Clin Orthop Relat Res (2018) 00:1-12
DOI 10.1097/CORR.0000000000000508

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

Clinical Research

No Increase in Survival for 36-mm versus 32-mm Femoral Heads in Metal-on-polyethylene THA: A Registry Study

Georgios Tsikandylakis MD, Johan Kärrholm MD, PhD, Nils P. Hailer MD, Antti Eskelinen MD, PhD, Keijo T. Mäkelä MD, PhD, Geir Hallan MD, PhD, Ove Nord Furnes MD, PhD, Alma B. Pedersen DMSc, MD, PhD, Søren Overgaard MD, PhD, Maziar Mohaddes MD, PhD

Received: 8 May 2018 / Accepted: 5 September 2018 / Published online: 0, xxxx

Abstract

Background During the past decade, the 32-mm head has replaced the 28-mm head as the most common head size used in primary THA in many national registries, and the use of 36-mm heads has also increased. However, it is

One of the authors (GT) has received research funding from the Göteborg Medical Society. The institution of one or more of the authors (GT, JK, MM) has received funding from the Felix Neubergh Foundation.
Clinical Orthopaedics and Related Research® neither advocates nor endorses the use of any treatment, drug, or device. Readers are encouraged to always seek additional information, including FDA approval status, of any drug or device before clinical use.
Each author certifies that his or her institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.
This work was performed at various hospitals in Denmark, Sweden, Norway, and Finland. The data were processed in Gothenburg, Sweden.

G. Tsikandylakis, J. Kärrholm, M. Mohaddes, Department of Orthopaedics, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden; Sahlgrenska University Hospital, Gothenburg, Sweden; and The Swedish Hip Arthroplasty Registry, Gothenburg, Sweden

N. P. Hailer, Section of Orthopaedics, Department of Surgical Sciences, Uppsala University, Uppsala, Sweden; and The Swedish Hip Arthroplasty Registry, Gothenburg, Sweden

A. Eskelinen, Coxa Hospital of Joint Replacement, Tampere, Finland; and The Finnish Arthroplasty Registry, Helsinki, Finland

K. T. Mäkelä, Department of Orthopedics and Traumatology, Turku University Hospital, Turku, Finland; and The Finnish Arthroplasty Registry, Helsinki, Finland

G. Hallan, O. N. Furnes, The Norwegian Arthroplasty Registry, Department of Orthopedic Surgery, Haukeland University Hospital, Bergen, Norway; and the Department of Clinical Medicine, Faculty of Medicine, University of Bergen, Bergen, Norway

A. B. Pedersen, Department of Clinical Epidemiology, Aarhus University Hospital, Aarhus, Denmark; and The Danish Hip Arthroplasty Registry, Aarhus, Denmark

S. Overgaard, Department of Orthopaedic Surgery and Traumatology, Odense University Hospital, Odense, Denmark; the Institute of Clinical Research, University of Southern Denmark, Odense, Denmark; and The Danish Hip Arthroplasty Registry, Aarhus, Denmark.

G. Tsikandylakis (✉), Department of Orthopaedics, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Sahlgrenska University Hospital/Mölndal R/4, Göteborgsvägen 31, SE-413 45 Gothenburg, Sweden, The Swedish Hip Arthroplasty Registry, Registercentrum Västra Götaland, SE-413 45 Gothenburg 431, 30 Mölndal, Sweden, email: tsikandylakis@gmail.com

All ICMJE Conflict of Interest Forms for authors and *Clinical Orthopaedics and Related Research*® editors and board members are on file with the publication and can be viewed on request.

Wolters Kluwer

unclear whether 32-mm and 36-mm heads decrease the revision risk in metal-on-polyethylene (MoP) THA compared with 28-mm heads.

Questions/purposes (1) In the setting of the Nordic Arthroplasty Registry Association database, does the revision risk for any reason differ among 28-, 32-, and 36-mm head sizes in patients undergoing surgery with MoP THA? (2) Does the revision risk resulting from dislocation decrease with increasing head diameter (28-36 mm) in patients undergoing surgery with MoP THA in the same registry?

Methods Data were derived from the Nordic Arthroplasty Registry Association database, a collaboration among the national arthroplasty registries of Denmark, Finland, Norway, and Sweden. Patients with primary osteoarthritis who had undergone primary THA with a 28-, 32-, or 36-mm MoP bearing from 2003 to 2014 were included. Patients operated on with dual-mobility cups were excluded. In patients with bilateral THA, only the first operated hip was included. After applying the inclusion criteria, the number of patients and THAs with a complete data set was determined to be 186,231, which accounted for 51% of all hips (366,309) with primary osteoarthritis operated on with THA of any head size and bearing type during the study observation time. Of the included patients, 60% (111,046 of 186,231) were women, the mean age at surgery was 70 (± 10) years, and the median followup was 4.5 years (range, 0-14 years). A total of 101,094 patients had received a 28-mm, 57,853 a 32-mm, and 27,284 a 36-mm head with 32 mm used as the reference group. The revision of any component for any reason was the primary outcome and revision for dislocation was the secondary outcome. Very few patients are estimated to be lost to followup because emigration in the population of interest (older than 65-70 years) is rare. A Kaplan-Meier analysis was used to estimate THA survival for each group, whereas Cox regression models were fitted to calculate hazard ratios (HRs) with 95% confidence intervals (CIs) for THA revision comparing the 28- and 36-mm head diameters with the 32-mm head diameters adjusting for age, sex, year of surgery, type of cup and stem fixation, polyethylene type (crosslinked versus conventional), and surgical approach.

Results In the adjusted Cox regression model, there was no difference in the adjusted risk for revision for any reason between patients with 28-mm (HR, 1.06; 95% CI, 0.97–0.16) and 32-mm heads, whereas the risk of revision was higher for patients with 36-mm heads (HR, 1.14; 95% CI, 1.04–1.26) compared with patients with 32-mm heads. Patients with 28-mm heads had a higher risk of revision for dislocation (HR, 1.67; 95% CI, 1.38–1.98) compared with 32 mm, whereas there was no difference between patients with 36-mm (HR, 0.85; 95% CI, 0.70–1.02) and 32-mm heads.

Conclusions After adjusting for relevant confounding variables, we found no benefits for 32-mm heads against 28 mm in terms of overall revision risk. However, when dislocation risk is considered, 32-mm heads would be a better option, because they had a lower risk of revision resulting from dislocation. There were no benefits with the use of 36-mm heads over 32 mm, because the transition from 32 to 36 mm was associated with a higher risk of revision for all reasons, which was not accompanied by a decrease in the risk of revision resulting from dislocation. The use of 32-mm heads appears to offer the best compromise between joint stability and other reasons for revision in MoP THA. Further studies with longer followup, especially of 36-mm heads, as well as better balance of confounders across head sizes and better control of patient-related risk factors for THA revision are needed.

Level of Evidence Level III, therapeutic study.

Introduction

During the past two decades, the size of the femoral head used in primary THA has increased according to many arthroplasty registry reports [12, 14, 15, 28, 31-33, 36]. The use of 36-mm heads appears to have stabilized during the past 2 years, whereas the use of 32-mm heads continues to increase and has replaced 28-mm heads in routine THA [31-33, 36, 37]. The primary intention with larger heads is to reduce the risk of THA dislocation. Multiple factors such as sex, preoperative hip diagnosis, approach, choice of implant and fixation, implant positioning, and small head sizes (< 28 mm) have been identified as risk factors for THA dislocation [18, 24, 34]. The use of larger bearings in THA should theoretically reduce the dislocation risk, provided that other risk factors remain constant, because larger heads provide wider impingement-free ROM [3, 9, 11] and greater jump distance [35].

Several clinical studies [4, 5, 17, 21, 23, 25, 39] have shown a lower dislocation risk in THA with heads of 32 mm or above when compared with 28-mm heads. In contrast, a Swedish registry study found no difference in the revision risk resulting from dislocation among 28-, 32-, and 36-mm heads [18]. Finally, one recent study from the Dutch registry comparing 32-and 36-mm heads found a higher risk of revision resulting from dislocation for 32-mm heads but only when the posterior approach was used [39].

However, the use of larger metal heads has also been associated with increased volumetric polyethylene wear and taper corrosion [7, 16], which might be expected to result in increased revisions for other indications [18, 20]. In the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), the 13-year survival of metal-on-crosslinked polyethylene (MoXLPE) THA with 32-mm heads is higher than that of larger heads that were revised more frequently as a result of aseptic loosening [1]. Most clinical studies [2, 4-6, 18, 21, 25] have compared 28-mm or smaller heads with larger ones, but there is, to our knowledge, only one study [39] comparing 32-mm with 36-mm heads in terms of a compromise between revisions for instability and other indications.

We therefore studied the effect of 28-, 32-, and 36-mm head sizes on primary THA survival in the Nordic Arthroplasty Registry Association (NARA), specifically addressing the following questions: (1) Does the revision risk for any reason differ among the 28-, 32-, and 36-mm head sizes in patients undergoing surgery with metal-on-polyethylene (MoP) THA? (2) Does the revision risk because of dislocation decrease with increasing head diameter (28-36 mm) in patients undergoing surgery with MoP THA?

Materials and Methods

We conducted a registry study of primary THAs performed from 2003 to 2014 that were registered in the NARA database, a collaboration among four national arthroplasty registries: Denmark, Finland, Sweden, and Norway. Finland and Norway have a common arthroplasty registry for both hips and knees (established in 1980 and 1987, respectively), whereas Sweden and Denmark have a separate registry only for hips (established in 1979 and 1995, respectively). The collaboration was initiated in 2007 among Denmark, Sweden, and Norway, whereas Finland joined in 2010 as a result of the reorganization of its database. The four registries contribute to NARA with data from all hip arthroplasties registered since 1995. Because there are structural differences among the registries, data are recoded and only data available in all four registries are merged into the NARA database [20]. The completeness of each national registry exceeds 95% (97.5% Danish [12], 98.3% Swedish [36], 96.7% Norwegian [33], and 95% Finnish [15]).

We retrieved data on all patients registered in the NARA database who had undergone primary THA to treat primary osteoarthritis (OA) with a femoral head size of 28, 32, or 36 mm during the study observation period. Dual-mobility cups were excluded. Because larger than 28-mm heads were rarely used before 2003 (Fig. 1), we excluded all THAs performed before 2003 (Fig. 2). Because MoP is the most common bearing used in the Nordic countries, accounting for 74% (239,922 of 322,996) of all 28- to 36-mm head THAs performed for the indication of OA between 2003 and 2014, we excluded THAs with all other bearing types. For patients operated on bilaterally, we included only the first operated hip. As a result, 186,231 patients (51% of 366,309 THAs resulting from OA registered in NARA between 2003 and 2014 of any bearing size and material) met the inclusion criteria and were grouped according to the head diameter used: 28 mm (101,094 [54%]), 32 mm (57,853 [31%]), and 36 mm (27,284 [15%]) (Fig. 2). The group with 32-mm heads was used as a reference. The mean age at primary THA was 70 (± 10) years and 60% (111,046 of 186,231) of patients were women (Table 1).

Patients had received their hip replacement at various hospitals in the Nordic countries. In the early stage of the study, 28-mm heads were predominantly used. Between 1995 and 2006, dislocation was the second leading cause of

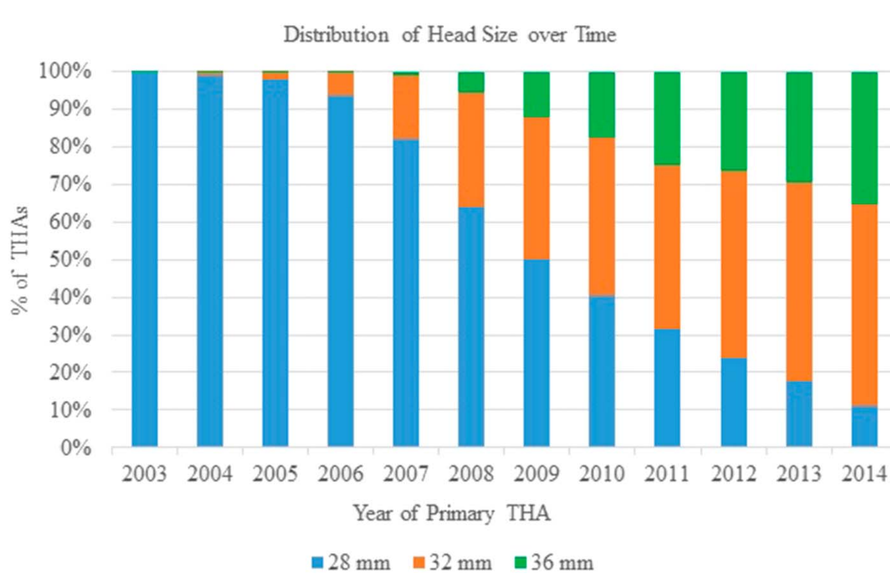

Fig. 1 Staple diagram showing the use of 28-, 32-, and 36-mm heads in the Nordic Arthroplasty Register Association database during the study observation period.

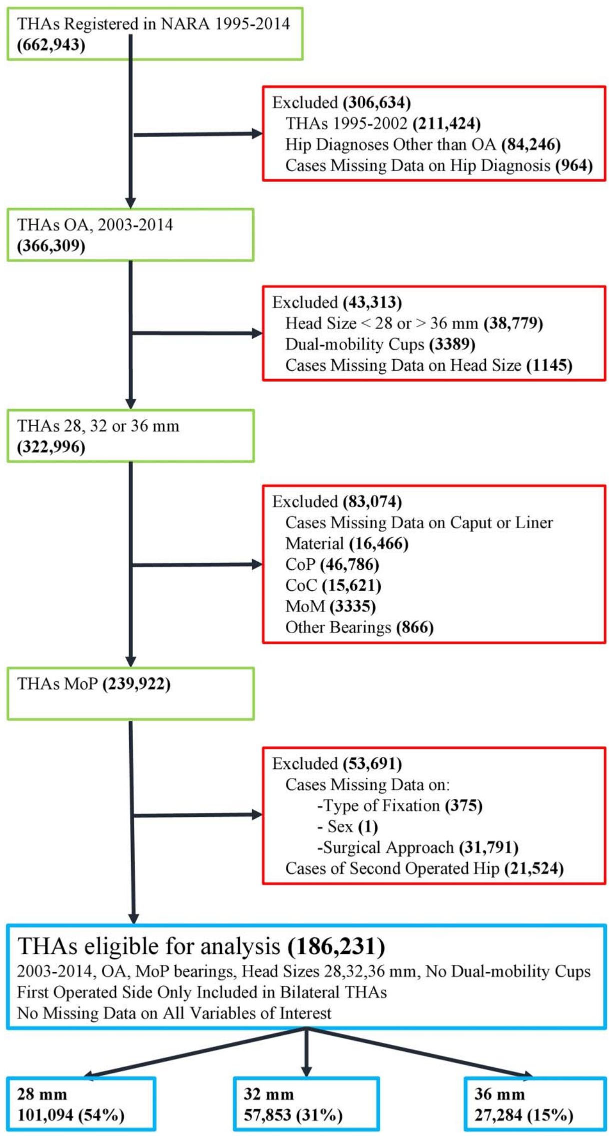

Fig. 2 The flowchart shows how the number of patients included in this study was determined (n = 186,231) after the inclusion criteria were applied to the total number of patients undergoing THA in the NARA database; CoP = ceramic on polyethylene; MoM = metal on metal.

revision in NARA with revision frequencies of 23% to 35% [19]. After the introduction of the more wear-resistant crosslinked polyethylene (XLPE), using larger heads to achieve greater THA stability became more acceptable and their use has been increasing annually. By 2010, more 32- and 36-mm heads were used than 28-mm heads, and the latter continued to diminish (Fig. 1). Different countries used different percentages of these head sizes during the study period (Table 2). For example, during the last 4 years, one country used 36 mm in 70% (16,296 of 23,193) of THAs, whereas another country used the 36-mm heads in only 3% (461 of 11,968). Despite increasing use of larger heads, only 19 of 214 hospitals (9%) were using 36 mm as the standard head size by the end of the study (Table 3).

There were also differences in implant designs, type of fixation, and surgical approach used in this study. There were 91 different stems in total, of which the four most common accounted for > 69% in each head size group (Table 1). The majority of stems were cemented in the 28- and 32-mm groups, but cementless in the 36-mm group. There were 13 different cups with the four most common accounting for > 55% in each group and a similar distribution of cup fixation as in stems across the groups (Table 1). The posterior surgical approach was used in 52% (52,325 of 101,094) of 28-mm, 62% (35,785 of 57,853) of 32-mm, and 93% (25,379 of 27,284) 36-mm head THAs.

After the primary procedure, any subsequent revision was reported to the respective national registry. This reporting includes revisions performed at the same or any hospital other than the hospital where the patient underwent their primary procedure provided it was within the same country. Although we lack detailed information, it is extremely rare that a patient operated on in a Nordic country will be revised outside their country of birth. Almost all patients return to their native country should they need an acute or subacute revision. In the population of interest (mainly older than 65-70 years), emigration is very rare. Patients were followed until THA revision and were censored at emigration, death, or December 31, 2014, whichever came first. The median followup in our study was 7 years for 28-mm, 2.8 years for 32-mm, and 2.1 years for 36-mm heads with a range of 0 to 12 years for all three head sizes. Despite the dissimilar followup among the groups, common among registries as new designs are introduced, our goal was to identify any potential early concerns associated with the use of 36-mm heads.

Variables, Outcome Measurements, Data Sources, and Bias

Variables extracted from the NARA database included age at the primary procedure, sex, preoperative hip diagnosis (only OA included), year of surgery, surgical approach, head size, implant fixation, bearing type, followup period, and reason for revision. The surgical approach was defined as either posterior or not, because further details were not available in one country. The posterior approach has been identified as a risk factor for revision resulting from dislocation compared with other approaches [2, 18, 39]. However, no major differences, in terms of revision risk, have been shown among nonposterior approaches such as between anterolateral and transtrochanteric [2] or lateral

Table 1. Demographics and technical aspects of THA in the study (n = 186,231)

	Head size (mm)			
Demographics and technical aspects	**28**	**32**	**36**	**28, 32, and 36**
Median followup (years; range)	7.0 (0-12)	2.8 (0-12)	2.1 (0-12)	4.5 (0-12)
Median year of surgery (range in years)	2007 (0-12)	2012 (0-12)	2012 (0-12)	2009 (0-12)
Age (years; SD)	70.8 (9)	70.1 (10)	68.9 (10)	70.3 (10)
Female (%)	62,644 (62)	35,325 (61)	13,077 (48)	111,046 (60)
Cemented cup (%)	86,617 (86)	39,672 (69)	3710 (14)	129,999 (70)
Number of different cup designs used (percent of the 4 most common cups)	13 (59)	13 (55)	12 (75)	13 (50)
Cemented stem (%)	80,839 (80)	35,990 (62)	6695 (25)	123,524 (66)
Number of different stem designs used (percent of the 4 most common stems)	88 (75)	91 (69)	56 (71)	114 (69)
Posterior approach (%)	52,325 (52)	35,785 (62)	25,379 (93)	113,489 (61)
Conventional PE (%)	85,489 (85)	14,588 (25)	1409 (5)	101,486 (55)
Crosslinked PE (%)	15,605 (15)	43,265 (75)	25,875 (95)	84,745 (45)

PE = polyethylene.

and anterior [30, 39], making the absence of further details on the specific nonposterior approach less concerning as a possible source of residual confounding. The bearing type was either metal-on-conventional polyethylene or metal-on-XLPE. Three authors (GT, JK, MM) had access to all the operations reported to the database for crosschecking data selection. Revision was defined as the exchange or removal of the entire implant or any of its parts. The primary outcome of our study was the risk of THA revision for any reason. The secondary outcome was the revision risk resulting from dislocation. It is known from previous reports [18, 25, 34] that age, sex, year of surgery, surgical approach, fixation type, and polyethylene type affect the revision risk, especially resulting from dislocation, and

Table 2. The regional variation in the use of 28-, 32-, and 36-mm heads in NARA in relation to 3 different time periods

		Number of THAs per head size group (percent of all heads)			
Nation	**Time period**	**28 mm**	**32 mm**	**36 mm**	**28, 32, and 36 mm**
1	2003-2006	8219 (91)	854 (9)	6 (0)	9079 (100)
	2007-2010	3673 (27)	5544 (40)	4614 (33)	13,831 (100)
	2011-2014	344 (2)	6553 (28)	16,296 (70)	23,193 (100)
	Total 2003-2014	12,236 (27)	12,951 (28)	20,916 (45)	46,103 (100)
2	2003-2006	9566 (98)	249 (2)	0 (0)	9815 (100)
	2007-2010	9247 (87)	1087 (10)	355 (3)	10,689 (100)
	2011-2014	6058 (51)	5449 (46)	461 (3)	11,968 (100)
	Total 2003-2014	24,871 (77)	6785 (21)	816 (2)	32,472 (100)
3	2003-2006	32,677 (99)	234 (1)	35 (0)	32,946 (100)
	2007-2010	22,626 (62)	13,064 (36)	763 (2)	36,453 (100)
	2011-2014	8656 (24)	24,304 (67)	3341 (9)	36,301 (100)
	Total 2003-2014	63,959 (61)	37,602 (36)	4139 (3)	105,700 (100)
4	2011-2014*	28 (2)	515 (26)	1413 (72)	1956 (100)
All	2003-2006	50,462 (97)	1337 (3)	41 (0) [100]	51,840 (100)
	2007-2010	35,546 (58)	19,695 (32)	5732 (10)	60,973 (100)
	2011-2014	15,086 (21)	36,821 (50)	21,511 (29)	73,418 (100)
	Total 2003-2014	101,094 (54)	57,853 (31)	27,284 (15)	186,231 (100)

*One of the national registries did not report on surgical approach until 2014, resulting in excluding all THAs registered in that nation before 2014; NARA = Nordic Arthroplasty Register Association.

Table 3. Number of hospitals that used a single head size in more than 95% of THAs during the last year of the study (2014)

Nation	Number of hospitals using a single head size in more than 95% of THA procedures (%)			Total number of hospitals reporting to NARA
	28 mm	32 mm	36 mm	
1	0 (0)	4 (10)	11 (28)	40
2	7 (13)	26 (48)	0 (0)	54
3	4 (5)	28 (37)	0 (0)	75
4	1 (2)	4 (9)	8 (18)	45
All nations	12 (6)	62 (29)	19 (9)	214

NARA = Nordic Arthroplasty Register Association.

could therefore affect the surgeon's choice of head diameter. We accounted for these potential confounders in the multiple regression model by adjusting for each of them. Cup size could also affect the surgeon's choice of head size, because larger cups can accommodate larger heads, but detailed information on cup size was not available, which made such an adjustment impossible. Implant positioning also could not be addressed, because no information from radiographs was included in the NARA database nor were patient comorbidities and body mass index.

Statistical Analysis

A Kaplan-Meier analysis was performed to estimate THA survival for each head size group with the endpoints of revision for any reason and revision resulting from dislocation. The survival curves were fairly parallel up to 7 years and then converged. At that time point the number of patients at risk dropped below 200 for the 36-mm group. We chose therefore to censor the analysis at 7 years as a result of nonproportionality occurring after this time (see Figure, Supplemental Digital Content 1). Cox multiple regression models were fitted to estimate the hazard ratio (HR) between the groups during the first 7 years of followup with 95% confidence intervals (CIs). We adjusted for the following: patient age at index surgery, sex, year of surgery, type of cup and stem fixation type, polyethylene type, and surgical approach. If data on any of the variables included in the regression model were missing, we excluded those patients (Fig. 2). As a result, one of the four registries contributed data only from 2014 because it did not report on surgical approach before that year. The final number of 186,231 patients had complete data of all the variables; hence, no further patients were excluded when the adjusted Cox regression model was applied. The Schoenfeld residuals were plotted against time to test the proportional hazard assumption in the Cox models. The level of statistical significance was set at a p value of < 0.05 in all analyses. A Kaplan-Meier analysis was performed using R software, Version 3.4.4 (R Foundation for Statistical Computing, Vienna, Austria). Hazard ratios were calculated using SPSS, Version 24 (IBM, Chicago, IL, USA).

Results

All-cause Revision

After controlling for potential confounding variables including age, sex, year of surgery, type of fixation, surgical approach, and type of polyethylene, the adjusted risk for revision for any reason was not different between patients who received 28-mm heads and those who received 32-mm heads; however, the risk was greater for those who received 36-mm heads. For patients with 28-mm heads compared with 32-mm heads, the HR was 1.06 (95% CI, 0.97–1.16; $p = 0.198$), whereas for patients with 36-mm heads, the HR was 1.14 (95% CI, 1.04–1.26; $p = 0.007$) compared with 32-mm heads (Table 4). A total of 5226 of 186,231 (2.8%) primary THAs were revised during the followup period.

Revision for Dislocation

After controlling for potential confounding variables such as age, sex, year of surgery, type of fixation, surgical approach, and type of polyethylene, patients with 28-mm heads were more likely to undergo revision for dislocation than were patients who received 32-mm heads, whereas there were no differences between those treated with 32- and 36-mm heads. In this adjusted model, patients with 28-mm heads had an HR for revision resulting from dislocation of 1.67 (95% CI, 1.38–1.98; $p < 0.001$), whereas patients with 36-mm heads had an HR of 0.85 (95% CI, 0.70–1.02; $p = 0.086$) compared with 32 mm (Table 4). There were 1359 (0.7% of 186,231 primary THAs) revisions for dislocation.

Table 4. Unadjusted and adjusted hazard ratios for revision for any reason and resulting from dislocation during the first 7 years after THA

	Unadjusted			Adjusted*		
Cause of revision	HR	95% CI	p value	HR	95% CI	p value
Any reason						
32 mm†	1.00			1.00		
28 mm	0.90	0.84-0.96	0.001	1.06	0.97-1.16	0.198
36 mm	1.52	1.39-1.66	< 0.001	1.14	1.04-1.26	0.007
Dislocation						
32 mm†	1.00			1.00		
28 mm	1.23	1.08-1.41	0.002	1.67	1.38-1.98	< 0.001
36 mm	1.57	1.31-1.88	< 0.001	0.85	0.70-1.02	0.086

*Adjustments were made for age, sex, year of surgery, surgical approach, implant fixation, and type of polyethylene.
†reference; HR = hazard ratio; CI = confidence interval.

Other Relevant Findings

Because there was no difference in the revision risk for any reason between the 28-mm and 32-mm heads, and we found an increased risk of overall revision for 36-mm compared with 32-mm heads, we performed a supplementary analysis looking at other revision indications. We fitted adjusted Cox regression models for the endpoints of revision resulting from (1) aseptic loosening; (2) periprosthetic joint infection; (3) periprosthetic fracture; (4) pain; or (5) any other reason. The adjusted risk for revision resulting from aseptic loosening after controlling for potential confounding variables such as age, sex, year of surgery, type of fixation, surgical approach, and type of polyethylene was lower for 28-mm heads (HR, 0.77; 95% CI, 0.64–0.94; p = 0.009), whereas the risk was higher for 36-mm (HR, 2.29; 95% CI, 1.79–2.92; p < 0.001) compared with 32-mm heads. The use of the posterior approach and XLPE liners was associated with a lower risk for revision resulting from aseptic loosening, but there were no differences for type of fixation (see Table, Supplemental Digital Content 2). For the rest of the endpoints, there were no differences among the three head sizes (Table 5).

Discussion

Larger head sizes have increasingly been used in primary THA because some studies suggest that they confer additional stability [3, 9, 11, 35]. Increasing the head diameter from 22 mm to 28 mm has resulted in lower dislocation rates, as reported in several studies [2, 4, 6, 18, 22] and more recent studies highlight the use of a 32-mm or larger head [4, 5, 21, 25, 39] to further reduce dislocation risk. This stabilizing effect may occur at the expense of THA survival, however, as a result of complications related to polyethylene wear and possibly taper corrosion, especially in larger MoP bearings [10, 13, 16, 26, 29]. Within the Nordic countries, the use of 32- and 36-mm heads was more common than other head sizes in primary MoP THA during the second half of our study period (Fig. 1). Most studies use 28-mm heads as a reference when comparing the risk of THA revision among different head sizes, and there is limited evidence relating to the benefits of 36-mm compared with 32-mm heads [39]. In this study, we investigated the revision risk for any reason and revision resulting from dislocation of the 32-mm MoP THA and compared that with 28-mm and 36-mm MoP bearing sizes. We found no difference in the revision risk for any reason between 28- and 32-mm heads, although the 28-mm head had a 67% higher risk of revision resulting from dislocation that would make it a less attractive choice when greater stability is desired. In our adjusted analyses, the 36-mm head size did not prove beneficial, because this size was associated with a 14% increase in the revision risk for any reason, and it did not reduce the revision risk resulting from dislocation compared with 32-mm heads.

Limitations

Our study has numerous limitations. There were differences among the head size groups, because considerably more uncemented THAs performed through a posterior approach and with XLPE liners were represented in the 36-mm group compared with smaller head sizes (Table 1). We found that there were also proportionally less females in the 36-mm group compared with the two groups receiving smaller head sizes (Table 1). This was expected because females tend to have a smaller acetabulum. There were also very few hospitals that generally adopted exclusive use of 36-mm heads by the end of our study (Table 3). These two circumstances suggest that surgeons who deliberately used 36-mm heads did not generally overream the acetabulum to

Table 5. Adjusted* hazard ratios for revision as a result of reasons other than dislocation during the first 7 years after THA

Cause of revision	HR	95% CI	p value	Revisions (percent of 186,231)
Aseptic loosening				1284 (0.7)
32 mm†	1.00			
28 mm	0.77	0.64-0.94	0.009	
36 mm	2.29	1.79-2.92	< 0.001	
Infection				1412 (0.8)
32 mm†	1.00			
28 mm	0.95	0.81-1.11	0.495	
36 mm	1.09	0.91-1.31	0.365	
Periprosthetic fracture				605 (0.3)
32 mm†	1.00			
28 mm	0.97	0.75-1.25	0.824	
36 mm	0.94	0.75-1.18	0.589	
Pain only				131 (0.1)
32 mm†	1.00			
28 mm	1.43	0.80-2.54,	0.225	
36 mm	1.62	0.94-2.82	0.085	
Other				434 (0.2)
32 mm†	1.00			
28 mm	1.09	0.81-1.45	0.579	
36 mm	1.26	0.94-1.70	0.130	

*Adjustments were made for age, sex, year of surgery, surgical approach, implant fixation, and type of polyethylene.
†reference; HR = hazard ratio; CI = confidence interval.

fit a bigger cup, but rather chose the largest available head that could be accommodated in a cup suitable for the patient's hip anatomy. Uncemented fixation has been associated with a higher 2-year revision risk compared with cemented fixation in the Nordic countries [34]. The posterior approach is also associated with a higher revision risk resulting from dislocation in most reports [2, 18, 39]. Although we lack further details on nonposterior approaches, it is unlikely that this would affect our results because no major differences in the risk of revision have been demonstrated among the various nonposterior approaches [2, 30, 39]. Despite the fact that sex and cup and stem fixation as well as surgical approach were taken into account in the multiple regression model, the accumulation of disproportionally more uncemented THAs through a posterior approach in the 36-mm group may have impacted this group when compared with smaller head sizes. Although the multiple regression model limited the number of available cases for comparison as a result of subgroups created by each covariate entering the model, it considerably altered the unadjusted results (Table 4) compensating for known confounders and highlighting their importance in the risk of revision for any reason and resulting from dislocation (see Table, Supplemental Digital Content 3).

There was a considerably longer followup for 28-mm heads compared with 32- and 36-mm heads (Table 1). Because 28-mm heads were used mainly with conventional PE, complications related to PE wear such as late dislocations and late loosening may be evident in this group but not in the 32- and 36-mm groups because of their shorter followup and the more frequent use of XLPE. However, the followup was long enough to capture early implant loosening that may have occurred resulting from undersized uncemented implants, for example. To some extent the discrepancies in followup and type of PE liner were compensated for by adjusting the regression model for year of surgery and type of PE.

We used revision resulting from dislocation as the outcome to study the stability of THA between head sizes. However, this outcome only reflects a portion of unstable THAs, because not all dislocating THAs are revised and closed reductions are not registered in the NARA database. On the other hand, it could be argued that it is the recurrent dislocations necessitating revision that should be measured rather than single dislocations treated nonoperatively taking into account that the threshold for revising an unstable THA may differ among patients, surgeons, hospital units, and countries. The high number of patients and hospitals included in this study makes it unlikely that the indications for revision resulting from dislocation will vary depending on which of the three head sizes were used.

In a nonrandomized, observational study such as ours, residual confounding might be present. Surgeons may have selected a 36-mm head when operating on patients whom they perceived to be at higher risk of dislocation. If so, the similar revision risk because of dislocation and the higher revision risk for any reason that 36-mm heads demonstrated compared with 32-mm heads might have been caused by selection bias. However, several hospitals included in the current study routinely use 36-mm heads when cup size permits. The surgeons' preoperative assessment of potential postoperative instability is difficult to study and information about comorbidities with a potential influence on the dislocation risk or any other complication leading to revision is not available in the NARA database. Therefore, as a result of the inherent nature of registry studies, a true causal relationship between head size and the risk of THA revision resulting from dislocation cannot be established based on our data. They can, however, constitute a sound basis for the generation of hypotheses, which might stimulate further research in better controlled studies.

All-cause Revision Risk

We found no difference in the risk of THA revision for any reason between the 28-mm and 32-mm heads. After controlling for potentially confounding variables, the use of 36-mm heads was associated with a 14% higher revision risk compared with 32-mm heads. Somewhat similar results were recently reported from a study in the Dutch Arthroplasty Register [39], in which 32-mm nonmetal-on-metal THAs had a lower 6-year cumulative revision rate for any reason compared with both 22- to 28-mm (as one group) and 36-mm heads. Our study compared specifically 28-mm with 32-mm heads, because 22-mm heads are no longer in use, in a larger population and found no difference between them. The AOANJRR has also reported a higher HR for revision for any reason in MoXLPE THA performed with heads larger than 32 mm compared with 32 mm [1]. In our study the comparison was between 32- and 36-mm heads excluding larger sizes that are seldom used in the Nordic countries and, if so, mainly in clinical trials. The revision risk for any reason as an outcome measurement was used to assess the safety of larger heads and to measure their potential benefits on the stability of THA against their potential risks. The absence of differences in revision risk in THAs with 28- and 32-mm heads indicates that 32-mm THA probably had a higher revision rate for reasons other than dislocation (as discussed subsequently), which was balanced by its reduced risk of revision resulting from dislocation compared with 28-mm THA. Accordingly, our results indicate that THAs with 36-mm heads were also revised more frequently for reasons other than dislocation (also discussed subsequently) compared with 32-mm THA. The transition from 28- to 32-mm heads in MoP THA in the Nordic countries was therefore not associated with any change in its overall revision risk, whereas an increase to 36-mm heads was associated with a slightly higher revision risk. This could reflect the use of more uncemented implants and their associated higher 2-year revision risk [34], as head size increased, especially in 36-mm heads, although the regression model was adjusted for implant fixation. We are unable to determine whether this finding is caused by some inferior properties related to an articulation with a 36-mm head, selection bias, or other yet to be determined factors. Longer term studies with improved control of patient-related risk factors for THA revision, perhaps including American Society of Anesthesiologists (ASA) grade, and investigating outcomes other than revision are needed to further investigate this issue.

Revision for Dislocation

After controlling for confounding variables, we found a 67% higher risk of revision resulting from dislocation in THAs performed with a 28-mm head compared with 32-mm heads. Further increase in head diameter to 36 mm had no obvious additional effect on the risk of revision resulting from dislocation. Several studies have compared the risk of revision resulting from dislocation among THAs with different head sizes [4, 18, 25, 39] (Table 6). Although there were differences in the confounders that regression models were adjusted for in these studies, findings in general have been consistent with a higher risk of revision resulting from dislocation when 28-mm [4, 25] or 22- to 28-mm heads [39] were used compared with 32-mm heads. Three of the studies mentioned [4, 18, 25] come from registries participating in NARA. Our study does not simply summarize previous reports but provides new and contemporary data about the use of 28-, 32-, and 36-mm MoP bearings, because of its more recent observation time and increased statistical power resulting from its large sample size. The Norwegian and Finnish studies [4, 25] did not provide any comparative data between 32- and 36-mm heads, because the former, extending up to 2000, did not include 36-mm heads and the latter, extending up to 2010, used 28 mm as a reference. The Swedish study [18] extended to 2010 but did not find any difference in the risk of revision resulting from dislocation between 28- and 32-mm or between 28- and 36-mm heads. One study [39] from the Dutch registry has reported a lower risk in 36-mm compared with 32-mm heads but only when the posterolateral

Table 6. Comparison of hazard ratios* for revision resulting from dislocation related to head size between the current study and studies performed in the Swedish [18], Finnish [25], Norwegian [4], and Dutch [39] arthroplasty registries

			28 mm‖		32 mm		36 mm	
Head size Study	Number†	FU‡	HR	95% CI; p value	HR	95% CI; p value	HR	95% CI; p value
Current study	186,231	4.5	1.7	1.4-2.0; < 0.001	1.0	Ref§	0.9	0.7-1.0; 0.086
Hailer et al. [18]	78,098	2.7	1.0	Ref§	0.8	0.6-1.1; 0.1	0.7	0.3-1.4; 0.3
Kostensalo et al. [25]	42,379	5.6	1.0	Ref§	0.4	0.3-0.4; < 0.001	0.4	0.2-0.7; 0.001
Byström et al. [4]	38,070	5.2	4.0	2.2-7.3	1.0	Ref§		
Zijlstra et al.‖ [39]	100,803	3.3	1.5	1.3-1.8	1.0	Ref§	0.6	0.5-0.8

*Not all of the multiple regression models used in the studies listed used the same confounders.
†sample size.
‡followup in years.
§reference.
‖in this study the 28-mm group included all head sizes of 22-28 mm and the results refer to posterolateral approach only; HR = hazard ratio; CI = confidence interval.

approach was used. By setting 32 mm as the reference, our study could provide comparative data both between 28 and 32 mm as well as between 32- and 36-mm heads in a larger setting of patients allowing adjustments for all major surgical factors confounding the outcome, including implant fixation and surgical approach. The higher revision risk resulting from dislocation that we report for 28-mm heads compared with 32-mm heads strengthens the evidence provided by previous reports about the stabilizing benefits of 32-mm heads. However, we were not able to show any further risk decrease with 36-mm compared with 32-mm heads despite adjustments in the regression model. The reason for this may be that larger heads were preferred in patients with an anticipated higher risk of dislocation, thus resulting in a selection bias. Another possible explanation could be the disproportionally higher representation of uncemented implants and posterior approach in the 36-mm group creating additional risk factors for THA dislocation that could not be compensated for by the adjustments in the regression model or any potential stabilizing effect of 36-mm heads versus 32-mm heads. If this is true, it could be argued that increasing the bearing size from 32 to 36 mm in MoP THA with the goal of achieving THA stability is less important than avoiding other risk factors for revision such as uncemented fixation and posterior approach.

Other Findings

In a supplementary analysis, our data indicated that THAs with 32-mm heads (versus 28 mm) and 36-mm heads (versus 32-mm heads) were revised more frequently for reasons other than dislocation. We found a greater risk of aseptic loosening with larger head sizes and the difference was considerably greater between 36 and 32 mm than 32 and 28 mm (Table 5). The posterior approach was associated with a lower risk of aseptic loosening possibly because of the improved exposure for stem alignment that this approach facilitates. Because of the relatively short followup in our study, especially for 32- (median, 2.8 years) and 36-mm heads (median, 2.1 years), it is difficult to explain this association in terms of PE wear related to the use of larger heads [26]. Because uncemented stems were overrepresented in the 36-mm head group, we could theorize that failed osseointegration related to undersized stems could have led to early revisions that were classified as loosening. However, there was no difference in the adjusted risk of aseptic loosening between cemented and uncemented stems (Supplemental Table 1). The combination of a thin polyethylene insert and increased frictional torque in larger MoXLPE bearings [29] that can be transmitted along the bone-implant interface might also explain the increased risk for aseptic loosening. Another potential explanation could be implant loosening related to taper corrosion. Although mainly observed in large metal-on-metal THA constructs, taper corrosion has also been reported in MoXLPE THA [8, 38]. It is possible that the higher frictional torque that has been reported in 36- to 40-mm MoXLPE bearings compared with 28 to 32 mm [29] is transmitted along the head-taper interface, leading to taper corrosion [10, 13, 27]. Finally, selection bias related to comorbidities and activity level could deter the use of larger heads in the NARA database. For example, elderly and more diseased patients with poorer bone quality may have received a larger head in an attempt to reduce the dislocation risk, albeit acknowledging that the threshold for revising such patients is generally high. Similarly, younger and more active patients may also have received larger heads to be provided a wider range of hip motion and lower dislocation risk, but be at higher risk for revision secondary to aseptic loosening in a population in whom surgeons would be less reluctant to revise. Because we lack data on both comorbidities and activity level, we were not able to adjust for these potential confounders.

We conducted a large registry study and were able to show differences in the risk of revision among 28-, 32-, and 36-mm heads in MoP THA with higher precision than in most previous studies using a well-defined multiple regression model. We could not demonstrate any benefits with 32-mm heads compared with 28-mm heads in terms of all-cause revision risk. However, our findings would still support the use of 32-mm heads rather than 28-mm heads when surgeons base their choice of head size on anticipated dislocation risk. The use of 36-mm heads was not associated with additional benefits in terms of further reduction in the dislocation risk. On the contrary, it was associated with an increased revision risk resulting from aseptic loosening compared with 32-mm heads, but there are some caveats. Because of inherent limitations in registry-based studies, further studies with longer followup and improved control for confounders are needed to further investigate the importance of head size in THA. However, based on the findings in this multinational registry study, we would encourage surgeons to favor 32-mm heads in routine MoP THA, because they appear to provide the best compromise between stability and overall implant survival.

Acknowledgments We thank all the surgeons, secretaries, and coordinators in the different Nordic countries for contributing data to the NARA database.

References

1. AOANJRR Australian Orthopaedic Association National Joint Replacement Registry. Annual report 2017: hip, knee & shoulder arthroplasty. Available at: https://aoanjrr.sahmri.com/documents/10180/397736/Hip%2C%20Knee%20%26%20Shoulder%20Arthroplasty. Accessed October 11, 2017.
2. Berry DJ, von Knoch M, Schleck CD, Harmsen WS. Effect of femoral head diameter and operative approach on risk of dislocation after primary total hip arthroplasty. *J Bone Joint Surg Am.* 2005;87:2456–2463.
3. Burroughs BR, Hallstrom B, Golladay GJ, Hoeffel D, Harris WH. Range of motion and stability in total hip arthroplasty with 28-, 32-, 38-, and 44-mm femoral head sizes. *J Arthroplasty*. 2005;20:11–19.
4. Bystrom S, Espehaug B, Furnes O, Havelin LI; Norwegian Arthroplasty Register. Femoral head size is a risk factor for total hip luxation: a study of 42,987 primary hip arthroplasties from the Norwegian Arthroplasty Register. *Acta Orthop Scand*. 2003;74:514–524.
5. Cafri G, Paxton EW, Love R, Bini SA, Kurtz SM. Is there a difference in revision risk between metal and ceramic heads on highly crosslinked polyethylene liners? *Clin Orthop Relat Res.* 2017;475:1349–1355.
6. Conroy JL, Whitehouse SL, Graves SE, Pratt NL, Ryan P, Crawford RW. Risk factors for revision for early dislocation in total hip arthroplasty. *J Arthroplasty*. 2008;23:867–872.
7. Cooper HJ, Della Valle CJ. Large diameter femoral heads: is bigger always better? *Bone Joint J*. 2014;96:23–26.
8. Cooper HJ, Della Valle CJ, Berger RA, Tetreault M, Paprosky WG, Sporer SM, Jacobs JJ. Corrosion at the head-neck taper as a cause for adverse local tissue reactions after total hip arthroplasty. *J Bone Joint Surg Am.* 2012;94:1655–1661.
9. Crowninshield RD, Maloney WJ, Wentz DH, Humphrey SM, Blanchard CR. Biomechanics of large femoral heads: what they do and don't do. *Clin Orthop Relat Res.* 2004;429:102–107.
10. Del Balso C, Teeter MG, Tan SC, Howard JL, Lanting BA. Trunnionosis: does head size affect fretting and corrosion in total hip arthroplasty? *J Arthroplasty*. 2016;31:2332–2336.
11. Delay C, Putman S, Dereudre G, Girard J, Lancelier-Bariatinsky V, Drumez E, Migaud H. Is there any range-of-motion advantage to using bearings larger than 36mm in primary hip arthroplasty: a case-control study comparing 36-mm and large-diameter heads. *Orthop Traumatol Surg Res.* 2016;102:735–740.
12. DHR Danish Hip Arthroplasty Register. Annual report 2016. Available at: http://danskhoftealloplastikregister.dk/wp-content/uploads/2015/11/DHR-%C3%A5rsrapport-2016.pdf. Accessed October 10, 2017.
13. Dyrkacz RM, Brandt JM, Ojo OA, Turgeon TR, Wyss UP. The influence of head size on corrosion and fretting behaviour at the head-neck interface of artificial hip joints. *J Arthroplasty*. 2013;28:1036–1040.
14. EPRD Endoprothesenregister Deutschland. Jahresbericht 2015: Mit Sicherheit mehr Qualität. Available at: https://www.eprd.de/fileadmin/user_upload/Dateien/Publikationen/Berichte/EPRD-Jahresbericht_2015_FINAL_Web.pdf. Accessed October 10, 2017.
15. FAR Finnish Arthroplasry Register. Total hip and knee arthroplasty report. Available at: https://www2.thl.fi/endo/report/#html/welcome. Accessed October 9, 2017.
16. Girard J. Femoral head diameter considerations for primary total hip arthroplasty. *Orthop Traumatol Surg Res.* 2015;101:S25–29.
17. Goel A, Lau EC, Ong KL, Berry DJ, Malkani AL. Dislocation rates following primary total hip arthroplasty have plateaued in the Medicare population. *J Arthroplasty*. 2015;30:743–746.
18. Hailer NP, Weiss RJ, Stark A,Karrholm J. The risk of revision due to dislocation after total hip arthroplasty depends on surgical approach, femoral head size, sex, and primary diagnosis. An analysis of 78,098 operations in the Swedish Hip Arthroplasty Register. *Acta Orthop*. 2012;83:442–448.
19. Havelin LI, Fenstad AM, Salomonsson R, Mehnert F, Furnes O, Overgaard S, Pedersen AB, Herberts P, Karrholm J, Garellick G. The Nordic Arthroplasty Register Association: a unique collaboration between 3 national hip arthroplasty registries with 280,201 THRs. *Acta Orthop*. 2009;80:393–401.
20. Havelin LI, Robertsson O, Fenstad AM, Overgaard S, Garellick G, Furnes O. A Scandinavian experience of register collaboration: the Nordic Arthroplasty Register Association (NARA). *J Bone Joint Surg Am.* 2011;93(Suppl 3):13–19.
21. Howie DW, Holubowycz OT, Middleton R. Large femoral heads decrease the incidence of dislocation after total hip arthroplasty: a randomized controlled trial. *J Bone Joint Surg Am.* 2012;94:1095–1102.
22. Jameson SS, Baker PN, Mason J, Gregg PJ, Brewster N, Deehan DJ, Reed MR. The design of the acetabular component and size of the femoral head influence the risk of revision following 34 721 single-brand cemented hip replacements: a retrospective cohort study of medium-term data from a National Joint Registry. *J Bone Joint Surg Br.* 2012;94:1611–1617.
23. Jameson SS, Lees D, James P, Serrano-Pedraza I, Partington PF, Muller SD, Meek RM, Reed MR. Lower rates of dislocation with increased femoral head size after primary total hip replacement:

a five-year analysis of NHS patients in England. *J Bone Joint Surg Br.* 2011;93:876–880.
24. Kennedy JG, Rogers WB, Soffe KE, Sullivan RJ, Griffen DG, Sheehan LJ. Effect of acetabular component orientation on recurrent dislocation, pelvic osteolysis, polyethylene wear, and component migration. *J Arthroplasty*. 1998;13:530–534.
25. Kostensalo I, Junnila M, Virolainen P, Remes V, Matilainen M, Vahlberg T, Pulkkinen P, Eskelinen A, Makela KT. Effect of femoral head size on risk of revision for dislocation after total hip arthroplasty: a population-based analysis of 42,379 primary procedures from the Finnish Arthroplasty Register. *Acta Orthop*. 2013;84:342–347.
26. Lachiewicz PF, Soileau ES, Martell JM. Wear and osteolysis of highly crosslinked polyethylene at 10 to 14 years: the effect of femoral head size. *Clin Orthop Relat Res.* 2016;474:365–371.
27. Langton DJ, Jameson SS, Joyce TJ, Gandhi JN, Sidaginamale R, Mereddy P, Lord J, Nargol AV. Accelerating failure rate of the ASR total hip replacement. *J Bone Joint Surg Br.* 2011;93:1011–1016.
28. LROI Landelijke Registratie Orthopedische Implantaten. Annual report of the Dutch Arthroplasty Register 2014: arthroplasty in the picture. Available at: https://www.lroi.nl/downloads/9/Report%20LROI%202014%20English.pdf. Accessed October 9, 2017.
29. Meneghini RM, Lovro LR, Wallace JM, Ziemba-Davis M. Large metal heads and vitamin E polyethylene increase frictional torque in total hip arthroplasty. *J Arthroplasty*. 2016;31:710–714.
30. Mjaaland KE, Svenningsen S, Fenstad AM, Havelin LI, Furnes O, Nordsletten L. Implant survival after minimally invasive anterior or anterolateral vs. conventional posterior or direct lateral approach: an analysis of 21,860 total hip arthroplasties from the Norwegian Arthroplasty Register (2008 to 2013). *J Bone Joint Surg Am.* 2017;99:840–847.
31. New Zealand Joint Registry. 17th year report: January 1999 to December 2015. Available at: https://nzoa.org.nz/system/files/NZJR%2017%20year%20Report.pdf. Accessed October 6, 2017.
32. NJR National Joint Registry. 14th annual report 2017: national joint registry for England, Wales, Northern Ireland and the Isle of Man. Available at: http://www.njrreports.org.uk/Portals/0/PDFdownloads/NJR%2014th%20Annual%20Report%202017.pdf. Accessed October 6, 2017.
33. Norwegian National Advisory Unit on Arthroplasty and Hip Fractures. Norwegian Arthroplasty Register: report June 2016. Available at: http://nrlweb.ihelse.net/eng/Rapporter/Report2016_english.pdf. Accessed October 4, 2017.
34. Pedersen AB, Mehnert F, Havelin LI, Furnes O, Herberts P, Karrholm J, Garellick G, Makela K, Eskelinen A, Overgaard S. Association between fixation technique and revision risk in total hip arthroplasty patients younger than 55 years of age. Results from the Nordic Arthroplasty Register Association. *Osteoarthritis Cartilage*. 2014;22:659–667.
35. Sariali E, Lazennec JY, Khiami F, Catonne Y. Mathematical evaluation of jumping distance in total hip arthroplasty: influence of abduction angle, femoral head offset, and head diameter. *Acta Orthop*. 2009;80:277–282.
36. SHAR Swedish Hip Arthroplasty Register. Annual report 2015: Available at: https://registercentrum.blob.core.windows.net/shpr/r/Annual-Report-2015-H19dFINOW.pdf. Accessed October 4, 2017.
37. Tsikandylakis G, Mohaddes M, Cnudde P, Eskelinen A, Karrholm J, Rolfson O. Head size in primary total hip arthroplasty. *EFORT Open Rev.* 2018;3:225–231.
38. Whitehouse MR, Endo M, Zachara S, Nielsen TO, Greidanus NV, Masri BA, Garbuz DS, Duncan CP. Adverse local tissue reactions in metal-on-polyethylene total hip arthroplasty due to trunnion corrosion: the risk of misdiagnosis. *Bone Joint J.* 2015;97:1024–1030.
39. Zijlstra WP, De Hartog B, Van Steenbergen LN, Scheurs BW, Nelissen R. Effect of femoral head size and surgical approach on risk of revision for dislocation after total hip arthroplasty. *Acta Orthop*. 2017;88:395–401.