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

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Background and purpose **Previous population-based registry studies have shown that larger femoral head size is associated with reduced risk of revision for dislocation. However, the previous data have not included large numbers of hip resurfacing arthroplasties or large metal-on-metal (> 36-mm) femoral head arthroplasties. We evaluated the association between femoral component head size and the risk of revision for dislocation after THA by using Finnish Arthroplasty Register data.**

Patients and methods **42,379 patients who were operated during 1996–2010 fulfilled our criteria. 18 different cup/stem combinations were included. The head-size groups studied (numbers of cases) were 28 mm (23,800), 32 mm (4,815), 36 mm (3,320), and > 36 mm (10,444). Other risk factors studied were sex, age group (18–49 years, 50–59 years, 60–69 years, 70–79 years, and > 80 years), and time period of operation (1996–2000, 2001–2005, 2006–2010).**

Results **The adjusted risk ratio in the Cox model for a revision operation due to dislocation was 0.40 (95% CI: 0.26–0.62) for 32-mm head size, 0.41 (0.24–0.70) for 36-mm head size, and 0.09 (0.05–0.17) for > 36-mm head size compared to implants with a head size of 28 mm.**

Interpretation **Larger femoral heads clearly reduce the risk of dislocation. The difference in using heads of > 36 mm as opposed to 28-mm heads for the overall revision rate at 10 years follow-up is about 2%. Thus, although attractive from a mechanical point of view, based on recent less favorable clinical outcome data on these large heads, consisting mainly of metal-on-metal prostheses, one should be cautious using these implants.**

The dislocation rate after total hip arthroplasty (THA) is influenced by the diagnosis and the medical condition of the patient (Wang et al. 2012), the surgical approach (Berry et al. 2005), femoral head size (Byström et al. 2003, Jameson et al. 2011, Wang et al. 2012), and the skills of the surgeon through component positioning (Witjes et al. 2009). Recurrent dislocation is one of the most common reasons for reoperations in THA (Byström et al. 2003).

Small femoral head size is a risk factor for dislocation (Byström et al. 2003, Jameson et al. 2011, Wang et al. 2012). Hip implants with larger femoral heads have been developed to reduce the dislocation rate. However, larger metal-on-polyethylene articulation increases the amount of volumetric wear debris (Oonishi et al. 1998). Metal-on-metal (MoM) and ceramic-on-ceramic bearing surfaces were developed to reduce wear. MoM articulation also allowed larger head sizes in hip resurfacing arthroplasty (HRA) and THA. However, it has been shown recently that the wear propensities of many MoM designs are poor (Grammatopolous et al. 2009, Langton et al. 2010). Large-diameter head THAs and HRAs have been used frequently in Finland during the last decade (Mokka et al. 2012, Seppänen et al. 2012).

We assessed the association between femoral head size and rate of revision for dislocation in primary THA and HRA based on data from the Finnish Arthroplasty Register.

Patients and methods

Since 1980, the Finnish Arthroplasty Register has been collecting information on total hip replacements (Paavolainen et al. 1991). Healthcare authorities, institutions, and orthopedic units are obliged to provide the National Institute for Health and Welfare with information essential for maintenance of the register. An English translation of the notification form used

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Table 1. The names and numbers (n) of study implants, mean follow-up times, and number of revised implants due to dislocation

Implant type Implant	n	Mean follow-up, years	Revised for dislocation
Cemented total hip arthroplasty			
Elite Plus	1,291	8.4	10
Lubinus IP & Lubinus SP I & Lubinus SP II/Lubinus IP	2,666	7.9	78
Exeter Universal/Ex All-poly & Ex Contemporary	12,119	6.2	159
Spectron/Reflection	4,192	4.3	27
Cementless total hip arthroplasty			
ML-Taper/MMC & Durom resurfacing cup	362	1.5	0
Spotorno/Morscher & Durom resurfacing cup	132	4.5	0
Synergy/R3 & BHR resurfacing cup	1,225	1.8	0
Biomet Bimetric/Biomet cups	10,029	5.1	140
ABG I/ABG I & ABG II	2,075	10.0	25
ABG II/ABG II	1,897	6.5	16
Accolade & Omnifit & Symax/Trident	160	4.4	0
Summit/Pinnacle & ASR resurfacing cup	2,045	3.2	11
Corail/ Pinnacle & ASR resurfacing cup	411	2.7	2
Hip resurfacing arthroplasty			
BHR resurfacing prosthesis	1,635	5.3	2
ASR resurfacing prosthesis	836	4.2	1
ReCap resurfacing prosthesis	587	3.3	1
Durom resurfacing prosthesis	287	4.1	0
Conserve Plus resurfacing prosthesis	430	2.9	0
Total	42,379	5.6	472

by the Finnish Arthroplasty Register has been described previously (Puolakka et al. 2001).

Only primary THAs and HRAs performed during the study period (1996–2010) were included. There were 79,382 THAs and HRAs at this point. Furthermore, only patients aged between 18 and 100 years at the time of operation were included. Patients with the first hip operated before 1996 were excluded because head size was not recorded before that. Patients with insufficient information on femoral component head size were excluded, which left 72,596 THAs and HRAs. Finally, only the most common implant designs with the head sizes of 28 mm, 32 mm, 36 mm, and > 36 mm were included, giving 42,379 hips altogether for final analysis (Table 1). The 5 most common HRAs, large-diameter head THAs with more than 100 implantations during the study period, and the 4 most common cemented implants were included. The proportion of all THAs that were large-diameter-head (LDH) MoM THAs was 15.0%.

Statistics

We analyzed survival rate for dislocation revision of 23,800 THAs with 28-mm heads, 4,815 THAs with 32-mm heads, 3,320 THAs with 36-mm heads, and 10,444 THAs and HRAs with a head size of > 36 mm. We used the Cox multiple regression model to adjust for potential confounding factors. The factors studied with the Cox model—apart from head size—were sex, age group (18–49 years, 50–59 years, 60–69 years, 70–79 years, and > 80 years), and time period of the operation. The study period was divided into 3 shorter time periods: 1996–2000, 2001–2005, and 2006–2010. Revisions were linked to the primary operation by using the patient's personal identification number. The endpoint for survival was defined as revision when either 1 component (including the femoral head) or the whole implant was removed or exchanged (Table 2). Revision for dislocation served as the endpoint. Patients who died or left Finland during the follow-up period were censored at that point. Cox regression analyses provided estimates of survival probabilities and adjusted risk ratios for revision, and 95% confidence intervals (CIs) were calculated. The Kolmogorov-type supremum test was performed to check the proportional hazards assumption. Age group was found to violate this assumption. Because the effect of age group was not of direct interest, the data were stratified by age group and a stratified Cox regression model was used. The baseline hazard function was set to be different for each stratum (age group), but other covariates were assumed to have the same risk ratio for each stratum. When the data were stratified by age group, other parameters fulfilled the assumption of proportional hazards. We used estimates from the Cox analyses to construct adjusted survival curves at mean values of the risk factors. The Wald test was used to calculate p-values for data obtained from the Cox multiple regression analysis. Differences between groups were considered to be statistically significant if the p-values were less than 0.05 in a 2-tailed test. All statistical analyses were done using SAS software version 9.2.

Table 2. Reasons for revision of 42,379 primary THAs and HRAs

Reason for revision	No. of revisions (%)
Aseptic loosening (both components combined)	476 (22)
Aseptic loosening (cup)	286 (13)
Aseptic loosening (stem)	166 (8)
Infection	192 (9)
Dislocation	472 (22)
Malposition	154 (7)
Periprosthetic fracture	216 (10)
Breakage of the implant	22 (1)
Other reason	198 (9)
Total	2,182 (100)

Table 3. The head-size groups

Head size	No. of hips	No. revised for dislocation	Mean follow-up, years
28 mm	23,800	414	7.6
32 mm	4,815	27	3.2
36 mm	3,320	17	2.4
> 36 mm	10,444	14	3.2

Table 4. The study data presented separately for male and female patients

Sex	No. of hips	No. revised for dislocation	Mean follow-up, years
Male	18,516	212	5.4
Female	23,863	260	5.8

Table 5. The study data presented separately for 5 age groups

Age group	No. of hips	No. revised for dislocation	Mean follow-up, years
18–49	2,951	15	5.6
50–59	7,638	77	5.6
60–69	12,974	160	5.9
70–79	14,538	174	5.5
80–100	4,278	46	4.6

Table 6. The study data presented separately for 5-year time periods

Period	No. of hips	No. revised for dislocation	Mean follow-up, years
1996–2000	9,248	162	9.7
2001–2005	15,571	227	6.6
2006–2010	17,560	83	2.5

Results

The head-size group of 28 mm, the reference group, was the largest group (56% of all hips) and had the longest follow-up time. The follow-up time of the other groups was remarkably shorter (Table 3). The proportion of female patients was 56% (Table 4). The age group of patients from 70 to 79 years constituted 34% of all cases (Table 5). The number of hips included in the study increased from 9,248 during the period 1996–2000 to 17,560 during 2006–2010 (Table 6).

The unadjusted dislocation revision rates during the first 30 postoperative days, 1–12 months postoperatively, 1–2 years postoperatively, and 2–5 years postoperatively—according to head size—are presented separately in Figure 1.

Table 7. Adjusted study data for time period, sex, and head size. The revision risks are assumed to be the same for every stratum (age group)

Parameter		Adjusted RR (95% CI)	p-value
Time period	2001–2005	1.20 (0.97–1.48)	0.09
Time period	2006–2010	1.41 (1.01–1.97)	0.05
Sex	M	1.23 (1.03–1.48)	0.02
Head size	32 mm	0.40 (0.26–0.62)	< 0.001
Head size	36 mm	0.41 (0.24–0.70)	0.001
Head size	> 36 mm	0.09 (0.05–0.17)	< 0.001

Large head size was statistically significantly associated with reduced dislocation revision rate (Table 7, Figure 2). The adjusted risk ratios in the Cox model for a revision operation due to dislocation were 0.40 (95% CI: 0.26–0.62; $p < 0.001$) for 32-mm head size, 0.41 (CI: 0.24–0.70; $p = 0.001$) for 36-mm head size, and 0.09 (CI: 0.05–0.17; $p < 0.001$) for > 36-mm head size compared to implants with a head size of 28 mm.

In the Cox model, male sex was significantly associated with increased dislocation revision rate (RR = 1.23, CI: 1.03–1.48; $p = 0.02$) (Table 7). Dislocation revision risk was higher for time period 2006–2010 than for 1996–2000 after adjustments in the Cox model (RR = 1.41, CI: 1.01–1.97; $p = 0.05$).

The risk of revision for dislocation with LDH MoM THAs and HRAs was similar (RR = 0.82, CI: 0.22–3.07; $p = 0.8$).

Discussion

The overall rate of revision for dislocation in Finland was low. Using 28-mm heads, only 2.5% of the hips were revised for dislocation at 12 years after surgery. However, we found that despite this observation, the 28-mm femoral head size had a 10-fold higher risk of reoperation due to dislocation than a head size of 37 mm or more over the same period of time. The trend towards larger femoral head size has resulted in fewer revisions due to dislocation. However, the Cox-adjusted dislocation revision rate for time period 2006–2010 was higher than for the time period 1996–2001.

In conducting a registry-based study, we were unable to compare the functional results between groups; nor did we perform any radiological analyses, which could have detected silent osteolysis or adverse biological reactions linked to MoM articulation (ARMD or pseudotumors) (Willert et al. 2005, Grammatopoulos et al 2009) considering LDH MoM THA or HRA. The endpoint in this study was a revision operation performed for dislocation. Although wear, osteolysis, and ARMD may predispose to dislocations, we believe that revision for dislocation is still a reliable endpoint for registry studies. In clinical studies from single centers, some patients are regularly lost to follow-up. In registry-based studies, however,

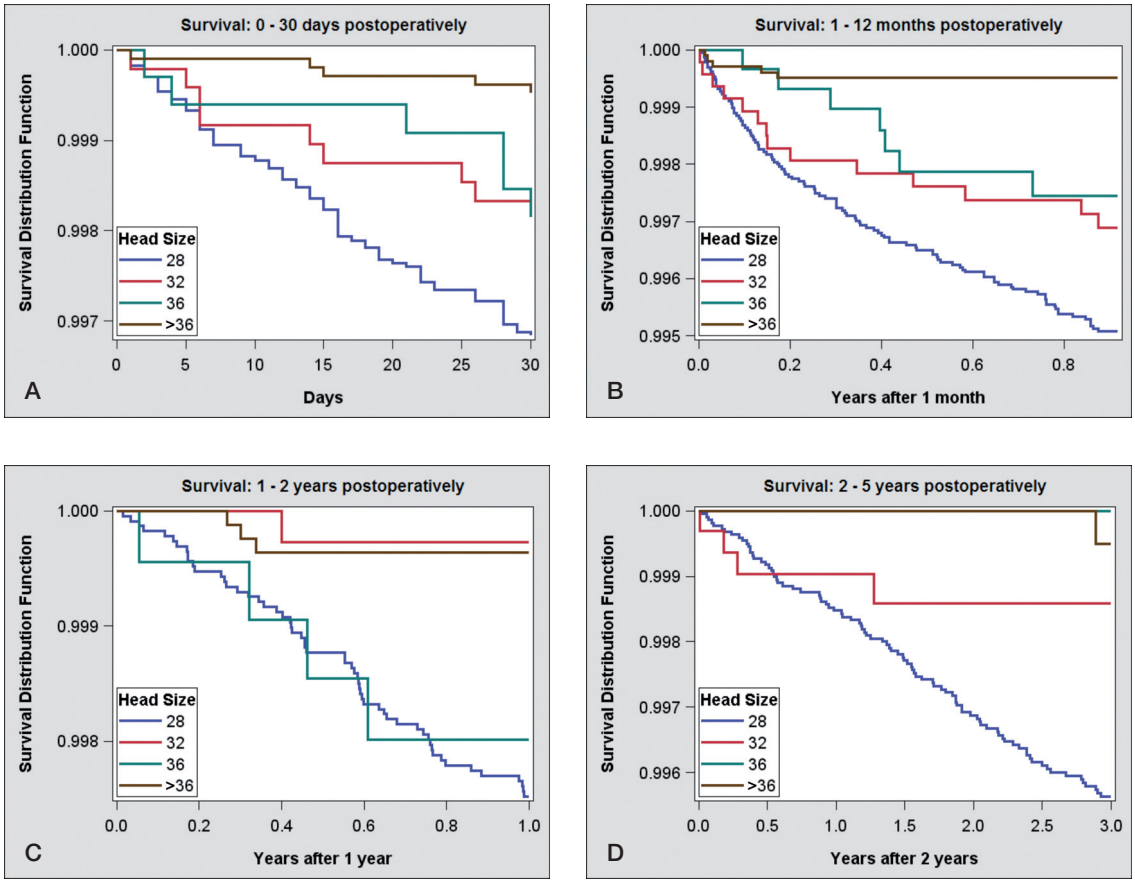

Figure 1. A. Unadjusted dislocation revision rate during the first 30 postoperative days according to head size. B. Unadjusted dislocation revision rate 1–12 months postoperatively according to head size. C. Unadjusted dislocation revision rate 1–2 years postoperatively according to head size. D. Unadjusted dislocation revision rate 2–5 years postoperatively according to head size.

information on all revision operations is available, no matter where the revisions are performed. The possibility of selection bias cannot be ruled out, as the most experienced orthopedic surgeons may have performed most of the LDH MoM THAs and HRAs. Any such bias should be minute, however, as the LDH MoM THAs were divided between 54 hospitals and HRAs between 46 hospitals. THAs with the head sizes of 28 mm and 32 mm were performed in 83 hospitals.

It is challenging to analyze exactly what kind of revision cases the malposition subgroup included. In theory, it is possible that a surgeon could classify the reason for revision as dislocation even when it was due to component malposition. A revision performed for adverse reaction to metal debris may similarly be coded as performed due to malposition. The malposition issue could theoretically bias our results. However, we do not believe that it has any serious effect on our overall message.

The posterior approach has been associated with a higher risk of revision for dislocation than the lateral approach (Byström et al. 2003, Berry et al. 2005). Unfortunately, there are no data on surgical approach available in the Finnish Arthroplasty Register. Furthermore, data concerning co-morbidity related to the increased dislocation risk—such as neurological disorders or alcohol abuse—are not available.

We analyzed LDH MoM THAs and HRAs separately as a head size group of > 36 mm. Hips in the head-size groups of 32 mm, 36 mm, and > 36 mm had shorter follow-up time than those in the reference group. More than 75% of dislocations occur within the first postoperative year (Jameson et al. 2011). Most revisions for dislocation in our patient series occurred during the first year after arthroplasty. Different risk factors may have different impact on risk of revision for dislocation at different postoperative times. To avoid bias, we performed survival analyses separately for early and late dislocation revisions. Head size of 28 mm was associated with higher risk of revision for dislocation than > 36 mm at all stages.

After adjustment in the Cox model, overall dislocation revision rate was lower in the time period 1996–2000 than in the later time period 2006–2010. Based on more experience with dislocating hips and newer revision implants (dual articulating systems, constrained liners, and large heads) which can solve the problem of dislocation, a lower threshold for reoperating

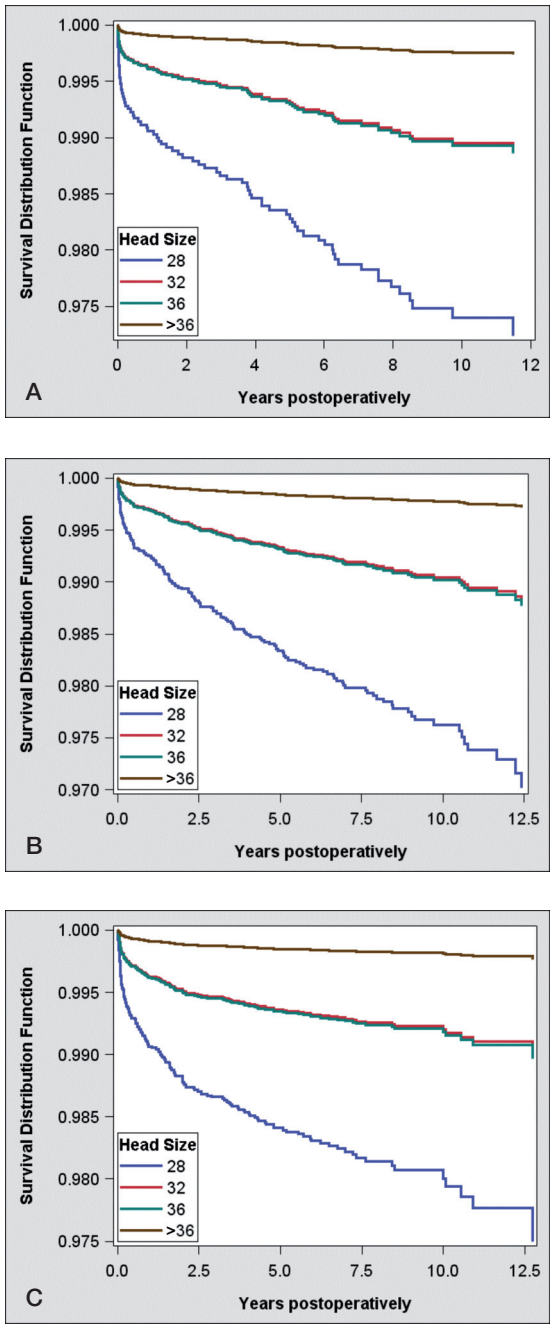

Figure 2. A. Survival data for implants in the 50- to 59-year age group, according to head size. B. Survival data for implants in the 60- to 69-year age group, according to head size. C. Survival data for implants in the 70- to 79-year age group, according to head size. In all cases, adjustments have been performed for sex and time period.

these patients is a likely explanation. Selection of more sick patients (Parkinson's disease, alcohol abuse) may also have occurred.

If both hips in the same patients had been operated, only the first one was included. Inclusion of bilateral cases in a survival analysis violates the basic assumption that all cases are independent. However, several reports have shown that the effect of including bilateral cases in studies of hip and knee joint prosthesis survival is negligible (Robertsson and Ranstam 2003).

Age group was not associated with rate of revision for dislocation in the Cox model. There was a reduced risk of such revisions in the youngest age group when using raw data. High dislocation risk in elderly patients has been found in some studies (Ekelund et al. 1992) but not in all (Paterno et al. 1997).

There were more male patients in the > 36-mm group. This was adjusted for as far as possible by the use of a regression model. In theory, selection bias can only be avoided by conducting a randomized controlled trial. However, it has been pointed out that well-designed observational studies provide reliable information on treatment effects, and the role of single randomized, controlled studies should not be overemphasized in clinical decision making (Benson and Hartz 2000, Concato et al. 2000).

Operative diagnosis may have an effect on dislocation rate (Byström et al. 2003), but it was not analyzed in the Cox model in our study. The operative diagnoses are not coded very logically in the Finnish Register. For example, the diagnosis of secondary arthritis may include patients with hip fracture, failed treatment of hip fracture, and developmental dysplasia. However, we believe that the diagnosis of primary osteoarthritis is reliably coded in our register. Thus, we also performed our analyses only for those THRs that were performed due to primary osteoarthrosis (data not shown). The effect of including only primary osteoarthritis as an operative diagnosis on our results was minimal.

Our data support previous findings that large head size is associated with reduced rate of revision for dislocation (Byström et al. 2003, Berry et al. 2005, Jameson et al. 2011). They also included LDH MoM THAs and HRAs (Table 1). Unfortunately, there is increasing evidence of higher revision risk for LDH MoM THAs and HRAs than for conventional THAs—for reasons other than dislocation (Kärrholm et al. 2008, NJR (a) England and Wales 2011). Chromium and cobalt ions caused by bearing surface wear have caused localized soft-tissue reactions (Langton et al. 2010). Some recent national recommendations are not to use LDH MoM THAs and/or HRAs before more safety data are available (NJR (b) England and Wales 2012, FAA 2012).

Large femoral head size in metal-on-polyethylene prostheses has been shown to increase the amount of wear debris and therefore increase the risk of osteolysis and aseptic loosening (Oonishi et al. 1998). There are new, harder polyethylene materials on the market which are considered to reduce the amount of wear debris. According to data based on the Norwegian Arthroplasty Register (Byström et al. 2003), dislocation rates were lower using 32-mm heads than using 28-mm heads. This has also been verified in other studies (Berry et al. 2005). The use of 36-mm heads reduced the risk of disloca-

tion following THA compared to 28-mm heads (Bistolfi et al. 2011). Our data support these earlier findings. If implants of > 36 mm are abandoned, prostheses with 32-mm and 36-mm heads should be used instead to prevent dislocation revisions. The rate of revision for dislocation using 28-mm heads actually increased during the study period. Nowadays, patients may have more comorbidities that affect to the risk of dislocation. Threshold to perform a total hip replacement may also be lower. It is also possible that in using many large-head implants with only a theoretical risk of dislocation, accurate component positioning has not been as accurate as it has been in the past. For bearing surface wear, however, implant positioning is extremely important, regardless of whether one uses metal-on-polyethylene or LDH MoM articulations.

The conclusion from this study is that larger femoral head size reduces the amount of revisions due to dislocations in THAs and HRAs. Less use of larger femoral head sizes because of wear issues may remarkably increase the number of revisions due to dislocation in the future. Although attractive from a mechanical point of view, based on recent unfavorable clinical outcome data for these large heads, which consisted mainly of MoM prostheses, one should be cautious using these implants.

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