

Two-Year Follow-up of Additive Manufactured, Fully 3D Printed Humeral Prosthesis

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INTRODUCTION:

A fully 3D printed prosthetic may offer numerous potential advantages including improved pore precision, overall porosity, topology optimization, spatial variability in stiffness, communication between pores, and strut size. However, there are numerous theoretical concerns surrounding inferior mechanical performance with fully 3D printed implants (e.g. potentially higher rates of fatigue, increased *in vivo* particle release, etc.) compared to conventionally fabricated ones.

We are aware of no reports on the clinical performance of fully 3D printed, off-the-shelf, humeral prostheses. To validate fully 3D printed humeral designs, the purpose of this study was to provide minimum 2-year postoperative clinical outcomes and survivorship of this novel 3D printed humeral prosthesis.

METHODS:

This is a case series of 26 prospectively followed patients who underwent anatomic total shoulder arthroplasty (TSA) with a fully 3D printed humeral prosthesis and a minimum postoperative follow-up of two years. Patient demographic information (**Table 1**) and preoperative and postoperative patient reported outcome measures (PROMs) were collected. Preoperative and postoperative X-rays were examined. Postoperative radiolucent lines, stress shielding, and osteolysis were identified by three independent reviewers. The primary outcome was TSA survivorship. Secondary outcomes were PROM scores and the presence of radiolucent lines at 2-year follow-up. Data are presented as frequencies (percentage) and mean \pm standard deviation with univariate significance testing results.

RESULTS:

At a minimum follow-up of 2 years, there were no revisions or reoperations with a prosthetic survivorship of 100%. At final follow-up, patients had significant increases in American Shoulder and Elbow Surgeons (ASES) and Visual Analogue Scale (VAS) scores (**Table 2**). The mean Single AlphaNumeric Evaluation (SANE) score at two years was 91 \pm 10. No osteolysis or stress shielding were identified on imaging review. The rate of any peri-prosthetic radiolucent line on XR was 4 of 26 (15%). All identified radiolucent lines were <0.5 mm. The most common location of radiolucent lines was at the greater tuberosity. There were no prosthetics with radiolucent lines in the medial calcar and medial meta-diaphyseal zones.

DISCUSSION AND CONCLUSION:

The results of early clinical follow-up of a fully 3D printed off-the-shelf humeral prosthetic are encouraging. Postoperative radiolucent lines appear to be minimal in thickness, infrequent, and likely clinical insignificant given 100% survivorship and reassuring PROM scores. Furthermore, when radiolucent lines appeared, it was only at the lateral, tension side of the humeral component. Further clinical follow-up of this and other 3D printed systems is necessary to confirm that additive manufacturing is a mechanically durable and viable method for standard TSA manufacture.

Table 1. Patient Demographics and Preoperative Variables.

Variable	Value [†]
Male Sex	13 (50%)
Age (years)	67 \pm 7
Body Mass Index (kg/m ²)	31.5 \pm 6
Diabetes	5 (19%)
Charlson Comorbidity Index	2.7 \pm 0.8
Preoperative Indication	
Osteoarthritis	25 (96%)
Inflammatory Arthritis	1 (4%)

[†] Continuous variables presented as mean \pm standard deviation, categorical variables presented as frequency (percentage).

Table 2. Two-Year Patient Outcomes.

Variable	Preoperative Value [†]	Postoperative Value [†]	Change [†]	p
Revision of Components		0 (0%)		
Reoperation		0 (0%)		
Patient Reported Outcome Measures				
ASES	37 \pm 16	93 \pm 8	57 \pm 19	$<0.001^*$
VAS (mm)	7 \pm 1	0.6 \pm 0.9	7 \pm 1	$<0.001^*$
Humeral radiolucent lines frequency by region [‡]				
Collar		1 of 26		
Medial calcar		0 of 26		
Medial metadiaphyseal		0 of 8		
Greater tuberosity		3 of 26		
Lateral metadiaphyseal		2 of 8		

[†] Continuous variables presented as mean \pm standard deviation, categorical variables presented as frequency (percentage).

[‡] Stemless components do not reach the metadiaphyseal region, therefore the percentages for these regions are calculated only considering stemmed components.

^α All radiolucent lines were <0.5 mm in thickness.