A multicenter, prospective 2-year analysis of the Sidus stem-free shoulder arthroplasty system

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Background: The purpose of this multicenter, prospective study was to evaluate the efficacy and safety of a stemless total shoulder arthroplasty compared with a traditional stemmed control.

Methods: Ninety-five shoulders were selected for participation in this Food and Drug Administration investigational device exemption clinical trial and underwent stemless total shoulder arthroplasty. Subjects returned for follow-up at 6 weeks, 6 months, 12 months, and 2 years postoperatively. Outcome measures included pain; range of motion; American Shoulder and Elbow Surgeons, Western Ontario Osteoarthritis of the Shoulder, and Short Form 12 scores; and radiographic review. Baseline data were compared with 2-year follow-up data to determine the rate of composite clinical success compared with the stemmed control.

Results: All outcome assessments demonstrated significant improvements (P < .007). The mean American Shoulder and Elbow Surgeons score improved from 20 to 89 (P < .0001), and the mean shoulder pain score decreased from 8.3 ± 1.6 to 0.7 ± 1.5 (P < .0001). The mean Western Ontario Osteoarthritis of the Shoulder score decreased from 1443 ± 256 to 203 ± 267 (P < .001). On the Short Form 12, the mean physical health score increased from 33 ± 7 to 48 ± 9 (P < .0001) and the mean mental health score increased from 50 ± 13 to 54 ± 8 (P = .007). Mean active forward elevation increased from 97° ± 27° to 143° ± 25° (P < .0001), and mean active external rotation increased from 21° ± 16° to 53° ± 18° (P < .0001). Kaplan-Meier analysis showed an implant survivorship rate of 98% at 2 years. The composite clinical success rate was 87% compared with 85% for the stemmed control.

Conclusions: This study showed that a stemless rough-blasted humeral implant with metaphyseal bone fixation provides good clinical and radiographic outcomes and survivorship at 2 years, with outcomes comparable to a traditional stemmed implant.

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Anatomic total shoulder arthroplasty (TSA) is a surgical procedure that can relieve pain caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, avascular necrosis, and other shoulder-related problems. TSA has successfully restored function and improved the quality of life for the large majority of patients after alternative physical and medical treatments have failed to provide pain relief.

The first shoulder arthroplasty was performed in 1893 by the French surgeon Jules-Émile Péan. In the 1950s, Charles S. Neer started the modern era of shoulder arthroplasty by performing
hemiarthroplasties of the humeral head.14 About 20 years later, with the addition of a glenoid component, Neer et al.15 described
complications.1,19,20 To avoid stem-related complications and
anatomic reconstruction by enabling the surgeon to adjust the
diameter of the medullary canal. The third generation of
Second-generation (modular) prostheses were developed to match
improvement in shoulder arthroplasty with anatomic reconstruc-
tion of the proximal humerus introduced in the early 1990s.
There has been a progressive
Implants,16 stemless implants may offer advantages such as bone
preservation.3,4
The Sidus stem-free shoulder system (Zimmer Biomet) is a
modular assembly (humer al anchor and humeral head com-
ponents), which can be adapted to an individual’s anatomy, provided that there is adequate bone stock to support the prosthesis. The
purpose of this investigational device exemption (IDE) clinical trial was to assess the clinical safety and efficacy of the Sidus stem-free
shoulder arthroplasty system at a minimum of 2 years after surgery
and compare the results with a historical stemmed humeral implant (control group).

### Materials and methods

This prospective, single-arm, historically controlled, multicenter study included 95 shoulders enrolled in the Food and Drug Administration–regulated IDE clinical trial (NCT01878253) entitled “Multicenter Trial of the Sidus Stem-Free Shoulder Arthroplasty System” conducted in the United States and Canada. Eleven clinical sites contributed data to this analysis. Enrolled patients signed informed consent forms prior to data collection. All candidates were considered for participation regardless of race, sex, and ethnicity but were required to meet specific inclusion and exclusion criteria to qualify for enrollment (Table 1). All subjects enrolled in the study received the Sidus humeral head and anchor.
Bone quality was not adequate to support stemless osteotomy plane to assess the proximal humeral bone quality. If the osteotomy, and then removed. The surgeon then palpated the meral punch was inserted over the central guide pin, impacted into was ensured that all 4 anchor collar. The appropriately sized hu-
and lesser tuberosity osteotomy, 7. After exposure, the humeral head was resected at the anatomic neck using either a freehand technique (52 patients) or resection guide (43 patients). Glenoid preparation was performed in accordance with the Anatomical Shoulder System (Zimmer Biomet) surgical technique.21 Following glenoid implantation, a trial humeral head was selected based on coverage of the humeral osteotomy. A central pin positioner was inserted into the trial head, along with a central guide pin. The trial head assembly was removed, leaving the central guide pin in the metaphysis. The metaphyseal anchor size was determined after it was ensured that all 4 anchor fins would completely seat within cancellous bone and there were no bony defects that could compromise prosthesis fixation. A countersink was inserted over the central guide pin and reaming of the resected humeral surface was performed for the anchor collar. The appropriately sized humeral punch was inserted over the central guide pin, impacted into the osteotomy, and then removed. The surgeon then palpated the osteotomy plane to assess the proximal humeral bone quality. If bone quality was not adequate to support stemless fixation, the surgeon switched to a stemmed prosthesis. If bone quality was adequate (assessed via the thumb test4), the Sidus humeral anchor implant (Zimmer Biomet) was placed over the central pin and impacted into position. The central guide pin was removed. The trial humeral head was placed onto the anchor, and a reduction was performed to assess appropriate sizing and stability. The Sidus humeral head was impacted until flush on the osteotomy plane. The shoulder was then reduced, the subscapularis was repaired, and the incision was closed (Fig. 1). All enrolled subjects followed a similar postoperative rehabilitation protocol, which involved early passive and active-assisted motion, with active motion at 6 weeks.

Outcome measures

Postoperative follow-up occurred at 6 weeks, 6 months, 1 year, and 2 years and then annually until the last subject enrolled completed 2 years of follow-up. At each visit, we collected data regarding pain, instability, range of motion, and patient satisfaction, as well as American Shoulder and Elbow Surgeons (ASES), Western Ontario Osteoarthritis of the Shoulder, and Short Form 12 (SF-12) scores. In addition, radiographs of the operative shoulder, including anteroposterior and axillary views, were obtained (Fig. 1). Radiographs were submitted for independent radiographic review (Medical Metrics, Houston, TX, USA) by 2 independent, board-certified radiologists specializing in skeletal evaluation. They were assessed for radiolucencies, device subsidence or migration, joint subluxation, device condition, and adverse events. Radiolu-
cency was measured as the distance perpendicular to the bone-implant interface in designated zones (Table II, Fig. 2).

Statistical analysis

Prior to study commencement, the sample size was calculated to provide a minimum 80% power to reject the null hypothesis of inferiority in favor of the alternative hypothesis of non-inferiority in the comparison of the percentage of successfully treated sub-
jects following the use of the Sidus stem-free shoulder vs. the historical stemmed control. The historical unmatched control group, which included subjects enrolled in the Joint Orthopaedic Initiative for National Trials of the Shoulder Canada study (“Cemented Versus Uncemented Fixation of Humeral Components in Total Shoulder Arthroplasty for Primary Osteoarthritis”12), was fixed at a sample size of 78 because of the number of uncemented stem subjects already enrolled in that study. A minimum unad-
justed sample size of 71 subjects for the treatment group was therefore required. When adjusted for a 10% rate of loss to follow-up, 3% rheumatoid arthritis, 2% post-traumatic arthritis, and 10% bilateral, the required sample size was 95.

By use of the database and results collected from the historical control, a clinical performance goal was calculated13,16,18 by an independent consultant with a master’s degree in experimental statistics (M Squared Associates, New York, NY, USA) to reduce inherent bias. All subjects used to determine the clinical perform-
ance goal were required to meet the same inclusion and exclusion criteria as the Sidus group (Table I). The criteria for historical

Figure 1 Anteroposterior (A) and axillary (B) radiographs at 2 years’ follow-up after Sidus shoulder arthroplasty for symptomatic right glenohumeral joint osteoarthritis.
control clinical success included a composite endpoint comprising positive results for all of the criteria shown in Table III. The Sidus shoulder cohort was measured against the same criteria to determine the rate of success. Study results were considered successful if the proportion of subjects in the Sidus group who were deemed to have success at the 2-year postoperative visit was non-inferior to the proportion in the control group. In addition, the safety of the Sidus implant was evaluated by monitoring the frequency and incidence of device-related adverse events or unanticipated adverse device effects in investigational subjects, as well as analyzing survivorship using revision or intended revision as an endpoint.

Results

Ninety-five shoulders in the IDE trial met the inclusion criteria for enrollment. Prior to 2 years postoperatively, 1 subject requested discontinuation from the study, 1 subject died, and 2 subjects underwent revision TSA. Of the 91 remaining shoulders, 86 (94.5% follow-up compliance)—therefore 90.5% of the original cohort—completed 2-year follow-up.

Of the 95 subjects enrolled in the combined cohort, 55 (58%) were men and 40 (42%) were women. The mean age at the time of surgery was 61 years (range, 33-81 years). The primary indication for TSA was osteoarthritis in 93% of cases (88 shoulders) and post-traumatic arthritis in 7% (7 shoulders). The mean body mass index was 31 (range, 18-53). Regarding race, 93% of the subjects were white, 4% were African American, and 1% was Asian; 2 subjects were unwilling to answer. Of the subjects, 82 (86%) reported no tobacco use whereas 13 (14%) reported tobacco use prior to surgery.

At the time of surgery, humeral bone quality was reported as normal in 72 subjects (76%) whereas 3 (3%) had cystic humeral bone, 1 (1%) had osteoporotic bone, 15 (16%) had sclerotic bone, and 4 (4%) had weak bone.

Clinical results

The results for the ASES shoulder pain score, ASES instability score, range of motion, and ASES overall score showed statistically significant improvements ($P < .0001$) at 6 weeks, 6 months, 1 year, and 2 years postoperatively compared with preoperative values. The average ASES shoulder pain score significantly improved from 8.3 at baseline to 0.7 at 2 years ($P < .0001$). The average ASES shoulder instability score significantly improved from 4.9 at baseline to 0.4 at 2 years ($P < .0001$). Regarding range of motion, active forward elevation increased from a mean of $97^\circ \pm 27^\circ$ to $143^\circ \pm 25^\circ$.
Additional details regarding complications are reported in Table V. With 98% survival at 2 years postoperatively. One revision, no device-related serious adverse events and no reoperation or revision of study implants during follow-up period

| Table III |
| Composite clinical success criteria |
| --- |
| ASES overall score improvement ≥ 30 points from baseline<sup>3,16,18</sup> |
| Radiographic success defined as follows: |
| No progressive radiolucencies of humeral component > 2 mm |
| No progressive migration or subsidence of humeral component > 5 mm |
| No device-related serious adverse events |
| No reoperation or revision of study implants during follow-up period |

ASES, American Shoulder and Elbow Surgeons.

(P < .0001) and active external rotation in adduction increased from a mean of 21° ± 16° to 53° ± 18° (P < .0001). Active external rotation at 90° of abduction increased from a mean of 26° ± 27° to 69° ± 25° (P < .0001). The mean ASES score improved from 20 ± 11 at baseline to 89 ± 13 at 2 years (P < .0001). The ASES success criterion (improvement ≥ 30 points from baseline to 2 years) was met in 85 shoulders (90%).

The mean Western Ontario Osteoarthritis of the Shoulder score significantly improved from a preoperative value of 1443 ± 256 to 203 ± 267 at 2 years (P < .0001). Significant improvements were also seen in the SF-12 physical and mental health scores (P < .0001 and P = .007, respectively); SF-12 physical scores improved from 33 ± 7 to 48 ± 9 and mental health scores improved from 50 ± 13 to 54 ± 8. Additional results are reported in Table IV.

Radiographic analysis

No humeral implants were found to have migrated or subsided at 2 years’ follow-up. Two cases of humeral radiolucency greater than 2 mm were reported at 2 years (≥4 mm in zone 1 and ≥4 mm in zone 5). These areas of lucency were not found to progress or be associated with migration, loosening, or symptoms, and outcome scores remained good (with ASES scores of 18 preoperatively and 97 at 2 years and 37 preoperatively and 87 at 2 years). The radiographic success criterion was met in 83 shoulders (87%).

Glenoid radiolucencies occurred more frequently. One patient had grade 5 glenoid radiolucency reported at 2 years that progressed from grade 2 at 6 months. The patient was asymptomatic at 2 years’ follow-up, and the device remained implanted (ASES scores of 11 preoperatively and 95 at 2 years). Four patients had grade 4 glenoid radiolucency at 2 years. One patient progressed from no radiolucency at 6 weeks to grade 4 at 6 months, 1 year, and 2 years postoperatively (ASES scores of 6 preoperatively and 75 at 2 years). One patient was reported to have grade 3 glenoid radiolucency at 6 months after surgery. This patient’s radiolucency was progressive and had increased to grade 4 at 1 year postoperatively. The same patient exhibited humeral radiolucency at 2 years. No loosening of the implant or dysfunction was reported (ASES score of 18 preoperatively and 100 at 2 years). The patient had no complaints of shoulder pain or instability and was not limited in activities of daily living. One patient reported grade 2 radiolucidity at 6 months that progressed to grade 4 at 1 year and 2 years postoperatively. This patient also remained asymptomatic (ASES score of 26 preoperatively and 100 at 2 years). One patient had grade 4 radiolucidity at 2 years that progressed from grade 1 at 6 weeks. This patient’s outcomes initially were quite favorable with an ASES score of 94 at 1 year. However, the score declined to 45 at 2 years, with activities of daily living becoming more difficult and pain reported as 7.6 of 10. Additional details regarding complications are reported in Table V.

Implant survivorship and revision

The Sidus shoulder cohort showed good survivorship rates, with 98% survival at 2 years postoperatively. One revision, conducted by a non-study surgeon at an outside hospital, was likely a result of subscapularis failure. A review of the revision operative report indicated the glenoid component was loose, the humeral head—metaphyseal anchor taper was disengaged, the anchor was loose, and the subscapularis was no longer intact. In addition, the patient was noted to have weak humeral bone. The revising surgeon hypothesized that the subscapularis was interposed between the head and anchor during the original implantation, which caused the head to not properly seat. A second revision was due to an acute subscapularis tear. At the time of open subscapularis repair, the humeral head component was incorrectly removed by using a bone tamp. As the bone tamp struck the humeral head, the entire Sidus implant shifted, necessitating a revision to a standard-length stemmed humeral component. No additional serious device-related adverse events have been reported.

Control comparison

The results of this study showed that 83 of the 95 Sidus shoulder patients included in the combined analysis met the success criteria, resulting in a clinical success rate of 87% (95% confidence interval, 79%-93%), which surpassed the historical stemmed rate of 85% (95% confidence interval, 72%-94%)<sup>10</sup> and was comparable to the 89% success rate reported for the Simpliciti Shoulder (Wright Medical Group, Nashville, TN, USA).<sup>4</sup> Further data from the historical control are reported in Table VI. Twelve shoulders included in the combined analysis did not meet the primary success criteria. Regarding these 12 shoulders, 1 subject withdrew from the study, 1 subject died, 5 subjects missed the 2-year visit, 2 subjects underwent revision of the Sidus components, 1 subject did not meet the minimum ASES score improvement from preoperatively to 2 years postoperatively (improvement < 30 points), and 2 subjects did not meet the radiographic success criterion.

Discussion

A variety of stemless shoulder designs have been available outside the United States since 2004. However, within the United States, the availability of stemless shoulder systems has been limited to only the Simpliciti total shoulder system, available in 2016; the Sidus stem-free shoulder, available in 2018; the Equinoxe Shoulder (Exactech, Gainesville, FL, USA), available in 2018; and the Arthrex Eclipse system (Arthrex, Naples, FL, USA), available in 2019. The Simpliciti and Equinoxe are porous-coated designs with a larger volumetric footprint, whereas the Sidus implant is rough blasted and has a smaller metaphyseal footprint. Even in the absence of porous coating, radiographic evidence in this cohort has shown that the Sidus shoulder has acceptable fixation and stability. In the article published by Churchill et al.,<sup>4</sup> the Simpliciti stemless implant’s clinical success was measured with similar composite clinical success criteria. The Simpliciti clinical success rate of 89% is comparable to the success rate in our study (87%) and the stemmed TSA historical control (85%).<sup>4,13</sup>

Other studies reporting clinical results of stemless total shoulder implants have shown findings comparable to those of stemmed TSA devices.<sup>5,9–11</sup> Long-term data were recently published for the Eclipse stemless shoulder arthroplasty (Arthrex) with an average follow-up period of 9 years (range, 90-127 months).<sup>9</sup> The results of the Eclipse study revealed significant clinical improvement from the preoperative measurements, with findings comparable to those of stemmed arthroplasties. In addition to clinical studies, stemless implants have been studied biomechanically and computationally.<sup>6,7,17</sup>
Stemless implants may also have an advantage in the event of revision. Holschen et al.\(^1\) reported on the results of anatomic implants revised to reverse shoulder arthroplasties. Patients who had previously undergone stemless TSA were found to have better post-revision Constant-Murley scores, in addition to better bone stock in the humerus, compared with revisions involving removal of a traditional stemmed humeral component.

Our study has several strengths including that it was a rigorous Food and Drug Administration—regulated clinical trial with thorough clinical research monitoring, adverse event reporting, and data accuracy. Comprehensive inclusion and exclusion criteria created homogeneity within the study population across 11 clinical sites in the United States and Canada. In addition, independent radiographic analysis of the historical control and the Sidus shoulder cohort offered consistency in radiographic evaluation and a reduction in bias.

This study is not without its limitations. The primary shortcoming is the observation period. Although 2-year data provide...
good knowledge concerning how the implant will perform in the short term, longer follow-up is required to determine if the positive short-term results are durable. In addition, a randomized clinical study with a concurrent control would have removed further bias, which may have been present owing to the differences in sites and potential operative techniques used between the Sidus shoulder investigators and the historical control investigators. Furthermore, the addition of the Constant-Murley score as an outcome would have allowed more comparisons to other total shoulder systems in the literature. Finally, this study was an industry-sponsored study, and as such, there are inherent biases. To limit the potential biases, independent evaluators were used whenever possible.

**Conclusion**

The results of this study demonstrate that the Sidus stem-free shoulder yields good clinical results at 2 years’ follow-up. The ASES scores, range of motion, pain, and patient satisfaction improved significantly ($P < 0.0001$) from preoperatively to 2 years postoperatively. Implant survivorship was 98% at 2 years, and radiographic results showed that 91 of the 93 surviving implants demonstrated no signs of humeral loosening, osteolysis, or migration. This prospectively monitored clinical cohort provides evidence that a rough-blasted stemless shoulder arthroplasty results in good clinical and radiographic outcomes with low complication and revision rates at 2 years’ follow-up.

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