



# The influence of bearing surfaces on periprosthetic hip infections: analysis of thirty nine thousand, two hundred and six cementless total hip arthroplasties

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## Abstract

**Purpose** Periprosthetic hip infection (PHI) is a devastating complication. The association between PHI and bearing surfaces as well as patient-related factors has been recently investigated, with contradictive outcomes. The dataset of Emilia-Romagna region Registry for Orthopaedic Prosthetic Implants (RIPO) has been assessed to investigate, if the bearing choice influenced the risk of septic loosening occurrence.

**Methods** RIPO data about 39,206 cementless total hip arthroplasties (THA), collected since 2003, were analysed. Age, gender, BMI, diabetes and bearing surfaces were evaluated. The end point of the study was the revision of at least a single component due to sepsis.

**Results** Adjusted and unadjusted survival rates showed that ceramic-on-ceramic (COC) implants had the lower incidence of PHIs, whereas metal-on-metal (MOM) THAs were significantly more prone to infection. In MOM cohort, stemmed implants were involved in 28 out of 30 cases. Among the demographical features and comorbid conditions, only diabetes statistically influenced the rate of sepsis.

**Conclusions** Bearing surfaces influenced the rate of PHI; in particular, stemmed MOM implants were at higher risk, probably due to metal debris consequent to taperosis. Despite the preliminary results, stemmed MOM THAs should be used with care, and diabetic patients should be warned about increased septic risks.

**Keywords** Septic loosening · Articular coupling · Diabetes · Ceramic · Metal · Polyethylene

## Introduction

Periprosthetic hip infection (PHI) is a devastating complication occurring in the 0.3%–2.9% of the primary total hip arthroplasties (THAs) [1, 2]. PHI occurrence involves multiple hospital readmissions, high costs, complex revision procedures and severe medical comorbidities [1, 3]. Thus, PHI prevention is paramount [1–4]. The infection preventive strategy acts at multiple levels, with pre-operative, intra-operative

and post-operative measures [4]. Surgical factors as antibiotic prophylaxis, laminar air flows and suits have been advocated to influence PHI rates to different extents [4, 5]. Furthermore, the biomaterials composing the prosthetic devices demonstrated to influence the rate of bacterial adhesion in *in vitro* studies: cobalt-chrome was more susceptible to infection than titanium [6]. Considering that liners and heads are the preferred sites for bacterial colonisation in THA, it is likely that the choice of articular couplings may influence the rate of PHI [6]. In particular, metal-on-metal (MOM) THAs were associated with a higher revision rate for PHI than other articular couplings [7–10]. However, the association with articular couplings is still controversial [8].

Thus, the Registry of Orthopaedic Prosthetic Implants (RIPO) was enquired about PHI rates and articular couplings in cementless THAs. Potential PHI risk factors, such as gender, age, body mass index (BMI) and diabetes were also analysed. The failed implant features were investigated in details as well.

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## Materials and methods

RIPO has been actively collecting data on all primary hip arthroplasty, and revision surgery performed in public and private hospitals of the Emilia-Romagna region (about 4,500,000 inhabitants), since January 2000 [11]. The registry involves 68 orthopaedic units in the region. It is designed to provide comparisons between the main national registries. Surgeons provide data, including demographics, type and fixation of the implants, by filling specific registry forms before the patient is discharged. The register capture rate is 98%, similar to Swedish and New Zealand registries [9, 12]. The 2% of missing data is mainly related to lack of adhesions [11]. The high capture rate is obtained acting on crossover comparisons with other databases, missing data retrievals and resident patient analyses. Limiting the analysis to resident patients is important to reduce the lack of follow-up data. In fact, due to the economical relationships with the region, all the procedures on patients living in Emilia-Romagna are billed back to the region itself, even when the treatment is performed elsewhere outside the region.

The RIPO was enquired about cementless THAs and the rates of revision due to PHI. Age at surgery, gender, BMI, diabetes and bearing surfaces are considered as potential risk factors for PHI and were consequently investigated [3, 6, 13]. Despite their importance, American Society of Anaesthesiologists (ASA) physical status class and cardiovascular diseases were not assessed, as they are not routinely recorded by the registry [3, 4]. Post-operative deep-vein thrombosis prophylaxis was not evaluated, as heparins were adopted after 99% of the surgeries. The antibiotic prophylaxis was excluded as well, as cefazolin + tobramycin was adopted in 86% of the patients with a 100% rate in MOP and MOM groups.

In the present study, only patients with primary coxarthrosis and developmental dysplasia were considered, in order to reduce possible confounding factors [8]. In addition, cemented or hybrid prostheses were excluded to avoid a possible bias related to the presence of antibiotic in the cement [3, 4]. Dual-mobility implants and other bearing surfaces adopted in a very low percentage of cases were excluded as well.

Diabetes is not directly detected by RIPO. Thus, a cross-over comparison between four population-based databases (RIPO, Hospital Discharge Form database and Pharmaceutical Territorial Assistance (PTA) and medicine directly dispensed by the health system databases) was performed, using the unique personal identification number provided to all patients. The estimation of the presence of diabetes at the time of intervention was assessed according to the criterion of Pedersen et al. [13]. Patients who presented at least one admission in the year before the THA with discharge diagnoses of type 1 or 2 diabetes (identified by 250.xx or

648.0x ICD-9-CM International Classification of Diseases codes) or with a drug prescription in the same period for insulin or oral antidiabetic drugs (identified with A10A or A10B in the Anatomical Therapeutic Chemical Classification System) were considered diabetic [13]. As the PTA database started in 2002, the reliable prevalence of diabetic population could be assessed only from 1st of January 2003 (1 year after). Thus, the data extraction about cementless THAs started from 1st of January 2003 on all patients residing in the Emilia-Romagna region.

Ethical approval was not necessary due to the features of the registries and databases, routinely collecting personal data and concealing the patient identities.

## Statistical analysis

The survival of patients for PHI was estimated using the Kaplan-Meier method. The end point was a revision for sepsis, with the exchange of at least one component, thus only deep infections were included. Cox's regression model was used for multiple adjustments of potential confounding factors and to investigate the predictive value of selected variables for cumulative patient survival. Results are expressed as risk ratios using Cox proportional hazard method. Differences between groups were determined by chi-square or ANOVA test, depending on data distribution. The analysis was performed using SPSS 14.0 for Windows, version 14.0.1, Chicago, Illinois.

## Results

A total amount of 39,206 implants were finally involved, with COC THAs being the largest cohort (55% of all the THAs). Among COC implants, the delta-on-delta coupling (CeramTec, Plochingen, Germany) was implanted in 71% of the cases [Table 1]. Considering the total amount of implants involved, the mean age of patients was 68 years (95% confidence interval 67.9–68.1), with a female prevalence (58%). Fifty-seven percent of patients were overweight or obese (BMI  $\geq$  25). The diabetic patients were 9% of the whole. The mean observation period was 5.5 years (range, 0–13 years—95% confidence interval 5.5–5.6). The demographic features of every single-bearing surface cohort were specified in Table 2.

The global rate of revisions due to septic loosening was 0.3% (118 cases). The unadjusted survival rate for all the bearing surfaces, calculated according to the Kaplan-Meier method, was 99.7% at 12 years [Fig. 1]. The survival rates of the four bearing surfaces were significantly different ( $p = 0.0015$ , Wilcoxon test). COC implants had the lower septic risk; whereas, MOM THAs were significantly subjected to

**Table 1** The most represented bearing surface was COC, followed by COP. XLPE cross-linked polyethylene

Bearing surfaces	No. of primary implants	Head-liner couplings	No. of primary implants
Ceramic-on-ceramic (CoC)	21,476	Delta-on-delta	15,308
		Alumina-on-alumina	4951
		Alumina-on-delta or vice versa	1217
Ceramic-on-polyethylene (CoP)	8965	Alumina-on-polyethylene	3221
		Delta-on-XLPE	4309
		Alumina-on-XLPE	758
		Delta-on-polyethylene	677
Metal-on-polyethylene (MoP)	5730	Metal-on-polyethylene	3065
		Metal-on-XLPE	2665
Metal-on-metal (MoM)	3035	Metal-on-metal	3035
Total			39,206

PHIs ( $p = 0.01$ ). The differences between the bearing surfaces were not detectable in the first six months ( $p < 0.05$ ).

Concerning the demographical features, there was a non-homogenous distribution among the groups (BMI distribution, chi-square test,  $p < 0.05$ ; mean age at THA,  $p = 0.001$ , ANOVA; diabetes, chi-square test,  $p < 0.05$ ; gender, chi-square test,  $p < 0.05$ ). Due to non-homogenous distribution of the possible risk factors, Cox proportional hazard method was used, with revision for septic loosening as end point. Therefore, five independent variables were entered into the analysis: gender, BMI, age at surgery, bearing surfaces and diabetes.

Gender, BMI and age at surgery did not influence the rate of revision for septic loosening. Diabetes statistically impacted the final result ( $p = 0.0046$ ). Bearing surfaces did statistically influence the results, with MOM THAs achieving a  $p$  value of 0.01 [Table 3].

The failed implants of the four groups were then analysed. All the failed stemmed THAs had a 12/14 mm taper in titanium alloy. No specific implant influenced the results. The COC and COP implants failed after a mean time of 2.1 years, whereas MOM failed after 3.3 years and MOP after 4.3 years. In COC and COP cohorts, the use of different types of ceramic and polyethylene did not statistically influenced the results ( $p >$

0.05). In the MOP groups, the cross-linked polyethylene was implanted in the 38% of the failed cases, with conventional polyethylene accounting for the vast majority of the septic failures [Fig. 2]. All head sizes were smaller than 36 mm (28 mm, 73%). In the MOM cohort, the failed implants (30) were stemmed THAs in 28 cases and resurfacing THAs in 2 patients. The rate of infection in stemmed THAs was six times higher than in resurfacing implants. Head size did not influence the PHI occurrence ( $p > 0.05$ ).

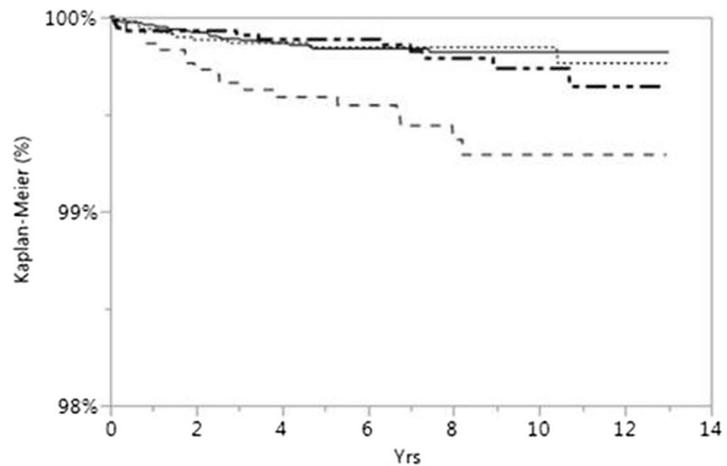
## Discussion

The PHI occurrence and its relationship with demographical features and bearing surfaces is a controversial issue [8]. MOM implants were frequently implicated in PHIs, whereas COC THAs were generally considered at lower risk [7–10, 14, 15]. In a meta-analysis, Lee et al. found that MOM bearings were more prone to revisions due to sepsis than COC THAs [7]. This finding was also confirmed by Bozic et al., investigating a Medicare population after adjusting for patient and hospital factors [15]. In a New Zealand registry study, Pitto and Sedel stated that COC implants were rarely revised for septic loosening, all other bearing surfaces achieving lower

**Table 2** The demographic data of the four cohorts showed that MOP had the highest mean age at THA and the largest prevalence of females. The longest mean follow-up was achieved in MOM group

Bearing surfaces	No. of primary implants	Mean age at THA and range	Female gender (%)	BMI $\geq 25$ (%)	Diabetic patients (%)	Mean follow-up (years)
COC	21,476	66 (13–93)	58	56	9	4.93
COP	8965	71 (18–94)	61	57	10	5.27
MOP	5730	72 (20–95)	63	59	9	6.98
MOM	3035	64 (16–93)	47	56	9	7.60
Total	39,206	68 (13–95)	58	57	9	5.51

**Fig. 1** The unadjusted survival curves of the four bearing groups were described according to Kaplan-Meier; the MOM THAs were more prone to infections. COC, continuous line; COP, dotted line; MOP, black dashed line with dots; MOM, grey dashed line

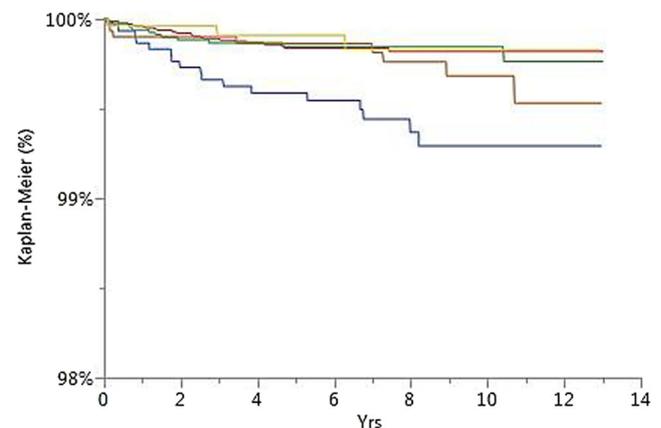


% survival (Confidence interval 95%)					
Bearing surfaces	1 Year	3 Years	5 Years	7 Years	10 Years
COC (n=21476)	100,0 (99.9-100.0)	99,9 (99.8-99.9)	99,8 (99.8-99.9)	99,8 (99.8-99.9)	99,8 (99.7-99.9)
Implants at risk	18953	14053	9602	5802	1909
COP (n=8965)	99,9 (99.9-100.0)	99,9 (99.8-99.9)	99,8 (99.7-99.9)	99,8 (99.7-99.9)	99,8 (99.7-99.9)
Implants at risk	7678	5726	4238	2902	1423
MOP (n=5730)	99,9 (99.8-100)	99,9 (99.8-100)	99,9 (99.7-99.9)	99,8 (99.6-99.9)	99,7 (99.5-99.9)
Implants at risk	5377	4700	3913	3044	1406
MOM (n=3035)	99,9 (99.6-99.9)	99,7 (99.4-99.8)	99,6 (99.3-99.8)	99,4 (99.1-99.7)	99,3 (98.8-99.6)
Implants at risk	2974	2841	2507	1770	661
Total (n=39206)	99,9 (99.9-100.0)	99,9 (99.8-99.9)	99,8 (99.8-99.9)	99,8 (99.7-99.8)	99,7 (99.7-99.8)
Implants at risk	34982	27320	20260	13518	5399

**Table 3** Due to the non-homogenous distribution of the possible risk factors, Cox proportional hazard method was used, being revision for septic loosening the end point. Diabetes and bearing surfaces statistically influenced the PHI incidence

	Hazard ratio	95% lower limit	95% upper limit	p value
Gender (Reference male)	0.75	0.45	1.27	0.28
BMI class (Reference obese)				0.84
Overweight	1.2	0.62	2.56	0.57
Normal	1.1	0.52	2.41	0.82
Age in years	0.15	0.019	1.19	0.07
Bearing surfaces (Reference COC)				0.05
MOM	2.56	1.26	4.95	0.01
MOP	1.33	0.6	2.7	0.47
COP	1.15	0.53	2.30	0.7
Diabetic (Reference no)	2.63	1.35	5.14	0.0046

and comparable outcomes [8]. Reports from registries highlighted a higher revision rate for PHI in MOM THAs. According to the English National Joint Registry, revisions

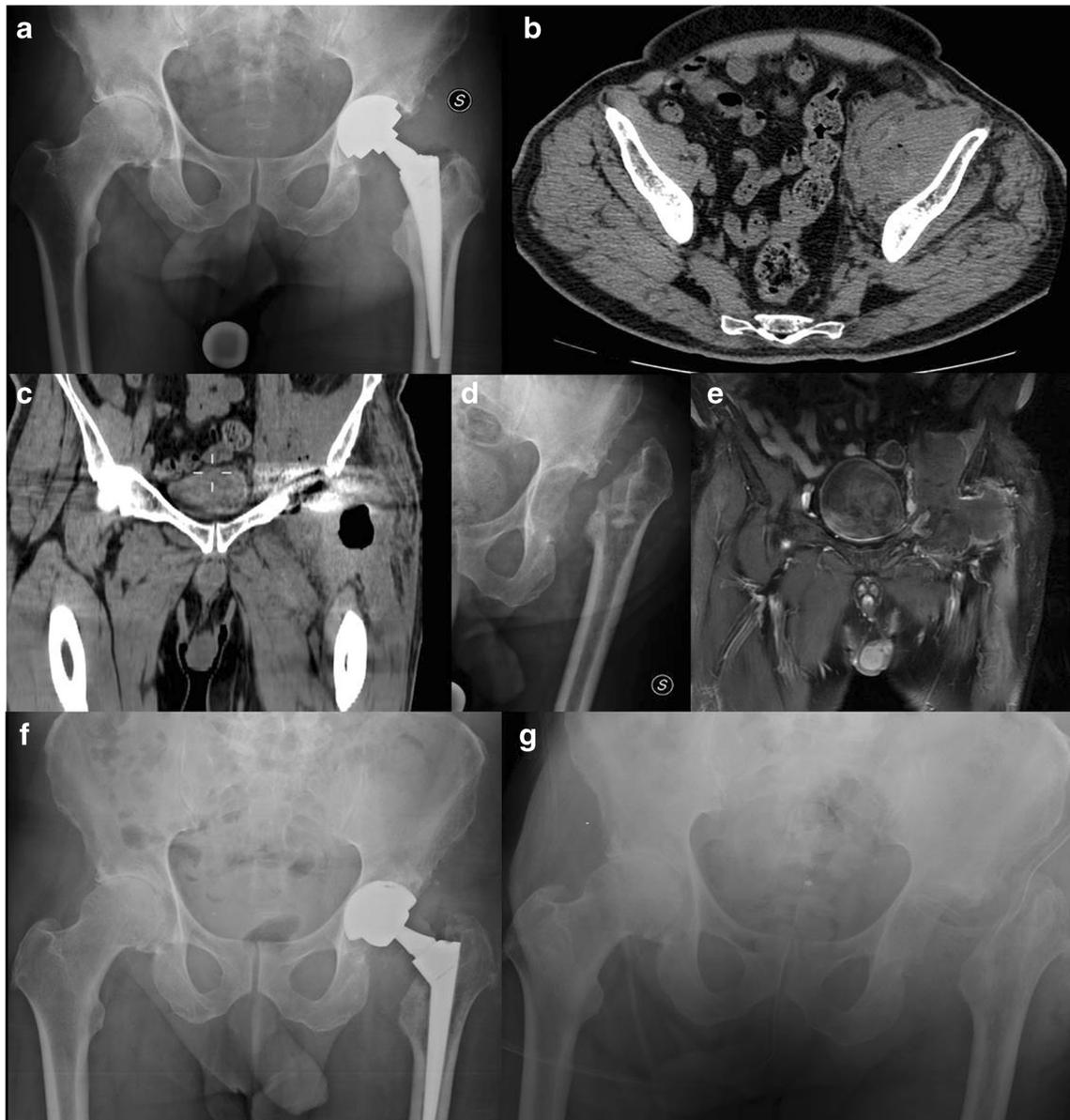


**Fig. 2** The unadjusted survival curves according to Kaplan-Meier showed that when the MOP group was split into two cohorts (conventional and cross-linked polyethylene), cross-linked polyethylene had ceramic-like performances. Red, COC; green, COP; blue, MOM; gold, metal on cross-linked polyethylene; brown, metal on conventional polyethylene

due to sepsis (not adjusted for any risk factors) were 0.62 per thousand patient years in COP THAs, 0.82 in COC and 0.83 in MOP implants; the higher rate was in MOM THAs (1.53) [16]. Similarly, the Australian Registry found a higher risk of revisions for sepsis in MOM implants with large heads; in COC implants septic complications occurred in less than 1% of the cases [9].

This present registry report highlighted that COC had a low rate of revisions due to sepsis with better performances than COP THAs [Fig. 1]. These results were not dependent on

ceramic or polyethylene type. On the other side, MOM implants had a statistically higher risk of PHI in unadjusted and adjusted populations [Table 3]. This finding was consistent with the previous literature. This high rate of PHI could be correlated with hyperemia and synovitis, enhancing bacterial seeding, coagulative necrosis and pseudotumor, thus acting as a scaffold for microorganisms [17–19] [Fig. 3]. Moreover, the cytotoxic effects of cobalt-chrome particles released by MOM implants may induce immunosuppression [19]. A novel finding of this RIPO report was related to the failed MOM implant



**Fig. 3** A 62-year-old male had an infection on a stemmed MOM 3 years after the implant (C-reactive protein > 100 mg/L and sedimentation rate > 30 mm/h, white blood cell count in the synovial liquid > 10,000 cells/ $\mu$ L, polymorphonuclear neutrophils in the synovial liquid > 90%, no bacterial isolation) (a). A large intrapelvic mass was evident with psoas involvement (b, c). The patient underwent implant removal (d); the incisional

biopsy confirmed the presence of a pseudotumor related to metallosis (e). After a prolonged antibiotic therapy, the patient was reimplanted. However, a septic relapse due to methicillin-resistant *Staphylococcus epidermidis* occurred, and the implant was definitely removed

investigation; revisions due to sepsis involved stemmed THAs in the vast majority of cases, regardless of the head size. Thus, it is likely that this outcome was due to trunnion corrosion, which was found to be independent from the head size [20]. The trunnion impact on infection was probably related to the large quantity of metal debris and it was time dependent [20]. In fact, MOM failures due to sepsis occurred later than COC and COP PHIs. Similarly, it is possible that the rate of infection in MOP THAs was partially related to wear, debris and patient susceptibility to them; cross-linked polyethylene performances were close to COC implants, whereas conventional polyethylene was more prone to sepsis, describing an intermediate trend between COC and MOM implants. Considering the rate of wear between conventional and cross-linked polyethylene significantly is different after 2 years and then is linearly increasing, infection rates might be influenced only by a large amount of wear only after six to eight years [21, 22]. In MOM wear and debris were much faster and much more abundant, justifying the different infection trends in the present series and the report by Pitto and Sedel [8]. However, the correlation between sepsis and polyethylene debris is a hypothesis and a hint for future works, and it could not be supported by this report; specific and calibrated studies are necessary.

Concerning the demographical features and the comorbid conditions, the only statistically significant factor was diabetes. This finding was quite surprising, as the previous studies by Bozic et al. and Triantafyllopoulos et al. including very large cases series did not show any statistically significant relationship [3, 15]. On the other side, BMI involvement was not statistically significant in this report differently from many papers about PHI risk factors [3, 15, 23].

The strong points of this report were the high number of cementless THAs, the long-term follow-up, the evaluation of different demographical features and comorbid conditions and the detailed assessment of the failed implants. The higher rate of revisions due to sepsis in MOM implants was confirmed, highlighting that stemmed MOM THAs were at very high risk (this finding is unedited). The weak points of this report were related to the nature of registry reports. A few concomitant pathologies and patient features could not be detected by RIPO and were excluded despite their importance. It is likely that a few septic patients might have not been addressed to surgery, due to unwillingness, failed diagnoses or poor medical conditions; thus, they were not captured. Similarly debridement procedures were not detected, underestimating the rate of septic patients, as well as unexpected septic diagnoses or reticent medical behaviours [24]. Nevertheless, the underestimation should have been equally distributed in the groups. Another cause of concern is related to the diagnosis in MOM THAs. Bozic et al. and Whitehouse et al. commented that the higher rate of revisions in MOP and MOM implants due to sepsis could also include some misleading “pseudo-septic”

reactions due to metal debris and trunnion corrosion [23, 25]. This hypothesis could not be surely ruled out by registries. An underestimation of PHI in resurfacing THAs could be due to non-modular features of these implants. Thus, the surgeons might have tended to perform a simple debridement procedure without any modular component exchange, which was not captured by the registry.

In conclusion, bearing surfaces influenced the rate of PHI. Diabetes was a significant factor affecting PHI rate. Although these data should be very preliminary and considered with special caution due to the abovementioned study limits, in stemmed MOM implants a significantly higher septic risk should be expected. In terms of septic risks, ceramic THAs seem the most reliable solution. Moreover, diabetic patients should be considered at high septic risk, and they should be warned about this possible increased complication. Retrieval reports and multicentre prospective studies may be advisable to better assess the potential demographic and implant-related risk factors for PHI occurrence.

## Compliance with ethical standards

**Conflict of interest** The senior author is paid consultant for Zimmer (Warsaw, US), Adler Ortho (Milan, Italy) and CeramTec (Plochingen, Germany). The other authors declare that they have no conflict of interest.

**Ethical approval** Ethical approval was not necessary as the registry collects personal data as standard practice and conceals the identity of the patients.

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