Prognosis of total hip replacement in Sweden

Follow-up of 92,675 operations performed 1978–1990

Henrik Malchau, Peter Herberts and Lennart Ahnfelt

A prospective, national multi-center study of all reoperations after total hip replacement (THR) was started by the Swedish Orthopedic Association in 1979. The material comprises all THR performed in Sweden, presently more than 10,000 yearly or 130 THR per 100,000 inhabitants; uncemented implants have been used in less than 2 percent. The main reasons for revision have been aseptic loosening 79 percent, infection 10 percent, technical error 6 percent, and dislocation 2 percent. The cumulative rate of revision for deep infection has dropped from 0.9 percent to < 0.5 percent for implants inserted 1979 and 1983, respectively. With the Charnley prosthesis as the gold, standard the performance of other prostheses was analyzed. Improved cementation techniques and anti-infection measures have continuously reduced the revision risk.

The register demonstrates that the average ortopedic surgeon cannot match the results achieved by experts. However, the vast majority of THR, worldwide, are not performed by experts. Quality-assurance in this sector of orthopedics demands a continuous analysis of the outcome of these operations.

Department of Orthopedics, University of Göteborg, Sweden
Correspondence. Dr H. Malchau, Department of Orthopedics, Sahlgren Hospital, S-413 45 Göteborg, Sweden
Tel +46-31-602076 Fax -825599
Presented as Scientific Exhibition at the Annual Meeting of the American Academy of Orthopedic Surgeons, 93-02-18, San Francisco, CA, U.S.A.

THR is one of the most successful and cost-effective operations ever introduced. The documented, clinical success rate at 10 years exceeds 90 percent. More than 800,000 THR are done worldwide each year, and this high incidence leads to a substantial number of complications. The most serious local complications are mechanical failure, technical error, and deep infection, and these complications often require revision.

In spite of the fact that we have learnt a lot about different failure mechanisms there is a need for continuous improvement and quality control of joint replacement procedures. One realistic method to ensure the public such a quality control is the continuous registration of complications. Since the number of revisions at each orthopedic center is relatively small, such registrations are preferably organized as multi-center studies. We then have access to a large number of operations, different operative environments, techniques, surgeons and prostheses. These are the important parameters and determinants of the long-term success or failure of the procedure.

On the initiative of the Swedish Orthopedic Association a prospective, national, multi-center study was established in 1979, collecting all reoperations after a THR in Sweden. All Swedish surgeons and hospitals performing THR are engaged in this ongoing study. We believe that it is the responsibility of the medical profession to ensure the public a continuous quality control, to improve on indications, and by feed-back to the orthopedic surgeons continuously improve the joint replacement procedure (Herberts et al. 1989).

Since the important determinants of the quality of the implant procedure are the patient, the surgeon and the implant itself we established a method to separately analyze these parameters. The information obtained in the register is disseminated to the profession yearly by reports of their rate of complications, as compared to that of the country in general. The central idea of the register is to continuously improve the quality of the whole joint replacement procedure.

We have previously reported revisions of primary THR performed 1967–1977. We report here all revisions after a primary THR performed in Sweden 1978–1990. The analysis is based on 92,675 primary THR and comprises 4,828 first-time revisions.

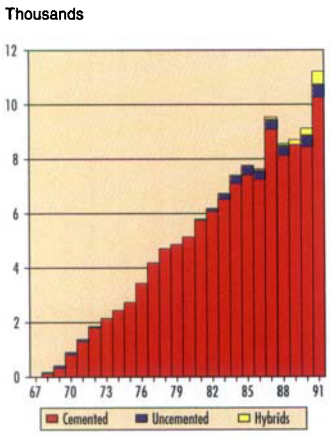


Figure 1. Primary THR in Sweden, 1967–1991.

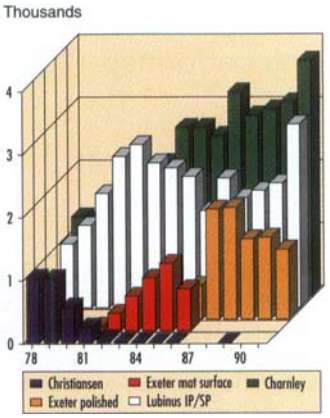


Figure 2. Annual use of four cemented prostheses, 1978–1991.

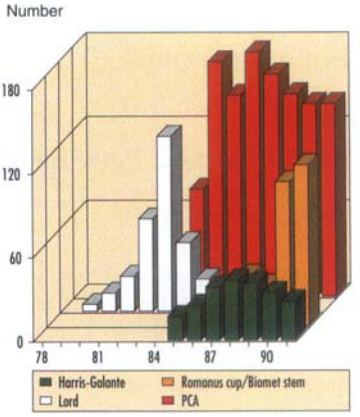


Figure 3. Annual use of four uncemented prostheses, 1978–1991.

Table 1. Most widely used primary THR in Sweden 1967–1991

Implant	n
Charnley	40,430
Lubinus IP and SP	28,325
Exeter mat and polished	11,255
Brunswik	5,949
Christiansen	5,120
Scan Hip	4,265
Charnley-Müller	3,002
Müller straight	2,881
Stanmore	2,653
McKee-Farrar	2,513
C.A.D.	2,240
Spectron	2,206

Table 2. Incidence of THR per 100,000 inhabitants

Year	Sweden	U.K.	France	Belgium	U.S.A.
1979	59				
1982	74				
1985	93				
1986	91				45–80
1988	101	54	108	116	
1989	102				64–80
1991	131				

Primary THR in Sweden 1967–1991

Sweden is situated in the northern part of Europe. The population of 8.46 million is mainly caucasian. The primary care system and all but a few hospitals are run by local and state governments, and most medical care is paid for from taxes. The prevalence of primary arthrosis of the hip is 2.1 percent and has remained unchanged over the last three decades. Since 1967, 123,966 primary THR have been performed (Figure 1 and Table 1).

If the U.S.A. incidence of 64 THR per 100,000 inhabitants (Table 2) equals the true demand, the number of THR in Europe, USA and Canada could be estimated as 495,000. If the Swedish incidence (130 THR per 100,000 inh.) equals the true demand, the corresponding figure would be one million THR yearly.

Table 3. Number of commonly used primary THR implants 1978–1990 and 1991

Implant	1978–1990	1991
Cemented		
Charnley	29,494	3,742
Lubinus IP	16,966	623
Lubinus SP	8,104	2,463
Exeter polished	6,637	1,110
Exeter mat surface	3,511	0
Scan Hip	3,501	770
Spectron	1,699	505
Bi-metric	580	333
Müller straight	2,609	271
Uncemented	2,863	471
PCA	1006	138
Romanus Bi-metric	168	115
Omnifit	10	31
Harris-Galante	198	28
ABG	0	25
Hybrids	672	479

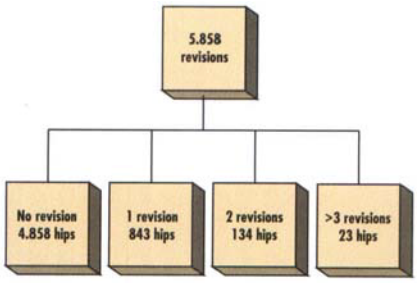


Figure 4. THR revisions 1979–1990.

Patients and methods

The definition and end-point for failure in this study was revision with exchange of one or both prosthetic components or permanent removal of the prosthesis. The prospective study started on January 1, 1979, and all orthopedic departments in Sweden were included. Complete copies of hospital records of all revised THR were collected and the data computerized. The system requires a unique identification number for each patient. From every hospital, information about types and numbers of implants per year is known.

In order to validate our previous statistical assumptions (Ahnfelt et al. 1990), we include an analysis on a population of primary THR operated upon 1979–1983. By means of the unique identification number for each patient in Sweden, individual data, such as age, sex, diagnosis and type of prosthesis are known. This information could be obtained since, during these years, all operating units reported demographic data, on all patients admitted to every hospital, to the National Board of Health and Social Welfare. Furthermore, from the National Register of Causes of Death we analyzed the death rate in the National Register of Revised THR.

The influence of patient-related factors, such as age, sex and primary diagnosis, for prosthetic survival was analyzed according to a modification of the methods described by Kaplan and Meier (1958). This analysis was made possible in the whole revision material by means of specific assumptions, as described previously by Ahnfelt et al. (1990). We used the smaller population of primary replacement with known individual data to validate our previous statistical methods.

Definitions

Reoperation. Any new hip operation on a patient who has previously undergone THR.

Revision. Exchange of one or both prothetic components or removal of the implant.

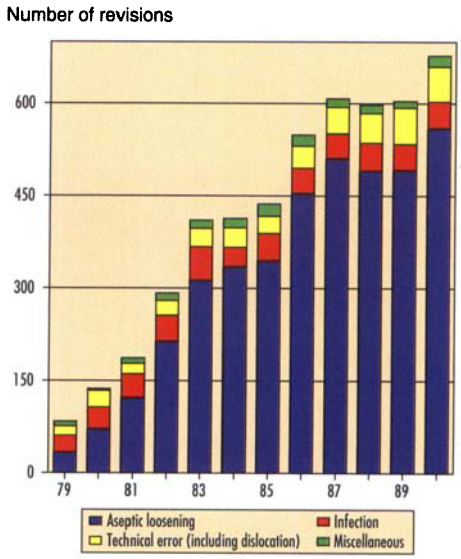


Figure 5. Reasons for revisions performed in Sweden 1979–1990 in patients with primary implants inserted 1978 or later.

Patients

In all, 92,675 primary THR were performed 1978–1990. In the period 1979–1983 we have complete information about 22,212 patients with respect to age, gender, diagnosis and type of prosthesis.

In the period 1979–1990, 5,858 revisions were performed in Sweden. One thousand were on patients with at least one previous revision. These cases are excluded from the material, and the following analysis is based on 4,858 revisions in hips with only one previous THR with the primary operation performed 1978 or later.

All departments performing THR in Sweden have given a detailed report of their surgical technique year-by-year since 1978. This information includes the use of a femoral plug, cleaning of the bone bed, pressurization by means of a proximal plug and type of cement. Furthermore, cement mixing and application techniques, including vacuum mixing, were described. The information makes it possible to make a statistical evaluation of the importance of surgical technique.

Prophylactic measures against deep infection by means of parenteral and local antibiotics are also reported. The type of operative environment including laminar air flow and body exhaust gowns are documented year-by-year for every department. Thereby the importance of prophylactic measures against deep infection, as graded in different classes, was also obtained. Revision for deep infection was the end-point for failure in the survival analysis.

Results

Aseptic loosening has emerged as a main problem and reason for revision (Table 4, Figure 5). Deep infection and technical problems have been reduced (Figure 6).

Figures 7 and 8 illustrate the survival rates of 71,142 primary THR that were cemented and 1,303 cementless implants.

Improved surgical techinque, cementing technique and more selective use of well-designed implants have resulted in a substantial reduction in the rate of aseptic loosening (Figure 9). The quality of the THR procedure has improved during the last decade.

The prophylactic measures used for preventing deep infection have been highly effective (Figure 10). We found no difference between prosthetic designs when failure leading to revision for infection was analyzed.

Table 4. Reasons for revision 1979–1990 (n 4,858). Number, *percentages*

Reason		
Aseptic loosening	3,836	*79.0*
Infection	472	*9.7*
Technical error	285	*5.9*
Dislocation	117	*2.4*
Bony fracture	50	*1.0*
Pain	21	*0.4*
Miscellaneous	77	*1.6*

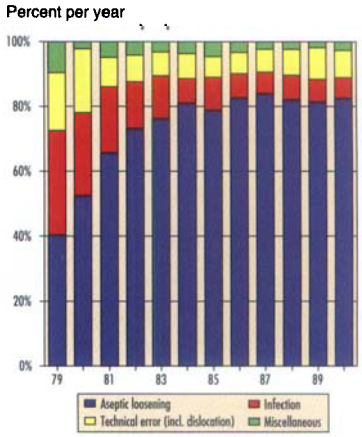


Figure 6. Type of failure in percentages per year for revisions in Sweden 1979–1990 in patients with primary implants 1978 or later.

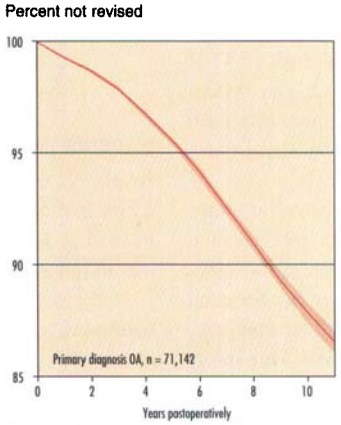


Figure 7. Percent not revised in 71,142 patients with primary diagnosis arthrosis and cemented implants.

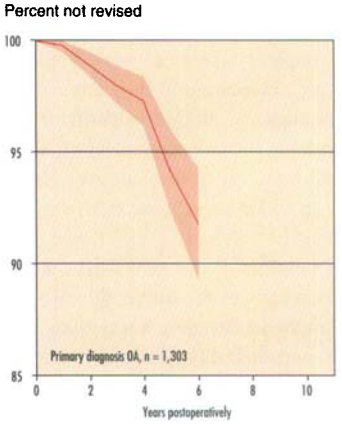
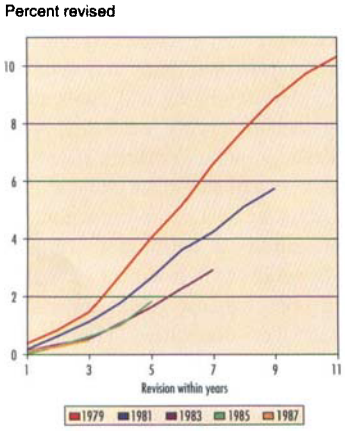


Figure 8. Percent not revised in 1,303 patients with primary diagnosis arthrosis and uncemented implants.



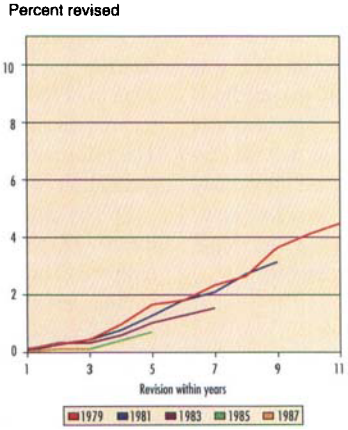


Figure 9. Cumulative rate of revision for aseptic loosening of all implants (left) and Lubinus (right) inserted in the years 1979, 1981, 1983, 1985, and 1987.

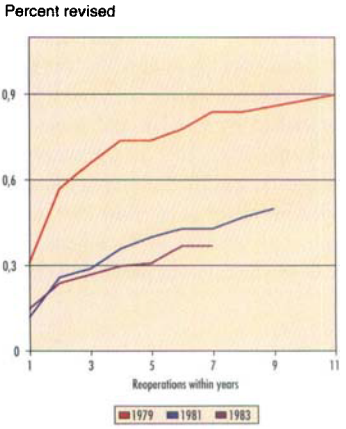


Figure 10. Cumulative rate of revision for deep infection of implant inserted 1979, 1981, and 1983.

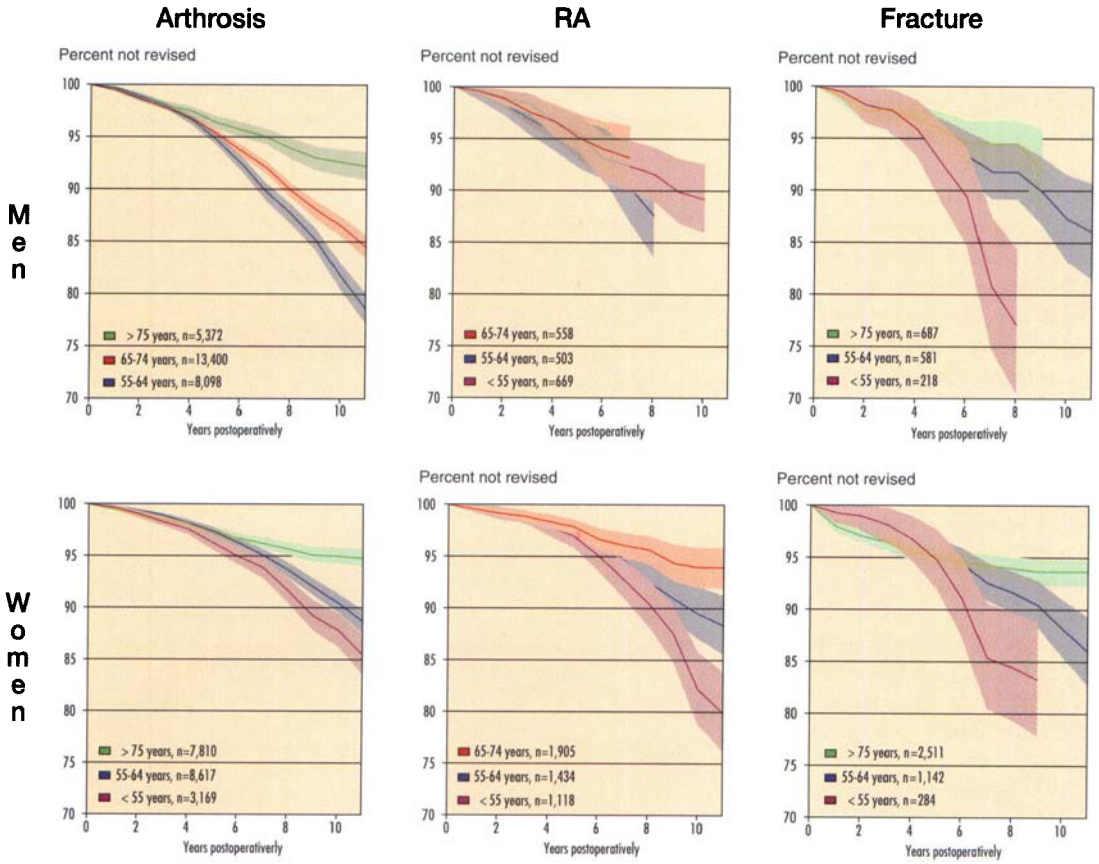


Figure 11. Percent not revised in men or women with primary diagnosis arthrosis, rheumatoid arthritis (RA) and hip fracture related to age.

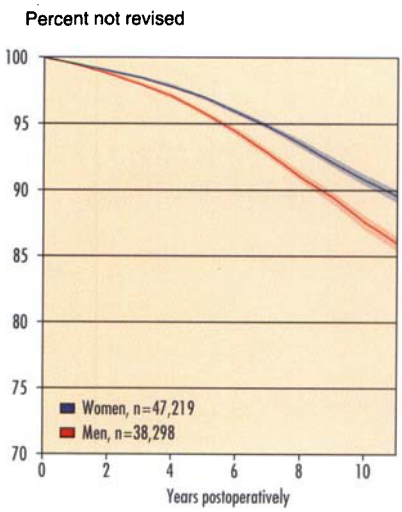


Figure 12. Percent not revised in men and women overall.

Patient-related factors

Survival analysis based on revision for aseptic loosening shows substantial differences associated with patient age, gender and diagnosis (Figures 11 and 12). On all curves are indicated the 95 percent confidence interval. Mean age at total hip replacement in Sweden is 68 years for both women and men.

With a few exceptions we find, in all three diagnostic groups, an increased risk for revision of aseptic loosening in the younger patient. It is important to keep the indications for THR strict and clear. For the elderly patient the outcome of THR is good, but in the younger patient population it is significantly worse and not acceptable. THR in patients below 55 years is still an experimental procedure that needs careful evaluation and follow-up. The Swedish register illustrates that neither cemented nor new and unproven implants and fixation principles should be widely used in younger patients before improved clinical results have been demonstrated.

Implant-related factors

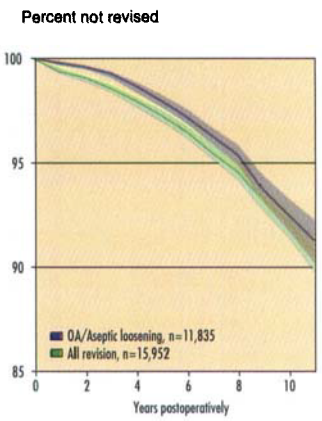
More than a hundred different types of prostheses have been used in Sweden from 1967 to 1990. 20 implants have been analyzed and provide the basis for the survival functions. In the statistical analysis, all types of revision and revision for aseptic loosening as end-point and definition for failure are included. On all the curves, 95 percent confidence intervals are indicated and on the majority of the diagrams the Charnley survival curve is plotted in red. Only implants operated on during the same time period are included to avoid bias due to the improved surgical technique.

In this material of 4,858 revisions, various procedures were used. Exchange of stem and cup in 2,420 cases (50%), exchange of the stem in 1,350 (28%), exchange of the cup in 747 (15%) and in 341 cases (7%) extraction of both components were done.

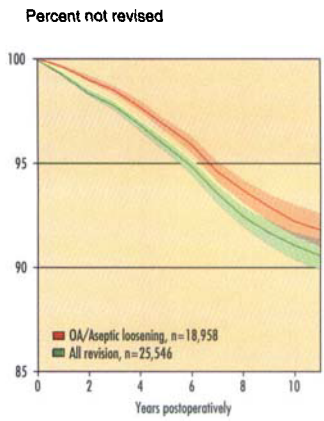
The implant-survivorship analysis describes the probability of failure due to revision for aseptic loosening. On the curves, the 95 percent confidence interval is indicated with a faint color. The standard error (and thus the width of the confidence interval) decreases with the number of prostheses at risk. The width of the confidence interval therefore depends on the number of patients who entered the study (the number at risk at time zero). None of the curves is depicted when less than 50 hips remain at risk. The standard error relates to the probability of survival for a given number of years from the operating date of the primary THR (Figure 13).

The Charnley, Lubinus and C.A.D implants have been used throughout the whole observation period. The performance of these implants has been good and no difference in survival rate is noted at the 10-year follow-up. The Exeter mat surface and Müller

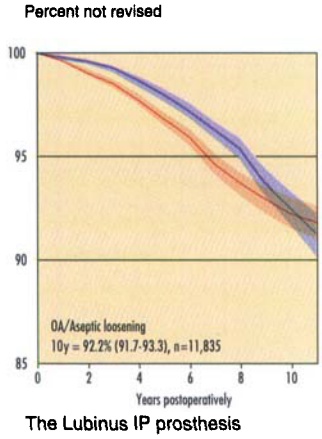
Figure 13. Observed survival related to implant



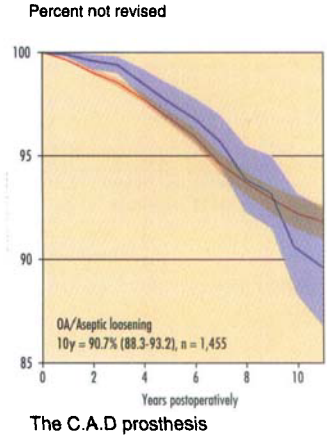
The Lubinus IP prosthesis



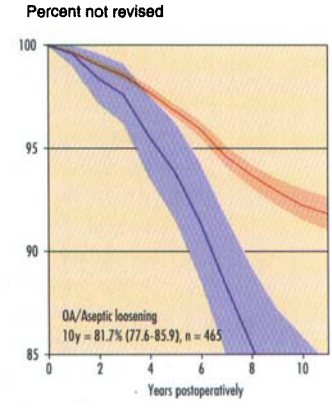
The Charnley prosthesis



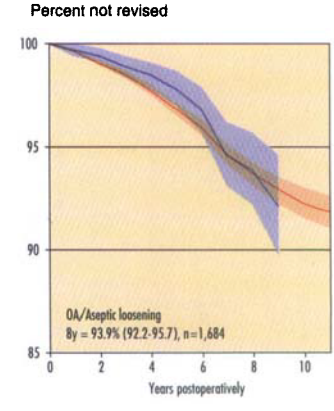
The Lubinus IP prosthesis



The C.A.D prosthesis

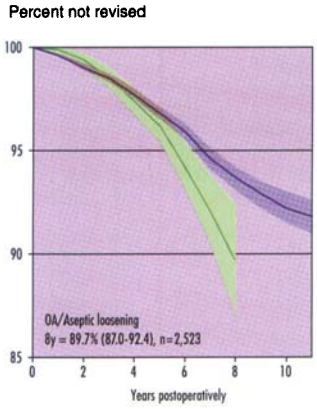


The Müller curved stem prosthesis

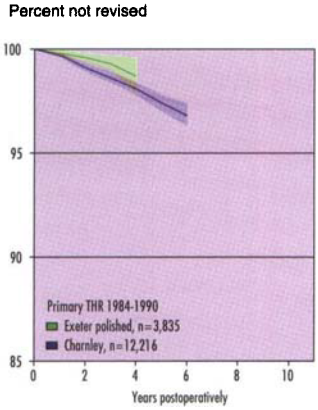


The Müller straight stem prosthesis

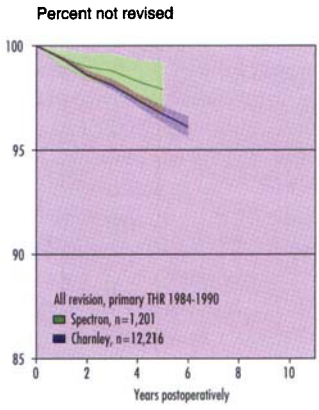
Figure 13. Continued...



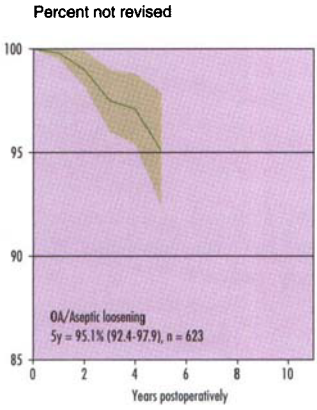
The Exeter mat surface prosthesis.



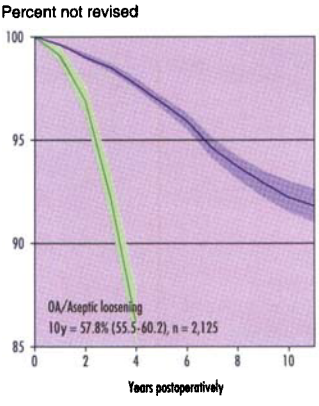
The Exeter polished surface prosthesis.



The Spectron prosthesis.



The PCA prosthesis.



The Christiansen prosthesis.

curved prostheses are in an intermediate group with a higher risk for revision. The worst performance is noted with the Christiansen prosthesis. The implants developed in the middle of the 1980s (Spectron, Lubinus SP, and Scan Hip) have a very low revision rate. Besides improved implant design, the contemporary technique with cement pressurization, femoral plugging and vacuum mixing of cement was more frequently used in combination with these implants. We have observed a significant improvement with a reduced rate of revision for aseptic loosening in the Spectron versus the Charnley designs. One explanation can be that the Charnley procedure is still widely performed with only the second generation of cementing technique.

Patients needed to assess differences between prostheses

The material sizes needed to assess differences between prostheses with respect to risk of revision were determined (Table 5). Six prostheses were considered; Charnley, C.A.D, Exeter polished, Spectron, Lubinus SP, and PCA. The estimated probabilities of prosthetic survival is listed in Table 6. It was assumed for simplicity that the yearly recruit-

	Charnley versus C.A.D.		Charnley versus Lubinus IP		Exeter polished versus Lubinus IP		PCA versus Spectron	
Power (%)	80	50	80	50	80	50	80	50
4 years	2,836	1,437	1,718	882	7,169	3,614	269	145
5 years	1,918	971	1,163	597	4,837	2,440	183	99

Table 6. The estimated probabilities of prosthetic survival

Implant	years	prob.
Charnley	7	0.94
C.A.D	7	0.95
Lubinus IP	7	0.96
PCA	5	0.94
Spectron	5	0.98
Lubinus SP	4	0.99
Exeter polished	4	0.98

Table 7. Previously used estimated patient survival rates (A) and the true survival rate (B)

Age group	RA				OA			
	Men		Women		Men		Women	
	A	B	A	B	A	B	A	B
< 54	0.87	0.84	0.82	0.83	0.83	0.78	0.82	0.79
55–64	0.90	0.90	0.92	0.93	0.77	0.81	0.87	0.88
65–74	0.94	0.93	0.96	0.95	0.84	0.87	0.90	0.92
> 75	1.00	1.00	0.96	0.96	0.91	0.93	0.95	0.96

ment was exactly the same for each year and for each one of the two prostheses which were compared. The time period up to statistical analysis was assumed to be 4 or 5 years, and the test was assumed to be two-sided at the level 0.05.

Thus for achieving the power of 80 percent when comparing Charnley and C.A.D in a study terminating after five years 5 x 2 x 1,918 = 19,180 patients have to be recruited.

Primary material

In previous presentations from the Swedish National THR study (Ahnfelt et. al 1990) we did not have the demographic data of the individual primary patients and the true mortality rate. In the statistical analysis we therefore estimated that the osteoarthrosis (OA) patients had a death rate equal to the general population and that the patient with rheumatoid arthritis (RA) had excess mortality. Through the National Board of Health and Social Welfare we received demographic data about primary THR patients operated on between 1979 and 1983, and the mortality rate in this group of patients has been obtained from the Cause of Death Register. A comparison between the old method (A) and the new, more correct method (B) has been performed and the results with respect to implant survival rate at 10 years are listed in Table 7. The difference between the two methods is that the estimated survival of the individuals with the old method was different from the true survival of the individuals.

However, both methods gave approximately the same results, but there are minor differences. In the younger OA group, information about the primary material gave a worse outcome, whereas a tendency to the opposite was observed in the middleaged and elderly part of the population. The difference between the two methods is close to the confidence limits. Thus the previous results are valid, but with the new data we have obtained a more exact result. All the results presented here were calculated with the new and more correct method.

Environmental factors and revision rate

All orthopedic units in Sweden report yearly factors of importance concerning their surgical environment, such as type of ventilation, surgical approach, cementing technique, type of bone cement and antibiotic regimen *(environmental factors).* The parameters are not reported per individual patient but for the department as a whole. By using Poisson models the hazard-functions of revision were estimated as functions of environmental factors (Table 8). The influence of these environmental elements on the risk of revision for aseptic loosening and for deep infection were calculated, taking the time span between the primary THR and revision into consideration.

The results reflect the important quality effect of the various technical and prophylactic measures on the outcome of 92,675 total hip replacements.

The stepwise logistic regression analysis illustrates the importance of the individual environmental factors. This can be an instrument for cost effective recommendations.

Conclusion

The public has a right to be assured that artificial hip replacement procedures do not introduce unexpected hazards associated with poor design, incompatible materials or deficient technique (Editorial, *Acta Orthopaedica Scandinavica,* 1987). The responsibility

Table 8. Environmental factors influencing the risk of revision

Type of environmental factor	*p*-value	Factor reducing the risk
Revision for aseptic loosening		
Year of implantation	< 0.001	Short implantation time
Diameter of anchorage holes	0.09	Not significant
Number of holes in acetabulum	< 0.001	Greater interlocking area
Bone bed preparation	< 0.001	Clean surfaces
Vacuum mixing of cement	0.001	Stronger cement
Distal femoral plug	< 0.001	Pressurization
Proximal femoral plug	0.02	Not significant
Acetabular pressurization	< 0.001	Pressurization
Revision for deep infection		
Quality of ventilation in operating theater	< 0.001	More effective air exchange
Use of exhaust gown	0.08	Not significant
Antibiotic-containing cement (gentamicin)	< 0.001	Gentamicin-impregnated cement

for continuous quality control must also lie within the medical profession, and the national registration of reoperations after THR in Sweden is an effective instrument for self-regulation within the profession and quality assurance (Faro and Huiskes 1992).

The outcome of THR in Sweden does not match the results of experts using modern cementing techniques (Mulroy and Harris 1990). This observation is explained by the great number of individual surgeons with different surgical skill and experience involved in a multi-center study of this type. However, we believe that our nation-wide results more accurately reflect the quality of the ordinary orthopedic surgeon. It is understandable that the average surgeon obtains inferior results because extra care, routine and know-how are available only at specialized centers.

This study gives survival results with narrow confidence limits of frequently used implants. In order to evaluate new implant designs and the long-term results of the uncemented implants, the study has to continue for several years. The statistical evaluation has revealed the great number of patients we need to detect significant differences after short-to-intermediate follow-up (2–5 years). This study has enabled us to eliminate implants with inferior function from the market and to illustrate the importance of prophylactic measures and improved surgical techniques.

In Sweden, cementless fixation techniques have been used almost exclusively in younger patients in attempts to obtain permanent ingrowth fixation. The only way to conclusively demonstrate the advantage of one fixation technique over the other in this particular patient population is by prospective randomized trials. Therefore, the national registration of THR-failures can only partly contribute to this ongoing discussion. We have demonstrated that in the young patients both cemented and cementless fixation techniques give failure rates that must be regarded as unsatisfactory and further technical development is, indeed, needed.

The following conclusions are well founded:

- The incidence of primary total hip replacement is increasing dramatically.
- The number of revisions has levelled off in spite of the increasing number of patients at risk.
- Aseptic loosening is the major problem in hip joint replacement and is the reason for more than 80 percent of the revisions. Deep infection, however, can be effectively prevented.
- Male gender and young age increase the risk of revision due to aseptic loosening.
- There are significant differences in prosthetic endurance between the three diagnostic groups: arthrosis, rheumatoid arthritis, and hip fracture.
- Type of implant is decisive for success or failure. A continuous registration of failure is important since problems related to joint replacement do not show up for very long times.
- The improved surgical and cementing techniques gave improved results. The reproducibility of the cementless fixation is not on par with the cemented.

We believe that the information obtained in this study will enable us to improve the indications for surgery and the implantation technique, and to recommend implants with a verified durability. The multi-center approach makes it possible to determine the long-term endurance within each diagnostic group for the different types of prostheses used in Sweden. Thereby we can reduce the numbers of procedures that do not serve our patients well.

References

1. Herberts P, Ahnfelt L, Malchau H, Strömberg C, Andersson G B J. Multi-center clinical trials and their value in assessing total joint arthroplasty. Clin Orthop 1989; 249: 48–55.
2. Kaplan E L, Meier P. Nonparametric estimation from incomplete observation. Am Stat Ass Journ 1958: 457–81.
3. Ahnfelt L, Herberts P, Malchau H, Andersson G. Prognosis of total hip replacement. Acta Orthop Scand (Suppl 238) 1990; 61: 1–26.
4. Mulroy R D, Harris W H. The effect of improved cementing techniques on component loosening in total hip replacement. J Bone Joint Surg (Br) 1990; 72: 757–60.
5. Faro L M C, Huiskes R. Quality assurance of joint replacement. Acta Orthop Scand (Suppl 250) 1992; 63: 1–33.
6. Editorial. Quality control of implants. Acta Orthop Scand 1987; 58: 477–8