The Univers VaultLock® All-Polyethylene Glenoid Maintains High Survivability at 5-Year Follow-Up

INTRODUCTION

Total shoulder arthroplasty (TSA) is associated with good functional outcomes and reasonable survival in the majority of patients.[1,2] However, glenoid component loosening remains a common cause for failure.[3,4] Pegged all-polyethylene components have an estimated survival rate of 99% and 83% at 5 and 10 years, respectively.[5] However, radiographic loosening occurs in the majority of cases at long-term follow-up.[4,5]

One alternative to completely cemented components is a hybrid all-polyethylene component with cemented peripheral pegs and a central peg designed for osseous integration. Theoretically, this component allows central osseous integration which may decrease radiographic loosening. Several studies have supported the use of these components.[6-8] However, most studies have been case series reporting only on one type of implant or the other without comparison between completely cemented and hybrid fixation.

The purpose of this study was to evaluate 2- and 5-year radiographic and functional outcomes of TSAs performed with the VaultLock glenoid (Arthrex Inc., Naples, FL), a hybrid all-polyethylene glenoid designed for hybrid fixation with peripheral cement and central osseous integration.

MATERIALS AND METHODS

Study Cohort

A multi-center retrospective study was performed of TSAs enrolled in the ShARC prospective registry. The inclusion criteria included those undergoing primary TSA performed with the VaultLock glenoid, an intact rotator cuff, and radiographic analysis available at 2 and 5 years postoperatively. The exclusion criteria were revision arthroplasty, a Walch Type C glenoid, and incomplete follow-up.

Radiographic Evaluation

Two-year postoperative as well as 5-year postoperative anteroposterior and axillary plain radiographs were analyzed for glenoid loosening. The Lazarus et al. classification was used to evaluate for glenoid loosening using a 0 to 5 scale.[9] For purposes of analysis, “relevant” changes were considered a score of 2 or greater, and a “loose” component was defined as radiolucency grade 3 or greater.[10] All radiographs were independently assessed a single time by three orthopaedic surgeons, followed by a repeat analysis after 3 months to establish both inter-rater reliability (ICC) and intra-rater reliability. Based on the evaluation of the radiographs by 3 trained orthopaedic surgeons, as described above, there was excellent (ICC 0.80, 95% CI 0.65-0.94) and substantial agreement (ICC 0.68, 95% CI 0.50-0.86) of Lazarus scores at 2 and 5 years. Intra-rater reliability was excellent (ICC 0.87, 95% CI 0.75–0.93) for Lazarus scores at 2 years.

Patient Evaluation

Function and ROM were assessed preoperatively and postoperatively at 2 and 5 years. Function was determined with the Single Assessment Numeric Evaluation (SANE) score, American Shoulder and Elbow Surgeons (ASES) score, Constant score, WOOS, VR-12 physical function, and VAS pain score at each time point. The VR-12 mental health score was also obtained. Range of motion was assessed at each site using a goniometer to determine forward flexion, external rotation with the arm at the side, and internal and external rotation with the arm at 90° of abduction.

Statistical Analysis

Continuous data was described by mean and standard deviations. Categorical data was presented as a number and percentage. Comparisons of continuous data were made with a Student’s t-test. Comparisons of categorical variables were performed with Chi-squared tests or

Fisher's exact tests for patients with expected frequency <5. Pairwise comparisons between baseline, 2-year, and 5-year outcomes were also analyzed. Paired t-tests were used for normally distributed data and Wilcoxon signed-rank tests were used for non-normally distributed data. Normality was evaluated with Shapiro-Wilk test prior to pairwise comparisons. Multiple comparisons were adjusted using the Bonferroni Correction. Minimal clinically important difference (MCID) was set at 21 for ASES score and 1.4 for VAS following total shoulder arthroplasty.[11]

Results

A total of 133 TSAs met the study criteria. Thirteen patients (9.8%) had repeat surgery prior to 5-year follow-up and were therefore excluded from analysis. Among the 13 repeat surgeries, 7 were minor (eg, capsular release) and 6 patients underwent revision shoulder arthroplasty (3 for subscapularis failure, 1 for humeral loosening, 1 for periprosthetic fracture, and 1 for glenoid loosening). Patient demographics of the 120 patients available for analysis are summarized in Table 1.

Table 1: Baseline Patient Characteristics

	VaultLock® (n = 120)
Age at surgery (years), mean (SD)	63.9 (7.8)
Body mass index (BMI), mean (SD)	30.1 (5.0)
Gender (male), n (%)	80 (67.2)
Smoker, n (%)	4 (3.3)
Diabetic, n (%)	11 (9.2)
Workers' compensation case, n (%)	3 (2.5)
Laterality (right), n (%)	67 (55.8)
Dominant arm, n (%)	60 (50.0)

Table 2: Baseline vs 5-Year PRO/Functional Outcome

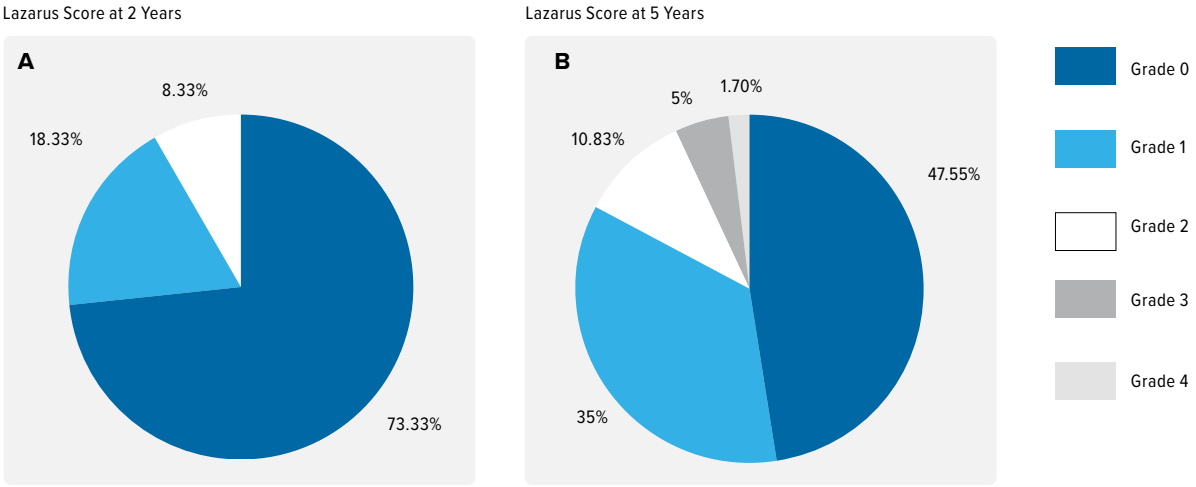
	Baseline	5 Years	P-Value
ASES mean (SD)	41.5 (16.0)	86.1 (17.4)	<0.001
ASES MCID at 5 yrs, n (%)		115 (86.5)	
VAS mean (SD)	6.0 (2.2)	1.3 (2.1)	<0.001
VAS achieve MCID at 5 yrs, n (%)		116 (87.2)	
WOOS – Total, mean (SD)	37.9 (19.5)	86.9 (17.8)	<0.001
SANE mean (SD)	33.3 (22.9)	79.3 (25.5)	<0.001
VR-12 physical, mean (SD)	36.2 (7.0)	47.7 (8.1)	<0.001
VR-12 mental, mean (SD)	51.9 (11.6)	56.0 (7.3)	<0.001
Total constant score, mean (SD)	44.8 (10.9)	59.3 (10.2)	<0.001
ROM – Active forward elevation, mean (SD)	112 (29)	146 (18)	<0.001
ROM – Active ER at side, mean (SD)	29 (19)	51 (15)	<0.001
ROM – Active ER at 90°, mean (SD)	34 (27)	74 (19)	<0.001
ROM – Internal rotation constant score, mean (SD)	3.7 (2.6)	6.7 (1.9)	<0.001
Constant strength in lbs, mean (SD)	22.2 (21.2)	42.5 (19.9)	<0.001
External rotation strength in lbs, mean (SD)	10.1 (4.2)	13.9 (7.0)	<0.001
Subscapularis strength in lbs, mean (SD)	10.8 (4.7)	16.2 (8.6)	<0.001

Radiographic findings are presented in Figure 1. At 2 years postoperatively, 92% of glenoids had grade 0 or 1 radiolucencies, and 8.3% had grade 2 radiolucencies. No glenoids were observed to have grade 3 changes consistent with radiographic loosening. At 5 years postoperatively, 83% of glenoids had grade 0 or 1 radiolucencies, 10.8% had grade 2 radiolucencies, and 6.7% had grade 3 or greater radiolucencies consistent with radiographic loosening. Progression of radiographic lucency by grade is presented in Table 3. Sixty-four percent of patients had no progression in Lazarus grade between 2 and 5 years postoperative. Only 7.5% of patients progressed by 2 Lazarus grades between short- and mid-term follow-up.

Table 3: Lazarus score progression between 2 and 5 years postoperatively

Score Progression: 2 vs 5 Years	Frequency	Percent
0	77	64.2
1	34	28.3
2	9	7.5
Total	120	100.00

Figure 1: Radiographic Evaluation of Glenoid Loosening A) Lazarus Score at 2-year Follow-up B) Lazarus Score at 5-Year Follow-Up



Glenoid implant survival was 99.2% at 5 years postoperatively (1 of 133 revised for glenoid loosening). Including the patient revised for glenoid loosening, radiographic survival free of loosening was 92.6% (9 of 121 with radiographic loosening) at 5 years postoperatively.

CONCLUSION

The VaultLock glenoid has a 99% survival free from revision for loosening at 5-year follow-up as well as a 92.6% rate of radiographic survival at 5 years postoperatively. The findings are consistent with or superior to prior published reports of all-polyethylene glenoids.

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