

A clinical and radiographic 13-year follow-up study of 138 Charnley hip arthroplasties in patients 50–70 years old

Comparison of university hospital data and registry data

Gunn Hulleberg¹, Arild Aamodt^{1, 2}, Birgitte Espehaug³, and Pål Benum¹

¹Department of Orthopedic Surgery, Trondheim University Hospital, Trondheim, ²Department of Neuroscience, Faculty of Medicine, Norwegian University of Science and Technology, Trondheim, ³The Norwegian Arthroplasty Register, Department of Orthopaedic Surgery, Haukeland University Hospital, Bergen, Norway
Correspondence GH: gunn.hulleberg@stolav.no
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Background and purpose Arthroplasty registers provide rates of implant survival in large populations based on implant revision. In an unrevised prosthesis population, some patients may have implants with clinically poor outcome or radiographic failure. We therefore evaluated medium-term clinical and radiographic results in patients with Charnley hip arthroplasties and compared our results with data from the Norwegian Arthroplasty Register (NAR).

Patients and methods From 1989 through 1991, 138 Charnley arthroplasties with plain Palacos cement were performed in 123 patients who were 50–70 years old. At follow-up after 13 (12–15) years, 26 patients had died (28 hips). The 84 unrevised patients (93 hips) were interviewed and underwent clinical and radiographic assessment. Prosthesis survival was estimated by the Kaplan-Meier method.

Results At follow-up, 83% of the patients were completely satisfied with their hip replacement. Mean Harris hip score (HHS) was 83 (SD 15), mean EQ-5D index was 0.75 (SD 0.24) and mean EQ-VAS score was 69 (SD 21). Most clinical assessments had poorer scores for Charnley category C (n = 47) than for Charnley category A + B (n = 46). Function, according to Charnley's modified Merle d'Aubigné and Postel scoring system, was improved compared to preoperative values. The survival at 10 years was 89% (95% CI: 84–95) and at 13 years it was 85% (95% CI: 79–92) with revision for any reason as endpoint. In addition to 20 revised hips,

8 implants were radiographically loose and 13 hips had HHS < 70, giving a clinical success rate of 76%. Only 4 primary operations (0.8%) had not been reported to the NAR, but all revisions had been reported.

Interpretation Clinical follow-up studies give essential information that is additional to that gained from revision-based outcome studies. To fully appreciate the clinical effectiveness of an implant, specific hip function, patient satisfaction, quality of life, and radiographic analysis must also be considered. The functional status of the patient has an important influence on the clinical outcome after hip replacement. ■

The Charnley low-friction arthroplasty was introduced more than 40 years ago (Charnley 1972), and it is the most extensively documented hip prosthesis in the literature (Soyer et al. 1997, Sochart and Porter 1998, Wroblewski et al. 1999, 2007, Callaghan et al. 2000). Comparison of clinical and radiological results from various studies is difficult, due to changes in prosthetic design, differences in study design, and differences in patient populations. In general, the Charnley prosthesis has more than 90% implant survival after about 10 years, and survival declines approximately 10% during each of the two following decades (Aamodt et al. 2004). Data from arthroplasty registers pro-

Table 1. Patient characteristics

	No. of THRs	% females	Median (range) age at operation	Median (range) age at follow-up	% < 80 years old at follow-up	% OA
All	138	75	66 (50–70)	–	–	83
Clinical evaluation	93	75	65 (50–70)	78 (63–85)	67	86
Charnley category A + B	46	70	64 (51–70)	77 (65–85)	83	87
Charnley category C	47	81	67 (50–70)	80 (63–85)	51	85
		p = 0.2	p = 0.03	p = 0.01	p = 0.001	p = 0.8

Charnley category A: unilateral hip disease, no additional limitations; category B: bilateral hip disease, no additional limitations; category C: multiple joint disease, other disease limiting mobility.
7 patients were classified as Charnley category A.

vide rates of implant survival in large populations. However, until recently such registers have not provided information on clinically poor outcome or unrecognized radiographic failures.

We evaluated medium-term clinical and radiographic outcome after Charnley arthroplasty in patients who were 50–70 years old, and who were operated at a teaching hospital using second-generation cementing technique. Furthermore, we compared the implant survival with data from the Norwegian Arthroplasty Register (NAR) and evaluated the completeness of the hospital data reported to the NAR.

Patients and methods

Study sample

According to the Norwegian Arthroplasty Register, 488 primary Charnley THRs were performed at Trondheim University Hospital from 1989 through 1991. Due to the shorter life expectancy of older people, we included only patients who had been 50–70 years of age at the time of the operation. This left 138 Charnley arthroplasties in 123 patients. Of these patients, 96 were women (75%; 104 hips) and 27 were men (34 hips). The median age of the patients at the time of surgery was 66 (50–70) years (Table 1). The preoperative diagnosis was primary osteoarthritis (OA) in 114 hips (83%), osteoarthritis secondary to congenital dysplasia in 13, rheumatoid arthritis in 7, sequelae after femoral neck fracture in 3, and avascular necrosis in 1.

At the time of clinical follow-up, 26 patients had died (28 hips) and 20 hips had been revised. 3 of the

revised hips were among the deceased cases. This left 84 patients for follow-up evaluation, 66 women (75%; 70 hips) and 18 men (23 hips). Median age at follow-up was 78 (63–85) years (Table 1). The mean follow-up period was 13 (12–15) (SD 0.9) years. All patients were interviewed and examined by one of the authors (GH) and underwent radiographic assessment. No patient was lost to follow-up, but 5 patients had incomplete data due to cognitive impairment or mental illness. Furthermore, 2 had moved and could not attend for clinical examination, and 2 did not want to undergo radiographic examination. Among the dead, unrevised patients, the average time from operation to the time of death was 8 (0.7–13) (SD 3) years. Reliable information concerning hip status of these patients was not available, but according to their hospital records there was no indication of any connection between the hip arthroplasty and the cause of death.

This study was approved by the regional medical research ethics committee, Central Norway (ref 103-03).

Clinical evaluation

Physical function was evaluated according to Charnley category (Charnley and Halley 1975), and specific hip function according to Charnley's modified Merle d'Aubigné and Postel scoring system (MdAP) (Charnley 1972) and Harris hip score (HHS) (Harris 1969). Furthermore, a visual analog scale (VAS) for patient satisfaction was recorded on a line between the statements "0 = completely satisfied" to "100 = completely unsatisfied". The EQ-5D instrument was used to measure health-related quality of life (Kind 1996). The

respondents classified their own health status in 5 dimensions within 3 levels of severity. The EQ-5D index value links a single index value to all the hypothetical health states described by the EQ-5D, while the EQ VAS records self-rated health status on a vertical graduated line between the statements “0 = worst imaginable health state” to “100 = best imaginable health state”.

Radiographic evaluation

Standard anterior-posterior radiographs of the pelvis and lateral radiographs of the hip were reviewed by 2 observers (GH and AA), and compared with initial postoperative radiographs and intervening controls. However, radiographs taken immediately after the operation were available for only 33 of the 84 patients. Radiographic findings were described in 14 Gruen zones of the femur and in 3 zones of the acetabular region (DeLee and Charnley 1976). Loosening of the femoral and acetabular component was classified according to the criteria of Mulroy and Harris (1997).

Implant and operation

All patients were operated in lateral decubitus position with direct lateral approach. A Charnley hip prosthesis was used in all patients. A stainless-steel polished stem with a 22.25-mm-diameter head and an ultra-high molecular weight polyethylene acetabular component (Charnley; Thackray/DePuy, Leeds, UK) were inserted with Palacos cement without Gentamicin. Second-generation cementing technique (vacuum mixing, intramedullary plug, and retrograde cement injection with a cement gun) was used. Prophylactic antibiotic with first-generation cephalosporin was given on the day of operation. Trondheim University Hospital is a teaching hospital in which training of orthopedic surgeons is one of the tasks. Hence, 26 different surgeons—most of whom were orthopedic surgeons in training—performed the operations. The number of THRs varied between 1 and 11 per surgeon, but 17 of the surgeons performed only 3 or less of the arthroplasties.

Bilateral procedures

Among the 123 patients in the study, 15 were included with both hips. It has been argued that this may represent a problem as standard survivor-

ship analyses assume uncorrelated data (Ranstam 2002). However, Lie et al. (2004) found that survival analyses, treating all operations as independent observations, generally gave equivalent results to those of more sophisticated analyses adjusting for possible dependencies. Thus, we based the survival analyses on all hip replacements ($n = 138$). The results presented with respect to the clinical examinations included 9 patients with bilateral prostheses, but were still based on standard statistical methodology. The validity of these results ($n = 93$) was investigated in additional analyses performed on a data set where bilaterally operated patients were included with one randomly chosen THR only ($n = 84$). The results were almost identical to those reported (data not shown), and all conclusions still applied.

Similar patient group at other hospitals

In order to compare the survival of Charnley THRs performed at Trondheim University Hospital with that observed at national level, operations performed at other hospitals were identified based on data in the Norwegian Arthroplasty Register. This group included all other operations reported to the NAR during the years 1989 to 1991 that had been performed with a Charnley arthroplasty cemented with plain Palacos cement in patients aged 70 or less ($n = 281$).

Statistics

The Mann-Whitney U test was used for statistical comparison of median values. Furthermore, the χ^2 test was used for categorical outcome factors. Multiple linear and logistic regression was used to study the effect of Charnley category (A + B; C) on different outcome measures with adjustment for sex and age at follow-up (< 80 , ≥ 80 years). Statistical comparison of mean values at surgery and follow-up was done with the Student t-test for paired samples. Student t-test for independent groups was performed for comparison with mean population EQ-5D index values (Burström et al. 2001). Levene's test was used to assess the assumption of equal population variances. The null hypothesis of equal variances was not rejected in any of the test situations.

Prosthesis lifetime was defined as the length of time from insertion of the prosthesis until re-

Table 2. Observed mean values (standard deviation) and linear regression results for specific hip function, patient satisfaction, and health-related quality of life

	HHS	HHS pain	VAS satisfaction	EQ-VAS	EQ-5D index
No. of respondents	93	93	89	88	89
Clinical evaluation	83 (15)	41 (6.5)	4.5 (15) ^c	69 (21)	0.75 (0.24)
Charnley category A ^a + B	92 (8.0)	42 (4.4)	1.6 (6.7)	79 (15)	0.88 (0.14)
Charnley category C	76 (15)	40 (8.0)	7.5 (19)	59 (22)	0.63 (0.25)
Estimated difference ^b	-14.4	-1.7	5.4	-17.9	-0.22
95% CI	(-20 to -9.1)	(-4.6 to 1.1)	(-1.3 to 12)	(-26 to -9.5)	(-0.31 to -0.13)
p (A + B vs. C)	p < 0.001	p = 0.2	p = 0.1	p < 0.001	p < 0.001

^a 7 patients were classified as Charnley category A (unilateral disease).
^b Linear regression with Charnley category, sex, and age in the model.
^c VAS satisfaction: median = 0 (0–85), interquartile range = 0.

sion (surgical removal or exchange of one or more components). When a patient died or emigrated, the prosthesis lifetime was censored at the relevant date. Kaplan-Meier estimated survival curves were established with revisions for any reason and revisions due to aseptic loosening as endpoint. In addition, Cox regression with follow-up until December 31, 2006 was used to compare prosthesis survival in the study group with that in THRs performed on similar patients at other hospitals with adjustment for potential differences in sex, age at the primary operation (< 60, 60–64, ≥ 65), and diagnosis (OA, other).

Survival was also calculated including clinical failures (radiographically loose components and/or low functional scores). In these cases, the lifetime of failed prostheses was defined as being from the date of insertion to the date of the clinical evaluation, or until revision due to loosening.

The S-PLUS software version 7.0 (Insightful Inc., Seattle, WA) and SPSS version 14.0 were used for statistical analyses.

Results

Complications

3 patients had 1 or more hip dislocations. 2 patients had an early (≤ 3 weeks) soft tissue revision due to postoperative infection and 1 patient had a deep venous thrombosis postoperatively. In addition, 1 patient had a neurolysis of the lateral femoral cutaneous nerve and 1 patient had 3 soft tissue revisions of fascia latae and the trochanteric bursa.

Charnley category

Co-morbidity was common, with only 7 of the patients having unilateral disease. As expected, there was a predominance of elderly in category C with 49% of the hips in patients aged 80 or more, as compared to 17% for patients in categories A and B (p = 0.001) (Table 1).

Harris hip score

Mean HHS was 83 (29–100) points, with 61 hips (65%) rated as good or excellent and 13 hips rated as poor (14%). Mean HHS varied among Charnley categories with the lowest score in category C (p < 0.001) (Table 2). The 13 patients with poor results were all rated as Charnley category C. The mean Harris hip pain score was 41 (10–44) points. If only pain was evaluated, 80 hips (85%) were rated as good or excellent. Similar pain scores were observed in all Charnley categories (p = 0.2) (Table 2).

Patient satisfaction

According to VAS, 83% of patients were completely satisfied with their hip replacement (VAS 0). Only 2 patients were not satisfied with the primary operation (VAS ≥ 80). They both had a loose femoral prosthesis at the radiographic evaluation. Median VAS satisfaction score was 0 (0–85) points. Differences in patient satisfaction between Charnley categories did not reach statistical significance (p = 0.1) (Table 2).

EQ-5D

Mean EQ-5D index was 0.75 (-0.74–1.0) points,

Table 3. Health score in EQ-5D dimensions, with regard to Charnley category, sex, and age. Estimated percentage of patients with moderate or severe problems and results of multiple logistic regression

	Mobility			Self-care			Activity			Pain			Anxiety		
	%	OR ^a	p	%	OR ^a	p	%	OR ^a	p	%	OR ^a	p	%	OR ^a	p
Charnley A ^b + B	17	1		0	1		11	1		30	1		16	1	
Charnley C	73	11.5	< 0.001	29	–	–	58	8.2	< 0.001	67	4.9	0.001	21	1.6	0.4
Gender															
Male	39	1		17	1		26	1		39	1		8.7	1	
Female	47	1.0	1.0	13	0.4	0.3	37	1.4	0.6	52	1.4	0.5	21	2.7	0.2
Age at FU (years)															
< 80	36	1		4.9	1		20	1		46	1		20	1	
≥ 80	63	1.6	0.4	33	5.5	0.03	63	4.9	0.004	53	0.8	0.6	13	0.5	0.3
Percentage 1 ^c	78			41			78			65			17		
Percentage 2 ^d	16			0.0			8.0			34			21		

^a Logistic regression with Charnley category, sex, and age in the model.

^b 7 patients were classified as Charnley A (unilateral disease).

^c Estimated percentage with moderate or severe problems in female patients aged ≥ 80 years in Charnley category C.

^d Estimated percentage with moderate or severe problems in female patients aged < 80 years in Charnley category A + B.

Table 4. Charnley's modified Merle d'Aubigné and Postel scores, preoperatively and at follow-up. Values are mean score

	Preoperatively	All			Charnley A + B		Charnley C	
		Follow-up	Change	p-value	Change	p-value	Change	p-value
Pain	2.7	5.5	2.8	< 0.001	2.8	< 0.001	2.8	< 0.001
Movement	3.4	5.3	1.8	< 0.001	1.9	< 0.001	1.7	< 0.001
Walking	2.6	4.3	1.8	< 0.001	2.5	< 0.001	1.0	< 0.001

and the mean EQ-VAS score was 69 (5–100). Again, we observed lower mean scores for Charnley category C compared to categories A and B ($p < 0.001$) (Table 2). Except for anxiety ($p = 0.4$), this finding was evident for all health dimensions (Table 3). The mean EQ-5D index values by age were 0.79 (SD 0.12) for 60–69 years, 0.81 (SD 0.20) for 70–79 years, and 0.64 (SD 0.24) for ≥ 80 years. Only patients in the group aged ≥ 80 years had statistically significantly lower health-related quality of life values than values for a general Swedish population ($p = 0.04$).

Age and sex

After adjustment for Charnley category, we found no statistically significant effect of gender on any of the outcome measures HHS, HHS pain, VAS satisfaction, EQ-VAS, or the EQ-5D index score. This was also the case for age at follow-up. We observed a difference in EQ-5D index between

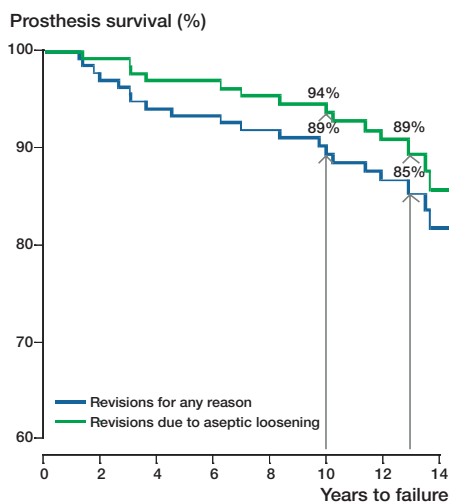
patients younger than 80 years and patients aged 80 or more at follow-up (estimated difference = -9.1, 95% CI: -18.6–0.4; $p = 0.06$). Age at follow-up affected both the degree of self-care and the degree of activity (Table 3).

Merle d'Aubigné and Postel score

Preoperative and follow-up MdAP scores were registered for pain, hip movement, and walking ability in 89, 87, and 87 hips, respectively. Compared to the preoperative hip function, the MdAP score after 13 years had improved ($p < 0.001$) (Table 4). Walking ability improved more in categories A and B than in category C. Based on pain score alone, 83 (89%) of the hips had a good or excellent result at follow-up (i.e. a score of 5 or 6).

Radiographic evaluation

91 hips were evaluated radiographically at follow-up; 4 had loose femoral components and 4 had



Kaplan-Meier estimated survival curves for 138 Charnley THRs.

loose acetabular components. Furthermore, 5 patients had a complete radiolucent line (RLL) around the femoral component. According to the strict radiographic criteria we used, a 100% RLL alone is not a sign of loosening unless absent in the initial postoperative radiographs. These 5 hips were not classified as loose because initial postoperative radiographs were missing and there were no additional signs of loosening.

Survival analysis

Prosthesis survival was studied in 138 hips, 20 of which had undergone revision. Mean time until revision was 6.9 (1.2–14) (SD 4.5) years. Both components had been revised in 8 hips, the acetabulum only in 2, and the femoral component only in 10. The indications for revision were aseptic loosening in 14 hips, infection in 5 (1 acute hematogenous and 4 chronic), and recurrent subluxations due to polyethylene wear in 1. Mean time until revision due to aseptic loosening was 8.3 (1.4–14) (SD 4.3) years. When revision for any reason was used as endpoint, the Kaplan-Meier estimated survival was 89% (95% CI: 84–95) at 10 years and 85% (95% CI: 79–92) at 13 years (Figure). With revision due to aseptic loosening as endpoint, the corresponding figures were 94% (95% CI: 89–98) and 89% (95% CI: 84–95) (Figure).

At the time of the clinical evaluation, 28 of the 138 hip implants corresponded to patients who had

died, 20 were revised, and 93 were classified as being successful (NAR data). However, we found 13 hips with HHS of < 70 and 8 hips with one radiographically loose component. Furthermore, we assessed 5 other hips with 100% RLL around the femoral stem. 4 of the hips with radiographically loose prostheses and 2 with 100% RLL were among the ones with HHS of < 70. On the other hand, 6 of the 13 with HHS of < 70 had a major co-morbidity that most likely affected clinical outcome more than the operated hip. Thus, altogether our retrospective study revealed 13 hips—in addition to the 20 revised hips—to be clinical failures, giving a clinical success rate of 76%, as compared to an estimated prosthesis survival rate of 85%. A worst case scenario, if not adjusting for co-morbidity and including prostheses with 100% RLL as failures, would give a clinical success rate of only 71%.

The revision rate for THRs in the study group was compared with that for similar patients at other hospitals in register data with extended follow-up. Cox-regression analysis revealed a higher revision rate for THRs in the study group (rate ratio = 2.1, 95% CI: 1.2–3.8; $p = 0.009$). This result was unaffected by adjustment for age at the primary operation, sex, or diagnosis. The estimated implant survival rate at other hospitals was 93% (95% CI: 90–96) at 13 years.

Comparison with the Norwegian Arthroplasty Register

In the surgical log-book for the period 1989–1991, we found 492 patients who had a primary Charnley THR at Trondheim University Hospital. Thus, 4 THRs (0.8%) had not been reported to the Norwegian Arthroplasty Register. All revisions were reported. One of our patients was wrongly registered as a revision, but had an intact arthroplasty. She had undergone a 2-stage revision in the opposite hip, and at the second operation the wrong hip was reported to the NAR. We found no other differences between register and hospital data.

Discussion

This study gives insight into the objective and subjective medium-term outcomes of primary

Charnley THR, a commonly used prosthesis. We found a prosthesis survival rate of 85% after 13 years, as expected for Charnley arthroplasties. In retrospective studies from single institutions, the mid-term survival for Charnley hips is reported to be between 81% and 92% (Garellick et al. 1994, Ortiguera et al. 1999, Allami et al. 2006), whereas the corresponding figures for register studies are between 90% and 95% (Havelin et al. 2000). However, the prosthesis survival rate in our study was substantially lower than in similar patients at other hospitals during the same period, according to register data. In the comparative group, only 3 of the 281 THRs were performed at a university hospital and this may explain some of the difference.

A comparison of outcome based on revision rate alone might be insufficient. In most cases, a revision is based on functional and/or radiographic failure. There might be differences in identification of failures, and this could be patient-, surgeon-, or system-related. Sometimes, patient co-morbidity may prevent revision surgery. Surgeons and hospitals should standardize their radiographic evaluation and measure patient function, to make identification of failures easier. Essential variables for functional measurements appear to be walking distance, hip flexion, and pain (Bryant et al. 1993). Health-related quality of life scores are also of value.

In addition, there may be differences in indications for revision between hospitals, regions, or even nations. Revision rates have been found to be higher at university hospitals than at local hospitals (Espeshaug et al. 1999, Havelin et al. 2000). This may be due to the centralization of high-risk patients, with additional medical conditions, to university hospitals. The high competence of some of the surgeons at a university hospital may lead to earlier revision of patients with clinically bad outcome, or revision of a patient that a local hospital could not handle. On the other hand, the quality of the surgical technique is an important factor to reduce the risk of revision due to aseptic loosening (Herberts and Malchau 1997). A low annual number of operations per orthopedic surgeon (Fender et al. 2003, Losina et al. 2004) and the high percentage of surgeons in training at a university hospital may also influence the prosthesis survival data reported. The large number of surgeons performing opera-

tions at university hospitals is confirmed by our study, as the 93 hip replacements were performed by 26 different surgeons.

At the follow-up evaluation, the average age of the patients was 78 years and 51% of the hips were in Charnley category C. In such a population, one must be aware of factors such as age and co-morbidity that might affect clinical outcome. It is well known that hip scores may decline over the course of a 10–20-year follow-up period due to increasing patient age and/or their medical condition rather than any factor relating to the hip arthroplasty. Brinker et al. (1996) showed that a non-hip diseased population with an average age of 65 years had a mean HHS of approximately 90, and not 100. On the other hand, the HHS is a commonly used score and can therefore be used as an indicator of outcome, and to compare studies. In our study the mean HHS was 83, and 65% of patients had a good or excellent result according to HHS. If evaluation of outcome was based on pain relief, 85% and 89% of the arthroplasties had a good or excellent result using the Harris and the Merle d'Aubigné scoring systems, respectively. Thus, THR appears to be effective for pain relief. Only 2 patients were not satisfied with their THR, as measured with the VAS score.

An HHS of less than 70 is regarded as a bad clinical outcome. The 13 patients with HHS of < 70 were all in Charnley category C, and their co-morbidity may be the main cause of the inferior functional result of the hip replacement. Callaghan et al. (1990) reported that the Charnley category affected all rating scales and recommended classifying the patients according to Charnley when reporting clinical results after total hip replacement. In our study, the patients in Charnley category C had a much lower HHS (Table 2). Also, walking ability according to MdAP improved least in category C. Furthermore, for EQ-5D health outcome in different dimensions, there were differences between Charnley category A + B and C regarding mobility, self-care, activity, and pain (Table 3). There were no differences in anxiety, which indicates that the outcome is physically based. Health-related quality of life measured as EQ-5D index for patients ≥ 80 years of age was lower than in a general population, and this coincides with patients in Charnley category C. Thus, one must be careful with inter-

pretation of standard outcome scores for patients in Charnley category C after total hip arthroplasty.

Evaluation of the reporting of primary THRs from Trondheim University Hospital to the Norwegian Arthroplasty Register (NAR) revealed that only 1 patient was wrongly registered, and that 0.8% (n = 4) of the operations in the period 1989–1991 had not been reported by the surgeons. This is comparable to results of a study from Stavanger, Norway, reporting that 0.4% of the primary hip replacements were missing in the registry data (Arthurs-son et al. 2005). The completeness of reporting and quality of the data reported is considered good, and our study confirms a high degree of completeness of registration in the NAR (Espehaug et al. 2006).

At follow-up, 20 arthroplasties had been revised, 8 hips had a radiographically loose component, and 13 hips had low functional score (HHS of < 70). This indicates that among unrevised hips in registry data, there may be several hips with poor outcome. A low revision rate might conceal several clinical failures that for some reason do not lead to revision, and as a result cannot be identified in the registers. All hospitals performing THR should measure their own results and should not rely solely on the registers. Thus, when we include patients with revised prostheses and clinical failures, the clinical success of hip replacement is inferior to the estimated survival based on register data. In our study, the clinical success of Charnley THR was 76% and the estimated survival was 85% after an average of 13 years. The difference in clinical success and estimated prosthesis survival emphasizes the value of clinical follow-up studies to document the effectiveness of implants.

Contributions of authors

GH: study design, data collection, analysis of radiographs, and data analysis. AA: study design, analysis of radiographs, and supervision. BE: statistical analysis. PB: study design. All authors were involved in writing of the manuscript.

No competing interests declared.

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