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Clinical and radiographic outcomes of an all-polyethylene fluted central peg glenoid component, implanted utilizing an off-label, uncemented technique, at a minimum 5-year follow-up



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Background: Glenoid component loosening remains an important concern in anatomic total shoulder arthroplasty. The aim of this study was to evaluate the clinical and radiographic results of a fully uncemented all-polyethylene fluted central peg bone-ingrowth glenoid component at a minimum 5-year follow-up.

Methods: Thirty-five shoulders in 31 patients (mean age, 73 years) with a mean follow-up of 100 months were retrospectively evaluated at an early and mid-term time point for Constant score (CS). Computed tomography visualized glenoid component fixation at both time points. **Results:** Mean CS improved from 40 preoperatively to 66 postoperatively at latest follow-up (P < .001). A mean CS of 74 at early follow-up remained consistent with a mean CS of 66 at latest follow-up (P = .158), with only strength demonstrating a decrease over time (P < .001). An initial osseointegration rate of 81% at early follow-up decreased to 71% at latest follow-up with 74% of the shoulders demonstrating progressive radiolucent lines, resulting in a radiographic loosening rate of 31%. Of the 35 shoulders, 4 were revised (survival rate of 88%), of which 2 due to symptomatic aseptic loosening.

Conclusions: Uncemented fixation of an all-polyethylene central peg bone-ingrowth glenoid was associated with satisfactory clinical and radiographic scores, and an acceptable revision rate at mid- to long-term follow-up. Despite initial bony osseointegration in the majority of cases, radiographic loosening over time remains a concern, potentially jeopardizing long-lasting fixation of this type of glenoid component when implanted in an off-label uncemented fashion.

Level of evidence: Level IV; Case Series; Treatment Study

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Keywords: Total shoulder arthroplasty; radiolucency; osseointegration; glenoid loosening; pegged glenoid; bone ingrowth; Anchor Peg Glenoid; cementless

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Anatomic total shoulder arthroplasty (aTSA) has shown to be excellent in the treatment of a variety of glenohumeral arthropathies, with better pain relief and function than hemiarthroplasty.^{16,19} Loosening of the glenoid component remains the most important cause of failure.^{4,22} Long-term clinical studies demonstrate revision rates between 30% and 40% at 10-15 years of follow-up because of glenoid component loosening.^{7,17} To overcome this type of failure, several implant designs have been introduced. Uncemented metal-backed tissue ingrowth designs were created to reduce glenoid loosening but have yielded higher revision rates due to mechanical failure as compared with allpolyethylene glenoid components.^{2,4} Within the allpolyethylene types, pegged components became the most favored, as they have shown less signs of loosening when compared with keeled designs.²⁴

Because of persistent concerns regarding loosening of the glenoid component, a design combining a biaxally pegged, all-polyethylene glenoid with a central fluted peg that allows bone ingrowth into the flanges was created and tested in an animal study.²⁸ In this canine model, the pegged all-polyethylene glenoid component, implanted in a cementless technique, demonstrated bone ingrowth between the flanges of the central peg, with a better fixation strength at 6 months as compared with a conventional keeled cemented implant. This type of bone-ingrowth component has been further studied in clinical trials, with good clinical outcomes and a reported osseointegration rate of the central peg ranging between 29% and 93% at a mean follow-up ranging between 24 and 80 months (Table I).^{1,3,8,12-15,27,29}

Whereas these clinical studies used a hybrid cementation technique by cementing all peripheral pegs, our prior study on short-term follow-up of this implant type used a fully uncemented technique, similar to the technique used in the animal study of Wirth et al,²⁸ and demonstrated an osseointegration rate of 81%.⁵ The premise behind this technique was to obtain similar outcomes as the hybrid cementation technique while having some benefits by potentially reducing heat-induced necrosis, having a shorter operating time, and potentially reducing cement-related difficulties in case of revision. The purpose of this study was to analyze the clinical and radiographic outcomes of aTSA using an uncemented all-polyethylene pegged bone-ingrowth glenoid component at a minimum 5-year follow-up.

Methods

In this retrospective follow-up study to a prior case series, patients who were treated with primary aTSA between 2006 and 2011 by a single surgeon (LDW) using an Anchor Peg Glenoid component (DePuy Synthes, a Johnson & Johnson company, Warsaw, IN, USA) implanted in a cementless fashion and those who underwent a pre- and postoperative computed tomography (CT) scan at short-term follow-up as part of 2 prior studies were considered for inclusion.^{5,6} This type of aTSA was considered for all patients presenting with avascular necrosis or primary osteoarthritis with the exception for patients with glenoid type C. Excluded were those having an impaired functional outcome due to other medical conditions not related to the shoulder surgery. After approval of the local ethical committee, these patients were recruited for follow-up at a minimum of 5 years postoperatively for question-naire evaluation, physical examination, and CT scan evaluation. After informed consent was obtained, clinical outcome instruments were assessed, including Constant score (CS) and both Mental (MCS) and Physical Component Summary (PCS) of the 12-Item Short Form Survey. Range of motion was measured using a goniometer, and strength measurements were made using a handheld Isometer device (IDO, Reading, Berkshire, UK).

CT scan evaluation

CT scans (Somatom Volume Zoom System scanner; Siemens, Erlangen, Germany: 140 kVp tube voltage, 512×512 acquisition matrix, ≤1.5-mm slice thickness, 500-mm field of view, 0.97-mm pixel size) were assessed in a standardized fashion, with an orthosis holding the upper arm adducted and the elbow flexed in 90°. Glenoid version, glenohumeral subluxation index (GHSI), and glenoid morphology were assessed on preoperative CT scans. Glenoid version and GHSI were repeated on postoperative CT scans. Glenoid version was assessed according to the Friedman method.¹⁸ GHSI was measured at the level of the center of the glenoid with a threshold for subluxation between 40% and 61% for conventional CT scans, as proposed by Jacxsens et al.9 Glenoid morphology of those having primary osteoarthritis was categorized according to the classification of Walch et al.²⁵ As in our prior short-term study, radiographic signs of loosening were assessed according to a modified Lazarus method, by measuring radiolucent lines (RLL) around the pegs and classifying them into 6 grades (0-5) (Fig. 1).⁵ Radiographic loosening was considered when the diameter of the RLL exceeded the diameter of the central and/or peripheral peg over the complete length of 1 peg (grades 2, 4, and 5), as evaluated on all 3 principal planes of the body. Glenoid components presenting RLL < grade 2 around the central peg were considered osseointegrated.

Statistical analysis

Patient characteristics and clinical outcome scores were evaluated using descriptive statistics. Medians and interquartile ranges were employed for continuous variables and frequencies for discrete variables. The Wilcoxon signed rank test was performed to evaluate changes in functional score from baseline during follow-up. The correlation between progression in RLL around the peripheral pegs with progression in RLL around the central peg was assessed by the spearman correlation test. To evaluate whether clinical scores were associated with RLL, the RLL grading was dichotomized, with grades 0 and 1 representing a minor RLL-grading and grade 2 or more representing major RLL-grading, similar to Parks et al.¹⁵ The association between clinical scores and RLL was evaluated with the Mann-Whitney U test. All analyses were performed in IBM SPSS Statistics version 22 (IBM, Armonk, NY, USA), with an α significance level ≤ 0.05 .

Study	LOE	Mean FU, mo (range)	Mean clinical scores	Imaging	OI rate (%)	RLL rate (%)	Survivorship (%)
Groh, 2010 ⁸	IV	34 (24-47)	n.r.	Rx	29	0	100
Churchill et al, 2010 ³	IV	67 (60-76)	SST 11.1, CS 82.4	Rx	85	25	100
Arnold et al, 2011 ¹	IV	43 (24-66)	SST 10.3, CS 81.3	СТ	91	31	100
Wirth et al, 2012 ²⁹	IV	36 (24-72)	SST 9.1, ASES 84.5	Rx	93	20	98
Nuttall et al, 2012 ¹⁴	IV	24	ASES 85, CS 63	RSA, CT	45	55	100
Noyes et al, 2015 ¹²	IV	80 (63-114)	ASES 84	Rx	81	29	97
Wijeratna et al, 2016 ²⁷	IV	47 (24-99)	ASES 97, OS 48	Rx, CT	88	6	95 [†]
Parks et al, 2016 ^{15,*}	IV	34 (24-60)	ASES 85, CS 69	Rx	88	18	95 [†]
Nuttall et al, 2017 ¹³	IV	24	ASES 75, CS 61	RSA	73	27	n.r.

Table I Literature overview on the results of a cemented all-polyethylene pegged bone-ingrowth glenoid component

LOE, level of evidence; FU, follow-up; OI, osseointegration; RLL, radiolucent lines; n.r., not reported; Rx, radiographs; SST, simple shoulder test; CS, Constant score; CT, computed tomography; ASES, American Shoulder and Elbow Surgeons shoulder score; RSA, radiostereometric analysis; OS, Oxford score.

* In this study, an Affiniti CortiLoc glenoid component (Wright Medical Group, Memphis, TN, USA) was used; in all other studies, an Anchor Peg Glenoid component (DePuy, a Johnson & Johnson company, Warsaw, IN, USA) was used.

[†] One revision was performed, because of aseptic loosening.

Results

A total of 41 shoulders in 36 patients were eligible for the study. One patient was excluded because of hemiplegia at the operated side secondary to intracerebral bleeding unrelated to the shoulder surgery. One patient was lost to follow-up, 3 patients declined a mid-term follow-up appointment, and 1 patient died due to an event unrelated to the index surgery. This resulted in a study group of 35 shoulders (25 right, 10 left) in 31 patients (10 male, 21 female) with a mean age of 73 years (range, 53-85 years) at surgery with a mean follow-up of 100 months (range, 61-127 months). Of the 35 shoulders with primary osteo-arthritis, glenoid morphology type was type A1 in 8 shoulders, A2 in 5 shoulders, B1 in 4 shoulders, and B2 in 14 shoulders. The remaining 4 shoulders had avascular necrosis of the humeral head.

Clinical outcomes

The mean CS improved from 40 (range, 13-73) preoperatively to 66 (range, 19-87) postoperatively at mid-term follow-up (P < .001). Pain, activity, and mobility improved significantly (P < .001), whereas no difference in strength was seen at a minimum 5-year follow-up (7 vs. 7, P = .630) (Table II). Over time, a marginal trend in decreasing CS was seen, as a CS of 74 (range, 58-93) at short-term followup dropped to 66 (range, 19-87) at mid-term follow-up (P = .158) (Table II). This was mainly due to a detoriation of strength between the early and mid-term time point (9 vs. 7, P < .001). Both mean MCS of 44 ± 8 and mean PCS of 50 ± 10 at short-term follow-up did not differ when compared with the mean MCS of 35 ± 6 and mean PCS of 37 ± 6 at latest follow-up (P = .760 and P = .840, respectively).

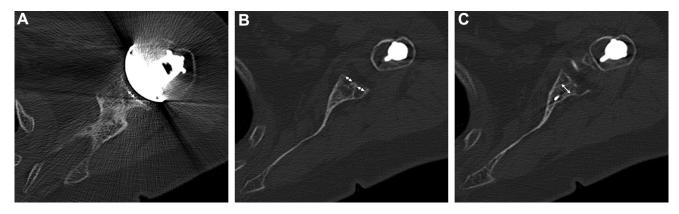


Figure 1 Computed tomography scan evaluation of a 79-year-old woman, 109 months after anatomic total shoulder arthroplasty of the left shoulder. Measurement of the superior (**A**) and inferior peripheral pegs (**B**), and measurement of the central peg (**C**) (*white arrows*) determined the grading of radiolucency. A width <5 mm for the peripheral pegs and a width <9 mm of the central peg were measured. In this case, no signs of loosening were seen with bone ingrowth in all compartments of the central peg.

	Mean (range)			P value		
	ТО	T1	T2	T0 vs. T1	T0 vs. T2	T1 vs. T2
Total Constant score	40 (13-73)	74 (58-93)	66 (19-87)	<.001	<.001	.158
Pain	4 (0-11)	13 (5-15)	12 (3-15)	<.001	<.001	.170
Activity	10 (4-17)	18 (7-20)	17 (6-20)	<.001	<.001	.834
Mobility	19 (4-36)	34 (18-40)	31 (6-40)	<.001	<.001	.459
Strength	7 (0-29)	9 (3-24)	7 (2-19)	.089	.630	<.001

Table II Constant scores from baseline to latest follow-up

TO, baseline; T1, short-term time point at a mean follow-up of 28.3 months; T2, mid-term time point at a mean follow-up of 100.8 months.

Radiographic outcomes

Mean postoperative retroversion was 8° (range, 3° -16°). A total of 30 shoulders had a GHSI within the threshold that is considered as centered; the 5 other shoulders were subluxed anteriorly. At the final follow-up, 11 (31%) shoulders were considered to be radiographically loose, with 7 shoulders demonstrating isolated radiographic loosening around the central peg, 3 shoulders demonstrating isolated radiographic loosening around the peripheral pegs, and 1 shoulder with gross radiographic loosening demonstrating a combined loosening of all pegs. In total, 29% of the shoulders had RLL \geq grade 2 around the central peg and 19% had RLL \geq grade 2 around the peripheral pegs (Tables III and IV). Of the 35 shoulders, 9 shoulders did not have any progressive RLL; yet, 74% (26 of 35) of the shoulders demonstrated progression of RLL, leading to a higher grading. A decrease in osseointegration of the central peg was noticed over time, with an osseointegration rate shifting from 81% at short-term to 71% at a mean follow-up of 8.4 years. Progression in RLL around the peripheral and central peg correlated significantly (P = .815, P < .001).

Adverse events

Overall, 4 of the 35 shoulders were revised after the index aTSA, leading to a survival rate of 88% at a mean followup of 8.4 years. All were converted to a reversed TSA after 2 years of follow-up. Two patients were revised because of symptomatic loosening, 1 patient underwent a revision because of a subscapular insufficiency, and 1 patient was revised and treated with antibiotics because of septic loosening secondary to a low-grade infection with *Cutibacterium acnes*.

Radiolucency vs. clinical outcome

When the variable loosening was dichotomized, no difference was found between the median CS of 67 (range, 40-87) of the no-loosening group (grades 0 and 1) and the median CS of 66 (range, 13-75) in the loosening group (grade 2 or more) (P = .787). A similar result was seen for MCS and PCS (P = .392 and P = .205, respectively).

Discussion

In the present follow-up study to a prior study reporting on the short-term results, clinical and radiographic outcomes after aTSA with an uncemented all-polyethylene pegged glenoid with a central bone-ingrowth peg are presented at a minimum 5-year follow-up. In this retrospective series of 35 shoulders, good clinical results were found with a mean improvement of 26 points in CS to the preoperative state and a survival rate of 88%. Radiographic evaluation demonstrated an osseointegration rate of 71% and a radiographic loosening rate of 31%. With a mean of 100 months, this study represents the longest follow-up after aTSA using this type of glenoid component implanted in an off-label uncemented technique in the current literature (Table I).

Short- to mid-term clinical studies have shown good to excellent clinical results after aTSA with an all-polyethylene pegged bone-ingrowth glenoid component reporting CS between 61 and 82 (Table I). With a mean CS of 66 and an associated improvement of the CS of 26 points from baseline to the latest follow-up, our clinical scores are consistent with the current literature on this type of glenoid component using a hybrid cementation technique, while exceeding the minimal clinically important difference of 12.8 for aTSA.²⁰

A detoriation in clinical outcomes over time is a known phenomenon in aTSA. Raiss et al¹⁷ reported in a longitudinal study of aTSA that the maximum CS score was reached at 2-year follow-up. Further follow-up demonstrated a plateau until 8 years after surgery, with a clear detoriation in CS afterward. In our study, we found a marginal trend in decreasing CS at a mean follow-up of 8.2 years. On the basis of our results, this drop in CS over time can be explained by a decrease in strength at later time points, whereas function and pain relief are maintained. Whether this decrease in strength is related to aTSA or is part of a natural aging process remains unclear.

With this type of glenoid component, osseointegration of the central peg is aimed for to provide long-lasting glenoid fixation. Yet, the osseointegration potential of the component has been debated. Whereas most clinical studies found an osseointegration rate of more than 70%,^{1,3,12,13,15,27,29} Groh⁸ and Nuttal et al¹⁴ described a

Score	Indicator	T1	T2
0	Lucency diameter <5	30	9
1	Lucency diameter 5-9 mm partial length in 1 or 2 pegs	2	20
2	Lucency diameter 5-9 mm complete length in 1 peg	0	3
3	Lucency diameter >9 mm partial length in 2 or more pegs	2	2
4	Lucency diameter >9 mm complete length in 2 or more pegs	0	0
5	Gross loosening	1	1

 Table III
 Radiographic grading system for peripheral pegs

T1: short-term time point at a mean follow-up of 28.3 months.

T2: mid-term time point at a mean follow-up of 100.8 months.

Table IV	Radiographic	grading	system	for the	central	pea

Score	Indicator	T1	T2
0	Lucency diameter <9	30	9
1	Lucency diameter 10-13 mm partial length	2	17
2	Lucency diameter 10-13 mm complete length	2	6
3	Lucency diameter >13 mm partial length	0	1
4	Lucency diameter >13 mm complete length	0	1
5	Gross loosening	0	1
T1. short-term time	point at a mean follow-up of 28.3 months		

T1: short-term time point at a mean follow-up of 28.3 months.

T2: mid-term time point at a mean follow-up of 100.8 months.

concerning osseointegration rate of 29% and 45%, respectively. Initial fixation of the glenoid component seems essential for the osseointegration potential of this glenoid type. Nuttal et al¹⁴ reported on a mode of failure seen for this type of glenoid component using a hybrid cementation technique due to early migration occurring within the first year postoperatively. Rotation of the glenoid component was associated with focal lucency and the absence of osseointegration at the central peg in 6 of 11 patients,¹⁴ and was reduced by 50% (3 of 11) when using a cannulated preparation system for the central peg.¹³ In a biomechanical study by Wiater et al,²⁶ the findings suggested that initial fixation was not significantly improved by cementing the peripheral pegs when compared with uncemented fixation. Fully cemented fixation, including cementation of the central peg, outperformed both hybrid and uncemented fixation, but would hinder osseointegration. In our prior short-term study, we have found signs of osseointegration in 81%, as evaluated on CT scan, suggesting that cementing the peripheral pegs is not essential to obtain bone ingrowth.³

To prove that osseointegration of the central peg leads to a biological, long-lasting fixation, follow-up studies at several time points are essential. The present study is the first to investigate the clinical and radiographic course of the index glenoid component at 2 time points over a midterm timeframe. Our results showed that over time progressive radiographic signs of loosening around the central peg can be observed. Even in cases with clear osseointegration of the central peg at an early time point, osteolytic zones with progressive RLL could be seen at latest follow-up (Fig. 2). This progression of RLL around the central peg was highly correlated with RLL around the peripheral pegs and led to a radiographic loosening rate of 31% at a mean follow-up of 100 months. On the basis of our results, only assumptions can be made. Potentially, this type of glenoid design might be subject to micromotion. Over time, this might lead to polyethylene deformation or polyethylene-related bone resorption leading to RLL. These results, however, emphasize that this type of glenoid component implanted in an uncemented technique does not overcome radiolucency progression, even if a good initial fixation with osseointegration of the central peg was obtained. The cause of this progression remains uncertain.

Although a survivorship rate of 88% lies within the range reported between 5 and 10 years of follow-up in longitudinal studies,^{17,21} our survivorship rate is rather low when compared with the current 5-year minimum follow-up literature on the same component, implanted using a hybrid cementation technique. Churchill et al³ reported a survivorship of 100% in 20 patients at a mean of 67 months (range, 60-76 months). Noyes et al¹² found a survivorship of 97% (1 revision because of aseptic loosening) in 42 patients at a mean follow-up of 80 months (range, 63-114 months). In our study, of the 4 revisions, 2 were glenoid component related demonstrating symptomatic loosening after the 5-year follow-up time point. Both demonstrated initial osseointegration around the central peg and

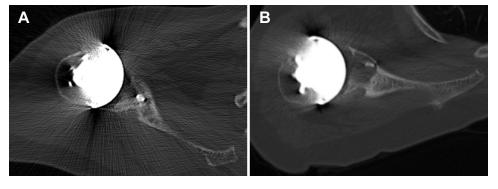


Figure 2 CT scan evaluation of a 69-year-old female patient assessed at a short- and mid-term time point after anatomic total shoulder arthroplasty of the right shoulder. At 24 months postoperatively, no signs of loosening and a well osseointegrated central peg are seen (**A**). Over time, the initial well-integrated central peg demonstrated radiographic signs of loosening with osteolytic areas and progressive radiolucencies around all pegs, as seen on CT scan at 94 months of follow-up (**B**). *CT*, computed tomography.

deteriorated over time toward a painful loosened glenoid component. These 2 cases further highlight the finding that an initial osseointegration of the central peg does not necessarily result in a long-lasting fixation of the glenoid component.

Although RLL play an important role in monitoring aTSA as they are part of almost all scoring systems to define loosening, the clinical importance of RLL is still unclear.^{10,24} Some authors found a clear association between RLL and clinical outcomes,^{23,30} others did not support these findings.^{11,17} In the present study, no difference in CS was found between the group with minor RLL grading and those having major RLL grading. However, both patients undergoing revision because of aseptic loosening were classified in the group presenting major RLL grading. This further stresses the discrepancy between clinical outcomes and radiolucency.

The present study is limited by the disadvantages associated with a retrospective study design and a relatively small study population. A hybrid cementation technique is recommended by the manufacturer of the glenoid component used in this study. Therefore, the uncemented fixation technique presented in this study should be considered as off-label use. The advantages of an uncemented technique could not be studied due to the retrospective study design and the absence of registering specific parameters that might give outcome on these specifically. Although CT scan evaluation is considered as more accurate to detect RLL,³⁰ the evaluation of radiographic parameter including GHSI and glenoid version is less accurate then more standardized imaging techniques such as 3-dimensional CT scans.9 Moreover, other signs of loosening including subsidence and glenoid component migration could not be assessed objectively because polyethylene is radiolucent and only 1 marker is incorporated by the manufacturer of the component. Lastly, the clinical scores have been assessed by several residents over time. Therefore, these clinical scores might be prone to some degree of interrater variability.

Conclusions

An uncemented off-label fixation technique of an allpolyethylene pegged glenoid with a central boneingrowth peg was associated with satisfactory clinical and radiographic scores, and an acceptable revision rate at mid- to long-term follow-up. Although early osseointegration could be obtained in the majority of cases, progressive radiolucency was noticed around the central and peripheral pegs at later follow-up. Therefore, initial bony fixation of the central peg does not necessarily lead to a long-lasting fixation of this glenoid component type when implanted in an off-label uncemented fashion and does not overcome radiographic loosening over time. Yet, radiographic loosening parameters were not associated with clinical scores, emphasizing the discrepancy between radiographic and clinical outcomes in aTSA.

Disclaimer

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