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# The association between glenoid component design and revision risk in anatomic total shoulder arthroplasty



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**Introduction:** Anatomic total shoulder arthroplasty (TSA) is a proven treatment for glenohumeral joint osteoarthritis, with superior results compared with hemiarthroplasty. However, glenoid component loosening remains a problem and is one of the most common causes of failure in TSA. Multiple component designs have been developed in an attempt to reduce loosening rates. The purpose of this study was to evaluate risk of revision after anatomic TSA according to the glenoid component design.

**Methods:** We conducted a cohort study including patients aged  $\geq 18$  years who underwent primary elective TSA for the diagnosis of osteoarthritis between 2010 and 2017. Patients with missing implant information, who received stemless humeral implants, or who received augmented glenoid implants, were excluded. Glenoid component designs used were categorized into 4 mutually exclusive treatment groups: polyethylene central-pegged ingrowth, polyethylene-metal hybrid, polyethylene all-cemented pegged, and polyethylene cemented keeled. Multivariable competing risk regression was used to evaluate the risk of glenoid loosening as a cause-specific revision by the glenoid component design.

**Results:** Of the 5566 TSA included in the final cohort, 39.2% of glenoid implants were polyethylene central-pegged ingrowth, 31.1% were polyethylene-metal hybrid, 26.0% were polyethylene all-cemented pegged, and 3.6% were polyethylene cemented keeled. At 6-year final follow-up, 4.1% of TSA were revised for any cause, and 1.4% for glenoid loosening. Compared with the polyethylene central-pegged ingrowth design, no difference in glenoid loosening revision risk was observed for the polyethylene-metal hybrid design (hazard ratio [HR] = 1.15, 95% confidence interval [CI] = 0.42-3.20). However, both the polyethylene all-cemented pegged (HR = 2.48, 95% CI = 1.08-5.66) and polyethylene cemented keeled (HR = 3.84, 95% CI = 1.13-13.00) designs had higher risks for revision due to glenoid loosening.

**Conclusions:** We observed glenoid component designs to be associated with differential risks in revision due to glenoid loosening with polyethylene all-cemented pegged glenoids and polyethylene cemented keeled glenoids having higher risks when compared with polyethylene central-pegged ingrowth glenoids. Surgeons may want to consider the glenoid component design when performing anatomic TSA.

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Shoulder arthroplasty is increasingly used for the treatment of degenerative conditions about the glenohumeral joint.<sup>9,26,36,47,49</sup> Anatomic total shoulder arthroplasty (TSA), specifically, has superior results when compared with hemiarthroplasty,<sup>4,10,16,29,43,46</sup> but glenoid component loosening remains a common complication in TSA.<sup>3,17</sup> However, not all cases of glenoid loosening are necessarily symptomatic. Although a meta-analysis reported that 7.3% of glenoids may show signs of asymptomatic radiographic loosening annually after primary anatomic TSA, only 0.8% of anatomical TSA are revised yearly due to glenoid loosening.<sup>39</sup>

In an attempt to reduce rates of symptomatic loosening, different glenoid component designs have been developed. Traditionally, glenoid components were of an all-polyethylene design, fixed to the glenoid with cement, using either a central keel or a pattern of pegs. To further improve fixation, some pegged designs also have a central noncemented polyethylene post designed to allow for bone ingrowth.<sup>53</sup> Polyethylene-metal hybrid glenoids have more recently come on the market, although only limited outcome data available are on these implants.<sup>5,13,15,19,20,32-34,37,38,51</sup> Research is needed to determine the impact of the glenoid component design on revision risk.

The purpose of this study was to examine whether there is a difference in risk of revision due to glenoid failure after primary elective anatomic TSA when comparing 4 mutually exclusive designs of a glenoid component: polyethylene central-pegged ingrowth, polyethylene-metal hybrid, polyethylene all-cemented pegged, and polyethylene cemented keeled.

# Materials and methods

# Study design and setting

We conducted a cohort study using an integrated health care system's Shoulder Arthroplasty Registry (SAR). This health care system covers over 12.3 million members throughout 8 geographical regions in the United States, including Colorado, Georgia, Hawaii, the Mid-Atlantic, Northern California, the Northwest, Southern California, and Washington.<sup>21</sup> Health care plan membership has previously been shown to be demographically representative of the geographical areas in which it covers.<sup>22,27</sup>

#### Data source

A detailed summary of data collection procedures, coverage, and participation rates for our SAR was published previously.<sup>8,41</sup> Briefly, this surveillance tool for all shoulder arthroplasty procedures performed within our institution collects patient, procedure, implant, surgeon, and hospital information using electronic intraoperative forms that are completed at the point-of-care by the operating surgeon. Information is then supplemented using data from the electronic health record, administrative claims data, membership data, and mortality records. Outcomes, such as revisions, are prospectively monitored using electronic screening algorithms and validated by trained clinical content experts using the electronic health record. Full coverage of all arthroplasties performed in all geographical regions was in place since 2009.

### Study sample

The study sample included patients 18 years or older who underwent primary elective TSA for the primary diagnosis of osteoarthritis between 2010 and 2017. Patients with missing implant information, patients who received stemless humeral implants, and patients who received augmented glenoid implants were excluded (n = 421). The final study sample comprised 5566 anatomic TSA performed by 185 surgeons at 50 health care centers.

# **Exposure of interest**

Glenoid component design was the treatment of interest. Glenoid component designs used within our registry can roughly be grouped into 4 mutually exclusive component designs: polyethylene central-pegged ingrowth, polyethylene-metal hybrid, polyethylene all-cemented pegged, and polyethylene cemented keeled. Polyethylene central-pegged ingrowth glenoids consist of a noncemented central peg designed to allow for bone ingrowth, with peripheral pegs that are designed to be cemented. Polyethylene-metal hybrid designs have a metal portion (typically a peg or a cage) designed to allow for bony ingrowth attached to a polyethylene component. Polyethylene all-cemented pegged glenoids consist of multiple pegs, often between 2 and 4, all of which are cemented into the glenoid vault. Polyethylene cemented keeled implants have a central keel that is cemented into the glenoid vault. There is a fifth glenoid design that consists of a fully metal-backed component secured to the bone with screws and a modular polyethylene portion. However, such metal-backed glenoids are not widely used in the United States at the current time and none were recorded in our registry during the study period. Specific devices used in the study sample grouped by component design are presented in Table I.

Company	Implant	
Polyethylene central-pegged ingrowth		
Arthrex, Naples, FL, USA	Univers VaultLock Glenoid	
Biomet, Warsaw, IN, USA	Comprehensive Total Shoulder System Modular Hybrid Glenoid (Polyethylene post)	
DePuy, Warsaw, IN, USA	Global Anchor Peg Glenoid	
Wright Medical (Tornier), Memphis, TN, USA	Affiniti Pegged Glenoid	
	Aequalis Perform Anatomic Glenoid System CORTILOC Pegged Glenoid	
Polyethylene-metal hybrid		
Biomet, Warsaw, IN, USA	Comprehensive Total Shoulder System Modular Hybrid Glenoid (Regenerex post)	
Exactech, Gainesville, FL, USA	Equinoxe Cage Glenoid	
Zimmer, Warsaw, IN, USA	Bigliani/Flatow The Complete Shoulder Solution Trabecular Metal Glenoid	
Polyethylene all-cemented pegged		
Arthrex, Naples, FL, USA	Univers Pegged Glenoid	
Biomet, Warsaw, IN, USA	Bio-Modular Choice Shoulder System Pegged Glenoid	
DJO Global, Dallas, TX, USA	Turon Modular Shoulder System Pegged Glenoid	
	Turon Modular Shoulder System e $+$ Pegged Glenoid	
	Altivate Anatomic e+ Pegged Glenoid	
Exactech, Gainesville, FL, USA	Equinoxe Pegged Glenoid	
Stryker, Mahwah, NJ, USA	Solar Total Shoulder System Pegged Glenoid	
	ReUnion TSA Self-Pressurizing Pegged Glenoid	
Synthes, Warsaw, IN, USA	Epoca Shoulder Prosthesis System Glenoid	
Wright Medical (Tornier), Memphis, TN, USA	Aequalis Shoulder System Pegged Glenoid	
	Aequalis Perform Anatomic Glenoid System Pegged Glenoid	
Zimmer, Warsaw, IN, USA	Anatomical Shoulder System Pegged Glenoid	
	Bigliani/Flatow The Complete Shoulder Solution Glenoid with Pegs	
Polyethylene cemented keeled		
Arthrex, Naples, FL, USA	Univers Keeled Glenoid	
Biomet, Warsaw, IN, USA	Comprehensive Total Shoulder System Keeled Glenoid	
DePuy, Warsaw, IN, USA	Global Keeled Glenoid	
Exactech, Gainesville, FL, USA	Equinoxe Keeled Glenoid	
Stryker, Mahwah, NJ, USA	Solar Total Shoulder System Keeled Glenoid	
	ReUnion TSA Self-Pressurizing Keeled Glenoid	
Wright Medical (Tornier), Memphis, TN, USA	Aequalis Shoulder System Keeled Glenoid	
	Aequalis Perform Anatomic Glenoid System Keeled Glenoid	
Zimmer, Warsaw, IN, USA	Anatomical Shoulder System Keeled Glenoid	
	Bigliani/Flatow The Complete Shoulder Solution Glenoid with Keel	

 Table I
 Classification of 4 glenoid implant designs: polyethylene central-pegged ingrowth, polyethylene-metal hybrid, polyethylene all-cemented pegged, and polyethylene cemented keeled

## **Outcome of interest**

Cause-specific revision for glenoid failure was the primary endpoint. This includes both loosening of the implant and fracture or other structural failure. Revision was defined as any reoperation performed after the index shoulder arthroplasty where an implant was exchanged, removed, or added. The indication for revision was reported by the operating surgeon, which was then validated by trained research associates. In this study, we modeled the timeto-first revision, regardless of any glenoid failure in subsequent revisions. Revisions were continuously monitored after the index procedure by the registry until either death, membership termination (leaving our health care system's plan), or study end date (December 31, 2017). Follow-up time was defined as the time from the index procedure to the date of revision surgery, the date of death, the date of health care membership termination, or the end date for the study, whichever came first. Of the 5566 TSA identified for the study sample, 95.8% had complete follow-up (no membership termination).

# Covariates

Potential confounders included patient age ( $<60 \text{ vs. } \ge 60 \text{ years}$ ), sex (male vs. female), body mass index (<30, 30-35,  $\ge 35$ ), American Society of Anesthesiologists (ASA) classification<sup>1</sup> (1-2 vs. 3+), diabetes (yes vs. no, based on diabetes registry), and Elixhauser comorbidities<sup>12</sup> (yes vs. no). Comorbidities with a standardized mean difference over 0.1 by the glenoid implant group were included in the final model; this included chronic pulmonary disease, deficiency anemia, peripheral vascular disease, and valvular disease. Surgeon variance was also considered because failure times within the same surgeon may be correlated.

## Statistical analysis

To account for different follow-up times, 6-year crude cumulative incidence of glenoid revision, which is the probability of revision due to glenoid failure in 6 years postoperatively, was calculated using the Aalen-Johansen estimate for competing revision reasons. Because revision rates may vary with time and polyethylene-metal hybrid glenoids were a relatively new introduction, for analysis, we set a follow-up limit to make the mean follow-up times between groups more equal. The follow-up limit was the time point at which there were still 30 patients at risk in the smallest glenoid design group. The remaining nonrevised TSA were censored at the follow-up limit. The follow-up limit in this analysis for the identification of mean follow-up time was 6 years and 26 days. We also calculated the completeness of follow-up as the sum of observed follow-up times divided by the sum of potential follow-up times.<sup>7</sup>

Risk for revision due to glenoid component failure was then modeled as cause-specific hazard functions using a mixed-effect Cox proportional hazard regression, censoring those subjects who experienced a competing event at the time of the occurrence of the competing event. Cause-specific hazard models allow us to estimate the effect of covariates on the rate of occurrence of the outcome of interest in those subjects who are currently event free.<sup>2</sup> Patients who died, terminated health care membership, or reached the study end date were censored in regression analysis. The model included the treatment variable and all potential confounders listed above as fixed effects; to adjust for surgeon differences and experience, the operating surgeon was included in the model as a random intercept. Hazard ratios (HR) and 95% confidence intervals (CI) were presented using the polyethylene central pegged ingrowth design as the reference group for the treatment variable. The proportional hazard assumption for the treatment variable was checked by plotting the Schoenfeld residuals against the vector of unique failure times and met, implying that the factors investigated have a constant impact on the hazard over time. To account for missing values (ASA: n = 1697, 30.5%; comorbidities: n = 885, 15.9%), fully conditional specification multiple imputations using the Markov chain Monte Carlo estimation method was performed to create 50 versions of the analytic data set. Each data set was separately analyzed using the same model, and the results were combined using Rubin's rules.<sup>45</sup> The imputation model included all variables and the baseline hazard function. Analyses were performed using R version 3.3.0. All tests were 2-sided and P < .05 was the statistical significance threshold used for this study.

#### Results

Of the 5566 TSA identified, 39.2% (n = 2183) of glenoid implants were polyethylene central-pegged ingrowth, 31.1% (n = 1733) were polyethylene-metal hybrid, 26.0% (n = 1448) were polyethylene all-cemented pegged, and 3.6% (n = 202) were polyethylene cemented keeled. The mean age was 68.6 years (standard deviation = 8.5). Most patients were male (52.1%), with a body mass index <30 kg/m<sup>2</sup> (51.8%), an ASA of 1-2 (55.9%), and without diabetes (73.7%). Characteristics by glenoid implant design are presented in Table II.

Over 6-year postoperative follow-up, 143 (cumulative revision probability = 4.1%) revisions for any cause were observed, 39 (cumulative revision probability = 1.4%) of which were due to glenoid failure. Cumulative revision for glenoid failure by the glenoid component design is

presented in Fig. 1. Compared with the polyethylene central-pegged ingrowth design, after adjusting for confounders, the polyethylene all-cemented pegged (HR = 2.48, 95% CI = 1.08-5.66, P = .032) and polyethylene cemented keeled (HR = 3.84, 95% CI = 1.13-13.00, P = .031) designs both had higher risks for revision due to glenoid failure (Table III). No difference in glenoid failure revision risk was observed for the polyethylene-metal hybrid design (HR = 1.15, 95% CI = 0.42-3.20, P = .786).

### Discussion

Although many different glenoid component designs for anatomic TSA are available for orthopedic surgeons, there is currently little evidence to help guide implant selection. In our US cohort of 5566 primary elective anatomic TSA, we found that risk for revision due to glenoid loosening differs according to the glenoid component design, with the polyethylene all-cemented pegged and polyethylene cemented keeled designs having higher revision risks compared with polyethylene central-pegged ingrowth.

We observed a 6-year cumulative revision incidence of 1.4% for glenoid loosening in our cohort. Although this estimate seems low, it is similar to a meta-analysis of 3853 TSA reporting an annual surgical revision rate of 0.8% for glenoid loosening.<sup>39</sup> Glenoid loosening appears to occur at a roughly constant rate; Hsu et al<sup>20</sup> noted approximately one-third of patients with glenoid failure presented within 5 years of their index surgery, one-third between 5 and 10 years, and the last third after 10 years. With longer term follow-up, it would stand to reason the absolute percentage of glenoids implanted that require revision should increase. Therefore, even a seemingly small annual revision rate can have a large impact on a high-volume center.

All-polyethylene glenoid components were long the implant of choice for TSA. A recent study from the Australian Orthopaedic Association National Joint Replacement Registry demonstrated superior results of cemented all polyethylene implants when compared with cementless metal-backed designs.<sup>37</sup> Looking specifically at polyethylene glenoids, the authors did not note a difference among keeled and pegged subtypes. It is debated whether keeled or pegged implants are superior. The overwhelming majority of the available literature on this topic is limited to all-cemented pegged glenoids (as opposed to centralpegged ingrowth designs), with inconsistent findings.  $^{11,14,20,25,28,31,39,44,48,50}$  Recently, Kilian et al<sup>25</sup> failed to observe a difference in radiographic or clinical outcomes at an average follow-up of 7.9 years when comparing all-cemented pegged and cemented keeled glenoids. Two studies from the Mayo Clinic separately reviewed the results of all-cemented pegged and cemented keeled glenoids, noting higher risks of radiographic and clinical failure with all-cemented pegged components.<sup>23,31</sup> In contrast, a meta-analysis of 1460 patients suggested a

Characteristic, n (%)	Central-pegged ingrowth	Metal hybrid	All-cemented pegged	Cemented keeled
Total N	2183	1733	1448	202
Age (yr)				
Mean $\pm$ SD	$68.3 \pm 8.6$	$\textbf{68.1} \pm \textbf{8.5}$	$69.7 \pm 8.3$	$\textbf{68.8} \pm \textbf{8.7}$
Median (IQR)	68 (63-74)	68 (63-74)	70 (64-76)	68 (63-75)
Age <60 yr	336 (15.4)	278 (16.0)	166 (11.5)	27 (13.4)
Male sex	1142 (52.3)	936 (54.0)	711 (49.1)	109 (54.0)
Body mass index (kg/m <sup>2</sup> )				
<30	1120 (51.4)	885 (51.1)	780 (54.1)	92 (45.8)
30-35	591 (27.1)	468 (27.0)	376 (26.1)	64 (31.8)
≥35	468 (21.5)	379 (21.9)	287 (19.9)	45 (22.4)
ASA classification $\geq$ 3	630 (43.0)	514 (43.6)	505 (46.8)	59 (40.7)
Diabetes	583 (26.7)	390 (22.5)	429 (29.6)	64 (31.7)
Chronic pulmonary disease	377 (20.1)	361 (24.2)	267 (23.4)	29 (17.0)
Deficiency anemia	193 (10.3)	127 (8.5)	103 (9.0)	18 (10.5)
Peripheral vascular disease	359 (19.2)	366 (24.5)	205 (17.9)	15 (8.8)
Valvular disease	100 (5.3)	64 (4.3)	64 (5.6)	3 (1.8)

Table II Characteristics of 5566 primary total shoulder arthroplasty patients, by the glenoid implant design (2010-2017)

SD, standard deviation; IQR, interquartile range; ASA, American Society of Anesthesiologists.

Missing data: ASA: n = 1697 (30.5%), chronic pulmonary disease: n = 885 (15.9%), deficiency anemia: n = 885 (15.9%), peripheral vascular disease: n = 885 (15.9%), valvular disease: n = 885 (15.9%).

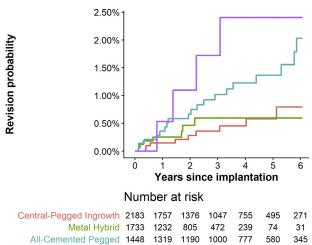


Figure 1 Cumulative unadjusted revision proportion due to glenoid loosening, estimated with Aalen-Johansen survival for

competing revision reasons.

significantly lower risk of revision with all-cemented pegged implants when compared with cemented keeled.<sup>50</sup>

Although the overall revision rate due to glenoid failure was low, our study suggests that the design of an allpolyethylene glenoid plays an important role in revision risk after anatomic TSA, as cemented keeled designs had a 4 times higher revision risk and all-cemented pegged designs a 2.6 times higher risk when compared with central-pegged ingrowth glenoids. Literature comparing the outcomes of central-pegged ingrowth glenoids with other designs is lacking. The only other study to date comparing outcomes of central-pegged ingrowth glenoids with all-cemented pegged glenoids did not find any differences in radiolucent lines around the glenoid component or aseptic loosening rates at an average follow-up of 35 months;<sup>24</sup> however, this study comprised only 42 patients and may have lacked sufficient statistical power to detect a clinical difference. It is worth noting, though, that several recent studies have reported promising outcomes with glenoids.<sup>6,18,30,32,33,35,40,52,54</sup> central-pegged ingrowth Parks et al<sup>40</sup> noted only 1 case of aseptic glenoid loosening in their prospective study of 80 patients who underwent TSA with a central-pegged ingrowth glenoid. Likewise, Wijeratna et al<sup>52</sup> also reported only a single revision for glenoid loosening out of 83 patients. On postoperative computed tomography imaging, all but 10 glenoids had bone in at least 5 of the 6 compartments of the central peg, thus demonstrating osseointegration. These findings, when taken in conjunction with our results, suggest that central-pegged ingrowth glenoids may perform better when compared with other all-polyethylene glenoids.

Polyethylene-metal hybrid glenoids are a relatively new introduction over the past several years in an attempt to improve component fixation to the glenoid and further reduce rates of loosening. Early designs were plagued by failure of the component at the polyethylene-metal junction and high rates of metal debris formation.<sup>5,13</sup> Failures were also noted to occur at earlier time points when compared with pegged designs.<sup>20</sup> More recent hybrid designs, however, have promising results at short- to intermediate-term follow-up,<sup>15,19,32-34,38,51</sup> although few studies have specifically compared all-polyethylene glenoids with polyethylene-metal hybrid designs.<sup>15,19,20</sup> Gulotta et al<sup>19</sup> failed to observe a difference when comparing outcomes between a polyethylene-metal hybrid glenoid using a

Implant design	6-yr cumulative revision incidence	HR <sup>*</sup> (95% CI)	Р
Central-pegged ingrowth	0.8% (0.4-1.7)	1.00 (reference)	_
Metal hybrid	0.6% (0.3-1.3)	1.15 (0.42-3.20)	.786
All-cemented pegged	2.0% (1.2-3.3)	2.48 (1.08-5.66)	.032
Cemented keeled	2.4% (0.9-6.4)	3.84 (1.13-13.00)	.031

**Table III** Crude incidence and adjusted association between the glenoid implant design and risk of revision due to glenoid loosening after primary total shoulder arthroplasty

HR, hazard ratio; CI, confidence interval.

\* Competing risks regression model adjusted for age, sex, body mass index, American Society of Anesthesiologists classification, diabetes, chronic pulmonary disease, deficiency anemia, peripheral vascular disease, valvular disease, and operating surgeon variance.

titanium central post and a polyethylene all-cemented pegged glenoid. In contrast, Friedman et al<sup>15</sup> found a lower revision rate with polyethylene-metal hybrid glenoids when compared with polyethylene all-cemented pegged glenoids. When looking specifically at glenoid-sided failure, though, the authors did not find a difference in revision rates between the 2 cohorts. We observed no difference in revision risk for polyethylene-metal hybrid glenoids when compared with polyethylene central-pegged ingrowth glenoids. Interestingly, Friedman et al<sup>15</sup> did report a unique mechanism of failure where the polyethylene separated from the caged central peg, which remained in the vault. Although seemingly rare, we have also observed such failures at our institution (Fig. 2).



**Figure 2** Retrieved polyethylene-metal hybrid glenoid component at revision surgery. The central cage was well-fixed in the glenoid vault, whereas the polyethylene had sheared off and was loose.

There are limitations to this study that must be considered. Our study is observational in nature, and as a result causation cannot be inferred. Although we attempted to account for confounding in our multivariable regression analysis, there is still potential for unmeasured confounding. For example, the choice of glenoid component implant is subject to surgeon preference, and surgeon experience may also have an impact on the cementing technique.<sup>28</sup> However, we did account for clustering by the operating surgeon in our regression model. The role native glenoid morphology may have had in our study is also unknown, although a recent study of 1270 ingrowth polyethylene glenoids did not observe inferior outcomes in type B glenoids and those with over 15° of retroversion.<sup>30</sup> It should also be understood that there are subtleties between glenoid designs that could potentially contribute to differences in loosening even within groups. Future studies to determine whether the differences in revision risk observed here are due to the glenoid component design or a specific implanted device are needed. Finally, although we found a statistically significant difference, including a 4 times higher risk for polyethylene cemented keeled and a 2.6 times higher risk for polyethylene all-cemented pegged designs, these may not be clinically significant as the overall incidence of revision for glenoid loosening was low. There was also some uncertainty around the effect estimates (ie, wider 95% CI).

Study strengths include our integrated health care system's SAR that prospectively collects data and validates all revisions and revision reasons, assuring high data integrity of our findings compared with other studies relying on administrative data sets with limited clinical information.<sup>42</sup> We had 100% coverage on a sample of patients and surgeons who are representative of the regional population served, thus increasing the generalizability of our findings. Our large sample size allows us to identify subtle differences in prosthesis performance that may be missed by previously underpowered studies. We minimized overestimation by modeling cause-specific revision as competing risk, rather than Kaplan-Meier separately on each event type while treating other events types as censored. Competing risk models are more desirable than Kaplan-Meier estimation because the latter assumes that all

other causes of revision are to be disallowed and competing endpoints are independent.<sup>2</sup>

# Conclusion

In a cohort of 5566 primary elective anatomic TSA with a follow-up limit of 6 years, the glenoid component design appears to be associated with a differential risk of revision due to glenoid loosening, with polyethylene allcemented pegged glenoids and polyethylene cemented keeled glenoids having a higher revision risk when compared with polyethylene central-pegged ingrowth glenoids. No difference was observed for polyethylenemetal hybrid glenoids. Surgeons may want to consider these data regarding the glenoid component design when performing anatomic TSA. Future studies to validate these findings and determine whether the observed differences are due to the glenoid design type or a specific device are needed.

# Disclaimer

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

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