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Minimum 5-year outcomes of pegged versus keeled all-polyethylene glenoids

Samuel G. Moulton, MD [a], Elliott W. Cole, MD, MPH [a], Reuben Gobezie, MD [b], Anthony A. Romeo, MD [c], Evan Lederman, MD [d,e], Patrick J. Denard, MD [a,f,*]

[a] Department of Orthopaedic & Rehabilitation, Oregon Health & Science University, Portland, OR, USA
[b] The Cleveland Shoulder Institute, Beachwood, OH, USA
[c] Shoulder & Elbow/Sports Medicine Division, Rothman Orthopaedic Institute, New York, NY, USA
[d] The Orthopedic Clinic Association, Phoenix AZ, USA
[e] University of Arizona College of Medicine—Phoenix, Phoenix AZ, USA
[f] Southern Oregon Orthopedics, Medford, OR, USA

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Background: Glenoid loosening remains one of the most common concerns at mid- to long-term follow-up after total shoulder arthroplasty (TSA). Pegged and keeled designs have been compared at short-term follow-up, but few studies have compared outcomes at mid-term follow-up. Our purpose was to compare minimum 5-year outcomes of pegged and keeled cemented, all-polyethylene glenoids in TSA. The hypothesis was that no difference in functional outcomes or loosening would be found between the 2 components.

Methods: We performed a multicenter retrospective study of TSAs with either a pegged or keeled cemented glenoid. At a minimum of 5 years postoperatively, functional outcomes and radiographic loosening were compared.

Results: Forty-seven TSAs were available for follow-up, including 20 pegged and 27 keeled components, at a mean of 79 months (range, 60-114 months) postoperatively. Overall, functional outcomes improved in both groups from preoperatively to postoperatively, and no difference was found between the 2 groups. Radiographic glenoid loosening (score $\geq$ 3) was observed in 9 of 27 keeled glenoids (33.3%) compared with 5 of 20 pegged glenoids (25%) (P = .54). Loosening was associated with lower postoperative forward flexion (P = .026), lower American Shoulder and Elbow Surgeons scores (P = .030), and higher visual analog scale pain scores (P = .007).

Conclusion: Radiographic glenoid loosening of a cemented, all-polyethylene component was associated with decreased functional outcomes at minimum 5-year follow-up of TSAs. However, this study showed no difference in loosening rates between keeled and pegged components.

Total shoulder arthroplasty (TSA) has increased in prevalence in the past 25 years.[1] TSA leads to improvement in functional outcomes and has a 10-year survival rate of approximately 90%.[2,11,15] Radiographic glenoid loosening is observed in up to 36% of cases at mid- to long-term follow-up.[11] Efforts should be made to identify factors associated with glenoid loosening.

The all-polyethylene glenoid component is considered the standard of care for glenoid resurfacing and is commonly divided into pegged and keeled designs.[4,10,12,14,16] Biomechanical data have shown that the keeled design incurs greater stress at the bone-cement interface.[7] Pegged designs have been reported to have lower rates of radiographic lucency at short-term follow-up.[3] Few studies, however, have compared the rates of radiographic loosening between pegged and keeled designs at mid-term follow-up.[6] Further mid-term clinical studies are thus needed to compare the outcomes of pegged and keeled components.

The purpose of this study was to compare the minimum 5-year outcomes of pegged and keeled cemented, all-polyethylene glenoids in TSA. The hypothesis was that no difference in clinical outcomes or loosening would be found between the 2 components.

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* Corresponding author: Patrick J. Denard, MD, Southern Oregon Orthopedics, 2780 E Barnett Rd, Ste 200, Medford, OR 97530, USA.
E-mail address: pjdenard@gmail.com (P.J. Denard).

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Materials and methods

We conducted a multicenter retrospective study of TSAs performed between 2008 and 2011 using a press-fit, standard-length humeral stem and either a pegged or keeled all-polyethylene, cemented glenoid (Univers II; Arthrex, Naples, FL). The inclusion criteria included patients who underwent primary TSA for either primary osteoarthritis or post-traumatic arthritis and patients with subjective outcome scores, range of motion (ROM) findings, and radiographs available at a minimum follow-up of 5 years postoperatively. The exclusion criteria included revision arthroplasty as the index procedure.

Surgical technique

TSAs were performed at 3 centers by 3 different surgeons using a consistent technique, with the only variance being the glenoid component. The deltopectoral approach was used to access the glenohumeral joint. The subscapularis was detached by tenotomy or lesser tuberosity osteotomy based on the surgeon's preferred technique, and anatomic cutting of the humeral head was performed respecting the native retroversion and inclination. The humeral canal was opened with a single reamer and then broached to accept the press-fit humeral component. All patients received a pegged or keeled cemented, all-polyethylene glenoid component with a curved backside (38-mm radius of curvature). The glenoid was prepared to accept the appropriate component, irrigated with pulse lavage, and dried with a sponge. Cement was serially pressurized for 3 cycles with a dedicated pressurization instrument per manufacturer recommendations. The component choice was based on surgeon preference.

Postoperatively, the shoulder was placed in a sling for 4 weeks. Passive ROM was allowed at 2 weeks, and strengthening was allowed at 8 weeks. Full activities were permitted at 4 months postoperatively.

Clinical assessment

Functional outcomes and ROM were assessed preoperatively and at a minimum of 5 years postoperatively. Function was determined with the visual analog scale (VAS) pain score, Simple Shoulder Test score, American Shoulder and Elbow Surgeons (ASES) score, and Single Assessment Numeric Evaluation (SANE) score. ROM was evaluated by the treating surgeons. A goniometer was used to determine forward flexion and external rotation at the side, whereas internal rotation was estimated to the nearest spinal level.

Radiographic assessment

Anteroposterior and axillary plain radiographs obtained immediately postoperatively and at a minimum of 5 years postoperatively were analyzed for glenoid loosening. All radiographs were assessed by an independent examiner (P.J.D.). Radiolucencies of the glenoid were graded from 0 to 5 according to the Lazarus grading scale for keeled or pegged components as follows[8]: grade 0, no radiolucency; grade 1, radiolucency at the superior and/or inferior flange or incomplete radiolucency around 1 or 2 pegs; grade 2, incomplete radiolucency at the keel or a maximum of 2 mm wide around 1 peg only, with or without incomplete radiolucency around 1 other peg; grade 3, complete radiolucency a maximum of 2 mm wide around the keel or around 2 or more pegs; grade 4, complete radiolucency more than 2 mm wide around the keel or around 2 or more pegs; and grade 5, gross loosening. For purposes of analysis, a "relevant" change was considered a score of 2 or greater based on a previous study.[6] A loose component was defined as grade 3 radiolucency or greater.

Table I
Demographic data of patients with keeled vs. pegged glenoids

	Keeled	Pegged	*P* value
Age, yr	67.5 ± 6.5	62.4 ± 7.4	.018
Sex: male, %	44.4	65.0	.166
Laterality: right, %	59.3	65.0	.694
Dominant arm, %	63.0	60.0	.836
Osteoarthritis, n	27	18	.097
Post-traumatic, n	0	2	

Statistics

A 2-way repeated-measures analysis of variance was conducted to examine the effect of the Lazarus grade on postoperative outcomes (ROM and VAS pain, ASES, Simple Shoulder Test, and SANE scores). Subgroup analysis was conducted using a 2-way analysis of variance examining the effect of loose vs. non-loose glenoid implants on postoperative outcome scores. Non-loose was defined as a glenoid score of 2 or less, whereas loose was defined as 3 or greater. A 2-proportion test was used to compare return to activity and satisfaction for the loose and non-loose subgroups.

Results

A total of 47 patients were available for 5-year follow-up after TSA, with 27 keeled and 20 pegged glenoid components. The average follow-up period was 79 months (range, 60-114 months). Among all patients, the average age was 65 ± 7.30 years; 25 men and 22 women were included. A comparison of patient demographic characteristics between the groups with pegged and keeled components is presented in Table I. The groups were similar with the exception of a slightly older age at baseline in the keeled group.

Overall, patient-reported outcomes (VAS pain, ASES, and SANE scores) and ROM improved at 5 years postoperatively in all patients, as well as in each type of glenoid component group. No difference in any patient-reported outcome score or ROM measure was found between the pegged group and the keeled group at 5 years postoperatively (Table II).

Relevant radiographic changes around the glenoid component were observed in 21 of 47 patients (45%), including 14 of 27 with keeled glenoid components (52%) and 7 of 20 with pegged glenoid components (35%) ($P = .25$). Radiographic glenoid loosening (score ≥ 3) was observed in 9 of 27 keeled glenoids (33.3%) compared with 5 of 20 pegged glenoids (25%) ($P = .54$). Lazarus grade 4 or 5 radiolucencies were observed in 8 of 47 patients (17%), including 4 of 27 with keeled components (15%) and 4 of 20 with pegged components (20%) ($P = .64$). Glenoid loosening was associated with lower postoperative forward flexion (mean, 136.9°; range, 80°-170°; $P = .026$), lower ASES scores (mean, 81; range, 10-100; $P = .030$), and higher VAS pain scores (mean, 1.3; range, 0-9; $P = .007$). When including implant type, we noted a statistically significant difference in the loose vs. non-loose subgroups in the keeled group for the VAS score ($P = .002$) and ASES score ($P = .017$); however, no statistically significant differences were found in the pegged group ($P > .156$). The return-to-activity and satisfaction rates were similar for the loose subgroup, at 93% (13 of 14 patients), and non-loose subgroup, at 88% (29 of 33 patients) ($P > .999$).

In the keeled group, pain and stiffness with glenoid loosening developed in 1 patient; rotator cuff tendinitis developed in 1 patient; and pain and stiffness developed in 1 patient, who was treated with a corticosteroid injection. No patients in the keeled

Table II
Subjective outcome scores and range of motion

	Keeled			Pegged			*P* value for pegged vs. keeled	
	Preop	5 yr Postop	*P* value for Preop vs. Postop	Preop	5 yr Postop	*P* value for Preop vs. Postop	Preop	Postop
FF, °	114.3 ± 25.3	141.1 ± 19.9	.001	117.0 ± 37.1	131.1 ± 30.0	.029	.792	.235
ER, °	32.6 ± 10.5	49.6 ± 13.4	.001	37.6 ± 22.7	51.3 ± 18.2	.003	.298	.736
IR	S1	L2	.001	L5	L2	.004	.299	.49
VAS pain score	6.5 ± 1.8	1.5 ± 2.5	.001	16.8 ± 2.9	0.9 ± 1.2	.001	.042	.315
ASES shoulder score	34.3 ± 14.7	76.8 ± 24.3	.001	5.2 ± 2.7	87.0 ± 12.7	.001	.065	.07
SST score	3.0 ± 2.2	8.4 ± 3.1	.001	44.6 ± 20.0	10.1 ± 2.2	.001	.069	.027
SANE score	34.6 ± 14.1	77.4 ± 25.0	.001	4.5 ± 2.7	89.1 ± 13.3	.001	.177	.04

Preop, preoperatively; *Postop*, postoperatively; *FF*, forward flexion; *ER*, external rotation; *IR*, internal rotation, *VAS*, visual analog scale; *ASES*, American Shoulder and Elbow Surgeons; *SST*, Simple Shoulder Test; *SANE*, Single Assessment Numeric Evaluation.

group underwent revision surgery. In the pegged group, arthroscopic glenoid removal for radiographic loosening was required in 1 patient, pain and stiffness with glenoid loosening developed in 1 patient, and rotator cuff tendinitis developed in 1 patient.

Discussion

At a minimum of 5 years postoperatively, no significant differences in patient-reported outcome scores or ROM were found between pegged and keeled cemented, all-polyethylene glenoid components. Radiographic loosening was observed in a substantial proportion of patients (20% to 33%), but no significant difference in loosening was found between the 2 components. These findings provide additional information about the radiographic performance of cemented, all-polyethylene components.

The findings in the literature comparing loosening or revision of pegged or keeled components are mixed, and most studies have included short-term follow-up. In a randomized controlled trial, Edwards et al[3] analyzed 25 keeled and 26 pegged components at a mean of 26 months postoperatively. At short-term follow-up, the keeled components had a higher percentage of radiolucent lines compared with the pegged components (46% vs. 15%, $P = .003$). Their study also found a higher percentage of progression of radiolucency in the keeled group from immediately after surgery to final follow-up (42% vs. 14%, $P = .044$). Although these findings suggested that pegged components were superior, the initial findings were limited by the short-term follow-up period (12-36 months). The mid-term results from the same group differed from their short-term results.[6] At 7.9 years' follow-up of 22 keeled and 16 pegged components from the same cohort, no difference in radiolucencies were found between the groups. Relevant changes (grade 2 or higher) were observed in 91% of the keeled components and 100% of the pegged components ($P = .617$). On the one hand, this finding suggests no difference between the 2 components. On the other hand, the fact that nearly all components had changes leads to questions about the polyethylene itself. In comparison, at a mean of 6.9 years postoperatively, we observed relevant changes in 62% of patients and glenoid loosening (grade 3 or higher) in only 20% of the pegged and 33% of the keeled components ($P = .319$). We also did not observe a statistically significant difference in relevant changes or loosening rates, but this could be because of our small sample size.

Larger studies have suggested a difference between pegged and keeled components. In a recent analysis of 215 glenoid failures, Hsu et al[5] found a significant increase in glenoid loosening among metal-backed or hybrid components and keeled components at an average of 8.2 ± 5.9 years between the index surgical procedure and revision. Loosening was present in 65% of revised pegged components, 86% of revised keeled components, and 80% of revised metal-backed or hybrid components ($P = .010$). However, their definition of failure using a higher Lazarus grade ($\geq$2 mm of glenoid loosening) results in fewer cases of component loosening included compared with our definition of loosening. In addition, generalizing their results to all TSAs is limited by the selection bias of analyzing solely glenoid component failures. In a meta-analysis of 1460 patients from 7 studies, Vavken et al[13] found that pegged glenoid components had a decreased risk of revision compared with keeled glenoid components (pooled risk ratio, 0.27; 95% confidence interval, 0.08-0.87; $P = .028$). However, most of the studies included only 2 years of follow-up. These studies demonstrate that differences in loosening and revision rates may exist when analyzing larger sample sizes of pegged and keeled glenoid components. However, generalized conclusions are limited by short-term follow-up and selection bias.

Our overall loosening rate of cemented, all-polyethylene components is comparable to loosening rates reported in the literature. In 39 shoulders, Raiss et al[11] found that 36% of glenoid components were loose at a mean of 11 years (range, 10-15 years) postoperatively. Likewise, we found that 28% of glenoid components were loose at a minimum of 5 years after surgery. The rates in this study and the aforementioned studies are concerning and require improvement. It is possible that other forms of fixation, such as hybrid polyethylene designs, will prove to be a viable alternative. For instance, Noyes et al[9] reported on 42 patients with an all-polyethylene component designed for central bony ingrowth with only peripheral cement. At 80 months (range, 63-114 months) postoperatively, they reported a 97% rate of survivorship, with few implants demonstrating radiolucencies. Eighty-one percent of the components demonstrated bony ingrowth, and the mean Lazarus score was only 0.81. On the basis of these results, bony ingrowth with partially cemented glenoid components may be an alternative to decrease loosening rates in the mid to long term. Direct comparison of cemented components and bony-ingrowth, partially cemented polyethylene components is needed to further evaluate the differences in loosening rates.

Correlations of radiographic glenoid loosening and clinical outcomes are mixed. Raiss et al[11] found no significant decrease in patient-reported outcome scores or ROM among patients with glenoid loosening at a mean of 11 years after surgery. On the other hand, Kilian et al[6] found significantly decreased SANE scores and Western Ontario Osteoarthritis of the Shoulder scores among patients with glenoid loosening at an average of 7.9 years' follow-up. In our study, patients with glenoid loosening at mid-term follow-up had decreased forward flexion, decreased ASES scores, and higher VAS pain scores. Collectively, these studies suggest that radiographic glenoid loosening has a negative effect

on clinical outcomes, but larger studies or meta-analyses are necessary.

The primary limitations of this study are the retrospective design and small cohort size. The choice between glenoid component types was based on surgeon preference. A large randomized controlled trial would be more appropriate for evaluating differences. The small sample size limited our ability to detect a difference between the 2 groups. Although no significant difference in glenoid loosening was found between the 2 groups, this may be because of the small sample size. In the meta-analysis by Vavken et al,[13] for instance, a revision could be prevented for every 23 to 115 pegged components inserted in place of keeled components. Our analysis was based on plain radiographs alone. Although plain radiographs are commonly used to evaluate glenoid radiolucencies, computed tomography would be more precise. Finally, serial examination (ie, evaluation at 1 and 2 years postoperatively) would be useful for determining the timing of development and rate of progression of radiolucencies.

Conclusion

At a minimum of 5 years' follow-up, postoperative radiographic loosening was common after implantation of an all-polyethylene component, and no statistically significant difference in loosening was found between pegged and keeled components in our small sample. However, radiographic glenoid loosening of all-polyethylene components was associated with decreased functional outcomes at minimum 5-year follow-up of TSAs. Thus, the rate of loosening remains a concern with both types of components, and larger studies are needed to compare the outcomes between pegged and keeled components.

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