Early Clinical Outcomes of the DePuy ACTIS Total Hip Arthroplasty Femoral Implant

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Early clinical outcomes were assessed for patients who underwent total hip arthroplasty (THA) with the recently released DePuy ACTIS femoral stem for primary osteoarthritis performed through a direct anterior approach. From 2017 to 2018, 226 THAs were retrospectively reviewed on patients with at least one year of postoperative follow-up (average follow-up time was 2.63 years [+/− 0.83]). The primary outcome measure was all-cause revision rate (1.91%), observing for failures related to dislocation (0.48%), aseptic loosening (0.48%), pain (0.48%), infection (0.0%), and fracture (0.48%). Mean preoperative Visual Analogue Scale scores were 6.07 (+/− 2.37) compared with 0.62 (+/− 1.5) postoperatively ($p < 0.001$). The DePuy ACTIS THA femoral implant demonstrated encouraging early clinical outcomes. Further follow-up and surveillance will evaluate how this stem compares with others in the market, but this study demonstrates reliability in evaluation of short-term outcomes.
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Key words: total hip arthroplasty, direct anterior approach, DePuy ACTIS, femoral stem, osteoarthritis

Total hip arthroplasty (THA) rates continue to rise.[1] As such, the industry has been widely growing with newer technologies available for use in the form of stems, cups, liners, and material modifications. With this increase in available options for treatment of primary hip osteoarthritis (OA), it is important that surgeons evaluate the outcomes of newly introduced implants independently and based on their patient cohort, not only for purposes of post-market research but also to provide the literature with real-world examples of outcomes to be expected when using these new technologies. Furthermore, it is imperative that clinicians evaluate the outcomes of the procedures, the effectiveness of addressing surgical indications, and the complication rates in a time where economic restraints are a considerable factor in daily clinical life.

When evaluating components for use in THA, surgeons base their decisions on multiple factors, such as patient demographics, experience with the implant, comorbidities, and factors specific to each surgeon's location of practice.[2] Moreover, hospital and outpatient facilities continue to demand lower implant prices from manufacturers, which leads to the creation of contractual agreements and preferred vendors, limiting surgeons' choices of implants. As such, there is an imperative need to evaluate each THA component available on the market through research and clinical performance. These evidence-based data allow providers to understand and compile patterns of failure of these implants for patient safety, cost-effective treatment decisions, and delivery of quality care. Also, the need for early evaluation of implants is enormous, as describing good or poor outcomes can impact thousands of patients across the world. Some implants have had dubious outcomes, which, had they not been reported early, could have caused significant morbidity.

Innovation in the industry consistently drives the release of new technology to improve outcomes and address the changing needs of the orthopaedic patient population and orthopaedic surgeons. The trend toward use of the direct anterior approach (DAA) in THA has led to advancement in implant design to improve utility through this approach. The DePuy ACTIS femoral stem was specifically designed to be used through tissue-sparing approaches, such as the DAA, in addition to more traditional approaches. This novel design incorporates a reduced lateral shoulder, collar, and triple-tapered geometry. The reduced lateral shoulder facilitates stem placement, whereas the collar and triple-tapered technology were designed to enhance stability and reduce subsidence rates. Given the originality of this design and implant, the purpose of this study was to evaluate the early (2+ year) clinical outcomes of this recently released THA stem used for primary THA through the DAA for OA. Of note, previous studies have evaluated this stem but were performed by either design surgeons and/or company-sponsored trials. The authors' group received no funding for this study.

Materials and Methods

Patients treated at a single academic medical center by two high-volume, fellowship-trained arthroplasty surgeons were reviewed and evaluated. Only patients treated with the ACTIS stem (DePuy Synthes, Johnson and Johnson, Raynham, MA) were evaluated. These were a series of 226 consecutive THAs in 213 patients who were treated at either an outpatient surgery center or at an academic hospital between May 2017 and August 2018. Perioperative and postoperative documentation was reviewed for each patient. Patients who did not have at least > 1-year documented follow-up in clinic were contacted via telephone and administered a brief questionnaire aimed to determine whether these patients had undergone any further surgery on their operative hip at outside institutions.

The authors' THA protocol includes a set of surgical optimizations, including review of comorbidity status, nasal decolonization, preop counseling, and consultant referrals when appropriate. This bundle includes smoking cessation programs, medical nutritional optimization, and screening for comorbidities known to increase complications and costs.

Patients are instructed to bathe and soap the days before surgery and to use a betadine scrub. For surgery, the operative site is shaved, perioperative antibiotics are given following national standard, and operating room traffic is limited. A DAA was used in all patients with the use of a Hana table,

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and all patients underwent anterior capsulectomy. Femoral heads and liners were all highly crosslinked polyethylene. All cups were Pinnacle (DePuy Synthes, Johnson and Johnson, Raynham, MA). Closure is done in the standard fashion with regular sutures, and a betadine irrigation solution is used prior to final implantation. No cement was used in this cohort of patients. A sterile silver-lined dressing is applied after skin closure, and patients are discharged the same day or the day after following evaluation by physical therapy. Follow-up is done in clinic at 1 week, 6 weeks, 3 months, 6 months, and annually thereafter. Physical therapy programs are selected based on shared decision-making with the patients.

The primary composite endpoint of this study was all-cause revision. This was composed of revision for dislocation, subsidence, aseptic loosening, and/or infection. Each endpoint was also individually tracked. A marker of patient outcomes was Visual Analog Scale (VAS) on a 10-point scale. These outcomes were recorded at each visit pre- and postoperatively. These outcomes were also asked via telephone questionnaire to patients who did not present to clinic for their follow-up appointments. Radiographical evaluation of loosening and subsidence was also undertaken and correlated clinically. Loosening and subsidence were dichotomized as present or absent by the attending surgeons. Statistical analysis was primarily descriptive in nature, and thus, only VAS pain scores were compared through paired t-tests from preop values to those at latest follow-up. This was done through the R Software (R Foundation, Vienna Austria).

Results

A total of 209 THAs performed on 197 patients met inclusion criteria (follow-up rate 92.4%). The mean follow-up was 2.63 years (+/− 0.83). Most of the population was female (61.5%), average age of 62.5 years, and the mean American Society of Anesthesiologists (ASA) score was 2.28 (standard deviation [SD] 0.5). The mean body mass index (BMI) was 29.5 (SD 5.78), and the percentage of patients with diabetes was 10.2 percent and smokers was 9.1 percent.

During follow-up, the all-cause revision rate was 1.91 percent (4/209). This was due to one patient (0.48%) presenting with a dislocation requiring revision to a constrained liner, one patient (0.48%) developing aseptic loosening requiring revision of the femoral component, one patient (0.48%) undergoing revision for persistent anterior hip pain, and one patient (0.48%) presenting with a periprosthetic fracture-dislocation requiring revision. Complications that did not warrant revision included one patient (0.48%) who developed a superficial wound dehiscence without further complication and one patient (0.48%) who had radiographic evidence of subsidence without clinical significance.

Complications not pertaining to implants included four patients (1.91%) who were diagnosed with an abductor tear. No patients were diagnosed with a prosthetic joint infection to date.

Regarding patient outcomes, the cohort developed a significant improvement in regards to pain, with mean preoperative VAS scores being 6.07 (+/− 2.37) compared with 0.62 (+/− 1.5) postoperatively ($p < 0.001$).

Discussion

The purpose of this study was to describe the early clinical outcomes of the recently launched to market DePuy ACTIS stem. This was done in order to provide post-market surveillance data from a non-sponsored study by high-volume arthroplasty surgeons. The authors' findings demonstrate positive early results with overall low all-cause revision rate. In a sample of 209 THAs performed in 197 patients, the authors demonstrated that implant-specific concerns during early implementation of this stem did not lead to a high complication rate. Aseptic loosening was only seen in one patient, and questioning whether the implant is at fault for this more so than patient-specific factors was beyond the scope of this brief communication.

Similar to the authors' report, previous authors have evaluated clinical outcomes of hip stems. Ghera and Pavat[3] recently reported on the early clinical outcomes of a hip stem. In their review of 71 DePuy proximal stems, the authors noted no dislocations but a "rounded off proximal medial edge" of the femur and loss of medial cortical bone in Zone 1 in 16 hips. Nonetheless, they reported no osteolysis but had one intraoperative fracture, one superficial infection, and no other stem complications. Furthermore, they reported improved outcomes, with no patients reporting thigh pain, albeit without statistical testing on the Harris Hip Score and the Oxford Hip Score. The implant evaluated in that series was of different characteristics than the ACTIS. Herndon et al.[4] evaluated risk factors for periprosthetic factors and included a sample size of seven ACTIS stems in their study, of which none developed a periprosthetic fracture. Kaszuba et al.[5] evaluated performance of the ACTIS stem in comparison to the DePuy CORAIL femoral stem, finding similar positive outcomes. Kobayashi et al.[6] studied stability of a novel cup in femoral neck fractures and had 10 patients implanted with the ACTIS stem, and none developed complications. As such, the authors' communication is one of the first to describe a reliable sample size of a novel stem in the North American population with minimized risk of selection bias, as no funding was given for this study.

Strengths of this study include evaluating a novel femoral stem designed with the DAA in mind with little reported outcomes in the literature thus far. Unlike other studies, this was done in an unbiased method, as none of the authors were design surgeons and the study was not a company-sponsored trial. Weaknesses of this study include sample size and average time of follow-up, as all-cause revision rates could have been higher if follow-up were conducted past the mean 2.63 years. However, due to the nature of this study and with the goal of wanting to provide time-sensitive data, the authors thought this follow-up time to be appropriate.

In conclusion, the recently launched hip stem ACTIS from DePuy provides satisfactory results at short-term (2.5 years) follow-up. Time will be the determining factor as to whether this stem is comparable to others available in the market.

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