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What Is the Frequency of Fracture of Ceramic Components in THA? Results from the Norwegian Arthroplasty Register from 1997 to 2017

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Abstract

Background Ceramic bearings in THA have been used to reduce wear and, more recently, to avoid metals in the bearing because of the risk of metal ions adverse effects. Potential disadvantages to ceramic bearings are their brittleness and the ceramic fracture risk, which may lead to revision surgery. The frequency of revision for a fracture ceramic bearing, however, has not been thoroughly studied.

Questions/purposes (1) What is the frequency of revision for a fractured ceramic bearing in ceramic-on-polyethylene (CoP) and ceramic-on-ceramic (CoC) THAs, and is there any difference between alumina ceramics and alumina matrix composites (AMC)? (2) What are the factors associated with this complication? (3) To what extent did the patients who underwent revision for a fractured ceramic bearing undergo subsequent revisions, and for what reason?

Methods The Norwegian Arthroplasty Register has collected data on hip arthroplasty since 1987 and has a completeness of reporting of 97.3% for primary THAs and 93.3% for revision. From 1997 to 2017, 146,171 primary THAs were registered in the Norwegian Arthroplasty Register. Of these, 31,479 had a CoP articulation and 5790 had a CoC articulation. Two manufacturers produced ceramic heads; one produced 25,678 alumina heads and the other made 2465 alumina heads. All 7901 AMC heads were made by the same manufacturer. Patients who underwent CoP THA were a median (range) of 63 years old (11 to 98) and CoC THA were a median (range) 61 years old (17 to 95); 38% (11,833 of 31,479) of the patients who underwent CoP THA and 41% (2379 of 5790) of the patients who underwent CoC THA were males. Femoral heads made of alumina (n = 28,143), zirconia (n = 1225), and AMC (n = 7901) ceramics were used. To assess revision frequency, we identified patients who underwent revision because of fracture of a ceramic head and/or liner, and calculated the Kaplan-Meier survivorship free of revision for fracture in CoC and CoP articulations. Alumina ceramics and AMC were compared. In terms of factors potentially associated with revision, patient factors (age, sex, and diagnosis), type of articulation (CoP or CoC),

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femoral head size, and femoral head/neck length were evaluated with Cox regression models to evaluate any association with ceramic fracture and a Poisson regression to compare alumina and AMC head fractures. To evaluate subsequent revisions, hips that were revised for ceramic fracture were evaluated for any further revisions; Kaplan-Meier survivorship free of further revisions was calculated, and revision causes were identified.

Results Survivorship free from revision for ceramic fracture was 99.9% (95% CI 99.9 to 99.9) for CoP bearings, and 99.8% (95% CI 99.6 to 100) for CoC bearings at 10 years, with 7467 and 1884 hips at risk in the two groups, respectively. The hazard ratio for ceramic head fracture was 3.6 (95% CI 1.7 to 7.6) for CoC compared with CoP. The risk of fracture was greater for alumina ceramics than for AMC heads (adjusted HR 14.1 [95% CI 4.2 to 47.0]; $p < 0.001$). Factors that were associated with revision for fracture of a ceramic head were male sex (HR 5.2 [95% CI 2.6 to 10.4]; $p < 0.001$), a CoC articulation compared with CoP (HR 3.6 [95% CI 1.7 to 7.6]; $p = 0.001$), a 28-mm femoral head compared with a 32-mm head (HR 2.7 [95% CI 1.1 to 6.4]; $p = 0.02$), and short head/neck length compared with a medium head/neck length (HR 2.5 [95% CI 1.1 to 5.3]; $p = 0.03$). Five of 50 patients undergoing revision for ceramic fracture underwent further revisions, resulting in a 5-year survivorship free from re-revision of 86% (95% CI 74.4 to 98.0). The reasons for re-revision were infection (n = 2), another ceramic head fracture (n = 2), and cup loosening (n = 1).

Conclusions Fracture of a ceramic THA bearing is rare and seems to affect about one in 1000 patients who receive such a bearing. To minimize the risk of this complication, surgeons should avoid small femoral heads (< 32 mm) and the shortest head/neck lengths. Surgeons should also know that the risk is increased in CoC articulations and in males. Bearings made of AMC appear to be at lower risk than those made from alumina ceramics. However, the long-term clinical wear performance of AMC bearings has not been extensively studied and should be studied further.

Level of Evidence Level III, therapeutic study.

Introduction

Ceramic bearings were introduced to reduce wear, limit osteolysis, and improve the longevity of THA implants. Alumina ceramic bearings entered the market in 1971, and several improvements in their production have resulted in the third-generation pure alumina that is still used today [6]. Alumina has extreme hardness, a low friction coefficient, and low wear. It is, however, mechanically fragile and can fracture. As a result, the tougher ceramic zirconia (zirkonium dioxide) was introduced in 1985 [3]. Although this ceramic was not as prone to fracture, its clinical performance was not as good as expected. The material was subject to phase transformation with time in vivo, and this resulted in increased wear [8], and so pure zirconia was abandoned. Alumina matrix composites (AMC) such as the Biolox Delta ceramic (CeramTec, Plochingen, Baden-Württemberg, Germany) are gradually replacing pure alumina in clinical practice [2, 15]. AMC typically consists of alumina (> 80%), zirconia (17%), and small amounts of strontium oxide and chromium oxide [14]. The reason for adding these materials was to strengthen the product and protect it from fracture while retaining the wear characteristics of alumina. The fracture of a ceramic component is a rare but serious complication and results in revision surgery. Hard bearings such as ceramics are highly recommended for use during revision of ceramic fractures, at least on the femoral side [16]. Remnants of fractured ceramic may damage a metal head and lead to massive release of metal ions and potentially serious and even life-threatening distant organ failure [5, 16, 19].

The frequency of ceramic fracture has been studied earlier, and in a review, Massin et al. [13] found fracture rates vary between 0% and 10% with a median close to 0 for alumina ceramic. The wide range they identified probably was a function of the fact that most studies on this have been underpowered to study this rare event. We are aware of only one study from a national register with a large cohort that studied ceramic fractures in CoC articulations [10]. They found that 0.1% of alumina heads and 0.01% of AMC heads were revised for fracture, and that the risk for liner fracture was 0.1% for both ceramic types. Small femoral heads and high BMI were identified as factors that were associated with ceramic fractures, whereas the influence of other factors like patient age and sex, femoral head/neck length, and the type of articulation have not, to our knowledge, been studied. The risk of repeat revision after ceramic head fracture is a concern because ceramic fractures leave small particulates in the joint that are difficult or impossible to remove [5,19]; third-body wear after such fractures therefore is a concern, but it has not been extensively studied. One paper found a 37% re-revision rate at 5 years after revision for a fractured ceramic component [1], but to our knowledge, this has not been evaluated in the setting of a large, national register, which might allow a more precise estimate than is possible in a retrospective multicenter study such as that one [1].

We therefore asked the following questions: (1) What is the frequency of revision for a fractured ceramic bearing in ceramic-on-polyethylene (CoP) and ceramic-on-ceramic (CoC) THAs, and is there any difference between alumina ceramics and alumina matrix composites (AMC)? (2) What are the factors associated with this complication? (3) To what extent did the patients who underwent revision for a fractured ceramic bearing undergo subsequent revisions, and for what reason?

Patients and Methods

The Norwegian Arthroplasty Register has collected data on THA since 1987, and the register has been thoroughly described in earlier publications showing completeness of reporting of 97.3% for primary THAs and 93.3% for revision [4, 9, 15]. Based on the patients' unique national identification numbers and the laterality of the hip, each patient was followed until implant revision, death, emigration, or end of the study (December 31, 2017), whichever came first. All hospitals in Norway participate. The Norwegian Arthroplasty Register has a license from the Norwegian Data Inspectorate (reference number 03/00058-20/CGN; latest license issued on September 15, 2014).

As part of the registry process, the surgeon completes a one-page form just after the surgery for primary THAs. The same form is used if the patient subsequently undergoes revision surgery, and the surgeon must indicate on the form the cause for revision. The revision causes for implant fractures studied in this paper were fracture of the femoral head and/or acetabular liner. The implants were recorded with the use of stickers from the manufacturers and the catalog numbers were entered into an implant library.

A revision was defined as a surgical procedure where a component was inserted, changed, or removed. The library contains information on the implants such as material, head size, neck length, and company name. The registry collects basic data on each patient, including age and sex, laterality, previous operations, primary or revision procedures, cause of primary and revision procedure, surgical time, implant information on catalog number level, antibiotic and thromboembolic prophylaxis, surgical approach to the hip and American Society of Anesthesiologists class from 2005. Information on patients who died or emigrated during the study period was obtained from the National Population Register. In the present study 0.4% (152 of 37,269) of study patients emigrated and 12% (4268 of 37,269) died before 10 years after the index operation. The proportion of patients who died before 10 years in the CoC group was 11% and in the CoP group 12%.

Before 1997, no CoC THAs were reported. Therefore, we only included data from 1997 to 2017 in the present study. Between 1997 and 2017, 146,171 primary THAs were reported to our register. A ceramic head was used in 25% (37,269 of 146,171) of these procedures. Of the total number of hips in the register, CoP comprised 22% (31,479 of 146,171) and CoC comprised 4%, and these two groups combined made the study cohort. Within the study population, alumina femoral heads were used in 77% (24,346 of 31,479) of the CoP hips, zirconia was used in 4% (1221 of 31,479), and AMCs were used in 19% (5912 of 31,479) (Table 1). The use of different ceramic articulations varied during the study period (Fig. 1), with an increase in AMC ceramic use starting in 2005, and a sharp increase in the use in 2013 with a corresponding decrease of alumina ceramic that same year. There were some differences in patient demographics between the study groups, the CoC group were 2 years younger, had higher percentage of males, higher percentage of patients with non-osteoarthritis, and more cementless fixation (Table 1).

Patients who underwent CoP were a median (range) of 63 years of age (11 to 98) and patients who underwent CoC THA had a median (range) age of 61 years (17 to 95); 38% (11,833 of 31479) of patients who underwent CoP and 41% (2379 of 5790) of the patients who underwent CoC THA were males. The median time from surgery to ceramic head fracture was 3.8 years (range 0.04 to 13.1). Two manufacturers produced ceramic heads: CeramTec (Plochingen, Baden-Württemberg, Germany; n = 25,678 Biolox® Forte

Table 1. Demographics of all patients in the Norwegian Register who received a ceramic-on-polyethylene or ceramic-on-ceramic bearing from 1997 to 2018

Parameter	Ceramic-on-polyethylene (n = 31,479)	Ceramic-on-ceramic (n = 5790)	p value
Age (years)[a]	63 (14)	61 (15)	< 0.001
Male sex (%)	38 (11,833)	41 (2379)	< 0.001
Diagnosis (% non-osteoarthritis)	29 (9093)	40 (2304)	< 0.001
Cup fixation (% cementless)[b]	49 (15,549)	99 (5749)	< 0.001
Alumina % (n)	77 (24,346)	66 (3797)	< 0.001
Zirconia % (n)	4 (1221)	0.1 (4)	
AMC % (alumina matrix composites) (n)	19 (5912)	34 (1989)	

[a]Data are presented as median (interquartile range); statistical test: Mann-Whitney (non-parametric); test used for categorical variables was the Pearson chi-square.
[b]Missing data n = 111 (86 in CoP and 25 in CoC).

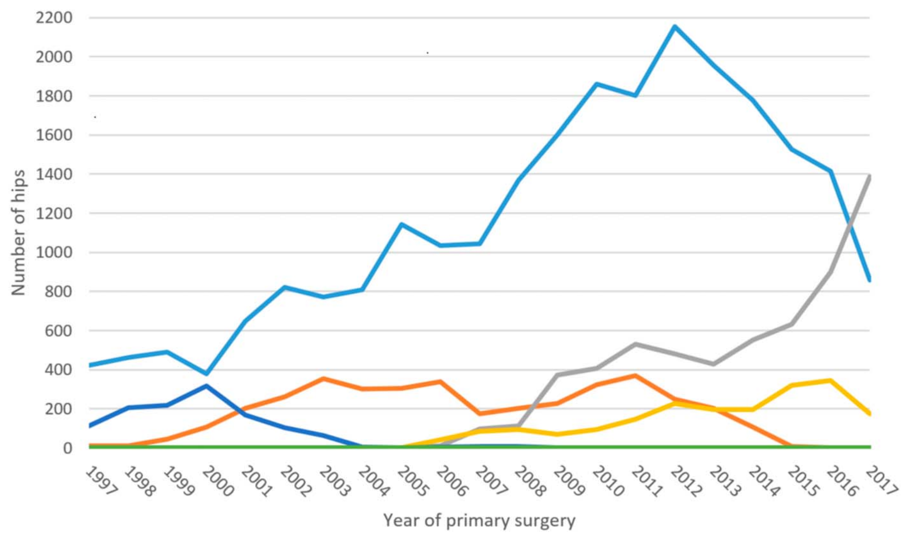

Fig. 1 This graph shows the number of different articulation types used during the study period; Alumina CoP, Alumina CoC, AMC CoP, AMC CoC, Zirconium CoP, Zirconium CoC; CoC = ceramic on ceramic; AMC = alumina matrix composites.

Alumina and Biolox Delta AMC ceramic heads) and Morgan Advanced Materials (Berkshire, UK; n = 2465 Vitox® Alumina heads). All 7901 AMC heads were the Biolox Delta, which were produced by CeramTec. All zirconia products were from CeramTec.

Statistics

Differences in demographic data were calculated with the Mann-Whitney test for median values, Pearson chi-square test for categorical variables or t-test. The median time of follow-up in the groups was estimated with the reverse Kaplan-Meier method [20].

To address our research questions about the frequency of ceramic fractures and factors associated with those fractures, we estimated Kaplan-Meier survivorship free of revision for ceramic fracture for CoC and CoP THAs at 10 years after primary surgery. The following factors were evaluated in Cox regression models with respect to association with revision for ceramic fracture: patient sex, age, and diagnosis (osteoarthritis versus non-osteoarthritis); year of primary surgery; type of ceramic (alumina, AMC); articulation type (CoP or CoC); and femoral head size and head/neck length. In those analyses, we calculated unadjusted hazard ratios for each variable, and the variables were also evaluated in a full model including sex, type of ceramic, type of articulation, femoral head size, and femoral head/neck length. The results are presented with 95% confidence intervals. Proportional hazard assumptions of the Cox regression models were assessed with tests and inspection of Schoenfeld residuals [18]. The outcome (revision for ceramic fracture) was infrequent, with only one event in the AMC group, and this brings large uncertainty to the results of the Cox regression analyses. A more appropriate handling was to use a Poisson regression analyses. Cox regression is the common method used when studying survival time (time-to-event), and Poisson regression is the recommended option used when studying counts or rates (events per time). These input variables are different, but the output measurement will be the same (here HR). Both analyses will reach the same conclusion, but the estimated variance and, hence the uncertainty, will differ. Assuming constant hazard rates, as we do in the Cox regression model with presumed proportional hazards, over fixed time intervals one can fit a survival model using Poisson regression (generalized linear model with a Poisson variance function). We therefore only report the results of the comparison of alumina and AMC heads using Poisson regression.

To address our research question about repeat revision surgery, we examined whether patients undergoing revision for a ceramic fracture underwent further revisions and the causes of these subsequent revisions. We performed Kaplan-Meier survivorship free from repeat revision at 5 years. Additionally, we identified the type of articulating surfaces that were used during revision procedures for a fractured ceramic component.

We considered p values less than 0.05 statistically significant, and all tests were two-sided. The statistical analyses were performed using IBM SPSS Statistics Version

24.0 (IBM Corp, Armonk, NY, USA) and R Version 3.6.0 (The R Foundation, Vienna, Austria).

Because follow-up length differed for the different types of ceramics, we analyzed a subset that included only primary operations from 2005 to 2017 to have similar follow up for Alumina and AMC heads (Fig. 1).

Results

Survivorship free from revision for ceramic fracture was 99.9% (95% CI 99.9 to 99.9) for CoP bearings, and 99.8% (95% CI 99.6 to 100) for CoC bearings at 10 years with 7467 and 1884 hips at risk at that time in the two groups, respectively. The HR for ceramic head fracture was 3.6 (95% CI 1.7 to 7.6; p = 0.001) for CoC compared with CoP. The risk of fracture was greater for alumina ceramics than for AMC heads, with all but one head fracture occurring in alumina ceramics (adjusted HR 14.1 [95% CI 4.2 to 47.0]; p < 0.001). The same comparison for CeramTec-only products (Biolox Forte [alumina] compared with Biolox Delta [AMC]) yielded an adjusted HR of 12.2 (4.0 to 37.6; p < 0.001) (Table 2). Thirty head fractures occurred in CoP THAs and 13 ceramic head fractures occurred in CoC THAs. The overall incidence of a ceramic fracture at median 6.3 years was 0.13%, the incidence of alumina femoral head fracture was 0.15% (95% CI 0.11 to 0.20), and the incidence of AMC head fractures was 0.01% (95 % CI 0.002 to 0.09). Incidence for alumina head fractures for Morgan was 0.36% (eight of 2465) and 0.13% for CeramTec (34 of 25,678). The ceramic manufacturer was not associated with an increased adjusted risk of alumina head fracture with the numbers available; Morgan (HR 2.5 [95% CI 0.8 to 7.5]; p = 0.1) compared with CeramTec. Ceramic liner fractures occurred in eight patients (six with alumina (four Morgan and two CeramTec), one with AMC (CeramTec), and one with zirconium (CeramTec), one of which also had a fractured femoral head (overall incidence of liner fracture, 0.14%). For CeramTec liners, the incidence was 0.08% and for Morgan liners, it was 0.24%. The number of liner fractures was too small to perform meaningful statistical analyses of factors associated with

Table 2. Risk factors for revision because of fracture of the femoral head

Revision for femoral head fracture	Number of fractures/total cohort	Hazard ratio (95% CI) Unadjusted	p value	Adjusted hazard ratio (95% CI)	p value
Patient sex					
Female (ref)	11 of 23,057	1 (ref)		1 (ref)	
Male	32 of 14,212	4.9 (2.5 to 9.7)	< 0.001	5.2 (2.6 to 10.4)	< 0.001
Type of ceramic					
AMC (ref)	1 of 7901	1 (ref)	0.015	1 (ref)	< 0.001[a]
Alumina	42 of 28,143	11.8 (1.6 to 85.7)		14.1 (4.2 to 47.0)	
Ceramtec heads					
AMC ref (Biolox® Delta[b])	1 of 7901	1 (ref)		1 (ref)	
Alumina (Biolox Forte[b])	34 of 25678	10.5 (1.4 to 76.4)	0.02	12.2 (4.0 to 37.6)	< 0.001
Articulation					
CoP (ref)	30 of 31,479	1 (ref)		1 (ref)	
CoC	13 of 5790	2.1 (1.1 to 3.9)	0.03	3.6 (1.7 to 7.6)	0.001
Femoral head size					
< 32 mm	33 of 18,530[c]	1.6 (0.8 to 3.5)	0.207	2.7 (1.1 to 6.4)	0.02
32 mm (ref)	9 of 15,962	1 (ref.)		1 (ref)	
≥ 32 mm	1 of 2777	0.7 (0.1 to 5.2)	0.688	2.7 (0.1 to 82.1)	0.6
Head/neck length[d]					
Short	16 of 6524	2.5 (1.1 to 5.3)	0.022	2.5 (1.1 to 5.3)	0.03
Medium	10 of 9938	1 (ref.)		1 (ref)	
Long	17 of 20,294	1.7 (0.8 to 3.8)	0.185	1.4 (0.6 to 3.0)	0.4

[a]Poisson regression adjusted for gender, headsize and neck length.
[b]CeramTec (Plochingen, Baden-Württemberg, Germany)
[c]There were 96 implants with 22-mm heads; the remaining heads were 28 mm.
[d]Missing head/neck length for 29 hips (none of them among the patients with fractures).
Cox regression analyses, unadjusted and adjusted for sex, type of ceramic, year of surgery, femoral head size, and femoral head/neck length; AMC = alumina matrix composite.

this event. Ceramic head fractures occurred at a median (range) 3.8 years (0 to 13) after the primary procedure, and liner fractures at a median (range) 6.4 years (0 to 16). In the sub-analyses of patients who underwent surgery from 2005 onward, we found the same results as in the main analyses.

After controlling for confounding variables including patient age, diagnosis, and year of surgery, we found the following factors were associated with an increased risk of ceramic head fracture: male sex (HR 5.2 [95% CI 2.6 to 10.4]; $p < 0.001$), a CoC articulation compared with CoP (HR 3.6 [95% CI 1.7 to 7.6]; $p = 0.001$), a 28-mm femoral head compared with a 32-mm head (HR 2.7 [95% CI 1.1 to 6.4]; $p = 0.02$), and short head/neck length compared with a medium head/neck length (HR 2.5 [95% CI 1.1 to 5.3]; $p = 0.03$) (Table 2).

Survivorship free from repeat revision after revision for ceramic bearing fracture was 86% (95% CI 74.4 to 98.0) at 5 years. Median (range) follow-up was 2.4 years (0.4 to 4.9). The reasons for re-revision was infection (n = 2), a second ceramic head fracture (n = 2) and cup loosening (n = 1). Both patients who had a second head fracture had an alumina CoC articulation in the primary and first revision procedure. Nine of 43 patients who underwent revision for a femoral head fracture received a metal head during the revision surgery. Two patients later underwent revision for infection. The remaining seven patients did not undergo further revisions, according to our data.

Discussion

Ceramic bearings are commonly used in THA because of their excellent wear properties and good outcomes scores after surgery [11, 21], but the risk of bearing fracture has been a concern. The incidence of ceramic fractures has been estimated to vary from 0% to 10% in different studies [13], but the true incidence is not known. Further, the association between different patient and implant factors and ceramic fracture is not clear, nor is the risk of repeat revision after a revision for a fractured ceramic bearing. We, therefore, studied a national cohort of 37,269 patients with CoP or CoC THAs to find the incidence of ceramic fracture, and to identify factors that were associated with fracture. We found a 10-year THA survival free from revision for ceramic fracture of 99.9% and 99.8% for CoP and CoC THAs, respectively. Factors that were associated with an increased risk of ceramic fracture were male sex, a CoC articulation, a 28-mm femoral head, short head/neck length, and alumina heads. Based on this, surgeons should know that ceramic fracture occurs in about 1 in 1000 primary THAs, that CoC articulations and male sex increase the risk, and that they should avoid small ceramic femoral heads (28 mm) made of alumina, and those with short head/neck lengths.

There are some limitations to the present study. First, despite a large study cohort, the number of ceramic fractures was low, especially for liners and AMC femoral heads. We identified only one AMC femoral head fracture of 7901 heads implanted. Alumina heads had a 14 times higher risk of femoral head fracture compared with alumina heads in our study. The high completeness of revision reporting in our registry of 93% over a 30-year period with complete follow-up of deaths and emigrations strengthen this finding. We have done studies where administrative records and our registry have been compared on an individual level identifying a completeness of reporting of 97% of the primary and 93% of the revisions (4, 15). When a patient undergoes revision, the surgeon must identify the cause for the revision. There are separate questions on the form for head fracture and liner fracture. One cause for revision is "other causes," and in 1.4% (32 of 2265) of the revision THAs with ceramic components, this reason was used with no further written explanation. If fracture of a ceramic bearing was the cause in some patients, these fractures will be underreported. We, therefore, believe that our reported incidence of ceramic fractures show a best-case scenario. The register only collects a certain number of variables, and we lack data on BMI, radiographic measures, patient activity level, and clinical outcome other than revision. These are variables that possibly could affect the risk of ceramic fracture. However, there is no reason to believe that these factors were unevenly distributed in the groups that were studied, and they should not affect the validity of our findings.

In this study, the overall incidence of ceramic bearing fracture was 0.13% at median 6.3 years, and it was more common in CoC than in CoP THAs. This is generally within the range of what has been observed before; these estimates are difficult to make because the rarity of the event leads to wide confidence intervals. According to CeramTec, a manufacturer of ceramics for THA, the incidence of fracture of an alumina femoral head is 0.022%, and for AMC it is 0.001% [2]. A study on CoC THAs from the UK joint registry found an incidence of 0.12% for alumina head fracture and 0.009% for AMC heads [10]. Similarly, a French study found an incidence of 0.18% for alumina and 0.0013% for AMC [13]. In the present study, these incidences were 0.13% and 0.01%, respectively for the CeramTec heads and liners. The fact that all of these studies seem to converge on numbers in approximately the same order of magnitude gives us confidence that they are probably close to correct. It seems beyond question at this point, as well, that the risk of fracture for alumina ceramics is greater than that for AMC. Although an alumina ceramic head is slightly less expensive than an AMC head (in 2020, the cost of a Biolox Forte Alumina head is USD 240 and a Biolox Delta AMC head is USD 400), we believe the cost difference is well justified by the magnitude of fracture risk reduction we observed; however, we have not performed a formal cost effectiveness analysis. In the present study, we identified eight liner fractures in 5790 CoC hips with an incidence of 0.13% (0.24% for Morgan and 0.08% for CeramTec liners). The incidence is comparable to that reported in other large registry studies [10, 13], and based on these studies, it seems that AMC ceramics have the same incidence of liner fracture as pure alumina.

We found that after controlling for confounding variables like patient age, diagnosis, and year of surgery, the following variables were associated with an increased risk of bearing fracture: male sex, CoC bearings (compared with CoP bearings), smaller femoral heads, and short trunnions. Our finding that 28-mm femoral heads were more likely to fracture than 32-mm heads is in line with results from other studies, but using event analysis such as Cox regression and studying also CoP articulations and in a large number of patients, we have been able to give what we believe are more precise estimates for the increased risk [10, 22]. Additionally, we found that short-neck heads had an increased risk compared with medium- or long-neck heads. This probably is because the ceramic is thinner at the tip of the taper bore in shorter heads, and a fracture is more likely to occur in this area. Other authors also found that 28-mm short-neck alumina heads were at risk for fractures, but they did not use Cox regression and were not able to give an estimate for the increased risk [12]. We believe, therefore, that the added effects of short-neck heads and small head diameters noticeably increase the risk of femoral head fracture, and so it seems prudent to avoid 28-mm or smaller ceramic heads if possible, at least for surgeons using pure alumina components. Our finding that males were at increased risk of fracture of a ceramic head compared with females differed from that observed in the National Joint Registry of UK and Wales [10]. We suspect that our finding is correct, since males in general are heavier than females and higher body weight imposes greater stresses on the ceramic; it is conceivable that the no-difference finding in the UK registry was a function of insufficient statistical power.

The risk of repeat revision after a revision for ceramic fracture was high, which is a finding that has been made before [1], but our study extends those earlier findings in several important ways. Most papers on the topic are case reports describing results in one or a few patients [5, 16, 19]. The largest prior study of which we are aware was a multicenter collection of revised alumina ceramic heads, which found survivorship free of repeat revision of 63% at 5 years; they found that cup retention, the use of a stainless steel femoral head, and lack of a complete synovectomy was associated with repeat revision [1]. We report 85% survival rate free of all revisions at 5 years with more contemporary ceramics. An uncommon but potentially important problem we identified was that two (4%) hips underwent a second revision for another ceramic fracture. A second ceramic fracture could be caused by damage to the stem taper by unknown patient factors that make these patients especially vulnerable for ceramic fracture. Nonetheless, because of the risk of third-body particulates remaining in the joint after a ceramic bearing fracture, there would be concern about revising a hip with a ceramic bearing fracture to a revision bearing that uses metal and polyethylene, and we recommend against this, as have others [17].

In summary, fracture of a ceramic THA bearing is rare. To minimize the risk of this complication, surgeons should avoid small femoral heads (< 32 mm) and the shortest head/neck lengths. Surgeons should also know that the risk is increased in CoC articulations, and in males. Bearings made of AMC appear to be at lower risk than those made from alumina ceramics. However, the long-term performance regarding wear properties of AMC bearings has not been extensively examined and should be studied further.

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References

1. Allain J, Roudot-Thoraval F, Delecrin J, Anract P, Migaud H, Goutallier D. Revision total hip arthroplasty performed after fracture of a ceramic femoral head. A multicenter survivorship study. *J Bone Joint Surg Am*. 2003;85:825-830.
2. CeramTec. Biolox forte and delta comparison. Available at: https://www.ceramtec.com/files/mt_biolox_forte_delta_comparison_en.pdf. Accessed March 10, 2020.
3. Clarke IC, Manaka M, Green DD, Williams P, Pezzotti G, Kim YH, Ries M, Sugano N, Sedel L, Delauney C, Nissan BB, Donaldson T, Gustafson GA. Current status of zirconia used in total hip implants. *J Bone Joint Surg Am*. 2003;85(A Suppl 4): 73-84.
4. Espehaug B, Furnes O, Havelin LI, Engesaeter LB, Vollset SE, Kindseth O. Registration completeness in the Norwegian Arthroplasty Register. *Acta Orthop*. 2006;77:49-56.
5. Gautam D, Pande A, Malhotra R. Fatal Cobalt Cardiomyopathy Following Revision Total Hip Arthroplasty - A Brief Report with Review of Literature. *Arch Bone Jt Surg*. 2019;7:379-383.
6. Hannouche D, Zaoui A, Zadegan F, Sedel L, Nizard R. Thirty years of experience with alumina-on-alumina bearings in total hip arthroplasty. *Int Orthop*. 2011;35:207-213.
7. Hannouche D, Zingg M, Miozzari H, Nizard R, Lubbeke A. Third-generation pure alumina and alumina matrix composites in total hip arthroplasty: What is the evidence? *EFORT Open Rev*. 2018;3:7-14.
8. Haraguchi K, Sugano N, Nishii T, Miki H, Oka K, Yoshikawa H. Phase transformation of a zirconia ceramic head after total hip arthroplasty. *J Bone Joint Surg Br*. 2001;83:996-1000.
9. Havelin LI, Engesaeter LB, Espehaug B, Furnes O, Lie SA, Vollset SE. The Norwegian Arthroplasty Register: 11 years and 73,000 arthroplasties. *Acta Orthop Scand*. 2000;71:337-353.
10. Howard DP, WPD H, FM A, P H, HP W. Ceramic-on-ceramic bearing fractures in total hip arthroplasty. *Bone Joint J*. 2017;99: 1012-1019.

11. Kim YH, Park JW. Eighteen-Year Follow-Up Study of 2 Alternative Bearing Surfaces Used in Total Hip Arthroplasty in the Same Young Patients. *J Arthroplasty*. 2020 Mar;35: 824-830 .
12. Koo KH, Ha YC, Jung WH, Kim SR, Yoo JJ, Kim HJ. Isolated fracture of the ceramic head after third-generation alumina-on-alumina total hip arthroplasty. *J Bone Joint Surg Am*. 2008;90: 329-336.
13. Massin P, Lopes R, Masson B, Mainard D. Does Biolox® Delta ceramic reduce the rate of component fractures in total hip replacement? *Orthop Traumatol Surg Res*. 2014;100:S317-S321.
14. Masson B. Emergence of the alumina matrix composite in total hip arthroplasty. *Int Orthop*. 2009;33:359-363.
15. Norwegian Arthroplasty Register Report 2019. Norwegian National Advisory Unit on Arthroplasty and Hip Fractures. Available at: http://nrlweb.ihelse.net/eng/Rapporter/Report2019_english.pdf. Accessed March 29, 2020.
16. Olmedo-Garcia NI, Zagra L. High risk of complications using metal heads after ceramic fracture in total hip arthroplasty. *Hip Int*. 2019;29:373-378.
17. Rambani R, Kepecs DM, Makinen TJ, Safir OA, Gross AE, Kuzyk PR. Revision Total Hip Arthroplasty for Fractured Ceramic Bearings: A Review of Best Practices for Revision Cases. *J Arthroplasty*. 2017;32:1959-1964.
18. Ranstam J, Robertsson O. Statistical analysis of arthroplasty register data. *Acta Orthop*. 2010;81:10-14.
19. Sanz Perez MI, Rico Villoras AM, Moreno Velasco A, Bartolome Garcia S, Campo Loarte J. Heart transplant secondary to cobalt toxicity after hip arthroplasty revision. *Hip Int*. 2019;29: 1-5.
20. Schemper M, Smith TL. A note on quantifying follow-up in studies of failure time. *Control Clin Trials*. 1996;17:343-346.
21. Solarino G, Piazzolla A, Moretti L, Vicenti G, Moretti B. A minimum 20-year outcome of 100 consecutive alumina-on-alumina arthroplasties performed by a single surgeon. *Hip Int*. 2018;28:10-14.
22. Varnum C, Pedersen AB, Kjærsgaard-Andersen P, Overgaard S. Comparison of the risk of revision in cementless total hip arthroplasty with ceramic-on-ceramic and metal-on-polyethylene bearings. *Acta Orthop*. 2015;86:477-484.