

ACTIS™ TOTAL HIP SYSTEM: EARLY CLINICAL RESULTS

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Introduction

Total Hip Arthroplasty (THA) relieves pain and restores function for patients suffering from osteoarthritis. Following regulatory clearance/approval, DePuy Synthes introduced the ACTIS™ Total Hip System, a collared titanium primary hip stem. As a part of our commitment to monitoring the performance of our products, DePuy Synthes engaged in a clinical evaluation to track early results of the ACTIS Total Hip System. The purpose of this report is to present those results up to one year follow-up.

The ACTIS Total Hip System was designed to provide surgeons with a prosthesis system to aid tissue sparing surgical approaches, such as the anterior approach. Such approaches have been shown to provide benefit to the patient in the short term after surgery,¹ may improve outcomes¹⁻¹¹ and improve the patient experience.^{1-6,9} In this short term evaluation of 1,183 patients, five adverse events were reported. There were no instances of dislocation, no radiolucent lines, and no signs of loosening.

Features of the implant as well as instrumentation are designed to allow for prosthesis insertion with minimal soft tissue, pelvis, and incision impingement. The ACTIS Total Hip System features DUOFIX™ Coating on the proximal portion of the stem, including the underside of the collar, to allow for biological fixation.

The ACTIS Total Hip System features a medial collar and triple taper geometry, that have been shown to improve primary stability of the stem while also offering a solution for a broader range of patient anatomies.^{12,13} A medial collar has been shown to provide the opportunity for improved initial stability,¹² resistance to early subsidence, and more physiologic compressive loads in the medial calcar.²² Improved outcomes are supported by enhanced initial implant stability.^{12,13}

The ACTIS Total Hip System is a fit and fill stem, with triple-tapered geometry. The stem is tapered in three separate planes to aid in short and long-term stability (see Figure 1). The ACTIS Total Hip System is tapered from proximal to distal in the anterior/posterior plane, proximal to distal in the medial/lateral plane and lateral to medial in the transverse or axial plane.

The ACTIS Total Hip System was designed to increase 1 mm in the anterior/posterior dimension in the horizontal plane consistently between each size stem. Additionally, the anterior/posterior taper of the ACTIS Total Hip System increases 0.25 degrees per size and designed to achieve proper fit across the entire range of stem sizes.



Horizontal plane grows 1 mm in the A/P per size

Figure 1

Methods

The ACTIS Total Hip System clinical evaluation and data collection period was established to assess the early post-operative performance of the system.

DePuy Synthes reviewed the data generated at staged time points to evaluate whether the ACTIS Total Hip System was performing as expected, and to make informed decisions about the broader commercial release of the system. A committee comprised of the DePuy Synthes Medical Director, DePuy Synthes Medical Safety Officer, Clinical Research, R&D, and the ACTIS Total Hip System designing surgeons was responsible for reviewing the data prior to proceeding to the next stage of the evaluation. The data reviewed at each stage of the evaluation included surgeon feedback, any reported adverse events, and post-operative radiographs.

In total, data was reviewed from 1,183 ACTIS Total Hip Systems. This included 670 stems implanted by four designing surgeons (3-US, 1-Austria), 93 subjects enrolled in a company sponsored clinical study and 420 ACTIS Total Hip Systems implanted by the early evaluators group (see Table 1).

Results

Radiographic Review: Three hundred and forty-three X-Rays in 325 patients were reviewed by Medical Safety Staff from Medical Affairs and Medical Safety with no adverse findings to report. No radiolucent lines and no signs of radiographic loosening were observed (see Figure 2).

Adverse Events: The following adverse events were reported during the final review. Two intra-operative calcar fractures occurred, and were treated intra-operatively, with uneventful patient recoveries. One periprosthetic fracture occurred at 2.5 weeks post-op, after the patient bent down. No surgery was performed, and only restricted weight bearing was directed. This patient was last seen nearly four months post-surgery, and had recovered without complications. A femoral perforation occurred with the broach as a fellow was broaching in the wrong direction. It was identified, the broach was redirected, and the patient was placed on protected weight bearing. No reamers or other tools were used. The surgeon reported that the patient had returned to full activity by 6 weeks post-operative.

Clinical evaluation period

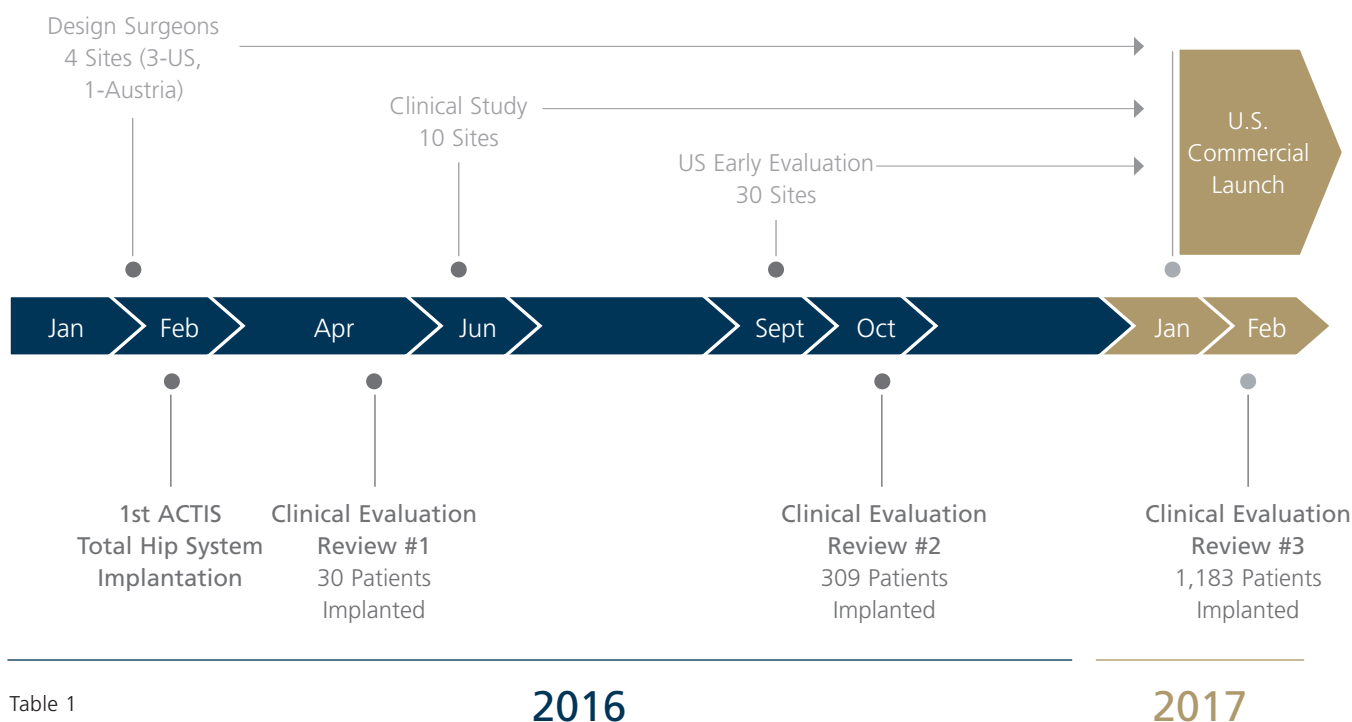
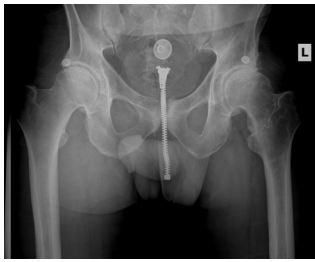


Table 1

Conclusion

Although this is a very early assessment of the outcomes of the ACTIS Total Hip System, the absence of reported thigh pain, good clinical results, and low prevalence of other adverse events are positive early findings. These early clinical results indicate the ACTIS Total Hip System performance is satisfactory. Long term clinical follow-up is ongoing.



A/P Pre-operative image.



Lack of radiolucent lines demonstrates excellent fixation.



A/P Pre-operative image.
1 Year A/P post-operative
image of the ACTIS Hip
System on the same
patient's left hip.

Figure 2

One study subject reported hip pain at 50 and 60 days post-operatively which required no treatment and was resolved without any complications. One study subject had a cellulitis at 20 days post-operatively, one study subject reported erythema at 36 days post-operative, and another study subject reported muscle spasm around their hip at 30 days post-operatively.

Discussion

Post-operative thigh pain has been reported following Cementless THA with many different stem designs.¹⁴⁻¹⁶ A simple survey of the available literature demonstrates reported thigh pain rates varying between <1% and 9.5%.^{16,20}

In 1,183 ACTIS Total Hip Systems, some out to 1 year post-operative, there has been only one report of thigh pain from within the ACTIS Total Hip System implantations, and this case has resolved with no additional treatment required. From this same group of 1,183 subjects, two intra-operative calcar fractures occurred, which is less than the 2.9%-27.8% reported in literature.²¹ No radiolucent lines and no signs of loosening were observed. These early findings indicate excellent stability with the ACTIS Total Hip System.

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