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Outcomes of Ceramic Bearings After Primary Total Hip Arthroplasty in the Medicare Population

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ABSTRACT

Background: The purpose of this study was to analyze the outcomes of ceramic bearings used in primary total hip arthroplasty (THA) in the Medicare population.

Methods: A total of 315,784 elderly Medicare patients (65+) who underwent primary THA between 2005 and 2014 were identified from the United States Medicare 100% national administrative hospital claims database. Outcomes of interest included infection, dislocation, revision, or mortality at any time point after primary surgery. Propensity scores were developed to adjust for selection bias in the choice of bearing type at index primary surgery.

Results: For primary THA patients treated with ceramic-on-polyethylene (C-PE) bearings and ceramic-on-ceramic (COC) bearings, there was significantly reduced risk of infection relative to metal-on-polyethylene (M-PE) bearings (C-PE hazard ratio [HR]: 0.86, $P = .001$; COC HR: 0.74, $P = .01$). For the C-PE cohort, we also observed reduced risk of dislocation (HR: 0.81, $P < .001$) and mortality (HR: 0.92, $P < .001$). There was no significant difference in risk of revision for either the C-PE or COC bearing cohorts when compared with M-PE. For the COC cohort, there was no significant difference in dislocation or mortality risk.

Conclusion: As in previous studies, we found that ceramic bearings have similar overall revision risk as M-PE bearings in primary THA at 8-9 years of follow-up. The results indicate that, after adjusting for selection bias and various confounding patient-, surgeon-, and hospital-related factors, Medicare primary THA patients treated with ceramic bearings exhibit lower risk of infection than those treated with M-PE bearings. In addition, C-PE bearings were associated with lower risk of dislocation and mortality.

Ceramic bearings, including ceramic-on-ceramic (COC) and ceramic-on-polyethylene (C-PE), are currently the most widely used alternative to metal-on-polyethylene (M-PE) bearings in total hip arthroplasty (THA) [1]. The long-term successful clinical survivorship of contemporary ceramic bearings is now well established [1,2]. Ceramic bearings were initially developed because of their improved wear resistance relative to M-PE [3,4]. More recently, the use of ceramic femoral heads have been shown to reduce the risk of metal release due to modular taper fretting and corrosion [5]. On the other hand, ceramic bearings have known disadvantages, including their increased cost [6]; low fracture risk [2,7-9]; and, with COC hips, squeaking [10].

It has been suggested that COC bearings may be associated with reduced dislocation risk [11,12] and reduced infection risk [13]. Interest in ceramic bearings as a potential mitigating factor for dislocation was first raised by researchers from France who, at long-term follow-up, observed fewer late dislocations, less tissue damage, and better preserved hip musculature around the hips of patients implanted with COC in the 1970s and 1980s as opposed to C-PE [11,14]. There can be little doubt that 32-mm diameter heads

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and gamma air-sterilized polyethylene liners, available to clinicians up to the 1980s, would be susceptible to much greater volumetric wear than COC hips and concomitant periprosthetic inflammation. It is also known, however, that modern highly crosslinked polyethylenes have greatly reduced the wear and risk of osteolysis in today's hip arthroplasties [15] so it is unclear how to apply the findings of Hernigou et al [11,14] to modern implants and surgical techniques. Thus, whether ceramic bearings reduce long-term dislocation risk is an open topic in the literature and is complicated by differences in head size, surgical approach, and polyethylene bearing materials over the years.

Recently Pitto and Sedel [13] introduced the concept that COC bearings may reduce infection risk. They analyzed clinical outcome data from the New Zealand Registry over a 15-year period and compared the risk of revision due to deep infection among ceramic bearings and metal bearings. Although they found a reduced risk of infection among patients treated with COC bearings, the only patient factors they accounted for in their Cox regression analysis were age and gender. However, the researchers did not account for patient health status (ie, comorbidities) or obesity, which are among the most important predictors of infection risk in THA [16]. The previous study also did not address surgeon bias in bearing selection with their analysis [17]. For these reasons, further exploration of the hypothesized association between ceramic bearing usage and risk of deep infection was warranted.

Our group recently studied the outcomes of ceramic bearings after revision surgery among Medicare beneficiaries [18]. We previously accounted for differences in patient health status by including comorbidities as potential confounders, and we employed propensity scores to account for potential surgeon bias in selection of bearing surfaces [17]. For revision THA patients treated with C-PE bearings, we observed a reduced risk of 90-day readmission (hazard ratio, HR: 0.90, $P = .007$) as well as a suggestion for reduced risk of infection with C-PE (HR: 0.88, $P = .14$). Among revision THA patients who received COC bearings, we observed a reduced risk of dislocation (HR: 0.76, $P = .04$). As our analysis used propensity scores [17] to account for the potential of confounding due to differences in patient and clinical factors between cohorts, our previous research [18] supported the hypothesis that ceramic bearings may influence patient outcomes besides survivorship.

The previous findings from revision THA [18] prompted us to examine the outcomes of ceramic bearings for primary THA, including revision, dislocation, infection, and mortality. Accordingly, we tested the hypothesis that ceramic bearings improve clinical outcomes of primary THA when compared with traditional M-PE bearings. We sought to answer the following research questions in the Medicare population: (1) does the use of C-PE bearings influence outcomes following THA as compared with M-PE; and (2) does the use of COC bearings influence outcomes following THA as compared with M-PE?

Methods

We used the Medicare 100% fee-for-service claims database for hospital stays to identify primary THA patients between October 1, 2005, and December 31, 2014. We applied the same exclusion criteria as in our previous study [18]: specifically we excluded patients <65 years old; those enrolled in a health maintenance organization; and those living outside of the 50 states. A 1-year pre-THA enrollment is also required. This 1-year period was used to compile health status and comorbidities prior to patients presenting themselves for THA. Thus, our present study is composed of elderly Medicare beneficiaries for primary hip arthroplasty.

Unique, encrypted Medicare beneficiary identifiers were used to follow patients longitudinally throughout the study period. Patient's Medicare entitlement status and mortality were tracked using a linked “denominator” file provided by the Centers for Medicare and Medicaid Services that accompanied the analytic data sets. The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM: 81.53) procedure code was used to identify primary THA patients. Our focus was to investigate outcomes as a function of bearing surface used in the primary THA, which was identified in the primary THA claim record using an ICD-9-CM code of 00.74 (M-PE), 00.76 (COC), and 00.77 (C-PE). These bearing surface codes were introduced in October 2005 for M-PE, metal-on-metal, and COC bearings. In October 2006, the code for C-PE was introduced. As a result, the C-PE cohort has 1 less year of follow-up than the other bearing surface cohorts in this study.

The 4 outcomes of interest included periprosthetic joint infection, dislocation, revision, or death at any time point following the index primary THA procedure during the study period. Periprosthetic joint infection was identified using an ICD-9-CM diagnosis code of 996.66 [19], whereas dislocation was identified using ICD-9-CM diagnosis codes of 718.35, 835.00-835.03, and 996.42 (effective October 2005) [20]. Revision was identified using ICD-9-CM revision codes (ICD-9-CM: 81.53, 00.70-00.73), and death was identified using the previously mentioned denominator file accompanying the inpatient analytical data set. We used the Kaplan-Meier approach to inspect the crude (unadjusted) survivorship of the M-PE, C-PE, and COC cohorts for each of the outcomes of interest.

Propensity scores were developed to adjust for selection bias in the choice of bearing type for primary THA surgery [18]. As discussed in a recent review [17], propensity scores were used to treat large data sets of retrospective registry data, such as the Medicare claims administrative data, for selection bias. We employed the same approach with the application of propensity scores an in our previous study [18]. Specifically, the propensity score calculates a patient's chance of receiving a C-PE or COC implant, given certain patient and hospital factors. The propensity score was calculated for each patient using the following predictors: age; sex; region; race; Medicare buy-in (a proxy for socioeconomic status); Charlson comorbidity score; revision calendar year; length of stay; hospital charge amount; hospital and surgeon joint arthroplasty volume; hospital location (urban/rural); hospital type (eg, public, private); size of hospital; diabetes; heart disease; obesity; and 2-way interactions among age, gender, race, Charlson score, hospital size, and hospital type. Separate scores were calculated for patients receiving C-PE and COC implants.

Cox regression incorporating propensity score stratification (10 levels) was then used to evaluate the impact of bearing surface selection on outcomes, after adjusting for patient-, hospital-, and surgeon-related factors [18]. The Cox model was stratified into 10 propensity strata, and the overall HRs were estimated as the relative risk of infection, dislocation, and other outcomes between the ceramic and conventional bearing. Because the Medicare data afford the study with a large cohort of THA patients, a 10-level stratification provides reasonably well-matched propensity levels between ceramic and conventional bearing patients. The Cox regression model incorporated the main study variables: bearing type (C-PE, COC, or M-PE) as well as the following potential confounding variables: patient age; race; resident Census region; patient diagnosis of diabetes, heart disease, or obesity; patient Charlson comorbidity index; hospital type, location, and size; hospital procedure volume; surgeon procedure volume; total hospital charges; length of stay; Medicare buy-in; operating room charges; and calendar year. Death and revision can be considered competing events for other outcomes such as infection and dislocation. Although the cumulative incidence function approach has been suggested as an alternative to the conventional Cox regression, it is not universally embraced. For this study, the competing risk is

Table 1
Overall Patient Demographics.

Effect	Level	Metal-on-Polyethylene	Ceramic-on-Polyethylene	Ceramic-on-Ceramic	Total	% Metal-on-Polyethylene	% Ceramic-on-Polyethylene	% Ceramic-on-Ceramic	% Total
	Total	235,800	70,496	9498	315,794	100.0	100.0	100.0	100.0
Age	65-69	57,092	28,394	3628	89,114	24.2	40.3	38.2	28.2
	70-74	62,594	19,460	2402	84,456	26.5	27.6	25.3	26.7
	75-79	56,148	12,258	1749	70,155	23.8	17.4	18.4	22.2
	80-84	39,480	7046	1113	47,639	16.7	10.0	11.7	15.1
	85+	20,486	3338	606	24,430	8.7	4.7	6.4	7.7
Charlson Index (CCI)	00	132,681	41,973	5659	180,313	56.3	59.5	59.6	57.1
	1-2	82,442	23,442	3153	109,037	35.0	33.3	33.2	34.5
	3-4	16,263	4127	508	20,898	6.9	5.9	5.3	6.6
	5+	4414	954	178	5546	1.9	1.4	1.9	1.8
Discharge type	Home	40,712	16,368	1592	58,672	17.3	23.2	16.8	18.6
	Home with home health services	76,197	27,889	3306	107,392	32.3	39.6	34.8	34.0
	Other facility	3227	699	170	4096	1.4	1.0	1.8	1.3
	Rehab facility	28,548	6283	1455	36,286	12.1	8.9	15.3	11.5
	Skilled nursing facility	87,116	19,257	2975	109,348	36.9	27.3	31.3	34.6
Hospital annual total joint arthroplasty volume	150-300	62,280	19,781	2683	84,744	26.4	28.1	28.2	26.8
	300-450	45,986	12,834	1555	60,375	19.5	18.2	16.4	19.1
	450-600	31,738	8596	1486	41,820	13.5	12.2	15.6	13.2
	600+	61,690	17,868	1866	81,424	26.2	25.3	19.6	25.8
	<150	34,106	11,417	1908	47,431	14.5	16.2	20.1	15.0
Hospital beds	001-149	45,691	16,552	2000	64,243	19.4	23.5	21.1	20.3
	150-299	62,845	18,330	2380	83,555	26.7	26.0	25.1	26.5
	300-499	65,304	16,025	2563	83,892	27.7	22.7	27.0	26.6
	500+	61,960	19,589	2555	84,104	26.3	27.8	26.9	26.6
Hospital ownership	Nonprofit	30,555	9784	1694	42,033	13.0	13.9	17.8	13.3
	Private	183,405	54,488	7088	244,981	77.8	77.3	74.6	77.6
	Public	21,840	6224	716	28,780	9.3	8.8	7.5	9.1
Hospital setting	Rural	25,629	5985	716	32,330	10.9	8.5	7.5	10.2
	Urban	210,171	64,511	8782	283,464	89.1	91.5	92.5	89.8
Hospital stay	1-2	45,004	22,109	1545	68,658	19.1	31.4	16.3	21.7
	3-4	159,405	42,407	6376	208,188	67.6	60.2	67.1	65.9
	5+	31,391	5980	1577	38,948	13.3	8.5	16.6	12.3
Hospital teaching	No	153,154	47,903	6684	207,741	65.0	68.0	70.4	65.8
	Yes	82,646	22,593	2814	108,053	35.0	32.0	29.6	34.2
Race	Black	8469	2872	408	11,749	3.6	4.1	4.3	3.7
	Other/unknown	4362	1571	292	6225	1.8	2.2	3.1	2.0
	White	222,969	66,053	8798	297,820	94.6	93.7	92.6	94.3
Resident region	Midwest	66,829	14,441	1960	83,230	28.3	20.5	20.6	26.4
	North East	55,633	14,254	2016	71,903	23.6	20.2	21.2	22.8
	South	61,130	23,940	3427	88,497	25.9	34.0	36.1	28.0
	West	52,208	17,861	2095	72,164	22.1	25.3	22.1	22.9
Sex	Female	148,387	42,318	5673	196,378	62.9	60.0	59.7	62.2
	Male	87,413	28,178	3825	119,416	37.1	40.0	40.3	37.8

Table 2
Summary of Hazard Ratios, COC, and C-PE, Compared With M-PE.

Postoperative Complication	COC vs M-PE		C-PE vs M-PE	
	HR	95% CI, *P* Value	HR	95% CI, *P* Value
Mortality	0.97	0.92-1.02, .235	0.92	0.88-0.95, <.001
Dislocation	0.97	0.83-1.13, .701	0.81	0.74-0.88, <.001
Infection	0.74	0.59-0.93, .010	0.86	0.78-0.94, .001
Revision	1.10	0.85-1.42, .461	0.95	0.89-1.01, .095

COC, ceramic-on-ceramic; C-PE, ceramic-on-polyethylene; M-PE, metal-on-polyethylene; HR, hazard ratio; CI, confidence interval.

addressed by calculating cause-specific hazards for each type of outcome separately. Records with nonobservance of the specific outcome due to death, revision, or other reasons (eg, end-of-study, termination of Medicare enrollment) are censored. About 13% died during the follow-up period and about 4% of the primary THA patients had a revision detected, and some of these revisions undoubtedly are associated with infection. Cumulative incidence function approach in data with modest level of competing risk censoring generally leads to results comparable to those using cause-specific hazard modeling. All statistical analyses were performed using SAS statistical software (version 9.4, Cary, NC).

Results

A total of 315,784 elderly Medicare patients who underwent primary THA between 2005 and 2014 with known bearing types were identified from the Medicare 100% hospital administrative database, including 70,495 patients who received C-PE, 9497 patients who received COC, and 235,792 patients who received M-PE bearings (Table 1). The THA patients in this study were 62% female, on average (±standard deviation) 74.3 ± 6.5 years old, 94% white, and 57% had no significant comorbidities (corresponding to a Charlson score of 0, Table 1). The usage of C-PE implants in THA was highest in the 65-69 years age category (32% of THAs in that cohort) and lowest among those ages 85+ (14% of THAs in that cohort). The percentage of patients receiving COC implants, on the other hand, was more uniform among all age cohorts and varied between 2% and 4% of THAs in each age category.

Utilization of C-PE and COC was the same between male (40%) and female (60%) patients, which is similar to the male and female ratio of 37% vs 63% for M-PE. Although patients with bearing codes were dominantly white in this study, the utilization of ceramic bearings was homogeneous across races. For instance, 22% of white patients, 24% of black patients, and 25% of patients of unknown/other races received C-PE whereas the utilization of COC bearings were 3%, 3%, and 5% for white, black, and unknown/other races, respectively. While patients in the midwest received the largest number of M-PE implants (66,829), patients in the south received the largest number of C-PE (23,940) and COC (3427) implants. Among patients with M-PE implants, 14.4% died during the study period, compared with 6.1% mortality among the C-PE and 15.8% among the COC patients. As an outcome, mortality is more common than dislocation (1.5%), infection (1.1%), or revision (4.0%).

For THA patients treated with C-PE bearings, there were reduced risks of dislocation (HR: 0.81, 95% confidence interval [CI]: 0.74-0.88, $P < .001$), infection (HR: 0.86, 95% CI: 0.78-0.94, $P = .001$) and mortality (HR: 0.92, 95% CI: 0.88-0.95, $P < .001$) compared to M-PE bearings (Table 2). We also observed a suggested trend for

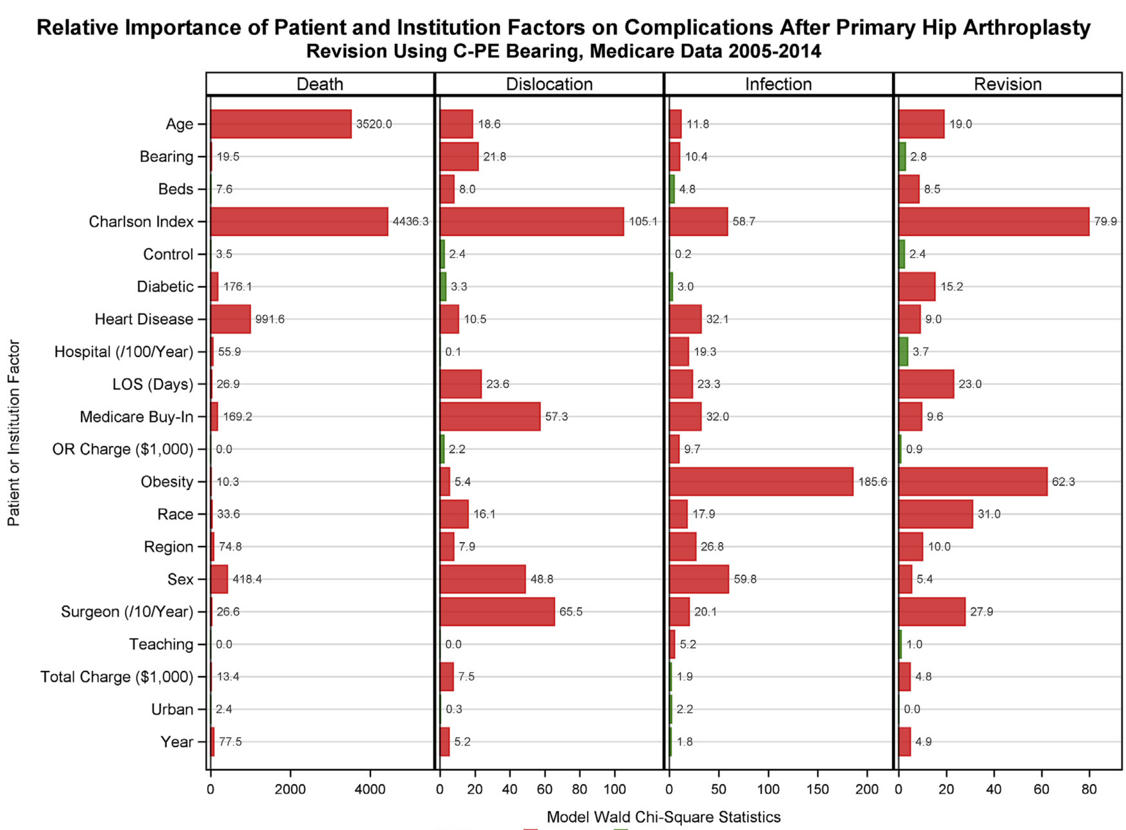

Fig. 1. Relative importance of patient, clinical, and institution factors on risk of mortality, dislocation, infection, and revision following primary total hip arthroplasty using C-PE vs M-PE bearings. The effect size for each factor is judged by the relative magnitude of the model Wald chi-squared statistic. C-PE, ceramic-on-polyethylene; M-PE, metal-on-polyethylene; LOS, length of stay; OR, operating room.

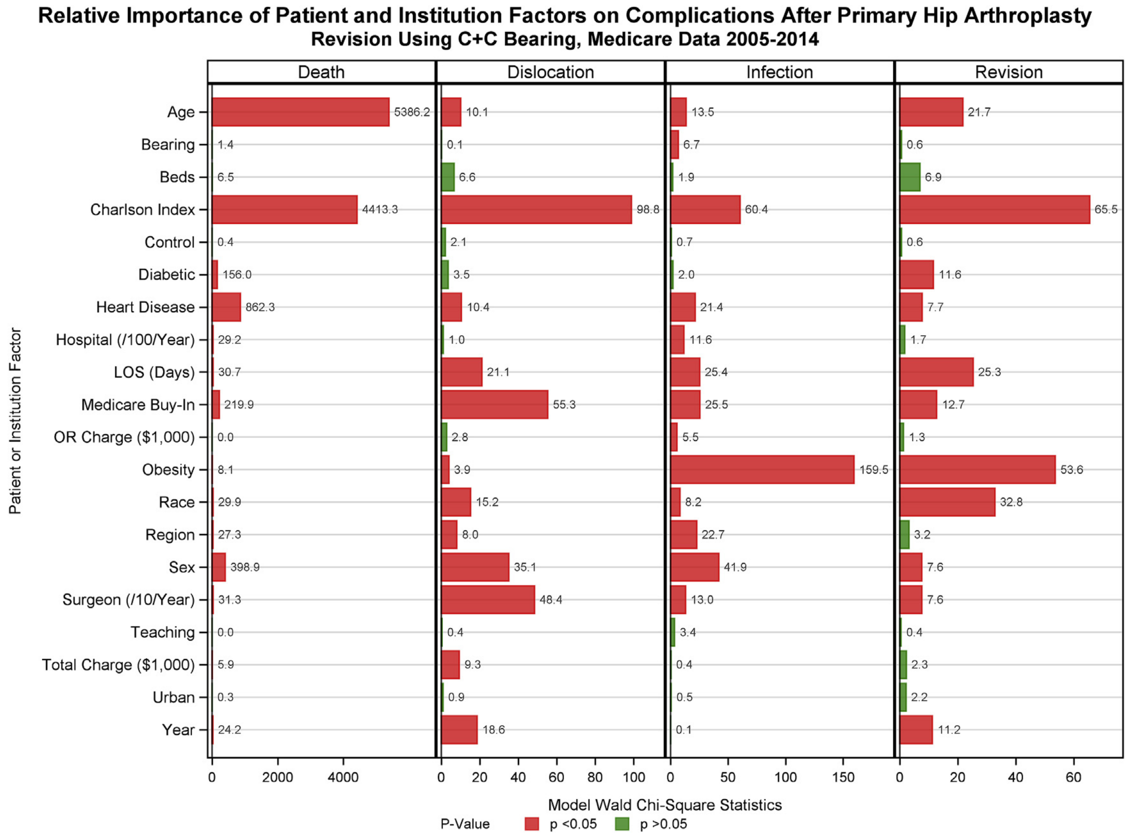

Fig. 2. Relative importance of patient, clinical, and institution factors on risk of mortality, dislocation, infection, and revision following primary total hip arthroplasty using COC vs M-PE bearings. The effect size of each factor is judged by the relative magnitude of the model Wald chi-squared statistic. COC, ceramic-on-ceramic.

reduced risk of revision with C-PE (HR: 0.95, 95% CI: 0.89-1.01) that did not reach statistical significance ($P = .10$). Based on the multivariate Cox model, the adjusted survivorship at 8 years, using infection as an end point (with 95% confidence intervals), was 98.3% (98.2%-98.4%) for M-PE, 98.5% (98.4%-98.7%) for C-PE, respectively. The Charlson comorbidity index consistently ranked among the most important predictors for death, dislocation, and revision and was the second most important predictor for infection (Fig. 1). Obesity was the most important risk factor for infection. Obesity was also the second most influential factor for revision.

For THA patients treated with COC, there was reduced risk of infection (HR: 0.74, 95% CI: 0.59-0.93, $P = .01$) (Table 2). After propensity score stratification and adjustment for confounders, there was no significant difference in risk of dislocation ($P = .70$), revision ($P = .46$), and mortality ($P = .24$) for the COC bearing cohorts when compared with M-PE. The adjusted survivorship at 8 years, using infection as an end point (with 95% confidence intervals), was 98.7.0% (98.5%-99.0%) for the COC cohort. When COC and M-PE cohorts were compared, Charlson index was the most important predictor for dislocation and revision (Fig. 2). For mortality, age was the most important predictor followed by Charlson score. Obesity was the most important predictor for infection.

Discussion

In this study of primary total hip surgery patients in the elderly Medicare population, we asked how the use of ceramic bearings influenced outcomes relative to M-PE. Overall, the findings for the C-PE cohort relative to M-PE supported our hypothesis that outcomes, specifically infection, dislocation, and mortality, were associated with ceramic bearing selection. The findings for the COC cohort likewise showed an association between ceramic bearing usage and reduced infection, but other outcomes were not significantly impacted.

In theory, the questions we posed in the present study could be addressed by a long-term prospective randomized controlled trial; however, due to the sample size considerations and the length of the study, such an approach is neither economically nor practically feasible. On the other hand, advanced statistical techniques, such as the propensity score approach we adopted for the present study, were developed specifically to address issues of selection bias that may be introduced in the nonrandom assignment of therapies to different arms of a clinical study [17]. In real-world clinical conditions, physicians naturally tailor interventions based upon their patients' characteristics and truly blinded random assignment of treatment is not realistic. For example, younger (and healthier) patients are more often selected for ceramic bearings than patients receiving M-PE bearings. It is precisely this type of selection bias that we sought to overcome by implementing the propensity score approach for the present study. Nonetheless, certain nonobserved cofounding factors may still be present, whose effect cannot be controlled by the propensity stratification or direct adjustment in the Cox model. Additionally, our study was limited to THAs in the Medicare records with known bearing codes. Over half of the THAs in the Medicare records did not include the ICD-9-CM codes that report the bearing material use. An informal review of the nonreporting patients has not revealed distinct differences that may have biased the study results; however, we cannot exclude the possibility of nonreporting bias based on the inherent limitations of the Medicare data set.

Our analysis was limited to the ICD-9-CM classification of procedures and diagnoses codes that comprise administrative billing data. We attempted to include and adjust for the procedure complexity and difficulty due to patient and clinical factors by considering the patient's Charlson comorbidity index and length of stay as proxies. We relied on the ICD-9-CM bearing codes for both types of ceramic bearings and the control (M-PE) bearings; however, these codes are general and do not distinguish between different polyethylene formulations, different types of ceramic biomaterials, or head size that were used clinically during the study period. In the 2000s, different formulations of highly crosslinked polyethylene and different types of ceramic bearing materials (eg, BIOLOX delta) were clinically introduced [21,22]. Furthermore, changes in femoral head size up to 40 mm were clinically introduced during this period for M-PE and C-PE bearings to improve joint stability and reduce dislocation risk [20]. Because COC bearings are regulated by the stringent Premarket Approval process, for many years, the only head size clinically available in the United States incorporating BIOLOX delta was 28 mm or 32 mm, with 36-mm COC bearings only being approved by the US Food and Drug Administration as recently as 2013. For these reasons, the granularity of the administrative bearing codes limits our ability to answer questions about specific formulations of bearing materials and head size, especially for COC bearings which, prior to 2013, were only available in head sizes of 32 mm or less throughout the United States.

THA outcomes such as revision and dislocation may be associated with surgical approach [23,24]. We were unable to account for potential differences in surgical approach using the Medicare database because this clinical information is not captured as part of the administrative billing records. As a result, this study is limited by its inability to address potential confounding between bearing selection and surgical approach.

Consistent with the findings of international registries [9,25], we found the revision risk was similar between ceramic bearing cohorts and M-PE cohort for the Medicare population. In our study, the longest follow-up was 8 years for the C-PE cohort and 9 years for the COC cohort. Longer term follow-up may be needed to detect differences in revision rates for the ceramic bearing cohorts relative to M-PE; however, for an elderly patient population such as Medicare beneficiaries, it may also be necessary to formally examine the competing risks of revision and mortality. In the present study, patients who died prior to revision were considered censored, and more detailed analysis of competitive risks was beyond the scope of the present study. Because mortality increases with follow-up, the risk of complications that present relatively early in a patient's history, such as infection and dislocation, warrant additional scrutiny as these complication risks will potentially impact a greater patient population.

Our findings pertaining to infection, like those of Pitto and Sedel [13], support an association between ceramic bearing usage and reduced risk of infection. In contrast with Pitto's study, which showed an effect only for COC bearings, we found lower infection risk was associated with both C-PE and COC bearing cohorts relative to M-PE. Data from recent national conferences would suggest that ceramics may be more resistant to infection than CoCr surfaces [26-29], which may help explain our findings in the present study. Certainly, the association between reduced infection and the use of ceramic bearings warrants further research.

Previous studies have reported that COC bearings have lower risk of dislocation compared with M-PE in primary THA [11,12]. Hernigou and coworkers compared the risk of dislocation in C-PE and COC bearings implanted from 1978 to 1985. However, the C-PE in that study incorporated historical, gamma air-sterilized polyethylene for the acetabular liner that would generate biologically active wear particles and helps to explain the periprosthetic soft-tissue damage as compared with COC in these historical cohorts. In our study, during which HXLPE was commonly used in the United States, we observed an association between reduced dislocation and C-PE bearing usage relative to M-PE but not with COC. Because dislocation risk is a function of head size, which was constrained in the COC cohort due to regulatory limitations in the United States, our findings are limited in this regard, for the reasons we already discussed. It remains unclear why the C-PE cohort fared better against dislocations than the M-PE.

The association between reduced mortality and the C-PE bearing cohort was unexpected and difficult to compare with the literature because relatively few studies examine the association between bearing usage and mortality [30]. In the United Kingdom, researchers studied whether metal-on-metal bearing usage was associated with increased revisions and reduced mortality [30]. In the present study, we found the C-PE group was associated with lower risk of complications, including infection and dislocation, which may help explain the lower mortality rate in the C-PE cohort.

In summary, we did not observe a lower risk of revision in either ceramic bearing cohort relative to M-PE. Our results indicate that, after adjusting for selection bias and various confounding patient-, surgeon-, and hospital-related factors, Medicare THA patients treated with ceramic bearings experienced reduced risk of infection and those treated specifically with C-PE bearings had, in addition to reduced infection risk, lower odds of dislocation and mortality. The findings of this study support further research into the association between ceramic bearings and complication avoidance in primary THA.

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