Effect of Femoral Head Size on Metal-on-HXLPE Hip Arthroplasty Outcome in a Combined Analysis of Six National and Regional Registries

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Background: HXLPE (highly cross-linked polyethylene) has greater wear resistance compared with UHMWPE (ultra-high molecular weight polyethylene), which may contribute to improving the outcomes of total hip arthroplasty with a large femoral head. However, no information is available regarding the effect of femoral head size on the survivorship of HXLPE hip prostheses. The aim of the present study was to provide evidence regarding whether femoral head size has an effect on the risk of revision when an HXLPE liner is used on a metal head.

Methods: A distributed health data network was developed by the ICOR (International Consortium of Orthopaedic Registries). Six national and regional registries are participating in this network: Kaiser Permanente, HealthEast, the Emilia-Romagna region in Italy, the Catalan region in Spain, Norway, and Australia. Data from each registry were standardized and provided at an aggregate level for each of the variables of interest. Patients with osteoarthritis who were forty-five to sixty-four years of age and had undergone uncemented total hip arthroplasty were included in the present study. Analyses were performed on the basis of individual patient profiles, utilizing the variables collected from each registry. The outcome of interest was the time to the first revision (for any reason). Survival probabilities and their standard errors were extracted from each registry for each unique combination of the covariates and were combined through multivariate meta-analysis utilizing linear mixed models to compare survivorship for <32-mm, 32-mm, and >32-mm femoral head sizes.

Results: A total of 14,372 total hip arthroplasties were included in the study. The five-year rate of revision surgery varied from 1.9% to 3.2% among registries. The risk of revision did not differ significantly between <32-mm and 32-mm head sizes (HR [hazard ratio] = 0.91, 95% CI [confidence interval] = 0.69 to 1.19) or between >32-mm and 32-mm sizes (HR = 1.05, 95% CI = 0.70 to 1.55).

Conclusions: The results of our study provide relevant data to orthopaedic surgeons deciding on the use of a larger articulation in a metal-on-polyethylene bearing. A larger head diameter should not be considered a detriment to device survival when an HXLPE liner is used. However, efforts to force the use of a large-size implant appear unsupported, as similar survivorship was observed for all head diameter groups.

Dislocation is a common reason for early to intermediate-term revision following total hip arthroplasty and has a major impact on patient quality of life[1,2]. The utilization of a large-diameter femoral head has been advocated to reduce the risk of dislocation by increasing hip motion prior to component impingement and increasing the head displacement required before hip dislocation, thus providing greater stability[3,4]. According to the National Joint Registry of England, Wales and Northern Ireland, the increased use of large femoral heads (≥36 mm) was associated with a decrease in the risk of revision due to dislocation[5].

For any given acetabular diameter, a larger-diameter head requires a concomitantly thinner acetabular bearing. This has been achieved with alternative acetabular bearing surfaces such as ceramic or HXLPE (highly cross-linked polyethylene). The development of first-generation HXLPE formulations was

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TABLE I Included Metal-on-HXLPE Implants According to Registry, Head Size, Age, and Sex

	Registry* *(no. [%])*					
	U.S., KP	Australia	Italy, E-R	U.S., HE	Norway	Spain, C
Head size < 32 mm						
Age, 45-54 yr	194 (23.0)	1109 (24.3)	26 (10.4)	56 (32.9)	33 (22.1)	30 (30.9)
Age, 55-64 yr	648 (77.0)	3462 (75.7)	224 (89.6)	114 (67.1)	116 (77.9)	67 (69.1)
Male	275 (32.7)	2110 (46.2)	121 (48.4)	63 (37.1)	51 (34.2)	61 (62.9)
Female	567 (67.3)	2461 (53.8)	129 (51.6)	107 (62.9)	98 (65.8)	36 (37.1)
Head size = 32 mm						
Age, 45-54 yr	347 (18.6)	554 (21.2)	1 (12.5)	23 (30.3)	3 (21.4)	14 (25.5)
Age, 55-64 yr	1516 (81.4)	2062 (78.8)	7 (87.5)	53 (69.7)	11 (78.6)	41 (74.5)
Male	723 (38.8)	1253 (47.9)	1 (12.5)	42 (55.3)	6 (42.9)	28 (50.9)
Female	1140 (61.2)	1363 (52.1)	7 (87.5)	34 (44.7)	8 (57.1)	27 (49.1)
Head size > 32 mm						
Age, 45-54 yr	352 (19.3)	367 (22.2)	6 (22.2)	15 (14.2)	2 (40.0)	7 (14.3)
Age, 55-64 yr	1471 (80.7)	1284 (77.8)	21 (77.8)	91 (85.8)	3 (60.0)	42 (85.7)
Male	1020 (56.0)	1060 (64.2)	23 (85.2)	71 (67.0)	5 (100.0)	30 (61.2)
Female	803 (44.0)	591 (35.8)	4 (14.8)	35 (33.0)	0 (0.0)	19 (38.8)

*KP = Kaiser Permanente, E-R = Emilia-Romagna region, HE = HealthEast, and C = Catalan region.

intended to modify medical-grade UHMWPE (ultra-high molecular weight polyethylene) to provide an extremely high wear resistance and improved oxidative stability[6]. The achievement of these objectives has been confirmed in the clinical setting, as a systematic review on the performance of HXLPE indicated a lower weighted mean value for the femoral head penetration rate into HXLPE compared with UHMWPE liners (0.042 compared with 0.137 mm/yr) and an 87% lower frequency of osteolysis in patients treated with HXLPE (OR [odds ratio] = 0.131, 95% CI [confidence interval] = 0.064 to 0.268)[7]. In addition, in a combined analysis of HXLPE data from three separate studies, Bragdon et al. reported a decreased rate of polyethylene wear and no instances of periprosthetic osteolysis as a result of polyethylene wear[8].

The reported increase in utilization of larger head diameters raises concerns regarding the acceptable minimum acetabular polyethylene liner thickness[7]. Although HXLPE has higher wear resistance compared with UHMWPE, the mechanical properties of HXLPE may be reduced compared with those of non-cross-linked polyethylene, leading to an increased fracture potential of an HXLPE liner, irrespective of the inner diameter. Despite the consistent results regarding wear resistance of HXLPE, one study indicated an association between larger-diameter (36 and 40-mm) femoral heads and higher volumetric wear rates and total volumetric wear at five to eight years of follow-up when HXLPE liners were used[9], which may offset the advantages related to HXLPE.

The aim of the present study was to provide evidence regarding whether femoral head size affects the risk of revision when an HXLPE liner is used. To answer this question, we used the distributed health data network of the ICOR (International Consortium of Orthopaedic Registries), which is an international collaborative project of orthopaedic registries, and the U.S. FDA (Food and Drug Administration)[10].

Materials and Methods

A distributed health data network was developed by the ICOR and used in this study to reduce barriers to participation (e.g., involving data security, proprietary information, legal issues, and privacy) relative to an approach involving a centralized data warehouse[11,12]. A distributed health data network is a decentralized model that allows secure storage and analysis of data from multiple registries[13]. Generally, the data from each registry are standardized and provided at the level of aggregation most suitable for the detailed analysis of each variable of interest, with the aggregated data combined across registries[10]. Analyses were performed on the basis of individual patient profiles, utilizing the variables collected from each registry.

The first step undertaken in developing the health data network was to evaluate the variation in international practice patterns, including patient selection, technology use, and procedural details. All interested registries participated, and a methodology committee discussed inclusion of key variables for analytic purposes. Next, each registry with an interest in participating completed simple tables depicting the mean and proportion for each patient and procedure-related characteristic. Six national and regional registries (Kaiser Permanente, HealthEast, the Emilia-Romagna region in Italy, the Catalan region in Spain, Norway, and Australia) participated in this study.

In the present study, we focus on metal-on-HXLPE articulations involving various head sizes (<32, 32, and >32 mm). The study included only patients with osteoarthritis who underwent total hip arthroplasty from 2001 to 2010. The outcome of interest was the time to the first revision (for any reason). A potentially complex relationship among fixation, age, and time to revision may exist. In order to limit the potential confounding effects of age and fixation, the analysis was further limited to patients who underwent total hip arthroplasty without cement and were forty-five to sixty-four years of age (Table I).

Statistical Analyses

Multivariate meta-analysis was performed with use of linear mixed models, with the profile of each patient as the unit of analysis[14]. The models estimated

TABLE II Fixed-Effects Models

	Effect of Head Size*	
	<32 mm, Relative to 32 mm†	>32 mm, Relative to 32 mm‡
Time in yr		
0 to 1	Ref.	Ref.
1 to 2	5.38 (3.64-7.94)	8.19 (5.13-13.05)
2 to 3	6.69 (4.53-9.89)	9.95 (6.18-16.03)
3 to 4	7.56 (5.11-11.19)	11.54 (6.81-19.56)
4 to 5	8.24 (5.56-12.22)	11.33 (6.82-18.83)
5 to 6	8.89 (5.97-13.24)	17.96 (7.51-42.96)
6 to 7	9.68 (6.48-14.47)	19.00 (8.07-44.77)
7 to 8	11.98 (7.84-18.29)	—
8 to 9	11.86 (7.63-18.43)	—
Sex		
Male	Ref.	Ref.
Female	1.06 (0.83-1.35)	1.16 (0.81-1.65)
Age in yr		
45 to 54	Ref.	Ref.
55 to 64	0.72 (0.55-0.95)	0.55 (0.37-0.81)
Fixed registry effects§	—	—
Head size in mm		
32	Ref.	Ref.
As stated in column heading	0.91 (0.69-1.19)	1.05 (0.71-1.53)

*The values are given as the HR, with the 95% CI in parentheses. Results are based on an iterative solution that updates the residual covariances until convergence. Confidence intervals are based on a Z distribution. †The estimated intercept was −5.25 (standard error, 0.26). ‡The estimated intercept was −5.55 (standard error, 0.30). §Fixed registry effects were included in this model, but the results are omitted from this table because a precondition of data sharing was no reporting of comparisons among registries.

the residual covariances as described previously[15] and also implemented a transformation[16-18] to ensure that the models could be fitted with use of existing SAS software (SAS Institute). Survival probabilities and their standard errors were extracted from each registry for each unique combination of the covariates (e.g., bearing, head size, and patient age) at each distinct event time. The results for each unique combination were then analyzed in one-year time intervals (e.g., one to two years after surgery); if multiple observations within the same interval were available, only the earliest was retained.

We fit two models, one that treated the registries as a set of fixed effects and another that treated the registries as random effects. Both models included the following variables: head size, intercept, age, sex, time since surgery (a dummy variable representing the year of surgery), and registry. Although the random-effects model offers some inferential advantage for combining studies[19,20], the estimates of the differences among registries in this model can be quite inaccurate with limited observational data per registry. Furthermore, the absence of randomization for bearing and head size groups could lead to confounding due to registry-level effects, which the random-effects model does not address but the fixed-effects model does[21]. Therefore, we determined that preference would be given to interpretation of the fixed-effects model, particularly if the parameter estimates differed substantially between the fixed and random-effects models[21].

The results of the fixed-effects model are given below and in Table II, and the results of the random-effects model are given in Table III in the Appendix. SAS version 9.2 was used for all analyses. Additional details regarding the model fitting are given in the Appendix.

Results

A total of 14,372 total hip arthroplasties were included in the study; 52% were in female patients. The five-year rate of revision surgery varied from 1.9% to 3.2% among the registries. Descriptive data according to the head size of the metal-on-HXLPE implants are presented in Table I.

TABLE III Random-Effects Models

	Effect of Head Size*	
	<32 mm, Relative to 32 mm†	>32 mm, Relative to 32 mm‡
Time in yr		
0 to 1	Ref.	Ref.
1 to 2	4.82 (3.28-7.10)	8.20 (5.04-13.34)
2 to 3	5.99 (4.07-8.81)	9.97 (6.08-16.37)
3 to 4	6.74 (4.58-9.93)	11.60 (6.69-20.07)
4 to 5	7.33 (4.97-10.82)	11.32 (6.68-19.20)
5 to 6	7.90 (5.33-11.70)	18.18 (7.34-44.99)
6 to 7	8.57 (5.77-12.73)	19.19 (7.87-46.80)
7 to 8	10.52 (6.92-15.98)	—
8 to 9	10.43 (6.75-16.11)	—
Sex		
Male	Ref.	Ref.
Female	1.04 (0.81-1.31)	1.14 (0.80-1.64)
Age in yr		
45 to 54	Ref.	Ref.
55 to 64	0.75 (0.57-0.99)	0.55 (0.37-0.82)
Head size in mm		
32	Ref.	Ref.
As stated in column heading	1.00 (0.77-1.31)	1.03 (0.71-1.51)

*The models were estimated with use of a restricted maximum likelihood approach. Results are based on an iterative solution that updates the residual covariances until convergence. Our simulations indicated that an optimal strategy for CI construction in the presence of random effects was to use $t_{\kappa-1}$ for fixed parameters with corresponding random effects and to use t_{n-p} otherwise (where $\kappa-1$ and $n-p$ indicate the degrees of freedom for the t distribution, κ is the number of registries, n is the number of observations, and p is the number of fixed effects). This is the approach taken in construction of the CIs in this table. †The estimated intercept was −5.23 (standard error, 0.29), and the random effect intercept was 0.004 (standard error, 0.062). ‡The estimated intercept was −5.56 (standard error, 0.30), and the random effect intercept was not applicable.

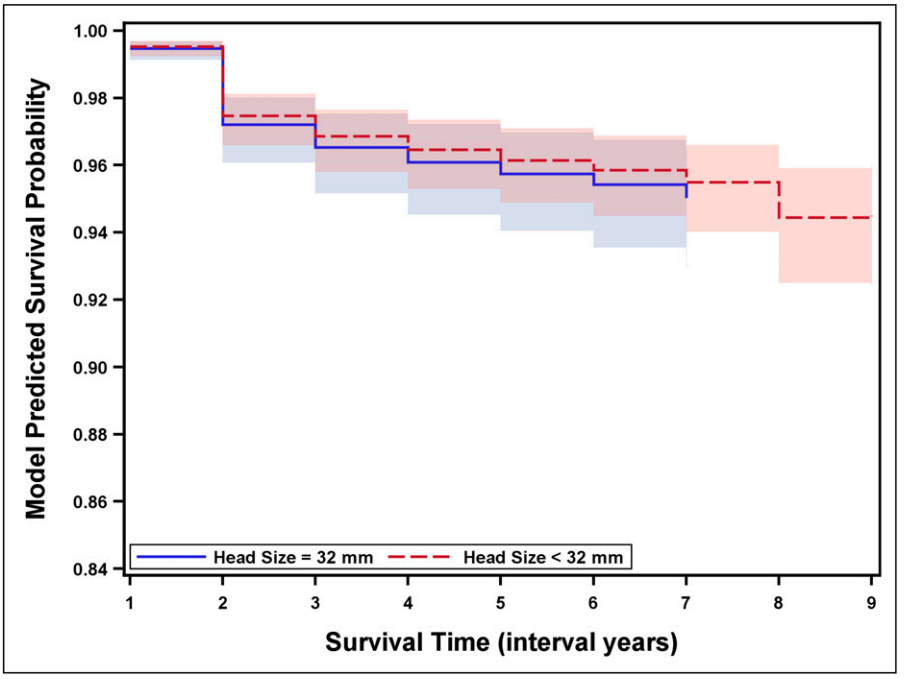

Fig. 1

Predicted survival for 32-mm compared with <32-mm head sizes according to the fixed-effects model. The shading indicates the 95% CI.

A head size of <32 mm was not associated with an increased risk of revision compared with a size of 32 mm (HR [hazard ratio] = 0.91, 95% CI = 0.69 to 1.19, p = 0.478) in the fixed-effects model. Similarly, a head size of >32 mm was not associated with an increased risk of revision compared with a size of 32 mm (HR = 1.05, 95% CI = 0.71 to 1.53, p = 0.822). Thus, there was no evidence of a difference in outcome between 32-mm heads and either larger or smaller heads. Predicted survival curves for these head size groups according to the fixed-effects models are compared in Figures 1 and 2.

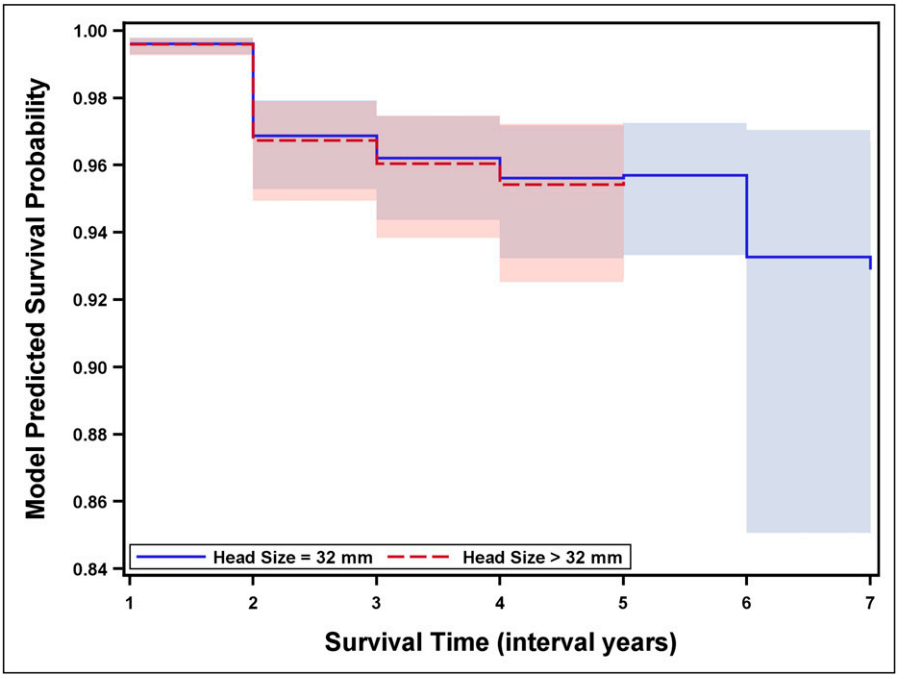

Fig. 2

Predicted survival for 32-mm compared with >32-mm head sizes according to the fixed-effects model. The shading indicates the 95% CI.

Discussion

The utilization of a larger femoral head diameter did not increase the risk of revision when it was utilized in combination with an HXLPE liner. Survivorship was not associated with head size in comparisons between 32-mm heads and larger and smaller sizes. Several studies have indicated the outcomes for HXLPE inserts on the basis of wear resistance or evidence of particle-induced periprosthetic osteolysis[7], but to our knowledge the present study is the first to compare survivorship among different head sizes in arthroplasties involving an HXLPE liner. The evidence of similar survivorship among all head sizes may support the increased use of larger heads to reduce dislocation. However, such a similarity in performance was not observed in a study based on data from the National Joint Registry of England, Wales and Northern Ireland, in which the overall seven-year revision rate for arthroplasties involving any type of polyethylene liner was higher for smaller (<28-mm) heads compared with 28-mm heads[22], and a similar difference was also reported in a systematic review on factors associated with hip arthroplasty revision[23]. A lower risk of revision due to dislocation was also reported for 32-mm heads compared with smaller heads by the Norwegian Arthroplasty Register[24]. In addition, the incidence of dislocation observed in a randomized clinical trial was five times lower in patients with a 36-mm articulation (0.8%) than in those with a 28-mm articulation (4.4%)[25]. Despite these results, it appears that head size does not influence the failure risk in the case of total hip arthroplasty with an HXLPE liner.

The literature provides conflicting results with respect to the effect of the liner type on outcomes. Johanson et al. reported intermediate-term results comparing cemented HXLPE and UHMWPE cups in arthroplasties with cemented femoral stems; they found no difference with respect to aseptic loosening[26]. However, Kremers et al. reported improved survivorship of revision total hip arthroplasties utilizing HXLPE compared with UHMWPE in a cohort of 3236 patients, and no liner revision for wear or osteolysis was recorded in any patient with an HXLPE liner[27]. In an analysis of the entire cohort in their study, as in the present study, femoral head size was not associated with the risk of repeat revision. Finally, in another randomized controlled trial in which the two types of polyethylene were compared, no differences were found with respect to the Harris hip score, WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index), or SF-12 (Short Form-12) score[28]. We did not compare different types of polyethylene in the present study, and further comparative studies would be necessary to assess the outcomes of different combinations of polyethylene type and head size.

Our study has some limitations. Registry data allow independent analyses of large volumes of procedures over an entire population. However, there are many different polyethylene liners on the market and we did not look at specific devices. There is a possibility that a head size effect does exist for some cross-linked polyethylene liners (e.g., some polyethylene formulations used in first and second-generation HXLPE liners). Similarly, grouping head sizes into only three categories (<32, 32, and >32 mm) may have slightly diluted the potential beneficial effect of a much larger femoral head size, such as that reported for a size of >36 mm in some studies[5]. Additionally, the head size effects varied from registry to registry; although these differences were small and clinically unimportant, it may be helpful to investigate the hypothetical effect of country-specific variations in practice patterns in future studies.

To our knowledge, this is the first report on head size effects in total hip arthroplasty outcomes that involves a multinational combination of registry data. Arthroplasty registries have emerged as an appropriate tool for systematically obtaining information on arthroplasty outcomes; these registries have the advantage of a naturalistic approach, as they evaluate prosthesis performance under normal conditions of use following implantation by orthopaedic surgeons with a variety of skill levels in a large variety of hospitals[10,29]. Furthermore, the utility of joint replacement registries for post-marketing surveillance has been highlighted[30]. Joint registries are also a useful tool to assess the performance of hospitals and surgeons, allowing for "benchmarking" to improve outcomes[31].

The results of our study provide relevant data to orthopaedic surgeons deciding on the use of a larger articulation in a metal-on-polyethylene bearing. On the basis of our results, a larger femoral head diameter should not be considered a detriment to device survival when an HXLPE liner is used. However, efforts to force the use of a large-size implant appear to be unsupported, as similar survivorship was observed for all head diameter groups.

Appendix—Details of the Model Fitting

Data Inclusion

For both of the described models, we chose to retain observations with a standard error of <0.025, given that our simulations indicated increased bias, increased root-mean-squared error, and poorer coverage when observations with greater degrees of imprecision (resulting from sparse data for certain covariate combinations) were retained. The 0.025 threshold was based on both the results of the simulation and a sensitivity analysis of the effect on model parameters when various levels of restriction (0.05, 0.025, and 0.0125) were applied.

Model Selection

For the random-effects model comparing <32-mm and 32-mm head sizes, we began with a model that included head size, intercept, age, sex, time since surgery (a dummy variable representing the year of surgery), intercept variance (a random effect), and residual variance fixed at 1. The random head size effect was estimated to be near zero (i.e., $<1.0 \times 10^{-10}$ according to restricted maximum likelihood estimation) and was therefore not included in the model. We considered the inclusion of a treatment-by-time interaction based on three indicator variables for time intervals of zero to two, two to four, four to six, and six to seven years, in order to improve the precision of estimation relative to the use of one-year intervals, but a likelihood-ratio test revealed no evidence of improved fitting (maximum-likelihood estimation, $\chi^2[3] = 0.74$, $p = 0.862$).

For the random-effects model comparing >32-mm and 32-mm head sizes, the steps taken paralleled those described above. The estimate for the random effect variance of the intercept (as well as that of head size) was near zero, which led us to remove it from the model. Therefore, this model had no random effects. The inclusion of a treatment-by-time interaction (two coefficients) did not significantly improve fitting according to a likelihood ratio test ($\chi^2[2] = 0.18$, $p = 0.916$).

Each corresponding fixed-effects model was based on the selected random-effects model. ■

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