ACTIS® Total Hip System:

Clinical Update

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Introduction

The ACTIS® Total Hip System is designed to be utilized with tissue sparing approaches, such as the anterior approach, as well as traditional approaches. The implant and instrumentation are designed to balance ease-of-insertion and may provide improved implant stability[1]. The system is indicated for cementless use for primary total hip arthroplasty (THA) and hemi-hip arthroplasty.

The ACTIS Hip Stem is a novel triple-tapered femoral stem manufactured from forged titanium alloy (Ti-6A1-4V) and has a sintered commercially pure titanium bead porous coating (POROCOAT® Porous Coating), and a thin layer of plasma-sprayed hydroxyapatite (HA) coating.

In 2016, the first ACTIS Hip Stem case was performed in the US. The following paper provides an overview of data reported five years after launch.

Two-Year Follow Up Clinical Study

The clinical study was initiated to obtain two-year information regarding the performance of the ACTIS Total Hip System in order to obtain and evaluate the clinical outcomes on a series of cementless primary total hip arthroplasty (THA) and hemi-hip arthroplasty (HHA) procedures using clinical safety and performance outcomes, radiographic information, patient reported outcome measures (PROMs) from the FJS-12 and HOOS, radiographic information and device and procedure related adverse event (AE) assessments.

The study design is a prospective, uncontrolled, non-randomized, multicenter study. All the planned 225 patients for THA were implanted between July 2016 and September 2017 (229/225, 102%) and 23 (23/30, 77%) HHA patients were implanted between January 2017 and March 2020. All patients (i.e., THA and HHA) were seen for a pre-operative clinic visit at the time of enrollment/consent, and had follow up visits at six-weeks, three-months, and a minimum of 1- and 2-years. Nine geographically diverse clinical study sites within the United States of America completed enrollment.

Survivorship and Revisions for THAs

There were five patients with reported revisions, with revision being defined as the removal of any implanted component for any reason. Of the five revisions, only one revision of the stem was reported and was due to infection.

The Kaplan-Meier Survival Estimate at 2-years (132 at risk) is 99.6% (95% C.I., 96.9 – 99.9). Revisions for the 5 THA patients includes 3 infections (2 high offset and 1 standard offset stems) and 2 recurrent dislocations (both standard offset stems).

Survivorship and Revisions for HHAs

There was one reoperation for infection which resulted in a head exchange only; the femoral component was not removed.

Demographics for THA

The mean age for the THA cohort was 61.2 (SD 10.83, range Min 25 – Max 91). The most common age range was 60-69 years (80/229, 34.9%), mean body mass index (BMI) was 31.6 (SD 18.02), most patients were male (127/229, 55.5%), and the most common diagnosis was osteoarthritis (217/229, 94.7%). For race, most patients were Caucasian/White (212/229, 93.4%), the remainder were reported as follows: African American/Black (14/229, 6.1%), American Indian/Alaskan Native (2/229, 0.9%), and Native Hawaiian/Pacific Island (1,229, 0.4%). For ethnicity, most patients were Not Hispanic or Latino (222/229, 96.9%), and the remainder were Hispanic or Latino (7/229, 3.1%).

Table 1: Reasons for Revisions and Reoperations (any component for any reason, per protocol)[2]

Total Hip Arthroplasty (THA)			
THA Patient	**Surgery Date**	**Revision Date or Radiographic Date**	**Revision Reason**
02-042 High Offset	22 Feb 2017	15 Mar 2017	Infection
01-024 STD Offset	03 Apr 2017	08 May 2017	Infection
09-040 STD Offset	03 Apr 2017	22 May 2017	Dislocation X 2
10-018 STD Offset	13 Apr 2017	17 Aug 2017	Recurrent dislocation
01-004 High Offset	17 Aug 2016	02 May 2018	Infection
Hemi-Hip Arthroplasty (HHA) (any component for any reason, per protocol)			
THA Patient	**Surgery Date**	**Revision Date or Radiographic Date**	**Revision Reason**
04-003 High Offset HHA Pt	07 Sep 2017	06 May 2018	Infection

Demographics for HHA

The mean age for the HHA cohort is 75.0 (SD 12.40, range Min 46 – Max 90). The most common age range was 80-89 years (8/23, 34.8%), mean body mass index (BMI) was 24.5 (SD 5.14), most patients were female (16/23, 69.6%), and the diagnoses were acute fracture of the proximal femur (21/23, 91.3%), Osteoarthritis (1/23, 4.3%) and Other (1/23, 4.3%).

For race, most patients were Caucasian/White (16/23, 69.6%), the remainder were reported as follows: African American/Black (6/23, 26.1%), and one patient did not report race (missing, 1/23, 4.3%). For ethnicity reported, most patients were Not Hispanic or Latino (22/23, 95.7%), and the remainder were Hispanic or Latino (1/23, 4.3%).

Harris Hip Score (HHS) Outcomes (Primary endpoint)

Harris Hip Score (HHS) was the primary endpoint at 2-years. Table 1 displays the 2 Year HHS outcomes for the combined cohorts as well as the THA and HHA cohorts individually.

Femoral Radiographic Outcomes THA

Femoral radiographs are collected pre-operatively and then post-operatively at 6-weeks, 3-months, 1- and 2-years. The three views required are AP Femur, Lauenstein Lateral and AP Pelvis. Radiographic analysis of the femoral component at 1- to 2-years as reported by an independent radiologist demonstrated no complete femoral radiolucent lines, no circumferential radiolucent lines, and no femoral subsidence.

Femoral Radiographic Outcomes HHA

Femoral radiographs are collected at the same intervals as the THA cohort. Radiographic analysis of the femoral component at 1- to 2-years as reported by an independent radiologist demonstrated no incomplete femoral radiolucent lines, no circumferential radiolucent lines, and no femoral subsidence.

Table 2: Harris Hip Scores for Actis THA and HHA Cohorts

Variable	Interval	n	Mean	Standard Deviation	Min	Max
Total Score THA & HHA combined	2 Year	156	95.7	9.22	44	100
Total Score THA only	2 Year	155	95.9	8.79	44	100
Total Score HHA only	2 Year	1	60		60	60

Actis study 2-year window: 669 to 1763 days postoperative

DePuy Synthes Outcomes Tracking System (DOTS Registry)

A total of 3,253 ACTIS Stems were implanted between February 2016 and September 2020 at several institutions. The primary diagnosis tallies (%) for THA were 3,078 (94.6%) for osteoarthritis, 49 (1.5%) for avascular necrosis, and 126 (3.9%) for other or missing. The mean age was 64.3 years (range 21 to 93) with 1569 female patients (48.2%) and the mean BMI was 28.1 (range 17 to 74). Operative approach included direct anterior (2991, 91.95%), anterolateral (152, 4.7%), posterior (10, 0.3%), two-incision (10, 0.3%), other (87, 2.6%), and missing (3, 0.1%). There was one intraoperative lateral femoral cortical perforation, resolved without treatment. No calcar fractures were reported. There were seven revisions of the femoral stem secondary to infection. No revisions were reported for stem subsidence or stem loosening. One reoperation occurred for excision of heterotopic bone formation. With survivorship defined as no revision of any component for any reason, Kaplan-Meier survivorship estimates (95% CI; N with further follow-up) were 99.4% (98.8%,99.7%; 837) at 1 year, and 99.0% (98.2%,99.5%; 253) at 2 years post-op. Mean total Harris Hip Scores (SD; N) were 52.6 (13.9; 2,604), 90.5 (11.1; 1,178), 95.7 (7.4; 1,083), and 95.4 (8.0; 343) at pre-op, less than one year (1-303 days post-op), 1 year and 2 years post-op respectively.

Published Data

Chitnis et al[3] recently published a retrospective real-world data study utilizing a claims database to investigate the early survival of the ACTIS Hip. The study identified 1213 ACTIS Hip patients and compared to a group of 6916 “other hips”. The 3-year revision rate for any reason for the ACTIS Hip was 1.08% (0.43, 2.72), and 2.63% (2.19, 3.16) for other hips. The authors provide an adjusted hazard ratio to assess the relative risk of revision and found that ACTIS Hip was associated with a 57% reduced risk of revision when compared to the other hip group (HR 0.43 (95%CI 0.19-0.97) P=0.042).

Kaszuba et al[4] conducted a short-term retrospective cohort study that compared the ACTIS Hip with the well established CORAIL® Hip System. There were 165 ACTIS Hip cases and 165 CORAIL Hip cases, and all operations were performed using the ANTERIOR ADVANTAGE™ Hip Replacement surgical technique. The ACTIS Hip was associated with a statistically significant reduction in hospital length of stay (1.54 +/-1.1 days vs. 2.09 +/-1.1 days, p<0.001). The clinical and radiographic findings were similar at 1 year, there were no revisions recorded in this study and the complication rates did not vary significantly between the groups.

Joint Registry Data

The 2019 Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI) Annual Report[5] details the cumulative percent revision (CPR) rates for conventional THA stem / cup implant combinations. The combination of the ACTIS Hip and the PINNACLE® Cup (N=589) has a CPR of 0.19 % (0.03, 1.34) at 1 year, which is the lowest of the 30 stem/cup combinations listed.

The American Joint Replacement Registry (AJRR) have analyzed their ACTIS Hip cohort (2020).[6] This provides annual survival estimates on a cohort of 20,737 ACTIS Hip implantations. At 4 years the KM survival is 99.76% (99.66, 99.83%). This compares favorably with the class survival at 4 years of 98.42% (98.38, 98.46%). The methodology of the AJRR data collection and linkage or records means that the number of revisions is potentially under-reported. This is true across the board and so the comparison of the ACTIS Hip data to the class data remains valid and informative.

Conclusion

Different sources of information demonstrate that the ACTIS Hip Femoral Stem has excellent clinical outcomes, and no revision rates at 5 years were reported. KM Survival estimates for THA include the 2-year clinical study at 99.6% (95% C.I., 96.9 – 99.9) and the DOTS data with 99.0% (98.2%,99.5%; 253) at 2 years post-op. Similar survival estimates are reported from independent data sources such as the AJRR and MARQCI joint registries and by Chitnis et al.

In the data above, most of the THA were performed via Direct ANTERIOR ADVANTAGE™ Hip Replacement showing the benefits of the optimized design of the ACTIS Hip Stem.

DePuy Synthes will continue to monitor the mid and long term performance of the ACTIS Hip Stem.

References

1. DePuy Synthes. Hamburg University Actis Cadaveric Stability Testing. 2015. Adaptiv #103156243.
2. Internal Database extract from DePuy Outcome Tracking System (DOTS), date of extract: 16OCT2020.
3. Chitnis et al. Survival analysis for all-cause revision following primary total hip arthroplasty with a medial collared, triple-tapered primary hip stem versus other implants in real-world settings. CURRENT MEDICAL RESEARCH AND OPINION 2020, VOL. 36, NO. 11, 1839–1845
4. Kaszuba, S.V et al. The Actis and Corail Femoral Stems Provide for Similar Clinical and Radiographic Outcomes in Total Hip Arthroplasty. HSS Jrnl (2020).
5. 2019 Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI) Annual Report
6. American Joint Replacement Registry. ACTIS Duofix Demographic and Survivorship Analysis. Report prepared for DePuy Synthes on Oct 27 2020

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Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.

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