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BRIEF REPORT



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

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ABSTRACT

Objective: Patients that undergo total hip replacement (THA) are at risk of revision surgery. This study evaluated the cumulative incidence of revision following a medial collared, triple tapered (MCTT) primary hip stem versus other implants in real-world settings using electronic medical records.

Methods: This was a retrospective cohort study that used the Mercy Healthcare Systems – Orthopedics Database (MHSOD) to identify ACTIS total hip system, a MCTT primary hip stem for THA, and any other primary THA between 2016 and 2020. A Kaplan-Meier analysis was conducted to evaluate the risk of revision over time between the MCTT hip stem and other implants. In order to control for the confounding, a multivariable Cox model was developed to evaluate the risk of revision between the two groups.

Results: There were 1213 patients treated with MCTT hip stem and 6916 patients treated with other implants. The Kaplan-Meier analysis showed statistically significant difference (p value = .006) in cumulative incidences for all-cause revisions between the MCTT hip stem and other implants. The cumulative incidence at 3 years was 1.08% (0.43–2.72%) for the MCTT hip stem, while it was 2.63% (2.19–3.16%) for other implants. After adjusting for patient demographics, clinical characteristics, prescribed medications, and surgeon characteristics, the multivariable Cox proportional hazard model showed the MCTT hip stem was statistically significantly associated with 57% lower risk of revisions compared with other implants (HR, 0.43; 95% CI, 0.19–0.97; p -value = .042).

Conclusions: This real-world study found that the incidence of revision after treatment with MCTT primary hip stem was significantly lower than for other implants.

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KEYWORDS

Total hip replacement; medial collared; triple tapered primary hip stem; revision surgery; real-world settings



Background

Total hip arthroplasty (THA) is a common procedure recognized to be effective for relieving osteoarthritis pain and restoring mobility in patients with osteoarthritis. As THA is reported to increase quality of life with regained physical function, the procedures are increasingly performed in both younger and older adults.¹ THA is projected to grow to 635,000 procedures, by 2030 in the United States (US).² The complications after THA mainly include dislocation, infection, and loosening of the femoral or acetabular component.³ A recent meta-analysis evaluated the duration of hip replacement and reported a revision-free survival of 89.4% (95% Confidence Interval, CI, 89.2–89.6) at 15 years, 70.2% (69.7–70.7) at 20 years and 57.9% (57.1–58.7) at 25 years.⁴

Various studies have evaluated the risk factors for revisions, which could include the type of surgical approach for primary THA, implant design and patient characteristics.^{5–7}

Posterolateral surgical approach was found to have higher risks of revision due to dislocation and infection.^{6,7} The head diameter of the THA implant was another factor associated with the risk of revision.⁸ Larger head diameters (>28 mm) had a lower risk of revision when compared to smaller heads. Revision rates were higher among patients with certain comorbid conditions like hypertension and those with paraparesis/hemiparesis.⁹ However, no composite effect of minimally invasive posterolateral approach with larger head diameters are studied.

The ACTIS total hip system is a medial collared, triple tapered (MCTT) cementless primary hip stem. A medial collar has been shown to provide improved stability, resistance to early subsidence, and more physiologic compressive loads in the medial calcar.^{10–12} Early results for this MCTT stem have shown a reduced cumulative revision rate when compared to other conventional hip implants.¹³ The tapered stem in

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three separate planes aids in short and long-term stability.¹⁴ The implant and instrumentation with this novel hip stem are designed to provide both ease of insertion and improved implant stability.¹⁴ However, there are limited published clinical studies on the benefits of collared cementless stems^{15,16}, none specifically analyzed ACTIS total hip system.

The MCTT primary hip stem is designed to support tissue sparing approaches, such as the anterior approach.¹⁴ The anterior approach has been shown to improve patient experience and outcomes including length of stay, health resource utilization and cost for primary THA as compared to traditional approaches with potential saving of \$6206 in the 90 day window.^{5,6,17–20}

This study was designed to evaluate the time to revision surgery (survivorship) of ACTIS total hip system, the MCTT primary hip stem, versus other implants in real-world settings using electronic medical records.

Methods

Database

The Mercy Healthcare Systems – Orthopedics Database (MHSOD) was used for this analysis, as these electronic medical record databases allow identification of device by device brand.

This dataset includes fully de-identified patient data from the Mercy Health hospital network (a specific health system). The Mercy hospital network includes about 44 hospitals and 350 outpatient facilities with 3000 integrated providers. The data will contain clinical information about patients who have undergone certain procedures, treatments, and visits at facilities within the Mercy health network from 2011 to 2020 (updated monthly) in the US Midwest region (specifically in the integrated delivery network in the states of Missouri, Kansas, Oklahoma, and Arkansas). The patient cohort in this dataset was selected based on medical billing and diagnosis codes associated with orthopedic condition (any ICD diagnostic or procedure code related to an orthopedic-related event) and includes approximately 800,000 patients. The database contains information on demographics, procedure information, medical device products used, medications, laboratory and diagnostic procedures, and diagnoses.

Study design

This was a retrospective cohort study. Figure 1 provides a visual representation of the timelines used in this study, and the data collected at each time point.

Adult patients (>21 years of age at time of THA) were included if they had a primary THA performed between 2016 and 2020: (1) during an inpatient admission, and (2) during an elective admission (no transfer from emergency services) (3) for primary cases, a diagnosis of osteoarthritis at time of THA. The date of the THA procedure was defined as the Index. The post-operative period was defined as the period starting *after* discharge (day 1 = date of discharge + 1 day).

No outpatient admissions for THA were considered as per the American Association of Hip and Knee Surgeons, orthopedic surgeons agree that outpatient total joint replacement should only be done on patients who are healthy and have the appropriate home setting/support to be discharged. This concept is novel, and orthopedic surgeons are still evaluating the benefits of this idea for patients.²¹ Hence, this study only considered inpatient admissions for THA.

Patients were excluded if they had: (1) bone neoplasm present on admission or within 30 days prior to index. (2) rheumatoid arthritis, any time, or (3) patients who died during the index admission (4) diagnosis of hip fracture within 5 days of index THA.

Variables

The primary exposure variable was treatment with ACTIS total hip system (manufactured by DePuy Synthes), the MCTT primary hip stem for THA versus compared to a cohort of primary THA patients with any other hip stem used. Patients treated with MCTT primary hip stem were categorized as MCTT hip stem patients. All other patients were included in the control arm. The main outcome of interest was revision THA surgery on same leg as index. The demographic variables assessed included age, gender, race, and marital status. The behavioral variables included alcohol use, tobacco use, and illicit drug use. Clinical variables included body mass index (BMI), 31 different comorbidities from Elixhauser comorbidity measure, functional comorbidity index, osteoporosis and any infection within six months prior to index

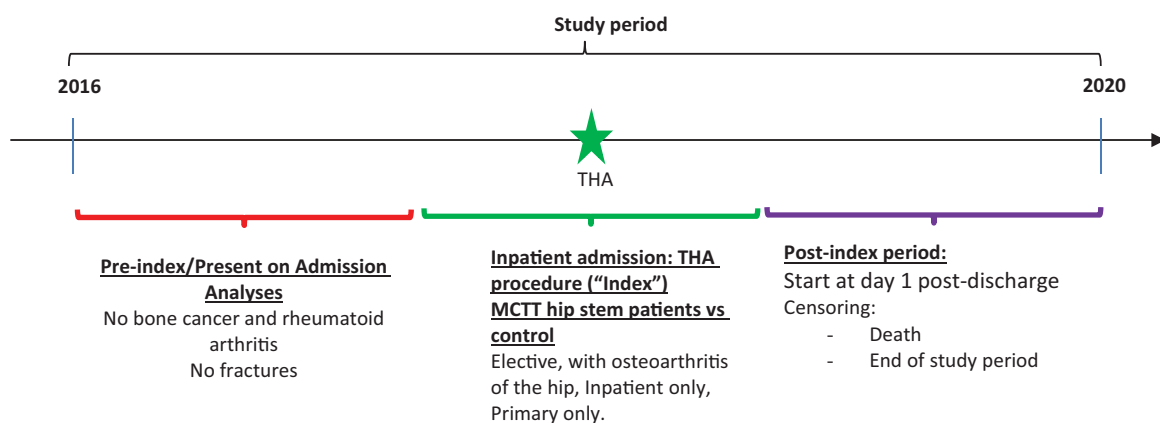


Figure 1. Visual representation of key study design considerations.

THA. Medications assessed included standard pain management therapies opioids, steroids, non-steroidal anti-inflammatory drugs (NSAIDs), and other medications like anticoagulants, antihypertensives, anxiolytics, and antidepressants within thirty days prior to index THA. Surgeon variables included surgeon volume and specialty.

Statistical analysis

Proportions, medians, means and standard deviations (SD) were calculated to describe the study population for each exposure group (MCTT hip stem vs other implants). Significance testing was performed using *t*-tests and chi-square tests. A Kaplan-Meier analysis was performed to evaluate risk of revision over time, for the MCTT hip stem and the comparator other implants cohort. Patients were censored if they died or at the end of the study period. The log rank test was used to evaluate the difference between the two groups. A multivariable Cox regression model was developed to evaluate the risk of revision after adjusting for patient and surgeon characteristics between the MCTT hip stem and other implants group. Hazards Ratio (HR), 95% Confidence interval (95% CI), and *p*-value were reported.

Results

A total of 8129 patients were included in the final analysis after applying the inclusion and exclusion criteria. Results of patient and surgeon characteristics are presented in [Table 1](#). There were 1213 patients treated with MCTT hip stem and 6916 patients treated with other implants. Most patients were females (54.50%) and Caucasian (92.73%). The mean (SD) age of the cohort was 65.99 (11.04) years. Only 16.93% patients had a normal weight and 7.57% patients had morbid obesity.

Among the comorbidities, the top five comorbid conditions were hypertension (58.28%), obesity (27.37%), depression (21.33%), cardiac arrhythmia (19.85%), and chronic pulmonary disease (18.16%) ([Supplemental Table 1](#)). NSAIDs (29.73%), opioids (27.35%) and antihypertensives (13.64%) were most frequently prescribed medications. 33.37% surgeons had a surgeon volume ≥ 80 THA surgeries in the index surgery year.

Survival analysis

The median time to follow-up post-THA discharge was 481 days for the overall cohort; the median time to follow up for patients with MCTT hip stem was 342 days and for patients with other implants was 521 days. There were 44 patients with MCTT hip stem and 1473 patients with other implants who had no revision or no death record, thus remaining at risk at the 3-year time-point. From 2016 to 2020, 7 MCTT hip stem and 128 other implants were revised. The Kaplan-Meier curves and the log-rank test evaluating MCTT hip stem and other implants showed statistically significant difference (*p* value = .006) in cumulative incidences for all-cause revisions ([Figure 2](#)). The cumulative incidence

(95% CI) was 0.64% (0.28–1.43%) at 1-year, 1.08% (0.43–2.72%) at 2-year, and 1.08% (0.43–2.72%) at 3-year for the MCTT hip stem, while it was 1.9% (1.57–2.29%) at 1-year, 2.29% (1.91–2.74%) at 2-year, and 2.63% (2.19–3.16%) at 3-year for other implants.

The multivariable Cox proportional hazard model after adjusting for the patient demographics, clinical characteristic, prescribed medications and surgeon characteristics showed the MCTT hip stem was statistically significantly associated with 57% lower risk of revisions as compared to other implants (HR, 0.43, 95% CI, 0.19–0.97, *p*-value = .042). Other factors that were significantly associated with the revision were age (age 65–74 years vs age ≥ 75 , HR, 0.51, 95% CI, 0.32–0.84, *p*-value = .008), prescription for an antidepressant (HR, 1.74, 95% CI, 1.05–2.89, *p*-value = .032), prescription for a NSAID (HR, 1.57, 95% CI, 1.09–2.26, *p*-value = .016), and diagnosis of psychoses (HR, 8.06, 95% CI, 2.65–24.53, *p*-value < .0001) and surgeon volume (1–24 vs 80-plus, HR, 2.18, 95% CI, 1.31–3.64, *p*-value = .003) ([Table 2](#)). [Supplemental Table 2](#) shows the results for the multivariable Cox proportional hazard model with all variables. An additional multivariable Cox proportional hazard model was constructed with limited variables and use of age and BMI as continuous variables showed similar results ([Supplemental Table 3](#)).

Discussion

This study presented a real-world retrospective cohort analysis of 1213 patients treated with the MCTT cementless primary hip stem design during total hip arthroplasty from 2016 to 2020 versus 6916 patients treated with other hip stem implants during the same period. The study used electronic medical records collected from a large multi-state US hospital network and reported 3-year cumulative incidence of all-cause revision. The study found an incidence of revision as 1.08% with the novel stem design versus 2.63% in the other group. After adjusting for the demographic, clinical and surgeon characteristics a 57% decreased incidence of revision related to the novel stem design was observed.

To our knowledge, no other study has evaluated the mid-term performance of the MCTT primary hip stem design. Our results corroborate with the Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI) report that showed a lower cumulative percent revision (95% CI) with the MCTT primary hip stem 0.19% (0.03, 1.34) compared with all primary conventional THA 1.50% (1.42, 1.59) at 1 year.¹³ However, the incidence of revision in this study is higher than the MARCQI report which could be due to the differences in the patient population and associated comorbidities. A difference in the median time to follow up was noted between the MTCC stem and other implants, which may be because the MTCC is a novel stem design with most patients entering the cohort in 2018 and 2019 whereas, for the other implants there was equal distribution of patients from 2016 to 2019.

The design rationale for this MCTT stem, a triple taper in conjunction with a collar, is to improve initial stability of the stem and to offer treatment to broader range of patient anatomies.^{10,22} The stem is tapered in three separate planes.

Table 1. Patient and surgeon characteristics at time of index THA surgery.

Variables	Overall	Implant		p-Value
		MCTT hip stem	Other Implants	
Number of patients	8129	1213	6916	
Age mean (SD) years*	65.99 (11.04)	65.18 (10.92)	66.13 (11.06)	.005
Gender				
Female	54.50%	52.84%	54.79%	.210
Male	45.50%	47.16%	45.21%	
Race*				
Caucasian	92.73%	94.64%	92.39%	<.0001
Black or African American	3.75%	1.24%	4.19%	
Other	3.52%	4.12%	3.42%	
THA surgery year*				
2016	20.59%	0.82%	24.06%	<.0001
2017	21.97%	19.13%	22.47%	
2018	23.48%	30.17%	22.31%	
2019	27.83%	40.40%	25.62%	
2020	6.13%	9.48%	5.54%	
Marital Status*				
Divorced	9.93%	9.23%	10.05%	<.0001
Married	63.85%	70.16%	62.74%	
Single	12.47%	9.73%	12.96%	
Widowed	12.01%	9.07%	12.52%	
Other or Unknown	1.75%	1.82%	0.02%	
Illicit Drug Use	5.67%	6.51%	5.52%	.225
Alcohol Use	52.25%	51.53%	52.37%	.771
Tobacco Use*				
Current	12.24%	3.87%	13.71%	<.0001
Never	47.42%	48.64%	47.21%	
Past	40.10%	47.40%	38.82%	
Not Available	0.23%	0.08%	0.26%	
Body Mass Index*				
Underweight: Less than 18.5	0.63%	0.25%	0.69%	<.0001
Normal: 18.5–24.9	16.93%	16.08%	17.08%	
Overweight: 25–29.9	32.19%	33.80%	31.91%	
Obese: 30–34.9	27.16%	28.44%	26.94%	
Very Obese: 35–39.9	15.52%	16.98%	15.27%	
Morbidly Obese: 40 and above	7.57%	4.45%	8.11%	
Comorbidities*				
Mean (SD) FCI score	3.78 (1.80)	3.92 (1.82)	3.75 (1.79)	.002
Medications				
NSAIDs*	29.73%	35.45%	28.73%	<.0001
Opioids*	27.35%	22.34%	28.22%	<.0001
Antihypertensives*	13.64%	10.72%	14.16%	.001
Antidepressants	9.96%	8.49%	10.22%	.063
Anxiolytics	5.39%	4.78%	5.49%	.310
Anticoagulants*	4.97%	1.65%	5.55%	<.0001
Steroids	3.37%	3.79%	3.30%	.378
Surgeon Specialty*				
Orthopaedic surgeon	99.43%	99.84%	99.36%	.044
Surgeon Volume*				
1–24	18.59%	3.30%	21.27%	<.0001
25–49	27.90%	6.51%	31.65%	
50–79	20.14%	19.29%	20.29%	
80 plus	33.37%	70.90%	26.79%	
Cementless Fixation*	94.27%	100.00%	93.26%	<.0001

AIDS, Acquired immunodeficiency syndrome; FCI, Functional comorbidity index; HIV, Human immunodeficiency virus; NSAIDs, Non-steroidal anti-inflammatory drugs; SD, Standard deviation.

*Indicates statistical significance.

It 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 third taper (lateral to medial in the transverse plane) is intended to enhance the load distribution in the medial calcar region, in order to reduce the risk of stress shielding and bone resorption.²² To enable tissue sparing surgical approaches, such as the Anterior Approach, the MTCC stem was designed with a reduced lateral shoulder to aid in stem insertion by helping avoid the Obturator Externus muscle and other short external rotators that attach to the medial aspect of the greater

trochanter. The natural loading of the femur with the MCTT medial collar should provide greater initial stability for early post-surgery weight bearing, and potentially reduce risks of subsidence and occurrence of femur fracture. However, the collar may also limit the degree of press-fit fixation, that could result in failure or calcar impingement in cases of stem subsidence.^{15,16,23} Although there is limited direct comparative literature on the benefits of collared stems, some studies and national registries have shown that the collared stem lowered the risk of loosening or fracture when compared to the collarless stem.²⁴

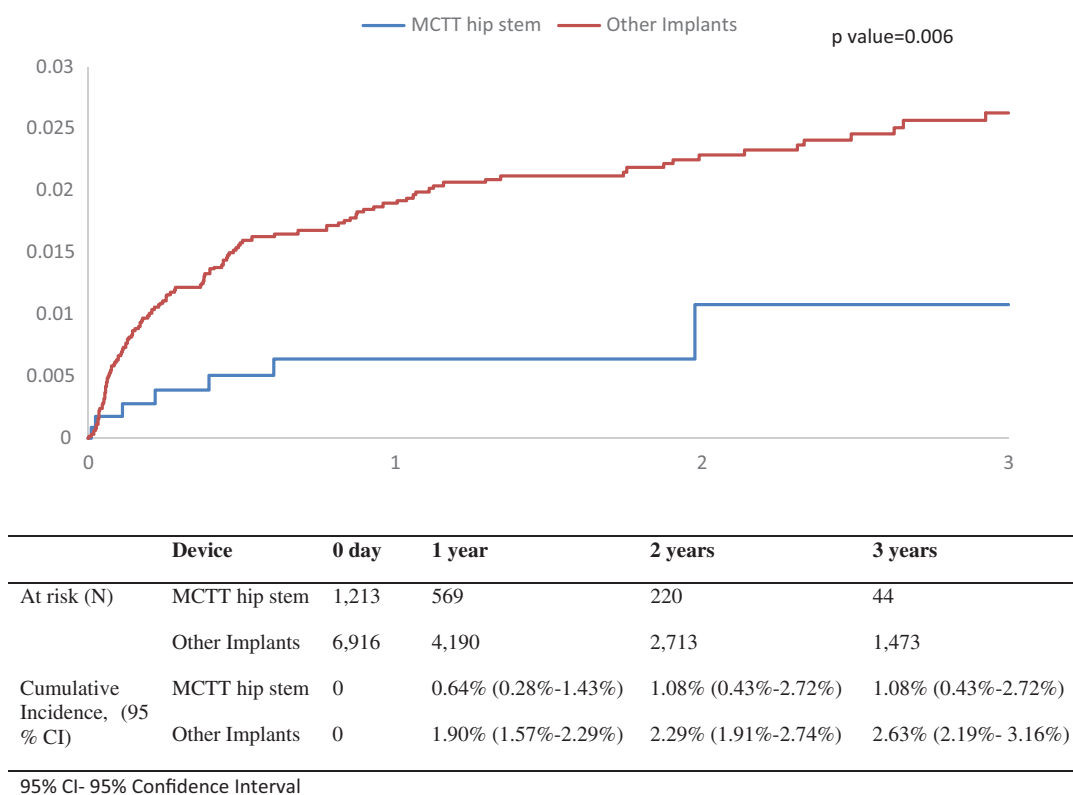


Figure 2. Kaplan-Meier curve for all-cause revision in patients with MCTT hip stem vs Other implants and their risk numbers. 95% CI: 95% Confidence Interval.

Table 2. Significant factors associated with risk of revision.

Variable	Hazard ratio	95% Confidence limits	<i>p</i> Value
MCTT hip stem vs Other Implants	0.43	0.19–0.97	.042
Age 65–74 years vs Age \geq 75	0.51	0.32–0.84	.008
Antidepressants vs Not	1.74	1.05–2.89	.032
NSAIDs vs Not	1.57	1.09–2.26	.016
Psychoses vs Not	8.06	2.65–24.53	<.0001
Surgeon volume 1–24 vs 80-plus	2.18	1.31–3.64	.003

The MCTT primary hip stem incorporates design features from a number of clinically established hip systems, including CORAIL, SUMMIT and TRI-LOCK. The survivorship for revision with CORAIL hip system has been found to be greater than 97% over a follow-up ranging from 12 to 20 years.^{25–27} The survivorship with SUMMIT at 10 years was 100% for the end points of femoral revision for loosening or femoral radiographic loosening.²⁸ The survivorship for revision with TRI-LOCK was 98.6% at 5 years.¹³ However, there are no earlier versions specifically of this MCTT primary hip stem studied.

An interesting pattern for incidence of cumulative revision was observed with MCTT primary hip stem. The MCTT primary hip stem showed an all-cause revision of 0.64% at 1 year which increased to 1.08% at 2 years but plateaued thereafter remaining the same at 3 years post-THA. This pattern is in contrast with other implants for THA, whereby revisions have climbed gradually past years 2 and 3.¹³ If the observed pattern holds for long term then surgeons could work to prevent the early failures. Although this study did not evaluate the specific reasons for revisions, The MARCQI report found dislocation/instability as the reason of revision in the first year following THA with the MCTT primary

stem.¹³ The common reasons for revisions in the first 2 years after conventional THA include periprosthetic fracture for femur, dislocation/instability, joint infection, aseptic loosening and pain.¹³ This study reported the revision up to 3 years post THA. Based on the study by Lettin et al. at least 40 surviving prosthesis (at risk) are required at the duration of follow-up chosen for the calculation in survival analysis.²⁹ We had 44 patients at risk in MCTT hip stem and 1473 patients at risk in other implants at the end of 3 years follow-up to allow a reliable estimate.

The study has certain important strengths. This study evaluated in the real-world setting the safety of MCTT primary hip stem, a novel stem design, when little is known about the mid-term results of this design. The study used a multi-variable regression model to control for covariates spanning patient demographic, clinical and surgeon characteristics to compare revisions between the two groups. The study used an electronic medical health record database that allowed identification of the MCTT primary hip stem design, which otherwise cannot be identified in large retrospective databases like claims and other electronic medical health records. The results of the study must be seen in light of the following limitations. Since this study is observational in nature, it would be difficult to draw causal inferences. Potential coding errors and misclassifications within the databases could not be identified and hence couldn't be rectified. The database did not provide any specific details on the other implants used beyond the fixation methodology. Future studies could conduct a head-to-head comparison of the MCTT stem with a well-established alternative hip stem. Surgeon volume is of importance as it has been shown to affect outcomes in

THA.³⁰ The surgeon volume was significantly higher among the MCTT hip stem as compared with other implants in bivariate analysis. However, this study used Multivariable Cox-proportional hazards model to adjust for this imbalance. No exclusion of patients who had osteoarthritis secondary to slipped capital femoral epiphysis (SCFE), avascular necrosis (AVN), perthes or osteosynthesis was considered. This study included all adults >21 years old with primary diagnosis of osteoarthritis at the time of elective THA. The study did not adjust for bisphosphonates or antiresorptive drugs that may be used as one of the pharmacological therapies to manage pain in osteoporosis. However, the comorbidity, osteoporosis was controlled in the regression model. In addition, we also controlled for standard pain management therapies like NSAIDs, opioids and steroids. This study notes a very small proportion of surgeons, 0.6% were non-orthopaedic surgeons. This may be due to data anomaly or involvement of trauma surgeons. However, this study includes only elective surgeries for THA. Also, surgeon specialty was adjusted for in the Cox regression analysis to control for confounding if any due to this variable. Under-reported or missing diagnoses based on patients' choice (not to seek care) or access challenges could not be captured. The findings from this database study are generalizable to similar populations with primary THA and the risk of revision over 3 years post THA. This study evaluated the risk of all-cause revisions only and did not analyze specific cause for revisions. Future studies could focus on specific cause for revisions, other complications associated with the components of the THA, such as collar²³ and follow patients over longer terms post THA.

Conclusions

This real-world study found that ACTIS total hip system demonstrated a low cumulative revision rate at 3 years post-THA of 1.08% (95% CI, 0.43–2.72%). The risk of revision was statistically significantly lower than the other implants (HR 0.43 (0.19–0.97) $p=.042$). Our findings are consistent with data available from other real-world data sources.¹³

Transparency

Declaration of funding

This study was funded by Johnson and Johnson, New Brunswick, NJ, USA.

Declaration of financial/other relationships

ASC, JM, AB, and CEH are employees and stockholders of Johnson and Johnson. JR is a contractor with Johnson and Johnson. Peer reviewers on this manuscript have received an honorarium from CMRO for their review work. A peer reviewer discloses their role as a consultant for DePuy-Synthes, Thompson Surgical Inc., and ConvaTec Inc. and an editorial board member for *Journal of Arthroplasty*, *Arthroplasty Today*, and *Reconstructive Review*. This peer reviewer has also received royalties from SLACK, Inc. and Johns Hopkins University Press. The remaining peer reviewers have no other relevant financial relationships to disclose.

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