# Prospective, Blinded, Randomized Controlled Trial of Stemless Versus Stemmed Humeral Components in Anatomic Total Shoulder Arthroplasty

## Results at Short-Term Follow-up

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**Background:** Stemless humeral components for anatomic total shoulder arthroplasty (aTSA) have several reported potential benefits compared with stemmed implants. However, we are aware of no Level-I, randomized controlled trials (RCTs) that have compared stemless implants with stemmed implants in patients managed with aTSA. We sought to directly compare the short-term clinical and radiographic outcomes of stemless and stemmed implants to determine if the stemless implant is noninferior to the stemmed implant.

**Methods:** We performed a prospective, multicenter, single-blinded RCT comparing stemless and short-stemmed implants in patients managed with aTSA. Range-of-motion measurements and American Shoulder and Elbow Surgeons (ASES), Single Assessment Numeric Evaluation (SANE), and Constant scores were obtained at multiple time points. Device-related complications were recorded. Radiographic evaluation for evidence of loosening, fractures, dislocation, or other component complications was performed. Statistical analysis for noninferiority was performed at 2 years of follow-up for 3 primary end points: ASES score, absence of device-related complications, and radiographic signs of loosening. All other data were compared between cohorts at all time points as secondary measures.

**Results:** Two hundred and sixty-five shoulders (including 176 shoulders in male patients and 89 shoulders in female patients) were randomized and received the allocated treatment. The mean age of the patients (and standard deviation) was 62.6 ± 9.3 years, and 99% of the shoulders had a primary diagnosis of osteoarthritis. At 2 years, the mean ASES score was 92.5 ± 14.9 for the stemless cohort and 92.2 ± 13.5 for the stemmed cohort (p value for noninferiority test, <0.0001), the proportion of shoulders without device-related complications was 92% (107 of 116) for the stemless cohort and 93% (114 of 123) for the stemmed cohort (p value for noninferiority test, 0.0063), and no shoulder in either cohort had radiographic signs of loosening. Range-of-motion measurements and ASES, SANE, and Constant scores did not differ significantly between cohorts at any time point within the 2-year follow-up.

**Conclusions:** At 2 years of follow-up, the safety and effectiveness of the stemless humeral implant were noninferior to those of the stemmed humeral implant in patients managed with aTSA for the treatment of osteoarthritis. These short-term results are promising given the potential benefits of stemless designs over traditional, stemmed humeral components.

**Level of Evidence:** Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

**Disclosure:** This study was sponsored and funded by Zimmer Biomet, the manufacturer of the implants in the study. On the **Disclosure of Potential Conflicts of Interest** forms, *which are provided with the online version of the article*, one or more of the authors checked "yes" to indicate that the author had a relevant financial relationship in the biomedical arena outside the submitted work (including with Zimmer Biomet, the sponsor of the study) (http://links.lww.com/JBJS/G113).

A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJS/G115).

As designs for anatomic total shoulder arthroplasty (aTSA) implants have evolved, the need for long humeral stems has been questioned as complications involving the humeral component are often related to the stem[1,2]. The idea of stemless implants was introduced in the 1980s by Levy and Copeland with the development of humeral resurfacing implants[3,4]. With those implants, the entire humeral head was not resected, resulting in the preservation of humeral bone stock at the cost of making glenoid exposure more challenging. Following their success, many "stemless" implants have been designed with canal-sparing stems that only engage the humeral metaphysis but still allow for standard humeral anatomic neck cuts, facilitating exposure of the glenoid.

**TABLE I Complete Inclusion and Exclusion Criteria**

| Inclusion Criteria | Exclusion Criteria |
|---|---|
| • Patients with non-inflammatory degenerative joint disease, including osteoarthritis.<br>• Patients in whom the device will be used for the correction of a functional deformity, specifically, deformities that prevent congru ent articulation of the glenohumeral joint. Examples include but are not limited to humeral head structural deformity, osteophyte for mation restricting range of motion, and so on.<br>• Patients with pain and/or loss of function in the shoulder for whom other treatment modalities have been unsuccessful. Examples of such treatment include but are not limited to activity modification, physiotherapy, and anti-inflammatory or other types of medication.<br>• Patients requiring unilateral or staged bilateral shoulder arthroplasty.<br>• Patients who are anatomically and structurally suited to receive the implants. During the preoperative templating, it must be confirmed that the humeral neck is of sufficient diameter to implant at least the smallest stemless humeral component and that the humeral neck cortex is intact.<br>• Patients who are 21-90 years of age at the time of surgery.<br>• Patients who are skeletally mature.<br>• Patients with an ASES score of ≤40.<br>• Patients who are willing and able to return for scheduled follow-up evaluations.<br>• Patients who have completed a valid, institutional review board-approved informed-consent form.<br>• Patients for whom the surgeon has confirmed intraoperatively that there is no cyst measuring >1 cm and that there is not >1 cyst at the implantation site<br>• Patients who agree to be blinded to treatment until evaluations are completed at the ≥22-month end point. | • Patients diagnosed with osteonecrosis or posttraumatic arthritis of the humeral head.<br>• Patients presenting with shoulder joint infection, sepsis, osteomyelitis, or distant foci of infections that may spread to the implant site.<br>• Patients with cuff tear arthropathy.<br>• Patients who have previously undergone a hemiarthroplasty, total shoulder arthroplasty, or reverse total shoulder arthroplasty in the affected shoulder.<br>• Patients presenting with malunion or nonunion of the tuberosities of the proximal part of the humerus.<br>• Patients with osteoporosis; osteomalacia; rheumatoid arthritis; metabolic disorders of bone, muscle, or connective tissue; gross deformity or any other condition of the proximal part of the humerus (defined as severe destruction or deformity of the proximal part of the humerus that precludes placement of the device) that in the investigator's medical judgment could compromise implant fixation or bone-healing.<br>• Patients with rapid bone destruction, marked bone loss, or bone resorption apparent on radiographs.<br>• Patients with neurological or other disorders that would affect the stability of the shoulder prosthesis (e.g., Charcot joint, uncontrolled seizures, etc.).<br>• Patients diagnosed with any condition (e.g., mental illness) that may limit the ability to complete the consent form or that would affect the capability or willingness to return to the clinic for assessments and/or follow directions.<br>• Patients with bone cancer, either primary or secondary, affecting the shoulder.<br>• Patients presenting with symptoms of chronic steroid use, defined as use of oral steroids for a chronic condition for 12 months prior to and including the date of surgery (inhaled and topical steroid use is allowed).<br>• Patients with a life expectancy of <3 years.<br>• Patients with severe shoulder instability.<br>• Patients with subscapularis incompetence.<br>• Patients with active medicolegal activity regarding the index shoulder.<br>• Patients known to be pregnant or planning to get pregnant, prisoners, and/or alcohol or drug abusers.<br>• Patients known to be involved in Workers' Compensation litigation regarding index shoulder.<br>• Patients with known metal allergy.<br>• Patients refusing to sign the institutional review board-approved consent form.<br>• Patients who are found intraoperatively to require a specific treat ment and are unable to be randomized.<br>• Patients who are found at the time of intraoperative examination to have a single cyst measuring >1 cm in size or multiple cysts at the implantation site. |

Fig. 1-A

**Figs. 1-A, 1-B, and 1-C** Images of the implants used in the present study. **Fig. 1-A** Photograph showing the Zimmer Biomet Comprehensive Mini humeral stem. (Reproduced with permission from Zimmer Biomet.)

Stemless humeral implants have several potential benefits over stemmed implants, including simplified recreation of native anatomy, particularly in cases of metadiaphyseal deformity[5-7]; decreased risk of intraoperative periprosthetic humeral shaft fractures resulting from stem impaction[1,2]; decreased operative time and blood loss[8,9]; and, importantly, preservation of humeral bone stock, with less bone removal at the time of the initial procedure, less bone loss over time (due to decreased stress-shielding), and easier explantation if revision is needed[10-12].

Short- and intermediate-term studies of stemless implants used in Europe since 2004 have shown good success with minimal complications[5-7,9,11,13-23]. However, to our knowledge, there have been no large, multicenter, randomized controlled trials (RCTs) comparing stemless and stemmed implants. Therefore, we performed such a trial with the objective of evaluating both the safety and effectiveness of a stemless implant compared with a stemmed implant, hypothesizing that the stemless implant would be non-inferior to the stemmed implant at the time of the 2-year follow-up.

## Materials and Methods

### *Trial Design*

The present study was a prospective, multicenter, single-blinded RCT in which patients were allocated evenly into treatment cohorts at 12 sites across the United States. Sites obtained institutional review board approval prior to study commencement, and no substantial methodological changes were made after study commencement. Three sites enrolled ≥25 shoulders, 7 enrolled 10 to 24 shoulders, and 2 enrolled <10 shoulders.

### *Patients*

Each site screened consecutive patients undergoing aTSA for eligibility. The inclusion and exclusion criteria are shown in Table I. Patients with osteoporosis, osteomalacia, or other disorders possibly compromising fixation of a stemless implant in the metaphysis were excluded.

### *Interventions*

The stemmed implants were Comprehensive Mini (83-mm) humeral stems (Fig. 1-A), which previously have demonstrated good results at short-term follow-up[24-26], and the stemless implants were Comprehensive Nano humeral stems (Figs. 1-B

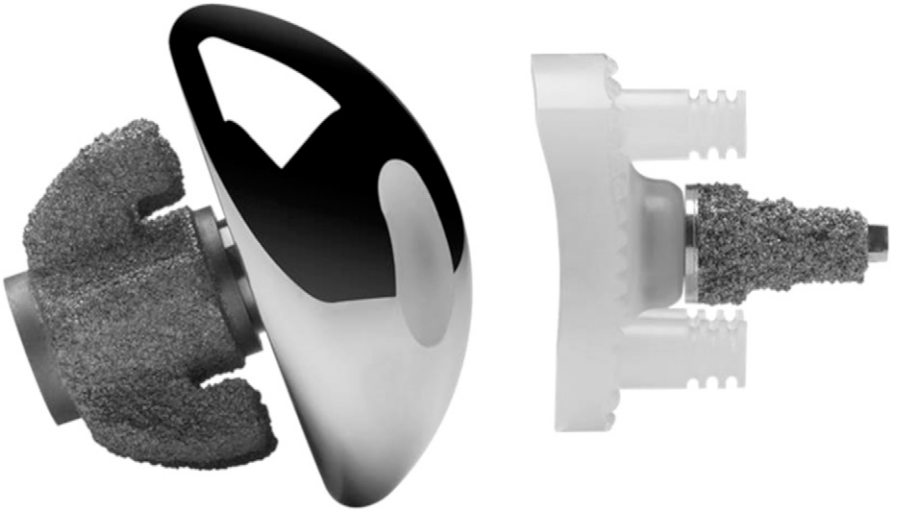

Fig. 1-B

Photographs showing the Zimmer Biomet Comprehensive Nano humeral stem and Versa-Dial humeral head (left) and the Comprehensive glenoid component with Regenerex post (right). (Reproduced with permission from Zimmer Biomet.)

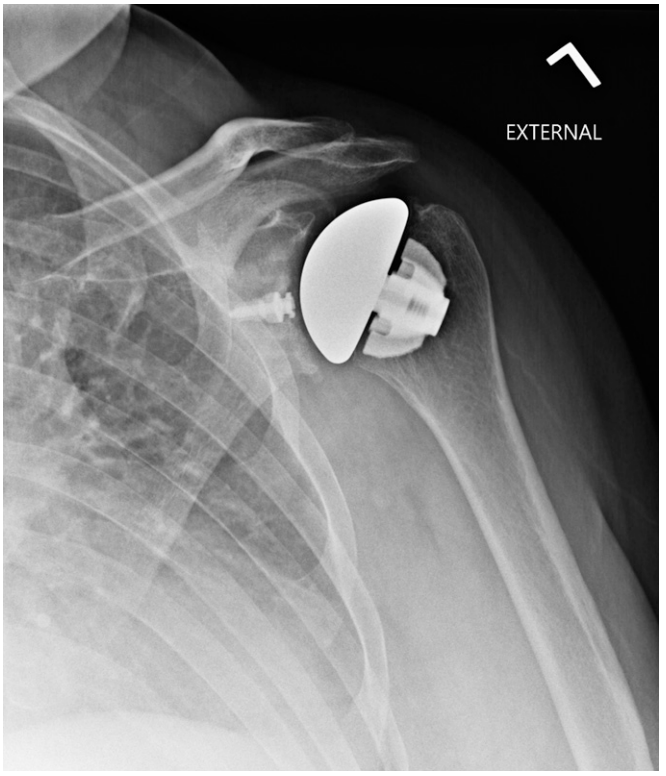


Fig. 1-C
Representative anteroposterior postoperative radiograph of the stemless implant, made 28 months postoperatively.

and 1-C). Comprehensive Versa-Dial humeral heads and Comprehensive glenoid components with Regenerex posts were used in all patients (Figs. 1-B and 1-C). All implants were manufactured by Zimmer Biomet.

Surgical procedures were performed according to the manufacturer's surgical techniques by surgeons with extensive experience in shoulder arthroplasty. Briefly, a deltopectoral approach was used, with subscapularis tenotomy or lesser tuberosity osteotomy and subsequent repair according to each surgeon's preference. The humeral neck was cut in either 30° of retroversion or the patient's native retroversion according to surgeon preference. In the stemmed cohort, the humeral canal was reamed and broached in standard fashion. In the stemless cohort, a guide pin was placed in the center of the humeral neck cut followed by a central surface reamer and broach. In both cohorts, the broach was left in place and a humeral cut protector was inserted. The glenoid was then exposed and prepared. Following trialing, the final glenoid and humeral components were implanted. A hybrid glenoid component was used in all cases, with peripheral polymethylmethacrylate-cemented pegs and a central bone-ingrowth, uncemented post. The humeral stems were uncemented in both cohorts. The subscapularis was repaired, the biceps tendon was tenodesed, and the incision was closed in a standard fashion.

Subjects were required to participate in a postoperative rehabilitation protocol as prescribed by their surgeon. A recommended rehabilitation protocol from Brigham and Women's Hospital was provided to all sites[27].

### *Outcomes*

Data were collected preoperatively, intraoperatively, and at 6 weeks, 3 months, 1 year, and 2 years postoperatively. Intraoperative data, including length of surgery, glenoid wear pattern, subscapularis management, and rotator cuff status, were recorded. The primary outcome measures used for noninferiority analysis were the American Shoulder and Elbow Surgeons (ASES) score at the 2-year follow-up time point, device-related complications (unanticipated adverse device events [UADEs], fracture, dislocation/subluxation, glenoid perforation, dissociation of the device, or revision/removal of any component), and radiographic signs of loosening. Secondary outcome measures were ASES scores at all other time points and Single Assessment Numeric Evaluation (SANE) scores, Constant scores, and range-of-motion measurements at all time points (except for Constant scores at 6 weeks because of ongoing healing and SANE scores preoperatively). Patients were given paper forms at each visit to complete questionnaires that were used to calculate outcome scores. Trained research staff measured range of motion with a large goniometer and measured abduction strength at 90° (for the Constant score) with a standard force gauge provided to each site. On rare occasions, if research staff were unavailable, data were collected by the surgeon. Constant scores were normalized by age and sex as described by Katolik et al.[28]. Intraoperative complications were recorded, and patients were assessed at each follow-up for any additional shoulder-related complications.

### *Radiographic Analysis*

Radiographs, including glenohumeral true anteroposterior internal and external rotation views and axillary lateral views, were made at each follow-up. Radiographic technique was standardized across all sites by providing a radiographic evaluation protocol with specific instructions for making images, including equipment set-up and subject positioning, and radiographs were repeated with technical adjustments as needed to ensure similar prosthesis profiles on all radiographs. Radiographic evaluation was performed by an independent, board-certified radiographic reviewer (Medical Metrics). Radiographs were assessed for fractures, dislocation/subluxation, component complications, and signs of component loosening. Loosening was defined as ≥5 mm of subsidence of the humeral component, ≥5 mm migration of the humeral and/or glenoid component, >2 mm of progressive radiolucency around the humeral component in ≥2 contiguous zones, or >2 mm of progressive radiolucency around the glenoid component in all zones.

### *Sample Size*

Noninferiority sample size calculations, performed with use of nQuery Advisor 7.0 software (Statsols) with a 1:1 ratio of investigational to control subjects to obtain 90% power while accounting for attrition, resulted in a sample size of 264 subjects.

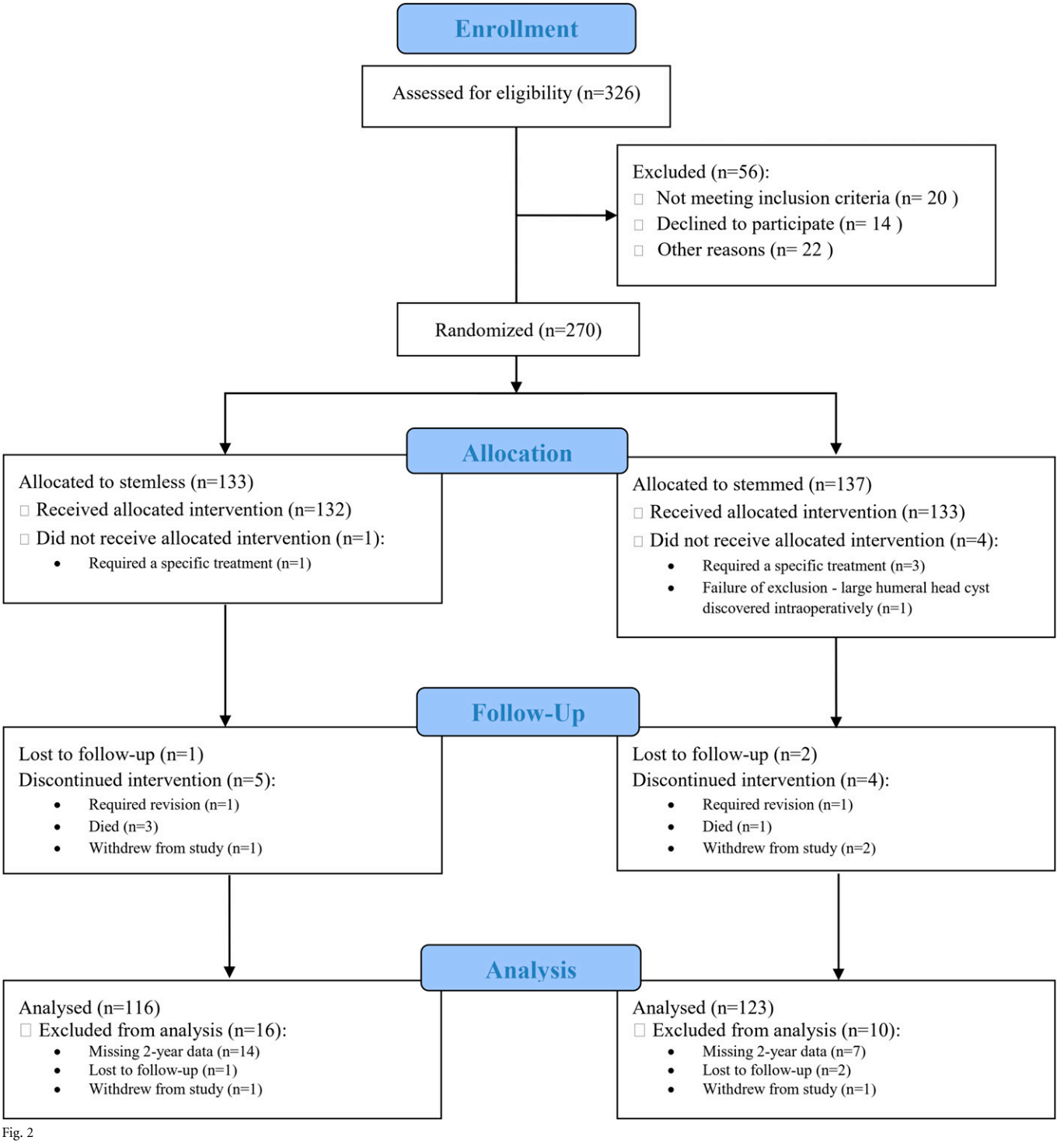


Fig. 2

Consolidated Standards of Reporting Trials (CONSORT) flow diagram outlining patient recruitment, allocation, and follow-up.

***Randomization and Blinding***

The randomization plan was produced by the sponsor with use of SAS 9.2 (SAS Institute) with balanced, blocked randomization (with a 1:1 ratio of investigational to control subjects) on a per-shoulder basis. Randomization was blocked by site, and each site received separate randomization plans with use of a predetermined block size undisclosed to the sites.

All efforts were made to keep patients blinded to their treatment. Treatment assignment was revealed to the surgeon after surgery had commenced, while the patient was under

**TABLE II Demographic Characteristics and Operative Data**

| Variable | Control (Stemmed) (N = 133) | Investigational (Stemless) (N = 132) | P Value |
|---|---|---|---|
| Demographic characteristics | | | |
| Female:male ratio *(no. of shoulders)* | 46:87 | 43:89 | 0.80 |
| Age at surgery* *(yr)* | 62.1 ± 9.6 (28-81) | 63.1 ± 9.0 (42-85) | 0.42 |
| Weight* *(kg)* | 90.3 ± 17.4 (52-131) | 91.9 ± 20.0 (48-154) | 0.49 |
| Height* *(cm)* | 173.2 ± 10.4 (140-196) | 173.2 ± 10.9 (142-196) | 0.92 |
| Body mass index* *($kg/m^2$)* | 30.1 ± 5.3 (19.5-44.6) | 30.6 ± 5.8 (18.6-47.8) | 0.46 |
| Race *(no. of shoulders)* | | | 0.81 |
| Caucasian | 125 | 126 | |
| African American | 6 | 4 | |
| Asian | 0 | 1 | |
| Hispanic or Latino | 2 | 1 | |
| Prior contralateral shoulder arthroplasty *(no. of shoulders)* | 19 | 15 | 0.58 |
| Operative data | | | |
| Unilateral:bilateral *(no. of shoulders)* | 124:9 | 127:5 | 0.41 |
| Total operative time* *(min)* | 97.2 ± 24.9 (44-180) | 97.1 ± 24.9 (42-163) | 0.99 |
| State of rotator cuff *(no. of shoulders)* | | | 0.64 |
| Degenerated/partial tear | 7 (5.26%) | 9 (6.82%) | |
| Full-thickness tear 1-3 cm | 1 (0.75%) | 2 (1.52%) | |
| Normal | 125 (93.98%) | 121 (91.67%) | |
| Subscapularis management *(no. of shoulders)* | | | 0.79 |
| Lesser tuberosity osteotomy | 41 (30.83%) | 43 (32.58%) | |
| Subscapularis tenotomy | 92 (69.17%) | 89 (67.42%) | |
| Glenoid morphology *(no. of shoulders)* | | | 0.14 |
| Anterior erosion | 5 (3.8%) | 6 (4.5%) | |
| Normal alignment | 44 (33.1%) | 51 (38.6%) | |
| Posterior erosion | 84 (63.2%) | 75 (56.8%) | |

*The values are given as the mean and the standard deviation, with the range in parentheses.

anesthesia. The patients were not permitted to view the postoperative radiographs until all patients in the study had reached 2 years of follow-up (with the exception of 6 patients who underwent revision).

### *Statistical Methods*

Primary end points were compared between cohorts for noninferiority with use of both a t test and the lower bound of a 1-sided 95% confidence interval (CI) for the difference between groups (investigational minus control) at ≥22 months. For the ASES score, a 9.5-point margin of noninferiority was used as studies have reported that the minimum clinically important difference (MCID) of the ASES score ranges from 9 to 21 points[29,30] and because, for many patient-reported outcome measures, the MCID is approximately half the standard deviation of change[31,32], which has been reported to be 19 points for ASES scores[33]. For radiographic signs of loosening and device-related complications, a 10% margin of noninferiority was used.

Secondary outcomes and demographic data were compared for differences with use of standard statistical tests appropriate for the data: the t test for range-of-motion measurements, the Wilcoxon rank-sum test for outcome measures, and the Fisher exact test for demographic and operative data.

### *Regulatory Oversight, Registration, and Safety*

This study was registered with clinicaltrials.gov (registration number NCT01936259). The details of the study are not published on the website because the investigational device exemption (IDE) study had not yet been closed by the U.S. Food & Drug Administration (FDA), although the implant has since been cleared for use by the FDA (510[k] number K182516). The present study was carried out and documented in accordance with U.S. federal regulations. Enrolled patients signed informed consent prior to data collection. Sites reported adverse events and protocol deviations to their institutional review board as necessary.

## Results

Recruitment began in August 2013 and concluded in October 2016. Three hundred and twenty-six patients were assessed

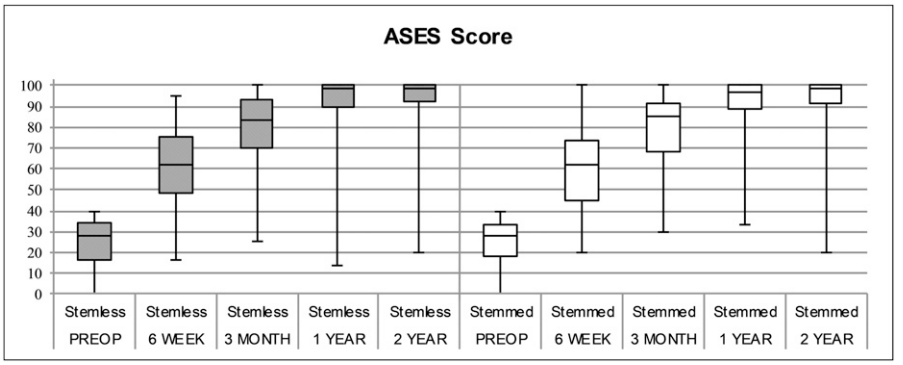


Fig. 3-A

**Figs. 3-A, 3-B, and 3-C** Box-and-whisker plots showing secondary outcome measures for both cohorts over time. There were no significant differences between cohorts at any time point. Median values are indicated with horizontal lines, IQRs are indicated with boxes, and maximum and minimum values are indicated with I-bars. **Fig. 3-A** ASES scores.

for eligibility, and 56 were excluded. Two hundred and seventy patients agreed to participate and were randomized to treatment with either a stemless (n = 133) or stemmed (n = 137) humeral component. One hundred and sixteen patients in the stemless cohort and 123 in the stemmed cohort reached the 2-year follow-up and were included in the analysis (representing follow-up rates of 87% and 90%, respectively) (Fig. 2). The trial was ended November 2018 when all enrolled subjects reached ≥22 months of follow-up.

There were no differences between the cohorts in terms of demographic or operative data (Table II). Of the 265 shoulders that received the allocated intervention, 176 (66%) were in male patients and 89 (34%) were in female patients. The mean age (and standard deviation) was 62.6 ± 9.3 years (62.1 ± 9.6 years in the stemmed cohort and 63.1 ± 9.0 years in the stemless cohort). The primary diagnosis was osteoarthritis for 99% of the shoulders. A lesser tuberosity osteotomy was performed in 33% of the shoulders in the stemless cohort and 31% of those in the stemmed cohort (p = 0.79), and a tenotomy was used in the remainder. The average operative time was 97.1 ± 24.9 minutes in the stemless cohort and 97.2 ± 24.9 minutes in the stemmed cohort (p = 0.99). Glenoid morphology did not differ significantly between the cohorts (p = 0.14). Blood loss data were not collected.

### *Primary Outcomes*

The mean ASES score at 2 years was 92.5 ± 14.9 (median, 98.3; interquartile range [IQR], 92.5-100.0; n = 112) for the stemless cohort, compared with 92.2 ± 13.5 (median, 98.3; IQR, 91.7-100.0; n = 121) for the stemmed cohort; evaluation of the difference of 0.27 points and the lower bound of the 95% CI for the difference of −2.81 points with a 9.5-point margin of noninferiority showed statistical noninferiority of the stemless implant (p value for noninferiority test, <0.0001) (Fig. 3-A).

With regard to device-related complications, 18 procedures (9 in the stemmed cohort and 9 in the stemless cohort) were identified as failures (Table III). In the stemless cohort, the reasons for failure included revision for infection (2 shoulders), intraoperative glenoid perforation (1 shoulder), and postoperative radiographic findings identified by the independent reviewer (including 1 humeral fracture, 4 glenoid fractures, and 1 case of anterior subluxation, all of which were treated nonoperatively with satisfactory outcomes). In the stemmed cohort, the reasons for failure included revision for infection (2 shoulders), revision to reverse TSA for postoperative subscapularis tears (2 shoulders), traumatic dislocation treated with closed reduction (1 shoulder), humeral fracture noted intraoperatively during stem impaction (1 shoulder), and radiographic findings (including 2 humeral fractures and 1 case of anterior subluxation, all of which

**TABLE III Summary of Failures**

| Reason for Failure | Count |
|---|---|
| Control cohort (stemmed) | |
| Revision for infection | 2 |
| Revision for subscapularis tear | 2 |
| Dislocation, traumatic | 1 |
| Humeral fracture, intraoperative | 1 |
| Humeral fracture, postoperative radiographic review | 2 |
| Anterior subluxation, postoperative radiographic review | 1 |
| Success rate | 93% (114 of 123)* |
| Investigational cohort (stemless) | |
| Revision for infection | 2 |
| Intraoperative glenoid perforation | 1 |
| Humeral fracture, postoperative radiographic review | 1 |
| Glenoid fracture, postoperative radiographic review | 4 |
| Anterior subluxation, postoperative radiographic review | 1 |
| Success rate | 92% (107 of 116)* |

*P = 0.0063 for noninferiority.

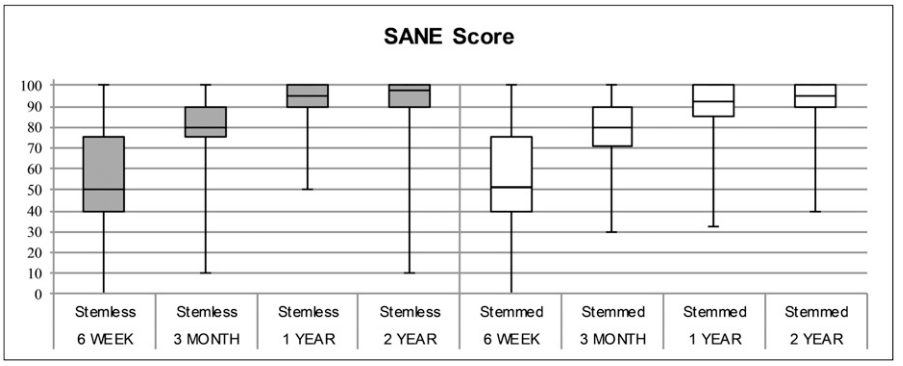


Fig. 3-B
SANE scores.

were treated nonoperatively with satisfactory outcomes). No UADEs were reported in either cohort. The success rates at 2 years were 92% and 93% for the stemless and stemmed cohorts, respectively; statistical evaluation of the difference of −0.44% and the lower limit of the 95% CI of −6.74% with a 10% margin of noninferiority showed statistical noninferiority of the stemless implant (p value for noninferiority test, 0.0063).

Last, no shoulder in either cohort had radiographic signs of loosening. No shoulder in either cohort had subsidence or migration of the humeral component. Two shoulders in the stemmed cohort showed humeral radiolucency of >2 mm, but the implants were not considered loose because the radiolucency was confined to only 1 radiographic zone; no shoulder in the stemless cohort showed humeral radiolucency of >2 mm. No shoulder in either cohort had evidence of subsidence or migration of the glenoid component. These findings demonstrated radiographic noninferiority of the stemless implant.

### *Secondary Outcomes*

No significant differences in the ASES, SANE, or Constant scores or range-of-motion measurements were observed between the cohorts at any time point within the 2-year follow-up ($p > 0.05$) (Figs. 3-A through 4-B) (see Appendix).

Secondary outcomes improved in both cohorts at the time of the 2-year follow-up. In the stemless and stemmed cohorts, mean active forward elevation increased from 107° ± 30° to 157° ± 21° and from 109° ± 29° to 157° ± 19°, respectively, and mean active external rotation with the arm at the side increased from 24° ± 21° to 62° ± 23° and from 29° ± 23° to 59° ± 15°, respectively. In the stemless cohort, the median normalized Constant score increased from 45.0% (IQR, 34.0-57.0%) to 104.5% (IQR, 94.0-111.0%) and the mean score increased from 46.3% ± 17.1% to 101.5% ± 16.7%. In the stemmed cohort, the median Constant score increased from 45.0% (IQR, 34.0-60.0%) to 102.0% (IQR, 92.0-111.0%) and the mean score increased from 47.2% ± 17.1% to 100.2% ± 15.0%. The median SANE score was 98.0% (IQR, 10.0%) for the stemless cohort and 95% (IQR, 10.0%) for the stemmed cohort at the time of the 2-year follow-up.

## Discussion

This single-blinded, multicenter RCT demonstrated that the studied stemless shoulder implant was noninferior to the studied stemmed shoulder implant at the time of short-term follow-up after aTSA for the treatment of primary osteoarthritis. All primary outcomes showed noninferiority of the stemless implant, and no secondary outcomes differed significantly between stemless and stemmed cohorts within the 2-year follow-up period. To our knowledge, the present study represents the first Level-I evidence supporting use of a stemless humeral component.

Our results compare favorably with and expand on the results of previous, smaller RCTs comparing stemless and

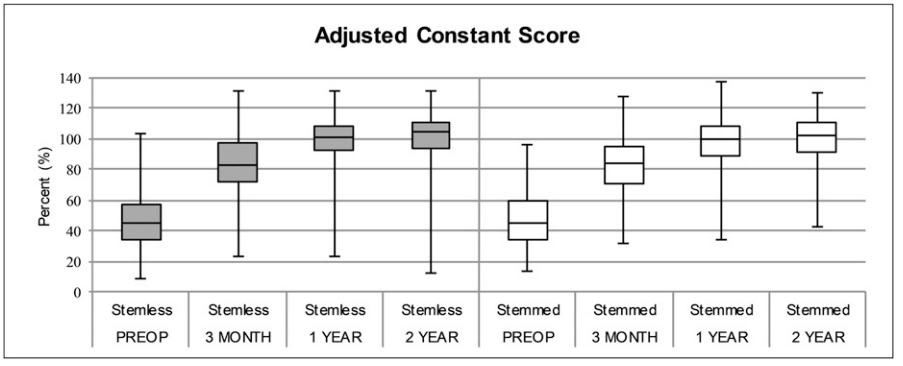


Fig. 3-C
Sex and age-adjusted Constant scores.

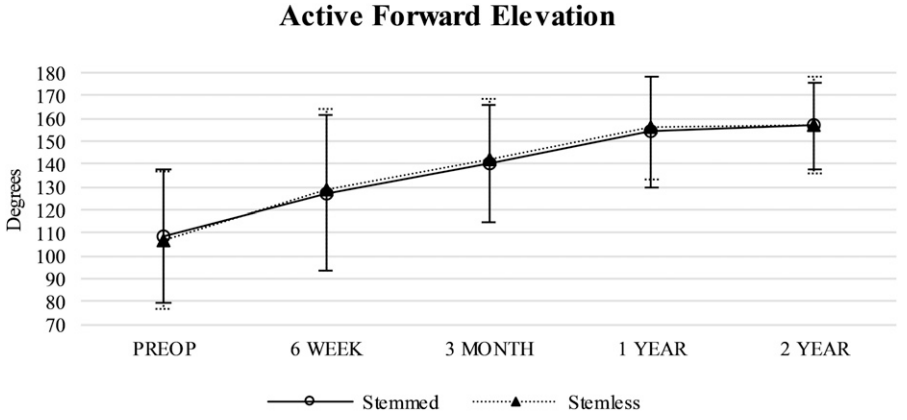


Fig. 4-A

**Figs. 4-A and 4-B** Line graphs showing the preoperative and postoperative mean range-of-motion measurements for both cohorts over time. There were no significant differences between cohorts at any time point in either measurement. Standard deviations are indicated with I-bars. (See Appendix for complete active and passive range-of-motion measurement data and comparisons.). **Fig. 4-A** Active forward elevation.

stemmed humeral implants. Most recently, in 2017, Uschok et al. reported on a 40-patient (Level-II) RCT, which showed no significant difference between stemmed and stemless cohorts in terms of the mean adjusted Constant score and range of motion at 2 and 5 years of follow-up; the mean adjusted Constant score in the stemless cohort improved from 70.7% ± 18.8% preoperatively to 83.6% ± 19.3% and 94.9% ± 18.6% at 2 and 5 years, respectively (with no significant difference between the scores at 2 and 5 years)[12]. In 2013, Razmjou et al. reported on a 74-patient (Level-II) RCT comparing 3 implants (1 stemless and 2 stemmed), which showed no significant differences in outcome scores and range of motion between cohorts, except that 1 stemmed implant had decreased external rotation at 90° of abduction at a minimum of 2 years of follow-up; the mean relative Constant score in the stemless cohort was 92 ± 24 points at 2 years[11]. Last, in 2013, Berth and Pap reported on an 82-patient RCT, which showed no significant difference between stemmed and stemless cohorts in terms of mean Constant scores and range-of-motion measurements at a minimum of 2 years of follow-up; the mean adjusted Constant score in the stemless cohort was 73.2 ± 11.3 points at 2 years[9].

The outcomes of the present study also compare favorably with those of previous large, prospective cohort studies of stemless prostheses. Churchill et al., in a study of a cohort of 157 patients who underwent stemless aTSA for the treatment of glenohumeral osteoarthritis, reported a mean adjusted Constant score of 104.1% ± 14.8% and a mean ASES score of 91.9 ± 11.4 at 2 years of follow-up[15]. Brunner et al., in a prospective multicenter study of 233 patients who underwent stemless aTSA, reported a mean relative Constant score of 78.9% (89% for patients with primary osteoarthritis) at an average of 23 months postoperatively[22].

Two other findings of the current study warrant mentioning. First, while decreased operative time has been reported as a potential benefit of stemless TSA[8,9], our data showed no significant difference between the 2 cohorts in terms of operative time. Possible explanations for this finding include (1) a learning curve effect in the current study and (2) the fact that the study by Berth and Pap compared cementless and cemented prostheses[9], whereas both cohorts in the current study received cementless prostheses. Second, 4 glenoid fractures in the stemless cohort were noted at the time of postoperative radiographic

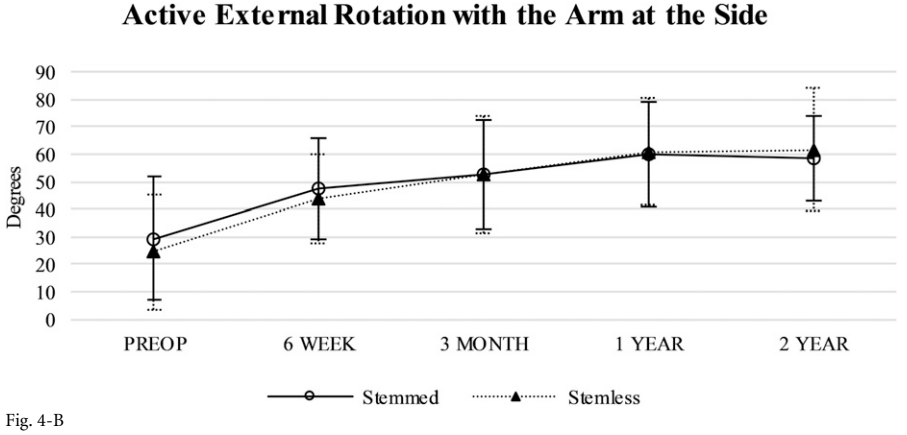


Fig. 4-B

Active external rotation with the arm at the side.

evaluation and not during surgery. The reason for this finding is unclear as there were no differences between the stemmed and stemless procedures with regard to the humeral neck cut or the glenoid exposure and preparation. All were fractures treated conservatively with observation, and all 4 patients did well clinically.

The current study had several strengths, the most notable being study design. The study was planned and powered such that statistical noninferiority of the stemless implant could be concluded. The multicenter nature of the study was another strength. In addition, no patients could cross over between treatment arms, avoiding confounding of the results.

The present study also had limitations. First, follow-up was only 2 years. Longer-term radiographic and clinical follow-up may reveal differences that are not apparent at short-term follow-up. However, it is worth noting that studies of similar stemless implants have shown no deterioration of shoulder function at intermediate-term follow-up[7,12,16,17,34]. Second, surgeons could not be blinded to treatment. To address this limitation, primary end points were chosen such that surgeon bias should have played little role: ASES scores are determined on the basis of a patient questionnaire, device failure modes were independent of the surgeon, and an independent radiographic reviewer assessed the radiographs. Third, given the low rates of device-related complications and component loosening in the present study, the 2-year follow-up rates of 87% and 90% may have introduced error; if even only a few of the patients who were lost to follow-up had device-related complications or component loosening, it could have had a substantial impact on the results. Last, it should be noted that the scope of this study was intentionally limited in order to answer a specific question, that is, whether a stemless implant is noninferior to a stemmed implant in patients with adequate metaphyseal bone quality. A single stemless implant was compared with a single stemmed implant, and patients who were considered to be poor candidates for a stemless implant (i.e., those with osteoporosis, osteomalacia, or other disorders possibly compromising fixation of the implant in the metaphysis) were excluded. The findings of this trial cannot necessarily be applied to other stemless designs, nor should they be applied to patients with poor metaphyseal bone quality.

In conclusion, this trial provides Level-I evidence that the short-term safety and effectiveness of this stemless implant was noninferior to a stemmed implant for patients who met the criteria to receive a stemless implant. While further studies are warranted to assess the long-term success of this implant, these early results are promising given the potential benefits of stemless designs over stemmed humeral components.

## Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/G114). ■

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