

## Introduction

Failures after total hip replacement (THR) can be defined by recording the number of reoperations. Such recordings are important if we want to assess the true value of new and sometimes expensive technology introduced in the field of joint replacement. Because each surgeon and orthopedic department have comparatively few reoperations, recordings of reoperations are preferably performed as multicenter clinical trials. This provides access to a large number of patients and makes it possible to analyze the importance of patient-related, surgical- and implant-related parameters.

Several important multicenter clinical studies have been performed in Sweden in the field of total joint replacement. Josefsson et al. (1981) analyzed the effect of gentamicin-containing bone cement for prevention of deep infection in THR; Lidwell et al. (1987) evaluated prophylactic measures for prevention of postoperative infections; and knee arthroplasties have been followed continuously since 1975.

In 1967, total hip replacement was introduced at several Swedish hospitals. In 1973, the method was employed at 33 hospitals, i.e., in all the departments of orthopedics in the country at that time. In 1978, hip replacements were carried out at 53 hospitals and by 1987 the number had grown to 81 hospitals.

The present study, like the corresponding knee survey, initiated by the Swedish Orthopedic Association, is a prospective, national recording of reoperations after total hip replacement in Sweden 1979–1986. The investigation is still active, with continuous reports from every orthopedic department of every reoperation for failure after THR.

### Aims of investigation

The aims of the investigation were the following:

- To determine the incidence of reoperation after THR.
- To evaluate the association of individual, surgical, and prosthetic parameters with THR failure.
- To determine the importance of different types of prophylactic measures in preventing complications leading to revision.
- To calculate survival functions for different age groups and different implants for prediction of the long-term risk of revision.
- To disseminate information to the orthopedic profession and to reduce the number of procedures that do not serve our patients well.
- To develop a data base for further assessment of the results of revision surgery after THR.

# Material

## Primary arthroplasties

The number of hip arthroplasties performed each year in Sweden has increased steadily (Figure 1). Up to 1987, 85,500 hip arthroplasties had been performed on some 70,000 patients by more than 550 surgeons. In 1987, 9,500 primary THRs were performed at 81 hospitals. In recent years, THR has spread from university and regional hospitals to smaller community hospitals.

There were major differences in the frequency of operations at the different hospitals. Certain hospitals performed more than 200 operations per year, while a few performed less than 50 hip arthroplasties per year. This does not necessarily mean that the individual surgeon is less experienced at smaller surgical units. On the contrary, all the operations at the smaller hospitals were usually performed by a few surgeons, whereas the larger units often had 20 or more surgeons.

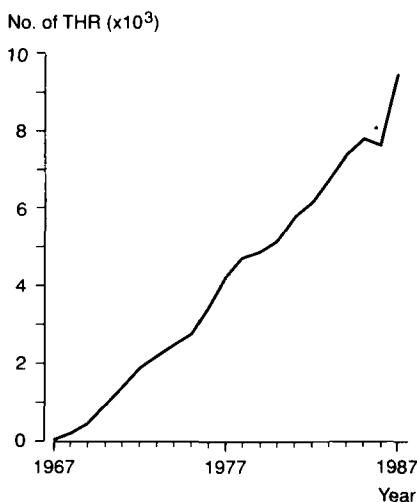


Figure 1. The number of total hip arthroplasties performed annually in Sweden in the period 1967–1987. \* Hospital strike.

The different implant designs used in Sweden from 1967 through 1987 and separately in 1987 are given in Tables 1 and 2. In 1987, the Charnley, Lubinus, and Exeter prostheses were the most common, and were used in more than 90 percent of Swedish hospitals. Altogether, some 10 types of cemented prostheses were in routine use in 1987. Cementless prostheses have been used during the last 10 years. In 1983 to 1987, they constituted about 4 percent of all the implanted primary prostheses. The figure has not changed up to 1987, because in Sweden the cementless hip arthroplasty is considered to be experimental, and is evaluated prospectively at certain centers only.

Table 1. The 11 most commonly used implants and the total number of resurfacing arthroplasties in Sweden 1967–1987

Type of prosthesis	n
Charnley	27,734
Lubinus	19,874
Brunswick	5,886
Exeter	5,803
Christiansen	5,095
Charnley-Müller	2,951
McKee-Farrar	2,510
Stanmore	2,166
Müller, straight stem	2,007
CAD	1,967
Müller, curved stem	1,699
Resurfacing	508

Table 2. The most commonly used cemented prostheses and the number of uncemented or hybrid arthroplasties (uncemented cup and cemented stem) in Sweden in 1987

Type of prosthesis	n
Charnley	3,235
Lubinus	2,060
Exeter	1,749
Scan-hip	580
Müller, straight stem	275
Stanmore	249
HD 2	229
Brunswick	212
Spectron	191
Uncemented	369
Hybrid	87

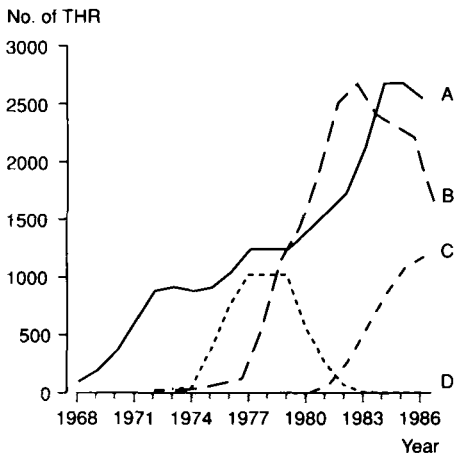


Figure 2. Distribution over time for four commonly used prostheses in the period 1968–1986. A Charnley, B Lubinus IP/SP, C Exeter, and D Christiansen.

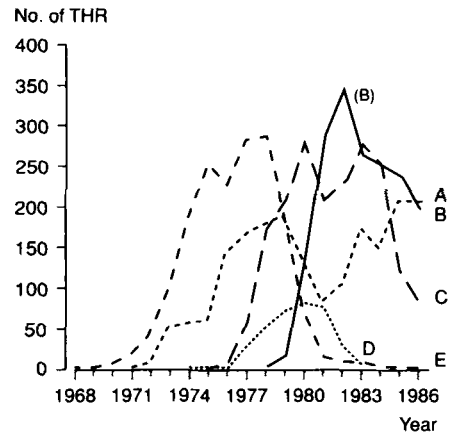


Figure 3. Distribution over time for five less commonly used prostheses in the period 1968–1986. A Stanmore, B Müller, straight, C CAD, D Müller, curved, and E Wagner.

Table 3. The annual number of reoperations, revisions, and primary THR 1979–1986. (For definitions, see p. 8)

Type of operation	1979	1980	1981	1982	1983	1984	1985	1986
Reoperations	584	576	780	946	1,222	1,171	1,215	1,278
Revisions	408	402	570	680	876	834	854	897
Primary THR	4,867	5,148	5,786	6,184	6,734	7,404	7,801	7,636

Table 4. 6,386 reoperations subdivided in the four types of operative procedure where Type I represent revision, Type II other major hip interventions, Type III minor hip interventions, and Type IV closed reductions

Type of reoperation	1979	1980	1981	1982	1983	1984	1985	1986
I	326	340	489	586	725	716	720	762
II	33	24	38	42	47	45	50	35
III	38	30	26	44	25	24	21	18
IV	69	88	96	124	187	193	203	222

Eleven prosthetic designs were each used in more than 1,000 hips between 1967 and 1987. The Charnley and Lubinus prostheses were the most widely used (27,734 and 19,874 hips, respectively). The market shares over the years of the most commonly used prostheses are shown in Figures 2 and 3. Surface replacements or double-cup prostheses were used over a few years only. During the period 1979–1982, about 2 percent of all the primary prostheses were surface replacements. This type of prosthesis was associated with a high rate of complications, however, and has been abandoned.

## Revisions

From January 1, 1979, through December 31, 1986, 7,772 reoperations were performed in Sweden (Table 3).

As regards reoperations, we mean any new hip operation on a patient with a total hip replacement on the same side. As regards revision, we mean exchange of one or both components or removal of the implant.

6,386 reoperations were performed in hips that had had no previous revision (Figure 4). These hips are

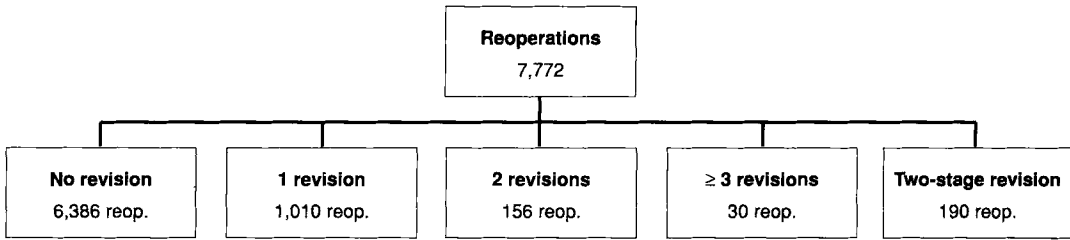


Figure 4. The whole material consists of 7,772 reoperations. The basic material of the study is the 6,386 reoperations without previous revision.

the basic material in the study. The reason for excluding patients with previous revisions was to make the material as uniform as possible.

The 6,386 reoperations were divided into four types depending on the operative procedure (Table 4). Type I represents revisions, Type II other major hip interventions, Type III minor hip interventions, and Type IV closed reductions.

The material that has been analyzed statistically is mainly based on the revisions (Type I). The reason for this was that the incidence of other major and mi-

nor hip procedures was small. Further, Type IV interventions were not reported up to 100 percent. Closed reduction can be performed on the ward or as an outpatient procedure, and therefore may not be classified as a reoperation and reported to this study.

Thus, the results were based on 4,664 first hip revisions performed in Sweden from 1979 through 1986. In cases where the operation was performed in two stages, the data from the last operation, with insertion of a new implant, have been excluded from the material.

## Methods

The prospective multicenter study started in January 1979 after an evaluation of a national pilot study, which showed that the data on reoperations gave valuable information about serious complications after THR in Sweden (Ahnfelt et al. 1980). By defining failures as a need for a reoperation, a certain number of hips with clinical or radiographic signs of failure will not be included. The magnitude of this problem cannot be determined from the present study. Complete hospital records of all reoperated on hip replacements were sent to a coordinating center in Gothenburg. All the Swedish orthopedic and surgical departments performing total hip replacements were engaged, and the study is still running. Data from the hospital records were transferred to computer forms for further analysis.

Between 1967 and 1986, almost 80 different types of prostheses with separate registration were used in Sweden. Sixty of these are included in the revision material. The material and design of the prostheses have changed over the years, and the vast majority are cemented designs. It was considered impossible to record each type of prosthesis separately, including minor changes of the type of alloy and design, as the surgeons did not state exactly which type and design they had used at the primary operation. Only major changes to the prostheses were recorded separately.

In the Lubinus material, Lubinus IP (Interplanta) and SP (Status Physiologicus) were recorded separately. The types of implants included in the material were recorded under the names the devices had when they were inserted. Definition of the different types of Müller prostheses caused special problems. The following types were recorded in the material: The present straight stem Müller prosthesis was recorded as Müller straight. The previous Müller with the curved stem was called Müller curved. A separate group was called Charnley-Müller; these designs have a Müller type of curved stem, a head size of 32 mm, and were manufactured by different companies than PROTEK. The very first Müller prosthesis with a large head (35 mm or more) is the last separate group of the Müller design; this group was named Old Müller.

### Data preparation and processing

Data from the individual case records were transferred to a computer form for subsequent entry into the data base. To be able to fill in the computer form, access to complete case records, including the discharge summary, operative report, and outpatient records was necessary. In addition, information was obtained from temperature charts, anesthesiology charts, radiologists' reports, laboratory reports, results of any bacteriologic cultures and pathology, and scintimetric reports. The form contained 132 variables. The original computer form is still in use. A new form was filled in for each reoperation, even if the patient was reoperated on twice on the same day.

Only a few persons participated in the registration and completion of the computer form, and therefore there was reason to believe that the case records were uniformly assessed in this study between 1979 and 1986.

The data were entered into the computer at Gothenburg University Computing Center using a double-entry technique in order to eliminate registration errors at an early stage. One and the same system operator was responsible for programming and data processing. In collaboration with a biostatistician, a statistical program was developed that was used for comparative analyses.

The data forms were returned to the participating departments; and if needed, corrections were made.

### Statistical analysis

Direct comparisons between the primary and the reoperation material were not possible because the study was not prospective for all primary arthroplasties in Sweden. Patients who underwent primary hip replacements were not followed individually, accordingly information on each of these operations was not recorded. The statistical analyses were therefore based on data from each patient's reoperation in relation to information about the primary diagnosis, gender and age distribution, the number and distribution of different prostheses, use of antibiotic prophylaxis,

and surgical technique in the primary material during a given year. For the same reason, multiple analyses of variance cannot be performed. In the statistical analysis the survival of the patients was also taken into consideration. From figures obtained from the National Central Bureau of Statistics, the hazard function of death for the different age groups was calculated.

#### *Estimation of the survival function for different types of implants*

The number of implants at risk for revision at different periods after the primary operation is not known, but can be estimated. The following notations were used:

R(t) the number at risk t years after the primary operation;

N(y) the number of operations during year y;

B(x) the frequency function of age at primary operation;

d(v) the hazard function of death, where v is the age (SCB 1980);

h(t) the hazard function of revision, where t is years after the primary operation.

The functions R(t) and h(t) are unknown. The following relation (1) is used:

$$R(t) = \sum_y N(y) \int_{20}^{99} B(x) \left\{ \exp - \int_0^t (d(x+v) + h(v)) dv \right\} dx dy$$

The derivation of the expression is based on the following: The implant is no longer at risk if the patient dies or if the implant is revised. The hazard function for not being at risk is the sum of the two hazard functions. If the patient is age x at the primary operation, then, the probability of still being at risk at t years after the operation is

$$\exp - \int_0^t (d(x+v) + h(v)) dv$$

Observe that the expression for R(t) contains the unknown hazard function h. The latter is estimated by the ratio

$$\frac{\text{the number of revisions in } (t, t + \Delta)}{R(t) \cdot \Delta} \quad (2)$$

in the interval (t, t + Δ).

So h(t) can first be estimated by the quantity (2), and then R can be calculated up to t + Δ in accordance with (1), then h is estimated at t + 2Δ, and R is calculated up to t + 2Δ, etc. The proportion S(t) of surviving implants at the time t is calculated by the general relationship between survival and hazard functions.

#### *Estimation of the survival function for implants depending on diagnosis, sex, and age*

The technique of estimation is the same as when different implants are studied. However, there are more of general data about the primary operation involved for the different diagnoses. For each diagnosis, there is a distribution of age at operation applied for the estimation. Further, the sex distribution of the patients of each diagnosis is used. For the patients with rheumatoid arthritis, a special death rate is used because of their higher risk of death (Koota et al. 1977). The proportion of patients with different diagnoses is used together with the total number of operated on patients each year combined with the older information.

#### *Tests*

Comparisons between different types of implants with respect to risk of revision and test of correlation between agegroup and risk of revision are performed by a test suggested by Merck et al. (1983). The test is a generalization of the optimal one for comparison of two Poisson distributions (Lehmann 1959).

Fisher's exact test has been used for comparisons with respect to different causes of complications.

All the tests applied are two-sided.

The importance of each type of prosthesis in failures caused by aseptic loosening and deep infection was analyzed. Each type of prosthesis was catalogued with respect to the year of implantation, and the data then related to the total number of such prostheses implanted that particular year. The different types of prostheses were then compared with respect to the number of unsuccessful arthroplasties in the rest of the material. Revision was used as the measure of failure in the statistical analysis. In this way, it was possible to analyze individual types of prostheses and compare those with other types of prostheses, as well as with the rest of the material.

## Definitions

The computer form for data processing included a detailed description of the information sought for each question. For certain variables, however, there were so many codes that not all of them could be included on the form. Separate code lists have therefore been used. The computer forms are not essential to this paper, and will not be presented in full. Some of the terms included on the form are essential and therefore defined below:

*Reoperation:* Any new hip operation on a patient who has previously undergone a total hip replacement on the same side.

*Revision:* Exchange of one or both prosthetic components or removal of the implant system.

*Hip fracture:* A cervical or trochanteric femoral fracture.

If only partial exchange of the prosthesis was performed at revision (e.g., replacement of the stem or cup), this was considered the first operation for a new implant system. Questions relating to antibiotic prophylaxis, the operative environment, etc. were then referred to this operation. The same applied if both components were exchanged simultaneously.

The different causes of reoperation were defined as follows:

*Deep infection* was considered to be present when four out of five or five out of six culture samples were positive with the same bacterial growth. Hips from which bacteria had been cultured after puncture or bi-

opsy before the reoperation were also classified as being infected. A few cases in which the culture was negative at reoperation were included among the infected hips. In these cases, the surgeon expressly stated that the patient was infected because abundant pus was found at surgery and the sedimentation rate was markedly elevated.

*Hematogenous infection:* These patients did not show any signs of infection in the initial postoperative phase. After an asymptomatic period, usually lasting several years, the patients suddenly experienced pain in the operated on hip, and other sources of infection, usually the urinary tract, upper airways, or skin, could be identified. This group is underrepresented in the material, mainly because the surgeon did not expressly state that the infection was hematogenous.

*Aseptic loosening:* The prosthesis was found to be loose at the reoperation, and no infection was demonstrated. If loosening was combined with implant failure or fracture, these complications were recorded in the implant failure and fracture groups. The possibility of an infection of low virulence being recorded as aseptic loosening is discussed separately.

*Implant failure:* All the failures of prosthetic material, femoral and acetabular, were included regardless of whether the implant was loose or not at the time of reoperation. If implant failure occurred in combination with infection, it was recorded in a separate group.

## Results

### Reasons for reoperation and revision

Aseptic loosening was the main cause for both reoperation and revision, and constituted 54 percent and 74 percent, respectively, (Tables 5 and 6). The reason for revision was deep infection in 11 percent, implant fracture in 5.7 percent, technical error in 5.3 percent, and bone fracture in 3.8 percent. Over the years aseptic loosening emerged as the major problem—70% of all revisions in 1979 and 85% in 1986—whereas the problem of deep infection became smaller—20% and 7%, respectively.

The incidence of complications differed in different diagnostic groups. This was evaluated by comparing the reasons for revision or reoperation within each diagnostic group with that in the whole material (Tables 7 and 8).

The distribution of type of failure in the arthrosis and rheumatoid arthritis groups was largely the same as for the whole revision material.

Table 5. The reason for reoperation of 6,386 hips without previous revision

Type of failure	n	Percent
Aseptic loosening	3,450	54
Technical error and dislocation	1,597	25
Infection	539	8
Implant fracture	266	4
Bony fracture	192	3
Miscellaneous	342	5

Table 6. The reason for revision (Type I in Table 4) of 4,664 hips without previous revision

Type of failure	n	Percent
Aseptic loosening	3,444	74
Infection	490	11
Implant fracture	266	6
Technical error and dislocation	245	5
Bony fracture	179	4
Miscellaneous	40	1

Table 7. The reason for revision in 4,564 hips divided in the four main diagnostic groups

Type of failure	Arthrosis		Inflammatory hip diseases		Fracture		Childhood diseases	
	n	Percent	n	Percent	n	Percent	n	Percent
Aseptic loosening <sup>1</sup>	2,713	75	253	71	262	63	153	80
Infection <sup>2</sup>	363	10	43	12	54	13	10	5
Technical error <sup>3</sup>	143	4	14	4	68	16	14	7
Miscellaneous	381	11	47	13	32	8	14	7
Total	3,600		357		416		191	

<sup>1</sup>Including all types of loosening (i.e., aseptic loosening, implant fracture, loosening with bone fracture etc).

<sup>2</sup>Including all types of deep infection, primary and secondary.

<sup>3</sup>Including dislocation.

Table 8. The reason for reoperation of 6,222 hips subdivided in the four main diagnostic groups. For aseptic loosening, infection and technical error, see footnotes in Table 7

Type of failure	Arthrosis		Inflammatory hip diseases		Fracture		Childhood diseases	
	n	Percent	n	Percent	n	Percent	n	Percent
Aseptic loosening	3,045	66	295	60	288	33	162	66
Infection	394	9	53	11	58	7	11	4
Technical error	884	19	123	25	488	56	48	20
Miscellaneous	285	6	21	4	44	5	25	10
Total	4,608		492		876		246	

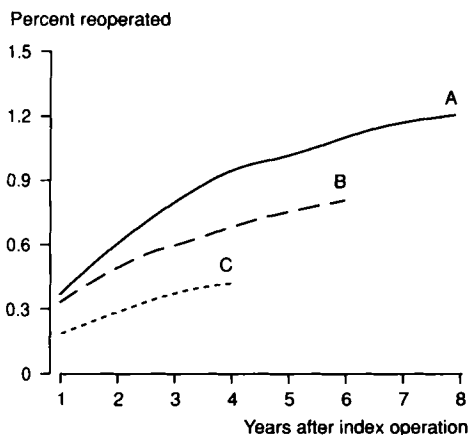


Figure 6. Cumulative infection rate for implants inserted in 1979 (A), 1981 (B), and 1983 (C). Included are only patients revised for deep infection.

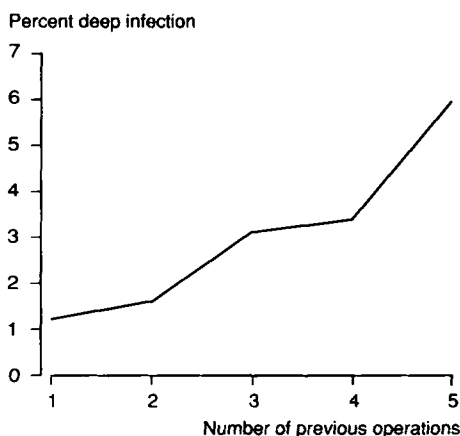


Figure 7. The relative risk of contracting a deep infection in patients with 1-5 previous surgical interventions; no patients with a previous revision for total hip replacement are included.

Table 9. The type of operative procedure undertaken in cases of deep infection (n 490)

Operative procedure	n	Percent
<b>One-stage</b>		
Exchange of both	238	49
stem	26	5
cup	22	4
<b>Two-stage</b>	144	29
<b>Permanent extraction</b>	60	12

Patients with complications after operation for hip fracture had an increased risk of technical errors, especially dislocations, and a reduced risk of aseptic loosening.

Patients with arthrosis secondary to pediatric hip disease had a reduced risk of infection in the revision material. Other causes for revision showed no differences.

#### Revision for infection

There were 490 deep infections, 33 of which were hematogenous. The mean period from primary operation to revision for infection was 2.7 years, with a standard deviation of 2.6 years.

The cumulative infection rate was calculated from the number of revisions verified to be deep infections and for implants inserted in 1979, 1981, and 1983. The infection rate in the entire revision material was 1.2 percent after 6 years. Over the years, there was an improvement with respect to deep infection (Figure 6). The different prophylactic measures introduced during these years were obviously effective. The rate of deep infection leading to revision in Sweden was less than 0.4 percent after 4 years for implants inserted in 1983.

Based on the entire reoperation material, the relative risk of contracting a deep infection increased with the number of previous operations performed on the same hip (Figure 7). The relative risk was nearly twice as high after two previous operations.

The most common operation undertaken in cases of deep infection was exchange of both prosthetic components, performed in 49 percent (Table 9). In 12 percent the components were removed without inser-

Table 10. Bacterial growth from tissue cultures in the 490 cases with deep infection

Type	n	Percent
<i>Staph. epidermidis</i>	145	30
<i>Staph. aureus</i>	121	25
<i>E. Coli</i>	36	7
<i>Streptococci</i>	34	7
<i>Propioni bact.</i>	25	5
<i>Enterococci</i>	18	4
Mixture	14	3
<i>Klebsiella</i>	14	3
<i>Peptococci</i>	10	2
Difteroid rods	9	2
<i>Pseudomonas</i>	9	2
<i>Proteus mirabilis</i>	7	1
<b>Others</b>	19	4
<b>Negative culture</b>	29	5

tion of a new implant. Some cases were mistaken as aseptic loosening, and only one of the components was exchanged, which eventually resulted in extraction of both components during the observation period in 18 out of 48 cases.

Tissue cultures in the infected cases revealed growth of *Staphylococcus aureus* and *albus* in 54 percent, gram negative bacteria in 14 percent and anaerobic bacteria in 10 percent. The remaining cultures consisted of *Streptococcus*, *Enterococcus*, and *Mycobacteria tuberculosis*, sometimes in combinations (Table 10).

### Revision for aseptic loosening

The material included 3,444 revisions performed because of aseptic loosening without implant and bone fracture. Figure 8 illustrates the cumulative rate of revision because of aseptic loosening for implants inserted in the years 1977, 1979, and 1981. In this calculation the Christiansen prosthesis and the resurfacing prosthesis (i.e., Wagner, Indiana, and ICLH) were excluded due to their uniformly poor results. All the other prostheses used in Sweden during these 3 years were included. At 9 years, the revision rate for aseptic loosening was 6 percent. There was no difference in the results of operations performed in any one of these 3 years; at 5 years the revision rates were almost exactly the same for the three groups. Unfortunately, the results cannot be used to determine the effect of cementing techniques. The modern cementing technique was only used by a few departments in Sweden in 1981.

The mean time to revision due to aseptic loosening was 6 years.

The surgical treatment in patients with aseptic loosening was exchange of one or both prosthetic components in more than 95 percent of the patients. The patients' primary diagnosis did not influence the type of revision as shown in Table 11. The significant

Table 11. Surgical treatments (percentages) in patients with aseptic loosening in 1,788 cases of arthrosis (OA) and 167 cases with rheumatoid arthritis (RA)

	OA		RA	
	< 65	> 65	< 65	> 65
Exchange of both	58	55	52	28
stem	33	34	28	28
cup	7	7	17	30
Permanent extraction	2	4	3	14

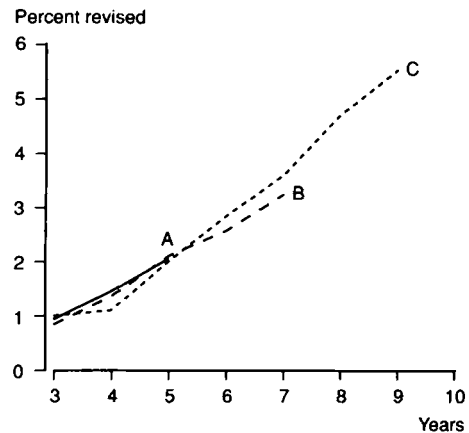


Figure 8. Cumulative rate of revision for aseptic loosening of implants inserted in the years 1977 (C), 1979 (B), and 1981 (A). The Christiansen and the resurfacing prostheses are excluded.

increase in loosening of the acetabular component in the older rheumatoid arthritis group corresponded to results reported earlier by Carlsson et al. (1983).

The diameter of the head of the femoral component did not influence the rate of loosening. We compared the Charnley (22 mm) and the Lubinus IP (32 mm) and found no difference in revision rate due to aseptic loosening and type of revision.

### Revision for implant fracture

Implant fractures occurred in 266 hips. Two were combined with deep infections. Two hundred and thirty of the fractures were on the femoral stem and the remaining 36 on the acetabular component. The mean time from implantation to revision for this diagnosis was 8 years.

Stem fractures occurred in all the older types of prostheses provided that there were at least 100 prostheses implanted in the primary material. Most of the fractures involved prostheses implanted between 1972 and 1977. Copies of different original devices were widely sold in Sweden during that period. This was especially the case for the Charnley and the Charnley-Müller devices. There was no reported stem fracture of an original Protasul® prosthesis. One of the implant fractures involved a detachable ceramic head component of an Osteal prosthesis.

## Patient-related parameters

### Age distribution

The median age were 2 years higher for women than for men at the time of revision (Table 12). The age distribution in the arthrosis group is similar to that of the total material. Patients with complications after hip fracture were older, and the rheumatoid arthritis and the congenital hip dislocation group were younger.

Table 12. Median age at primary THR and revision, sex and side distribution in 3,600 hips with osteoarthritis (OA) and 357 hips with inflammatory hip disease, 416 hips with previous fracture, and 191 cases with osteoarthritis secondary to childhood disease of the hip

Diagnose	Arthrosis	Arthritis	Fracture	Childhood diseases
<b>Median age at primary THR</b>				
Women	64	53	61	54
Men	66	56	68	48
<b>Median age revision</b>				
Women	70	61	65	58
Men	72	63	73	55
<b>Men (percentage)</b>				
Women	58	37	29	27
<b>Women (percentage)</b>				
Right	42	63	71	73
<b>Right (percentage)</b>				
Left	55	52	44	53
<b>Left (percentage)</b>				
	45	48	56	47

Table 13. The different types of previous operations performed on the 4,664 revised cases

Previous operations	n
Osteosynthesis for hip fracture	409
Osteotomy	232
Endoprosthetic hip arthroplasty	184
Arthrodesis	23
Resection arthroplasty	10

Table 14. The reason for revision in patients previously operated on with osteotomy, endoprosthesis, and hip fracture in comparison with the group without previous surgery

Type of failure	Osteotomy		Endoprosthesis		Hip fracture		No previous surgery	
	n	Percent	n	Percent	n	Percent	n	Percent
Aseptic loosening	183	79	135	73	257	63	2,769	76
Infection	18	8	25	14	56	14	350	10
Technical error	13	6	14	8	61	15	109	3
Miscellaneous	18	8	10	5	35	9	411	11
Total	232		184		409		3,639	

### Sex distribution

There was a slight dominance of women (51 percent), which accords with the sex distribution in the Swedish population. The sex distribution was different, however, if allowance was made for the patient's primary diagnosis (Table 12). For primary arthrosis and arthrosis secondary to trauma of the hip, there was a male dominance. This indicated a higher rate of aseptic loosening in males, as the sex distribution in primary materials for arthrosis in Sweden was 2/3 for men and women. For rheumatoid arthritis, complications after hip fracture, and congenital hip dislocation, there was a marked female dominance.

### Side distribution

As in most other reported materials, our study showed that the right side dominated when the reason for the primary replacement was disease and the left side when it was injury (Langan 1979, Ansorge and Hack 1983).

### Previous surgical intervention

The most common previous operation was internal fixation of a fracture. Previous femoral osteotomy and insertion of an endoprosthesis in the femoral shaft was uncommon (Table 13). Previous hip fracture reduced the risk for aseptic loosening and increased the risk of dislocation, as well as increased the risk for deep infection. The risk of infection was also increased in the endoprosthetic group ( $p < 0.05$ ). The risk of dislocation was increased if the patient had previously undergone hemiarthroplasty (Table 14).

*Patient-related factors and prosthetic survival*

Failure due to aseptic loosening in patients with arthrosis is illustrated in Figures 9 and 10 for men and

women in different age groups. For each age group the number of hips included at the start (Year 1) is depicted, the asterisks on the curves indicate a 50 percent reduction in number of analyzed hips. None

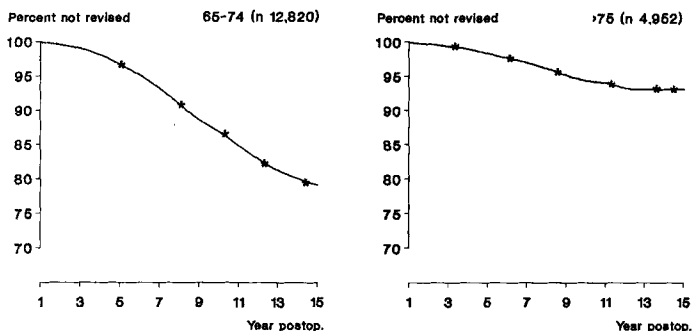
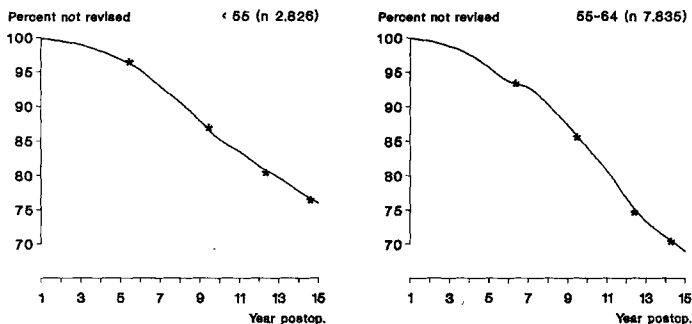


Figure 9. Survival rate for men with the primary diagnosis osteoarthritis and in different age groups. n indicates the number of hips included at the start. \* Indicates 50 percent reduction in number of analyzed hips.

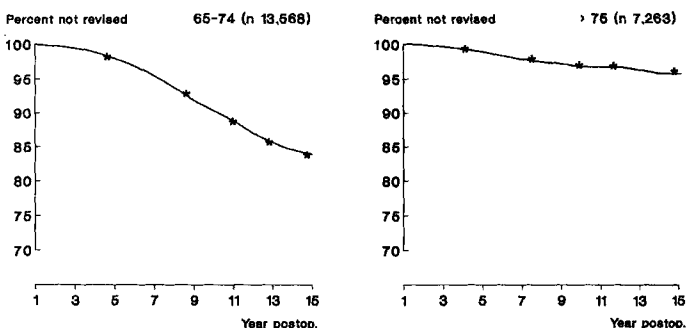
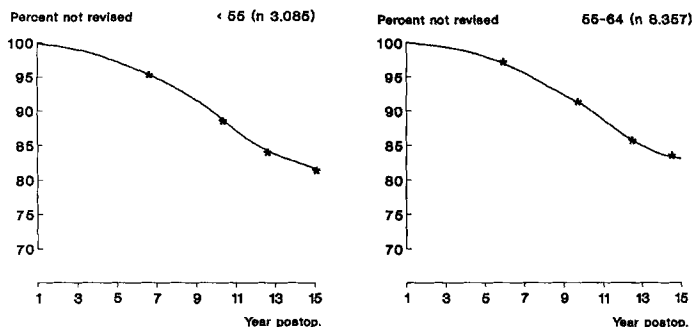


Figure 10. Survival rate for women with the primary diagnosis osteoarthritis and in different age groups. n indicates the number of hips included at the start. \* Indicates 50 percent reduction in number of analyzed hips.

of the curves is followed when less than 20 hips remain in a specific group. This was done in accordance with Dorey and Amstutz (1986), who have drawn attention to the risk of misleading interpretation of the right-hand tails of these curves. The

figures show that men had more aseptic loosening than women in all the age groups.

Young patients with rheumatoid arthritis had more aseptic loosening among both sexes (Figures 11 and 12). Also, in this group, men had more loosening

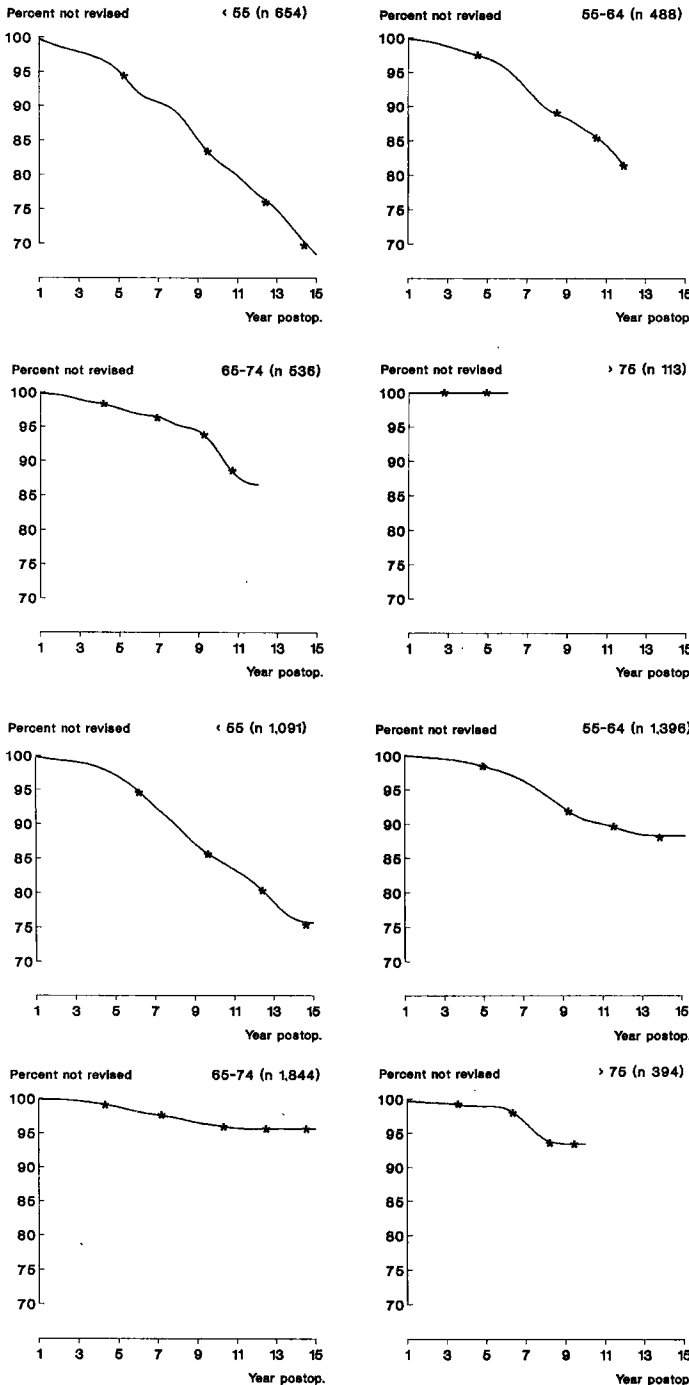


Figure 11. Survival rate for men with the primary diagnosis rheumatoid arthritis and in different age groups. n indicates the number of hips included at the start. \* Indicates 50 percent reduction in number of analyzed hips.

Figure 12. Survival rate for women with the primary diagnosis rheumatoid arthritis and in different age groups. n indicates the number of hips included at the start. \* Indicates 50 percent reduction in number of analyzed hips.

than women except above 75 years of age.

For patients with a previous hip fracture, there was a striking difference between the different age groups; men had an extremely high percentage of aseptic loosening in the youngest age group (Figures

13 and 14).

Comparing the four different age groups within the three diagnostic groups, we found the following relations. In the arthrosis group the men aged 55–64 years had the highest risk for revision; the group

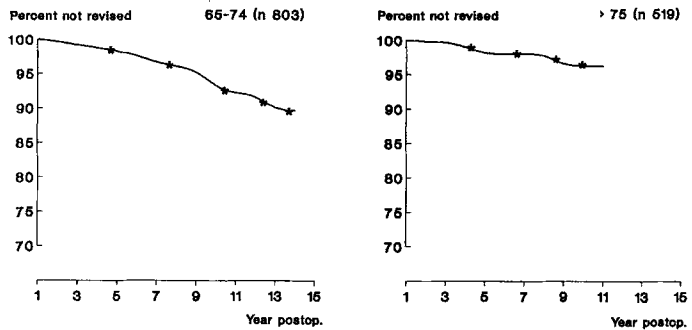
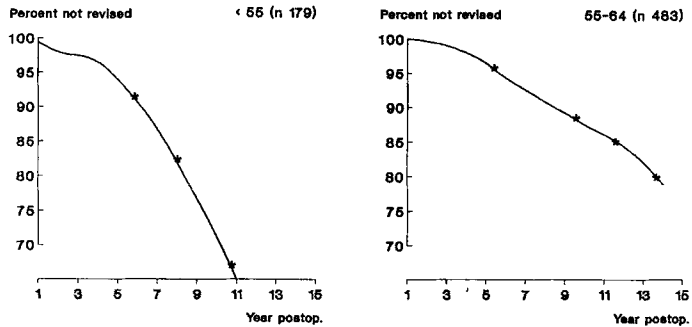


Figure 13. Survival rate for men with the primary diagnosis hip fracture and in different age groups. n indicates the number of hips included at the start. \* Indicates 50 percent reduction in number of analyzed hips.

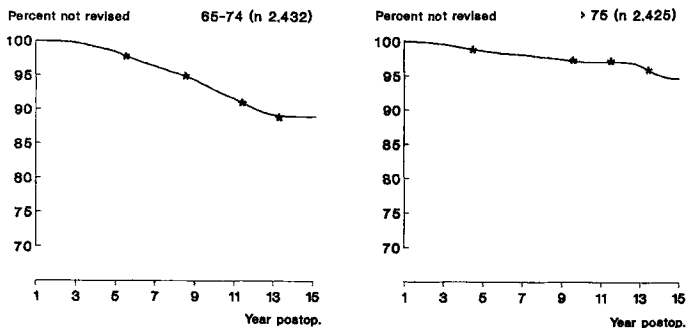
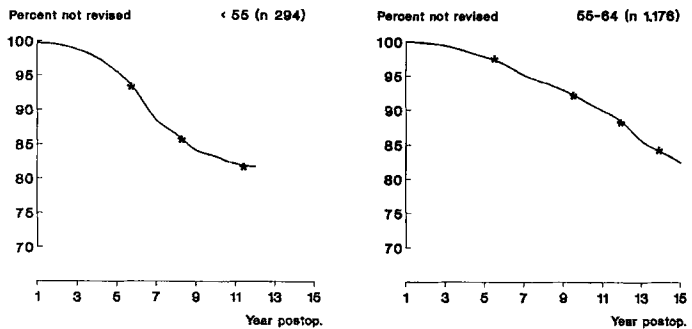


Figure 14. Survival rate for women with the primary diagnosis hip fracture and in different age groups. n indicates the number of hips included at the start. \* Indicates 50 percent reduction in number of analyzed hips.

Table 15. The 15 most commonly revised implants in Sweden 1967–1987

Type of prosthesis	Year	Total	Revised
Christiansen	73–83	5,095	1,365
Charnley	68–86	24,499	971
Brunswick	70–86	5,674	483
Lubinus IP	77–86	14,736	428
Charnley-Müller	70–86	2,951	288
McKee-Farrar	68–79	2,510	250
Müller, curved	71–80	1,699	214
Wagner	77–83	399	149
Stanmore	72–86	1,917	101
Müller, straight	79–86	1,732	57
CAD	76–86	1,895	48
Exeter	80–86	4,054	38
Richard II	79–84	613	34
McKee-Arden	79–82	194	33
Lubinus SP	82–86	2,731	18

below aged 55, the group 65–74 years, and the group over aged 75 had a successively reduced risk of aseptic loosening. For women with arthrosis the risk of revision for aseptic loosening decreased with increasing age, significant differences existed between the four observed groups ( $p < 0.001$ ). We found the same relation in the hip fracture and rheumatoid arthritis groups; the younger and more active patients had an increased risk of revision due to aseptic loosening.

## Nonpatient-related parameters

### Type of implant

The most common types of prostheses used in the primary THR in the 4,664 revised hips are listed in Table 15, as well as the number of primary implanted hips during the period 1968–1986.

The survival curves with respect to type of implant were, however, calculated using the primary THRs from 1974–1986.

There were no differences between different implants when failure leading to revision for infection was analyzed. There were obvious and statistically significant differences between various implants with respect to revision for aseptic loosening.

The statistical comparison between the different types of implants was as mentioned on page 15 performed by a test suggested by Merck et al. (1983), and the prostheses implanted from 1974 onward were included in the analysis (Figure 15). Only the

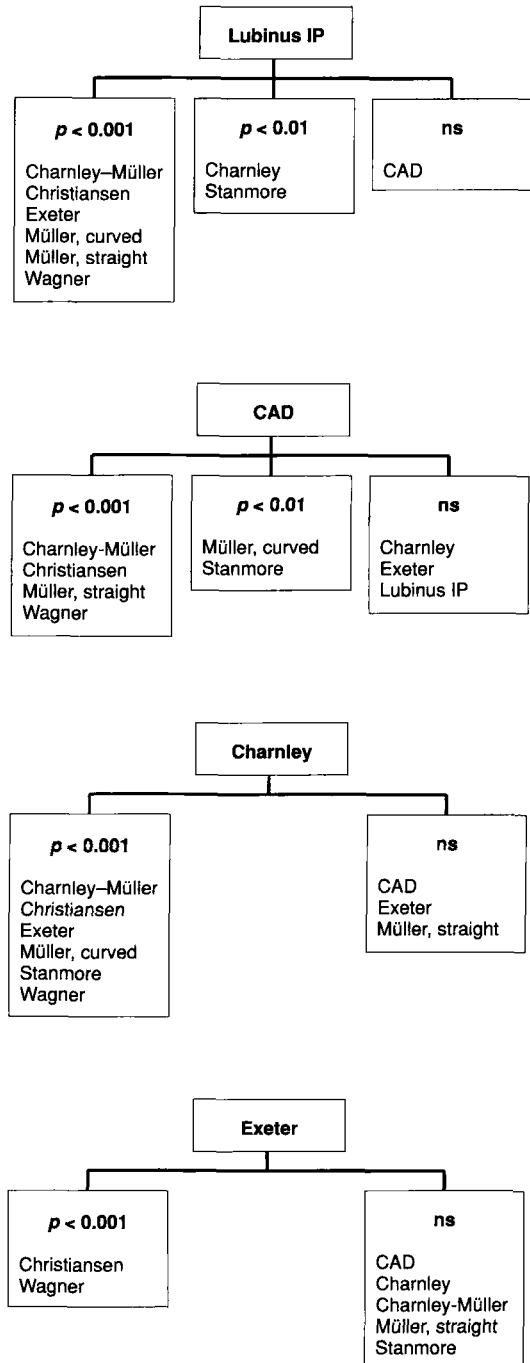
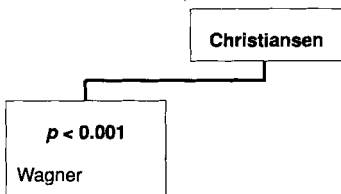
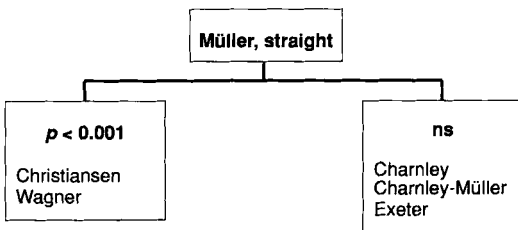
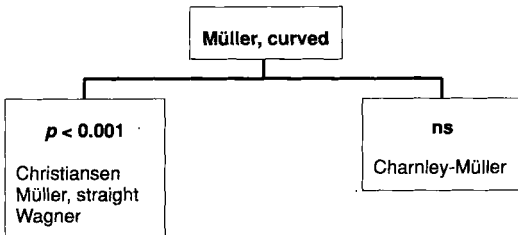
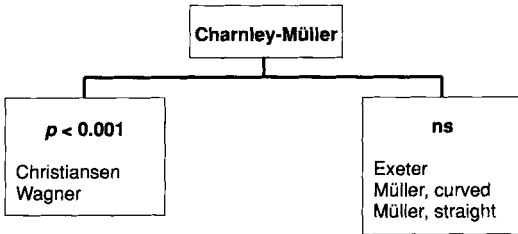
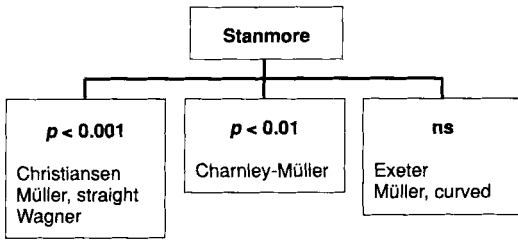


Figure 15. Comparison of 10 different implants with respect to risk for revision for aseptic loosening. The figure should be interpreted as follows. The prosthesis placed at the top level is superior with significance level of  $p < 0.001$  to the prostheses placed underneath that window and superior with  $p < 0.01$  under that window. No significant difference with respect to prostheses listed underneath the window with ns.



patients revised because of aseptic loosening are included (no stem fracture included). The prostheses are compared year by year when the primary implant was inserted, and therefore no comparison has been done between prostheses not used in the same time period. Comparison was done between 10 prostheses, and the Lubinus IP had the least risk for revision due to aseptic loosening. The CAD performed extremely well, and even the Charnley and Stanmore prostheses showed good results. In an intermediate group, we found the Charnley-Müller, the Müller straight, the Müller curved, and the Exeter. The Christiansen prosthesis and the double-cup devices, here represented by the Wagner prosthesis, formed a separate group with the highest risk of loosening.

For the most commonly used implants, survival curves were also calculated. In this analysis the calculations were made with revision for aseptic loosening as the end-point and definition for failure. In the survival curves are included prostheses inserted from 1974 onward. The results are illustrated in Figures 16-25. On the figures are indicated the numbers of observation years for 4 different years for each prosthesis. The observation years approximate fairly well the numbers of primary hips operated on with the specific prosthesis in the different years.

The Charnley, CAD, and Lubinus IP prostheses performed well over the years. At 10 years, the observed survival without revision for aseptic loosening was 92 percent for the Charnley prosthesis. At 9 years, the survival for the Lubinus IP prosthesis was 93 percent and for the CAD prosthesis 95 percent at 8 years. The observed survival at 10 years for the Stanmore device was 89 percent and for the Charnley-Müller device 85 percent. The Müller curved showed at 10 years a survival rate of 84 percent. At 5 years we found a survival for the Exeter device of 95 percent and for the Müller straight at 6 years 95 percent.

The most disastrous implant designs that were used in Sweden were the Christiansen trunnion-bearing and the Wagner resurfacing prostheses. At 10 years, the observed survival for the Christiansen prosthesis was 63 percent and for the Wagner prosthesis it was 28 percent.

The Christiansen prosthesis which was a trunnion-bearing device, became very popular for a short time in Sweden in the late 1970s. More than 5,000 such prostheses were implanted during the course of a 5-year period, most of them between 1976 and 1980. Up to 1986, 1,524 Christiansen prostheses used in primary and revision surgery were revised. The survival analysis predicts that a further 200 prostheses will be revised during the next 4 years.

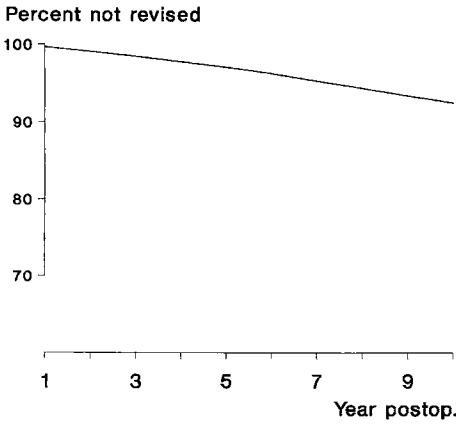


Figure 16. The observed survival for the Charnley prosthesis.  $n_{\text{year } 1} = 15,520$ ;  $n_3 = 11,380$ ;  $n_6 = 6,354$ ; and  $n_{10} = 1,799$ .

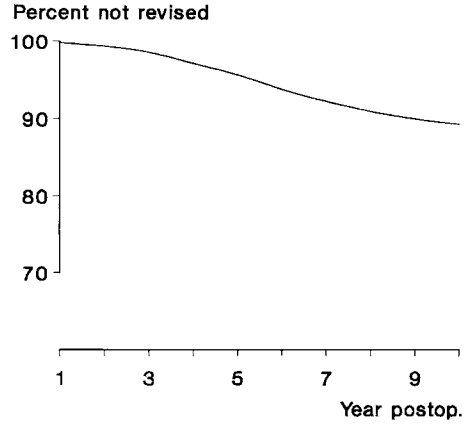


Figure 19. The observed survival for the Stanmore prosthesis.  $n_{\text{year } 1} = 1,352$ ;  $n_3 = 1,118$ ;  $n_6 = 720$ ; and  $n_{10} = 157$ .

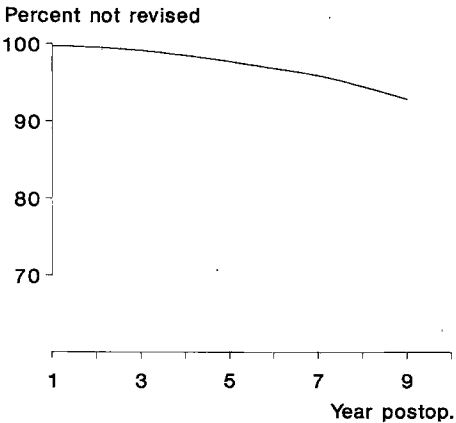


Figure 17. The observed survival for the Lubinus IP prosthesis.  $n_{\text{year } 1} = 13,493$ ;  $n_3 = 10,227$ ;  $n_6 = 3,627$ ; and  $n_9 = 287$ .

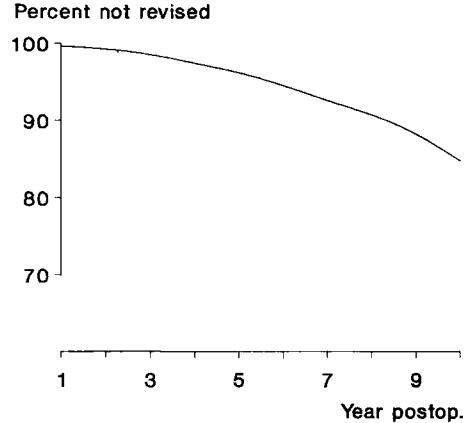


Figure 20. The observed survival for the Charnley-Müller prosthesis.  $n_{\text{year } 1} = 1,570$ ;  $n_3 = 1,967$ ;  $n_6 = 1,492$ ; and  $n_{10} = 511$ .

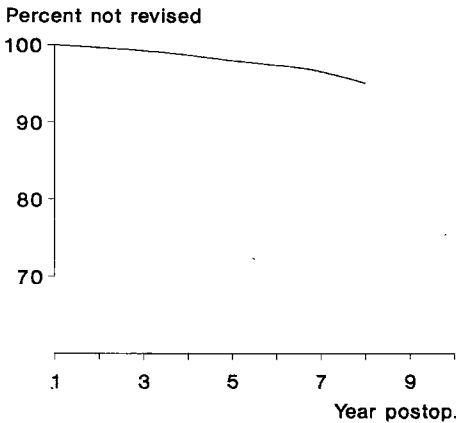


Figure 18. The observed survival for the CAD prosthesis.  $n_{\text{year } 1} = 1,748$ ;  $n_3 = 1,300$ ;  $n_6 = 775$ ; and  $n_8 = 165$ .

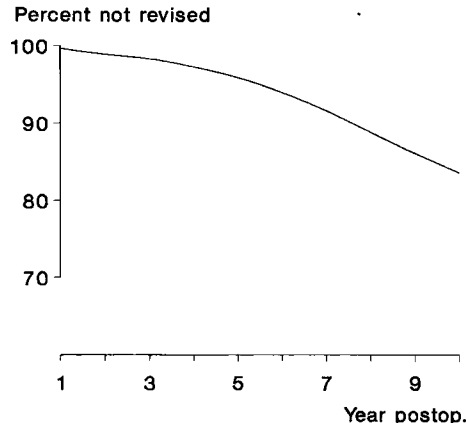


Figure 21. The observed survival for the Müller curved prosthesis.  $n_{\text{year } 1} = 847$ ;  $n_3 = 1,215$ ;  $n_6 = 1,166$ ; and  $n_{10} = 385$ .

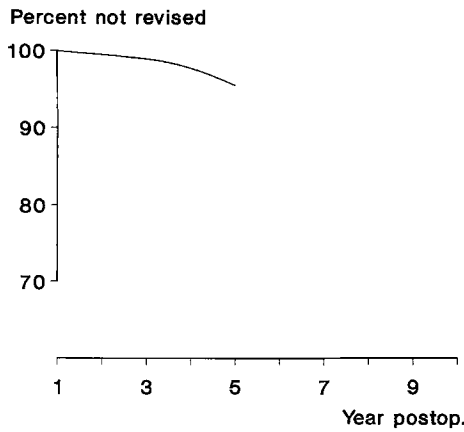


Figure 22. The observed survival for the Exeter prosthesis.  $n_{\text{year } 1} = 2,756$ ;  $n_3 = 837$  and;  $n_5 = 74$ .

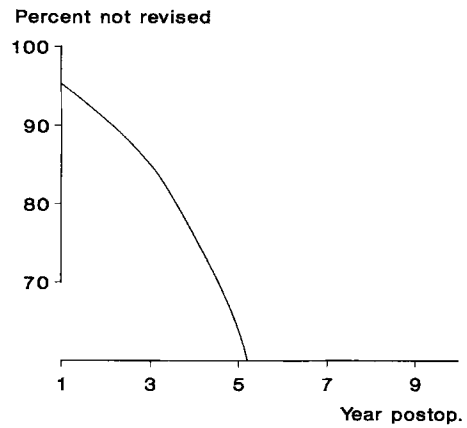


Figure 25. The observed survival for the Wagner prosthesis.

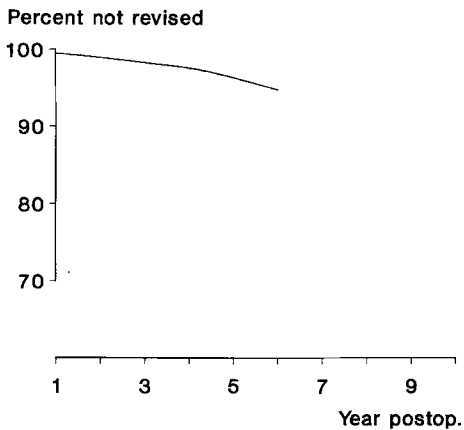


Figure 23. The observed survival for the Müller straight prosthesis.  $n_{\text{year } 1} = 1,477$ ;  $n_3 = 937$  and;  $n_6 = 117$ .

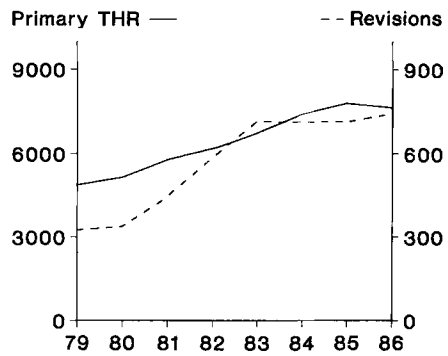


Figure 26. The total number of primary total hip replacements (y-axis to the left) and the total number of revisions (y-axis to the right) in the period 1979-1986.

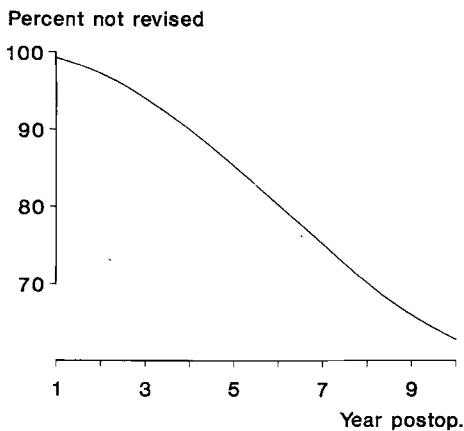


Figure 24. The observed survival for the Christiansen prosthesis.  $n_{\text{year } 1} = 3,825$ ;  $n_3 = 4,414$ ;  $n_6 = 3,205$ ; and  $n_{10} = 491$ .

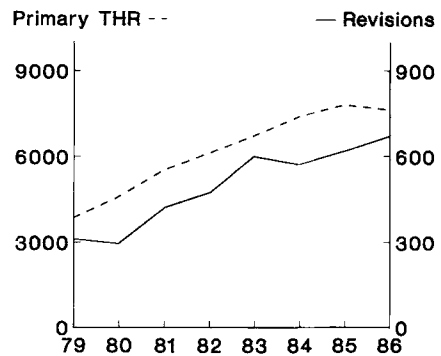


Figure 27. The same as Figure 26 but excluding the Christiansen device.

In order to evaluate the influence of the Christiansen prosthesis on the incidence of revision in Sweden, the material was analyzed after excluding both primary and revision THRs with this implant. In Figures 26 and 27, the number of revisions with and without the Christiansen prosthesis is compared with the number of primary operations performed each year with and without this device. The figures illustrate that if this prosthetic type had not been introduced in Sweden, the increase in the number of revisions over the years would be much less, and would parallel the increase in the number of primary arthroplasties.

#### *Type of hospital*

The rates of revision for aseptic loosening and deep infection were compared between different types of hospitals. Statistical differences were found between three different types of hospitals: university hospitals (tertiary hospitals), regional hospitals (secondary hospitals), and community hospitals (primary hospitals).

University hospitals reported more infections than the other two groups. The reason could be the selection of special problem cases that demanded long-term and extensive procedures.

When comparing aseptic loosening among all the prostheses except the Christiansen prosthesis and the surface replacements, the regional hospitals did better than the others ( $p < 0.001$ ).

#### *Operating surgeon*

The material was analyzed in relation to the surgeon who implanted the primary prosthesis. Information on the number and type of primary prostheses a certain surgeon had implanted each year was available for 37 surgeons. These orthopedic surgeons mainly worked at Malmö General Hospital or Sahlgren Hospital and East Hospital in Gothenburg. Information on specific surgeons working at community hospitals was also available. Most of the latter had performed all the orthopedic surgery at their hospitals during long periods. All the surgeons were categorized as experienced surgeons and performed 30 to 70 hip arthroplasties annually.

The double-cups (surface replacements) and the Christiansen prostheses were excluded, knowing that these prostheses could misbalance the analysis. Considering aseptic loosening, there were some statistical differences. Two of 33 surgeons had fewer complications of aseptic loosening than the others and 1 had more ( $p < 0.001$ ) reoperations than any of the others. Most surgeons performed equally well.

If the complications were analyzed considering the number of performed primary prosthetic operations per year, there were no statistical differences. One should consider that all of these surgeons were well trained and experienced, and the number of complications due to dislocation were very few and with no statistical differences, with one exception. This special surgeon had a higher incidence of dislocation after primary hip arthroplasty even though he performed more than 200 primary operations a year.

## Discussion

The primary reason for multicenter investigations on hip arthroplasty is the need to have access to a large number of patients. The size of the material needed in order to be able to draw scientifically valid conclusions strongly supports the multicenter approach. The results thereby represent a mixing of the departments, and they are more applicable to the mean or median departments than a single center study.

In order to study all complications after THR, each patient undergoing total hip replacement would have to be followed prospectively. The number of arthroplasties performed in Sweden each year is so high that it is impossible to follow every single patient without a very expensive and complex system. It therefore seemed logical to concentrate on a registration of failures necessitating further surgery. Reoperations are the worst-case scenarios for complications and as such do not provide complete information about the prevalence of all the complications. The patient's age and the physician's willingness to perform a second operation certainly will also influence the results. Nevertheless, we feel that recording and analysis of reoperations provide a good estimate of severe complications. This view is shared by many investigators, and in several studies the rate of reoperation has been recommended as a good estimate of the rate of serious complications after total hip replacement (Nolan et al. 1975, Gronert et al. 1975, Wolf 1978, Morscher and Schmassmann 1983, Pellicci et al. 1985). The pilot study performed in 1977 allowed us to test our assumption, and showed that the method was suitable and gave reliable information on the occurrence of serious complications. A great interest to participate was also expressed by the Swedish orthopedic surgeons (Ahnfelt et al. 1980).

The present study was administered and monitored by a coordinating center in Gothenburg. The administrative burden on the individual hospitals was minimized by only requiring them to send copies of case records. This proved to be a great advantage, and 100 percent participation of the relevant hospitals in Sweden was achieved. To encourage the hospitals to continue their participation, the coordinating center provided annual reports to each hospital. These reports also served as a means of checking that the information entered into the data base was correct. Only a few individuals were responsible for filling in, recording, and documenting the computer forms.

Interpretation of complications was thus uniform and independent of where and when the patient was reoperated on.

Galante (1985) discussed the need for a standardized system for evaluating the results of hip arthroplasty. At present, different scoring systems are used (Harris 1969, Charnley 1979), but the problem is that the different systems are not comparable (Andersson 1972).

During recent years, it has been stated (Dobbs 1980, Dorey and Amstutz 1986, 1989) that probably the best solution to the problem of reporting results after joint replacements is to use survival analysis. Both Amstutz and Dobbs emphasized the importance of defining criteria of survival or failure precisely before analyzing the results.

Survival analysis is usually performed using the method described by Kaplan and Meier (1958). The observed number of complications during a certain number of years is plotted on a diagram after excluding the natural dropout. The slope of curve is used to calculate the survival during a nonobserved period. The use of Kaplan-Meier curves presupposes that the investigator states the exact period during which the observations were made, upon which calculation the survival curve is based. Many are careless about giving this very important information when presenting their results. Dorey and Amstutz (1989) concluded that in spite of a high percentage lost to follow-up the survivorship analysis is a valid technique to use in long-term evaluation of patients who have had a joint replacement.

The material was representative for all of Sweden with respect to complications of Types I and II. After 8 years' data collection, no hospital had yet pointed out that revisions (Type I) or major surgical procedures (Type II) are missing in the material. Minor surgical procedures (Type III) and closed reductions (Type IV) had almost certainly not been completely reported as discussed on page 10.

### Patient-related factors

There are only a few reports in the literature describing side distribution of hip affections. Danielsson (1964) found a right-side preponderance for arthrosis,

Langan (1979) a right-side preponderance for rheumatoid arthritis, and Ansoorge and Hack (1983) a left side preponderance for hip fractures. Among our reoperations, we also found a left side dominance for hip fractures (56 percent) and a right side dominance for arthrosis (55 percent) and inflammation of the hip joint (52 percent). The literature offers no explanation of these differences.

Regardless of the primary diagnosis, the incidence of revision after primary hip replacement differed between the sexes at different ages. This factor was analyzed in different diagnostic groups. For patients with arthrosis, men had more aseptic loosening than women in all the age groups. Body weight could be a factor explaining the difference but also factors related to the implant loading. The younger and more active patients had more loosening than elderly, presumably because of mechanical reasons. There was, however, one exception. Men between 55 and 64 years of age were revised more frequently for aseptic loosening than patients younger than 55 years. There is no obvious explanation for this observation. The diagnosis primary arthrosis might be wrong in this young group of patients. It is probably a mixture of primary arthrosis and arthrosis secondary to congenital disorders. The patients with congenital diseases of the hip have a lifestyle of low activity and will not after total hip replacement raise their activity level as much as the patient with a few years' disability after a primary arthrosis. Furthermore, a restrictiveness in operating on young patients would leave the bilateral diseased patients with an unoperated on contralateral side that will set a limit for the physical activity. The significant increase in aseptic loosening in the younger patient compared with the older patients and male compared with female accords with the findings of several authors (Carlsson and Gentz 1980, Chandler 1981, Olsson et al. 1981, Collins 1982, Stauffer 1982, Sutherland et al. 1982, Dorr et al. 1983, Cornell and Ranawat 1986, Mjöberg et al. 1986, Johnsson et al. 1988). In the present study, it was, unfortunately, impossible to clearly evaluate whether it was a cup or a stem loosening that was leading to revision.

For rheumatoid arthritis the results were similar, and young patients did worse among both sexes, probably because of mechanical reasons. Especially the acetabular component in rheumatoid arthritis is at risk of loosening. For RA patients below aged 65 years, we found a 17 percent exchange rate of the cup, compared with 7 percent in the osteoarthritis group. Thirty percent of the patients over aged 65 years were revised with a cup exchange compared with 7 percent in the arthrosis group. This agrees with the results reported by Unger et al. (1987), who found

in a radiographic analysis five times more loose acetabular components compared with the femoral stems in a 10-years follow-up. The main reason for this finding is probably insufficient bone quality.

For patients with a previous hip fracture, the results were especially disastrous for young men. Most likely these patients were otherwise healthy, and therefore after successful replacement they returned to a normal and, from the replacement point of view, too high an activity after the replacement. The young patient with a hip fracture quite often has a history of alcohol abuse and metabolic disorders with secondary osteomalacia. These factors in combination with a high activity level could explain the high rate of aseptic loosening.

The distribution of primary diagnoses in the revision material (Table 16) was comparable to that observed in other large materials (Olsson et al. 1981, Salvati et al. 1981, Stauffer 1982, Surin and Sundholm 1983). In each diagnostic group the reason for revision varied. The statistical analyses were done between the different diagnostic groups and the whole material. There were no significant differences between aseptic loosening in the osteoarthritis group compared with the rheumatoid arthritis and fracture groups. Although patients with rheumatoid arthritis are known to have up to a three times higher risk of infection than arthrosis patients (Poss et al. 1984), we could not confirm this in the present study. Multiple joint destructions and low grade of activity probably explained the low incidence of revision for aseptic loosening among patients with rheumatoid arthritis.

Somewhat surprisingly, the elderly patients previously operated on, often several times, because of hip fractures did not have an increased rate of reoperation due to infection. The most probable explanation is that many of these patients actually did have an infection, but were never reoperated on because of poor general health and old age. Furthermore there are an obvious risk that these old patients die before the infection is diagnosed.

The older patients with hip fracture were less often operated on because of loosening, which may reflect low activity and low body weight. The increased risk of dislocation in this group of patients had been pointed out in previous studies (Carlsson and Gentz 1977, Lindberg et al. 1982) and was confirmed in our study. The reason may be poor muscle control and postoperative confusion.

There was a tendency for patients with congenital hip dislocation to be reoperated on more often because of aseptic loosening. For these patients the operative procedures can be demanding both with respect to the stem and the socket, which contributes to

aseptic loosening. A meticulous operative technique and bone transplantation may improve the situation for this group of patients in the future (Chandler et al. 1981, Dorr et al. 1983, Capello et al. 1984, Gordon et al. 1985, Trancik et al. 1986).

The risk that the primary hip arthroplasty will be revised for loosening was related to previous hip surgery. After femoral osteotomy, revision for loosening was somewhat more common. The osteotomy may have caused changes in the anatomy of the proximal femur, thereby reducing the opportunity for good cementing technique and optimal placement of the prosthetic stem.

### Infection and aseptic loosening

The Swedish reoperation material showed that current infection prophylaxis was quite acceptable. The overall infection rate was about 1 percent after 8 years in all types of primary hip replacements. We studied the cumulative infection rate for implants inserted in 1979, 1981, and 1983. There was a significant improvement with respect to this serious complication indicating that different prophylactic measures had been effective. In Lidwell's (1987) multicenter study of the occurrence of infection in different operative environments, systemic antibiotics alone gave an infection rate of 0.85 percent with a mean follow-up of 2 years. If ultraclean air ventilation and systemic antibiotics were combined, the infection rate was reduced to 0.4 percent. Lidwell's material included both hip and knee arthroplasties, and the main indication was osteoarthritis. The patients had not undergone previous surgery on the joint in question. The corresponding figure for patients with coxarthrosis in the Swedish material was 0.3–0.5 percent after 4 years when operations were performed under all types of infection prophylaxis and data were pooled.

Arthrography and scintimetry have been used for differential diagnosis of infection and loosening. Arthrography was only performed in 20 cases and the efficiency of this diagnostic tool cannot be evaluated. Scintimetry of reoperated on infected patients showed an increased uptake around the prosthesis in 86 percent. Eleven percent showed a normal uptake in spite of subsequent positive culture. Of the patients with aseptic loosening, 72 percent showed an increased uptake around the prosthesis. The method is thus of no help in the differential diagnosis of infection and aseptic loosening, as also found by Kamme and Lindberg (1981) and Uri et al. (1984). Scintimetry is a diagnostic method with high sensitivity but

poor specificity, and has its main value as a screening tool. The type of scintimetry has not been specified, and therefore we cannot compare the specificity of, e.g., technetium versus gallium scintimetry.

Glynn and Sheehan (1983) pointed out the risk of a deep infection developing in patients with large post-operative hematomas. This material supports this observation, as more than a quarter of the patients operated on because of a deep infection had developed some form of wound complication after the primary operation. Also superficial wound infections were more common among patients who later developed a deep infection, which supports the observations by Surin and Sundholm (1983). Only 5 percent of the patients with other reasons for reoperations, such as loosening, developed wound problems after the primary operation. The erythrocyte sedimentation rate (ESR) is a useful method of distinguishing infection from mechanical loosening (Carlsson et al. 1977, Forster and Crawford 1982, Sanzén 1988), but it is not specific. The difference between the ESR before reoperation and before the primary hip arthroplasty rarely exceeded 40 mm in patients reoperated on for aseptic loosening in this material (18 out of 1,130). The ESR difference was less than 20 mm in 74 out of 285 infections in spite of the presence of a deep infection with positive cultures.

The cumulative rate of revision for aseptic loosening was calculated for implants inserted in 1977, 1979, and 1981, excluding the Christiansen prosthesis. The results obtained was an accurate picture of loosening for all the other prostheses. At 9 years, the revision rate for loosening is 6 percent. There was no significant difference in the revision rate for operations performed during these 3 years, which were prior to the improved cementing techniques currently in use. This cumulative rate of revision for aseptic loosening is comparable to several other long-term follow-ups in the literature (Salvati et al. 1981, Stauffer 1982, Johnsson et al. 1988).

Russotti et al. (1988) showed in a clinical and radiographic review of 251 consecutive cemented THR the effect of using contemporary technique and prosthetic designs. No revision and no reoperation were performed in the series, and 98 percent of the patients had an excellent result with a 5-year minimum of follow-up. They suggest that results from a study of cemented THR using contemporary technique and prosthetic designs should represent the standard for comparison when evaluating alternative total hip replacement systems, i.e., cementless techniques.

## Implant-related factors

Certain types of prostheses cannot be compared to others statistically because they were used during different time periods. Also the statistical methods used for comparison of different types of prostheses does not permit the comparison of very large materials with small materials. The approximations made become so great that mathematical comparison of such data is meaningless.

In their study of infection after total hip replacement, Josefsson et al. (1981) reported a high rate of early loosening associated with the Christiansen prosthesis. Loosening occurred about 2–3 years earlier than with other prostheses. Surprisingly enough, no reports that the prosthesis was associated with an increased rate of loosening had then come from Norway, although the prosthesis had been used there for many more years.

There were several reasons for the high rate of loosening with the trunnion-bearing Christiansen arthroplasty. The sharp angle between the stem and neck probably increased the load on the bone-cement interface and thereby initiated stem loosening. The 37-mm-diameter head also necessitated a large, but thin-walled socket. Such a design resulted in variation in the load in the cement-bone interface, thereby contributing to loosening of the cup. The plastic material (Delrin®-polyacetate) of the socket is probably the main cause in the Christiansen loosening catastrophe. The wear of this material causes an usually powerful synovial reaction, where the fibrin actively breaks down the bone tissue (Mathiesen et al. 1983). Mathiesen et al. (1986) suggested that an increased wear, possibly in combination with a poorly polished head, is the most probable mechanism of loosening in the Christiansen total hip arthroplasty. Ohlin and Persson (1989) analyzed 18 cases of the Christiansen prosthesis with isolated socket loosening and found an average socket wear of 0.4 mm per year. They found in all the cases an obvious bone resorption beneath the collar of the stem, and concluded that the socket wear led to a foreign-body reaction with bone resorption, and that this was the main cause of the failures noted with the Christiansen prosthesis.

It is obvious that the Christiansen experience in Sweden is important and that implants without clinically well-documented behavior should not be widely introduced. If the cost of one revision due to aseptic loosening is USD 12,500 as calculated by Persson et al. (1986), the total cost for the Christiansen disaster, taking no consideration of the individual patient's suffering, is about USD 20 millions.

The Wagner double-cup device was also extremely often revised both due to cup loosening and fractures or loosening around the femoral component. The studies of the distribution of forces in this implant system was performed by Oh and Harris (1982) and showed that a thin-walled plastic acetabular component increased the risk of loosening. The disadvantages of this type of prosthesis has also been described by Freeman and Bradley (1983), Amstutz et al. (1984) and Ritter and Gioe (1982). All of this information led to that less than 10 double-cup arthroplasties were performed in Sweden in 1985, and none thereafter.

Although possible, it was not considered meaningful to analyze other causes of reoperation by survival analysis because the number of observations per complication for each prosthesis was limited.

In organizing multicenter clinical trials, certain requirements must be fulfilled. The most important is that economic resources are available for a sufficiently long-term time period. The annual costs for the project center was approximately USD 50,000, i.e., less than a total of 10 primary operations. The administration and monitoring of the product must be run in a specific coordinating center. One full-time secretary is necessary and also a contact person at every local department. Good computer facilities and a skilled biostatistician must be available.

It is considered unique that we in Sweden report problems and failures centrally, but the need for an extra large number of patients that are available only in multicenter trials can be illustrated by the following example. With two different types of prostheses with a probability of failure of 5 and 3 percent, respectively, over a 5-year-period 2,960 patients are needed to obtain a significance level of 0.05. The required number of patients can thus be obtained much faster from a multicenter investigation.

This type of project will never lead to revolutionary revelations, but it will serve as means of testing hypotheses. The feedback of the information to the medical profession at the country's various hospitals has enabled orthopedic surgeons there to compare their own results with those generally obtained in Sweden. This leads to increased awareness of the need for good surgical techniques and enables local surgeons to choose an implant that will serve both themselves and their patients well. The central idea throughout this research work has therefore been to disseminate information and to improve upon patient information, indications for surgery, and surgical performance.

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