

CLINICAL ARTICLE SUMMARY

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

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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 (Tornier, Inc. which is affiliated with Wright Medical) is a press-fit, porous-coated, canal-sparing humeral implant that relies on metaphyseal fixation only. This prospective, single-arm, multi-center 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 $103_{-} \pm 27_{-}$ to $147_{-} \pm 24_{-}$ ($p < 0.0001$) and the mean external rotation, from $31_{-} \pm 20_{-}$ to $56_{-} \pm 15_{-}$ ($p < 0.0001$). 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.

Reference:

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