



Patient-related predictors of implant failure after primary total hip replacement in the initial, short- and long-terms

A NATIONWIDE DANISH FOLLOW-UP STUDY INCLUDING 36 984 PATIENTS

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We examined the association between patient-related factors and the risk of initial, short- and long-term implant failure after primary total hip replacement. We used data from the Danish Hip Arthroplasty Registry between 1 January 1995 and 31 December 2002, which gave us a total of 36 984 patients. Separate analyses were carried out for three follow-up periods: 0 to 30 days, 31 days to six months (short term), and six months to 8.6 years after primary total hip replacement (long term). The outcome measure was defined as time to failure, which included re-operation with open surgery for any reason.

Male gender and a high Charlson co-morbidity index score were strongly predictive for failure, irrespective of the period of follow-up. Age and diagnosis at primary total hip replacement were identified as time-dependent predictive factors of failure. During the first 30 days after primary total hip replacement, an age of 80 years or more and hip replacement undertaken as a sequela of trauma, for avascular necrosis or paediatric conditions, were associated with an increased risk of failure. However, during six months to 8.6 years after surgery, being less than 60 years old was associated with an increased risk of failure, whereas none of the diagnoses for primary total hip replacement appeared to be independent predictors.

A number of patient- and procedure-related factors have been proposed as predictors of implant failure.¹⁻⁷ However, some of these factors, including diagnosis and type of implant, have not been consistently associated with a risk of failure. Studies in other patient groups^{8,9} have suggested that many predictive factors are time dependent, e.g. in breast cancer a positive steroid hormone status is initially a positive predictive factor and becomes a negative factor for metastasis after three to five years of follow-up. To the best of our knowledge, the possible time dependence of predictors for failure of total hip replacement (THR) have not previously been examined.

The objective of this study was to assess whether the effect of a range of predictors for failure of THR, including gender, age, diagnosis at primary THR and co-morbidity, varied during follow-up by comparing the role of the predictors in three different follow-up periods: within 30 days, between 31 days and six months (short term), and beyond six months (long term).

Patients and Methods

Data sources. Information on all primary and revision THRs in Denmark from 1995 was collected from the nationwide population-based

Danish Hip Arthroplasty Registry.¹⁰ All 45 orthopaedic departments in Denmark, including five departments in private hospitals, report to the Registry. The registered data, including pre-, peri- and post-operative data are collected by the operating surgeon using standardised forms.

From the Danish National Registry of Patients, which was established in 1977, we collected information about the civil registry number, the dates of all admissions and discharges and up to 20 diagnoses for every discharge from public hospitals in Denmark. Diagnostic classification is in accordance with the Danish version of the International Classification of Diseases. The eighth edition (ICD-8) was used from 1977 to 1993 and the tenth edition thereafter. All diagnoses at discharge are assigned by the physician who discharges the patient. Using the national registry of patients it is possible to construct the complete in-patient history for each patient.

From the central personal registry we collected data on all changes in vital status, including changes in address, date of emigration and the date of death for the entire study population. These data have been available for all Danish citizens since 1968.

Table I. Characteristics of the patients undergoing primary total hip replacement between 1995 and 2003

		Number of patients	Number of revisions (%)
Gender	Female	21 707	611 (2.8)
	Male	15 277	521 (3.4)
Age groups (yrs)	10 to 49	2226	107 (4.8)
	50 to 59	5360	194 (3.6)
	60 to 69	10 597	336 (3.2)
	70 to 79	13 067	368 (2.8)
	≥ 80	5734	127 (2.2)
Primary diagnosis	Primary osteoarthritis	27 942	799 (2.9)
	Sequelae of trauma	5285	185 (3.5)
	Avascular necrosis	1093	52 (4.8)
	Rheumatoid arthritis	925	31 (3.4)
	Paediatric conditions	1101	47 (4.3)
	Other diagnoses	638	18 (2.8)
Charlson co-morbidity index	Low (0)	27 148	725 (2.7)
	Medium (1 to 2)	7288	171 (2.3)
	High (>2)	2548	236 (9.3)
Fixation technique (implants)	Cemented	20 423	567 (2.8)
	Cementless	6088	159 (2.6)
	Hybrid A	10 077	392 (3.9)
	Hybrid B	93	4 (4.3)
	Unknown implants	303	10 (3.3)
Hospital type	University	6010	217 (3.6)
	Other	30 974	915 (3.0)
Total		36 984	1132 (3.1)

Study population. From the Danish Hip Arthroplasty Registry we identified 42 413 primary THRs performed in Denmark between 1 January 1995 and 31 December 2002. We excluded 5320 patients who had undergone primary THR on the contralateral hip to avoid the possible independent effect of this on implant failure, 100 who had emigrated, eight that were erroneously registered as having had a third primary THR and one patient with an incorrect revision date. In total 36 984 primary THR patients were available for further analysis.

Possible predictors of THR failure. Gender, age, diagnosis leading to the primary THR and co-morbidity were included as possible predictors. Age at surgery was divided into five groups: 10 to 49 years, 50 to 59 years, 60 to 69 years, 70 to 79 years and 80 years and over. The diagnosis for primary THR was grouped into six categories: primary osteoarthritis, the sequelae of trauma (fresh fracture of the proximal femur, late sequelae from fracture of the proximal femur, fracture of the acetabulum and traumatic hip dislocation), avascular necrosis, rheumatoid arthritis, paediatric conditions (congenital hip dislocation, Morbus, Perthes' disease, epiphysiolysis and acetabular dysplasia) and other diagnoses. Co-morbidity at the time of surgery was assessed by computing the Charlson co-morbidity index,¹¹ which was originally developed and validated for the prediction of short- and long-term mortality in patients admitted to a department of internal medicine.¹² The index includes 19 major disease categories, translated into corresponding ICD-8 and ICD-10 hospital discharge codes used in the national registry of patients. The Charlson co-morbidity index score applies a weighting of one, two, three or six

points to each of the 19 disease categories and is then summarized. We separated the patients into three levels: low index (0), which corresponded to patients with no previously-recorded disease categories in the Charlson co-morbidity index; medium index (patients with one or two disease categories); and a high index (patients with more than two disease categories).

Analyses. The outcome measure was time to failure, defined as a new surgical intervention involving partial or complete removal of a component. Conditions not requiring open surgical intervention, such as closed reduction of a dislocation, were not included as failures. Follow-up started on the day of primary THR and ended on the day of revision, death or 30 June 2003, whichever came first. The Cox proportional hazards analysis was used to examine the time-dependent association between possible patient-related predictors and the time to implant failure. The follow-up after primary THR was divided into three periods. A total of 36 984 patients were available in the initial period which commenced on the day of operation and continued until a revision was performed or 30 days after surgery. If patients did not undergo revision in the first 30 days they were included in the second period, which extended to six months. This number of patients in this group reduced to 36 585. If the patients survived six months without revision they were included in the third period, of which 35 168 were. The association was examined by estimating the relative risk and 95% confidence intervals (CI) for each predictor. We estimated both crude and mutually-adjusted relative risks for the possible predictors and non-patient related covariates previously reported to be associated with implant fail-

Table II. Predictors of implant failure from any cause 0 to 30 days after primary total hip replacement

	Number of patients	Number of revisions	Crude relative risk (95% CI)*	Adjusted relative risk (95% CI)
Gender				
Female	21 707	93	1.0 (ref)	1.0 (ref)
Male	15 277	93	1.4 (1.1 to 1.9)	1.5 (1.1 to 2.0)
Age group (yrs)				
10 to 49	2226	20	2.1 (1.3 to 3.6)	1.0 (0.6 to 1.8)
50 to 59	5360	32	1.4 (0.9 to 2.2)	1.0 (0.6 to 1.6)
60 to 69	10 597	45	1.0 (ref)	1.0 (ref)
70 to 79	13 067	58	1.1 (0.7 to 1.6)	1.3 (0.9 to 1.9)
≥ 80	5734	31	1.3 (0.8 to 2.0)	1.6 (1.0 to 2.6)
Primary diagnosis				
Primary osteoarthritis	27 942	113	1.0 (ref)	1.0 (ref)
Sequelae of trauma	5285	35	1.7 (1.1 to 2.4)	1.6 (1.1 to 2.4)
Avascular necrosis	1093	16	3.6 (2.2 to 6.1)	2.9 (1.7 to 5.0)
Rheumatoid arthritis	925	5	1.3 (0.6 to 3.3)	1.3 (0.5 to 3.3)
Paediatric conditions	1101	13	2.9 (1.7 to 5.2)	2.6 (1.4 to 4.8)
Other diagnoses	638	4	1.6 (0.6 to 4.2)	1.4 (0.5 to 3.8)
Charlson co-morbidity index				
Low (0)	27 148	131	1.0 (ref)	1.0 (ref)
Medium (1 to 2)	7288	25	0.7 (0.5 to 1.1)	0.7 (0.5 to 1.1)
High (>2)	2548	30	2.4 (1.6 to 3.6)	2.3 (1.6 to 3.5)

Relative risks are mutually adjusted for other patient-related predictors, fixation technique and hospital type

* CI, confidence interval

† ref, reference value

ure, including the method of fixation (cemented, cementless, hybrid A (cemented femoral and cementless acetabular component), hybrid B (cementless femoral and cemented acetabular component), and other unknown implants) and hospital type (university and others).^{13,14} Further adjustment for implant type and femoral head size was also made, but this did not influence the risk estimates (data not shown).

By the application of log-log plots¹⁵ and Schoenfeld residuals,¹⁶ Cox's proportional hazard model was found to be suitable. Further, by applying the Wald statistical test,¹⁶ the extended Cox's model for time dependent patient characteristics was found to be suitable for the period of study. All analyses were performed using the Stata Statistical Software, Release 8.0 (Stata Corporation, College Station, Texas).

Results

A total of 1132 primary THRs were revised (3.1% of the 36 984 procedures) between 1 January 1995 and 30 June 2003 (Table I).

Possible predictors for implant failure 0 to 30 days after primary THR (Table II). The main causes for failure during this period were dislocation, peri-prosthetic femoral fracture and deep infection. Men sustained more dislocations than women (70% of revisions in male patients were due to dislocation *vs* 59% in women), and male gender was associated with an increased adjusted relative risk of failure of any cause of 1.5 (95% CI 1.1 to 2.0). There was a tendency towards increased adjusted relative risk of failure with increasing age. In patients aged 80 years and over, the adjusted relative risk of failure during this period was 1.6

(95% CI 1.0 to 2.6) compared with patients aged between 60 and 69 years. The sequelae of trauma, avascular necrosis and paediatric conditions were all associated with increased risk of failure compared with primary osteoarthritis, yielding adjusted relative risks of 1.6 (95% CI 1.1 to 2.4), 2.9 (1.7 to 5.0) and 2.6 (95% CI 1.4 to 4.8), respectively. Finally a high co-morbidity index score was found to be a strong predictor of THR failure compared with a low co-morbidity index score, with an adjusted relative risk of failure of 2.3 (95% CI 1.6 to 3.5).

Possible predictors for implant failure 31 days to 6 months after primary THR (Table III). Dislocation, peri-prosthetic femoral fracture and deep infection remained the most frequent causes of failure. No clear differences in failure rate regarding gender or age were evident in this period, although low relative risks were noted for age groups 10 to 49 and 50 to 59 years. The sequelae of trauma, avascular necrosis and other diagnoses were all associated with an increased relative risk of failure compared with primary osteoarthritis. The adjusted relative risks were 2.8 (95% CI 2.0 to 4.0), 2.3 (95% CI 1.2 to 4.6) and 2.4 (95% CI 1.0 to 5.9), respectively. A high co-morbidity index score was also a strong predictor of failure with an adjusted relative risk of 3.0 (95% CI 2.1 to 4.5) compared with patients with a low co-morbidity index score.

Possible predictors for implant failure 6 months to 8.6 years after primary THR (Table IV). Aseptic loosening was the most frequent reason for failure during this period. Male gender remained a predictor for THR failure. The adjusted relative risk was 1.2 (95% CI 1.0 to 1.4). In contrast to the second period, younger age appeared to be associated with an increased risk of failure. The adjusted relative risks for fail-

Table III. Predictors of implant failure from any cause 31 days to six months after primary total hip replacement

	Number of patients	Number of revisions	Crude relative risk (95% CI)*	Adjusted relative risk (95% CI)
Gender				
Female	21 502	101	1.0 (ref [†])	1.0 (ref)
Male	15 083	74	1.0 (0.8 to 1.4)	1.2 (0.9 to 1.6)
Age group (yrs)				
10 to 49	2204	9	0.8 (0.4 to 1.7)	0.5 (0.2 to 1.1)
50 to 59	5312	20	0.8 (0.5 to 1.3)	0.6 (0.4 to 1.1)
60 to 69	10 537	52	1.0 (ref)	1.0 (ref)
70 to 79	12 937	67	1.1 (0.7 to 1.5)	1.1 (0.8 to 1.6)
≥ 80	5595	27	1.0 (0.6 to 1.8)	0.9 (0.6 to 1.5)
Primary diagnosis				
Primary osteoarthritis	27 716	102	1.0 (ref)	1.0 (ref)
Sequelae of trauma	5167	53	2.8 (2.0 to 4.0)	2.8 (2.0 to 4.0)
Avascular necrosis	1073	9	2.3 (1.2 to 4.5)	2.3 (1.1 to 4.6)
Rheumatoid arthritis	915	2	0.6 (0.2 to 2.4)	0.6 (0.1 to 2.3)
Paediatric conditions	1087	4	1.0 (0.4 to 2.7)	1.9 (0.4 to 3.3)
Other diagnoses	627	5	2.2 (0.9 to 5.5)	2.4 (1.0 to 5.9)
Charlson co-morbidity index				
Low (0)	26 865	115	1.0 (ref)	1.0 (ref)
Medium (1 to 2)	7210	24	0.8 (0.5 to 1.2)	0.7 (0.5 to 1.2)
High (>2)	2510	36	3.4 (2.3 to 4.9)	3.0 (2.1 to 4.5)

Relative risks are mutually adjusted for other patient-related predictors, fixation technique and hospital type

* CI, confidence interval

† ref, reference value

Table IV. Predictors of implant failure from any cause six months to 8.6 years after primary total hip replacement

	Number of patients	Number of revisions	Crude relative risk (95% CI)*	Adjusted relative risk (95% CI)
Gender				
Female	20 666	417	1.0 (ref [†])	1.0 (ref)
Male	14 502	353	1.2 (1.1 to 1.4)	1.2 (1.0 to 1.4)
Age group (yrs)				
10 to 49	2122	78	1.5 (1.2 to 1.9)	1.7 (1.3 to 2.3)
50 to 59	5137	142	1.2 (1.0 to 1.5)	1.3 (1.0 to 1.6)
60 to 69	10 173	238	1.0 (ref)	1.0 (ref)
70 to 79	12 423	243	0.9 (0.7 to 1.0)	0.9 (0.7 to 1.0)
≥ 80	5313	69	0.6 (0.5 to 0.8)	0.6 (0.5 to 0.8)
Primary diagnosis				
Primary osteoarthritis	26 804	253	1.0 (ref)	1.0 (ref)
Sequelae of trauma	4850	97	1.0 (0.8 to 1.2)	1.0 (0.8 to 1.2)
Avascular necrosis	1030	27	1.2 (0.8 to 1.8)	0.9 (0.6 to 1.3)
Rheumatoid arthritis	882	24	1.1 (0.8 to 1.7)	0.9 (0.6 to 1.3)
Paediatric disorders	1048	30	1.2 (0.9 to 1.8)	1.0 (0.6 to 1.4)
Other diagnoses	554	9	0.8 (0.4 to 1.5)	0.6 (0.3 to 1.2)
Charlson co-morbidity index				
Low (0)	25 672	478	1.0 (ref)	1.0 (ref)
Medium (1 to 2)	7081	122	0.7 (0.6 to 0.8)	0.7 (0.6 to 0.8)
High (>2)	2415	170	2.8 (2.4 to 3.4)	2.8 (2.3 to 3.3)

Relative risks are mutually adjusted for other patient-related predictors, fixation technique and hospital type

* CI, confidence interval

† ref, reference value

ure were 1.7 (95% CI 1.3 to 2.3) and 1.3 (95% CI 1.0 to 1.6) among patients aged 10 to 49 and 50 to 59 years, respectively, when compared with patients aged 60 to 69 years. In contrast, age between 70 and 79 years and age 80 years and over were associated with a reduced adjusted relative risk for failure of 0.9 (95% CI 0.7 to 1.0) and 0.6

(95% CI 0.5 to 0.8), respectively, compared with the reference group. There were no evident differences in the risk estimates among the diagnoses for primary THR. A medium co-morbidity index score was associated with reduced adjusted relative risk of failure of 0.7 (95% CI 0.6 to 0.8), whereas a high co-morbidity index score was again

strongly associated with an increased adjusted relative risk of failure of 2.8 (95% CI 2.3 to 3.3), compared with a low co-morbidity index score.

Discussion

The main strengths of our study included the availability of nationwide population-based data sources with a documented overall high¹⁷ or moderate to high validity.¹⁸⁻²⁰ The sources included detailed and prospectively collected data which are rarely available, including laterality of both primary THRs and revisions, and the complete hospitalisation history of each individual since 1977.

One limitation of the study was a less rigorous registration of revisions in the Danish Hip Arthroplasty Registry of 81%, which may have affected failure rates and could (at least in theory) lead to bias, although we have no reason to believe so. A number of unmeasured issues including genetic factors, medication at follow-up, timing of surgery, surgeon volume, patient's social status, physical activity of the patient and rehabilitation programmes might have acted as confounding factors in this observational study. However, these data were not available. Additionally, detailed information about the surgeon is not available in the hip arthroplasty registry.

Predictors of short-term implant failure after primary THR.

The association between male gender and short-term THR failure appeared to be explained by a higher rate of dislocation sustained by males than by females. This finding contrasts with that of Woolson and Rahimtoola,²¹ who found no gender difference in the incidence of dislocation during the first three months after primary THR. Our findings of an increased risk of failure among elderly patients are, however, in accordance with their findings, and can probably be attributed to the increased risk of falls among the elderly.^{21,22} Further, the risk of hip fracture increases²³ as the bone mineral density declines at a rate of 1% to 2% per year after 35 to 40 years of age.²⁴ This suggests that rehabilitation programmes directed at avoiding falls might be helpful for this group of high-risk patients in the short term.

Different mechanisms are likely to account for the differences in short-term failure risk according to the diagnoses for primary THR. Patients with the sequelae of trauma have usually experienced multiple trauma and suffer higher dislocation rates.²⁵ THR for the treatment of paediatric disorders may be compromised by anatomical abnormalities and difficulty in the identification of the true acetabulum at the time of the operation, which make these patients more susceptible to post-operative dislocation.^{25,26} Finally, avascular necrosis of the femoral head has been linked with both steroid therapy and alcoholism,²⁷ which may lead to recurrent dislocations, reduced bone mineral density, impaired growth and remodelling, and a higher risk of falls.²³

The association between a high co-morbidity index score and failure of THR found in our study was also reported by

Mahomed et al,²⁸ who examined the association between co-morbidity in patients older than 65 years and the risk of post-operative complications.

Predictors for long-term implant failure after primary THR.

A few other studies^{5,6,29} have also examined the role of gender, and found males to have a higher risk of overall long-term THR failure. However, women have been reported to have a worse functional status than men before primary THR.³⁰ Our findings could indicate that the same pattern may apply after primary THR. Furthermore, fewer women appear to discuss the possibility of surgery with their physician.³¹ It should be a matter of concern if the increased risk of failure among males reflected that general practitioners and orthopaedic surgeons were consciously or unconsciously using different thresholds when deciding which patients should undergo a revision. Such a pattern has been observed in other areas, with women being less likely to be referred for cardiac catheterisation than men, despite having identical clinical symptoms.³² Furthermore, Franks and Clancy³³ reported that male patients had a higher rate of referrals from primary care physicians to any kind of specialist. It should be noted that the risk of gender-related differences is probably most evident if decision-making on whether to perform a THR or revision is not based on a clear clinical consensus.

The decline in relative risks of failure with increasing age found in our study is in accordance with the results from a number of other studies.^{5,7,29} Body-weight and physical activity decrease significantly with age,^{34,35} reducing the stress on the components and subsequent revisions due to aseptic loosening.

The influence of the primary diagnoses for the THR and the reported risk estimates for failure are inconsistent in the literature,^{5,36-39} probably because of differences between the study populations and the lack of attention to the possible time dependency of this predictor in the statistical analyses.

A number of diseases included in the Charlson co-morbidity index such as stroke, liver disease, diabetes and cancer, are known to be associated with increased bone resorption and mortality rate.⁴⁰⁻⁴³ Our finding of a high co-morbidity index score being a strong predictor for long-term THR failure supports the hypothesis that such effects on bone metabolism may have important long-term clinical implications for patients.

In summary, during the first 30 days after primary THR male gender, an age of 80 years or more, primary hip diagnoses, including the sequelae of trauma, avascular necrosis and paediatric conditions, as well as a high co-morbidity index, are predictors of THR failure. However, during long-term follow-up (from 6 months to 8.6 years after surgery) male gender, an age of 59 years or less and a high co-morbidity index were predictors of THR failure.

These findings may be useful pre-operatively in identifying patients at a high risk of failure during specific periods of follow-up, in particular those with multiple predictors of

failure, in order to inform the patient of potential complications.

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