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## Age-Related Outcomes in Stemless TSA

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## ABSTRACT

**Background:** Stemmed humeral components have been used successfully in shoulder arthroplasty since the 1950's. Stem-related complications, including fracture, stress-shielding, loosening, and osteolysis, present a rare but difficult challenge in shoulder arthroplasty. Stemless (also called canal-sparing) humeral components utilize a standard humeral head osteotomy and rely on metaphyseal rather than diaphyseal fixation. To date, limited information is available on its age-related outcomes.

**Questions/purposes:** When using a stemless humeral component in total shoulder arthroplasty, we asked if there were differences in (1) range of motion and functional outcome scores, and (2) radiographic changes and revision rates, between patients of different ages.

**Methods:** Stemless shoulder arthroplasty was performed on 157 patients with minimum of two-year follow-up. Clinical and radiographic examination was documented and compared between patients <60, 60-69, and ≥70 years old. Thirty-two (20.4%), 77 (49%), and 48 (30.6%) patients were found to be <60, 60-69, and ≥70 years old, respectively.

**Results:** At final follow-up, only age groups 60-69 and ≥70 years showed significant improvements in strength ( $p=0.001$ ) and internal rotation range of motion ( $p<0.001$ ). Postoperative ASES ( $p<0.001$ ) and age-adjusted Constant scores ( $p<0.001$ ) at 2-year follow-up were significantly higher in the older age groups. Overall change in adjusted Constant score ( $p=0.007$ ) and internal rotation range of motion ( $p=0.047$ ) showed greatest improvement in the older age groups. One revision operation was required in each age group ( $p=0.326$ ). No humeral component had evidence of radiographic loosening, subsidence, or migration at final follow-up.

**Conclusions:** This is the first report of age-related outcomes in stemless humeral component shoulder arthroplasty. At a minimum 2-year follow-up, this study highlights improvement in out-comes for all age groups, with slightly more significant improvements in older patients.

## INTRODUCTION

Recently, stemless (also called canal-sparing) humeral implants have been introduced, providing an alternative to traditional stems. These newer designs maintain their stability through press-fit, metaphyseal fixation, thereby leaving the diaphysal bone untouched. Advantages of canal-sparing implants include avoidance of stem-related fractures, decreased operative time, and optimized humeral head positioning independent of the shaft axis [3]. In addition, revision cases, when necessary, can be performed more easily, with maximized bone preservation. Studies have shown good clinical and radiographic results at short-term follow-up [6, 10, 11, 13].

Currently, little information is available in the literature exploring age-related outcomes with use of stemless humeral components. Specifically, some concern exists that these designs may not be appropriate in the older patient population due to a greater prevalence of osteoporosis. The aim of this study was to examine the age-related outcomes after implantation of the SIMPLICITI™ Shoulder System (Wright Medical, Bloomington, MN, USA) canal-sparing humeral implant. It expands on a previously published paper [6], utilizing a dataset containing a large cohort of patients.

## STUDY QUESTIONS

When using a stemless humeral component in total shoulder arthroplasty, we asked if



*SIMPLICITI Shoulder System*

there were differences in (1) range of motion and functional outcome scores, and (2) radiographic changes and revision rates, between patients of different ages.

#### **MATERIALS AND METHODS**

This study was a retrospective analysis of prospectively collected data from multiple institutions receiving IRB approval, involving 16 surgeons at 14 sites throughout the United States. Between July 2011 and November 2012, all patients who were indicated for an anatomic total shoulder replacement, met inclusion/exclusion criteria, and agreed to have a SIMPLICITI humeral implant, were consented for the procedure. 157 patients were enrolled. They were then divided into 3 groups, depending on age (<60, 60-69, and  $\geq$ 70 years old).

The study consisted of 45 females and 112 males, with a mean age of 66 years (range, 37-84). Of the 157 patients enrolled, 32 (20.4%), 77 (49.0%), and 48 (30.6%) patients were in age groups <60, 60-69, and  $\geq$ 70 years of age, respectively. Eight patients were dropped from the study for the following reasons: (1) explanted during index procedure, (1) explanted post-index procedure, (1) deceased, (2) lost to follow-up for unknown reasons, and (3) withdrew consent from the study. These patients were not included in the final outcomes assessment, leaving 149 patients (94.9%) with a minimum of 2-year follow-up.

#### **CLINICAL EVALUATION**

Comprehensive examinations were performed preoperatively, and at regular postoperative intervals up to 2 years. Clinical performance was assessed by ROM (using a long arm goniometer), age-adjusted Constant score, Simple Shoulder Test (SST), American Shoulder and Elbow Surgeons (ASES) score, and strength evaluation as proposed by Bankes et al. [2]. Complications, as defined by the need for revision surgery, were also noted.

#### **RADIOGRAPHIC EVALUATION**

Standard postoperative radiographs were obtained at each follow-up visit and evaluated by three independent musculoskeletal radiologists. Evaluations included signs of component loosening, osteolysis, subsidence, and migration, as has been previously defined [6].

#### **STATISTICAL ANALYSES**

Data was summarized using SAS 9.4 (Cary, NC, USA). Descriptive data was calculated including mean, standard deviation, range, and median. Comparisons among the three age groups were performed using ANOVA analysis and paired Student's t-test was used for improvement from preoperative assessments. Significance was set at  $p < 0.05$ .

#### **RESULTS**

The clinical outcomes for the three age groups are shown in Table I. At 2-year follow-up, all age groups showed significant improvement from preoperative evaluation in ASES score ( $p < 0.001$ ), adjusted Constant score ( $p < 0.001$ ), SST ( $p < 0.001$ ), and scapular plane/external rotation ROM ( $p < 0.001$ ). Only age groups 60-69 and  $\geq$ 70 years showed significant improvements in strength ( $p = 0.001$ ) and internal rotation ROM ( $p < 0.001$ ).

## Age-Related Outcomes in Stemless TSA

All preoperative scores were similar between age groups. Postoperative ASES ( $p < 0.001$ ) and age-adjusted Constant scores ( $p < 0.001$ ) at 2-year follow-up were significantly higher in the older age groups. Overall change in adjusted Constant score ( $p = 0.007$ ) and internal rotation ROM ( $p = 0.047$ ) showed greatest improvement in the older age groups as well. All other comparisons were not statistically significant.

Table I: Mean preoperative, 2-year postoperative, and change in functional outcome scores and range of motion (degrees), stratified by age

	<60 yo (n=29)	60-69 yo (n=73)	≥70 yo (n=47)	P-value
<b>PRE-OP<sup>1</sup></b>				
ASES	33.2 ± 17.2	39.6 ± 16.2	39.1 ± 17.9	0.182
Adj. Constant	51.2 ± 15.0	55.9 ± 17.1	58.2 ± 16.4	0.191
Strength <sup>3</sup>	12.8 ± 6.9	13.1 ± 6.4	11.3 ± 5.9	0.293
SST	4.0 ± 2.3	4.3 ± 2.6	4.6 ± 2.9	0.522
IR, °	70.2 ± 20.1	61.8 ± 27.6	64.4 ± 21.3	0.264
ER, °	35.4 ± 23.7	28.8 ± 19.6	31.3 ± 18.5	0.296
SP, °	107.1 ± 25.3	102.3 ± 25.0	100.9 ± 30.8	0.582
<b>2 YEAR POST-OP<sup>2</sup></b>				
ASES	84.1 ± 18.6	94.3 ± 7.8	93.1 ± 7.9	<0.001*
Adj. Constant	90.5 ± 19.6	105.6 ± 10.2	110.6 ± 12.4	<0.001*
Strength <sup>3</sup>	16.2 ± 8.3	15.9 ± 7.1	14.8 ± 8.6	0.696
SST	10.1 ± 2.2	11.0 ± 1.5	10.7 ± 1.7	0.053
IR, °	72.4 ± 15.7	74.5 ± 16.3	73.7 ± 17.4	0.842
ER, °	54.9 ± 17.1	55.8 ± 14.4	58.2 ± 15.9	0.611
SP, °	142.4 ± 25.3	149.6 ± 21.0	144.5 ± 26.5	0.306
<b>CHANGE</b>				
ASES	48.8 ± 18.9	54.2 ± 18.9	54.3 ± 20.0	0.390
Adj. Constant	37.8 ± 21.0	49.1 ± 20.1	52.3 ± 15.9	0.007*
Strength <sup>3</sup>	2.6 ± 9.4	2.4 ± 5.9	3.2 ± 6.1	0.834
SST	6.0 ± 2.4	6.7 ± 2.9	6.1 ± 3.1	0.354
IR, °	1.4 ± 24.8	13.9 ± 27.3	8.7 ± 12.9	0.047*
ER, °	20.5 ± 26.2	26.9 ± 22.9	27.5 ± 16.9	0.345
SP, °	32.5 ± 27.2	47.4 ± 30.2	44.1 ± 30.3	0.075

ASES=American Shoulder Elbow Surgeons, SST= Simple Shoulder Test, IR=internal rotation, ER=external rotation, SP=scapular plane

<sup>1</sup> values listed for entire 157 patient cohort

<sup>2</sup> values for 149 patients (available at follow-up)

<sup>3</sup> Strength component of Constant Score

\* Statistically significant

Revision surgery was required in three cases (1.9%), with one case in each age group. The first patient, a 71 year old, suffered a subscapularis repair failure 15 months after the index procedure, requiring revision to a reverse total shoulder arthroplasty. The second patient was a 63 year old who required irrigation and debridement at 4 weeks postoperatively due to infection. After treatment with a humeral head exchange, the infection subsequently cleared. The third revision was in a 48 year old who had glenoid loosening at 18 months postoperatively, treated with glenoid component revision with impaction grafting. In all three revision scenarios, the humeral component was noted to be stable and well-fixed. As there was a revision operation in each age group, no significant difference existed when comparing the mean ages between revision and non-revision groups, as shown in Table II.

Table II: Comparison of mean age between revision and non-revision groups.

Reoperation	N	Mean age	P-value
Yes	3	60.67 ± 11.68	0.3255
No	154	65.6 ± 8.54	

Other than the glenoid component revision due to loosening (as described above), radiographic assessment of all other implants at 2 year follow-up did not show any signs of loosening, osteolysis, migration, or translation.

## DISCUSSION

Limitations to the current study were noted. A concurrent control group was not evaluated so that results could be directly compared to the outcomes of a stemmed implant. In addition, this study represents short-term follow up, with longer follow up needed to determine the durability of these age-related results.

## Age-Related Outcomes in Stemless TSA

This is the first study looking at age-related outcomes following stemless total shoulder arthroplasty. Results showed significant increases in all outcome scores in addition to most ROM planes, illustrating uniform benefit to patients regardless of age. With certain outcomes and ROM, more improvement at final follow-up was noted in older age groups, which was consistent with the findings found by Fehring et al [8].

These functional results are comparable to results found in prior studies that have evaluated stemmed components. In a study by Denard et al. which evaluated the stemmed AEQUALIS™ implant system in patients younger than 55 years of age, the postoperative adjusted Constant Score was 80.0 in patients not requiring revision of the glenoid component (mean follow up of 115.5 months). In addition, active forward elevation was 128 degrees, with external rotation to 33 degrees [7]. In a similar study by Raiss et al., evaluating patients younger than 60 years of age who had also received the AEQUALIS stemmed implant, the average adjusted Constant Score was 83 at mean follow up of 7 years. External rotation improved to 30.5 degrees and for-ward elevation to 128 degrees [19]. Though the results from the present study show a better functional outcome score (Constant Score- 90.5) and higher ranges of motion specific to this young age group, definitive conclusions comparing stemmed and stemless implants cannot be drawn due to the variability in follow up. Outcomes for older patients receiving a stemmed implant were also similar to those found in the present study. In a paper by Iriberry et al., patients over 80 years of age receiving the AEQUALIS implant had a postoperative adjusted Constant Score of 110, at mean follow up of 7 years. In fact, when compared to patients younger than 70 years of age, the authors found better

functional outcome scores in the older groups, similar to the results found in the present study concerning stemless implants [12].

Radiographically, the present study found no failures of the humeral component at 2 years, with only 1 case of glenoid loosening in a younger patient that required revision. The humeral implant maintained durability in younger patients, who may be considered to be at higher risk for loosening due to higher levels of activity. The SIMPLICITI canal-sparing system also maintains adequate metaphyseal fixation in older patients, where poor bone quality may be a concern. Though the follow-up is short-term, these results show that in properly selected patients, the SIMPLICITI canal-sparing system can be an effective arthroplasty option, regardless of patient age. With this in mind, certain clinical scenarios may preclude the use of the stemless implant. Cysts noted in the metaphysis or “poor” bone density (metaphyseal bone that is easily compressible or unable to maintain the position of the blazer) are reasons to convert to a stemmed implant for improved fixation. It is, therefore, prudent to have the stemmed implant system available during the procedure, in the event that stemless components cannot be used.

## CONCLUSIONS

This study demonstrates good results in patients receiving the SIMPLICITI canal-sparing system for shoulder osteoarthritis at short-term follow-up, regardless of age. All age groups can be expected to have improved functional scores and range of motion with minimal risk of humeral component loosening. Older age groups may have slightly improved results when compared to younger groups. Future studies need to be performed to assess the long-term durability of these outcomes.

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### REFERENCES

- 1) Athwal GS, Sperling JW, Rispoli DM, Cofield RH. Periprosthetic humeral fractures during shoulder arthroplast. J Bone Joint Surg Am 2009;91:594-603.
- 2) Bankes MJ, Crossman JE, Emery RJ. A standard method of shoulder strength measurement for the Constant score with a spring balance. J Shoulder Elbow Surg 1998;7:116-121.
- 3) Berth A, Pap G. Stemless shoulder prosthesis versus conventional anatomic shoulder prosthesis in patients with osteoarthritis: a comparison of the functional outcome after a minimum of two years follow-up. J Orthop Traumatol 2013;14:31-37.
- 4) Bohsali KI, Wirth MA, Rockwood CA, Jr. Complications of total shoulder arthroplasty. J Bone Joint Surg Am 2006;88:2279-2292.
- 5) Churchill RS. Stemless shoulder arthroplasty: current status. J Shoulder Elbow Surg 2014;23:1409-1414.
- 6) Churchill RS, Chuinard C, Wiater JM, Friedman R, Freehill M, Jacobson S, Spencer E Jr, Holloway GB, Wittstein J, Lassiter T, Smith M, Blaine T, Nicholson GP. Clinical and Radio-graphic Outcomes of the Simpliciti Canal-Sparing Shoulder Arthroplasty System: A Prospective Two-Year Multicenter Study. J Bone Joint Surg Am 2016;98:552-560.
- 7) Denard PJ, Raiss P, Sowa B, Walch G. Mid-to long-term follow-up of total shoulder arthro-plasty using a keeled glenoid in young adults with primary glenohumeral arthritis. J Shoulder Elbow Surg 2013;22:894-900.
- 8) Fehringer EV, Kopjar B, Boorman RS, Churchill RS, Smith KL, Matsen FA, 3rd. Character-izing the functional improvement after total shoulder arthroplasty for osteoarthritis. J Bone Joint Surg Am 2002;84-A:1349-1353.
- 9) Flury MP, Frey P, Goldhahn J, Schwyzer HK, Simmen BR. Reverse shoulder arthroplasty as a salvage procedure for failed conventional shoulder replacement due to cuff failure--midterm results. Int Orthop 2011;35:53-60.
- 10) Habermeyer P, Lichtenberg S, Tauber M, Magosch P. Midterm results of stemless shoulder arthroplasty: a prospective study. J Shoulder Elbow Surg 2015;24:1463-1472.
- 11) Huguet D, DeClercq G, Rio B, Teissier J, Zipoli B, Group T. Results of a new stemless shoulder prosthesis: radiologic proof of maintained fixation and stability after a minimum of three years' follow-up. J Shoulder Elbow Surg 2010;19:847-852.
- 12) Iriberry I, Candrian C, Freehill MT, Raiss P, Boileau P, Walch G. Anatomic shoulder re-placement for primary osteoarthritis in patients over 80 years: outcome is as good as in younger patients. Acta Orthop 2015;86:298-302.
- 13) Kadum B, Mafi N, Norberg S, Sayed-Noor AS. Results of the Total Evolutive Shoulder Sys-tem (TESS): a single-centre study of 56 consecutive patients. Arch Orthop Trauma Surg 2011;131:1623-1629.

## Age-Related Outcomes in Stemless TSA

- 14) Kumar S, Sperling JW, Haidukewych GH, Cofield RH. Periprosthetic humeral fractures after shoulder arthroplasty. *J Bone Joint Surg Am* 2004;86-A:680-689.
- 15) Maier MW, Lauer S, Klotz MC, Bulhoff M, Spranz D, Zeifang F. Are there differences between stemless and conventional stemmed shoulder prostheses in the treatment of glenohumeral osteoarthritis? *BMC Musculoskelet Disord* 2015;16:275.
- 16) Mariotti U, Motta P, Stucchi A, Ponti di Sant'Angelo F. Stemmed versus stemless total shoulder arthroplasty: a preliminary report and short-term results. *Musculoskelet Surg* 2014;98:195-200.
- 17) Neer CS, 2nd. Articular replacement for the humeral head. *J Bone Joint Surg Am* 1955;37-A:215-228.
- 18) Neer CS, 2nd. Replacement arthroplasty for glenohumeral osteoarthritis. *J Bone Joint Surg Am* 1974;56:1-13.
- 19) Raiss P, Aldinger PR, Kasten P, Rickert M, Loew M. Total shoulder replacement in young and middle-aged patients with glenohumeral osteoarthritis. *J Bone Joint Surg Br* 2008;90:764-769.
- 20) Razmjou H, Holtby R, Christakis M, Axelrod T, Richards R. Impact of prosthetic design on clinical and radiologic outcomes of total shoulder arthroplasty: a prospective study. *J Shoulder Elbow Surg* 2013;22:206-214.
- 21) Wagner ER, Houdek MT, Elhassan BT, Sanchez-Sotelo J, Cofield RH, Sperling JW. What Are Risk Factors for Intraoperative Humerus Fractures During Revision Reverse Shoulder Arthroplasty and Do They Influence Outcomes? *Clin Orthop Relat Res* 2015;473:3228-3234.
- 22) Wieser K, Borbas P, Ek ET, Meyer DC, Gerber C. Conversion of stemmed hemi- or total to reverse total shoulder arthroplasty: advantages of a modular stem design. *Clin Orthop Relat Res* 2015;473:651-660.



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