CORE

Metadata, citation and similar papers at core.ac.uk

Provided by Warwick Research Archives Portal Repository

Original citation:

Howard, D., Wall, Peter D. H., Fernandez, Miguel, Parsons, Helen and Howard, P.. (2017) Ceramic on ceramic bearing fractures in total hip Arthroplasty : an Analysis of data from the national joint registry. Bone & Joint Journal.

Permanent WRAP URL:

http://wrap.warwick.ac.uk/88016

Copyright and reuse:

The Warwick Research Archive Portal (WRAP) makes this work by researchers of the University of Warwick available open access under the following conditions. Copyright © and all moral rights to the version of the paper presented here belong to the individual author(s) and/or other copyright owners. To the extent reasonable and practicable the material made available in WRAP has been checked for eligibility before being made available.

Copies of full items can be used for personal research or study, educational, or not-for-profit purposes without prior permission or charge. Provided that the authors, title and full bibliographic details are credited, a hyperlink and/or URL is given for the original metadata page and the content is not changed in any way.

Publisher's statement:

http://dx.doi.org/10.1302/0301-620X.99B8.BJJ-2017-0019.R1

A note on versions:

The version presented here may differ from the published version or, version of record, if you wish to cite this item you are advised to consult the publisher's version. Please see the 'permanent WRAP URL' above for details on accessing the published version and note that access may require a subscription.

For more information, please contact the WRAP Team at: wrap@warwick.ac.uk

warwick.ac.uk/lib-publications

Ceramic-on-Ceramic Bearing Fractures in Total Hip Arthroplasty: An Analysis of Data from the National Joint Registry

Journal:	*The Bone & Joint Journal*
Manuscript ID	BJJ-2017-0019.R1
Manuscript Type:	Original Article
Keywords:	ceramic, CoC, fracture, tribology, hip, replacement, arthroplasty, registry, NJR

Aims: Ceramic-on-ceramic (CoC) bearings in total hip arthroplasty (THA) are commonly used but concerns exist regarding ceramic fracture. This study aims to report the risk of revision for fracture of modern CoC bearings and identify factors that might influence this risk, using data from the National Joint Registry (NJR).

Patients and Methods: We analysed data on 111,681 primary CoC THA's and 182 linked revisions for bearing fracture recorded in NJR. We used implant codes to identify ceramic bearing composition and generated Kaplan-Meier estimates for implant survivorship. Logistic regression analyses were performed for implant size and patient specific variables to determine any associated risks for revision.

Results: 99.8% of bearings were CeramTec Biolox® products. Revisions for fracture were linked to 7 of 79,442 (0.009%) Biolox® Delta heads, 38 of 31,982 (0.119%) Biolox® Forte heads, 101 of 80,170 (0.126%) Biolox® Delta liners and 35 of 31,258 (0.112%) Biolox® Forte liners. Regression analysis of implant size revealed smaller heads had significantly higher odds of fracture ($\chi2=68.0$, $p<0.0001$). The highest fracture risk were observed in the 28mm Biolox® Forte subgroup (0.382%). There were no fractures in the 40mm head group for either ceramic type. Liner thickness was not predictive of fracture ($p=0.67$). BMI was independently associated with revision for both head fractures (OR 1.09 per unit increase, $p=0.031$) and liner fractures (OR 1.06 per unit increase, $p=0.006$).

Conclusions: We report the largest study of CoC bearing fractures to date. The risk of revision for CoC bearing fracture is very low, however previous studies have underestimated this risk. There is good evidence that the latest generation of ceramic has greatly reduced the odds of head fracture but not of liner fracture. Small head size and high patient BMI are associated with an increased risk of ceramic bearing fracture.

Introduction

The use of ceramic-on-ceramic (CoC) as a bearing combination in total hip arthroplasty (THA) is a popular choice, particularly in the younger patient population(1) which may, in part, be attributable to the decline in use of metal-on-metal (MoM) bearings(2-4). CoC offers several highly desirable tribological properties including extreme hardness and scratch resistance, excellent wettability and lubrication, and very low wear rates. Furthermore, unlike MoM the material and wear particles afford high biocompatibility with no serious adverse local or systemic reactions reported(5) making it a particularly favourable choice amongst surgeons and their patients.

One of the main concerns with the use of CoC is the risk of fracture. Ceramic bearing fractures require revision surgery which has an associated morbidity. The fracture risk of early generation ceramics were reported to be as high as 13.4%(6), however with improved design and manufacturing processes the fracture risk is reported to be very low (0.001 to 0.021%).(5)

A number of variables have been implicated as increasing risk of ceramic bearing fracture, including ceramic composition and generation(5), small head size and short neck length adjustment(7), thin liners(8) and high body weight.(9) The primary aim of our study was to report the risk of revision for fracture of CoC bearings. Secondary aims were to identify implant factors (brand, generation, head size and liner thickness) or patient factors (age, sex, BMI and ASA grade) that might influence the risk of revision for fracture.

Patients & Methods

Data Source and Procedures. We analysed data from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR).(1) Data from all primary THAs with at least one ceramic bearing component and for which linked outcome data (revision or death) were known were extracted from the NJR. From this all cases of CoC implantation were analysed.

To differentiate between liner and cup failures, the unit of analysis for the dataset was per implanted bearing. The following variables were extracted: implant catalogue number, size (head diameter, liner inner diameter, cup outer diameter), patient age, sex, BMI, ASA, and outcome including reason for revision or death.

Ceramic composition and manufacturer was determined for all cases using the catalogue number. For liners, the dimension of interest was liner thickness, however this value was not available in our dataset nor is it routinely available from manufacturers. Being directly proportional to liner thickness for a given cup design, the combined thickness of the cup and liner as measured at the rim was therefore calculated as a direct surrogate (Fig. 1). Recognising that cup thickness may vary slightly between manufacturers, the single most common cup and liner combination was also analysed for comparison (Pinnacle cup, DePuy with Biolox® Delta liner). In cases where BMI was reported as <10 or >60 (thought possible but considered highly unlikely), these were treated as missing values as per other large scale registry studies.(10)

Statistical Analysis. As the number of revisions for ceramic fracture were anticipated to be small, we calculated simple summary statistics to describe the extracted data (including: means and standard deviations of continuous variables, proportions of categorical data). Comparisons between categorical data were made using X^2 tests. Summary statistics were also generated for primary ceramic-on-polyethylene (CoP) articulations for comparison and additionally for revision bearing combinations following fracture events.

Prosthesis time incidence rates (PTIR = number of events/total time at risk for all implants) were calculated per 1000 implant years for each bearing type with 95% confidence intervals. Kaplan-Meier estimates of the survival function (the probability that an implant does not have a fracture at time t) were generated for the different ceramic compositions. Implants that experienced an outcome other than a fracture (i.e. patient death or implant revision for reasons other than bearing fracture) were censored. Log-rank (LR) tests were used to compare survival curves for different groups. The LR test is a non-parametric test to compare two survival curves across the whole-time period.

We used single logistic regression models to model the odds of revision for fracture (implant fracture v any other outcome) based upon: component type (head or liner), ceramic composition, head size, liner thickness, patient age, sex, BMI and ASA grade. Multivariate models were then constructed to adjust for patient level variables. Complete cases of variables were required for a given implant for entry in the multivariate models. Furthermore, categorical variables with categories where no fractures occurred were combined to maximise the number of implants which were entered in the models. Categorical variables with more than two levels were tested for overall significance to the model using the Wald chi-squared test. P-values of <0.05 were considered significant and all analyses were conducted using R (R Foundation for Statistical Computing, version 3.2.2. Vienna, Austria).

Results

The dataset contained a total of 212,296 total hip replacements, each containing at least one ceramic bearing component. 111,681 (52.6%) of these combinations were CoC, with the remainder being predominantly ceramic on polyethylene (44.5%). The majority of CoC bearings reviewed were manufactured by CeramTec (Plochingen, Germany) (n=222,852, 99.8%), all of which were either Biolox Delta or Biolox Forte brand: 79,442 Biolox® Delta and 31,982 Biolox® Forte heads; 80,170 Biolox® Delta and 31,258 Biolox® Forte liners. Surgery was performed by 2,879 separate lead surgeons under the care of 1,717 consultants. The mean patient age of cases was 59.8 (SD 11.1 years) with a male to female ratio of 0.83:1 (n=50,672:61,009). Death accounted for 3.07% of cases (n=3,425) and all cause revisions 1.91% (n=2,134). Aseptic loosening 0.54% (n=607), pain 0.38% (n=399), dislocation 0.30% (n=332) and infection 0.28% (n=309) were the most common causes for revision.

There were 182 (0.16%) revisions due to ceramic bearing fracture. The breakdown of revisions for fracture by component and ceramic type are shown in Table I. The total proportion of fractures between liners and heads were significantly different (χ^2=46.6, p< 0.01).

Age, sex and ASA data were complete but BMI data incomplete, with 41.36% (n=46,194) having no BMI recorded. 58.40% (n=65,224) of cases were identified with a BMI between 10 and 60. 0.03% (n=28) had a BMI <10, and 0.21% (n=235) had a BMI >60. It was observed that entry of BMI data onto the register was poor in the earlier years of data collection when compared to the latest entries (11.3% complete 2003/4 vs. 77% complete 2014/15).

The PTIR for Biolox® Delta was 0.03 (95% CI: 0.01 – 0.06) for head fractures and 0.39 (95% CI: 0.32 – 0.48) per 1000 patient-years for liner fractures. For Biolox® Forte, the rate was 0.21 (95% CI: 0.15 – 0.29) for head fractures and 0.19 (95% CI: 0.13 – 0.27) for liner fractures. For comparison, in CoP articulations with Biolox® Delta heads there were 4 of 51,482 (0.008%) cases revised for head fracture, with a PTIR of 0.03 (95% CI: 0.01 – 0.07) equalling that of CoC. For CoP with Biolox® Forte heads there were 11 of 42,057 (0.026%) cases revised for head fracture, with a PTIR of 0.05.

The median time to revision for fracture was 1.1 years (0 - 5.6) for Biolox® Delta heads, 4.7 (0.5 – 10.4) years for Biolox® Forte heads, 1.3 (0 – 6.6) years for Biolox® Delta liners and 3.7 (0 – 9.3) years for Biolox® Forte liners. There was a significant difference in survival curves for Biolox® Delta and Biolox® Forte ceramics for both head fractures (LR test; p<0.001) and liner fractures (LR test; p=0.002), see figs. 2 & 3.

The breakdown of revisions for fracture by head size are shown in Table II. Single logistic regression analysis of head size showed that smaller heads had significantly higher odds of being revised for fracture when compared to larger heads (model n=111,681; 28mm head reference, χ^2=68.0, p<0.0001), see Table III. Head size remained a significant predictor when adjusting for co-varieties of age, sex, ASA and BMI (model n=65,224; p=0.0001). Increasing BMI (OR=1.09 per unit increase; CI 1.02-1.16; p=0.031) was also found to be independently associated with fracture. For a 10 unit increase in BMI, odds of revision were increased by 2.36 (e.g. a person with a BMI of 40 is 2.36 times as likely to have a revision for head fracture than a person of BMI 30). ASA (reference ASA=1; χ^2=2.3, p=0.310), younger age (OR=0.97; CI 0.93–1.00; p=0.112) and male gender (OR=1.36; CI 0.51–3.67; p=0.607) altered the odds ratio but these findings were not significant.

The combined liner and cup thickness was calculated for 99.2% (n=110,745) of cases, 0.8% of omitted cases were due to missing liner catalogue numbers and custom implants of unknown size. 51.95% (n=57,529) of these implant combinations measured <10mm, 48.05% (n=53,216) ≥10mm, each with revision rates for fracture of 0.122% and 0.126% respectively. Single logistic regression analysis of thickness revealed no significant difference in revision for liner fracture (n=110,745; <10mm reference; OR 1.03; CI 0.78–1.37, p=0.842), see Table IV. Restricting cases to those of DePuy Pinnacle cups (44mm to 66mm) with Biolox® Delta liners only gave comparable results (model n=36,942; <10mm reference; OR 1.03; CI 0.69–1.56; p=0.896). When adjusting for co-varieties of age, sex, ASA and BMI, again no significant difference in revision rate for calculated thickness was identified (model n=64,770; p=0.671). Increasing BMI (OR=1.06 per unit increase; CI 1.02-1.09; p=0.006) was found to be independently associated with revision for fracture. For a 10 unit increase in BMI, odds of revision increased by 1.73. Male gender (OR=1.23; CI 0.82–1.84; p=0.404) increased the odds ratio but these findings were not significant.

Resulting bearing combinations following revision for CoC head fracture, liner fracture or both were established for 161 of 178 procedures (90%). Known combinations consisted of: CoC 70.2% (n=113), MoP 14.9% (n=24), CoP 8.1% (n=13), CoM 3.1% (n=5), MoM 3.1% (n=5) and MoC 0.6% (n=1).

Discussion

We report the largest study of CoC bearing fractures to date. Our study supports previous reports based on much smaller datasets that bearing fractures are relatively rare events in 3rd and 4th generation ceramics (proportion of revisions for head or liner fracture = 0.16%). Despite revision for bearing fracture events being rare, it is apparent that liner fractures are more common (0.126%) than head fractures (0.009%) with latest generation Biolox® Delta (p<0.01). Reasons for the difference in the proportion of revisions for fracture between heads and liners are not clear but may relate to differences in implant design, implantation technique and functional biomechanics. Overall survivorship of liners were similar between the latest two generations, although it does appear that Biolox® Delta liner fractures tended to happen earlier than for Biolox® Forte. We also showed that the risk of revision for Biolox® Delta head fractures in CoC vs CoP bearing combinations were equal.

The NJR dataset used is representative of practice in the UK and shows that the overwhelming majority of ceramic components are manufactured by CeramTec. Their third generation Biolox® Forte (1995) ceramic is manufactured from pure alumina (aluminium oxide, Al_2O_3) and their fourth and latest generation Biolox® Delta (2000) is a zirconia-toughened alumina (ZTA) composite ceramic consisting of 82% alumina and 17% zirconia (ZrO_2). Trace substances include Yttrium oxide to stabilise the zirconia in tetragonal crystal form (Y-TZP) for improved hardness, Strontium for formation of platelets to improve toughness, and chromium which gives Biolox® Delta its distinctive pink colouration.(11)

The predominant mode of failure with early generation ceramics was aseptic loosening due to monobloc implant design and poor fixation at the bone-implant interface(12, 13). The highest reported odds of fracture for first generation ceramics were 13.4% in a series of 67 patients, all of which were head fractures and attributed at this point to a poor trunnion-head interface.(6) With improvements in component manufacturing, Morse taper design and surgical technique the rate of fracture had notably reduced by the 1980's with numerus medium to long term series reporting no fracture at all(14-17), although high rates of aseptic loosening remained problematic.(18) As fractures of the latest generations of ceramic are relatively rare events, it is not unusual for fracture data of head, liner and generation to be found pooled together in the literature.(8, 19-22) Few studies have looked specifically at differences in odds of fracture between 3rd and 4th generation ceramics. Hamilton et al. reported two Biolox® Delta liner fractures in a multicentre series of 177 patients (1.1%). One case was asymptomatic yet underwent revision which revealed a mal-seated liner in the cup with peripheral chipping. The other showed a similar radiographic appearance but remained unrevised at the time of writing. CeramTec's own reporting programme appears to underestimate the risk of fractures with reported rates for Biolox® Delta and Biolox® Forte heads of 0.02% and 0.001%(23) respectively, and 0.021% for both liner generations.(5)

We found a significant decrease in risk of revision for fracture with larger head sizes, but no significant difference for liner thickness. Increasing patient BMI was associated with an increase in odds of revision for bearing fracture, but age, sex and ASA grade were not.

Small femoral head size has been cited as a risk factor for head fracture. Koo et al.(7) identified 5 head fractures in a series of 367 third generation CoC THA's, all of which were 28mm short heads. Although our study did not analyse head-neck length variations, the highest fracture rates were observed in the 28mm Biolox Forte subgroup (0.382%) and there were no fractures in the 40mm head group for either ceramic type, therefore this theory is supported by our findings. Of note, there were no revisions for fracture seen in the Biolox® Delta 28mm head group, however a difference in size distribution between the two generations of ceramic was evident; 32mm and 28mm heads accounted for 56.8% and 27.8% of Biolox® Forte heads respectively, whereas 36mm heads (64.9%) were most commonly used with Biolox® Delta, reflecting a change in practice over time and a move to larger head size.

High body weight has been implicated as a possible cause for increased fracture risk but has not been verified in any large-scale studies.(9, 24) Our analysis identified a small but significant association of increasing BMI as an independent variable for both head and liner fractures. This observed relationship may be attributable to the reduction in optimal component positioning with larger patients and thus an increased likelihood of edge loading, cyclic impingement and fracture propagation rather than increased load on the material alone.(8, 25-27)

Narrow liner thickness is also cited as increasing risk for a liner fracture,(8) however there is no real evidence to support this assumption(28) and our study did not reveal any significant difference between thickness groupings. Malseating of a ceramic liner in the acetabular cup due to improper impaction technique or prominent screw placement are a widely accepted as causes for liner failure.(22, 29-31) This may help to explain why there is no reduction in fracture risk with the latest generation ceramic, however such data was not available within our dataset for further analysis. Other reported causes for fracture are in cases of sudden trauma.(8, 32) A so called 'sandwich' type liner (consisting of a polyethylene layer situated between the head and a thinner than usual ceramic liner)(29) resulted in high fracture rates of up to 17.6% and such designs therefore falling out of favour.(33-35)

The selection of revision bearing combination post ceramic bearing fracture has an important role in determining subsequent implant survivorship and patient morbidity due to the risk third body wear from ceramic particulate debris. The majority of bearing fractures in our dataset were revised to CoC, however the use of metal bearing combinations and subsequent risk of catastrophic wear, metallosis and highly elevated circulating blood metal ion levels is a cause for concern.(36-38)

There are several limitations to our study. BMI data quality were variable throughout the data collection period. Limited BMI entries particularly from the earlier registry years reduced the overall number of cases available for multivariate analysis, however, large groupings helped keep overall numbers in each analysis sufficiently large to run the models. The NJR does not record data on liner fractures that have gone unrevised. Complete liner fractures would almost always be expected to be symptomatic and undergo revision, but asymptomatic fractures such as a chip of the rim would not be included and are arguably not relevant in this context. Intraoperative bearing fractures are also not reported by this study. True liner thickness would have been preferable for our liner analysis but this was not possible with the dimensions available in our dataset, hence a calculated direct surrogate was used. Not all liner designs and their interface with the acetabular cup are the same - more research is required to better understand the effect of these differences on fracture risk.

Due to the small number of reported events, logistic regression is vulnerable to small-sample bias, which often over estimates observed effect sizes. However, bias in this analysis is unlikely to have a large impact on the interpretation of the results due to the large overall sample size.(39) Data quality and completeness remains an issue with registry data,(40) and it is possible that some revisions for bearing fracture may be unreported in the dataset. Randomisation between treatment groups is not possible with observational data and causality is difficult to establish in isolation. However, the purpose of the study was to estimate the risk of revision for ceramic fracture and identify associated risk factors, not to test a hypothesis or assign causality; with very low event rates anticipated, the analysis of registry data was ideally suited to address these aims. Using data collected from a large population with high rates of consent and compliance gives confidence in the results, with good generalisability and external validity.

In conclusion, the risk of revision for CoC bearing fracture is very low, however previous studies have underestimated this risk. There is good evidence that the latest generation of ceramic has reduced the odds of head fracture but not of liner fracture, suggesting that factors other than ceramic composition are responsible for liner fracture events.

References

1. NJR 13th Annual Report. Northgate Public Services (UK) Ltd: National Joint Registry for England, Wales, Northern Ireland and the Isle of Man; 2016.

2. Rajpura A, Kendoff D, Board TN. The current state of bearing surfaces in total hip replacement. Bone Joint J. 2014;96-B(2):147-56.

3. Macdonald N, Bankes M. Ceramic on ceramic hip prostheses: a review of past and modern materials. Arch Orthop Trauma Surg. 2014;134(9):1325-33.

4. Sedrakyan A, Graves S, Bordini B, Pons M, Havelin L, Mehle S, et al. Comparative effectiveness of ceramic-on-ceramic implants in stemmed hip replacement: a multinational study of six national and regional registries. J Bone Joint Surg Am. 2014;96 Suppl 1:34-41.

5. Sentuerk U, von Roth P, Perka C. Ceramic on ceramic arthroplasty of the hip: new materials confirm appropriate use in young patients. Bone Joint J. 2016;98-B(1 Suppl A):14-7.

6. Knahr K, Böhler M, Frank P, Plenk H, Salzer M. Survival analysis of an uncemented ceramic acetabular component in total hip replacement. Arch Orthop Trauma Surg. 1987;106(5):297-300.

7. 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(2):329-36.

8. Hannouche D, Nich C, Bizot P, Meunier A, Nizard R, Sedel L. Fractures of ceramic bearings: history and present status. Clinical orthopaedics and related research. 2003(417):19-26.

9. Hothan A, Morlock M, Hoenig E. The effect of body weight on the choice of material for the bearing couple in artificial hip joints. Seminars in Arthroplasty. 2013;24(4):218-39.

10. Smith AJ, Dieppe P, Howard PW, Blom AW. Failure rates of metal-on-metal hip resurfacings: analysis of data from the National Joint Registry for England and Wales. Lancet. 2012;380(9855):1759-66.

11. CeramTec. Increased Fracture Strength and Excellent Wear Properties: BIOLOX® Delta: CeramTec; 2016. [Accessed Jan 3rd 2017] Available from: https://www.ceramtec.com/ceramic-materials/biolox/delta/.

12. O'Leary JF, Mallory TH, Kraus TJ, Lombardi AV, Lye CL. Mittelmeier ceramic total hip arthroplasty. A retrospective study. J Arthroplasty. 1988;3(1):87-96.

13. Boutin P, Christel P, Dorlot JM, Meunier A, de Roquancourt A, Blanquaert D, et al. The use of dense alumina-alumina ceramic combination in total hip replacement. J Biomed Mater Res. 1988;22(12):1203-32.

14. Petsatodis GE, Papadopoulos PP, Papavasiliou KA, Hatzokos IG, Agathangelidis FG, Christodoulou AG. Primary cementless total hip arthroplasty with an alumina ceramic-on-ceramic bearing: results after a minimum of twenty years of follow-up. J Bone Joint Surg Am. 2010;92(3):639-44.

15. Yoon TR, Rowe SM, Kim MS, Cho SG, Seon JK. Fifteen- to 20-year results of uncemented tapered fully porous-coated cobalt-chrome stems. Int Orthop. 2008;32(3):317-23.

16. Huo MH, Martin RP, Zatorski LE, Keggi KJ. Total hip replacements using the ceramic Mittelmeier prosthesis. Clin Orthop Relat Res. 1996(332):143-50.

17. Jazrawi LM, Bogner E, Della Valle CJ, Chen FS, Pak KI, Stuchin SA, et al. Wear rates of ceramic-on-ceramic bearing surfaces in total hip implants: a 12-year follow-up study. J Arthroplasty. 1999;14(7):781-7.

18. Jeffers JR, Walter WL. Ceramic-on-ceramic bearings in hip arthroplasty: state of the art and the future. The Journal of bone and joint surgery British volume. 2012;94(6):735-45.

19. Sadoghi P, Pawelka W, Liebensteiner MC, Williams A, Leithner A, Labek G. The incidence of implant fractures after total hip arthroplasty. Int Orthop. 2014;38(1):39-46.

20. Zywiel MG, Sayeed SA, Johnson AJ, Schmalzried TP, Mont MA. Survival of hard-on-hard bearings in total hip arthroplasty: a systematic review. Clin Orthop Relat Res. 2011;469(6):1536-46.

21. Porat M, Parvizi J, Sharkey PF, Berend KR, Lombardi AV, Barrack RL. Causes of Failure of Ceramic-on-Ceramic and Metal-on-Metal Hip Arthroplasties. Clin Orthop Relat Res. 2012;470(2):382-7.

22. Hamilton WG, McAuley JP, Dennis DA, Murphy JA, Blumenfeld TJ, Politi J. THA With Delta Ceramic on Ceramic: Results of a Multicenter Investigational Device Exemption Trial. Clin Orthop Relat Res. 2010;468(2):358-66.

23. Lee GC, Kim RH. Incidence of Modern Alumina Ceramic and Alumina Matrix Composite Femoral Head Failures in Nearly 6 Million Hip Implants. J Arthroplasty. 2016.

24. Poggie RA, Turgeon TR, Coutts RD. Failure analysis of a ceramic bearing acetabular component. J Bone Joint Surg Am. 2007;89(2):367-75.

25. Sariali E, Stewart T, Jin Z, Fisher J. Effect of cup abduction angle and head lateral microseparation on contact stresses in ceramic-on-ceramic total hip arthroplasty. J Biomech. 2012;45(2):390-3.

26. Elkins JM, Pedersen DR, Callaghan JJ, Brown TD. Fracture propagation propensity of ceramic liners during impingement-subluxation: a finite element exploration. J Arthroplasty. 2012;27(4):520-6.

27. Elkins JM, Pedersen DR, Callaghan JJ, Brown TD. Do obesity and/or stripe wear increase ceramic liner fracture risk? An XFEM analysis. Clin Orthop Relat Res. 2013;471(2):527-36.

28. Massin P, Lopes R, Masson B, Mainard D, (SFHG) FHKS. Does Biolox Delta ceramic reduce the rate of component fractures in total hip replacement? Orthop Traumatol Surg Res. 2014;100(6 Suppl):S317-21.

29. Traina F, De Fine M, Di Martino A, Faldini C. Fracture of ceramic bearing surfaces following total hip replacement: a systematic review. Biomed Res Int. 2013;2013:157247.

30. McAuley JP, Dennis DA, Grostefon J, Hamilton WG. Factors affecting modular acetabular ceramic liner insertion: a biomechanical analysis. Clin Orthop Relat Res. 2012;470(2):402-9.

31. Lee SC, Jung KA, Nam CH, Kim TH, Ahn NK, Hwang SH. Acetabular screw head-induced ceramic acetabular liner fracture in cementless ceramic-on-ceramic total hip arthroplasty. Orthopedics. 2010;33(5).

32. Garcia-Cimbrelo E, Garcia-Rey E, Murcia-Mazón A, Blanco-Pozo A, Martí E. Alumina-on-Alumina in THA: A Multicenter Prospective Study. Clin Orthop Relat Res. 2008;466(2):309-16.

33. Viste A, Chouteau J, Desmarchelier R, Fessy MH. Fractures of a sandwich ceramic liner at ten year follow-up. Int Orthop. 2012;36(5):955-60.

34. Lopes R, Philippeau JM, Passuti N, Gouin F. High Rate of Ceramic Sandwich Liner Fracture. Clin Orthop Relat Res. 2012;470(6):1705-10.

35. Wang T, Sun JY, Zha GC, Dong SJ, Zhao XJ. Mid term results of total hip arthroplasty using polyethylene-ceramic composite (Sandwich) liner. Indian J Orthop. 2016;50(1):10-5.

36. Whittingham-Jones P, Mann B, Coward P, Hart AJ, Skinner JA. Fracture of a ceramic component in total hip replacement. J Bone Joint Surg Br. 2012;94(4):570-3.

37. Rizzetti MC, Liberini P, Zarattini G, Catalani S, Pazzaglia U, Apostoli P, et al. Loss of sight and sound. Could it be the hip? Lancet. 2009;373(9668):1052.

38. Zywiel MG, Brandt JM, Overgaard CB, Cheung AC, Turgeon TR, Syed KA. Fatal cardiomyopathy after revision total hip replacement for fracture of a ceramic liner. Bone Joint J. 2013;95-B(1):31-7.

39. Nemes S, Jonasson JM, Genell A, Steineck G. Bias in odds ratios by logistic regression modelling and sample size. BMC Med Res Methodol. 2009;9:56.

40. Sabah SA, Henckel J, Cook E, Whittaker R, Hothi H, Pappas Y, et al. Validation of primary metal-on-metal hip arthroplasties on the National Joint Registry for England, Wales and Northern Ireland using data from the London Implant Retrieval Centre: a study using the NJR dataset. Bone Joint J. 2015;97-B(1):10-8.

	Liners			Heads		
Ceramic Type	Implants	Fractures	Proportion	Implants	Fractures	Proportion
Biolox Delta	80170	101	0.126%	79442	7	0.009%
Biolox Forte	31258	35	0.112%	31982	38	0.119%
Others	253	1	0.395%	257	0	0.000%
TOTAL	111681	137	0.123%	111681	45	0.040%

Table I: Summary of all bearing implants and fractures by ceramic type.

	All heads			Biolox® Forte heads				Biolox® Delta heads			
Size	Total	% size	% fractures	Total	% size	n fractures	% fractures	Total	% size	n fractures	% fractures
28mm	16332	34	0.21%	8898	27.82%	34	0.38%	7388	9.30%	0	0.00%
32mm	35198	6	0.02%	18158	56.78%	3	0.02%	16946	21.33%	3	0.02%
36mm	56582	5	0.01%	4926	15.40%	1	0.02%	51539	64.88%	4	0.01%
40mm	3569	0	0.00%	0	0.00%	0	0.00%	3569	4.49%	0	0.00%
TOTAL	**111681**	**45**	**0.04%**	**31982**	**100%**	**38**	**0.119%**	**79442**	**100%**	**7**	**0.009%**

Table II: Head fractures

	Head fractures				
	Variable		OR	95% CI	p
Single Logistic Regression (n=111,681)	Head Size	28mm	1	-	<0.0001
		32mm	0.08	0.04 - 0.17	
		36-40mm	0.04	0.02 - 0.09	
Multiple Logistic Regression (n=65,224)	Head size	28mm	1	-	<0.0001
		32mm	0.10	0.03 - 0.31	
		36-40mm	0.05	0.02 - 0.17	
	ASA	1	1	-	0.31
		2	0.43	0.17 - 1.09	
		3+	0.40	0.06 - 2.55	
	Sex	Female	1	-	0.606
		Male	1.36	0.51 - 3.67	
	Age (per year)		0.97	0.93 – 1.00	0.111
	BMI (per unit)		1.09	1.02 - 1.17	0.031

Table III: Logistic regression models for head fractures

	Liner fractures				
	Variable		OR	95% CI	p
Single Logistic Regression (n=110,048)	Liner + cup thickness	<10mm	1	-	0.842
		≥10mm	1.03	0.78 - 1.37	
Multiple Logistic Regression (n=64,770)	Liner + cup thickness	<10mm	1	-	0.671
		≥10mm	0.90	0.60 - 1.35	
	ASA	1	1	-	0.081
		2	0.85	0.52 - 1.40	
		3+	1.78	0.91 - 3.48	
	Sex	Female	1	-	0.404
		Male	1.23	0.82 - 1.84	
	Age (per year)		1.00	0.98 - 1.02	0.792
	BMI (per unit)		1.06	1.02 - 1.09	0.00624

Table IV: Logistic regression models for liner fractures

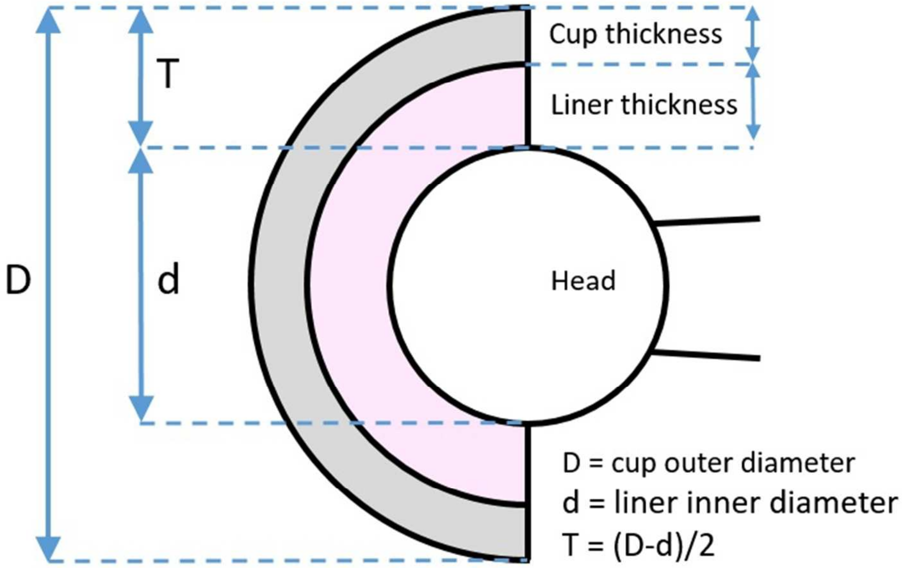
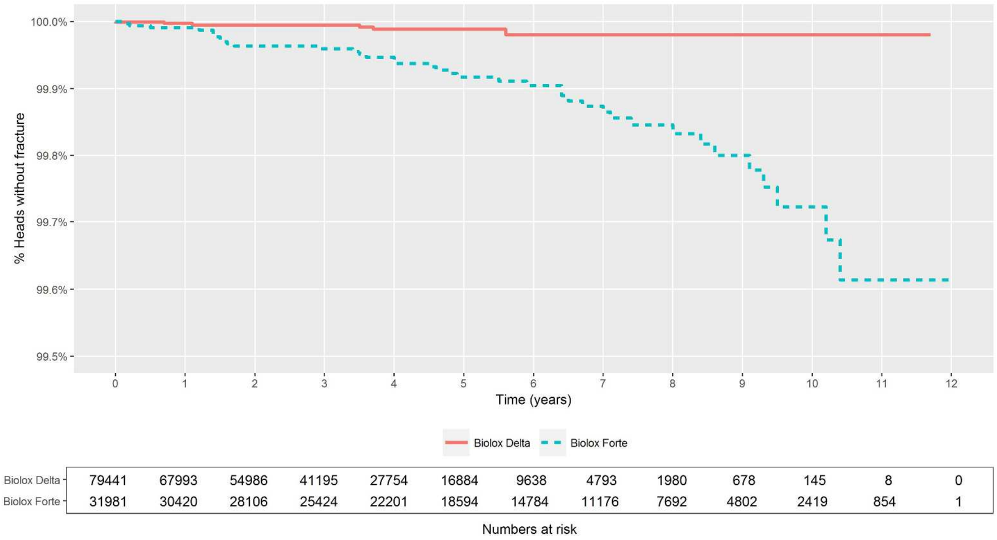


Fig. 1 - Proportional to liner thickness for a given cup design, the measurement T indicates the value used in our liner analysis.

141x86mm (144 x 144 DPI)



Biolox Delta	79441	67993	54986	41195	27754	16884	9638	4793	1980	678	145	8	0
Biolox Forte	31981	30420	28106	25424	22201	18594	14784	11176	7692	4802	2419	854	1

Fig. 2: Kaplan Meier plot of revisions for ceramic head fracture, with censoring for competing risks.

901x481mm (96 x 96 DPI)

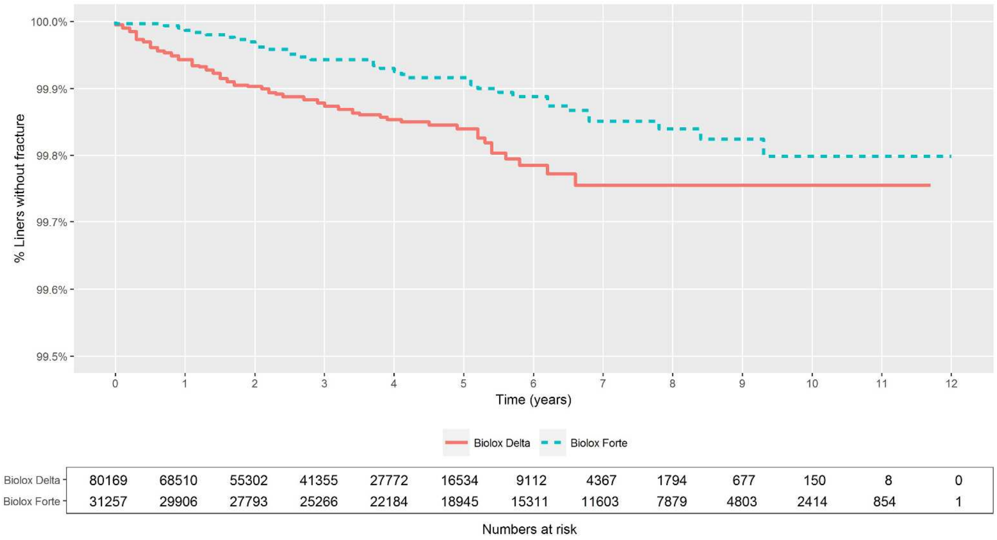


Fig. 3: Kaplan Meier plot of revisions for ceramic liner fracture, with censoring for competing risks.

901x481mm (96 x 96 DPI)