Title: The Midterm Results of the Delta Xtend Reverse Shoulder System: A Five-Year Outcome Study

Running Title: Five Year Results of Reverse Shoulder

Key Words: reverse shoulder arthroplasty; shoulder replacement; outcomes study; range of motion; long term outcome

Source of Funding: Depuy Synthes (J&J Company, Warsaw, USA) provided funding for this study

ABSTRACT

Object: The purpose of this study was to examine the mid-term functional outcomes, radiographic results, and revision rates of patients treated with the Delta Xtend Reverse Shoulder System for both primary and revision arthroplasty indications.

Methods: A retrospective review was conducted of records for all individuals who underwent a reverse shoulder arthroplasty using the Delta Xtend Reverse Shoulder Prosthesis at a single institution. Radiographic analysis as well as pain and functional measures using the ASES, Quick DASH, SST, SF-12, Penn, SANE, EQ-5D and VAS, and VR-12 scores. Patients were evaluated for five-year outcomes.

Results: Fifty patients were available for 5-year outcomes. Thirty-three cases were primary arthroplasty cases and 17 were revision arthroplasty cases. Postoperative radiographs at five years out from surgery were available for 46 patients. The mean AGT overall was 32.6mm: 31.7mm the primary cases and 34.8mm for revision cases. Sirveaux scapular notching was: 65.2% (30/46) at Grade 0, 23.9% (11/46) at Grade 1, and 10.9% (5/46) at Grade 2. Overall, 32/46 of stems were in neutral position, 10/46 were in valgus position, and 4/46 were in varus position. There was no significant correlation between stem position and scapular notching. The mean outcome scores for all patients at five years were good to excellent. Two revision patients demonstrated loosening of the humeral stem on radiographs. Nine patients demonstrated calcification of the long head of the triceps tendon.

Conclusions: In conclusion, the Delta Xtend Reverse Shoulder System has shown to be a reliable arthroplasty system for patients with CTA or failed prior arthroplasty. Patients are generally quite functional at five years out from their reverse shoulder arthroplasty using this

implant. Radiographic measures used to interpret the status of the implant demonstrate that AGT is well maintained and scapular notching is minimal for the majority of cases.

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Introduction

Cuff tear arthropathy (CTA) was originally described by Neer in 1983 as a condition in which a patient suffered from both a significant rotator cuff tear with subsequent arthritic changes in the glenohumeral joint [1,2]. For years, patients with this condition were a difficult population to treat. The benefits seen with anatomic total shoulder replacement are predicated on a well-functioning rotator cuff which allows for proper biomechanics of the humeral head with the glenoid surface. For patients who do not have an intact rotator cuff, this ability is lost. In the 1970s, many surgeons believed that a constrained prosthesis was the solution to this problem, allowing the overlying deltoid muscle to provide the sole moment arm for glenohumeral motion. These constrained designs underwent multiple incarnations in both the anatomic and inverted orientation, but often failed with high rates of component loosening.

In 1985, Paul Grammont developed the first semi-constrained reverse arthroplasty that overcame some of the biomechanical difficulties seen with CTA [2,3]. The Delta I was the first prosthesis by Grammont which took the concept of an inverted design and combined it with a distal and medial glenohumeral center of rotation to help increase the moment arm of the deltoid muscle. This revolutionary design transformed the shear forces that were responsible for glenoid loosening and converted them to compressive forces to stabilize the center of rotation. Grammont et al. first reported on eight rotator cuff deficient patients treated with this prosthesis and found that three of the patients achieved 100 to 130 degrees of forward elevation at 6 months [2,3]. Although some of these implants were later observed to go onto loosening, the design allowed for the evolution to the modern Delta reverse total shoulder system.

The Delta Xtend Reverse Shoulder System (Depuy Synthes, J&J Company, Warsaw, USA) is just the latest implant design in this lineage. The humeral component consists of a cementless

modular titanium hydroxyapatite (HA)-coated or Monobloc cobalt-chromium (Co-Cr) cemented stem. The humeral articulation offers various polyethylene (PE) cup thicknesses. This is combined with a glenoid baseplate component secured with the use of a central peg available in three sizes along with two variable angle locking and two compression screws. The metaglene is smaller with a curved back to help with bone preservation and placed at the inferior margin of the glenoid in an effort to reduce scapular notching. Most importantly, the center of rotation (COR) is positioned on the glenoid bone surface for increase resistance to shear forces commonly attributed to loosening.

The goal of this study was to examine the mid-term functional outcomes, radiographic results, and revision rates of patients treated with the Delta Xtend Reverse Shoulder System. Both primary and revision arthroplasty patients were followed at a minimum of 5 years out from their surgery.

Materials and Methods

This was a retrospective, single institution study. After obtaining Institutional Review Board approval, patients who underwent reverse total shoulder surgery utilizing the Delta Xtend Reverse Shoulder Prosthesis were identified through retrospective chart review from January 2008 to December 2011. Subjects who underwent primary or revision reverse total shoulder arthroplasty during this time were contacted and asked to be seen for a 5-year postoperative visit. All surgeries were performed at a single institution by a single surgeon who performs a high-volume shoulder arthroplasty practice. Postoperative rehabilitation included sling immobilization for 2 weeks followed by the initiation of PROM exercises at 2-4 weeks, AROM exercises at 4-8 weeks and incorporation of strengthening from weeks 12-20. The primary objective of this study was to determine survivorship during this time period which was evaluated by the removal or intended removal of the device. Radiographic analysis as well as pain and functional performance measures using the American Shoulder and Elbow Surgeons (ASES) Assessment and the Single Assessment Numerical Evaluation (SANE) were also performed.

198 patients were identified as having undergone a reverse total shoulder arthroplasty with the Delta Xtend Reverse Shoulder System (DePuy Synthes, J&J Company). All patients were contacted at a time period five years postoperatively and asked to complete a questionnaire examining various outcomes measures including: American Shoulder Elbow Score (ASES), Quick DASH score, Simple Shoulder Test (SST) score, SF-12 Mental and Physical scores, Penn Pain, Function, and Satisfaction scores, Single Assessment Numeric Evaluation (SANE) score, EQ-5D and EQ-VAS scores, and VR-12 Mental and Physical scores. Utilizing the AP external view, subjects were evaluated for acromion-greater tuberosity (AGT) distance, the presence of

scapular notching using Sirveaux's classification, and humeral stem position in the coronal plane.

Demographic and surgical information was collected for analysis of contributing factors including age, sex, operative side, height, weight, body mass index (BMI), operative time, preoperative Favard, Hamada, and Sirveaux grades, surgical approach, size of implants (humeral stem and glenosphere), and whether the procedure was a primary or revision surgery.

Results

Demographics

Fifty patients of the original 198 were available for follow up at least five years postoperatively (Table 1). There were 37 females (74%) and 13 males (26%). The average age of the patients at the time of surgery was 71.52 years (range: 51.02 to 84.87) and at follow up was 78.48 years (range: 56.88 to 93.66). The average weight was 175.5 pounds (range: 112 to 340). The average height was 64 inches (range, 54.5 to 74). The average BMI was 30.1 (range: 19.2 to 47.3). The surgery was performed on the right side in 31 patients (62%) and on the left side in 19 patients (38%). Thirty-three (66%) of the cases were done as a primary arthroplasty while 17 (34%) were performed in a revision arthroplasty setting. The deltopectoral approach was used in 26 patients (52%) while the superior approach was used in 24 patients (48%). The average operative time was 130.8 minutes (range: 68 to 360).

Primary Cases

The average age of the thirty-three primary cases at the time of surgery was 72.8 years with an average of 79.8 years at follow-up. Twenty-six (78.8%) of the cases were performed in females while only seven (21.2%) were performed in males. The average weight was 174.6 pounds. The average height was 63.8 inches. The average BMI was 30.1. The surgery was performed on the right side in 21 (63.6%) patients and on the left side in 12 (36.4%) patients.

Preoperative radiographs were available for 75.8% (25/33) of the patients evaluated at five years of follow-up (Figure 1 and 2). The mean preoperative AGT distance measured at 4.9 mm (range, 0 to 17.6). The preoperative Favard classification for primary cases were: 17 Favard Group A, 7 Favard Group B, and 1 Favard Group C. The preoperative Hamada classification for primary

cases was: 2 at Grade 1, 5 at Grade 2, 7 at Grade 3, 10 at Grade 4, and 1 at Grade 5. The preoperative Sirveaux classification for primary cases was: 2 at E0, 13 at E1, 6 at E2, and 4 at E3.

The average operative time for all primary cases evaluated was 117.2 minutes. The deltopectoral approach was used in 14 (42.4%) patients and the superior approach was used in 19 (57.6%) patients. A size 38 glenosphere was used in 78.8% (26/33) of cases. A size 42 glenosphere was used in 21.2% (7/33) of cases. Standard humeral stem sizes were used in thirty-two of the primary cases: six stems at size 8 standard, seventeen at size 10 standard, seven at size 12 standard, and two at size 14 standard. One case used an 8 long stem.

Revision Cases

The average age of the seventeen revision cases at the time of surgery was 69 years with an average of 75.9 years at follow-up. Eleven (64.7%) of the cases were performed in females while six (35.5%) were performed in males. The average weight was 177.3 pounds. The average height was 64.3 inches. The average BMI was 30. The surgery was performed on the right side in 10 (58.8%) patients and on the left side in 7 (41.2%) patients.

Preoperative radiographs were available for 52.9% (9/17) of the patients evaluated at five years of follow-up. Many of the preoperative radiographic measures used for the primary cases were unable to be evaluated in the revision cases due to the nature of cases being revisions of prior arthroplasties. Only four cases could be evaluated using the Favard and Hamada classification. The preoperative Favard classification for those cases were: 2 Favard Group A and 2 Favard group C. The preoperative Hamada classification for those cases were: 2 at Grade 2 and 2 at

Grade 5. The preoperative Sirveaux classification for the nine cases with appropriate radiographs was: 1 at E0, 1 at E1, 4 at E2, and 3 at E3.

The average operative time for all revision cases evaluated was 160.7 minutes. The deltopectoral approach was used in 12 (70.6%) cases while the superior approach was used in 5 (29.4%) cases. A size 38 glenosphere was used in 82.4% (14/17) of revision cases. A size 42 glenosphere was used in 17.6% (3/17) of revision cases. Standard humeral stem sizes used in six of the revision cases: four stems at size 8 standard and two stems at size 10 standard. The remaining stems used were all long: nine stems at size 8 long, one stem at size 10 long, and one stem at size 12 long.

Five Year Follow-Up Outcomes

The available five-year outcome data for the fifty patients varied significantly. Due to constraints in patient willingness to participate in five-year follow-up and the logistics of being evaluated, some outcome scores were unavailable for patients. Table 2 demonstrated the mean outcomes scores for the patients available at five years after their surgery. The "n" is noted for each outcome measure as certain measures were able to be evaluated in more patients than others.

Postoperative radiographs at five years out from surgery were available for 92% (46/50) patients (Figure 3 and 4). Of those patients without five-year postoperative radiographs, 75% (3/4) were revision cases and 25% (1/4) were primary cases. The mean AGT measured on the available five-year postoperative radiographs was 32.6mm (range, 10.7 to 50.6). The mean AGT measured for the primary cases was 31.7mm. The mean AGT measured for the revision cases was 34.8mm.

Scapular notching was also assessed on five-year postoperative radiographs. For all patients, the breakdown of Sirveaux scapular notching was: 65.2% (30/46) at Grade 0, 23.9% (11/46) at Grade 1, and 10.9% (5/46) at Grade 2. For primary patients, the breakdown of Sirveaux scapular

notching was: 65.6% (21/32) at Grade 0, 25% (8/32) at Grade 1, and 9.4% (3/32) at Grade 2. Lastly, for revision patients, the breakdown of Sirveaux scapular notching was: 64.3% (9/14) at Grade 0, 21.4% (3/14) at Grade 1, and 14.3% (2/14) at Grade 2.

Postoperative radiographs were also evaluated for stem positioning. Overall, 69.6% (32/46) of stems were in neutral position, 21.7% (10/46) were in valgus position, and 8.7% (4/46) were in varus position. For primary patients, 71.9% (23/32) were in neutral position, 25% (8/32) were in valgus position, and 3.1% (1/32) were in varus position. For revision patients, 64.3% (9/14) were in neutral position, 14.2% (2/14) were in valgus position, and 21.4% (2/14) were in varus position. There was no significant correlation between stem position and scapular notching.

Two patients demonstrated loosening of the humeral stem on radiographs. Both of these patients were revision cases. One patient sustained a periprosthetic fracture distal to the humeral stem and was treated successfully in a Sarmiento brace. Nine patients (19%) demonstrated calcification of the long head of the triceps tendon. This was the most common radiographic finding.

Discussion

The use of reverse total shoulder arthroplasty has increased significantly over the past decade. As a newer orthopaedic procedure compared to the more established surgeries of total hip and knee replacement, there remains a keen interest in understanding the long term outcomes of reverse total shoulder arthroplasty. In our study, we examined the five year outcomes of the latest Delta Xtend Reverse Shoulder System. In 2005, Boileau et al. examined the mid-term results of the Delta shoulder prosthesis in forty-five patients and found a 78% satisfaction rate at a mean follow-up of 40 months [4]. The authors found significantly improved Constant and ASES scores for patients after surgery compared to their preoperative values [4]. For our patient population, we demonstrated an average ASES score of 64.1 for all patients with primary cases averaging 67.9 and revisions averaging 55.6. These values are similar to Boileau et al.'s findings which ranged from 50 for revision cases to 77 for primary CTA cases. The authors of that study reported that reverse TSA performed for revision purposes clearly offer less predictable results when compared to those cases done for primary CTA. Our study echoes this finding as the large majority of scores measured at 5 years were worse for revision cases compared to primary cases.

Gruber et al. examined longer term outcomes of the Delta Xtend and found that the mean Constant Scores of patients averaging five years out from surgery was 65.8 (range, 21 to 93) [5]. The authors of that study concluded that good results are achieved in five years after reverse TSA with use of the Delta Xtend prosthesis. Those authors also evaluated radiographs of patients at five years out from surgery and found that 64% (7/11) of available images demonstrated notching. Of those patients with notching, radiographs only demonstrated Grade 1 or 2 notching on the Sirveaux classification scale. This was increased compared to our radiographic findings. We demonstrated only 34.4% (17/50) of patients with notching. Like the study by Gruber et al,

those patients with notching were only Grade 1 or 2 [5]. This rate of notching is much lower than prior studies that found rates of notching ranging from 62% to 94% from four to eight year postoperatively [5, 6, 7, 8].

This study did have several limitations. First, all the cases were done by a single surgeon who performs a high-volume of shoulder arthroplasties. The results of this patient series may not be universally relatable to the general orthopaedic surgeon population who performs reverse shoulder arthroplasties at a much lower rate. One of the more obvious and most concerning limitations is lack of homogeneity amongst patient follow up at five years. As seen in the table of outcome measures, there was great variation in the number of patients who were assessed for the various outcome scores. In some instances, there were no patients available for certain scores. This can lead to a lack of consensus amongst the various outcomes measured as some patients only impacted the mean of a certain score. Lastly, despite being able to assess scores of patients at five years out from surgery, there was very poor and inconsistent evaluation of these same scores at preoperative, immediate postoperative, and one to two-year postoperative time points. This made it quite difficult to trend how patients progressed in their outcomes and impossible to compare five-year scores to those at earlier time points. Instead, we are left only to evaluate the five-year data as a snapshot in time at long-term follow-up and are only able to compare this to historical controls at earlier postoperative periods.

Conclusions

In conclusion, the Delta Xtend Reverse Shoulder System has shown to be a reliable arthroplasty system for patients with CTA or failed prior arthroplasty. Patients are generally quite functional at five years out from their reverse shoulder arthroplasty using this implant. Radiographic measures used to interpret the status of the implant demonstrate that AGT is well maintained and scapular notching is minimal for the majority of cases. This study demonstrates that the Delta Xtend Reverse Shoulder System does a good job of providing properly indicated patients with good long-term outcomes.

Acknowledgements

None

Patient Consent

Patients were properly informed of this study prior to consent. All collected data was de-identified. This was approved by our IRB. No new drugs or devices were used in this study.

Disclosure:

The authors report no conflict of interest concerning the materials or methods used in this study of the findings specified in this paper.

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253 **Legend**

254 **Table 1: Patient and Surgery Demographics**

255 **Table 2: Average Outcome Scores for All Patients , Primary Patients, and Revision**

256 **Patients with the Delta Xtend Reverse Prosthesis**