# Clinical and Radiographic Outcomes of the Simpliciti Canal-Sparing Shoulder Arthroplasty System: A Prospective Two-Year Multicenter Study

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Stemmed humeral arthroplasty components have been the standard of care since the 1950s with designs becoming smaller with next generations of platform systems. In the early 2000s, the first commercially available stemless device was introduced in Europe to address long-term concerns of proximal humeral bone loss due to stress shielding, humeral stem loosening and osteolysis. Also, for patients who may need surgical treatment, removal of a well-fixed stem can create challenges and result in proximal humeral bone destruction. Attempting to reduce the potential humeral complications of anatomic shoulder arthroplasty, stemless designs are reliant on metaphyseal fixation only and provide access to the glenoid in the same manner as using a stemmed humeral component. Clinical concerns of utilizing only a metaphyseal system include acute loosening, or loosening resulting from progressive osteolysis or stress shielding.

This prospective, single-armed multicenter study was performed to evaluate clinical and radiographic outcomes in patients utilizing Wright's SIMPLICITI™ Shoulder System for anatomic shoulder arthroplasty. Patient results were measured at a minimum of 2 years follow-up.

## KEY TAKEAWAYS

- 157 patients with glenohumeral arthritis were enrolled in a single arm, prospective study to evaluate SIMPLICITI results at 14 U.S. sites.
- In this first-of-a-kind shoulder Investigational Device Exemption (IDE) evaluation, both patient outcomes and radiographic results were evaluated at 2 weeks, 3, 6, 12 and 24 months.
- Of the 157 enrolled patients, a total of 149 patients completed all of the evaluations at the designated time points through a minimum of 2 years effectively having a study compliance rate of 94.9%.
- Functional evaluations included: range of motion, strength, pain level, Constant score, Simple Shoulder Test (SST) score, and American Shoulder and Elbow Surgeons (ASES) scores. Preoperative scores were compared to 2 years postoperative results.
- To evaluate migration, subsidence and osteolysis, radiographic evaluations were performed at evaluation periods of 2 weeks, 1 and 2 years postoperatively.
- Outcomes that reached statistical significance ($p < 0.0001$) included: mean age and sex-adjusted Constant, SST, and ASES scores.
- At the conclusion of the study, there were no complications associated with migration, subsidence or osteolysis of the implants. Study postoperative complications which resulted in revision surgery included 1 infection, 1 glenoid component loosening, and 1 subscapularis repair failure.
- In conclusion, this study demonstrated significantly improved patient outcomes with low complication rates at a minimum of 2 years following use of the SIMPLICITI humeral component in addition to no radiographic evidence showing signs of loosening, osteolysis, migration or subsidence of the humeral or remaining glenoid components.



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