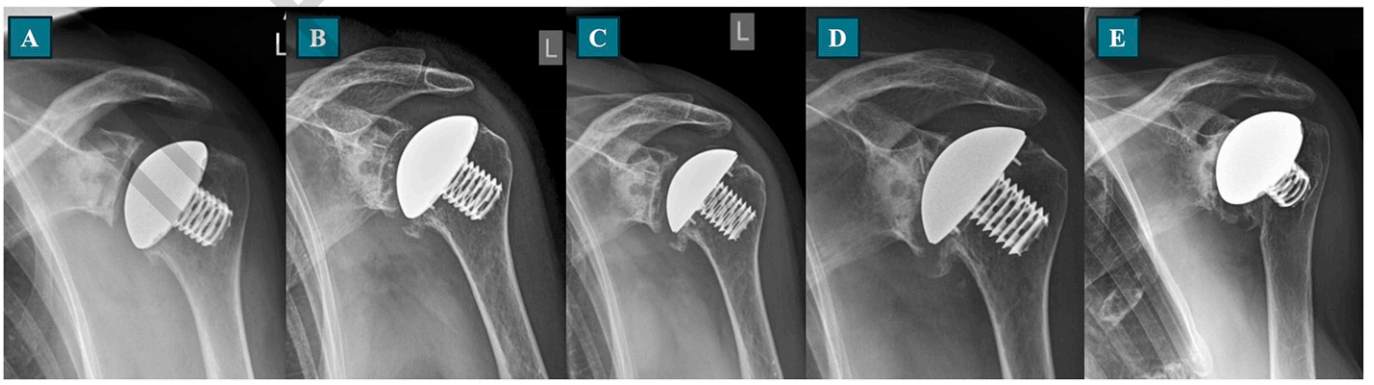

Fig. 2

Figs. 2-A through 2-E Standard anteroposterior radiographs showing the progression of glenoid component loosening following aTSA. **Fig. 2-A** Radiograph taken at 6 weeks. **Fig. 2-B** Radiograph taken at 6 months, with initial implant integration observed. **Fig. 2-C** Radiograph taken at 24 months, with the first signs of radiolucency apparent. **Fig. 2-D** Radiograph taken at 60 months, indicating increasing radiolucency and tilt of the marker in the superior peg. **Fig. 2-E** Radiograph taken at 96 months, revealing complete glenoid subsidence and medialization of the humerus.

not exceed 1 variable per 10 events in order to minimize overfitting[19]. Following this guideline, we included 9 factors in this analysis: patient age at surgery, sex, diagnosis, medial glenoid cement penetration, material of the humeral head component (titanium-coated versus cobalt-chromium), and the presence of anterior, posterior, superior, and inferior overhang of the humeral component. Factor selection was based on both clinical relevance and existing evidence in the literature. We assessed the PH assumption for each variable in the Cox model using Schoenfeld residuals, with PH test values reported. To assess the stability of our findings, we conducted sensitivity analyses by building simplified models that included only the most relevant predictors.

Results

Demographics and Patient Characteristics

Of 211 patients in the registry who underwent primary aTSA with a stemless humeral component and a pegged all-polyethylene glenoid, 197 patients (primary OA, 153 patients; secondary OA, 44 patients) were eligible for inclusion in the analysis; the remaining 14 patients were excluded due to previous osseous reconstruction of the humerus or glenoid. The mean age of the cohort was 65 ± 9 years, and patients with primary OA were significantly older than patients with secondary OA. Forty-six percent of the overall cohort was female, and the proportion of female patients in the secondary OA group (61%) was higher than that in the primary OA group (42%; p = 0.022) (Table I).

Instability was noted as the primary reason for secondary OA (52%). In the secondary OA group, 32% of patients were treated for fracture sequelae, 6.8% had rheumatoid arthritis, 4.6% had humeral head necrosis, and 4.6% had OA with coexisting upper-border subscapularis tears without retraction that could easily be repaired during subscapularis closure.

There were no further differences in the preoperative characteristics (functional scores [Constant score, QuickDASH, SPADI] and morphologic parameters [OA grade, CSA, and LAI]) between the primary and secondary OA groups. Preoperative radiographic evaluations, including the OA grade distribution, CSA, and LAI, are displayed in Table I.

The mean operative time in the primary OA group (99 ± 22 minutes) was significantly shorter than the mean operative time in the secondary OA group (109 ± 23 minutes), with a mean difference of 9.6 minutes (95% confidence interval [CI]: 17, 1.8; p = 0.016). Blood loss during surgery was comparable between the 2 groups (primary OA, 208 ± 112 mL; secondary OA, 217 ± 100 mL; p = 0.700). In the entire cohort, 14 patients (7.1%) received a cobalt-chromium head: 13 with primary OA (8.5% of the primary OA group) and 1 with secondary OA (2.3% of the secondary OA group). In contrast, 179 (91%) of the patients in the entire cohort received a titanium-coated head: 136 with primary OA (89% of the primary OA group) and 43 with secondary OA (98% of the secondary OA group). For 4 patients (2.0% of the entire cohort), all of whom had primary OA, no documentation of head type was available. Titanium-coated implants were used to minimize the risk of an allergic reaction to chromium, cobalt, or nickel.

Correct component size matching was detected in 68% of the overall cohort (74% of the primary OA group and 48% of the secondary OA group). Conversely, an oversized humeral component was found in 32% of the entire cohort (26% of the primary OA group and 52% of the secondary OA group).

The clinical follow-up rates were as follows: 94% (186 of 197 patients) at 2 years, 76% (150 of 197) at 5 years, and 17% (33 of 197) at 10 years. At 5 years, 24% of patients were registered as dropouts; specifically, 11% of patients were unable to be contacted, 7% refused to participate, 3% dropped out due to death, and a further 3% could not complete follow-up due to severe illness.

Radiographic follow-up rates showed similar trends: 90% (177 of 197 patients) at 2 years, 61% (121 of 197) at 5 years, and 15% (30 of 197) at 10 years.

Postoperative Radiographic Results

There were no postoperative differences between the OA groups with respect to the radiographic measurements assessing structural and positional implant integrity, including humeral screw positioning (Table II).

Over the 5-year postoperative period, the mean GHD decreased by 2 ± 1 mm in the entire aTSA cohort, indicating significant polyethylene wear (p < 0.0001). The changes in GHD from immediately postoperatively to 2 years postoperatively and from 2 to 5 years postoperatively were highly significant (p < 0.0001) in both groups. Both the CSA and LAI remained unchanged over time in the OA groups (Fig. 3). Intraoperative images illustrating glenoid wear, osteolysis, and implant breakage are shown in Figure 4.

Complications

A total of 101 revisions were reported for our cohort; 85 were assessed at our institution (Table III). Overall, the revision frequency was 51% and did not differ significantly between the primary and secondary OA groups. Severe complications necessitating revision surgery primarily consisted of symptomatic glenoid component loosening (85% of revisions), followed by periprosthetic humeral fracture (9%), early rotator cuff failure (3%), and low-grade infection (3%). Humeral component loosening was not observed as the primary mode of failure in any of the patients. None of the patients required surgical intervention solely for late cuff repair.

Differences in Time to Revision

The median implant survival from aTSA to revision surgery in the entire cohort was 84 months (95% CI: 78 to 98 months). The Kaplan-Meier survival analysis indicated that the median time to revision surgery significantly differed by both OA type and sex. Patients with primary OA had a significantly longer median time between surgeries (95 months; 95% CI: 84 to 108 months) than those with secondary OA (71 months; 95% CI: 60 to 88 months; p = 0.027; Fig. 5-A). Female patients had significantly less time between surgeries (median, 84 months; 95% CI: 72 to 96 months) than male patients (median, 105 months; 95% CI: 79 to 133 months; p = 0.016; Fig. 5-B).

TABLE I Preoperative Patient Characteristics and Operative Parameters of the Entire Cohort and OA Subgroups

	Overall* (N = 197)	Primary OA* (N = 153)	Secondary OA* (N = 44)	Mean Difference (95% CI)†	P Value†
Age at surgery *(yr)*	65 ± 9	67 ± 8	59 ± 10	8.4 (5.0, 12.0)	<0.001
Sex					0.022
Female	91 (46%)	64 (42%)	27 (61%)		
Male	106 (54%)	89 (58%)	17 (39%)		
Constant score†	35 ± 16	36 ± 16	34 ± 17	1.2 (−4.7, 7.2)	0.700
QuickDASH§	46 ± 17	46 ± 17	45 ± 18	1.0 (−5.3, 7.4)	0.700
SPADI#	42 ± 20	42 ± 20	42 ± 23	−0.26 (−8.3, 7.8)	0.900
OA grade**					0.361
A1/2	109 (55%)	82 (54%)	27 (61%)		
B1/2/3	83 (42%)	66 (43%)	17 (39%)		
C/D	5 (3%)	5 (3%)	0 (0%)		
CSA *(deg)*	30.2 ± 5.3	30.0 ± 5.3	30.9 ± 5.3	−0.88 (−2.7, 0.95)	0.300
LAI	0.65 ± 0.12	0.65 ± 0.11	0.66 ± 0.13	−0.01 (−0.05, 0.04)	0.800

*Values are given as the mean ± standard deviation or as the frequency, with the percentage in parentheses. †Mean differences with 95% CIs and p values for primary versus secondary OA, based on Welch 2-sample t tests (for continuous variables) or 2-sample tests for the equality of proportions (for categorical variables). ‡Constant score (0 = worst and 100 = best) based on the Constant-Murley questionnaire[11]. §QuickDASH score (0 = best and 100 = worst) based on the abbreviated Disabilities of the Arm, Shoulder and Hand questionnaire[27]. #SPADI score (0 = worst and 100 = best) based on the Shoulder Pain and Disability Index questionnaire[12]. **Primary OA grade indicates osteoarthritic changes of the glenoid according to Walch et al.[13], categorized as follows, with centering assessed on axial radiographs and classified as centered or (posteriorly) decentered: A1 = centered humeral head, minor erosion; A2 = centered humeral head, major erosion; B1 = posteriorly subluxated humeral head, narrow posterior joint space, subchondral sclerosis and osteophytes; B2 = posteriorly subluxated humeral head, retroverted glenoid with posterior erosion; B3 = monoconcave and posterior wear with >15° of retroversion or >70% of posterior humeral head subluxation, or both; C = glenoid retroversion of >25° (regardless of erosion), biconcave, posterior bone loss, posterior translation of the humeral head; D = glenoid anteversion or anterior humeral head subluxation of <40°. Secondary OA grades were classified as follows: A1 and A2 = centered humeral head; B1, B2, B3 = decentered humeral head.

TABLE II Postoperative Radiographic Parameters in the Entire Patient Cohort and OA Subgroups

	Overall* (N = 197)	Primary OA* (N = 153)	Secondary OA* (N = 44)	SMD (95% CI)†	P Value†
Cement penetration				0.01 (−0.33, 0.34)	
Yes	81 (41%)	63 (41%)	18 (41%)		
No	116 (59%)	90 (59%)	26 (59%)		
Inclination angle *(deg)*	140 ± 8	140 ± 8	140 ± 8	−0.31 (−3.0, 2.4)	0.8
Humeral screw position				0.34 (0.00, 0.68)	
Central	131 (66%)	101 (66%)	30 (68%)		
Anterior	29 (15%)	22 (14%)	7 (16%)		
Posterior	37 (19%)	30 (20%)	7 (16%)		
Humeral component overhang†					
Inferior	44 (22%)	37 (24%)	7 (16%)	8.3% (−5.9%, 22%)	0.3
Superior	56 (28%)	42 (27%)	14 (32%)	−4.4% (−21%, 13%)	0.7
Anterior	11 (5.6%)	9 (5.9%)	2 (4.5%)	1.3% (−7.2%, 9.9%)	0.9
Posterior	85 (43%)	65 (42%)	20 (45%)	−3.0% (−21%, 15%)	0.9
GHD *(mm)*	4.34 ± 0.98	4.28 ± 1.00	4.58 ± 0.87	−0.29 (−0.61, 0.03)	0.072

*Values are given as the frequency, with the percentage in parentheses, or as the mean ± standard deviation. †Standardized mean differences (SMDs) with 95% CIs and p values for primary versus secondary OA, based on Welch 2-sample t tests (for continuous variables) or 2-sample tests for the equality of proportions (for categorical variables). ‡Some patients had >1 area of overhang.

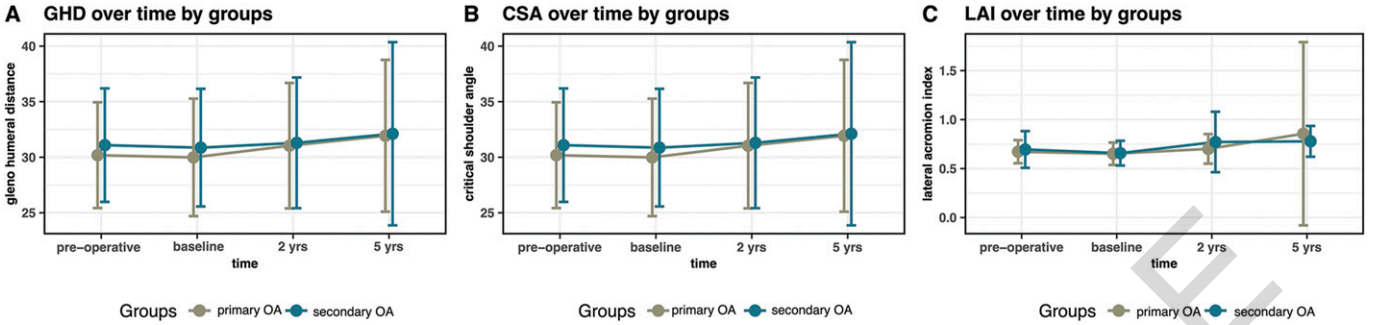

Fig. 3

Longitudinal comparison of glenohumeral distance (GHD) (**Fig. 3-A**), critical shoulder angle (CSA) (**Fig. 3-B**), and lateral acromion index (LAI) (**Fig. 3-C**) over a 5-year period following aTSA in patients with primary versus secondary OA. Data points and error bars indicate mean values and standard deviations, respectively.

The time to revision surgery did not significantly differ between patients with Walch type A (centered humeral head) and those with Walch type B or C (posteriorly subluxated humeral head), nor did it differ on the basis of glenoid and humeral component matching (per manufacturer guidelines) (Figs. 5-C and 5-D).

Factors Influencing the Risk of Revision

The proportionality assumption of the Cox model was met, as all factors showed nonsignificant results in the PH tests ($p > 0.05$). Several factors significantly impacted the likelihood of revision surgery (Table IV). After adjusting for the surgeon as a random factor, the following variables were associated with an increased risk of revision: the presence of anterior humeral component overhang ($p = 0.036$), secondary OA ($p = 0.039$), and cement penetration ($p = 0.023$). Conversely, the presence of inferior humeral component overhang ($p = 0.036$) was associated with a reduced risk of revision. Female sex, the material of the humeral head component, and posterior and superior humeral component overhang were not associated with the risk of revision. The hazard ratios (HRs) are summarized in Table IV.

Significant values, with only minimal changes in the HRs, were also observed for the predictors that were included in the simplified model: secondary OA (HR, 1.798; 95% CI: 1.066 to 3.033; $p = 0.028$), cement penetration (HR, 1.667; 95% CI: 1.055 to 2.590; $p = 0.028$), and anterior overhang (2.26; 95% CI: 1.027 to 4.972; $p = 0.043$).

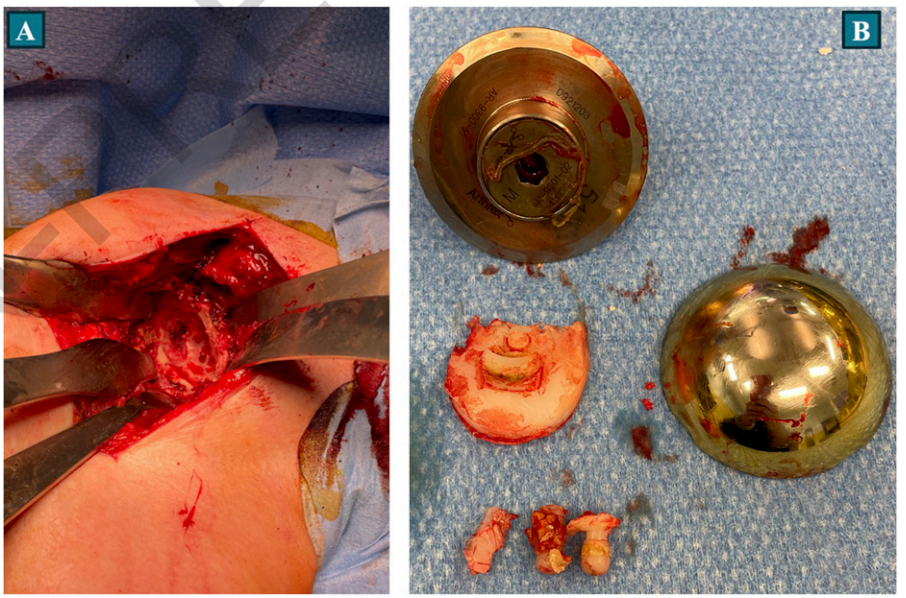

Fig. 4

Figs. 4-A and 4-B Intraoperative images of an aTSA implant explantation. **Fig. 4-A** Intraoperative view following explantation of the polyethylene glenoid with a 4 × 2-cm bone defect. The glenoid defect was caused by osteolytic processes. **Fig. 4-B** Explanted components with severe glenoid wear and superior glenoid abrasion, with the pegs completely separated from the body of the glenoid component and titanium-coating wear marks on the humeral component.

TABLE III Revision Characteristics of the Entire Patient Cohort and OA Subgroups

	Overall* (N = 197)	Primary OA* (N = 153)	Secondary OA* (N = 44)	SMD (95% CI)†	P Value†
No. of revisions	101 (51%)	77 (50%)	24 (55%)	−4.2% (−22%, 14%)	0.700
Glenoid component loosening	86 (85%)	65 (84%)	21 (88%)		
Periprosthetic humeral fracture	9 (9%)	7 (9%)	2 (8%)		
Early rotator cuff failure	3 (3%)	3 (4%)	0 (0%)		
Low-grade infection	3 (3%)	2 (3%)	1 (4%)		
Time to revision *(mo)*	75 ± 30	77 ± 32	66 ± 23	12 (2.4, 21.0)	0.015

*Values are given as the frequency, with the percentage in parentheses, or as the mean ± standard deviation. Percentages for the revision indications are out of the number of revisions. †Standardized mean differences (SMDs) with 95% CIs and p values for primary versus secondary OA, based on Welch 2-sample t tests (for continuous variables) or 2-sample tests for the equality of proportions (for categorical variables).

Discussion

Our study evaluated the longevity of the Arthrex Eclipse aTSA implant with a stemless humeral component and a cemented pegged all-polyethylene glenoid, focusing on complications that led to revisions in patients with primary and secondary OA. Early glenoid component loosening led to alarmingly high revision rates at a median of 72 months. Prior studies of this glenoid component reported radiographic loosening rates between 25% and 100% after 5 years[6,20], suggesting a biomechanical issue. Our findings also showed a significant decrease in the GHD within the first 5 years, indicating early polyethylene wear. The pegged design may be inferior to keeled glenoids, which

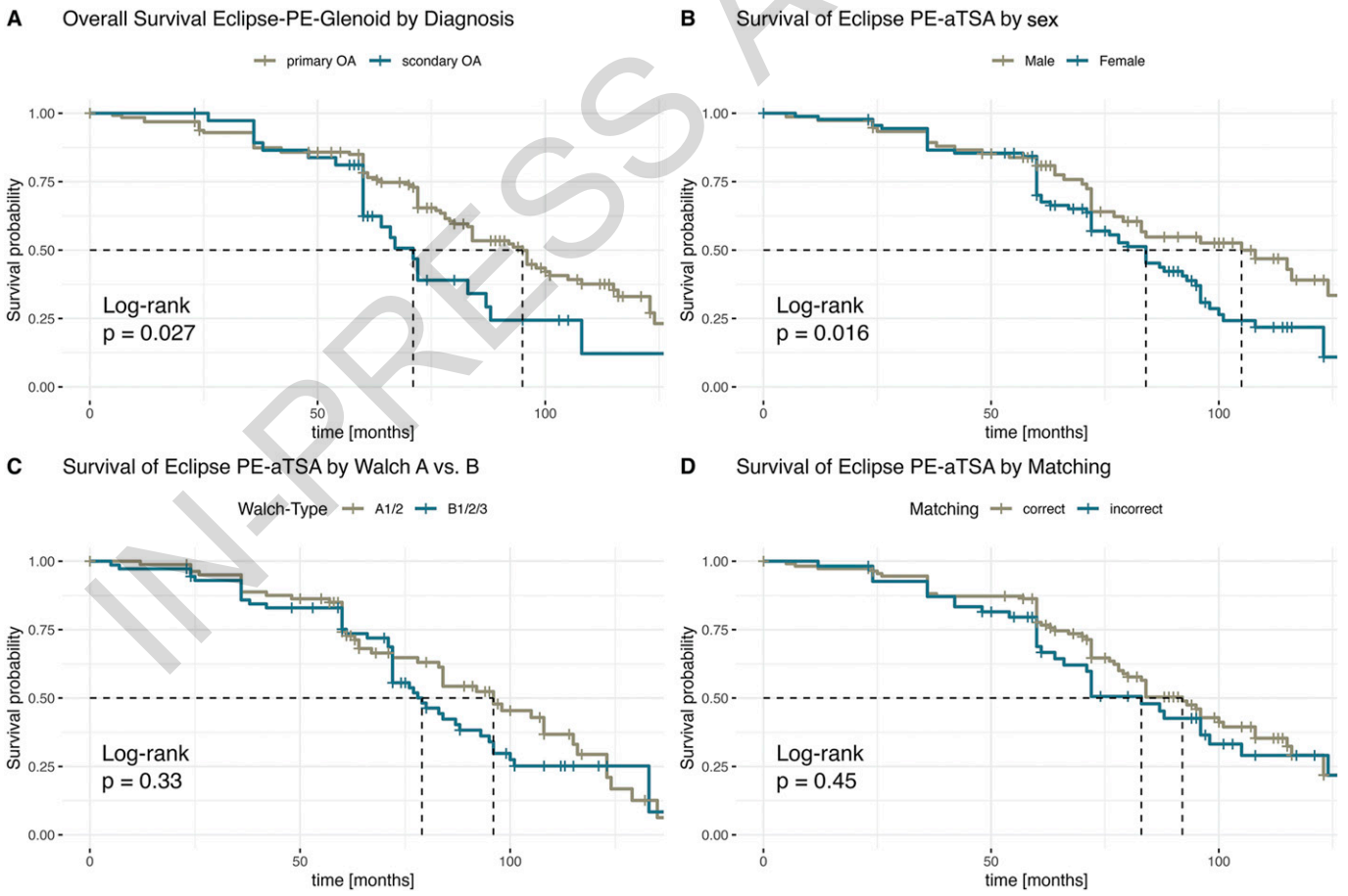

Fig. 5

Kaplan-Meier aTSA implant survival curves stratified according to OA type (**Fig. 5-A**), sex (**Fig. 5-B**), centered or decentered humeral head (**Fig. 5-C**), and correct or incorrect size matching of the glenoid and humeral components (**Fig. 5-D**). Log-rank p values are shown. PE = polyethylene.

TABLE IV Multivariable Cox Regression Analysis for Predictors of Revision

	HR (95% CI)*	P Value*,†	PH Value†
Age	0.995 (0.969-1.022)	0.745	0.147
Female sex	1.363 (0.852-2.180)	0.195	0.898
Secondary OA	1.828 (1.030-3.244)	0.039	0.262
Cement penetration	1.709 (1.078-2.717)	0.023	0.299
Titanium head	0.710 (0.286-1.761)	0.460	0.437
Inferior overhang	0.544 (0.307-0.963)	0.036	0.054
Posterior overhang	0.842 (0.510-1.391)	0.443	0.378
Superior overhang	0.807 (0.468-1.393)	0.443	0.417
Anterior overhang	2.445 (1.058-5.646)	0.036	0.760

*Hazard ratios (HRs) with 95% CIs and p values based on univariate Cox regression analyses. An HR value of 1.00 indicates no influence of the factor on implant survival, >1.00 indicates an increase in revision risk, and <1.00 indicates a decrease in revision risk. †A p value of ≤0.05 indicates a significant influence. ‡A proportional hazards (PH) value of ≤0.05 indicates a significant difference in PH between groups. A PH value of >0.05 indicates that the PH assumption was not violated. There was no significant evidence to suggest that the covariate effects changed over time.

have demonstrated 5-year survival rates of 96.4%[21]. Non-cross-linked polyethylene has also been linked to higher revision risks[22].

Our revision rates are substantially worse than those reported for other aTSAs, which have shown 88% revision-free survival at 5 years[23] and 81% survival after 20 years[24]. The present study identified secondary OA, medial glenoid cement penetration, and anterior overhang as factors contributing to early loosening. Patients with secondary OA had shorter implant survival times. Medial glenoid cement penetration was associated with a higher revision risk, contrary to the findings of Hsu et al.[25]. Anterior overhang may exacerbate subscapularis failure, especially when the subscapularis tendon is repaired after a tenotomy, and may worsen early joint decentering and polyethylene wear. Incorrect size matching of the humeral and glenoid components, another biomechanical characteristic[26], was not found to be a relevant influencing factor.

Frequent implant loosening led to discontinuation of the use of this implant at our center. The manufacturer was notified in 2016, and extracted components were returned. Concurrently, a report of suspicion was submitted to the Swiss Agency for Therapeutic Products (Swissmedic). According to the manufacturer, the titanium-coated humeral heads and the cemented pegged glenoid implants were withdrawn from the market in September 2022.

Limitations

The single-center design and standardized implant usage may limit the generalizability of our findings. A post hoc power analysis showed sufficient power for key predictors (i.e., secondary OA, medial glenoid cement penetration) but underpowered results for others (i.e., sex, humeral component material). Race and ethnicity data were not collected in our registry at the time of inclusion, which we acknowledge as a limitation given the study's Swiss setting. Larger, multicenter studies are needed to validate these findings.

Conclusions

Our findings indicate a high rate of glenoid component loosening as the primary cause of revision in patients with primary and secondary OA undergoing aTSA with the Arthrex Eclipse with cemented pegged all-polyethylene glenoid components. This outcome emphasizes the need for careful consideration of implant design, patient selection criteria, and implant positioning and cementation in order to optimize implant survival. ■

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