

RESEARCH ARTICLE

Short-Term Results of a Convertible Diaphyseal-fit Anatomic Shoulder Arthroplasty System

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Abstract

Objectives: The purpose of this analysis is to present a two-year follow-up of patient-reported outcomes, revision rate, and notable radiographic features of a convertible, diaphyseal-fit anatomic total shoulder arthroplasty system (ATSA).

Methods: From June 2012 to June 2015, 100 shoulders were treated with ATSA using a convertible, diaphyseal-fit stem. Functional outcomes and radiographic findings were assessed preoperatively and at 6 months, 1 year, and 2 years postoperatively. Complications and reoperations were also determined.

Results: Ninety-three shoulders were analyzed in this study. Patients were 47.3% male and had an average age of 67.3±8.1-years-old (range 44.7-89.1). Two-year clinical outcomes show a revision rate of 4.3%. Average pre-operative ASES was 37.1±18.9 (6.7-86.7), SST (77.4%) was 3.1±2.4 yes responses (0-9), and SANE (88.2) was 25.4±21.5% (0-85.0%). At two years post-operative average (75% follow-up) ASES was 89.3±15.1 (37.0-100), SST was 10.0±2.5 yes responses (0-12), and SANE was 85.6%±17.0% (33.0-100%). Radiographic analysis at two years identified 2 shoulders (4%) with glenoid radiolucency (both Lazarus grade 1), 5 shoulders with at least one humeral radiolucent line (10%), and 9 shoulders (18%) with stress-shielding. There were 12 shoulders (24%) with distal pedestal formation. This finding was associated with the presence of radiolucent lines ($P=0.002$).

Conclusion: This two-year analysis identified improvement in ASES, SST, and SANE scores and a low revision rate. Presence of a distal pedestal was associated with increased rates of radiolucent lines. Further analysis with longer-term and more robust follow-up will improve our understanding of the risks and benefits of this shoulder system.

Level of evidence: II

Keywords: Anatomic total shoulder arthroplasty, Implant surveillance, Patient-reported outcomes, Revision shoulder arthroplasty, Total shoulder arthroplasty

Introduction

The utilization of total shoulder arthroplasty is increasing.^{1,2} Anatomic total shoulder arthroplasty has a track record of success with 85% survivorship at 20 years.³ Following a number of analyses demonstrating the superiority of anatomic total shoulder arthroplasty over hemiarthroplasty, anatomic total shoulder arthroplasty has become the

mainstay of treatment for the majority of patients with end-stage primary osteoarthritis that have an intact rotator cuff and have failed non-operative management.⁴⁻⁷ While utilization of reverse shoulder arthroplasty is increasing in frequency, anatomic shoulder arthroplasty remains the gold standard for end-stage primary osteoarthritis with no significant

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bony deformity and an intact rotator cuff. Traditionally, humeral stems were designed for cement fixation or uncemented, metaphyseal fixation.

The Titan Shoulder System (Integra LifeSciences, Austin, TX) has a diaphyseal fitting, smooth-finished humeral stem, a porous coated proximal body in the metaphysis, and a humeral head with varying radii of curvature for equivalent base diameters. The modularity of the proximal body allows for the conversion of an anatomic to reverse shoulder arthroplasty. The feature of modularity to allow for conversion to a reverse shoulder arthroplasty may be of increasing importance as the incidence of revision shoulder arthroplasty continues to increase.⁸⁻¹¹ Systems without modularity require extraction of the humeral stem at the time of revision surgery from an anatomic to reverse shoulder arthroplasty. Humeral stem extraction can increase the morbidity of the revision surgery with higher rates of humeral fracture and nerve injury.¹²⁻¹⁵ Successful revision with a convertible implant has been found to decrease intra-operative morbidity in revision shoulder arthroplasty.¹⁶⁻¹⁸ The diaphyseal fitting humeral stem may also be beneficial as lesser tuberosity osteotomy becomes more prevalent for subscapularis management as this implant does not rely on the bone of the metaphysis.¹⁹⁻²¹ The metaphyseal fixation utilized in some shoulder systems may be compromised with a larger osteotomy site.

The purpose of this study was to evaluate the short-term outcomes of the Titan Shoulder System. We analyzed patient-reported outcomes, revision rates, and radiographic results over two years.

Materials and Methods

Patient Population

Following Institutional Review Board approval, 100 patients were prospectively enrolled between June 2012 and June 2015 to undergo primary anatomic total shoulder arthroplasty with the Integra Titan Total Shoulder System. Patients were excluded if they had an emotional or neurological condition that would pre-empt their ability or willingness to participate in the study such as mental illness, or drug or alcohol abuse. Patients were enrolled at the pre-operative clinic visit before surgery. They were excluded from analysis if full operative details were not available, if a different system were utilized at the time of surgery (for example, if an intra-operative decision were made to utilize an augmented component), or if an anatomic total shoulder arthroplasty was not performed (for example, if the patient only underwent a hemiarthroplasty). Demographics of age, gender, body mass index (BMI), diagnosis, and concurrent procedures were recorded.

Surgical Technique

All surgical cases were performed through a standard deltopectoral approach by two fellowship-trained shoulder surgeons. A lesser-tuberosity osteotomy was utilized in all exposures. The Titan Shoulder System was utilized with an all-polyethylene, cemented, pegged

component in all cases. Intraoperative decision-making about the size and exact configuration of the components was performed by the treating surgeon.

Clinical and Radiographic Outcomes

The patient-reported outcomes measured in this study were American Shoulder and Elbow Surgeons (ASES) Score, the Simple Shoulder Test (SST), and Single Assessment Numerical Evaluation (SANE). These scores were recorded pre-operatively and at six months, one year, and two years postoperatively.^{22,23,24} Intraoperative and postoperative complications were recorded. Additionally, all-cause revision shoulder arthroplasty was recorded along with time to revision and diagnosis at the time of revision. Patients that required revision shoulder arthroplasty did not have patient-reported outcomes analyzed.

Radiographic Outcomes

Post-operative radiographs at two-year follow-up were reviewed for each patient. Four radiographic measures were reviewed: Lazarus grade of glenoid radiolucency, presence of humeral component radiolucent lines, presence of distal pedestal formation, and presence of humeral stress-shielding.^{25,26,27} The association of distal pedestal formation with the presence of humeral radiolucent lines and the presence of stress shielding was analyzed.

Statistical Analysis

Descriptive statistics were calculated for patient-reported and radiographic outcomes. The presence of distal pedestal formation was assessed for association with both humeral radiolucency and stress-shielding by chi-square analysis. All statistics were calculated with Microsoft Excel (2013; Redmond, WA).

Results

Patient Population

There were 100 patients prospectively enrolled in the study. Seven patients were excluded from the analysis (four required an augmented component by a different manufacturer at the time of surgery, one underwent a hemiarthroplasty and open rotator cuff repair, and two had incomplete implant records). Of the 93 remaining patients, 44 (47.3%) were male, the average age at the time of surgery was 67.3±8.1-years-old (44.7-89.1), and the average body mass index (BMI) was 31.4±7.1 (18.8-49.0). Eighty-nine of 93 patients (95.7%) had primary osteoarthritis, two (2.2%) had avascular necrosis, one (1.1%) had rheumatoid arthritis, and one (1.1%) had post-traumatic arthritis (open reduction, internal fixation of glenoid fracture). Five of 93 patients (5.4%) underwent a concurrent procedure: two supraspinatus repairs, one hardware removal (single screw from the glenoid), one enchondroma biopsy, and one bone grafting of a cyst of the greater tuberosity. There were no intra-operative complications. There were 6 (6.5%) post-operative complications. There was one periprosthetic joint infection, two subscapularis failures (one underwent a primary repair at 0.89 years and one underwent a

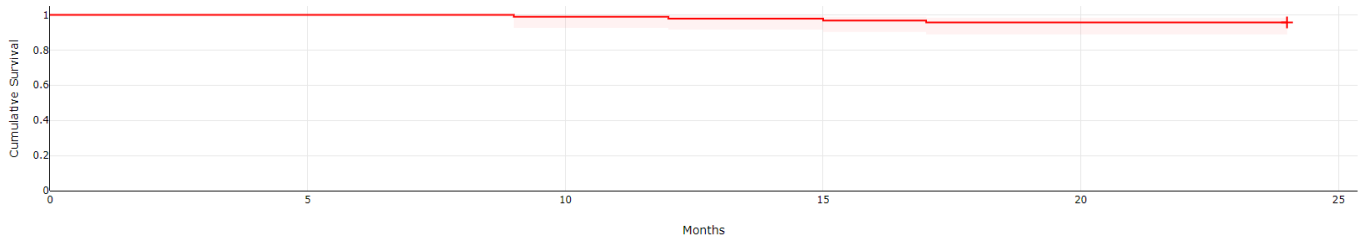


Figure 1. Kaplan-Meier survival curve for free revision-free survivorship.

revision to a reverse shoulder arthroplasty at 1.02 years), two posterior-superior rotator cuff failures, and one patient admitted to the hospital within the first two weeks post-operatively for *Escherichia coli* bacteremia (without surgical site infection). All four patients who underwent revision surgery had primary osteoarthritis as the diagnosis without prior surgeries indicated in the medical record.

Revision Arthroplasty

Four patients required revision arthroplasty (4.3%) at an average of 1.25 ± 0.21 years (1.02-1.44) for two-year survivorship of 95.7%. One patient was diagnosed with periprosthetic joint infection and underwent an explanation with antibiotic spacer placement at 1.3 years postoperatively. One patient was diagnosed with subscapularis failure and was converted to a reverse total shoulder arthroplasty at 1.0 years postoperatively. Two patients were diagnosed with posterior-superior rotator cuff failure and converted to a reverse total shoulder arthroplasty at 0.8 and 1.4 years postoperatively. Neither of the patients who underwent revision for rotator cuff failure had concomitant rotator cuff repair. Kaplan-Meier analysis was performed and demonstrated in Figure 1.

Clinical Outcomes

Pre-operatively, the average ASES score (100% of patients had this recorded) was 37.1 ± 18.9 (6.7-86.7), the

average SST (77.8%) was 3.1 ± 2.4 yes responses (0-9), and average SANE (88.2%) was 25.4 ± 21.5 (0-85.0). At two years post-operative average (75% follow-up) ASES was 89.3 ± 15.1 (37.0-100), SST was 10.0 ± 2.5 yes responses (0-12), and SANE was $85.6 \pm 17.0\%$ (33.0-100%). The average difference from pre-operative patient-reported outcome scores to two-year post-operative scores was calculated. For ASES scores the average difference was an improvement of 49.5 ± 22.0 (-5.9-88.0). For SST scores, the average difference was an improvement of 6.7 ± 2.9 yes responses (0-12). Finally, for the SANE score, the average difference was an improvement of 58.6 ± 28.6 (-14.4 - 100)

Radiographic Outcomes

There were 50/89 patients (56.2%) that did not go on to revision surgery with radiographs at a two-year follow-up. Two patients (4%) had radiographic evidence of glenoid radiolucent lines (both Lazarus grade 1) [Figure 1]. Five shoulders (10%) had humeral radiolucent lines, all of which were less than 2mm in thickness. The patients that had radiolucent lines had an average of 3 zones of radiolucency (3 zone 1, 2 zone 2, 1 zone 3, 4 zone 4, 1 zone 5, 1 zone 6, 2 zone 7, and 1 zone 8) [Figure 2]. Nine shoulders (18%) had radiographic evidence of humeral stress shielding [Figure 3]. Twelve shoulders (24%) had the formation of a distal pedestal at the humeral stem [Figure 4]. Chi-square analysis found



A



B

Figure 2A and 2B: A) Two-week and B) Two-year postoperative radiographs of a patient with Lazarus grade 1 glenoid loosening

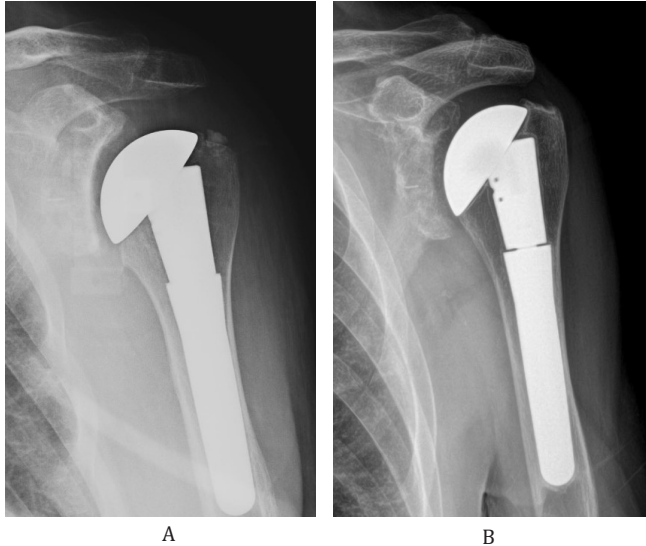


Figure 3A and 3B. A) Two-week and B) Two-year postoperative radiographs of a patient with four zones of radiolucent lines (zones 1, 4, 7, and 8).

distal pedestal formation to be significantly associated with an increased rate of humeral radiolucent lines (33.3% incidence in shoulders with a distal pedestal compared to 2.6% incidence in shoulders without a distal pedestal, $\chi^2=9.552$, $P=0.002$). Patient-reported outcomes of those with humeral radiolucent lines or stress-shielding were compared to those without these findings were compared by a two-sample t-test assuming unequal variances. There was no significant difference in ASES scores (90.0 ± 8.9 in shoulders with radiolucent lines or stress shielding versus 90.1 ± 14.8 in shoulders without, $t=0.045$, $P=0.965$), SST scores (10.7 ± 1.4 versus 9.9 ± 2.4 , $t=1.327$, $P=0.201$), or SANE scores ($88.0\%\pm 10.5\%$ versus $84.6\%\pm 15.4\%$, $t=0.745$, $P=0.467$).

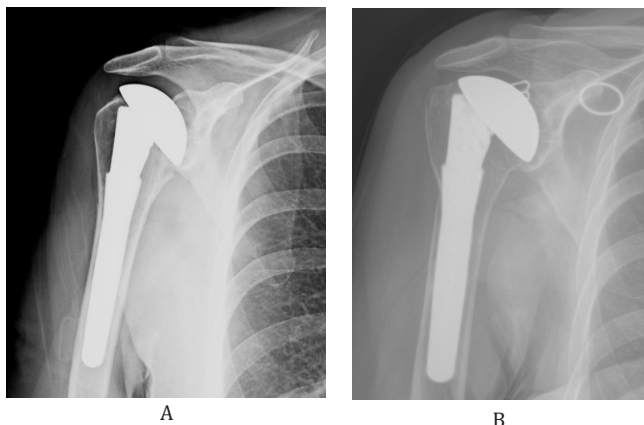


Figure 4A and 4B. A) Two-week and B) Two-year postoperative radiographs of a patient with three zones of humeral loosening.

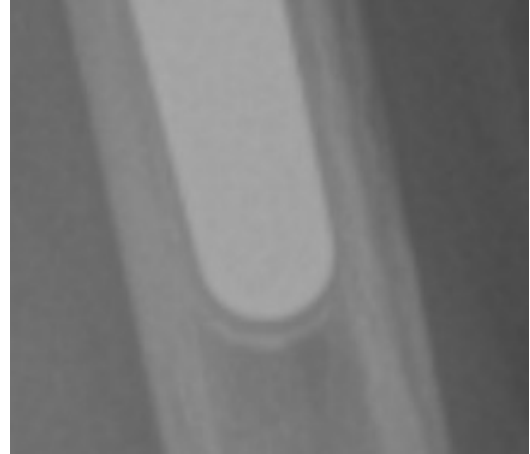


Figure 5. Distal pedestal formation of the humeral stem.

Discussion

This analysis of short-term outcomes of a convertible, diaphyseal-fit anatomic shoulder arthroplasty system identified high survivorship at 2 years and improvement in functional outcomes. Stress-shielding and pedestal formation did not appear to correlate with the functional outcome or implant survivorship at early follow-up.

The survivorship of 95.7% at two years is comparable to historical revision rates for anatomic total shoulder arthroplasty. Revision rates in anatomic total shoulder arthroplasty range from 2 to 20% at mid-term follow-up.^{6,28-31} None of the revisions in this study were considered to be implant-related. There was no catastrophic implant failure and no revision for aseptic component loosening. Regarding patient-reported outcomes, the average ASES score improved by fifty points and the average SST score improved by nearly seven yes responses from pre-operatively to two-year follow-up. This is similar to the degree of improvement in ASES and SST scores demonstrated by both Simovitch et al (using a wide range of shoulder arthroplasty systems) and Flurin et al (using a single, modular, metaphyseal fitting, uncemented humeral implant with mostly keeled glenoids).³²⁻³³

The radiographic analysis identified a glenoid radiolucency rate of 4%. Both of these patients had grade 1 radiolucency. This is lower than the previously described rates of 6.8% to 9.4% for pegged glenoids.³⁴⁻³⁵ This analysis identified humeral radiolucent lines in 10% of shoulders and stress-shielding in 18%. Additionally, pedestal formation was associated with identified in 24% of patients. While the clinical implications of pedestal formation have not been described in the shoulder, it has been associated with prosthesis instability when identified at the tip of the femoral component in hip arthroplasty.^{36,37} The significant association identified in this study between pedestal formation and prosthetic loosening is suggestive that this relationship may hold true in the humeral component of the shoulder as well.

The findings of this analysis must be interpreted in

the context of the limitations. These results are only two-year follow-ups, longer-term follow-up would be ideal to determine any future issues with this implant system. Additionally, with the limited population size, it is possible that this study is underpowered to truly identify the effect of distal pedestal formation on both humeral loosening and stress shielding. Additionally, one of the limitations is that the average patient had an elevated BMI, recent analysis has suggested that this variable may negatively impact clinical outcomes, but it is unclear what effect this had on our cohort. The strengths of this study are that it is one system and patients were followed longitudinally. Just over 75% of patients had two-year follow-ups. Post-operative rehabilitative and radiographic protocols were also the same for all patients. Despite these limitations, we were able to demonstrate that at two years, anatomic total shoulder arthroplasty with the Integra Titan Shoulder System showed improvement in reported patient-reported outcomes with a low revision rate and low

rates of radiographic signs of loosening.

This two-year analysis of the convertible, diaphyseal-fit anatomic shoulder arthroplasty system demonstrated improvement in ASES, SST, and SANE scores at year two-year follow-ups and a low revision rate. Further analysis will be needed to determine the impact of early humeral stress-shielding and pedestal formation on mid and long-term results.

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