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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 ($P \leq .007$). 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 ($P < .0001$). 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.

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.[8,11,13,19]

The first shoulder arthroplasty was performed in 1893 by the French surgeon Jules-Émile Péan.[2] In the 1950s, Charles S. Neer started the modern era of shoulder arthroplasty by performing

All clinical sites participating in this study received institutional review board (IRB) or ethics committee approval prior to study commencement. This study was approved by the Thomas Jefferson University IRB (no. 13C.291); Saint Joseph's IRB (no. 012-13-2); Chesapeake IRB (no. Pro00008424); Queen's University Research Ethics Board (REB) (no. SURG-274-13Romeo 6009897); University of Calgary REB (no. REB13-0561); Western Research REB (no. 104317); University of California, San Francisco IRB (no. 13-10947); Western IRB (no. 20131850); Penn State University IRB (no. 43571); Washington University IRB (no. 201310170); and Stanford University IRB (no. 32106).

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Table I
Sidus shoulder IDE inclusion and exclusion criteria

Inclusion criteria
• The patient must be aged ≥ 22 yr.
• The patient is skeletally mature.
• The patient must have signed the IRB- or EC-approved informed consent form.
• The patient is a candidate for a total shoulder arthroplasty (replacement of humeral head and glenoid).
• The patient has a diagnosis of primary osteoarthritis of the shoulder of grade III or higher.
• The patient has experienced symptoms of shoulder pain and/or loss of function for at least 6 mo and has a maximum ASES score of 40.
• The patient has no findings to indicate an etiology of acute trauma, infection, or avascular necrosis of the operative shoulder.
• The patient has undergone no previous reconstructive shoulder surgery. Acceptable previous shoulder surgical procedures include arthroscopy, soft-tissue repair, and pinning and/or screw fixation owing to a historical fracture.
• The patient is willing and able to comply with the required postoperative therapy as defined in the protocol.
• The patient is willing and able to comply with the required follow-up schedule as defined in the protocol.
Exclusion criteria
• The patient is a prisoner.
• The patient is a known current alcohol or drug abuser.
• The patient has a psychiatric illness or cognitive deficit that precludes informed consent.
• The patient has a chronic renal impairment or failure.
• The patient has sensitivity to implant materials.
• The patient has a vascular insufficiency due to large or small vessel disease that could inhibit postoperative healing.
• The patient is currently receiving, or has received within the last 3 mo, chronic systemic or inhaled steroids. This exclusion does not apply to those patients with occasional inhaler use for seasonal allergies.
• The patient has a local rash or skin infection around the intended operative site.
• The patient has ongoing worker's compensation or third-party liability claims related to the operative shoulder.
• The patient underwent a contralateral shoulder replacement < 6 mo ago.
• The patient will require a contralateral shoulder replacement < 6 mo after the current planned shoulder replacement.
• The patient has evidence of major joint trauma, infection, avascular necrosis, cuff tear arthropathy, chronic dislocation, massive rotator cuff tear, or previous shoulder surgery (other than arthroscopy, soft-tissue repair, or pinning and/or screw fixation owing to a historical fracture).
• The patient has significant muscle paralysis.
• The patient has Charcot arthropathy.
• The patient has metaphyseal bony defects at the bone-implant interface that could inhibit prosthesis fixation.
• The patient has preoperative computed tomography scans or other radiographic images of the shoulder that show insufficient glenoid or humeral bone stock to allow for implantation of the prosthesis.
◦ Insufficient bone stock exists in the presence of metabolic bone disease (ie, osteoporosis or severe osteopenia), cancer, and radiation.
• The patient has severe glenoid deficiency.
• The patient has a prior fracture of the operative shoulder with the presence of malunion or nonunion.
• The patient has a prior tuberosity fracture with the presence of malunion or nonunion.
• The patient has an active joint or systemic infection.
• The patient has a life expectancy < 2 yr.
• The patient has an unacceptably high operative risk.
• The patient is unwilling to sign the protocol-required informed consent form.
• The patient is unwilling to complete protocol-required radiographic imaging or the required follow-up period of 2 yr.
• The patient is known to be pregnant.
• The patient has intraoperative findings that indicate insufficient bone stock or local deformities that could inhibit prosthesis fixation. Final assessment of bone quality will be completed intraoperatively on resection of the humeral head and prior to insertion of the anchor as described in the surgical technique. If there is any doubt regarding bone quality affecting the stable fixation of the anchor, the surgeon must use a stemmed prosthesis.

IDE, investigational device exemption; *IRB*, institutional review board; *EC*, ethics committee; *ASES*, American Shoulder and Elbow Surgeons.

hemiarthroplasties of the humeral head.[14] About 20 years later, with the addition of a glenoid component, Neer et al[15] described TSA for the treatment of osteoarthritis, which served as the basis for modern shoulder implants.[16] There has been a progressive improvement in shoulder arthroplasty with anatomic reconstruction of the proximal humerus introduced in the early 1990s. Second-generation (modular) prostheses were developed to match the wide variation observed in the dimensions of the humeral head and the diameter of the medullary canal. The third generation of humeral head implants further advanced the concept of an anatomic reconstruction by enabling the surgeon to adjust the inclination and the eccentric offset of the humeral head. Despite these improvements, humeral components are still subject to complications.[1,19,20] To avoid stem-related complications and facilitate anatomic reconstruction independent of the constraints of a stem, stemless shoulder implants were developed.[3,4,9,11]

The first stemless humeral component, the Total Evolutive Shoulder System (TESS; Zimmer Biomet, Warsaw, IN, USA), was implanted in France in 2004. Since its inception, the demand for humeral canal–sparing TSA systems has grown. Although patient outcome measures indicate comparable results to stemmed 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 (humeral anchor and humeral head components), 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 I). All subjects enrolled in the study received the Sidus humeral head and anchor (Zimmer

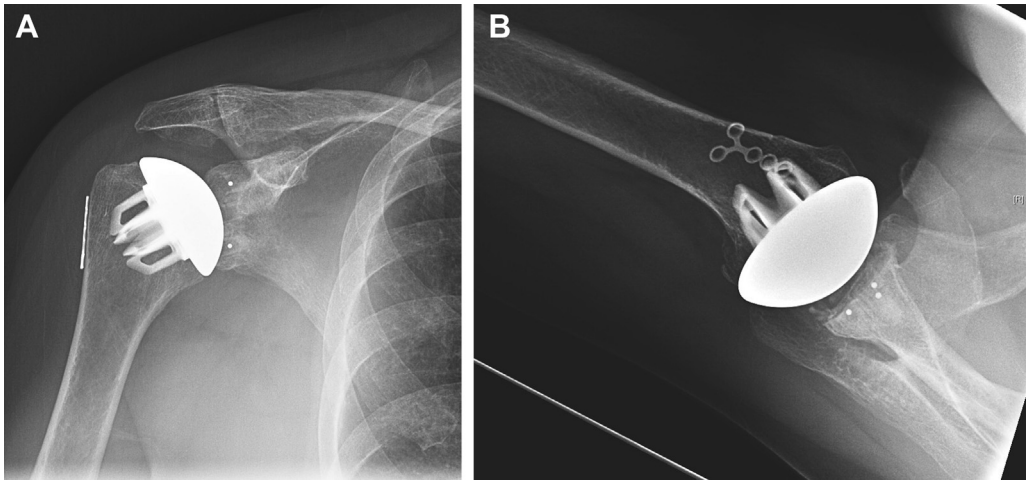

Figure 1 Anteroposterior (**A**) and axillary (**B**) radiographs at 2 years' follow-up after Sidus shoulder arthroplasty for symptomatic right glenohumeral joint osteoarthritis.

Biomet) and the Anatomical Shoulder polyethylene glenoid component (Zimmer Biomet).

Surgical technique

All participating surgeons were required to complete study-specific cadaveric and didactic training prior to implantation. Surgical preparation began with determination of implant size through preoperative radiographic templating. All surgeons used the deltopectoral approach with the patient in the beach-chair position. Subscapularis management was left to surgeon preference. A subscapularis peel approach was used in 65 patients; tenotomy, 23; 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 test[4]), 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. Radiolucency 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 subjects 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"[13]), was fixed at a sample size of 78 because of the number of uncemented stem subjects already enrolled in that study. A minimum unadjusted 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 calculated[13,16,18] 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 performance goal were required to meet the same inclusion and exclusion criteria as the Sidus group (Table I). The criteria for historical

Table II
Grading scales for humeral and glenoid radiographic findings

Glenoid radiolucency (adapted from Lazarus et al[12])
Grade 0: no evidence of radiolucency at the bone-glenoid implant interface
Grade 1: presence of incomplete radiolucency around 1 or 2 pegs
Grade 2: presence of complete radiolucency (≤2 mm wide) around 1 peg only, with or without incomplete radiolucency around 1 other peg
Grade 3: presence of complete radiolucency ≤ 2 mm wide around 2 or more pegs
Grade 4: presence of complete radiolucency > 2 mm wide around 2 or more pegs
Grade 5: presence of gross loosening
Humeral radiolucency
Grade 0: no evidence of radiolucency
Grade 1: presence of radiolucency < 1 mm in width
Grade 2: presence of radiolucency 1 to < 2 mm in width
Grade 3: presence of radiolucency 2 to < 3 mm in width
Grade 4: presence of radiolucency 3 to < 4 mm in width
Grade 5: presence of radiolucency ≥ 4 mm in width
Humeral migration
Grade 0: no evidence of migration
Grade 1: presence of migration < 2 mm
Grade 2: presence of migration 2 to < 5 mm
Grade 3: presence of migration ≥ 5 mm
Humeral subsidence
Grade 0: no evidence of caudal change in position of humeral component ≥ 5 mm
Grade 1: presence of caudal change in position of humeral component ≥ 5 mm

control clinical success included a composite endpoint comprising positive results for all of the criteria shown in Table III.[13,16,18] 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 noninferior 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 posttraumatic 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° ± 27° to 143° ± 25°

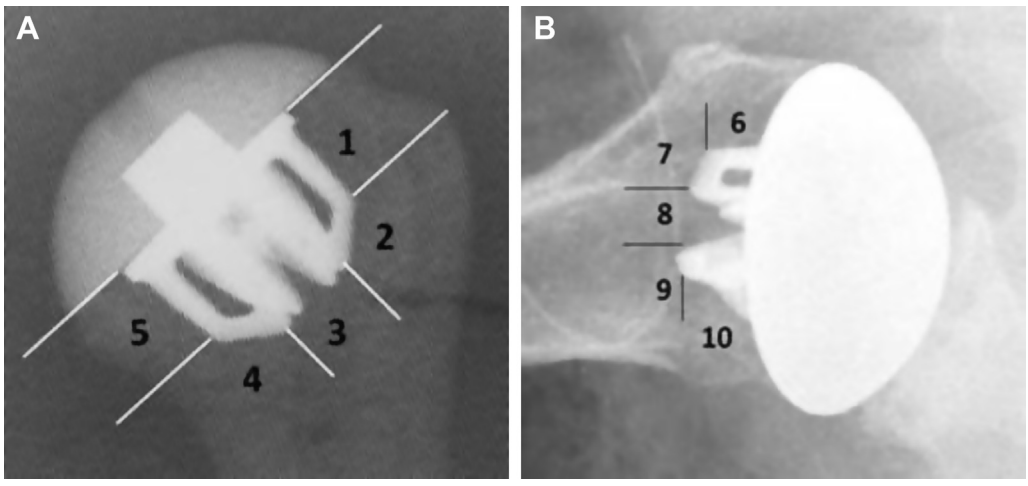

Figure 2 Radiolucency zones for Sidus shoulder device on anteroposterior (**A**) and axillary (**B**) views.

Table III
Composite clinical success criteria

ASES overall score improvement ≥ 30 points from baseline[13,16,18]
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%).[22]

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 radiolucency 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 radiolucency 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%)[10] and was comparable to the 89% success rate reported for the Simpliciti Shoulder (Wright Medical Group, Nashville, TN, USA).[4] 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,[4] 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%).[4,13]

Other studies reporting clinical results of stemless total shoulder implants have shown findings comparable to those of stemmed TSA devices.[5,9–11] 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).[9] 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.[6,7,17]

Table IV
Sidus shoulder IDE clinical outcome results

Outcome	Mean ± SD (n)	Difference from preoperative, mean ± SD	*P* value compared with preoperatively
ASES score			
Preoperative visit	20.48 ± 11.43 (95)		
6-week visit	59.83 ± 18.25 (94)	39.15 ± 20.08	<.0001
6-mo visit	80.29 ± 20.06 (90)	59.71 ± 21.26	<.0001
1-yr visit	88.13 ± 14.47 (88)	67.7 ± 17.02	<.0001
2-yr visit	89.37 ± 13.26 (86)	69.07 ± 17.27	<.0001
Shoulder pain (ASES)			
Preoperative visit	8.25 ± 1.55 (95)		
6-week visit	2.01 ± 2.42 (95)	−6.25 ± 2.71	<.0001
6-mo visit	1.29 ± 2.23 (90)	−6.94 ± 2.58	<.0001
1-yr visit	0.68 ± 1.45 (88)	−7.59 ± 2.06	<.0001
2-yr visit	0.7 ± 1.48 (86)	−7.61 ± 2.05	<.0001
Instability score (ASES)			
Preoperative visit	4.89 ± 3.7 (95)		
6-week visit	1.13 ± 1.87 (94)	−3.81 ± 4.14	<.0001
6-mo visit	0.61 ± 1.38 (90)	−4.19 ± 3.85	<.0001
1-yr visit	0.4 ± 0.88 (88)	−4.57 ± 3.62	<.0001
2-yr visit	0.39 ± 1.04 (86)	−4.66 ± 3.58	<.0001
WOOS score			
Preoperative visit	1442.81 ± 256.16 (95)		
6-week visit	803.72 ± 351.79 (95)	−639.09 ± 358.23	<.0001
6-mo visit	337.37 ± 391.5 (88)	−1096.2 ± 430.65	<.0001
1-yr visit	218.48 ± 304.26 (87)	−1214.95 ± 363.36	<.0001
2-yr visit	203.22 ± 267.38 (86)	−1237.6 ± 359.7	<.0001
SF-12 mental composite score			
Preoperative visit	49.99 ± 13.46 (95)		
6-week visit	55.08 ± 10.46 (93)	5.06 ± 12.76	.0002
6-mo visit	55.51 ± 8.43 (90)	4.95 ± 10.77	<.0001
1-yr visit	54.53 ± 9.09 (88)	4.12 ± 11.58	.0013
2-yr visit	54.47 ± 8.26 (86)	3.96 ± 13.18	.0066
SF-12 physical composite score			
Preoperative visit	32.66 ± 6.88 (95)		
6-week visit	36.47 ± 8.29 (94)	3.7 ± 8.73	<.0001
6-mo visit	44.24 ± 10.56 (90)	11.71 ± 10.55	<.0001
1-yr visit	46.17 ± 10.33 (88)	13.47 ± 10.28	<.0001
2-yr visit	47.57 ± 8.7 (86)	14.77 ± 8.38	<.0001

IDE, investigational device exemption; *SD*, standard deviation; *ASES*, American Shoulder and Elbow Surgeons; *WOOS*, Western Ontario Osteoarthritis of the Shoulder; *SF-12*, Short Form 12.

Stemless implants may also have an advantage in the event of revision. Holschen et al[10] 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

Table V
Summary of Sidus shoulder IDE complications

	Device-related adverse events reported during IDE clinical study of Sidus stem-free shoulder	
	No. of occurrences	Occurrence rate, n (%)
Adverse event		
Dermatologic	1	1 of 95 (1.1)
Greater tuberosity fracture	1	1 of 95 (1.1)
Glenoid implant loosening	4	4 of 95 (4.2)
Other shoulder-related or general complication		
Glenohumeral subluxation	5	5 of 95 (5.3)
Glenoid radiolucency	23	23 of 95 (24.2)
Progressive glenoid radiolucency	8	8 of 95 (8.4)
Humeral radiolucency	1	1 of 95 (1.1)
Intermittent shoulder pain	2	2 of 95 (2.1)
Subscapularis failure	1	1 of 95 (1.1)
Rotator cuff tear	4	4 of 95 (4.2)
Mechanical clicking	2	2 of 95 (2.1)
Mild calcar resorption	1	1 of 95 (1.1)
Revisions	2	2 of 95 (2.1)
Total No. of subjects who experienced adverse events	28	28 of 95 (29.5)

IDE, investigational device exemption.

Table VI
Summary of historical control results

Assessment	Success, n (%)
Overall patient success	41 of 48 (85.4)
Subcomponents of patient success criteria	
ASES score improvement from baseline ≥ 30 points	44 of 48 (91.7)
Radiographic success	48 of 48 (100.0)
No serious adverse events	43 of 48 (89.6)
No revision or reoperation	47 of 48 (97.9)

ASES, American Shoulder and Elbow Surgeons.

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 ($P < .0001$) 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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References

1. Athwal GS, Sperling JW, Rispoli DM, Cofield RH. Periprosthetic humeral fractures during shoulder arthroplasty. J Bone Joint Surg Am 2009;91:594–603. https://doi.org/10.2106/JBJS.H.00439.
2. Bankes MJ, Emery RJ. Pioneers of shoulder replacement: Themistocles Gluck and Jules Emile Péan. J Shoulder Elbow Surg 1995;4:259–62.
3. Churchill RS, Athwal GS. Stemless shoulder arthroplasty—current results and designs. Curr Rev Musculoskelet Med 2016;9:10–6. https://doi.org/10.1007/s12178-016-9320-4.
4. Churchill RS, Chuinard C, Wiater JM, Friedman R, Freehill M, Jacobson S, et al. Clinical and radiographic outcomes of the Simpliciti canal-sparing shoulder arthroplasty system: a prospective two-year multicenter study. J Bone Joint Surg Am 2016;98:552–60. https://doi.org/10.2106/JBJS.15.00181.
5. Collin P, Matsukawa T, Boileau P, Brunner U, Walch G. Is the humeral stem useful in anatomic total shoulder arthroplasty? Int Orthop 2017;41:1035–9. https://doi.org/10.1007/s00264-016-3371-4.
6. Comenda M, Quental C, Folgado J, Sarmento M, Monteiro J. Bone adaptation impact of stemless shoulder implants: a computational analysis. J Shoulder Elbow Surg 2019;28:1886–96. https://doi.org/10.1016/j.jse.2019.03.007.
7. Favre P, Seebeck J, Thistlethwaite PA, Obrist M, Steffens JG, Hopkins AR, et al. In vitro initial stability of a stemless humeral implant. Clin Biomech (Bristol, Avon) 2016;32:113–7. https://doi.org/10.1016/j.clinbiomech.2015.12.004.
8. Gartsman GM, Russell JA, Gaenslen E. Modular shoulder arthroplasty. J Shoulder Elbow Surg 1997;6:333–9.
9. Hawi N, Magosch P, Tauber M, Lichtenberg S, Habermeyer P. Nine-year outcome after anatomic stemless shoulder prosthesis: clinical and radiologic results. J Shoulder Elbow Surg 2017;26:1609–15. https://doi.org/10.1016/j.jse.2017.02.017.
10. Holschen M, Franetzki B, Witt KA, Liem D, Steinbeck J. Is reverse total shoulder arthroplasty a feasible treatment option for failed shoulder arthroplasty? A retrospective study of 44 cases with special regards to stemless and stemmed primary implants. Musculoskelet Surg 2017;101:173–80. https://doi.org/10.1007/s12306-017-0467-y.
11. Krukenberg A, McBirnie J, Bartsch S, Böhler N, Wiedemann E, Jost B, et al. Sidus stem-free shoulder system for primary osteoarthritis: short-term results of a multicenter study. J Shoulder Elbow Surg 2018;27:1483–90. https://doi.org/10.1016/j.jse.2018.02.057.
12. Lazarus MD, Jensen KL, Southworth C, Matsen FA 3rd. The radiographic evaluation of keeled and pegged glenoid component insertion. J Bone Joint Surg Am 2002;84-A:1174–82. https://doi.org/10.2106/00004623-200207000-00013.
13. Litchfield RB, McKee MD, Balyk R, Mandel S, Holtby R, Hollinshead R, et al. Cemented versus uncemented fixation of humeral components in total shoulder arthroplasty for osteoarthritis of the shoulder: a prospective, randomized, double-blind clinical trial—a JOINTs Canada Project. J Shoulder Elbow Surg 2011;20:529–36. https://doi.org/10.1016/j.jse.2011.01.041.
14. Neer CS II. Articular replacement for the humeral head. J Bone Joint Surg Am 1955;37-A:215–28.
15. Neer CS II, Watson KC, Stanton FJ. Recent experience in total shoulder replacement. J Bone Joint Surg Am 1982;64:319–37.
16. 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;22:206–14. https://doi.org/10.1016/j.jse.2012.04.016.
17. Santos B, Quental C, Folgado J, Sarmento M, Monteiro J. Bone remodelling of the humerus after a resurfacing and a stemless shoulder arthroplasty. Clin Biomech (Bristol, Avon) 2018;59:78–84. https://doi.org/10.1016/j.clinbiomech.2018.09.009.
18. Tashjian RZ, Deloach J, Green A, Porucznik CA, Powell AP. Minimal clinically important differences in ASES and Simple Shoulder Test scores after nonoperative treatment of rotator cuff disease. J Bone Joint Surg Am 2010;92:296–303. https://doi.org/10.2106/JBJS.H.01296.
19. van de Sande MA, Brand R, Rozing PM. Indications, complications, and results of shoulder arthroplasty. Scand J Rheumatol 2006;35:426–34. https://doi.org/10.1080/03009740600759720.
20. Wirth MA, Rockwood CA. Complications of shoulder arthroplasty. Clin Orthop Relat Res 1994:47–69.
21. Zimmer. Anatomical shoulder system surgical technique. Warsaw IN: Zimmer; 2011.
22. Zimmer. Multicenter trial of the Sidus stem-free shoulder arthroplasty system (protocol CIU 2012-12E). Warsaw IN: Zimmer; 2013.