# Femoral head size is a risk factor for total hip luxation

# A study of 42,987 primary hip arthroplasties from the Norwegian Arthroplasty Register

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ABSTRACT On the basis of the Norwegian Arthroplasty Register, which has recorded nearly all primary hip prostheses and revisions in Norway since 1987, we studied risk factors for prosthesis luxation leading to revision. 7 prosthesis brand combinations used in 42,987 primary operations were included from 1987-2000. We found that femoral head size was an important risk factor; 28 mm heads led to revision more often than 32 mm ones (failure rate ratio (FRR) 4.0, 95% confidence interval (CI) 2.2-7.3). Charnley (22 mm head) performed equally well or better than the 28 mm heads. The Exeter stem and cup is the type of prosthesis on the Norwegian market with more than two femoral head sizes (26, 28, 30, 32 mm) and 26 mm heads led to revision due to luxation significantly more often than 30 mm heads (FRR 4.1, 95% CI 2.2-8.1). Old age, preoperative diagnosis, and choice of prosthesis brand combination were also important factors affecting the revision rate due to luxation. A posterior approach increased the risk of revision more than a lateral one (FRR 1.9, 95% CI 1.4-2.5). Gender, trochanteric osteotomy and duration of the operation did not affect the results.

The incidence of prosthetic component luxation in primary total hip arthroplasty (THA) is not common, ranging from less than 1% to 8% (Garcia-Cimbrelo and Munera 1992), but it is one of the commonest postoperative complications (Vaughn 1993). It is second only to component loosening as a cause of reoperation (Lindberg et al. 1982). Luxation therefore remains a major challenge to all prosthetic surgeons, often entailing the need for additional surgical procedures.

Many authors have advocated the routine use of smaller femoral head components to reduce the volumetric wear rate (Bartel et al. 1986, Livermore et al. 1990, Garcia-Cimbrelo and Munera 1992), altough only a few clinical studies support this recommendation (Astion et al. 1996). However, it is generally believed that smaller head sizes increase the number of dislocations (Bartz et al. 2000), but this is not well documented in the literature (Morrey 1992). Hedlundh et al. (1996a) found no difference between 22 mm and 32 mm heads, but the smaller size resulted oftener in recurrent dislocations.

According to a calculation, one must perform 3,720 primary operations to detect a 2% difference in two treatments of THA dislocations, with a power of 80% (Bartz et al. 2000). The Norwegian Arthroplasty Register (NAR) contains prospective data from more than 60,000 primary THAs from 1987 to 2000 and thus provides one of the best materials available for studying factors affecting the outcome of THA. With the help of the NAR, we assessed the risk of prosthetic component luxation that led to revision in primary total hip arthroplasty, with special reference to femoral head size.

# Patients and methods Study material

Patients were selected from the records of the NAR

	Primary op	Median	Percent	Mean follow-	l	Femoral I	nead sizes (n)		
	(1)	age (year)	men	up (year)	22 mm	26 mm	28 mm	30 mm	32 mm
Exeter / Exeter	5,625	71	29	5.5		1,079	681	3,838	27
SP / SP	778	73	31	5.0			449		329
Titan / Tropic	850	68	31	4.9			487		363
Titan / Titan	4,143	75	28	5.1			2,336		1,807
Corail / Atoll	1,192	55	39	5.2			876		316
Corail / Tropic	2,272	55	37	4.6			1,405		867
Charnley/Charnley	28,127	72	28	5.3	28,127				
All combinations	42,987	72	29	5.3	28,127	1,079	6,234	3,838	3,709

#### Table 1. The study population selected from the Norwegian Arthroplasty Register

that has access to data about nearly all primary THAs performed in Norway (4.4 million inhabitants) since September 1987 (Havelin et al. 2000). Information was obtained from a form filled in by the surgeon after each operation at all 68 hospitals performing THAs. Revisions were linked to the primary operation, using the unique identification number assigned to each resident of Norway. As of May 2000, 61,467 primary THAs have been recorded. The definition of revision operation included removal or change in the prosthetic components. The addition of a ridge on the acetabular contour to prevent luxation does not have a separate code in the NAR and revision operations due to this are not recorded.

The following inclusion criteria were used.

In selecting the types of prosthesis, the femoral/ acetabular component combination had to have been used in  $\ge 400$  primary operations. This number was based on a revision rate due to luxation in 0.5–1.5%, which would give an expected number of 2 cases for each type of prosthesis.

The femoral/acetabular component combination should have been used with 2 or more femoral head sizes.

The femoral/acetabular component combination Charnley/Charnley (22 mm femoral head) was included as a reference.

The study material was thus reduced to 7 femoral/acetabular component combinations in 42,987 total hip replacements (Table 1).

#### Selected types of prostheses

We selected the following prostheses: Exeter polished, tapered, cemented, stainless steel stem and cemented all-polyethylene cup (Stryker Howmedica Osteonics, France); SP II cemented cobalt chrome stem and cemented all-polyethylene cup (Link, Germany); Titan cemented titanium stem with modular steel or ceramic (alumina) head, cemented all-polyethylene cup (DePuy, France); Tropic uncemented titanium threaded HA-coated cup with polyethylene liner (DePuy, France); Corail uncemented titanium HA-coated stem with modular steel or ceramic (alumina) head (DePuy, France); Atoll hemispherical titanium press-fit HA-coated cup with polyethylene liner (DePuy, France); and the Charnley cemented stainless steel stem and cemented all-polyethylene cup (DePuy, U.K.).

#### Statistics

The end-point for survival was defined as a revision operation for luxation of the prosthesis. The probability of survival and relative risks (failure rate ratios = FRR) were calculated, using multiple Cox regression analysis. The results may be confounded by several risk factors. Thus, whenever relevant, the regression models included the following variables.

Femoral head size (22, 26, 28, 30, 32 mm), prosthesis brand stem/cup combination (Charnley/ Charnley, Exeter/Exeter, SP/SP, Titan/Titan, Titan/ Tropic, Corail/Atoll, Corail/Tropic), time periods of primary operation (1987–90, 1991–95, 1996– 2000), duration of surgery ( $\leq 60 \text{ min}, 61–90 \text{ min},$ 91–120 min, > 120 min), diagnosis (coxarthrosis, rheumatoid arthritis, sequealae after hip fracture, sequealae after hip dysplasia, sequealae after dysplasia with luxation, sequealae after Perthes'/ Epiphysiolysis disease, ankylosing spondylitis, other (miscellaneous), surgical approach (lateral, Table 2. Survival analysis of femoral head size (Cox-model) with the end-point defined as revision due to luxation. Prosthesis combinations with 28 mm and 32 mm femoral head sizes were included with 32 mm as the reference. Adjustment was made for age, gender, diagnosis and surgical approach

Head	Primary op	Revised	Mean follow-	Una	djusted	Ad	justed
size	(n)	(n)	up (year)	FRR	95% CI	FRR	95% Cl
32 mm	3,709	14	7.2	1	-	1	-
28 mm	6,234	71	3.3	4.6	2.6-8.3	4.0	2.2-7.3
22 mm ª	28,127	188	5.3	2.2	1.2-3.7	2.2	1.3-3.8
All	38,070	273	5.2				

FRR = Failure Rate Ratio, CI = Confidence Interval.

<sup>a</sup> Charnley/Charnley (22 mm) combination included for comparison.



Figure 1. Prosthesis survival rates until revision for luxation in the study population with 28mm and 32mm femoral head sizes (n = 9943), using the Charnley/Charnley (22 mm) (n = 28127) as reference. The curves were adjusted for age, gender, diagnosis and surgical approach.

posterior). The 'lateral' group also included operations reported as anterolateral (n = 3,803), age ( $\leq 59, 60-69, 70-79, \geq 80$  years) and gender.

The regression analyses were done on the entire study population, but also on various subgroups to better assess the effect of confounders. For example, one group with only 28 mm femoral heads were selected from the study population to eliminate the effect of femoral head size during assessment of the other risk factors. In studying the effect of femoral head size, the Exeter/Exeter group was selected as well as one group with only 28 mm and 32 mm head sizes.

The software SPSS was used for the statistical analysis (SPSS Inc 1999).

#### Results

#### Femoral head size

We found a more than fourfold increase in the risk of revision for luxation of the 28 mm head size, as compared to the 32 mm (Table 2, Figure 1). The 28 mm group was compared separately with the Charnley group (22 mm) and showed a slight overrisk (FRR 1.8, 95% CI 1.3–2.5).

In the various age-groups, the 32 mm head size was compared to 28 mm. With 32 mm as the reference, the risk was much greater with the 28 mm head size in the older age groups ( $\geq$  80 years (n = 1,147): adjusted FRR 7.8, 95%CI 1.8–34; 70–79 years (n = 3,535): adjusted FRR 8.6, 95%CI 2.0–37; 60-69 years (n = 2,550): adjusted FRR 4.5, 95%CI 1.0–21). In patients  $\leq$  59 years (n = 2,711), we found no statistically significant difference between the 28 mm and 32 mm heads.

The Exeter/Exeter combination is the only prosthesis type on the Norwegian market with 3 head sizes (26, 28 and 30 mm) that is implanted in large numbers. It is therefore suitable for studying the effects of femoral head size. The Exeter/Exeter 26 mm group ran a higher risk of revision due to luxation than the 30 mm group (Table 3, Figure 2). The Exeter/Exeter 28 mm group was small, with relatively few revisions. When the Charnley/Charnley Table 3. Survival analysis of femoral head size (Cox-model) with the end-point defined as revision due to luxation. Only Exeter/Exeter combinations with 26mm, 28mm and 30mm femoral head sizes are included. Adjustment was made for age, gender, diagnosis and surgical approach

Head	Primary op	Revised	Mean follow-	Una	djusted	Ad	justed
size	(n)	(n)	up (year)	FRR	95% CI	FRR	95% Cl
30 mm 28 mm 26 mm 22 mm ª All	3,838 681 1,079 28,127 33,725	15 3 23 188 229	5.4 2.7 7.7 5.3 5.3	1 1.7 4.2 1.7	- 0.5-5.9 2.2-8.1 1.0-2.9	1 1.8 4.2 2.3	- 0.5-6.2 2.2-8.1 1.2-4.3

FRR = Failure Rate Ratio, CI = Confidence Interval.

<sup>a</sup> Charnley/Charnley (22 mm) combination included for comparison.



Figure 2. Prosthesis survival rates until revision for luxation, using the Exeter/Exeter combination (n = 5598) with three femoral head sizes. The Charnley/Charnley combination (n = 28127) was included for comparison. The curves were adjusted for age, gender, diagnosis and surgical approach.

22 mm group was used as reference, the 26 mm Exeter group again showed a higher rate of revision (FRR 1.8, 95%CI 1.1–3.1).

#### Time of primary operation

We found a higher frequency of revision due to luxation in the latter part of the last decade than in the early years of the NAR (Havelin et al. 2000). A separate study was therefore undertaken on 28 and 32 mm femoral head sizes to compare various time intervals for the primary operation (Table 4). There was a 7-fold increase in the risk of revision for luxation when the primary operation was performed in 1996–2000, as compared to 1987–1990. However, this risk declined and was no longer statistically significant after adjustment (femoral head size). Separate analyses carried out on operations with 28 mm and 32 mm femoral heads gave similar results. However, as only 4 patients were operated on with 28 mm heads during the years 1987–1990, and 34 patients with 32 mm heads in 1996–2000, these strata could not be compared.

The same analysis was done on the Charnley/ Charnley prosthesis combination. The risk was higher in 1996–2000 than in 1987–1990 (adjusted FRR 2.3, 95% CI 1.5–3.6).

#### Combinations of prostheses brands

Survival of the prostheses brands with respect to revision for luxation was studied, with adjustment for age, gender, diagnosis and surgical approach. All prostheses showed the same values as Charnley/Charnley, except the Corail/Atoll combination which showed a lower survival rate than the others (Table 5). Since this type of prosthesis was commoner in the ages < 59 years, the same analysis was done on this age group separately and the same pattern was found, but it was not statistically significant. The same test was used for the 60–69 year age group only and the Corail/Atoll was the only type that showed a higher risk (2.8, 95%CI 1.1–7.4) than the Charnley/Charnley.

The same analysis was done, but we compared

Table 4. Survival analysis of the time periods for the primary operation (Cox-model) with the end-point defined as revision due to luxation. Only 28mm and 32mm femoral head sizes were included. The time period 1987–1991 is used as reference. Adjustment was made for age, gender, diagnosis, surgical approach, prosthesis type and femoral head size. It was the femoral head size that made a significant difference in the adjusted figures; the other potential confounders had only a minor effect

Time period	Primary op	Revised	Mean follow-	Una	adjusted	Adjusted	(excl FHS)	Adju	sted
	(n)	(n)	up (yrs)	FRR	95% Cl	FRR	95% Cl	FRR	95% CI
1987–1990	1,600	3	8.5	1	-	1	-	1	-
1991–1995	4,264	51	6.0	6.7	2.1-22	5.4	1.6-18	2.8	0.8-10
1996–2000	4,079	31	2.1	7.1	2.1-24	5.9	1.8-20	2.1	0.5-8.4
All	9,943	85	4.8						

FHS = Femoral Head Size, FRR = Failure Rate Ratio, CI = Confidence Interval.

Table 5. Survival analysis of the various prosthesis combinations (Cox-model) with the endpoint defined as revision due to luxation. Adjustment was made for age, gender, diagnosis and surgical approach

Prosthesis combination	Primary op	Revised	Mean follow-	Unadjusted		Adj	usted
	(n)	(n)	up (year)	FRR 95% CI		FRR	95% CI
Charnley/Charnley	28,127	188	5.3	1	-	1	-
Exeter / Exeter	5,625	41	5.5	1.1	0.8-1.5	0.7	0.5-1.1
SP / SP	778	4	5.0	0.8	0.3-2.2	0.8	0.3-2.1
Titan / Tropic	850	3	4.9	0.6	0.2-1.7	0.6	0.2-1.
Titan / Titan	4,143	39	5.1	1.4	1.0-2.0	1.2	0.8-1.7
Corail / Atoll	1,192	18	5.2	2.2	1.3-3.6	1.9	1.0-3.4
Corail / Tropic	2,272	18	4.6	1.3	0.8-2.1	1.3	0.7-2.3
All combinations	42,987	311	5.3				

FRR = Failure Rate Ratio, CI = Confidence Interval.

Table 6. Survival analysis of the various prosthesis combinations (Cox-model) with the endpoint defined as revision due to luxation. Only 28 mm femoral head sizes are included, with the Charnley/Charnley (22 mm) combination as reference. Adjustment was made for age, gender, diagnosis and surgical approach

Prosthesis combination	Primary op (n)	Revised (n)	Mean follow- up (year)	Una FRR	djusted 95% Cl	Adj FRR	usted 95% CI
Charnley/Charnley Exeter / Exeter SP / SP Titan / Tropic Titan / Titan Corail / Atoll All combinations	28,127 681 449 487 2,336 876 34,361	188 3 4 1 36 17 259	5.3 2.7 2.3 3.4 3.4 4.9 5.0	1 1.0 2.1 0.4 2.9 2.9	- 0.3–3.1 0.8–5.5 0.1–2.8 2.0–4.2 1.7–4.8	1 0.7 1.7 0.4 2.3 2.8	- 0.2-2.3 0.6-4.7 0.1-2.6 1.6-3.4 1.5-5.3

FRR = Failure Rate Ratio, CI = Confidence Interval.

only the 28 mm femoral head to the 22 mm (Charnley). The Titan/Titan and the Corail/Atoll had significantly lower survival rates at 8 years

(Table 6, Figure 3). A separate analysis of the various prosthesis brands in the 60–69 year age group again indicated that the Corail/Atoll is inferior.



Figure 3. Prosthesis survival rates until revision for luxation, using selected prosthesis combinations all of which had a 28 mm femoral head size (n = 6234). The Charnley/Charnley combination (n = 28127) was included for comparison. The curves were adjusted for age, gender, diagnosis and surgical approach.

#### Diagnosis

The only diagnosis affecting the revision rate for luxation was the sequela of femoral neck fracture (Table 7). The same analysis was carried out separately on the Charnley/Charnley prosthesis combination with similar results.

#### Duration of surgery

The duration of the primary operation may affect the revision rate for luxation. However, in a material with 28 and 32 mm femoral head sizes, we found no significant differences between the timestrata  $\leq 60 \min (n = 1,385), 61-90 \min (n = 5,250),$ 91–120 min (n = 2,395) or > 120 min (n = 807), although the risk tended to increase in all groups, as compared to 61–90 min (e.g., adjusted FRR 1.7, 95%CI 0.8–3.5 for > 120 min). The same result was found when we confined the analysis to the Charnley/Charnley group alone.

#### Surgical approach

The posterior group (n = 9,940) ran a slightly higher risk of revision for luxation than the lateral group (n = 32,682); adjusted FRR 1.9, 95%CI 1.4–2.5. The same analysis was performed on the Charnley/Charnley (22 mm) group alone and this gave a similar result (adjusted FRR 1.6, 95%CI 1.1–2.5). We did the same analysis on the 28 mm femoral head group, and similar results were again found.

To evaluate the effects of the surgical approach further, the "lateral" group was divided into those who had or had not had a trochanteric osteotomy (n = 7,130) (n = 25,337), but no difference was found. The same was seen when we analyzed the findings in the Charnley/Charnley group separately.

Table 7. Survival analysis of the influence of diagnosis (Cox-model) with the end-point defined as revision due to luxation. Only 28mm and 32mm femoral head sizes were included. Coxarthrosis is used as reference. Adjustment was made for age, gender, surgical approach, prosthesis type and femoral head size

Diagnosis	Primary op (n)	Revised (n)	Mean follow- up (year)	Una FRR	adjusted 95% Cl	Adj FRR	usted 95% Cl
Coxarthrosis	6,091	45	4.8	1	_	1	_
Rheumatoid arthritis	457	3	4.8	0.9	0.3-2.8	1.2	0.4–3.8
Sequele fracture	1,157	16	4.2	2.0	1.1–3.5	1.9	1.0-3.3
Sequele dysplasia	1,129	6	5.3	0.7	0.3–1.6	0.8	0.3–1.9
Sequele dysplasia/lux	x 211	5	6.0	2.3	0.8-6.4	2.3	0.7-6.8
Seq. Perthes'/Epiphys	siol 217	1	5.2	0.6	0.1–4.3	0.5	0.1-4.0
Ankylosing spondyliti	s 95	2	4.7	2.8	0.7–12	2.4	0.5–10
Other	474	6	4.5	1.7	07–4.1	1.5	0.6–3.8
All	9,831	84	4.8				

FRR = Failure Rate Ratio, CI = Confidence Interval.

Table 8. Survival analysis of age at the primary operation (Cox-model) with the end-point defined as revision due to luxation. Only 28mm and 32mm femoral head sizes were included. The age-group 60–69 years is used as reference. Adjustment was made for gender, diagnosis, surgical approach, prosthesis type and femoral head size

Age I	Primary op	Revised	Mean follow-	Una	djusted	Adj	usted
	(n)	(n)	up (year)	FRR	95% Cl	FRR	95% CI
60–69 <60 70–79 ≥80 All	2,550 2,711 3,535 1,147 9,943	13 25 24 23 85	5.1 5.0 4.7 3.8 4.8	1 1.7 1.3 4.4	- 0.9–3.4 0.7–2.6 2.2–8.8	1 1.0 1.4 4.5	- 0.5-2.3 0.7-3.0 2.1-9.7

FRR = Failure Rate Ratio, CI = Confidence Interval.

#### Age

The effects of age at primary operation were studied separately on 28 and 32 mm femoral head sizes (Table 8). The risk for revision of luxation was 4.5 times higher in the age group  $\ge$  80 as compared to 60–69 years. However, in the highest age group, 21 of 23 revisions were performed in patients with the Titan/Titan prosthesis. When we limited the material to patients with a Charnley/Charnley prosthesis, the risk of revision for luxation among those  $\ge$  80 years of age vs. 60–69 years was less and not statistically significant (adjusted FRR 1.2, 95%CI 0.7–1.8).

#### Gender

No clear difference in the rate of revision due to luxation was noted between men and women.

#### Discussion

The stability of the joint depends on soft-tissue laxity, component position, prosthetic features, surgical approach and co-morbid conditions (Amstutz et al. 1975, Eftekhar 1993, Morrey 1997).

#### Femoral head size

Our main findings are that in order to reduce the occurrence of revision due to luxation, it seems safer to use larger femoral head sizes (30–32 mm) in primary modular THA. It was clear in all analyses that the 28 mm heads performed less satisfactory than the 32 mm ones, and in the separate

analysis of Exeter/Exeter (with 26, 28 and 30 mm heads) the 26 mm head was not as good as the 30 mm one. The higher risk entailed by 26 mm and 28 mm femoral heads was evident also after adjusting for a number of potential confounders. This is of interest as regards the trend towards smaller head sizes, to reduce the wear of the artificial joint surfaces (Oparaugo et al. 2001). However, with a smaller head size, the range of motion and thereby the stability of the prosthesis will also decline (Amstutz et al. 1975, Harris 1996), which still increase the risk of luxation. Our results contradict previous statements that femoral head size is of minor importance in causing luxations (Wroblesky 1986, Morrey 1992, Woolson and Rahimtoola 1999), but are supported by others (Kelley et al. 1998, Garellick et al. 1999, Yuan and Shih 1999). They also accord with the findings of Hedlundh et al. (1996a), who observed more recurrent luxations with 22 mm femoral heads than with 32 mm ones. Several studies have found less stability with 22 mm designs than with 32 mm ones, but have failed to show statistical significance (Ritter 1976, Kahn et al. 1981, Morrey 1992, Hedlundh et al. 1996a, Kesteris et al. 1998). This is probably due to the number of patients included in the study (Bartz et al. 2000); a problem overcome in this study which has more than 42,000 patients. According to our findings and the increasing numbers of revisions due to luxation in recent years, it seems appropriate to place more emphasis on the problem of luxation. Thus, when clinical considerations, such as age and much physical activity, do not call for 22 mm, 26 mm or 28 mm head sizes, the use of 30 mm or 32 mm femoral heads should be considered in primary modular THA.

The combination Charnley/Charnley is very common (over 50% of all primary THA in Norway) and was used as a reference in many of the analyses in this study because most surgeons performing prostheses are familiar with it. Our results showed that the Charnley/Charnley 22 mm performed better or in the same way as the 28 mm prosthesis combinations. In a multi-center study by Hedlundh et al. (1996a) the number of luxations with 3197 Charnley 22 mm arthroplasties was compared with 2,875 Lubinus 32 mm. They found that recurrent luxations and reoperations were commoner in the Charnley group. In our study, it might have been expected that the Charnley/Charnley combination should have entailed reoperations for luxation more frequently than the 28 mm group (Kelley et al. 1998), but we found similar results in these groups. We can not entirely explain this finding. It may be that some of these were revised by adding an acetabular ridge, a revision operation that is not registered in the NAR. The Charnley technique- the "gold standard" may have become so well established among these surgeons over a long period that the rate of intraoperative technical errors is lower than with other types of prostheses, and new types come onto the market continuously and are used by an increasing number of surgeons. Moreover, in this study, we have not included the outer acetabular diameter as a parameter that has been shown to affect the rate of luxations (Kelley et al. 1998). In our study the total number of Charnley prostheses revised for luxation was 0.67 % which is slightly higher than 0.4 % reported in a long-term follow-up (Wroblewsky et al. 2002).

### Time periods

We found a higher risk of revision due to luxation in 1996–2000 than in 1987–1990. When this analysis was adjusted for femoral head size, the increase in risk was largely eliminated. This clearly indicated that the trend in the past years towards smaller femoral heads is responsible for the increase in the rates of luxation.

It has been shown previously that the surgical experience affects the luxation rate after THA (Woo and Morrey 1982, Morrey 1992, Hedlundh et al. 1996b). The NAR contains no information about the experience of the surgeon, but it is possible that prosthetic surgery is a growing trade with more and more inexperienced surgeons performing an ever increasing number of primary operations. This could be why the increased revision for luxation in the last period also occurred in the Charnley group.

THA is increasingly used as primary treatment for displaced femoral neck fractures despite its known instability (Johansson et al. 2000, Furnes et al. 2001).

#### Combinations of prosthesis brands

We found that the Corail/Atoll and Titan/Titan with 28 mm heads performed inferiorly to other types with adjustment for potential confounders. We are therefore concerned about these types of prostheses, and especially the Corail/Atoll, which was the only type showing an increased risk, as compared to the Charnley in the 60–69-year old population. With 32 mm heads, both of these prosthesis combinations were as good as other brands. It is possible that luxation may coincide with aseptic loosening as a cause of revision. This was ruled out after analyzing the data specifically.

#### Diagnosis

The preoperative diagnosis has been shown to affect the outcome of THA, as regards luxation. Our finding that femoral neck fractures result in more revisions for luxation than coxarthrosis is not surprising and accords well with previous reports on luxation (Woo and Morrey 1982, Nilsson et al. 1989, Gregory et al. 1991, Hedlundh et al. 1995, Furnes et al. 2001). There was no over-risk for patients with RA, as opposed to a recent report (Hedlundh et al. 1995), which studied plain luxations, even when an open procedure was not used, while we used revision for luxation as the endpoint. Moreover, Hedlundh et al. included only 3,199 patients with 383 cases having RA, while our study included 42,987 patients with 1,566 cases having RA. However, although we showed that revision for luxation is not commoner in RA patients, it is still possible that plain luxations are commoner in this group than in coxarthrosis.

# Duration of surgery

The duration of the operation has not been extensively investigated before. It can be speculated that a lengthy operation would be commoner among less experienced surgeons and result in more luxations. However, the duration of surgery did not affect the risk of luxations leading to revision. In a series of 60 patients who had at least 1 luxation, this group had about the same duration of surgery as the 118 controls who never had a luxation (Hedlundh and Fredin 1995). In our study of more than 42,000 THAs, we had similar results.

#### Surgical approach

We found that the anterolateral or lateral approach taken together (here "lateral") was safer, regardless of femoral head size, than the posterior approach. The surgical approach as a cause of hip instability has been discussed repeatedly (Weaver 1975, Carlsson and Gentz 1977, Lindberg et al. 1982, Robinson et al. 1990, Hedlundh et al. 1995). Much diversity in recording, principles of selection etc., limit the value of this comparison. In the study by Hedlundh et al. (1995) covering 3,199 Charnley arthroplasties with luxations, they found that the surgical approach had no effect, even after adjustment for the preoperative diagnosis and gender, and no difference on the revision rate between the transtrochanteric or posterior approach (Hedlundh et al. 1995). At least 2 studies have found that patients who have had a posterior approach to the hip have a higher rate of luxation than those who have had either an anterior or a transtrochanteric approach (Roberts et al. 1987, Turner 1994). On the basis of other studies (Ritter 1976, Morrey 1992, Hedlundh et al. 1996a) with posterior or transtrochanteric approaches, it has been recommended that if 26 mm heads or smaller are used, the anterolateral approach is the safest (Yuan and Shih 1999). In a study of 6,707 patients, Morrey (1992) found about twice as many luxations with the posterior approach as compared to the anterior or lateral approach, regardless of femoral head size (Morrey 1992). In the present study of more than 42,000 primary arthroplasties-we had fewer revisions due to luxation with the lateral approach than with the posterior approach. A lengthy follow-up period, as in this study, increases the frequency of luxations (Woo and Morrey 1982, Hedlundh et al.

1992), which further adds weight to our results.

Trochanteric osteotomy can influence the revision rate for luxation, but could not be confirmed in this study in the Charnley group or the study group.

#### Age

Age may be a risk factor for luxations leading to revision; with femoral head sizes 28 and 32 mm, patients aged 80 years or more had a 4-fold increase in risk, as compared to those 60-70 years old. This accords with the findings of others, who have reported high luxation risks in old patients (Newington et al. 1990, Ekelund et al. 1992, Woolson and Rahimtoola 1999). Analyses based on the Charnley/Charnley group showed a small, but not statistically significant, increase in the risk of revision due to luxation in older patients. Paterno et al. (1997) detected no age-dependent differences in luxation rates after adjustment for excessive intake of alcoholic beverages. When we studied femoral head size in various age groups, it was clear that the risk of revision due to luxation was much higher in the 28 mm group than in the 32 mm one in all age groups over 60 years. This has not been reported before.

## Methodological considerations

As regards the methodology, we chose to use revision for luxation as the end-point. This is because the registration of luxations in patient records may be incomplete (Woo and Morrey 1982) and established registers have been found to miss as many as 1/3 of the luxations when a revision operation is not performed (Hedlundh et al. 1992). The Norwegian Arthroplasty Register, on the other hand, probably misses only a few revisions for luxation (Havelin et al. 2000), and revision is a very distinct clinical indicator of a luxation problem unrelated to the surgeon's preoperative assessment.

A weakness in our study is that some reoperations for recurrent luxation include only the addition of a protecting ridge on the acetabular component and these cases are not registered in the NAR and therefore not accounted for. All the results and conclusions that we have presented are based on revision as the end-point. Only patients with recurrent luxations undergo surgical revision, and the rate of surgical treatment for recurrent luxations has been reported to be about 40% (Daly and Morrey 1992). This means that our end-point is very strict and conservative and our data would probably be even stronger had we used "luxation" only as the end-point. The fact that we can present statistically significant findings that are sometimes contrary to previously published data is probably due to the large size of the study. It could be argued that observational studies, despite a vast patient material, are easily confounded and lack the precision of randomized controlled studies (Pocock and Elboume 2000). This has repeatedly been debated, but it has been concluded that if potential confounders are controlled, observational studies give results similar to those of controlled randomized trials (Benson and Hartz 2000).

#### Conclusion

In conclusion, we have shown that femoral head size is important for the revision rate due to luxation. In modular prostheses, 30 mm or 32 mm femoral head sizes, as compared to smaller ones, had a lower rate of revision due to luxation, and this association was especially strong in older patients. 28 mm femoral heads were at statistically significant higher risk than 32 mm ones and this was true of all patients over 60 years of age. The trend in recent years towards smaller femoral head sizes has resulted in more frequent revisions due to luxation. However, this was not true of the Charnley prosthesis (22 mm). Our study indicates that in patients where wear is not a problem, such as in patients of advanced age and with low physical activity and especially in combination with sequela after a hip fracture, the surgeon should consider using 30 mm or 32 mm head diameters in modular THA. In the younger age groups, the benefit of lower wear rate with smaller head sizes needs to be weighed against the increase in the luxation rate. To facilitate the decision, more investigations must be done to study the percentage of revisions for aseptic loosening, wear and osteolysis with various head sizes, as compared to the luxation rate.

No competing interests declared.

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