A commentary by George S. Athwal, MD, FRCSC, is linked to the online version of this article at jbjs.org.

Clinical and Radiographic Outcomes of the Simpliciti Canal-Sparing Shoulder Arthroplasty System

A Prospective Two-Year Multicenter Study

R. Sean Churchill, MD, Christopher Chuinard, MD, J. Michael Wiater, MD, Richard Friedman, MD, FRCSC, Michael Freehill, MD, Scott Jacobson, MD, Edwin Spencer Jr., MD, G. Brian Holloway, MD, Jocelyn Wittstein, MD, Tally Lassiter, MD, Matthew Smith, MD, Theodore Blaine, MD, and Gregory P. Nicholson, MD

Background: Stemmed humeral components have been used since the 1950s; canal-sparing (also known as stemless) humeral components became commercially available in Europe in 2004. The Simpliciti total shoulder system (Wright Medical, formerly Tornier) is a press-fit, porous-coated, canal-sparing humeral implant that relies on metaphyseal fixation only. This prospective, single-arm, multicenter study was performed to evaluate the two-year clinical and radiographic results of the Simpliciti prosthesis in the U.S.

Methods: One hundred and fifty-seven patients with glenohumeral arthritis were enrolled at fourteen U.S. sites between July 2011 and November 2012 in a U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE)-approved protocol. Their range of motion, strength, pain level, Constant score, Simple Shoulder Test (SST) score, and American Shoulder and Elbow Surgeons (ASES) score were compared between the preoperative and two-year postoperative evaluations. Statistical analyses were performed with the Student t test with 95% confidence intervals. Radiographic evaluation was performed at two weeks and one and two years postoperatively.

Results: One hundred and forty-nine of the 157 patients were followed for a minimum of two years. The mean age and sex-adjusted Constant, SST, and ASES scores improved from 56% preoperatively to 104% at two years ($p < 0.0001$), from 4 points preoperatively to 11 points at two years ($p < 0.0001$), and from 38 points preoperatively to 92 points at two years ($p < 0.0001$), respectively. The mean forward elevation improved from 103° ± 27° to 147° ± 24° ($p < 0.0001$) and the mean external rotation, from 31° ± 20° to 56° ± 15° ($p < 0.0001$). The mean strength in elevation, as recorded with a dynamometer, improved from 12.5 to 15.7 lb (5.7 to 7.1 kg) ($p < 0.0001$), and the mean pain level, as measured with a visual analog scale, decreased from 5.9 to 0.5 ($p < 0.0001$). There were three postoperative complications that resulted in revision surgery: infection, glenoid component loosening, and failure of a subscapularis repair. There was no evidence of migration, subsidence, osteolysis, or loosening of the humeral components or surviving glenoid components.

Conclusions: The study demonstrated good results at a minimum of two years following use of the Simpliciti canal-sparing humeral component. Clinical results including the range of motion and the Constant, SST, and ASES scores improved significantly, and radiographic analysis showed no signs of loosening, osteolysis, or subsidence of the humeral components or surviving glenoid components.

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

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In 1955, Neer described the use of a stemmed monoblock hemiarthroplasty for proximal humeral fractures[1]. Indications expanded to include shoulder osteoarthritis and, after the addition of a prosthetic glenoid component, the first results of total shoulder arthroplasty were reported in 1974[2]. Over the next forty years, the humeral stem evolved but remained the mode of fixation of a prosthetic humeral head to the humerus.

Stem-related complications, although rare, present a difficult challenge in shoulder arthroplasty[3-20]. The prevalence of periprosthetic humeral fractures during total shoulder arthroplasty is 1.5%[3], and the prevalence of such fractures following total shoulder arthroplasty is between 1.6% and 2.4%[12]. While many periprosthetic fractures are treated nonoperatively, others require surgical management with conversion to a long-stem component, open reduction and internal fixation, or conversion to a reverse arthroplasty[3,5,6,16,19,20]. Long-term concerns associated with humeral stems include proximal humeral bone loss due to stress shielding, humeral stem loosening, and osteolysis[13,14,17]. For patients who require surgical treatment, removal of a well-fixed humeral stem can be difficult and can result in additional destruction of proximal humeral bone[21-24]. Ultimately, bone loss, regardless of its etiology, can limit reconstructive options and the clinical success of revision operations[8,21,23,24].

Canal-sparing (also known as stemless) humeral components became commercially available in Europe in 2004. The Simpliciti total shoulder system (Wright Medical, formerly Tornier) is a press-fit, porous-coated, canal-sparing humeral implant that relies on metaphyseal fixation only. Canal-sparing shoulder arthroplasty does not violate the humeral canal and potentially provides a solution to stem-related complications. Not to be confused with humeral resurfacing (implantation of a metallic cap over the remaining humeral head bone stock), canal-sparing arthroplasty requires a standard humeral head osteotomy at the level of the anatomic neck, similar to that used for a standard stemmed humeral component. Surgical access to the glenoid is the same as that used for primary anatomic total shoulder arthroplasty. Canal-sparing shoulder arthroplasty relies on metaphyseal fixation of the humeral component. The humeral canal is not disturbed, thus eliminating the need for diaphyseal humeral preparation, and revision is potentially made easier by preservation of the humeral bone. Furthermore, restoration of the anatomic position of the humeral head is more reliable because the prosthetic humeral head is centered on the humeral cut, regardless of the relationship between the metaphysis and diaphysis.

As is the case with stemmed implants, canal-sparing arthroplasty can have complications such as acute loosening due to poor host-bone quality or inadequate implant design, and mid-term to long-term loosening secondary to progressive osteolysis or stress shielding.

The purpose of this study was to determine the clinical and radiographic outcomes, after a minimum of two years of follow-up, to establish the safety of a canal-sparing humeral component for total shoulder arthroplasty.

Materials and Methods

We performed a prospective, single-arm, multicenter study of 157 consecutive patients who had indications for total shoulder replacement, met the inclusion and exclusion criteria, and had consented to receive a

TABLE I Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Age ≥ 22 yr	Metal or polyethylene allergies
Clinical indication for total shoulder replacement due to osteoarthritis and/or posttraumatic arthritis	Current infection of shoulder
Preoperative Constant score > 20 points	Distant or systemic infection
Willingness and ability to comply with study protocol	Medical condition or balance impairment that could lead to falls
	Prior open shoulder surgery
	Any full-thickness rotator cuff tear identified before or at time of surgery
	Lack of sufficient-quality bone to seat and support implant
	Nonfunctional deltoid muscle
	Neuromuscular compromise of shoulder
	Active metastatic or neoplastic disease
	Chemotherapy treatment within 6 mo before surgery
	>5 mg/day of corticosteroids, excluding inhalers, within 3 mo before surgery
	Pregnancy or plan to become pregnant during study period
	Inability to understand study or a history of noncompliance with medical advice
	Alcohol or drug abuse
	Ongoing participation in manual labor or sports activities that could affect shoulder outcome
	Current enrollment in any clinical research study that might interfere with this study

TABLE II Screening Evaluations and Enrollment

Medical history
Pregnancy test for women of child-bearing age
Physical examination
Shoulder radiographs: true anteroposterior view, axillary view
Range of motion: elevation in scapular plane, internal rotation with arm at side, external rotation with arm at side
Constant score
SST score
ASES score

Simpliciti canal-sparing total shoulder arthroplasty and participate in the study. The study was done at fourteen study sites (by sixteen surgeons) throughout the U.S.; the participants at each center obtained approval for the study from their individual institutional review board.

The Simpliciti implant was used for 31.4% (157) of the 500 primary anatomic total shoulder arthroplasties performed by the study surgeons during the enrollment period. Of the patients who did not receive the Simpliciti implant, 171 (49.9%) were male, 170 (49.6%) were female, and two (0.6%) did not have their sex recorded.

The index operations were performed between July 2011 and November 2012. To control bias, the U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) study protocol for the Simpliciti canal-sparing arthroplasty system was followed for all patients and at all centers. This protocol included preoperative inclusion and exclusion criteria and a preoperative screening evaluation (Tables I and II). Subjects who did not meet the inclusion and exclusion criteria were not asked to provide informed consent to be included in the study. Criteria such as bone quality and full-thickness rotator cuff tears were evaluated intraoperatively. One hundred and eighty-one subjects signed the consent form, and 157 underwent implantation of the Simpliciti component (i.e., were considered enrolled in the study). Preoperative screening (Table II) and intraoperative evaluation led to exclusion of twenty-four patients (thirteen male and eleven female) after they signed the informed consent form, for the reasons described in Table III.

The Simpliciti humeral component, called a "nucleus," is a canal-sparing implant with a three-fin design that engages the metaphyseal region of the proximal part of the humerus (Figs. 1 and 2). The humeral preparation technique creates a press-fit impaction of the nucleus into the metaphyseal bone, providing initial fixation. The fins and undersurface of the collar are coated with an asymmetrical, titanium-bead, sintered porous coating that promotes bone ingrowth for long-term implant stability. The Simpliciti implant is available in three sizes and has a female Morse taper similar to the taper in standard stemmed shoulder arthroplasty systems. Numerous humeral heads are available in a variety of heights and diameters to allow for anatomic reconstruction and soft-tissue balancing of the shoulder. The surgeon pairs the implant with a corresponding Affiniti, Aequalis pegged, or Aequalis keeled glenoid component (Wright Medical, formerly Tornier).

All surgical procedures were performed by a shoulder reconstruction specialist. A standard deltopectoral surgical approach was used, and subscapularis management was performed via a tenotomy, lesser tuberosity osteotomy, or subscapularis peel according to the surgeon's preference. The humeral osteotomy was performed at the anatomic neck in native retroversion; at this point, the surgeon evaluated the quality of the metaphyseal bone. Initial evaluation involved visual inspection of the neck cut surface. If cystic formation or bone voids were evident, the bone quality was not deemed acceptable for implantation. Next the surgeon attempted to compress the neck cut surface with his/her thumb. Bone that was easily compressed with minimal force was also considered not sufficient for implantation. If the physician subjectively determined that the bone had sufficient strength to support the press fit of the nucleus, the humerus was prepared with the standardized surgical technique outlined in the protocol: a guide-pin was placed in the center of the cut surface of the humeral head, and sequential bone preparation was completed with cannulated instrumentation (Fig. 3). With the three-finned blazer in place, the surgeon tested for stability. If the blazer rotated within the bone, the bone was considered inadequate for implantation of the canal-sparing device. If the bone was still considered acceptable, a metallic humeral cut protector was secured to the trial Simpliciti nucleus to prevent proximal humeral bone damage during glenoid exposure and preparation. The glenoid was then prepared and the glenoid component was implanted via

Fig. 1

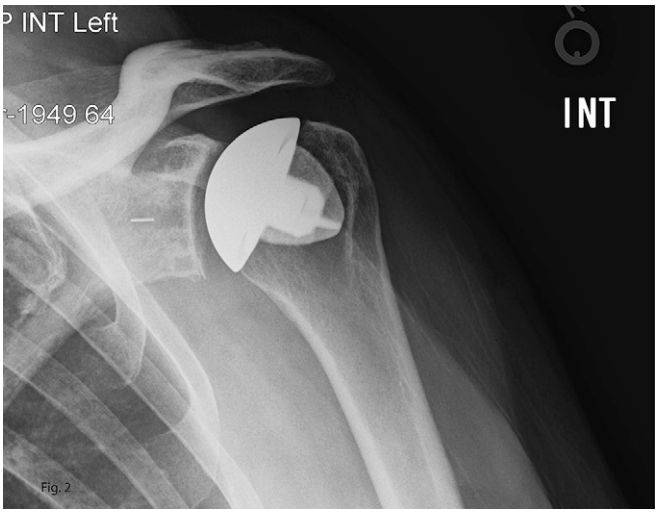

Fig. 2

Fig. 1 Simpliciti nucleus and modular humeral head. Published with permission from Wright Medical, formerly Tornier. **Fig. 2** Anteroposterior shoulder radiograph of the Simpliciti canal-sparing total shoulder system after two years of follow-up. Published with permission from Wright Medical, formerly Tornier.

TABLE III Reasons for Exclusion Based on Screening

Reason for Exclusion	% (No. with Reason/Total No. of Exclusions)
Constant score < 20 points	17% (4/24)
Lack of sufficient sound bone to seat and support implant	33% (8/24)
Full-thickness rotator cuff tear at time of surgery	25% (6/24)
Alcohol or drug abuse	4% (1/24)
Enrollment closed	8% (2/24)
Other*	13% (3/24)

*Surgery cancelled due to abnormal laboratory values (one patient), subject decided against replacement surgery (one), or health-insurance issue (one).

standard technique. The cut protector was then removed to complete trialing of the humeral head implant, prior to removal of the trial nucleus. The definitive Simpliciti nucleus was then inserted 75% of the way into the metaphyseal bone, and the appropriate centric humeral head implant was attached. Impaction of the humeral head implant seated the Morse taper, and further impaction seated the Simpliciti nucleus onto the humeral head cut surface. The surgeon then performed subscapularis repair (in 79% of the patients, with 44% having tendon-to-tendon repair, 33% having tendon-to-bone repair, and 2% having transosseous tendon-to-tendon repair) or lesser tuberosity repair (in 21% of the patients) and surgical wound closure according to his/her preference in standard fashion.

The postoperative rehabilitation protocol involved initiation of therapy within twenty-four hours after surgery. Postoperative sling immobilization was used on the initial day, and using it beyond the initial day was according to surgeon preference; the duration of sling use ranged from one day to one month. Range-of-motion therapy was performed for the first six weeks, advancing according to surgeon preference. Active shoulder strengthening was initiated at eight weeks and continued as necessary.

Postoperative follow-up visits were at two weeks, three months, six months, twelve months, and twenty-four months. Study investigators or qualified research staff performed all study evaluations, including range-of-motion measurements (using a long-arm goniometer) and calculation of Constant, Simple Shoulder Test (SST), and American Shoulder and Elbow Surgeons (ASES) scores (Table IV). Strength testing was performed using a standard method, as proposed by Bankes et al.[25]. Radiographs obtained at two weeks, twelve months, and twenty-four months postimplantation were analyzed for signs of system loosening, migration, osteolysis, and subsidence by three independent musculoskeletal radiologists who were blinded to each other's results. Each radiologist, who was board-certified and had more than two years' experience with the radiographic evaluation of orthopaedic devices, was trained on the study protocol and procedure for interpreting the radiographs. Subsidence was defined as translational motion of the implant relative to the humerus or to the glenoid cavity leading to sinking or impaction into the proximal part of the humerus. Migration was defined as any other translation or rotation of the implant relative to the humerus. Osteolysis was defined as focal or extended periprosthetic lobulated radiolucency representing bone loss due to implant-associated inflammatory processes at the implant-bone interface. Loosening was determined by evaluating the presence of radiolucent lines within seven zones around the prosthesis (Fig. 4) and was defined as a

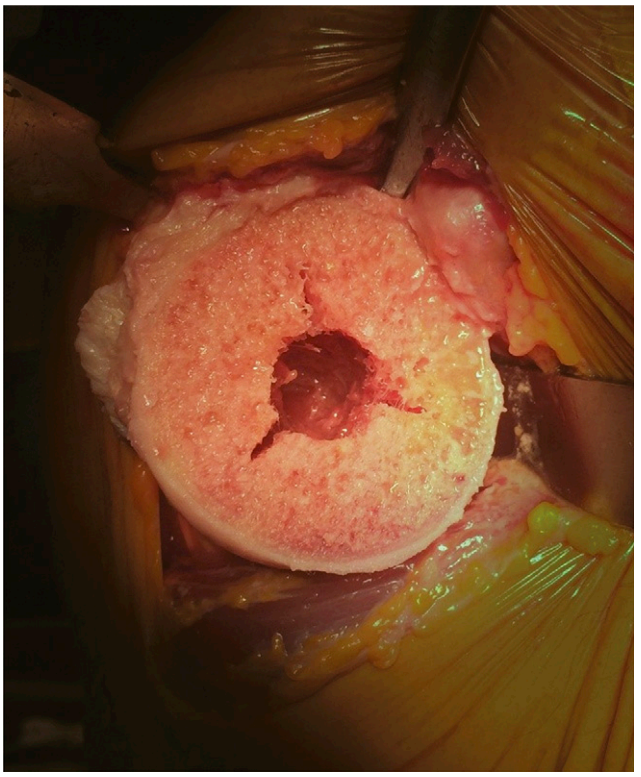

Fig. 3

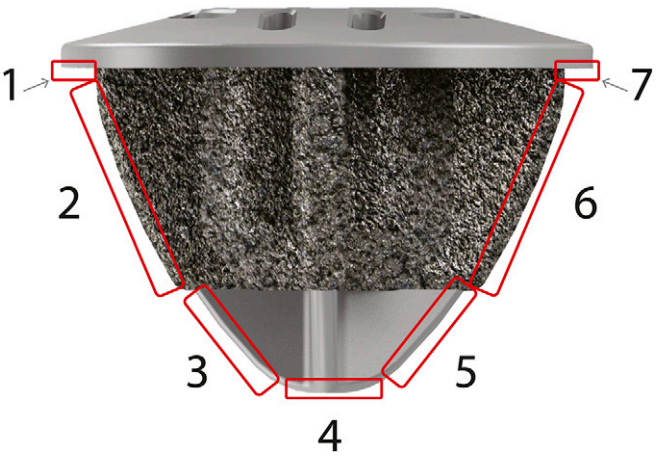

Fig. 4

Fig. 3 Prepared proximal part of the humerus. Published with permission from Wright Medical, formerly Tornier. **Fig. 4** Radiographic zones for the Simpliciti nucleus. Published with permission from Wright Medical, formerly Tornier.

TABLE IV Summary of Tests and Procedures at Each Follow-up Visit

Time	Test and Procedure
2 wk	Physical examination
	Wound check
	Shoulder radiographs
	True anteroposterior view in internal rotation
	True anteroposterior view in neutral rotation
	Axillary view
	Adverse-event query
3 and 6 mo	Physical examination
	Range of motion
	Elevation in scapular plane
	Internal rotation with arm at side
	External rotation with arm at side
	Constant score (does not have to be obtained at 3 mo if physician concerned about status of subscapularis; physician can wait until 6 mo)
	ASES score
	SST score
	Adverse-event query
12 and 24 mo	Physical examination
	Shoulder radiographs
	True anteroposterior view in internal rotation
	True anteroposterior view in neutral rotation
	Axillary view
	Range of motion
	Elevation in scapular plane
	Internal rotation with arm at side
	External rotation with arm at side
	Constant score
	ASES score
	SST score
	Adverse-event query

continuous radiolucent line around the entire device. The maximum thickness of the radiolucent line within each zone was recorded as <1 mm, 1 to 2 mm, or >2 mm. If there was disagreement about the radiolucent line measurement, it was considered to be the measurement chosen by two of the three radiologists. There were no instances in which the three radiologists recorded three different measurements. The radiographic measurements were evaluated by an independent statistician to determine intraobserver and interobserver agreement.

Statistical Methods

This study was prospectively powered to demonstrate non-inferiority to a performance goal based on a historical success rate of 75% for stemmed implants and a non-inferiority margin of 10%[26]. The Simpliciti total shoulder implant was considered successful at twenty-four months postoperatively if there was no continuous radiolucent line around the prosthesis, the age and sex-adjusted Constant score was >85%, no revision surgery had been performed, and the patient did not have a system-related serious adverse event. It was determined that a sample size of 133 subjects would provide at least 80% power with a one-sided alpha of 0.05, but 157 subjects were enrolled to allow for up to 15% attrition at twenty-four months. The Simpliciti total shoulder system was considered successful if, at twenty-four months postoperatively, it had met the performance goal in the study. Patients who required revision of any component of the Simpliciti total shoulder system were considered to have had a failure of the system.

Data were summarized using SAS 9.4 software. Descriptive statistics including the mean, standard deviation, range, and median for continuous data and the count and percentage for categorical data were calculated. For continuous assessments over time, post-hoc comparison of changes from baseline to each visit were evaluated for significance with the use of a paired Student t test with an alpha of 0.05 considered significant; no adjustments for multiple testing were made.

Results

The mean age of the forty-five women and 112 men was sixty-six years (range, thirty-seven to eighty-four years). Of the 157 enrolled subjects, eight were dropped from the study because of explantation during the index procedure (one patient), explantation after the index procedure and conversion to a reverse total shoulder arthroplasty (one), death (one), loss to follow-up for unknown reasons (one), and withdrawal of consent to be included in the study (three). The data for these patients were not included in the final twenty-four-month efficacy analysis. All of the 149 subjects remaining (95%), forty-two women and 107 men, had a minimum of two years of follow-up. The diagnosis was primary glenohumeral osteoarthritis in 96% of the subjects and posttraumatic osteoarthritis in 4%. The mean body mass index was 31 kg/m^2 (range, 18 to 48 kg/m^2). The dominant limb was operated on in 53% of the cases.

No intraoperative complications or humeral fractures occurred. All surgical wounds healed, and there was one postoperative infection requiring revision surgery.

Clinical Results

All shoulder outcome measures (Constant score, age and sex-adjusted Constant score, SST score, and ASES score), the range of motion, and pain scores were significantly improved ($p < 0.0001$) at the three, six, twelve, and twenty-four-month intervals, compared with baseline. The strength measurements were significantly improved ($p < 0.0001$) at twelve and twenty-four months, compared with baseline.

The mean Constant score improved from 44 points preoperatively to 81 points at the final (two-year) follow-up evaluation ($p < 0.0001$), and the mean age and sex-adjusted Constant score improved from 56% to 104% ($p < 0.0001$). The mean SST score improved from 4 to 11 points ($p < 0.0001$), and the mean ASES score improved from 38 to 92 points ($p < 0.0001$). The mean elevation in the scapular plane (and standard deviation) improved from 103° ± 27° to 147° ± 24° ($p < 0.0001$), the mean internal rotation with the arm at the side improved from 64° ± 24° to 74° ± 17° ($p < 0.0001$), and the mean external rotation improved from 31° ± 20° to 56° ± 15° ($p < 0.0001$). The mean pain score on a visual analog scale (VAS) significantly decreased from 5.9 to 0.5 ($p < 0.0001$), and the mean elevation strength measured with a dynamometer significantly improved from 12.5 to 15.7 lb (5.7 to 7.1 kg) ($p < 0.0001$) (Table V).

TABLE V Summary of Primary Results

Characteristic	Mean ± Stand. Dev. (No. of Patients) [T Test P Value]				
	Baseline	3 Mo	6 Mo	12 Mo	24 Mo
SST score *(points)*					
Value	4.3 ± 2.7 (157)	8.3 ± 2.6 (156)	10.0 ± 2.2 (156)	10.6 ± 1.9 (154)	10.8 ± 1.7 (148)
Change from baseline	—	3.9 ± 3.1 (156) [p < 0.0001]	5.7 ± 3.0 (156) [p < 0.0001]	6.2 ± 3.0 (154) [p < 0.0001]	6.4 ± 2.9 (148) [p < 0.0001]
ASES score *(points)*					
Value	38.2 ± 17.0 (157)	75.2 ± 17.2 (156)	85.6 ± 14.7 (156)	90.3 ± 13.1 (154)	91.9 ± 11.4 (149)
Change from baseline	—	37.0 ± 23.4 (156) [p < 0.0001]	47.4 ± 21.6 (156) [p < 0.0001]	51.9 ± 20.8 (154) [p < 0.0001]	53.2 ± 19.2 (149) [p < 0.0001]
Pain VAS score *(points)*					
Value	5.9 ± 2.5 (157)	1.5 ± 1.8 (156)	0.9 ± 1.6 (156)	0.6 ± 1.3 (154)	0.5 ± 1.2 (149)
Change from baseline	—	−4.4 ± 2.9 (156) [p < 0.0001]	−5.0 ± 2.7 (156) [p < 0.0001]	−5.2 ± 2.7 (154) [p < 0.0001]	−5.3 ± 2.5 (149) [p < 0.0001]
Elevation in scapular plane *(deg)*					
Value	102.8 ± 26.9 (157)	123.2 ± 30.3 (155)	138.3 ± 22.9 (155)	143.8 ± 23.1 (154)	146.6 ± 23.7 (149)
Change from baseline	—	20.4 ± 37.7 (155) [p < 0.0001]	35.5 ± 30.1 (155) [p < 0.0001]	40.6 ± 29.3 (154) [p < 0.0001]	43.5 ± 30.0 (149) [p < 0.0001]
Internal rotation *(deg)*					
Value	64.3 ± 24.4 (157)	73.0 ± 17.5 (155)	73.7 ± 16.9 (155)	75.5 ± 15.3 (154)	73.9 ± 16.5 (149)
Change from baseline	—	9.0 ± 20.1 (155) [p < 0.0001]	9.4 ± 18.5 (155) [p < 0.0001]	11.5 ± 19.6 (154) [p < 0.0001]	9.8 ± 23.5 (149) [p < 0.0001]
External rotation *(deg)*					
Value	30.9 ± 20.2 (157)	48.1 ± 16.1 (155)	53.7 ± 14.2 (155)	55.3 ± 15.4 (154)	56.4 ± 15.4 (149)
Change from baseline	—	17.1 ± 21.7 (155) [p < 0.0001]	22.9 ± 20.3 (155) [p < 0.0001]	24.1 ± 21.7 (154) [p < 0.0001]	25.8 ± 21.9 (149) [p < 0.0001]
Strength *(lb*)*					
Value	12.5 ± 6.4 (153)	11.6 ± 5.5 (89)	12.8 ± 6.0 (138)	14.7 ± 6.7 (146)	15.7 ± 7.8 (143)
Change from baseline	—	−1.3 ± 5.8 (89) [p = 0.0433]	0.4 ± 5.6 (138) [p = 0.4176]	2.0 ± 6.0 (146) [p = 0.0001]	2.7 ± 6.7 (143) [p < 0.0001]
Constant score *(points)*					
Value	44.3 ± 13.5 (153)	66.0 ± 12.3 (89)	74.6 ± 11.5 (138)	79.4 ± 9.9 (146)	80.7 ± 10.5 (143)
Change from baseline	—	22.1 ± 16.6 (89) [p < 0.0001]	30.4 ± 14.0 (138) [p < 0.0001]	34.9 ± 13.3 (146) [p < 0.0001]	35.9 ± 14.7 (143) [p < 0.0001]
Adjusted Constant score *(%)*					
Value	55.6 ± 16.6 (153)	84.1 ± 17.2 (89)	94.9 ± 16.8 (138)	101.5 ± 15.0 (146)	104.1 ± 14.8 (143)
Change from baseline	—	28.4 ± 21.7 (89) [p < 0.0001]	39.4 ± 19.3 (138) [p < 0.0001]	45.6 ± 18.3 (146) [p < 0.0001]	47.8 ± 19.7 (143) [p < 0.0001]

*1 lb = 0.45 kg.

Clinical success, defined as an age and sex-adjusted Constant score of >85%, no revision surgery, no continuous radiolucent line, and no serious system-related adverse event, was achieved in 88.7% of the subjects (83.6% lower bound of the 95% confidence interval). This success rate exceeded the performance goal of 65% success (75% − 10%). The individual

components of the success criteria were comparable between the Simpliciti implants in this study and historical data for stemmed implants obtained from the unpublished Tornier Aequalis post-market surveillance database[26].

Radiographic Results

At two years postoperatively (n = 149), there were no radiolucent lines and no evidence of migration, subsidence, osteolysis, or loosening in any zones of the humeral components or surviving glenoid components.

Safety Results

There were no revisions for loosening of the humeral component. There were five revision operations, two at the time of the index procedure and three postoperatively. Of the two revisions performed during the index procedure, the first was due to insufficient bone quality for fixation of the nucleus and a stemmed component was implanted. This was one of the patients who was excluded on the basis of intraoperative evaluation, showing poor bone quality. The second was performed after a size-2 component was implanted and the surgeon felt that it was not sufficiently stable and a larger size was needed; it was replaced with a size-3 component intraoperatively and the patient was doing well at the time of writing.

Three revisions were performed postoperatively. One patient underwent conversion to a reverse total shoulder arthroplasty because of subscapularis failure at fifteen months postoperatively and was subsequently dropped from the study; the components were found to be well fixed with evidence of bone growth into the humeral component. The second revision operation was an irrigation and debridement procedure with humeral head exchange performed four weeks postoperatively because of infection; the nucleus was felt to be well fixed and was left in place. The infection subsequently resolved. The third revision was due to glenoid loosening at eighteen months; at the revision operation the nucleus was found to be well fixed and left in place and the revision of the glenoid component was performed with impaction grafting.

Discussion

There have been a few recent reports on the short-term results of canal-sparing shoulder arthroplasty with prosthetic designs other than the Simpliciti system, performed for various indications. In what we believe to be the first report on canal-sparing shoulder arthroplasty, published in 2010, Huguet et al.[27] reported the results at a minimum of three years following use of the TESS implant (Biomet) in sixty-three shoulders operated on for various conditions. They noted that the mean Constant score improved from 30 points postoperatively to 75 points at the last follow-up evaluation and that the revision rate was 11%. The most recent postoperative radiographs indicated no subsidence, loosening, osteolysis, stress shielding, or radiolucent lines surrounding the surviving components. Since that initial report, five more articles regarding various aspects of canal-sparing shoulder arthroplasty have been published[28-32].

Our patients had significant improvements ($p < 0.0001$) in Constant, SST, ASES, and pain scores as well as in range of motion and strength at a minimum of two years postoperatively, results similar to those reported after stemmed total shoulder arthroplasty[33,34]. Radiographs showed no failures of the humeral component at two years and no instances of radiolucent lines, migration, osteolysis, or subsidence of the nucleus or surviving glenoid component. While the follow-up period in this study was short, the data suggest that the Simpliciti canal-sparing humeral component is safe and effective for the treatment of shoulder osteoarthritis and is an acceptable alternative to a standard stemmed humeral component in patients with acceptable bone quality.

The strengths of this study include the multicenter, prospective format as well as the large sample size of 157 patients, all of whom received a total shoulder arthroplasty. The rigorous study inclusion and exclusion criteria provided a uniform patient population. With follow-up data points at two weeks (for safety results and radiographs), three months, six months, twelve months, and twenty-four months, progressive improvements in the Constant, SST, and ASES scores were observed. Radiographic analysis by independent musculoskeletal radiologists at three scheduled follow-up intervals at two weeks, twelve months, and twenty-four months also strengthens this study compared with other canal-sparing arthroplasty studies[27-32], and demonstrates radiographic evidence of stability of this prosthesis at two years postoperatively.

This study had several weaknesses, involving patient enrollment, bone assessment, and outcome measurement. Given that historical data for the Tornier Aequalis system, a stemmed implant, were available for comparison purposes, only a single-armed format was deemed necessary to assess the safety and efficacy of the Simpliciti system. Without a concurrent control group, the results that we observed cannot be explicitly compared with those of other systems. No attempt was made to record the number of patients who met the inclusion/exclusion criteria but declined to participate in the study. In addition, bone-quality assessment was a subjective evaluation at the time of the operation. No objective test was performed on the bone to indicate whether it had sufficient strength to accept the implant. Lastly, the outcome measurements were performed by either the surgeon or qualified research personnel involved in the study rather than by medical personnel blinded to the patient's operation or the prosthesis implanted.

In conclusion, the present study demonstrates good results using the canal-sparing Simpliciti total shoulder system (a press-fit, bone-ingrowth, canal-sparing humeral component) after a minimum of two years of follow-up. The clinical results, including the range of motion and Constant, SST, and ASES scores, were comparable with historical results for stemmed humeral systems. Radiographic analysis showed no signs of loosening, subsidence, or migration of the humeral components or surviving glenoid components. Future studies are needed to

establish the intermediate and long-term effectiveness and survivorship of the device. ■

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R. Sean Churchill, MD[1]
Christopher Chuinard, MD[2]
J. Michael Wiater, MD[3]
Richard Friedman, MD, FRCSC[4]
Michael Freehill, MD[5]
Scott Jacobson, MD[6]
Edwin Spencer Jr., MD[7]
G. Brian Holloway, MD[7]
Jocelyn Wittstein, MD[8]
Tally Lassiter, MD[8]
Matthew Smith, MD[9]
Theodore Blaine, MD[10]
Gregory P. Nicholson, MD[11]

[1]Aurora Medical Center-Grafton,
Grafton, Wisconsin

[2]Great Lakes Orthopaedic Center,
Traverse City, Michigan

[3]Beaumont Health,
Royal Oak, Michigan

[4]Department of Orthopaedics,
Medical University of South Carolina,
Charleston, South Carolina

[5]Sports and Orthopaedic Specialists,
Edina, Minnesota

[6]Ortho & Neuro Center of the Cascades,
Bend, Oregon

[7]Knoxville Orthopaedic Clinic,
Knoxville, Tennessee

[8]Clinical Research Division,
Bassett Healthcare Network Research Institute,
Cooperstown, New York

[9]Missouri Orthopaedic Institute,
Columbia, Missouri

[10]Department of Orthopaedics and Rehabilitation,
Yale University School of Medicine,
New Haven, Connecticut

[11]Midwest Orthopedics at Rush,
Rush University Medical Center,
Chicago, Illinois

E-mail address for R.S. Churchill:
Sean.churchill@aurora.org

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